100. Plenary Session 1 [Yasuda auditorium October 12th 18:15-19:15]

Recent development of case-only studies in Asia-Pacific region

Keynote speaker: **Kiyoshi Kubota**, NPO Drug Safety Research Unit Japan

How to detect and remove biases specific to case-crossover studies

In his talk, two biases are mentioned as biases specific to case-crossover studies which are particularly important when the exposure is chronic or successive. One of those biases is “bias due to within-subject exposure dependency” which is bias produced by the conditional logistic regression for matched case-control studies when the exposure status is NOT independent between periods. For binary exposure, this bias can be detected when the Mantel-Haenszel odds ratio (OR) is substantially different from the OR by the conditional logistic regression for matched case-control studies and can be removed by the Mantel-Haenszel method. The second type of bias is “bias due to lack of pairwise exchangeability” which is equivalent to “bias due to the exposure time trends” in many cases but can occur even without the exposure time trends on a population level. This bias can be detected when the OR of control subjects is substantially different from 1.0 and can be removed by the case-time-control approach. Those two biases can occur separately and simultaneously, and when they occur simultaneously, the simultaneous use of the remedies for these two biases (i.e., the Mantel-Haenszel method and case-time-control approach) is needed to remove them. Several relevant studies including those using real-world data and simulation studies are also explained.

Co-presenter: **Angel Wong**, London School of Hygiene and Tropical Medicine

Self-controlled case series: the best thing since sliced bread?

Self-controlled case series (SCCS) has been used to investigate the association between drug or vaccine exposure and acute outcomes for post-market drug safety surveillance. As SCCS can eliminate time-invariant confounding by comparing risks of outcome within an individual, some studies used SCCS to complement cohort study design to obtain robust results.
In this plenary session, Angel will present her previous work on using active comparators in SCCS to reduce time-varying confounding and address protopathic bias using routine clinical data from Hong Kong. She will also discuss her recent work implementing SCCS in environmental pharmacoepidemiology using Japanese claims data linked to meteorological records. With these new applications of SCCS, is SCCS the best thing since sliced bread?

Moderators:
Arnold Chan, TriNetX, LLC
Nobuhiro Ooba, Nihon University, School of Pharmacy

200. Plenary Session 2: [Yasuda auditorium October 13th 09:00-10:00]

Causal estimands: Should we ask different causal questions in randomized trials and in the observational studies that emulate them?

Keynote speaker: **Miguel Hernán**, Harvard T.H. Chan School of Public Health

In comparative effectiveness and safety research, causal estimands are answers to questions that can be articulated by specifying a hypothetical randomized experiment: the target trial. Epidemiologists and others have precisely defined causal estimands when using observational data to emulate target trials. Recently, drug regulators have adopted a framework that defines causal estimands when using data from actual randomized trials. One might expect that both sets of estimands largely overlap because the results of observational studies are often compared with those from randomized trials, which implies that different study designs are used to try to answer similar causal questions. This talk considers causal estimands for comparative effectiveness and safety research, and why or why not they should be standardized across study designs.

Moderators:

Hiraku Kumamaru, The University of Tokyo

Soko Setoguchi, Rutgers University

300. Plenary Session 3 [Yasuda auditorium October 14th 1015-1115]

Translating pharmacoepidemiology research into real-world practice in the Asia-Pacific region

Keynote speaker: **Yea-Huei Kao,** National Cheng Kung University

This keynote session celebrates the lifelong achievements of Dr. Yeahuei Kao Yang in building and promoting pharmacoepidemiology programs in Taiwan and across the Asia-Pacific region. Dr. Yang's contributions have been instrumental in fostering the next generation of researchers who generate pharmacoepidemiology evidence, as well as those who translate this evidence into clinical practice. In recent years, the integration of real-world evidence (RWE) from pharmacoepidemiology research has become essential to regulatory decisions, including drug approvals, new indications, and drug safety monitoring. Regulatory agencies have encouraged these practices through official guidelines, primarily targeting industry stakeholders.
Moreover, RWE from pharmacoepidemiology and findings from clinical trials are increasingly incorporated into package inserts, prescribing information, and clinical guidelines endorsed by medical societies. These materials, aimed at clinical practitioners such as physicians and pharmacists, are intended to promote the safer and more effective use of medications.
In honor of Dr. Yang's vision, this keynote session will hear Dr. Kao-Yang's vision and achievement and the panel will reflect from multidisciplinary perspectives to enhance medication safety and efficacy in the Asia-Pacific region by bridging research and clinical practice.

Moderator:
Frank May, ISPE

Panelists:
Ching-Lan Cheng, National Cheng Kung University

Nam-Kyong Choi, Ehwa Women's University
Yagi Tatsuya, Hamamatsu University School of Medicine

Symposia

SY1. Symposium 1: Navigating Oncology Real-World Data Landscape in Asia Pacific Region: Access, Collaboration, and Future Directions for Enhanced Utilization

While real-world data (RWD) and real-world evidence (RWE) are widely recognized and utilized in healthcare research, the specific applications and the approaches for access and cross-sector/cross-region collaborations in utilizing oncology RWD in the Asia Pacific region remain limited. By overviewing the data sources and environment and use cases from Japan, Taiwan, China, South Korea, and Australia, speakers from diverse background will identify the opportunities and possible approaches of cross-sector collaborations for potential needs of using oncology RWD in the region. The symposium will enhance participants' awareness of the diverse landscape of RWD sources available for oncology studies in the Asia Pacific region. It aims to foster meaningful cross-regional collaborations, transcending geographic boundaries and promoting the effective utilization of oncology RWD to drive impactful research. Researchers, healthcare professionals, policymakers, and industry representatives both in the Asia Pacific region and outside of the region will benefit from attending.

Presenters

- Kiyoshi Kubota, NPO Drug Safety research Unit
- Edward Chia-Cheng Lai, Institute of Clinical Pharmacy & Pharmaceutical Sciences
- Yvonne Lee, IQVIA Solutions Asia

Moderators:
Lei Chen, Merck Sharp & Dohme
Benjamin Daniels, UNSW

SY2. Symposium 2: Leveraging Electronic Health Records in Japan pharmaceutical industry: current status, issues, futures

Japan Pharmaceutical Manufacturers Association (JPMA) has been promoting the use on real world data (RWD) and real-world evidence (RWE) in pharmacovigilance, drug development, and medical research. Large scale public and commercial databased of health insurance claims are well established in Japan and commonly used in pharmaceutical industry. However, electronic health records (EHR) of medical facilities are less utilized compared with the claims databases. EHRs contain large array of variables recorded during medical examination that enable use for a wider range of purposes in each area. The reasons for less EHR's usage are intertwined with multiple factors such as fewer EHR databases available for pharma companies, limited structured variables in databases, non-standardized data among medical facilities, etc. EHR databases are important data source for pharmaceutical industry activities and pharmacoepidemiology research in any Asian countries. Attendees from Asian countries can learn the application of EHR databases and the strengths and limitations from cases in Japan and can join the discussion from their viewpoints.

Presenters

- Kanae Togo, Pfizer
- Yasunari Sadatsuki, Bayer Yakuhin
- Seitaro Yoshida, Chungai Pharmaceutical Co Ltd
- Takayuki Imaeda, Pfizer

Moderators:
Takayuki Imaeda, Pfizer
Chieko Ishiguro, National Center for Global Health and Medicine

SY3. Symposium 3: Deprescription Dynamics: Insights and Strategies for Optimizing Medication Management in Diverse Healthcare Landscapes

The practice of deprescription, the systematic process of reducing or discontinuing medications that are no longer necessary or may be causing harm, has gained significant attention in recent years. This symposium proposal aims to explore the multifaceted aspects of deprescription, including its clinical, societal and economic implications. The session also addresses the preparedness of future healthcare professionals regarding their ability and confidence in deprescription. Experts from various fields will share their insights on deprescription strategies, challenges, and opportunities, fostering discussions on how to optimise medication use and improve patient outcomes. The topic of deprescription is of paramount interest to ISPE's membership, particularly in the Asian region, due to several compelling reasons. Asia is undergoing rapid demographic changes, with projections indicating that by 2050, more than half of the world's older population will reside in this region. This demographic shift is accompanied by an increased prevalence of chronic diseases and polypharmacy, where patients are prescribed multiple medications concurrently. Such practices elevate the risks of adverse drug events, medication interactions, and unnecessary healthcare expenditures. Moreover, cultural influences often shape healthcare-seeking behaviors in Asia, contributing to higher rates of medication use and potentially inappropriate prescribing practices. Additionally, limited access to healthcare resources and primary care providers in certain Asian countries exacerbates the complexities associated with medication management. Therefore, exploring deprescription strategies tailored to the diverse healthcare landscapes and patient populations in Asia is imperative for promoting rational medication use, enhancing patient safety, and optimizing healthcare resources.

Presenters

- Amal Anand, Rutgers University
- Atiqulla Shariff, JSS College of Pharmacy, JSS AHER, Mysuru
- Shilpa Palaksha, JSS College of Pharmacy, JSS AHER, Mysuru
- Jisha Myalil Lucca, Gulf Medical University

Moderators

Frank May, ISPE

Krishna Undela, National Institute of Pharmaceutical Education and Research

SY4. Symposium 4: Evaluation of vaccination policy

According to the World Health Organization, immunization is a key component of primary health care and an indisputable human right. It is also one of the best health investments money can buy, as vaccines are critical to the prevention and control of infectious disease outbreaks, and therefore, also underpin global health security. Vaccines are medical products and vaccination policy is a public health intervention strategy. As the International Society for Pharmacoepidemiology defines, "pharmacoepidemiology is a scientific discipline that uses epidemiological methods to evaluate the use, benefits and risks of medical products and interventions in human populations". Despite, not much attention is given to vaccines and vaccination policies in pharmacoepidemiology academic gatherings and, as a result, there is a perceived paucity of knowledge of vaccines and vaccination policy among pharmacoepidemiologists. Moreover, pharmacists make up a substantial proportion of the pharmacoepidemiology community and are also important stakeholders in primary health care delivery but, unlike physicians, not much is being done to empower them with the appropriate

knowledge on vaccines and vaccination policies. Although vaccination has substantially reduced global deaths from infectious diseases, some infectious diseases such as measles are still common in many developing countries, including those in Asia. According to the Organisation for Economic Co-operation and Development, "all countries and territories in Asia-Pacific have established vaccination programmes including a minimum number of routine vaccines and additional vaccines are included at national or subnational level based on local morbidity, mortality and cost-effectiveness analysis". Despite, there is a paucity of published evidence on the effectiveness of the various vaccination programs and any variabilities in effect across strata of various population characteristics – knowledge that is highly relevant to public health and is needed for optimization of vaccination policies across the Asia-Pacific region.

Presenters

- George Okoli, The University of Hong Kong
- Simon Bell, Monash University
- Grace Wangge, Monash University, Indonesia
- Ching-Lan Cheng, National Chen Kung University

Moderators
Jenni Ilomaki, Monash University
George Okoli, The University of Hong Kong

SY5. Symposium 5: Use of Real-world data for regulatory decision making: the value of collaborations

The integration of real-world data (RWD) to generate real-world evidence (RWE) into regulatory decision-making processes has become increasingly significant, offering valuable insights that complement traditional clinical trial data. Factors such as the nature of today's innovative medicines that are being put on the market, as well as the need for rapid evidence generation are two of the pivotal aspects that have fuelled this development. This development has also spurred a need for guidance, and during the past years several RWD/ Real world evidence (RWE) guidances documents have been published by regulatory agencies world wide. These agencies, depend to a large extent on research institutions or the pharmaceutical industry to conduct RWD/RWE studies to generate the evidence needed, and only a few have in-house capacity to conduct their own studies. As a result, several collaborations have been established to facilitate the conduct of RWD studies for regulatory decision making. Many of these include collaborations where different types of databases are used, sometimes from different countries. This poses challenges related to heterogeneity in both the data source, the data specifics and the populations that these might represent. However, these collaborations have also resulted in improved transparency, better data sharing practices, and the development of analytical processes for multi-database/multi-country studies. This symposium provides an opportunity to exchange experiences and information on different types of RWD and RW databases used to inform regulatory decision making. In addition, it will provide insights into the potential facilitations and barriers for both regional as well as global collaborations. The symposium will also facilitate better understanding of data and data sources within and outside Asia.

Presenters

- Helga Gardarsdottir, Utrecht University
- Olaf Klungel, Utrecht University
- Edward Chia-Cheng Lai, Institute of Clinical Pharmacy & Pharmaceutical Sciences
- Kristian Filion, McGill University
- Ju-Young Shin, Sungkyunkwan University (SKKU)
- Kenneth Man, University College London

Moderators
Helga Gardarsdottir, Utrecht University
Olaf Klungel, Utrecht University

SY6. Symposium 6: Student Initiatives in Training of Newcomers in Pharmacoepidemiology in Non-native English-speaking Countries

Senior pharmacoepidemiologists have developed a comprehensive curriculum aimed at introducing essential principles to newcomers in the field. Despite these efforts, significant challenges remain, especially in Asian countries, where linguistic and structural differences hinder non-native English speakers from fully understanding the educational materials. The absence of contextually relevant materials and examples further complicates the learning process for these students. The teaching materials often lacked proper translation, and the absence of locally relevant examples reduced engagement and enthusiasm for learning. Recognizing these challenges, we realized the importance of discussing the current situation of pharmacoepidemiology training and its challenges across different countries. Therefore, a strategy for fostering a student discussion network and facilitating the exchange of opinions is essential. Through student initiatives, we provide insights to tailor educational resources that contributes to the strategic growth of ISPE's membership and engagement.

1. Addressing Unique Regional Challenges The linguistic and structural differences in Asian countries present unique challenges in pharmacoepidemiology education. Using students' perspective, ISPE can develop targeted strategies to improve understanding and engagement among non-native English speakers in the region.

2. Promoting Inclusivity and Accessibility Ensuring educational materials were properly applied in different countries is crucial for inclusivity. This topic aligns with ISPE's commitment to equal access to education and can help bridge the gap for students in non-native English-speaking countries.

3. Fostering Student-led Initiatives Student initiatives are vital for identifying and addressing training challenges. Highlighting these efforts can inspire more student-led solutions, enhancing the overall quality of pharmacoepidemiology education in Asia.

4. Enhancing Asia Region Collaboration By addressing these educational challenges, ISPE can strengthen its global network, especially in Asia Pacific. This symposium will facilitate collaboration between students and professionals worldwide, contributing to ISPE's strategic growth and global involvement.

Presenters

- Min Fan, University of Hing Kong
- Daniel Hsiang-Te Tsai, National Cheng Kung University
- Shiori Nishimura, The University of Tokyo Graduate School of Medicine
- Mita Restinia, National Cheng Kung University

Moderators
Yunha Noh, McGill University
Chin Yao Shen, National Cheng Kung

SY7. Symposium 7: Government-Industry-Academia Collaboration in Postmarket Outcome Validation Studies in the Era of Real-World Data: Design Considerations, Challenges and Future Opportunities

In the United States and Europe, real-world data (RWD), including claims data and electronic health record data, are commonly used for post-approval observational studies, with real-world evidence algorithms developed and validated to identify various disease outcomes. In Japan, the Good Post-marketing Study Practice (GPSP) has been revised to allow the use of RWD for post-market safety studies, requiring an outcome validation study beforehand. However, there are still few examples of validation studies in Japan and even fewer examples of government-industry-academia collaboration. This symposium will summarize on regulatory expectation, design considerations, and challenges in designing and conducing outcome validation studies. It will also offer additional insights and suggestions for future opportunities. Validation studies in general and especially the challenges in conducting them are of great interest to ISPE's membership, particularly in the Asia-Pacific region, due to the unique challenges and opportunities it presents. And the majority of RWE algorithms and methodological advancements have primarily been developed using data sources from the United States or Europe. Asian countries often have stricter privacy laws that prohibit direct access to patient identifiers in RWD, necessitating multi-institutional efforts for data sampling and analysis. Additionally, there is limited funding for clinical research, which requires robust government-industry-academia collaboration involving clinical and method experts, government support, and industry innovation. This symposium aims to address these challenges and foster a better environment for high-quality postmarket studies, including validation studies, by leveraging diverse resources and expertise.

Presenters
- Naoki Nakashima, Kyushu University
- Kensuke Kataoka, Tosei General Hospital
- Mari Matsui, Pfizer R&D Japan
- Yujing Huang, Eli Lilly and Company
- Hotaka Maruyama, Pharmaceuticals and Medical Devices Agency

Moderators
Kazuto Nomura, Pfizer
Soko Setoguchi, Rutgers University

SY8. Symposium 8: Real-world data in Japan, overview and examples: JSPE Medical and healthcare database utilization committee

Real-world data (RWDs) play an important role in the pharmacoepidemiological studies. Especially, it is vital to select a database based on data suitability for purpose. In recent years, various medical information databases such as electronic medical records, claims data, medical registries, and personal health records (PHRs) have become available in Japan. Therefore, researchers need to understand their suitability for the epidemiological design they are going to study based on the generation process and characteristics of each database. To build evidence properly, it is useful to learn about points to consider from actual research cases. RWDs have own characteristics depends on healthcare systems. In recent years, some pharmacoepidemiological studies using multinational data have been reported. Therefore, we believe that it is useful to share the Japanese healthcare environment, available medical information databases, their generation process, characteristics, and research cases with researchers in other countries, including those in the Asian region.

Presenters

- Shinobu Imai, Showa University Graduate School of Pharmacy
- Ryo Watanabe, Kanagawa University of Human Services
- Miho Ishimaru, Tokyo Medical and Dental University
- Maki Komamine, Pharmaceuticals and Medical Devices Agency

Moderators
Akihiro Nakajima, Teijin Pharma
Kanae Togo, Pfizer

SY9. Symposium 9: Three approaches to conduct real-world studies across multiple healthcare systems: common research question, common protocol, and common data model

It is vital for rationale drug development and assessment of medicines to understand the diversity of patient phenotypes and of delivery of care among healthcare systems across Asia. In addition, there is an opportunity to learn from the similarities and differences in population biology and in the use of healthcare services within the region. The challenge to executing and interpreting such pan-region or pan-global observational studies is coordinating multiple investigators using diverse data systems within a heterogeneity of operating environments. λ Enhancing Methodological and Interpretative Skills: This session will provide a framework for in-depth discussions on research methodologies and the interpretation of results, enhancing the analytical skills and knowledge base of ISPE members. λ Expanding Research Networks: This session will offer ISPE members a valuable opportunity to broaden their research connections, fostering collaborations and partnerships within the pharmacoepidemiology community. λ Fostering a Growth-Oriented Scientific Community: This session will share the experience from analyzing various Asian healthcare database, to cultivate a scientific community that has a growth mindset, and to encourage continuous learning, innovation, and progress in pharmacoepidemiology.

Presenters
- Chin Yao Shen, National Cheng Kung University
- Ching Lung Cheung, The University of Hong Kong
- Jeff Lange, Amgen
- Hojoon Lee, Amgen Korea
- Suzu Chia-Hsien Chang, Amgen Japan

Moderators
Chieko Ishiguro, National Center for Global Health and Medicine
Chi-chuan Wang, National Taiwan University

SY10. Symposium 10: Medical Device Epidemiology in Asia: Examples and Challenges

The use of medical devices in clinical practice is rapidly increasing, including new modalities like Software as a Medical Device (SaMD). These devices can compete with or complement pharmaceuticals, making their interaction with drugs a key theme in pharmacoepidemiology. However, unlike drug epidemiology, evaluating medical devices is challenging due to issues like identifying devices in databases. In this session, speakers will present case studies on invasive cardiovascular devices, robotic surgery systems, and SaMD, demonstrating how studies are used for regulatory and reimbursement purposes. Participants will gain insights into Asia's regulatory environment, learn best practices, and discuss strategies to improve study integration into regulatory frameworks. The session will offer valuable insights into how epidemiological studies for medical devices may be conducted in Asia. By learning the methodologies and challenges faced in Japan and China, participants can identify common issues that also affect their own countries, such as difficulties in identifying devices within existing databases and the need for special considerations due to facility or operator factors. The session will also explore how these studies are utilized for regulatory and reimbursement purposes, providing a framework that can be adapted and harmonized across different nations.

Presenters

- Hiraku Kumamaru, University of Tokyo
- Mary Ritchey, CERobs Consulting
- Hironobu Tokumasu, Ohara Healthcare Foundation Clinical research Center
- Yongjing Zhang, Global Epidemiology, Johnson & Johnson

Moderators
Hiraku Kumamaru, University of Tokyo
Mary Ritchey, CERobs Consulting

SY11. Symposium 11: Early-career pharmacoepidemiologists: perspectives and progress from Asia

Early-career researchers have few opportunities to learn about pharmacoepidemiological research and researchers' careers overseas. Especially, researchers in pharmacoepidemiology use electronic health records (EHR) databases in their region to investigate the usage, safety, and effectiveness of medicines. However, we lack an in-depth understanding of EHR databases in other regions. To encourage future researchers in pharmacoepidemiology, young researchers should be given opportunities to deepen their knowledge of pharmacoepidemiological research using EHR databases in each region and to discuss future research directions. This symposium is expected to be a highly valuable opportunity for early-career researchers, who are responsible for the future of pharmacoepidemiology, to learn about pharmacoepidemiological research and connect with fellow researchers across different regions of Asia. This symposium is organized by the Youthful Experience Committee in the Japanese Society for Pharmacoepidemiology and has received a recommendation from the Local Host Committee.

Presenters
- Toshiki Fukasawa, Kyoto University
- Na-Young Jeong, Ewha Womans University
- Jui Wang, National Taiwan University & National Taiwan University Health Data Research Center
- Eric Wan, University of Hong Kong
- Nhung Trinh, University of Oslo

Commentator
Jenni Ilomaki, Monash University

Moderators
Celine Chui, The University of Hong Kong
Masao Iwagami, University of Tsukuba

SY12. Symposium 12: Leveraging regulatory pharmacoepidemiology for informed decision making in Asia

In Asian region, similarly in the rest of the world, the value of the real-world data (RWD)/ evidence (RWE) has been increasing. The pivotal clinical trial data informing the regulatory decision making for initial marketing authorization have usually been generated in the trials in which Asian are under-represented and not considered differences in local clinical practice and therefore not ready to be generalized to estimate benefits and risks in Asian population. Asian RWD/RWE is expected to supplement those data and to inform regulatory/reimbursement decisions. Given that Asian population represents more than 60% of world population and recent issuance of regulatory guidance for burgeoning pharmacoepidemiological studies in Asian countries/regions, the inequality in the data underpinning regulatory decision making for pharmaceutical products could be further mitigated through the approach to the common foundation/flamework leveraging use of Asian RWD in pharmacoepidemiological studies. Audience and the Societies are to learn and discuss the perspectives and potential collaboration on regulatory use of pharmacoepidemiological studies to generate Asian specific RWE.

Presenters
- In-sook Park, Korea Regulatory Science Centre
- Lih-jiuan Hsu, Center for Drug Evaluation
- Yoshiaki Uyama, Pharmaceuticals and Medical Devices Agency
- Kazuhiro Kajiyama, Pharmaceuticals and Medical Devices Agency

Moderators
Hisashi Urushihara, Keio University
Yoshiaki Uyama, Pharmaceuticals and Medical Devices Agency

SY13. Symposium 13: From Asia to the World – Engaging in the ISPE Strategic Plan 2024-2029

The International Society for Pharmacoepidemiology (ISPE) is an international organization dedicated to advancing the health of the public by providing a global forum for the open exchange of scientific information, collaboration, and the development of new epidemiologic research methods, policy, education, advocacy, and leadership for the field of pharmacoepidemiology. Every five years, ISPE develops a new strategic plan to guide our efforts in achieving our mission. ISPE Strategic Plan 2024-2029 will begin at the ISPE Annual Meeting in August 2024. The plan provides four themes for the next five years: we at ISPE Inspire, Secure, Prepare, and Empower. Objectives range from engaging with emerging and innovative science, to enhancing our leadership capacity and better including diverse perspectives and geographic regions into global advancement of our field. Pharmacoepidemiology is growing and changing rapidly in Asia ISPE desires increases in scientific exchange, collaboration, and communication around the world. This symposium will address how we can better incorporate Asian voices into ISPE's global discussions. This session provides a forum for participants to learn more about ISPE and how to participate in the organization throughout the year. It also provides an opportunity to better align the opportunities for engagement to the needs and goals of Asian ISPE members.

Presenters

- Mary Ritchey, CERobs Consulting
- Yea-Huei Kao, School of Pharmacy, Institute of Clinical Pharmacy and Pharmaceutical Science, College of Medicine, National Cheng Kung University
- Hiraku Kumamaru, University of Tokyo
- Sri Harsha Chalasani, JSS College of Pharmacy - Mysuru

Moderator

Mary Ritchy, CERobs Consulting

SY14. Symposium 14: Climate Change and Pharmacoepidemiology in Asia

According to the World Meteorological Organization, Asia was more affected by weather, climate and water-related hazards in 2023 than any other region in the world. Factors associated with climate change, such as typhoons, flash floods, extreme temperatures, and elevated air pollution can directly and indirectly effect the health of residents. Medications have the potential to exacerbate or mitigate climate-related adverse events and may also be disrupted by extreme climate disasters. Pharmacoepidemiologists have the unique knowledge and skills to lead and collaborate on studies to measure this unique intersection of the environment and medications. We will bring together experts to discuss the impacts and research opportunities between climate change and pharmacoepidemiology in Asia. People in Asia are at great risk for adverse health impacts from climate events. Health risks may be exacerbated or mitigated by the types of medications patients are taking. Furthermore, timely availability of medications or procedures may be delayed by severe climate events. The field of environmental pharmacoepidemiology is increasingly important yet still not as well recognized as other fields in pharmacoepidemiology. We will provide an opportunity for pharmacoepidemiologists to be exposed to this growing field and opportunities for them to be involved and/or lead environmental pharmacoepidemiologic research in their local countries.

Presenters

- Masahiro Hashizume, University of Tokyo
- Soko Setoguchi, Ruthers University
- Harish C. Phuleria, Indian Institute of Technology Bombay
- Benjamin Bates, Rutgers University
- Shu Ping Huang, Changhua Christian Hospital

Moderator

Benjamin Bates, Rutgers University

SY15. Symposium 15: From Blueprint to Reality: Development, Conversion, and Application in the Common Data Model Approach Among Asia-Pacific Databases

Constructing a common data models (CDM) for multinational studies in Asia is essential to provide evidence of drug effectiveness and safety, supporting or challenging results from clinical trials predominantly involving Western populations. However, many obstacles need to be addressed when implementing CDM in the Asia-Pacific region, which has diverse database structures, healthcare behaviors, regulations, and economic statuses. This symposium will explain the reasons for selecting the common data model as a preferred way to conducting the multi-national study. We will show the our experience of construct the CDM among Asia countries and point out the problems we faced during the process, including complex CDM design, vocabulary mapping and different interpretation by different analysts. We will invite 3 speakers to give us some thought to deal with these problems focusing on how to leverage the complexity of CDM format, the necessity of mapping vocabulary and how to make the protocol easy for understanding. The topic addresses critical challenges and opportunities in conducting multinational epidemiological research using a common data model (CDM) in Asia-Pacific countries. With rapid advancements in healthcare data collection and analysis technologies, there is a growing need for standardized methods to ensure data consistency, transparency, and reproducibility across diverse healthcare systems. The symposium will explore practical solutions to these challenges, such as developing a CDM format that balances simplicity with the need to support complex regulatory decision-making processes, examining the necessity of mapping codes during CDM conversion, and facilitating better communication and interpretation of study protocols. By focusing on these issues, the symposium aims to enhance the quality and reliability of real-world evidence generated in the Asian context, which is crucial for informed regulatory decision-making and healthcare policy development. Furthermore, this topic can help reduce errors encountered by future researchers in constructing CDMs. The insights and experiences shared by experts will provide valuable guidance for researchers and policymakers, fostering greater international collaboration and advancing the field of pharmacoepidemiology in the region.

Presenters
- Brian Li, National Cheng Kung University
- Chin Yao Shen, National Cheng Kung University
- Celine Sze Ling Chui, School of Nursing and School of Public Health
- Bin Hong, Sungkyunkwan University
- Hsun Yin Liang, Taiwan Drug Relief Foundation

Moderators
Suzu Chia-Hsien Chang, Amgen Japan
Edward Chia-Cheng Lai, Institute Of Clinical Pharmacy And Pharmaceutical Sciences

SY16. Symposium 16: Maternal and perinatal health studies using Real-World Data

The growing availability of real-world data (RWD) has provided invaluable and timely evidence on medication safety among pregnant women, who are traditionally underrepresented in trials. Yet, with a range of RWD available for pregnancy studies, from insurance claims to electronic health records, fit-for-data considerations and approaches are needed to generate valid real-world evidence (RWE). Therefore, this symposium will provide an overview of various RWD available in Asia for use in pregnancy studies, accompanied with case examples to demonstrate methodological and analytical considerations when assessing maternal/neonatal outcomes associated with prenatal exposure to medications, with challenging in expanding to multi-national study. The symposium is intended for researchers, regulatory, pharmaceutical industry, and clinicians with an interest in providing RWE in a vulnerable population of pregnant women and their offspring. Given the growing availability of diverse sources of RWD for perinatal pharmacoepidemiology studies, there is a need for more in-depth discussions on fit-for-data considerations and approaches needed to generate valid RWE. To address these issues, this symposium is intended for researchers, regulatory, pharmaceutical industry, and clinicians with an interest in providing RWE in pregnant women and their offspring. This symposium will also provide an overview on the progress, achievements, and future directions of perinatal pharmacoepidemiologic research conducted from Asian and European populations and RWD sources and discuss on how to better foster future collaborations within and beyond Asia, to ensure an effective and safe use of drugs or vaccines in a vulnerable population of pregnant women and their offspring, and explore the utilization of mother's data to predict children's future.

Presenters

- Kenneth Man, University College London
- Adrienne Chan, The University of Hong Kong
- Ju-Young Shin, Sungkyunkwan University (SKKU)
- Avery Shuei-He Yang, Institute of Clinical Pharmacy and Pharmaceutical Sciences, National Cheng-Kung University

Moderators

Adrienne Chan, The University of Hong Kong
Kenneth Man, University College London

Oral presentations

Session: Methods [Yasuda, October 13th 13:00-14:30] O100-O105

Moderators: Kenneth Man and Takuhiro Yamaguchi

O100

Research status of applying common data model in pharmacoepidemiology: a systematic review

Meng Zhang[1,2], Yongqi Zheng[1,2], Conghui Wang[1], Ling Gao[1], Feng Sun[1,2]
[1]Department of Epidemiology and Biostatistics, School of Public Health, Peking University, Beijing, China, [2]Key Laboratory of Epidemiology of Major Diseases (Peking University), Ministry of Education, Beijing, China

Introduction
The transformation of medical data into the common data model (CDM) enables multi-center collaborative research, enhancing the ability to address questions regarding drug effectiveness and safety. However, the application of the CDM in pharmacoepidemiologic research remain unclear.
Aims
To systematically summarize global work on the use of CDM in pharmacoepidemiologic research.
Methods
Five English databases (PubMed, Web of Science, EMBASE, Scopus, Virtual Health Library) and four Chinese databases (CNKI, Wan-Fang Data, VIP, SinoMed) were electronically searched to collect relevant studies on applying CDM in pharmacoepidemiologic research from inception to January 2024. Two reviewers independently screened studies and extracted information on research details, CDM-related, pharmacoepidemiology-related information, and whether reporting guidelines were applied.
Results
This study included 309 studies, with 308 in English and 1 in Chinese. The median number of centers was 7 (IQR 4-8), with a median sample size of 267,182 (IQR 16,228-1,531,144). The top 3 CDMs used were VSD (52.8%), OMOP (24.3%), and Sentinel (6.1%). 79.9% of the studies utilized US data sources. Korea (18.4%), China (2.6%), and Japan (2.6%) contributed part of Asian data. The focus was on vaccines in 56.0% of the studies, drugs in 43.4%, and devices/surgeries in 0.6%. The most commonly studied vaccines were influenza vaccines (54/173) and COVID-19 vaccines (21/173). Primary drugs included antidiabetic drugs (21/134) and antibiotics (12/134). Research directions predominantly encompassed safety (77.3%), drug/vaccine utilization (17.2%), effectiveness (8.0%), and others. Safety events were primarily concentrated on the nervous systems diseases (58/237) and autoimmune diseases (49/237). Only 16 studies used reporting guidelines.
Discussion
Our study provides a comprehensive perspective on all CDMs, related drugs/vaccines, and treatment areas, identifying the feasibility of CDMs in pharmacoepidemiologic studies. However, the future direction of CDM applications still needs further expansion, with a focus on enhancing the standardization of research reports.

O101

The utility of event-specific methods in causality assessment of drug-adverse reaction

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Introduction:
Assessing the causal relationship between drugs and adverse events is a crucial step in pharmacovigilance. Suspected adverse drug reaction case reports from clinical practice to regulatory authorities often fail to assess causality due to a lack of information, particularly in the case of fatal cerebral haemorrhage. We have previously used a new algorithm (ACAD-FCH) to evaluate the causal relationship between drugs and fatal cerebral haemorrhage, and have examined the usefulness of this event-specific causal evaluation method.
Aims:
This study aimed to discuss the type of evaluation methods required to improve the quality of reports of suspected adverse drug reactions and the information needed for evaluation, based on an analysis of causality assessment of the fatal cerebral haemorrhage cases.
Methods:
The medical records of patients who died at the University of Tokyo Hospital in 2020 were reviewed, and cases with intracranial haemorrhage were selected. Two evaluators independently assessed these cases using three methods (ACAD-FCH, Naranjo algorithm, and WHO-UMC scale). The number of 'Yes', 'No', and 'No information/Do not know' responses were summed and compared. Inter-rater reliability was evaluated using agreement rates and kappa coefficients with 95% confidence intervals (CI).

Results:
Among 316 deaths, 24 cases with intracranial haemorrhage were evaluated. The proportion of 'No information/Do not know' responses was 35.6% (95% CI 31.4–40.6%) for ACAD-FCH and 66.9% (95% CI 62.5–71.1%) for the Naranjo algorithm. The agreement rates and kappa coefficients were 0.917 (0.798–1.00) and 0.867 (0.675–1.00) for ACAD-FCH, 0.708 (0.512–0.904) and 0.139 (−0.236 to 0.513) for the Naranjo algorithm, and 0.50 (0.284–0.716) and 0.326 (0.110–0.541) for the WHO-UMC scale.

Discussion:
For causality assessment between a drug and an adverse event, event-specific criteria and evaluation methods are preferable. Using event-specific methods may ensure appropriate reporting with the necessary information for causality assessment.

O102

Performance of Matching with Oversample and Replacement Strategy for Imbalanced Real-world Dataset.

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Introduction: Propensity score matching (PSM) is widely used in electronic medical record studies to create balanced treatment groups. However, the unbalanced comparators in clinical dataset might lead to a comparator bias. This imbalance often leads to models favoring the majority class, resulting in inadequate predictions for the minority class, specifically in false negative bias.

Aims: To evaluate the performance of PSM with oversampling and replacement strategy using electronic medical record databases.

Methods: A retrospective, new user-active comparator, cohort comparing Proton-pump inhibitors (PPIs) to Histamine-2 antagonists for Stroke events was applied to assess the performances with covariate balance with average standard mean difference (SMD), area under the receiver operating characteristic (ROC) curve, and bootstrapping bias with its bias standard error. The average effect of treatment on the treated (ATT) with hazard ratios were also compared among PSM models

Results: PSM with generalized boosted model (PSM-GBM) with replacement and oversample strategy produced estimates with better balanced covariates than PSM with 1:1 matching without replacement. The ROC was 0.81 for PSM-GBM. Moreover, the bootstrapping bias (0.018) is relatively small compared to the bootstrap standard error (0.189), indicating that the difference between the original coefficients and the mean coefficients from bootstrap resampling is not substantial. In PSM-GBM, the bias standard error being equal to the bootstrap standard error suggests that there might be variability in the bias estimate across bootstrap samples. Nevertheless, the ATT outcomes were not statistical difference among PSM models.

Discussion: Matching with replacement and oversample strategy performs well for this unbalanced dataset. Although, there may not be strong evidence of false negative bias based solely on this comparison, further investigation into the stability and robustness of the Cox proportional hazards model, potentially through additional validation methods, would be warranted to confirm the absence of bias.

O103

Evaluation of Logistic Regression Model for Analyzing Pooled Observational Epidemiological Databases

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Introduction:Pooling observational epidemiological databases increases sample size and improves accuracy of estimates. Two strategies exist for estimating parameters from pooled data: one-stage and two-stage. Although the traditional logistic regression model (LRM) is commonly used for single databases, its performance in pooled data is not well studied.

Aims:We aimed to assess the performance of LRM for analysing pooled epidemiological databases using simulated datasets.

Methods:We simulated 10 datasets with four scenarios: fixed intercept and slope with no differences between databases, fixed intercept and random slope indicating heterogeneity, random intercept and fixed slope, and random intercept and random slope. Sample sizes varied from 5000 to 12000, with a pooled size of about 60000. The outcome (Y) and exposure (X) were generated from the Bernoulli distribution, with Y prevalence of 3%, 20%, and 50%. Each scenario was replicated 1000 times. Two levels of variation (0.1 and 0.25) were introduced for random intercept and slope. Performance was measured by bias, RMSE, and coverage probability.

Results:When there is no heterogeneity between databases, one-stage models, particularly the weighted fixed effect LRM, perform best with the lowest RMSE (0.045) compared to random effect and two-stage models. With heterogeneity, fixed effect LRM show poor performance (coverage < 0.80), worsening with increased heterogeneity or outcome prevalence. Here, random effect LRM perform better. Unweighted random effect models have better RMSE but higher bias and coverage than weighted models. Two-stage unweighted random effect LRM show superior coverage (0.93) compared to one-stage (0.90). With 3% prevalence, two-stage models perform worst, but at 50% prevalence, the gap narrows, showing similar results.

Conclusion:The performance of LRM depends on research scenarios. Both one- and two-stage methods can yield similar results, but heterogeneity significantly influences performance. For heterogeneous databases, either one-stage or two-stage random effect unweighted LRM may be used, but the two-stage method is recommended.

O104

Synchronization of time zero in pharmacoepidemiology studies using target trial emulation approach

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Introduction: Many pharmacoepidemiology studies adopted target trial emulation approach in recent years, which was considered as a useful framework for avoiding potential sources of bias. However, there is evidence that key methodological details are missing from the report of such studies.
Aims: The objective for this meta-research study is to evaluate if the three key time points (i.e., meeting eligibility, initiating treatment, and starting follow-up) are aligned to avoid bias when emulating a target trial, and whether the authors described a solution to properly address potential bias when these three key time points are not aligned.

Methods: We performed a comprehensive literature search on PubMed, Embase, Web of Science till February 20, 2023 (We plan to include all eligible studies published from inception until May 2024, and we are now updating this research). Studies were assessed for inclusion/exclusion by two independent reviewers based on a pre-defined eligibility criteria. Any disagreement was resolved by a third reviewer. Pharmacoepidemiology studies published in English language claiming to have used target trial emulation framework were included. Study characteristics and information regarding methodological elements were extracted and evaluated by two independent reviewers based on a predesigned form.

Results: Fifty-five pharmacoepidemiology studies were identified. In 15 (27.3%) studies, follow-up started at eligibility, but treatment strategy is assigned after follow-up, which may introduce immortal time bias and misclassification bias. Among them, only 7 (43.8%) studies described a solution to mitigate these biases.

Conclusions: Most studies did not explicitly define their target trial and failed to comply with the principles of target trial emulation framework. Methodological and reporting quality of pharmacoepidemiology studies using target trial emulation framework needs improvement. Our findings indicate that evidence-based guidelines for the conduct and reporting of such studies may be useful.

O105

Baseline Adjustment to Compare Post-marketing Surveillance Study and Randomized Clinical Trial

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Aim/Objective:
After the approval of a new drug in Japan, post-marketing surveillance (PMS) studies are conducted to primarily detect safety signals within a diverse patient population. In this study, our objective is to demonstrate how baseline adjustment influences the comparison results when comparing the safety and efficacy outcomes between PMS and randomized clinical trials (RCTs) via simulation study. Meanwhile, we propose a few causal inference approaches which can be considered to adjust the baseline imbalances for this kind of comparisons.
Methods:
To represent typical scenarios encountered in RCTs and PMS studies, we created a simulated dataset consisting of both baseline covariates and outcomes. We applied logistic regression models to generate efficacy and safety outcomes, considering the broader target population in the PMS setting. Causal inference methodologies, such as propensity score matching, g-formula, and ATT weighting, were employed to estimate adjusted results. Performance evaluation was based on bias and mean square error (MSE) measures.

Results:
Our simulation study revealed that g-formula and ATT weighting demonstrated better performance in mitigating bias. However, the naive method outperformed in terms of MSE. Notably, when the proportion of adverse events was extremely low, ATT weighting exhibited increased bias with the marginal effect of weighted outcome compared to other methods.

Conclusion:
Our simulation study quantitatively evaluated the impact of adjusting these baseline differences in comparing simulation data that mimic PMS and RCTs. Depending on the situation, our findings suggest that causal inference methods of g-formula or ATT weighting might be the alternative approach for this comparison. As PMS and RCTs are different sources of evidence, there would be other potential unmeasurable factors which cause the differences in outcomes. By adjusting the baseline imbalances, we would be able to focus on the remaining possible differences between PMS and RCTs.

Session: COPD / Asthma [Sanjo, October 13th 13:00-14:30] O106-O111
Moderators: Michael Falster and Yoshinori Takeuchi

O106

Comparative Cardiovascular Safety of Fixed-dose Combinations of LABA/LAMA/ICS versus LABA/ICS in COPD

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Introduction:
Triple combinations of long-acting β2 agonist/long-acting muscarinic antagonist/inhaled corticosteroids (LABA/LAMA/ICS) are recommended for COPD patients with persistent symptoms and high risk of acute exacerbation. The increasing use of triple combination therapies has followed the reimbursement of the fixed-dose combination (FDC) dosage form since 2017. Numerous clinical trials were conducted to investigate the effectiveness of LABA/LAMA/ICS compared to LABA/ICS. However, real-world evidence regarding cardiovascular safety remains limited.
Aims:
This cohort study aimed to investigate the cardiovascular safety of LABA/LAMA/ICS FDC versus LABA/ICS FDC in patients with COPD in real-world settings.
Methods:
We identified patients with COPD who initiated LABA/LAMA/ICS or used LABA/ICS FDC from a nationwide Taiwanese database between 2017 and 2022. The outcomes of interest were hospitalized composite cardiovascular events, including acute myocardial infarction, unstable angina, heart failure, cardiac dysrhythmia, and ischemic stroke. We estimated propensity scores (PS) for each patient based on their baseline demographics, comorbidities, concurrent medications, and resource utilization. The Cox proportional regression model was applied to estimate the hazard ratios (HR) and the 95% confidence intervals (CI) for composite and individual cardiovascular outcomes comparing LABA/LAMA/ICS versus LABA/ICS after 1:10 variable-ratio PS matching.
Results:
The study population consisted of a total of 58,371 patients (n=8,189 for LABA/LAMA/ICS and n=50,182 for LABA/ICS). After 1:10 variable-ratio PS matching, 28,851 patients (n=5,836 for LABA/LAMA/ICS and n=23,015 for LABA/ICS) were included in the analysis. The HR of composite cardiovascular events comparing LABA/LAMA/ICS to LABA/ICS was 1.00 (95% CI, 0.78-1.28). The results did not materially change for individual cardiovascular outcomes and were similar across subgroup analyses stratified by patient characteristics, including age, sex, and COPD duration.
Conclusion:
In this population-based cohort study, we did not observe an increased cardiovascular risk associated with LABA/LAMA/ICS FDC compared to LABA/ICS FDC in patients with COPD.
Keywords:
Chronic obstructive pulmonary disease, LABA/LAMA/ICS, LABA/ICS, cardiovascular safety

O107

Cost-effectiveness of triple therapy compared to dual therapy in chronic obstructive pulmonary disease: A systematic review and meta-analysis

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Introduction.
Chronic Obstructive Pulmonary Disease (COPD) is one of the major global public health concerns, projected to become the third leading cause of mortality by 2030. Economic considerations persist regarding the selection between dual therapy and triple therapy for COPD treatment.
Aims.
To evaluate the cost-effectiveness of triple therapy with dual therapy in terms of quality-adjusted life years (QALYs) and exacerbations avoided in patients with COPD.
Methods.
A systematic search was performed in PubMed, Google Scholar, Scopus, and Cost-Effectiveness Analysis (CEA) Registry for eligible cost-effectiveness and cost-utility studies published up to 31st October 2023. The risk of bias in the included studies was assessed using the modified Economic Evaluations Bias (ECOBIAS) checklist. Monetary values were extracted and standardized to purchasing power parity, then adjusted to 2023 U.S. Dollars. The pooled incremental net benefits (INBs) of quality-adjusted life years (QALYs) and exacerbations avoided for triple therapy versus dual therapy in COPD were analyzed using either Fixed or Random-effects models based on heterogeneity assessed by the I^2 statistic and Cochran's Q test.
Results.
Out of 116 studies, 10 were eligible, predominantly from high-income countries. The overall pooled INB of QALYs for triple therapy versus dual therapy was US$4969.19 (95% CI US$3620.16, US$6318.21; P=0.00001). In subgroup analysis, Budesonide/Glycopyrrolate/Formoterol fumarate (B/G/F) (2 studies) demonstrated the highest INB of US$5717.96, followed by Fluticasone Furoate/Umeclidinium/Vilanterol (FF/UMEC/VI) (6 studies) with an INB of US$5675.90. However, Tiotropium/Fluticasone/Salmeterol (TFS) (2 studies) showed the lowest value among the three. Regarding exacerbations avoided, the pooled INB was US$21163.81 (95% CI US$4788.62, US$37539.00; P=0.005). B/G/F exhibited the most favorable outcome with an INB of US$45540.51, followed by FF/UMEC/VI (US$14832.51) and TFS (US$10249.29), respectively.
Discussion.
The comparison of triple therapy to dual therapy reveals significant differences in cost-effectiveness for improving QALYs and reducing exacerbations in COPD, with B/G/F showing the most favorable outcomes. However, the substantial heterogeneity highlights the need for further research and deeper understanding in this field. Heterogeneity is caused by study design (model or alongside clinical trials), population, country, GDP, or economic perspective taken.

O108

Comparative effectiveness of inhaled corticosteroid in combination therapy for patients with chronic-obstructive-pulmonary-disease

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Background:
Chronic-obstructive-pulmonary-disease (COPD) is the fourth leading cause of death worldwide. Inhaled corticosteroid (ICS) is increasingly used as effective anti-inflammatory agents for the combination therapy of COPD. But evidence on the effectiveness of ICS in dual/triple combination therapy was limited and inconsistent.
Aims:
To compare the hospitalization and mortality outcomes of dual/triple therapy using ICS for patients with COPD.
Methods:
We used the linked health records to emulate a randomized target trial design, and identified 2210 patients with COPD who initiated long-acting β2 agonist (LABA)/ICS or LABA/long-acting muscarinic antagonist (LAMA) or LABA/LAMA/ICS from two tertiary hospitals between 2017 and 2023. Primary outcomes were all-cause hospitalization and mortality. Secondary outcomes were acute exacerbations of chronic-obstructive-pulmonary-disease (AECOPD) and major adverse cardiovascular events (MACE). We applied cloning, censoring and inverse probability censoring weighting to estimate hazard ratios (HRs) and 95% confidence intervals (CIs) for different combination therapies.
Results:
For all-cause hospitalization, LABA/ICS (HR: 0.84; 95%CI: 0.55-1.30) and LABA/LAMA/ICS (0.89, 0.34-2.30) demonstrated the marginally lower risks than LABA/LAMA, respectively. Mortality outcomes indicated the similar pattern. For AECOPD, LABA/ICS had a marginally lower risk (0.89, 0.37-2.18) in comparison with LABA/LAMA, whereas LABA/LAMA/ICS had a marginally higher risk (3.03, 0.53-17.13). For MACE, LABA/ICS showed a marginally lower risk than LABA/LAMA (0.76, 0.29-1.98).
Conclusion:
Our study found that when combination therapeutic strategies were used, little reduction in all-cause hospitalization and mortality were observed for triple therapy including ICS than dual therapy without ICS. Although triple therapy is often used in patients with COPD to reduce the risk of moderate to severe acute exacerbations, little benefit was observed and triple therapy with ICS might relate to an increased risk of AECOPD. Such uncertainty of the therapeutic benefit for triple therapy with ICS should be further investigated in the real-world settings.

O109

Combination of chinese and western medications among chronic obstructive pulmonary disease patients

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Aim/Objective: Although traditional Chinese medicine (TCM) is commonly prescribed as an adjuvant therapy for chronic obstructive pulmonary disease (COPD), evidences supporting the effect of the TCM and western medicine (WM) combination remain unclear. We aimed to evaluate the efficacy of concurrent use of TCM and WM for chronic disease management in patients with COPD.
Methods: Patients who had COPD were selected as the study cohort from the National Health Insurance Research Database of Taiwan. The date of the initial COPD diagnosis, along with the following 365 days, is considered the index period, with the day of the first diagnosis designated as the COPD diagnosis date and the addition of 365 days as the index date. Those COPD patients were classified as TCM users or TCM nonusers. An 1:4 propensity score matching will be conducted, pairing one TCM user with four TCM nonusers. Within 730 days after the index date, the occurrence of acute exacerbations (AE) of COPD is defined as the study outcome. The stratified univariate and multivariate Cox proportional hazard models were used to present hazard ratios and 95% confidence intervals.
Results: The study cohort comprised 1,414,906 eligible patients. After propensity score matching, TCM users remained 86,510 cases and 346,034 TCM nonusers were selected. After adjusting for the confounding effects of demographics, comorbidities, and use of other medications, we obtained consistent results for the 3 models. Compared with TCM nonusers, those using TCM concurrently with WM had a lower risk of AE. The adjusted hazard ratio from Models 1 to 3 were 0.90 (95% CI: 0.88-0.92), 0.91 (95% CI: 0.89-0.94), and 0.76 (95% CI: 0.74-0.79), respectively.
Conclusion: For patients with COPD, the concurrent uses of TCM and WM could decrease the risk of AE.

O110

Trends of pneumococcal vaccination coverage among U.S. chronic obstructive pulmonary disease populations

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Introduction
Although CDC recommended pneumococcal vaccination for all chronic obstructive pulmonary disease (COPD) patients, the vaccination coverage within this high-risk group especially in aged 19-64 remains suboptimal.
Objective
To investigate the trend, pattern, and the characteristics associated with pneumococcal vaccine uptake among US COPD population from 2018 to 2022.
Methods
The 2018 - 2022 U.S. National Health Interview Survey were used to conduct this study. Adults with COPD and age between 19-64 years were identified through self-reported survey questionnaires. The pneumococcal vaccination coverage was the dependent variable which was measured by respondents self-reported the following question: “Have you ever had a pneumonia shot?” Prevalence and trends of pneumococcal vaccination coverage was adjusted for the NHIS complex sampling design with the clustering and stratification. Multivariable logistic regression models were performed to identify factors associated with pneumococcal vaccination coverage.
Results
Prevalence of pneumococcal vaccination among aged 19-64 years with COPD was increased from 39.5% in 2018 to 43.37% (P=0.18). In adjusted analysis, those who were more likely to receive pneumococcal vaccine were women (OR:1.73, 95% CI:1.11-2.68), Asian (OR:6.92, 95% CI:1.33-36.07), having health insurance (OR:3.69, 95% CI:1.33-1.21), being former drinkers (OR:3.36, 95% CI:1.28-8.80), and having additional comorbidities (OR:2.28, 95% CI:1.38-3.75). Characteristics including education, household income, having a usual place for healthcare, BMI, smoking status were found not statistically significantly associated with the pneumococcal vaccine uptake in the multivariable-adjusted model.

Conclusion
Pneumococcal vaccination coverage in COPD aged 19-64 years with COPD has slightly increased from 2018 to 2022. Healthcare professionals should still actively advocate for pneumococcal vaccination for all COPD patients, especially men, uninsured, and those without other comorbidities.

Keywords: Pneumococcal vaccination; chronic obstructive pulmonary disease (COPD); coverage; vaccination

O111

Antidiabetic agents and asthma exacerbation in patients with asthma and diabetes

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-Introduction
Better glycemic control in diabetic patients may reduce asthma exacerbations. Sodium-glucose cotransporter 2 (SGLT2) inhibitors and GLP-1 receptor agonists (GLP-1 RAs) show similar glucose-lowering effects, while dipeptidyl peptidase-4 (DPP-4) inhibitors may be less effective.

-Aims
To evaluate the effects of SGLT2 inhibitors and GLP-1 RAs versus DPP-4 inhibitors on asthma exacerbations in diabetic patients.

-Methods
We conducted a retrospective cohort study using the National Health Insurance Research Database (NHIRD). Adult patients with type 2 diabetes and asthma, without a history of asthma exacerbation, were newly prescribed SGLT2 inhibitors, GLP-1 RAs, or DPP-4 inhibitors between 2016 and 2020. Target trial emulation and propensity score matching were used to enhance causal inferences. The composite asthma exacerbation outcome was defined as clinical visits for asthma exacerbation or systemic corticosteroid use. Patients were followed until the outcome, death, or December 31, 2020. Hazard ratios (HR) and 95% confidence intervals (CI) were estimated using the Cox proportional hazards model.

-Results
The first cohort included 27,170 patients (4,897 on SGLT2 inhibitors, 22,273 on DPP-4 inhibitors). The second cohort included 23,839 patients (440 on GLP-1 RAs, 23,399 on DPP-4 inhibitors). SGLT2 inhibitors (HR 0.82; 95% CI 0.73-0.93) and GLP-1 RAs (HR 0.71; 95% CI 0.48-1.04) showed lower risks of composite asthma exacerbation compared with DPP-4 inhibitors. Results for individual outcomes were consistent with the primary analysis. SGLT2 inhibitors (HR 0.64; 95% CI 0.57-0.71) and GLP-1 RAs (HR 0.91; 95% CI 0.68-1.21) also demonstrated lower all-cause mortality risk.

-Discussion/Conclusion
Our study suggests significant differences in asthma exacerbation risk between SGLT2 inhibitors and DPP-4 inhibitors in routine care. GLP-1 RAs also showed a lower risk, though not statistically significant due to sample size limitations. SGLT2 inhibitors might be a choice for type 2 diabetes patients with asthma, but further large-scale studies are needed to validate these findings.

O112

Validating a Cox-Regression Model to Predict Mortality in HFrEF Patients Using Real-World-Data

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Sacubitril-valsartan was shown to reduce all-cause mortality by 16% compared to enalapril in ambulatory patients with symptomatic heart failure with reduced ejection fraction (HFrEF). Thus, the development and validation of a risk prediction model for mortality in HFrEF, taking in consideration treatment options, has the potential to improve patient outcomes and allow for a better selection of therapies in HFrEF patients.
The aim is to develop and validate a mortality risk prediction model for HFrEF using real world data. Electronic medical record data was sourced from Brigham and Women's Hospital, two-thirds were randomly allocated to a derivation cohort and the other third to a validation cohort.
There were 2417 patients in the derivation cohort and 1033 in the validation cohort. The mortality rate was around 17% in both cohorts. Using the chi-square test, the main effect covariates that did significantly contribute to the model, as determined by a p-value of < 0.05, were included in the multivariable cox proportional model that includes: treatment intervention (ARNi or ACEi/ARBs), age, eGFR<60, prior renal and diabetes diagnosis, prior hospitalization, and current SGLT-2i use.
The Cox regression analysis revealed that ARNi administration has a lower hazard ratio(HR) of 0.755 (95%CI: 0.603–0.946) compared to ACEI/ARBs. Additionally, SGLT-2i showed a lower HR of 0.295 (95%CI: 0.187–0.467), further supporting its effectiveness in having longer time to all-cause mortality in HFrEF patients. The validation cohort showed that the adjusted model discriminated well with a ROCAUC = 0.696 (95%CI,0.65–0.73).
We have developed and validated a mortality risk prediction model based on routinely collected data of HFrEF patients. The model highlighted that ARNi and SGLT-2i had a longer time to all-cause mortality compared to those who didn't receive these treatments. The validation cohort showed that the adjusted model discriminated well between HFrEF patients who died and those who did survive.

O113

Superior Effectiveness of Prasugrel over Ticagrelor in Individuals with Acute Coronary Syndrome

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INTRODUCTION
There is ongoing debate about the optimal choice of P2Y12 receptor inhibitors for treatment of acute coronary syndrome due to limited direct comparative evidence and concerns about the generalizability of some underpowered analyses. Real-world data provides a valuable source that can potentially validate and complement randomized trial findings in routine clinical practice.
AIMS
To examine whether real-world evidence from this observational database study supports the same guideline recommendations as the randomized controlled trial ISAR-REACT5.
METHODS
This study aimed to emulate ISAR-REACT5 as closely as possible. Propensity score matching on 71 preexposure characteristics was employed to balance confounders. Study protocols were registered before analysis began. The study utilized a German health claims database between 2013-2021. Eligibility criteria were closely adopted from ISAR-REACT5. A total of 17,642 propensity score-matched individuals (n=8,821, each) with acute coronary syndrome and either ticagrelor or prasugrel treatment after hospital discharge were analyzed. Primary outcome was the composite of all-cause mortality, myocardial infarction, or stroke within one year of treatment initiation. Safety outcome was bleeding. Outcomes of this study were compared to ISAR-REACT5 on predefined binary metrics, including regulatory and estimate agreement.
RESULTS
Concordance was quantified in 5 of 6 for regulatory agreement, and 6 of 6 for estimate agreement. The primary composite endpoint occurred in 9.2% of ticagrelor-treated individuals and 7.5% of those treated with prasugrel (HR, 1.24; 95% CI, 1.12-1.37). Safety end point bleeding revealed no significant differences between treatment groups. Subgroup analysis demonstrated superiority for prasugrel in individuals with ST-segment elevation myocardial infarction.
CONCLUSION
This study reiterates the superior effectiveness of prasugrel over ticagrelor in individuals with acute coronary syndrome undergoing invasive strategy in a real-world setting, particularly in those with ST-segment elevation myocardial infarction. It also highlights how carefully-designed observational studies can complement and extend findings from randomized trials, informing clinical decision making.

O114

Aspirin versus clopidogrel on incident type 2 diabetes in patients with CVD

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Introduction: Data suggests that low-dose aspirin may lower the risk of type 2 diabetes in healthy older adults, but its benefits for those with cardiovascular disease (CVD) are uncertain. Moreover, choosing between aspirin and clopidogrel for CVD management is controversial due to their varying effects on cardiovascular and bleeding events.

Aims: To compare the effects of low-dose aspirin versus clopidogrel on the risk of incident type 2 diabetes, cardiovascular events, and bleeding events among patients with CVD.

Methods: We emulated a pragmatic trial to compare aspirin and clopidogrel monotherapy among patients with coronary artery disease, stroke/transient ischaemic attack, or peripheral arterial disease. We used overlap and inverse probability of censoring weight to account for confounding and artificial censoring. We estimated the observational analogues of intention-to-treat (ITT) and per-protocol (PP) effects in hazard ratios (HRs) and eight-year absolute risk (AR) using pooled logistic regression models.

Results: 78,012 and 33,280 patients initiated aspirin or clopidogrel monotherapy after CVDs were included. Aspirin was not associated with a lower risk of diabetes (ITT effect: HR, 1.01; 95%CI, 0.96-1.07; AR, 13.2% vs 13.4%. PP effect: HR, 1.04; 95%CI, 0.96-1.12; AR, 13.5% vs 13.1%) or bleeding events (ITT effect: HR, 1.01; 95%CI, 0.95-1.06; AR, 13.2% vs 12.7%. PP effect: HR, 0.98; 95%CI, 0.91-1.07; AR, 12.6% vs 12.4%), compared with clopidogrel. Aspirin was associated with a higher risk of cardiovascular events than clopidogrel in ITT analysis (HR, 1.06; 95%CI, 1.02-1.11; AR, 21.1% vs 20.0%) but not in PP analysis (HR, 1.03; 95%CI, 0.98-1.09; AR, 17.9% vs 17.8%).

Discussion: Aspirin and clopidogrel have similar risks concerning incident diabetes, acute cardiovascular events, and bleeding events among patients with CVD. The results provide evidence of the real-world comparative effectiveness of the two most commonly used antiplatelet drugs and could guide the choice of antiplatelet therapy for patients without diabetes.

O115

Potential interactions between digoxin and direct oral anticoagulants: cohort & case-crossover designs

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Introduction: Direct oral anticoagulants (DOACs) are commonly co-prescribed with digoxin, but whether there is a drug interaction between them is unclear.
Aims: To investigate potential drug-interactions between DOACs and digoxin.
Methods: We identified DOAC users during 1/1/2011-31/12/2019 using data from Clinical Practice Research Datalink Aurum in cohort design with propensity-score to compare the hazards of effectiveness outcomes (ischaemic stroke, myocardial infarction, venous thromboembolism, cardiovascular mortality, all-cause mortality) and safety outcomes (intracranial bleeding, gastrointestinal bleeding, other bleeding), respectively in DOAC+digoxin users versus DOAC+beta-blockers users. A case-crossover design was conducted to compare odds of exposure to different drug initiation patterns in hazard period versus referent period.
Results: Of 397,459 DOAC users, we identified 25,251 co-prescribed digoxin and 109,779 co-prescribed beta-blockers in cohort study. A lower proportion of DOAC+digoxin users were men (46%) in contrast with that of DOAC+beta-blocker users (53%). No increased risk of pharmacologically predictable DOAC safety outcomes or specific effectiveness outcomes was seen with DOAC+digoxin. A higher risk of all-cause mortality (hazard ratio[HR]:1.35; 99% CI:1.14–1.61) was observed with DOAC+digoxin, versus DOAC+beta-blockers. In the case-crossover study, a 20% higher odds of all-cause mortality was seen with initiating digoxin while taking DOAC (odds ratio[OR]:1.20; 99%CI:1.03–1.39); and a 60% higher odds was also seen with initiating DOAC while taking digoxin (OR:1.59; 99%CI:1.37–1.84).
Discussion/Conclusion: We found no increased risk of bleeding when DOACs are used with digoxin, suggesting combined use does not lead to drug-drug interaction. Future work is recommended to investigate the underlying mechanism of association with all-cause mortality.

O116

Anticoagulant Discontinuation After Minor Bleed and Stroke Risk Among Atrial Fibrillation Patients

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Introduction: Oral anticoagulants (OACs) are essential for managing atrial fibrillation (AF) to prevent thrombotic events. However, they are frequently discontinued due to concerns about bleeding, particularly in patients who experience minor bleeding episodes.

Aims:
To examine the association between the discontinuation of direct OACs (DOACs) and the incidence of stroke/transient ischemic attack (TIA) among older AF patients who experienced minor bleeding.
Methods:
This target trial emulation study used a Japanese governmental claims database (Shizuoka Kokuho Database). Patients aged ≥65 with AF who initiated DOACs between 2013 and 2020 and experienced minor bleeding within 12 months were included. Minor bleeding was defined as outpatient bleeding not leading to hospitalization. We compared treatment assignment in patients who continued vs. discontinued DOACs within 2 months after minor bleeding, with discontinuation defined as a lapse of over 60 days without a prescription refill. Using the clone-censor-weight method, we assessed stroke/TIA events as the primary outcome. A per-protocol analysis was performed, adjusting for selection bias with inverse probability of artificial censoring weights and stabilized weights for death. Weighted pooled logistic models were used, adjusting for baseline covariates, including frailty, linear time, and squared time, with robust standard error estimation. We estimated approximate hazard ratios (HRs) and 95% confidence intervals (CIs).
Results:
Among 2,617 patients who initiated DOACs and experienced minor bleeding, the median age was 79 years (25th–75th percentile: 74–84), and 46% were women. A total of 270 patients discontinued DOACs within 2 months after minor bleeding, while 2,347 continued. Discontinuation was associated with a higher risk of stroke/TIA (adjusted HR [95% CI]: 1.82 [1.10-3.01]).
Discussion/Conclusion:
Among contemporary older AF patients who initiated DOACs, discontinuation after minor bleeding was associated with an increased stroke/TIA risk. This finding underscores the importance of carefully considering the continuation of DOACs despite minor bleeding episodes.

O117

Fish oil supplementation, Life's Essential 8, and cardiovascular mortality in diabetic patients

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Introduction: The utility of fish oil in reducing the risk of cardiovascular disease (CVD) mortality in people with diabetes remains unclear and inconsistent. Till date, no studies have investigated the effect of cardiovascular health (CVH) on the cardioprotective benefits of fish oil supplementation in people with diabetes.

Aims: To investigate the potential modifying effect of CVH level, as assessed using the Life's Essential 8 (LE8) score, on the association between habitual fish oil supplementation and CVD mortality in people with type 2 diabetes (T2D).
Methods: Participants with T2D in the UK Biobank were included. CVH level was categorized by the mean LE8 score (55 points). Multivariable-adjusted Cox models were used to evaluate the longitudinal association between habitual fish oil supplementation status and CVD mortality. We performed stratified analysis across different CVH levels, and tested potential interaction between fish oil supplementation and CVH level.
Results: The analysis included 19,003 participants (mean age 59.9±6.9 years, 36.1% women), of whom 39.6% were habitual fish oil users. During a median follow-up of 13.7 years, 914 CVD deaths were documented. We found that habitual fish oil supplementation was significantly associated with a lower risk of CVD mortality among participants with better CVH (i.e., LE8 score ≥55 points; hazard ratio [HR]=0.65, 95% confidence interval [CI] 0.50–0.84, P<0.001), but not among those with poorer CVH (i.e., LE8 score <55 points; HR=1.02, 95% CI 0.83–1.25, P=0.867). The interaction between habitual fish oil supplementation and CVH level on CVD mortality was significant (P=0.017).
Conclusions: Only people with a relatively high baseline CVH level may obtain additional cardiovascular benefits from fish oil supplementation. The findings reinforced the great importance of promoting multilateral holistic lifestyle modification and interventions to improve the survival and quality of life of people with diabetes.

Keywords: Fish oil supplement, Life's Essential 8, cardiovascular health

Session: Infectious Disease and Antibiotics [Med-1F, October 13th 13:00-14:30] O118-O123

Moderators: Junichi Kawakami and Olaf Klungel

O118

Risk of macrolides and fluoroquinolones on fatal arrhythmia: a nested case-control study

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Introduction: Although macrolides and fluoroquinolones can cause fatal arrhythmia, few studies have evaluated this risk in Japanese populations.

Aims: To assess the 30-day risk of fatal arrythmia caused by macrolides and fluoroquinolones compared with second- or third-generation cephems using a Japanese medical claims database.
Methods: We utilized Japanese medical claims data provided by JMDC Inc. for the period April 2012 to March 2021. We constructed a cohort of patients who were dispensed macrolides, fluoroquinolones, or cephems, and who met the eligibility criteria. We used the nested case-control (NCC) study design. Among the full cohort, cases were defined as patients who experienced an outcome within 30 days after exposure, and controls were sampled from the at-risk population at the time each case occurred. We sampled five control subjects per case by simple random sampling. Exposure was defined as the dispensing of macrolides or fluoroquinolones, and cephems were used as a comparator. The outcome was defined as hospitalization with a diagnosis of arrhythmia or sudden death. Hazard ratios (HRs) were estimated using an inverse probability of treatment (IPT)-weighted Cox model. The IPT weights were calculated by fitting an inverse probability of sampling-weighted generalized logistic model conditioned on sex, age, Charlson comorbidity index, medication history, and medical history.
Results: The full study cohort comprised ~2.8 million people (~1.5 million males; mean age [standard deviation]: 33.9 [18.4] years). We extracted 332 cases and 1,660 controls. Compared with cephems, for macrolides the crude HR was 0.99 (95% confidence interval: 0.76–1.32) and the IPT-weighted HR was 0.98 (0.73–1.34). In contrast, for fluoroquinolones the crude HR was 0.89 (0.65–1.22) and the IPT-weighted HR was 0.79 (0.58–1.09).
Discussion: The use of macrolides and fluoroquinolones may not increase the risks of fatal arrhythmia or other cardiovascular diseases in Japanese people, but the accumulation of further safety data is necessary.

O119

Antibiotic De-escalation via the use of Novel Metric among Cancer Patients: A DASC-based Approach

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Introduction: Defined daily dose (DDD) and days of therapy (DOT) are the widely used traditional metrics for antimicrobial stewardship. DOT only counts number of days patient received antibiotics however does not account for spectrum of antibiotics hence may not accurately measure antibiotics regimens and de-escalation strategies. Days of Antibiotic Spectrum Coverage (DASC) is a novel metric which can measure both duration and spectrum of antibiotics has gained popularity. However, it has not been utilized in cancer patients who are more susceptible to infections and often receive antibiotics.

Aim: To evaluate the antibiotic consumption via DASC and DOT among cancer patients.
Methodology: A prospective observational study was carried out in oncology wards for the duration of one year (January 2023-December 2023). DASC is the sum of antibiotic spectrum scores multiplied by duration of treatment. Data was analyzed using descriptive statistics, Karl Pearson's and Spearman's rank correlation coefficient.
Results: Among the 213 cancer patients, males (62.4%) predominate over female with mean age 51.5 years. The overall DOT, DASC, and de-escalation DASC score was found to be 13850.2, 12640, and 1880 respectively. The de-escalation rate was 14.8%. On correlation, we observed significant positive correlation between monthly DASC and DASC/patients ($\rho=0.73$, $p<0.01$), and between DASC and monthly DOT ($\rho=0.692$, $p<0.05$) whereas significant negative correlation was observed between DASC/DOT ratio and DOT/patients ($r=0.692$, $p<0.05$).

Discussion: The integration of DASC alongside DOT offers a more comprehensive evaluation of stewardship efforts. The monthly DASC vs DOT and monthly DASC vs DOT/patients showed parallel trends. Higher DASC/DOT ratio is indicative of broad-spectrum antibiotic use and vice-versa. There was no correlation between DASC/DOT ratio with other metric indicating it as a independent and robust metric. Thus, use of DASC can lead to more accurate measurement of AMS efforts in compared to DOT/DDD in challenging facilities like oncology wards.

O120

Clinical and Economic Impact of Clinical Pharmacist-Steered Handshake Antibiotic Stewardship in Surgery

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Introduction: Antibiotic stewardship programmes (ASPs) are specifically important for surgical specialties due to their impact on the use of antibiotics as prophylaxis and therapy.
Aim: To assess the clinical and economic impact of clinical pharmacist-initiated Handshake Antibiotic Stewardship in surgical units of a tertiary care hospital.
Methods: This was a prospective interventional study carried out primarily by a clinical pharmacist at the Surgical units in two phases: the pre-implementation and the post-implementation phases. The clinical and economic outcomes were assessed in both the pre-implementation and the post-implementation phases of the antibiotic stewardship programme. The paired t-test and the Wilcoxon sign rank test were used to compare both phases. The chi-square test was used to determine the association between various categorical variables such as length of stay, surgical prophylaxis, SSIs, culture-susceptibility tests, etc. The data was analyzed using SPSS 26.0 version and the results with $p< 0.05$ were considered statistically significant.

Results: There was a statistically significant ($p< 0.001$) decrease in the number of days of surgical antimicrobial prophylaxis during the post-implementation phase. The post-implementation phase witnessed a statistically significant reduction in DDD per 10000 patient days and DOT per 1000 patient days of antibiotics. During the pre-implementation phase, 6.03% of culture and susceptibility tests were performed, whereas 10.27% were performed in the post-implementation phase. De-escalation of antibiotics was done in 8.31% of patients during the pre-implementation phase, whereas it was done in 16.21% of patients in the post-implementation phase. Also, there was a significant reduction in the length of stay during the post-implementation phase. A net cost saving of 784346.02 INR was achieved post-implementation. Furthermore, there was a significant reduction in the probability of length of stay and lab monitoring in the post-implementation phase.

Conclusion: ASP can improve the clinical and economic outcomes of surgical patients

O121

Prevalence of MALDI-TOF MS for patients with bacteremia using Japanese administrative claims database from FY 2018 to 2020

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Introduction. Matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS) is used in the treatment of infectious disease, which has been reported to reduce mortality, length of hospital stay, and time to effective therapy for infectious disease. However, reports on the use of MALDI-TOF MS in multicenter settings are limited in Japan.

Aims. This study aimed to survey the prevalence of MALDI-TOF MS for patients with bacteremia.
Methods. We conducted a retrospective descriptive study used inpatient claims data from fiscal year (FY) 2018 to FY 2021, collected by Medical Data Vision, Inc. Eligible patients for this study were those who: 1) were admitted for infection, 2) had blood culture collected and susceptibility testing performed during the hospitalization period, 3) were administered antimicrobials for at least three days, and 4) were 18 years or older. We investigated the prevalence of MALDI-TOF MS. In addition, the patient's background was described by whether antimicrobials changed or no changed. Moreover, described median days to change antimicrobials and the mean daily cost of before and after the antimicrobials change.
Results. 114,820 patients were included in this study and 5% (5,741 patients) were used MALDI-TOF MS. There were 4,232 patients in the antimicrobial changed group and 1,509 patients in the no changed group. Significant differences were observed in age (p=0.0004) and sex (p=0.0005). The median (interquartile range) days to antimicrobial change was 6 (3-11) days. Mean daily antimicrobial costs before and after antimicrobial change were 11.0 USD per day and 9.4 USD per day, and the difference was 1.6 USD per day (95% Confidence Interval 0.9-2.1; p<0.001).
Conclusion. Prevalence of MALDI-TOF MS using for patients with bacteremia was not higher than anticipated. On the other hands, there is a possibility of effectiveness for infectious therapy; and therefore, more detailed research is needed in the future.

O122

Effectiveness of nirmatrelvir/ritonavir and molnupiravir in non-hospitalized adults with COVID-19: systematic review

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Aim: To determine the effectiveness of nirmatrelvir/ritonavir and molnupiravir among vaccinated and unvaccinated non-hospitalized adults with COVID-19.
Methods: Observational studies of nirmatrelvir/ritonavir or molnupiravir compared to no antiviral drug treatment for COVID-19 in non-hospitalized adults with data on vaccination status were included. We searched MEDLINE, EMBASE, Scopus, Web of Science, WHO COVID-19 Research database, and medRxiv for reports published between 1 January 2022 and 8 November 2023. The primary outcome was a composite of hospitalization or mortality up to 35 days after COVID-19 diagnosis. Risk of bias was assessed with ROBINS-I. Risk ratios (RR), hazard ratios (HR) and risk differences (RD) were separately estimated using random-effects models.

Results: We included 30 cohort studies on adults treated with nirmatrelvir/ritonavir (n=462,279) and molnupiravir (n=48,008) in the systematic review and 22 studies in the quantitative synthesis. Nirmatrelvir/ritonavir probably reduced the composite outcome (RR 0.62, 95% CI 0.55–0.70; I^2=0%; moderate certainty) with no evidence of effect modification by vaccination status (Psubgroup=0.47). In five studies, RD estimates against the composite outcome for nirmatrelvir/ritonavir were 1.21% (95% CI 0.57% to 1.84%) in vaccinated and 1.72% (95% CI 0.59% to 2.85%) in unvaccinated subgroups.

Molnupiravir may slightly reduce the composite outcome (RR 0.75, 95% CI 0.67–0.85; I^2=32%; low certainty). Evidence of effect modification by vaccination status was inconsistent among studies reporting different effect measures (RR Psubgroup=0.78; HR Psubgroup=0.08). In two studies, RD against the composite outcome for molnupiravir were −0.01% (95% CI −1.13% to 1.10%) in vaccinated and 1.73% (95% CI −2.08% to 5.53%) in unvaccinated subgroups.

Conclusion: Among cohort studies of non-hospitalized adults with COVID-19, nirmatrelvir/ritonavir is effective against the composite outcome of severe COVID-19 independent of vaccination status. Further research and a reassessment of molnupiravir use among vaccinated adults are warranted.

Keywords: Antiviral drugs, COVID-19, effectiveness, vaccination status

O123

Risk factors for S.aureus and MRSA carriage in children: a case-control study

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Introduction. Staphylococcus aureus is a kind of commensal bacteria that potentially increase the risk of staphylococcal infections especially among children who with a weaker immune system. Prolonged carriage in child may lead to potential serious invasive bacterial infection.

Aims. To study the epidemiology and risk factors for bacterial carriages of S.aureus and MRSA in Hong Kong children and adolescent.

Methods. We recruited and obtained nasal swabs from children and adolescents, aged 0-18 years during their clinical follow-up visit in Hong Kong Children's Hospital specialist out-patient clinic along with surveys completed by caregivers regarding information on recent antibiotic usage, travel and infection history. Bacterial colonization test was freshly performed after receiving the samples. Subjects with S.aureus colonization were case, while the subject without colonization acting as a control. Risk factors were analysed using logistic regression models.

Results. Of all 207 subjects, 62 were case (30%); 4% were MRSA carrier; with 52.9% of male; mean age 8.39; 79.6% prior antibiotic use; 52.4% prior pneumococcal vaccination; 80.1% prior respiratory symptoms and 54.5% with chronic medical condition.

Female and younger age when comparing age 0-3, 4-12 and 13-18 years old have a lower risk of S.aureus and MRSA colonization (OR: 0.48, 95%CI: 0.37-0.61; OR: 0.03, 95%CI: 0.02-0.04). Other significant risk factors for S.aureus and MRSA carriage including increase in household size (OR:1.6, 95%CI: 1.21-2.02 ; OR:5.64, 95%CI: 4.37-7.29), having any domestic pets (OR: 1.14, 95%CI: 0.89-1.48; OR: 1.71, 95%CI: 1.33-2.21), prior respiratory symptoms (OR: 1.08, 95%CI: 0.84-1.34; OR: 1.98, 95%CI: 1.53-2.55), overseas travel history in past 12 months (OR: 4.33, 95%CI: 3.36-5.59; OR: 5.71, 95%CI: 4.42-7.37).

Discussion. Prevalence of S.aureus and MRSA carriage higher than previously reported. The risk factors identified in this study will help inform the profile of potential high risk for S. aureus and MRSA carriage.

Keywords: MRSA, Staphylococcus aureus

Session: Diabetes [Yasuda, October 13th 16:45-18:15] O124-O129

Moderators: Manabu Akazawa and Edward Chia-Cheng Lai

O124

SGLT2 Inhibitors and Risk of CKD-MBD in Patients with T2D and CKD

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Introduction: Sodium-glucose cotransporter-2 (SGLT2) inhibitors offer beneficial renal effects in type 2 diabetes (T2D) patients with chronic kidney disease (CKD). Evidence extending these benefits to CKD-mineral and bone disorders (CKD-MBD) is lacking.
Aims: To investigate the incidence of CKD-MBD after SGLT2 inhibitor use in T2D patients with CKD.
Methods: We emulated CREDENCE, DAPA-CKD and EMPA-KIDNEY trials using Taiwan's largest multi-institutional electronic medical records database. We included adults with T2D and CKD stages 1-3, initiating SGLT2 inhibitors or glucagon-like peptide-1 receptor agonists (GLP-1 RAs) during 2016-2021, with follow-up until December 31st, 2023. We controlled baseline characteristics using propensity scores with inverse probability of treatment weighting. The primary outcome was the incident composite CKD-MBD outcomes, namely: (1) hyperphosphatemia; (2) hypocalcemia; (3) serum iPTH levels >65 pg/mL and (4) serum 25-hydroxyvitamin D levels <20 ng/mL. Subgroup analysis assessed these outcomes' association with individual inhibitors.
Results: The weighted cohort included 11,968 T2D patients with CKD stages 1-3, newly receiving SGLT2 inhibitors (n=10,661) or GLP-1 RAs (n=1,307). After the median 3.2 years follow-up, SGLT2 inhibitors were associated with lower cumulative incidence of composite CKD-MBD (HR: 0.82; 95%CI: 0.79-0.86), compared to GLP-1 RAs. Regarding individual outcomes, SGLT2 inhibitors were associated with significantly reduced risk for incident hyperphosphatemia (HR: 0.83; 95%CI: 0.76-0.91), hypocalcemia (HR: 0.82; 95% CI: 0.78-0.86), serum iPTH levels >65 pg/ml (HR: 0.66; 95% CI: 0.57-0.78) and serum 25-hydroxyvitamin D levels <20 ng/mL (HR: 0.65; 95% CI: 0.47-0.90). Subgroup analysis indicated the risk of composite CKD-MBD was significantly lower for empagliflozin (HR: 0.82; 95% CI: 0.77-0.87), dapagliflozin (HR: 0.82; 95% CI: 0.76-0.88), and canagliflozin (HR: 0.88; 95% CI: 0.78-1.00).
Conclusion:
SGLT2 inhibitors were associated with a reduced risk of composite and individual CKD-MBD outcomes. To reduce CKD-MBD incidence in T2D patients with CKD stages 1-3, SGLT2 inhibitors may be considered.

O125

Trends in Antidiabetic Medication Use among Patients with Diabetes in the U.S.

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Introduction
Poorly controlled diabetes can lead to severe complications and increased mortality. Proper treatment is essential to prevent or delay the onset of these complications. In 2018, the American Diabetes Association updated its pharmacologic therapy guidelines based on comorbidities. However, few studies have investigated medication use patterns since the guideline updated. Our study aimed to track trends in antidiabetic medication usage and investigate whether patients with diabetes receive appropriate treatment.
Methods
Data from the 2018-2021 Medical Expenditure Panel Survey were used, which is a nationally representative annual survey in the U.S. with comprehensive information of medication use. Diabetes diagnoses were identified using ICD-10-CM codes, and antidiabetic medications were categorized using the Multum Lexicon database. Descriptive statistics were estimated using survey weights. Wald Chi-square tests were used to assess trend changes between 2018 and 2021. After pooling the 2018 and 2021 data, multivariable logistic regression models were used to calculate the adjusted odds ratio (aOR).
Results
The diagnosis of diabetes slightly increased from 2018 to 2021(7.4% vs. 7.6%, p=0.74). Among patients with diabetes, antidiabetic medication use significantly rose from 87.8% to 91.4% (p<0.05). Notable increases were observed in the use of metformin (59.1% vs. 65.0%, p<0.05), sodium-glucose cotransporter-2 (SGLT-2) inhibitors (4.5% vs. 10.0%, p<0.01), and glucagon-like peptide-1 receptor agonists (6.4% vs. 7.6%, p=0.38). Monotherapy use decreased (50.4% to 47.8%, p=0.29), while the use of triple therapy increased (9.7% to 12.5%, p=0.12). Patients with dyslipidemia were significantly more likely to use any antidiabetic medication (aOR: 2.24; 95% CI: 1.50-3.33) than those without dyslipidemia. Older patients (≥65 years) were more likely to use sulfonylureas (aOR: 1.66; 95% CI: 1.19-2.31) than younger patients.
Conclusion
The use of antidiabetic medications among patients with diabetes has significantly increased, particularly in the case of metformin and SGLT-2 inhibitors. This observed increase aligns with current guideline recommendations.

O126

Glycemic Variability and Persistent Acute Kidney Injury: Multicenter Study with External Validation

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Introduction:
While the relationship between glycemic variability (GV) and acute kidney injury (AKI) has been a subject of interest, the specific association of GV with persistent AKI following noncardiac surgery is not well-established.

Aims:
This retrospective cohort study aimed to describe the patterns of different GV metrics within 48 hours after noncardiac major surgery, evaluate the association between GV and persistent AKI within the 7-day postoperative window, and compare the risk identification capabilities of various GV metrics for persistent AKI.

Methods:
A total of 10,937 patients across three medical centers in eastern China were enrolled. GV was characterized using coefficient of variation (CV), mean amplitude of glycemic excursions (MAGE), and blood glucose risk index (BGRI). Multivariable logistic regression examined the relationship between GV and AKI. Optimal cutoff values were determined through risk identification models, independent cohort from the INSPIRE database was used for external validation.

Results:
Higher GV was associated with an increased risk of persistent AKI (CV: OR = 1.26, 95% CI: 1.08-1.46; MAGE: OR = 1.31, 95% CI: 1.15-1.49; BGRI: OR = 1.18, 95% CI: 1.08-1.29). Compared to models that did not consider glycemic factors, MAGE and BGRI independently contributed to predicting persistent AKI (MAGE: AUC = 0.768, p = 0.011; BGRI: AUC = 0.764, p = 0.014), with cutoff points of 3.78 (MAGE) and 3.02 (BGRI), respectively. Classification of both the internal and external validation cohorts using these cutoffs demonstrated good performance, achieving the best AUC values of 0.768 for MAGE in the internal cohort and 0.777 for MAGE in the external cohort.

Discussion:
Postoperative GV is an independent risk factor for persistent AKI. Specific cutoff points are useful to stratify at-risk patients. These findings indicate that stabilizing GV may potentially mitigate adverse postoperative kidney outcomes, highlighting the importance of glycemic control in the perioperative period.

O127

Comparison of Suicidal-Related Behaviors Between GLP-1RAs and DPP4 Inhibitors in Taiwan

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- Introduction: GLP-1RAs are frequently prescribed for managing type 2 diabetes. However, concerns have arisen regarding the risk of suicidal attempts associated with GLP-1RAs following the EMA announcement about a potential link. We conducted a study using a nationwide database to evaluate the risk.

- Aims: To evaluate the association between suicidal-related outcomes and the use of GLP-1RAs compared to the use of DPP4 inhibitors in the type 2 diabetes population in Taiwan.

- Methods: This is a retrospective cohort study. We applied propensity score matching, pairing controls for each case with the ratio of 1:1. Individuals enrolled in Taiwan's National Health Insurance Research Database (NHID) from 2016 to 2021 were included. The index date was defined as the date of the first prescription of GLP-1RAs or DPP4 inhibitors. Patients who initiated both medications simultaneously, used the opposite medication within three years prior to the index date, or had a record of suicidal attempts or depression within three years prior to the index date were excluded. The outcomes of interest were suicidal-related behaviors, including suicidal attempts and suicidal death. We applied an intention-to-treat design, and the follow-up period was defined from the index date to the occurrence of the outcome of interest, death, or the end of the study period (December 31, 2024), whichever came first. We evaluate the hazard ratio through Cox proportional hazard model.

- Results: We identified 694,054 cases of DPP4 inhibitors and 8,986 cases of GLP-1RAs. The HRs for suicidal attempts, suicidal deaths, and composite outcomes were 1.00 (0.61, 1.63), 0.75 (0.17, 3.35), and 0.97 (0.61, 1.55) respectively.

- Discussion/Conclusion: Our study indicates the risk of suicide-related outcomes is comparable between GLP-1RAs and DPP4 inhibitors, suggesting no significant difference in safety regarding suicidal behaviors.

- Keywords: GLP-1RAs, DPP4i , suicidal-related outcomes, National Health Insurance Research Database

O128

Comparing cardio-hepatic benefits of GLP1rA and pioglitazone: A target trial emulation study

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Introduction: Both glucagon-like peptide-1 receptor agonist (GLP1rA) and pioglitazone on its own have been shown to possess cardio-hepatic benefits in patients with type 2 diabetes. However, their comparative effects in reducing adverse cardiovascular and liver outcomes remains undetermined.

Aims: We conducted this territory-wide target trial emulation study to compare the risks of developing major adverse cardiovascular events (MACE) and adverse liver outcomes between GLP1rA and pioglitazone users who had type 2 diabetes.

Methods: Using electronic health records of the Hospital Authority of Hong Kong, we emulated a target trial with an active-comparator new-user design on eligible patients with type 2 diabetes who were newly prescribed GLP1rA or pioglitazone between January 2008 and December 2022. New users of GLP1rA and pioglitazone were matched one-to-one using propensity score matching (PSM). Cox proportional hazards models were used to estimate the hazard ratios (HRs) of developing the primary outcomes of MACE and the adverse liver outcomes, using both intention-to-treat (ITT) and per-protocol (PP) analyses.

Results: A total of 8,786 patients were included after PSM. While there were no notable difference in the risk of developing adverse liver outcomes between new users of GLP1rA and pioglitazone (p=0.964 and p=0.895 in ITT and PP analyses, respectively), new users of GLP1rA had significantly lower risk of MACE compared to pioglitazone in both ITT (HR 0.73, 95% CI 0.61-0.88, p<0.001) and PP (HR 0.70, 95% CI 0.52-0.95, p=0.021) analyses. The results were consistent across most subgroup and sensitivity analyses.

Conclusion: With similar hepatic benefits, GLP1rA, as compared to pioglitazone, provides more reduction in MACE and may be the more promising agent for managing patients with type 2 diabetes who are at risk of both adverse cardiovascular and hepatic events, such as those with co-existing metabolic dysfunction-steatotic liver disease.

Associations between Newer Glucose-Lowering Drugs and Cognitive Impairment in Adults with Diabetes

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Cognitive impairment (CI) is a growing sequela of type 2 diabetes (T2D). Three newer glucose-lowering drugs (GLDs) are used as second-line therapy for T2D, i.e., glucagon-like peptide-1 receptor agonist (GLP-1RA), sodium-glucose transport protein 2 inhibitors (SGLT2i), or dipeptidyl peptidase 4 inhibitors (DPP4). Some data suggest that these GLDs may have cognitive benefits, however, comparisons across drug classes are scarce. We investigated the associations between newer GLD and cognitive health among adults with T2D.

Adults with diagnosed or self-reported T2D were identified from the Medical Expenditure Panel Surveys (2010-2020). We used Multum Lexicon codes to identify the person's GLD use. We studied three groups: (1) adults filling Metformin plus DPP4, (2) adults filling Metformin plus SGLT2i, and (3) adults filling Metformin plus GLP-1RA. CI was measured during the survey interview using a questionnaire. The three groups were matched with a 1:1 multigroup propensity score algorithm based on age, sex, socioeconomic status, and comorbidities (e.g., obesity, cardiovascular disease). Logistic regression analyses were then conducted to compare the associations between newer GLD use and cognitive health, further adjusting for residual unbalanced covariates after matching.

We identified 418 (55.29%), 183 (29.22%), and 107 (15.49%) individuals who used Metformin plus DPP4, GLP-1RA, and SGLT2i, respectively. Prevalence of cognitive impairment was highest in the Metformin plus DPP4 group (15.19%, 95% Confidence Interval (CI): 14.81%-21.89%), followed by the Metformin plus SGLT2i (12.02%, 95% CI: 6.15%-12.14%), and lowest in Metformin plus GLP-1RA group (9.87%, 95% CI: 7.84%-14.38%). Adjusted for confounders, individuals using Metformin plus DPP4 were 1.83 times (95% CI: 1.08-3.09), and those using Metformin plus SGLT2i 1.79 times (1.14-2.83) more likely than those using Metformin plus GLP-IRA to report CI.

GLP-RA use was associated with lower odds of CI compared with either DPP4 or SGLT2i. Further studies are warranted to investigate the potential causal relationship.

Session: Eyes and Kidney [Sanjo, Oct 13th 16:45-18:15] O130-O135

Moderators: Masao Iwagami and Grace Wangge

O130

Ophthalmic complications of platinum-based chemotherapy: Insights from disproportionality analysis and systematic review

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Background:
Anti-cancer drugs, particularly platins, have been showing ocular adverse events (OAEs) in patients undergoing chemotherapy.
Aim:
To evaluate the potential association between the use of platins (cisplatin, carboplatin, and oxaliplatin) and the risk of OAEs by analyzing spontaneous reports and reviewing case reports.
Methods:
A retrospective case/non-case study was conducted using spontaneous reports on OAEs by platins from the FDA Adverse Event Reporting System (FAERS) database. A disproportionality analysis was performed by calculating the Proportional Reporting Ratio (PRR) with χ2, Reporting Odds Ratio (ROR), and the Information Component (IC) to identify OAE signals for platins. In parallel, a review of case reports for OAEs from platins was conducted by a systematic literature search in PubMed and Google Scholar, published till 31st March 2024.
Results:
A total of 4262 spontaneous reports of OAEs caused by platins were identified from the FAERS Database. Using disproportionality analysis, 69 signals were identified for platins and OAEs (carboplatin: 42, oxaliplatin: 16, cisplatin: 11). Choroidal infarction [PRR=215.1; χ2=4527.1; lower bound (LB) ROR=140.7; IC025=5.1] and orbital haemorrhage [PRR=120.0; χ2 =300.5; LB ROR=35.1; IC025=1.3] were the strong signals identified for carboplatin. Optic disc hyperaemia [PRR=208.2; χ2=742.5; LB ROR=74.1; IC025=2.2] and blindness cortical [PRR=23.7; χ2=382.5; LB ROR=14.8; IC025=3.1] were the signals identified for oxaliplatin and cisplatin, respectively. Of 69 signals, 52 disappeared, and 17 were retained after signal refinement analysis. A total of 32 case reports of OAEs associated with platins were identified through a systematic search in PubMed and Google Scholar, strengthening the association between platins and OAEs.
Conclusion:
The study revealed a potential risk of OAEs when using platins as an anticancer medication. It is vital to update safety profiles for carboplatin and oxaliplatin in the prescribing information leaflet (PIL) due to insufficient data concerning ocular toxicity.

O131

Comparative Effectiveness Between Topical alpha-2 Agonist, Carbonic Anhydrase Inhibitor and Prostaglandin Analog combination therapy for Second-Line Glaucoma Treatment?

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Introduction

Three different fixed-combination therapies with distinct pharmacological mechanisms, including Brimonidine/Timolol (FC-BT), Dorzolamide/Timolol (FC-DT), and Travoprost/Timolol (FC-TT), are approved for patients with glaucoma who respond poorly to topical beta-blockers. However, the comparative effectiveness of these therapies remains unclear.

Aims

To compare the treatment effects of three different combination therapies for glaucoma treatment in Taiwan.

Methods

We conducted a nationwide retrospective cohort study by analyzing Taiwan's National Health Insurance Database. Adult patients who newly received topical fixed-combination therapies (FC-BT, FC-DT, and FC-TT) for glaucoma between 2010 and 2019 were included. The date of the first medication prescription was defined as the index date, and FC-DT was considered as the reference group for the comparison. We applied a propensity score overlapping weighting approach to ensure comparable baseline characteristics. The effectiveness outcomes included the incidence of curative procedures (i.e., incisional surgery or laser for glaucoma), blindness, and treatment persistence (i.e., the addition of other antiglaucoma medications and discontinuation of initial fixed-combination therapies).

Results

We identified a total of 59,535 patients receiving topical fixed-combination therapies for glaucoma (42.1% FC-BT, 52.7% FC-DT, and 5.83% FC-TT). In the comparison between FC-BT and FC-DT, the incidence rate for curative procedures was 35.03 (95% CI 33.38-36.74) and 38.56 (36.80-40.37) per 1,000 person-years, respectively, yielding an adjusted hazard ratio for curative procedures of 0.92 (0.86-0.98). In the comparison between FC-TT and FC-DT, the incidence rate for curative procedures was 31.10 (27.87-34.61) and 37.96 (34.33-41.88) per 1,000 person-years, respectively, yielding an adjusted hazard ratio for curative procedures of 0.83 (0.72-0.96). No significant differences were observed in other effectiveness outcomes, including blindness and treatment persistence, among these comparisons.

Conclusion

Our findings suggest that compared to FC-DT, both FC-BT and FC-TT as second-line treatments for glaucoma are associated with a lower rate of curative procedures.

O132

Comparative Glaucoma Risks Associated with Topiramate and Phenytoin: A Comparative Cohort Study

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Introduction: Topiramate, a second-generation anti-epileptic drug (AED), is FDA-approved for treating epilepsy, preventing migraines, and, when combined with phentermine, for weight loss in patients with a BMI over 30. Recommended dosages are 400 mg/day for epilepsy and 100 mg/day for migraines. Serious adverse effects, though rare, include acute glaucoma, metabolic acidosis, nephrolithiasis, hepatotoxicity, and teratogenicity.

Aims: To compare the risk of glaucoma associated with topiramate versus phenytoin in epilepsy patients.

Methods: Using the TriNetX platform, we conducted a comparative cohort study on newly diagnosed epilepsy patients treated with either phenytoin or topiramate, excluding those with a prior history of glaucoma from 2011 to 2023. Patients were matched by age and sex. A time-to-event analysis was performed, and data were censored at primary or secondary endpoints, last follow-up, medication changes, or new medications. The comparative risk of glaucoma was analyzed using the Cox proportional hazards model.
Results: We collected 80,193 phenytoin and 66,268 topiramate patients who were diagnosed as epilepsy. After matching, we had 41,505 patients in each cohort. After adjusting by age and sex, the comparative hazard ratio was 1.22 with 95% CI, 1.10-1.35, comparing to phenytoin.
Discussion/Conclusion: Topiramate was associated with a higher risk of glaucoma than phenytoin in epilepsy patients. Topiramate-induced myopic shift occurs due to ciliochoroidal effusion, leading to anterior rotation of the ciliary body and forward displacement of the lens-iris diaphragm, causing angle closure glaucoma. Prompt recognition and treatment are crucial to prevent permanent vision damage. Increased awareness among healthcare providers regarding topiramate's potential to cause acute angle closure glaucoma (AACG) is necessary. Patients should be informed about AACG symptoms and advised to seek immediate medical attention for visual disturbances to prevent long-term complications.

O133

Glaucoma eye drops and risk of asthma attacks: A target trial emulation

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Introduction: Glaucoma is treated primarily with medication such as topical prostaglandins and β-blockers. Although the side effects include asthma attacks, the quantitative risk has not been sufficiently assessed.
Aim: To assess topical prostaglandins and β-blockers at risk factors for asthma attacks compared with other glaucoma medications using a population-based cohort study with a target trial emulation framework.
Methods: We used a Japanese administrative claims database, to construct a cohort of patients aged ≥20 years who were newly prescribed prostaglandins, β-blockers, or other glaucoma medications from April 2012 to March 2021. We estimated the intention-to-treat (ITT)-hazard ratio (HR) for asthma attacks using inverse probability of treatment (IPT)-weighted Cox models. The IPT weight was computed with a generalized logistic model conditioned on the patient's sex, age, medical history, medication history, body mass index, smoking history, and occurrence of outcome up to 1 year before the index date. We also estimated the per-protocol (PP)-HR using IPT- and inverse probability of censoring (IPC)-weighted Cox models with adjustment for nonrandom treatment changes. The IPC weight was calculated using pooled logistic models conditioned on the variables employed to compute the IPT weight plus 60-day time points.
Result: We extracted 28,362 patients (males: 19,369 [68.3%]; mean age [standard deviation]: 53.8 [8.9] years), 16,201 patients (10,209 [63.0%]; 52.6 [9.4] years), and 13,472 patients (7,793 [57.9%]; 54.5 [9.5] years) treated with prostaglandins, β-blockers, and other glaucoma medications, respectively. Compared with other glaucoma medications, the crude HR, ITT-HR, PP-HR (95% confidence interval) for prostaglandins were 0.89 (0.71–1.13), 1.00 (0.78–1.27), and 0.91 (0.69–1.20), respectively. For β-blockers, the respective values were 0.67 (0.50–0.89), 0.72 (0.54–0.97), and 0.58 (0.40–0.83).
Conclusion: Prostaglandins and β-blockers do not increase the risk of asthma attacks compared with other glaucoma medications, regardless of treatment changes.

O134

Acute Kidney Disease Risk and Postoperative Glycemic Variability After Cardiac Surgery

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Introduction:
Blood glucose instability can lead to organ damage through various mechanisms. Intraoperative glycemic fluctuations are known risk factors for postoperative acute kidney injury (AKI). However, no previous research has specifically investigated the relationship between postoperative glycemic variability (GV) and acute kidney disease (AKD) or long-term renal dysfunction.
Aims:
To investigate the association between postoperative GV, calculated using five methods, and the risk of AKD in patients undergoing cardiac surgery involving cardiopulmonary bypass.
Methods:
We conducted a multicenter retrospective study involving 8,090 adult patients from three academic medical centers in Eastern China between 2015 and 2023. Seven-day postoperative GV was calculated using the standard deviation (SD), coefficient of variation (CV), mean amplitude of glycemic excursions (MAGE), average daily risk range (ADRR), and time out of target range (TOR). The primary focus was on the occurrence of AKD between 8 and 90 days post-surgery, categorized into persistent AKD and delayed AKD based on AKI status in the first 7 days.
Results:
During the 8-90 day postoperative period, AKD occurred in 522 of 8,090 (6.5%) patients. Postoperative GV was significantly higher in the AKD group ($p<0.001$ for each metric). After adjusting for relevant covariates, each GV metric was significantly associated with elevated AKD risk (standardized hazard ratio (SHR) from 1.20 (95% CI: 1.12-1.27, for SD) to 1.30 (95% CI: 1.20-1.40, for TOR). When categorizing kidney disease subtypes, GV was correlated with persistent AKD but not with delayed AKD.
Discussion:
Our study highlights the association between GV and increased AKD risk in adults undergoing cardiac surgery, especially in patients with prolonged kidney injury. These findings underscore the importance of stabilizing blood glucose levels in the postoperative period to mitigate AKD risk and highlight the need for prospective studies to explore causal relationships and identify potential clinical interventions.

O135

Validation of Kidney Failure Risk Equation for Renal Anemia in Asians

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Introduction:
The Kidney Failure Risk Equation (KFRE) was developed to predict the risk of progression to end-stage kidney disease (ESKD). Although validated in multinational cohorts, the KFRE's applicability to the Asian population remains uncertain due to under-representation in these studies.

Aims:
This study aimed to validate the KFRE equation using data from the Tianjin CKD Cohort to verify its applicability to the Asian population.

Methods:
National cohort data from Tianjin Inspur Healthcare Big Data was utilized. Between January 2018 and June 2023, a total of 127,916 adult patients were enrolled, including 60,668 patients with G3 to G5 chronic renal failure. Using the original KFRE (4-variable, 6-variable, and 8-variable equations), we predicted the 2- and 5-year risk of ESKD progression. Renal failure was defined as ESKD requiring kidney replacement therapy (KRT) within 2 or 5 years. The predictive performance, discrimination, and calibration of these models were assessed using the area under the receiver operating characteristic curve (ROC-AUC), Harrell’s C-index, and calibration curves.

Results:
The cohort included 60,668 patients, with 28,923 treated continuously for 2 years and 11,832 for 5 years. Among them, 6,500 and 2,867 progressed to renal replacement therapy, respectively. The KFRE model discriminated poorly for 2-year (C-statistics of 0.52, 95% CI 0.51 to 0.53; 0.54, 95% CI 0.53 to 0.55; and 0.54, 95% CI 0.53 to 0.55) and 5-year (C-statistics of 0.52, 95% CI 0.51 to 0.53; 0.53, 95% CI 0.51 to 0.55; and 0.54, 95% CI 0.53 to 0.55) ESRD predictions. The poorly calibrated Brier scores (0.5, 0.46, and 0.49 at 2 years and 0.56, 0.52, and 0.55 at 5 years) indicate that predictions were less accurate than observations.

Discussion:
This external validation study demonstrates that the KFRE performs poorly in predicting ESKD progression in Asian populations.

Session: Eyes and Kidney [Ito, Oct 13th 16:45-18:15] O136-O141
Moderators: Azusa Hara and Jenni Ilomaki

O136

Risk of Polymyalgia Rheumatica Following COVID-19 Vaccination in South Korea: SCCS study

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Introduction:
While several studies have reported some cases of experiencing polymyalgia rheumatica (PMR) following COVID-19 vaccination, studies using large databases are lacking to clarify the association.
Aims:
To investigate the risk of PMR after the COVID-19 vaccination using self-controlled case series (SCCS) analysis.
Methods:
To perform SCCS analysis, we used the National Health Insurance Database, linked with the COVID-19 registry from the Korea Disease Control Agency between February 2021 and August 2023. We identified adults aged 50 years or older who received at least one dose of vaccines and were diagnosed with PMR diagnosis within the observation period, defined as 240 days after the first dose of the vaccine. The risk window was defined as 28 days after COVID-19 vaccination, and the control window encompassed the remainder of the observation period excluding the risk window. Incidence rate ratios (IRRs) were estimated using conditional Poisson regression with 95% confidence intervals (CIs), stratified by dose and vaccine type. Sensitivity analyses were also conducted by varying risk windows and outcome definitions.
Results:
Among 44,818,078 COVID-19 vaccine recipients, 376 patients were diagnosed with PMR during the study period. The analysis indicated that COVID-19 vaccination was not associated with an increased risk of PMR (IRR, 0.74; 95% CI, 0.59-0.94). Rather, the risk of PMR was slightly reduced after the first dose (0.52; 0.34-0.79), with no significant association with the second and third doses of COVID-19 vaccine (0.83; 0.59-1.16 for second dose, 0.77,0.48-1.25 for third dose). Subgroup and sensitivity analyses were also aligned with the main findings.
Conclusion:
In this study, there was no association with the increased risk of PMR following COVID-19 vaccination. While these findings support evidence for the safety of COVID-19 vaccines, interpretation of the decreased risk of PMR should be cautious, and further research is needed to confirm these findings.

O137

Gender Differences in Adverse Events Following COVID-19 Vaccination in South Korea

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Introduction:
Analyzing adverse events (AEs) from COVID-19 vaccination by gender is crucial for identifying potential differences in incidence and severity.
Aims:
To examine gender differences in the types of AEs reported for COVID-19 vaccines in the Korea Institute of Drug Safety and Risk Management's Korea Adverse Event Reporting System database (KIDS KAERS DB).
Methods:
Using the KIDS KAERS DB (2307A0006) from 26 February 2021 to 31 December 2022, we analyzed AEs following COVID-19 vaccination. We categorized AEs into two levels according to the Medical Dictionary for Regulatory Activities (MedDRA): the primary System Organ Class (SOC) for broad categorization and the Preferred Term (PT) for detailed information on individual AEs. At the SOC and PT levels, we calculated the percentage of AEs reported by each gender and determined the female-to-male (F/M) ratio of these percentages, along with 95% confidence interval (CI).
Results:
A total of 887,917 cases were reported, mostly in females (68.4%) and individuals aged 19 to 65 years (78.7%). At the SOC level, females exhibited significantly higher rates in three categories, with the highest F/M ratio in metabolism and nutrition disorders at 1.67 (95% CI: 1.32–2.12). Males had higher rates in nine categories, with the largest difference in cardiac disorders (F/M ratio: 0.44, 95% CI: 0.42–0.46). At the PT level, females reported higher rates in 27 categories, with the greatest disparity in oropharyngeal pain (F/M ratio: 3.0, 95% CI: 2.11–4.26). Males had higher rates in 37 categories, with the most significant difference in death (F/M ratio: 0.29, 95% CI: 0.26–0.33).
Discussion/Conclusion:
Our findings reveal significant gender differences in AEs following COVID-19 vaccination, underscoring the need for gender-specific data in vaccine safety monitoring. Identifying AEs more likely reported by each gender helps healthcare providers better monitor and manage these events, improving patient outcomes and vaccination confidence.

O138

Sequential analysis of COVID-19 vaccine safety in Korea

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Introduction:
During the COVID-19 vaccination programs, the need for near-real time vaccine active surveillance has increased to provide timely information for regulatory decision-making.
Aims:
To conduct sequential testing of potential adverse events following COVID-19 vaccination in the Korean population
Methods:
The population-based active surveillance study was conducted utilizing a linked database of COVID-19 registry and the national health insurance claims data. Subjects included individuals aged over 12 who received either monovalent or bivalent vaccines from February 2021 to March 2023. For three pre-specified outcomes (acute myocardial infarction, myocarditis, and anaphylaxis) and a negative control event (colonic diverticulitis), monthly sequential testing was performed within vaccinated individuals. Using a maximized sequential probability ratio test (MaxSPRT), the incidence of each outcome following COVID-19 vaccination was compared with historical background rates with adjustments for multiple testing and claims processing delay. All analyses were stratified by four age groups, vaccine platform, and dose.
Results:
Sequential analyses identified safety signals for myocarditis following ribonucleic acid vaccines in aged 12 to 64 (Range for relative risks [RRs]: 2.41–7.89) and protein subunit vaccines in aged group 40 to 64 (Range for RRs: 30.00–33.33), and for anaphylaxis following ribonucleic acid vaccines in aged over 18 (Range for RRs: 2.49–17.30) and non-replicating viral vector vaccines in aged over 18 (Range for RRs: 1.61–40.95). These results were consistent with sensitivity analyses reflecting monthly incidence rates. No safety signals were observed for acute myocardial infarction and colonic diverticulitis.
Discussion/Conclusion:
The sequential testing detected safety signals for myocarditis and anaphylaxis shortly after vaccination program, which were acknowledged by the Korea Disease Control and Prevention Agency as associated with COVID-19 vaccines. This method can be proposed to effectively detect safety signals requiring further causality assessment for a newly introduced vaccines in the future.

O139

Global burden of vaccine-induced thrombotic thrombocytopenia: analysis of the international pharmacovigilance database

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Introduction. The scarcity of studies on vaccine-induced thrombosis and thrombocytopenia syndrome (TTS) limits the comprehensive understanding of vaccine safety on a global scale.
Aims. Our study aimed to assess the global burden of vaccine-induced TTS, identify the vaccines most associated with it, and suggest clinical implications regarding vaccination.
Methods. This study employed the World Health Organization international pharmacovigilance database, extracting records of vaccine-induced immune thrombotic thrombocytopenia from 1967 to 2023 (total reports, n=131,255,418). Global reporting counts, reported odds ratios (ROR), and information components (IC) were calculated to identify the association between 19 vaccines and the occurrence of vaccine-induced TTS across 156 countries.
Results. We identified 24,233 cases (male, n=11,559 [47.7%]) of vaccine-induced TTS among 404,388 reports of all-cause TTS. There has been a significant increase in reports of vaccine-induced TTS events over time, with a noteworthy surge observed after 2020, attributed to cases of TTS associated with COVID-19 vaccines. MMR vaccines were associated with most TTS reports (ROR [95% CI], 2.87 [2.75-3.00]; IC [IC0.25], 1.51 [1.43]), followed by hepatitis B, rotavirus diarrhea, encephalitis, hepatitis A, Ad5-vectored COVID-19, pneumococcal, and typhoid vaccines.
Discussion. Concerning age and sex-specific risks, reports of vaccine-induced TTS were more associated with females and younger age groups. The age group between 12-17 years exhibited significant sex disproportion. Most of these adverse events had a short time to onset and the fatality rate was 2.20%, the highest rate observed in the age group over 65 years and the lowest in the age group between 0-11 years.

O140

The risk of acute gastroenteritis following co-administration of rotavirus vaccine

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Introduction:
The rotavirus vaccine (RV), including RotaTeq and Rotarix, is routinely co-administered with vaccines in the National Immunization Program (NIP) supporting 17 species, but data on concomitant administration effectiveness is limited.
Aims:
To evaluate hospitalization risk for acute gastroenteritis following administration of the RV and NIP vaccine concomitantly versus solely.
Methods:
We performed a retrospective cohort study using a linked database from the Korea Disease Control and Prevention Agency and National Health Insurance Service. The study included infants who completed RV vaccination between June 1, 2016, and December 31, 2022. The index date was defined as the date of each RV dose administration. Concomitant vaccination was defined as receiving both RV and NIP vaccines on the same day, while sole vaccination referred to RV vaccination only. The acute gastroenteritis-related hospitalizations were identified using the ICD-10 code A00-A09 and monitored for 14 days from the index date. We employed 1:1 propensity score matching to compare sole and concomitant vaccination for each RV dose. Using a conditional Poisson regression model, we calculated the incidence rate ratio (IRR) and 95% confidence interval (CI) adjusted by sociodemographic variables and birth-related comorbidities.
Results:
Among 1,476,994 infants who fully received the RV, the most frequently co-administered NIP vaccine combination was 'DTaP-IPV/Hib + PCV13' in all doses. Except for the third dose of RotaTeq, there were no statistically significant differences in IRRs between concomitant and sole vaccinations (Rotateq dose 1: IRR=0.93(95% CI: 0.64-1.34), dose 2: IRR=1.18(95% CI: 0.79-1.77) / Rotarix dose 1: IRR=0.74(95%CI: 0.74-1.02), dose 2: IRR=0.72(95%CI: 0.52-1.02)). For the third dose of RotaTeq, concomitant vaccination showed a significantly lower risk than sole vaccination (IRR=0.56, 95% CI: 0.36-0.87).
Discussion/Conclusion:
Concomitant administration of RV and NIP vaccines was not associated with an increased risk of acute gastroenteritis. These results support the coadministration of RV and NIP vaccines.

O141

Gastroenteritis hospitalizations before and after rotavirus vaccine: descriptive study using nationwide database

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Aim/Objective:
Rotavirus (RV) is a major cause of severe gastroenteritis and hospitalization in children. In Japan, the oral vaccines Rotarix® and Rotateq® were introduced in November 2011 and became publicly funded in October 2020. Evaluating the impact of these vaccines in clinical practice is important; however, they have not been verified on a large scale.
Methods:
This study conducted a descriptive epidemiological analysis using the JMDC claims database; the target population was approximately 3.8 million children under age 12 from 2005 to 2023. The outcome was the number of hospitalizations for gastroenteritis and RV enteritis cases per 1,000 persons per year in children. It compared three time periods: before, after, and after the initiation of public funding of RV vaccine. Intussusception was evaluated as a secondary outcome, and congenital heart disease served as a control. The secondary analysis was an interrupted time series analysis (ITS), examining changes in the monthly slope.
Results:
Before the vaccine introduction, there were 8.0 hospitalizations per 1,000 for gastroenteritis and 2.2 for RV enteritis. These numbers dropped to 5.1 and 1.1 after vaccine introduction and to 3.1 and 0.2 after public funding began, indicating a 61% decrease in gastroenteritis and an 89% decrease in RV enteritis hospitalizations ($p<0.001$). The time series analysis showed a monthly reduction of 0.7% in hospitalizations post-vaccine introduction ($p=0.006$). There were no significant changes in intussusception ($p=0.496$) and congenital heart disease cases ($p=0.262$).
Discussion and conclusion:
The analysis revealed a significant decrease in hospitalizations due to gastroenteritis by 61% and RV enteritis by 81% after introducing the vaccines. However, public funding coincided with the coronavirus disease 2019 (COVID-19) pandemic, complicating the evaluation of its direct effects. Continued observation is recommended to assess the long-term benefits of rotavirus vaccination.

Session: Opioids / Signal Detection [Med-1F, Oct 13th 16:45-18:15] O142-O147

Moderators: Benjamin Daniels and Hisashi Urushihara

O142

High-risk opioid prescribing and persistent opioid use in Australian workers with injuries

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Introduction: Opioid prescribing to injured workers has increased despite limited evidence supporting the benefits may often outweigh the risks.

Aims: To determine the prevalence and identify predictors of early high-risk and persistent opioid prescribing in injured Australian workers.

Methods: Injured workers with time loss workers' compensation claim for back and neck conditions who filled at least one opioid prescription within the first 90 days after injury from January 01, 2010 to December 31, 2019 were included. High-risk opioid prescribing practices in the first 90 days were measured using one of four indicators of risk (high-total opioid volume on first dispensing occasion—exceeding 350mg oral morphine equivalent, high average daily dose over 90 days—higher than 50mg oral morphine equivalent, initiation of long-acting opioids, and concurrent psychotropic prescriptions). Persistent opioid use was determined using group-based trajectory modelling over the subsequent 1-year period. Multivariable logistic regression was used to identify predictors of high-risk opioid prescribing and persistent opioid use.

Results: A total of 6,278 injured workers were included. At least one indicator of high-risk opioid prescribing was identified in 67.1% of the sample in the first three months. Persistent opioid use was identified in 24.8% of the sample over the subsequent year. Early high-risk opioid prescribing was associated with double the odds of persistent use (aOR 2.07, CI: 1.80-2.38). Injured workers in inner and outer regional Australia had higher odds of early high-risk prescribing (aOR 1.26, CI: 1.11-1.44) and (aOR 1.43, CI: 1.10-1.87), respectively, compared to those in major cities.

Discussion: Two-thirds of injured workers receiving opioids in the first 90 days showed evidence of high-risk prescribing indicators, with one-quarter exhibiting persistent opioid use over the subsequent year. Early high-risk opioid prescribing doubles the odds of opioid persistence. There is a need for further research and scrutiny of opioid prescribing in this population.

O143

Association of benzodiazepines and mortality among patients with non-opioid substance use disorder

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Background: The prevalence of non-opioid substance use has gradually increased worldwide. Benzodiazepines have been frequently used to manage substance withdrawal syndrome due to their sedative and anti-anxiety effects. However, the use of benzodiazepines is associated with a risk of overdose death. To our knowledge, no large nationwide study has focused on death and the receipt of benzodiazepines among patients with non-opioid substance use.

Objectives: To evaluate the association of benzodiazepines and mortality among patients with non-opioid substance use disorder

Methods: We included patients with non-opioid substance use between 2010 to 2019 using Taiwan's NHIRD database and Taiwan Illicit Drug Issue Database. The cohort entry date was defined as the date of the first arrested record during the study period. We classified patients into two treatment strategies of initiating benzodiazepine within one month versus non-benzodiazepine treatment within one month. To emulate the target trial, we applied cloning, censoring, and weighting approach. The primary outcome of interest was all-cause mortality. We estimated the hazard ratio, five-year absolute risks, risk differences and risk ratio with 95% confidence intervals (CIs) with pooled logistic regression.

Results: We included a total of 167,891 patients with non-opioid substance use. The hazard ratio of all-cause mortality was 2.51 (95% CI, 2.29 to 2.84). The five-year absolute risk of all-cause mortality was 6.03% (95% CI, 4.48% to 7.82%) among benzodiazepine users, and 1.48% (95% CI, 1.30% to 1.62%) among non-benzodiazepine users, respectively. The five-year absolute risk difference and risk ratio between the two treatment strategies for all-cause mortality were 4.52% (95% CI, 2.96% to 6.40%) and 4.04 (95% CI, 2.94 to 5.54), respectively.

Conclusion: The use of benzodiazepines is associated with an increased risk of all-cause mortality among patients with non-opioid substance use. Healthcare providers should balance the effectiveness and safety of benzodiazepines for this population.

O144

Prevalence and risk factors of cannabis use after legalization in rural communities

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Aim:
Thailand became the first country in Asia to legalize cannabis in 2021, which increased access to medicinal and recreational cannabis. However, our understanding of cannabis use remains limited. This study aimed to examine the prevalence, risk factors, knowledge, and attitude of cannabis use after cannabis legalization in rural communities.
Methods:
People aged 18 years and over were surveyed using an online self-questionnaire. Samples were randomly recruited according to the proportion of people in each district in 2023. Descriptive statistics and logistic regression were used to conduct this analysis.
Results:
A total of 476 respondents were enrolled. Their mean age was 49.34 (SD=12.08) years. Cannabis users were found to 61 respondents (12.82 %). Total adverse effects after using cannabis are 21.31%. Risk factors associated with cannabis user were male (AORs; 3.49, [95%CI; 1.79 - 6.83], $p < 0.001$), cancer (AORs; 12.48, [95%CI; 1.87 - 83.04], $p = 0.009$), alcohol consumption(AORs; 2.43, [95%CI; 1.25 - 4.72], $p = 0.009$), smoking (AORs; 3.11, [95%CI; 1.09 - 8.85], $p = 0.033$), source of cannabis information from friend and family inducement (AORs; 4.25, [95%CI; 2.27 - 7.97], $p < 0.001$). Most respondents demonstrated an understanding of cannabis regulations, medical cannabis use, and expressed a positive attitude. However, knowledge of recreational use, especially for cooking, seemed lower, indicating a need for more precise information.
Conclusion:
The prevalence of cannabis use among rural communities has grown significantly. Five major risk factors associated with cannabis use in rural areas: male gender, cancer, alcohol consumption, smoking, and friend-and-family inducement. This calls for increased awareness and prevention strategies like monitoring use, promoting health education, and creating safe use guidelines for both medical and recreational cannabis. Future research on the causal relationship between factors and adverse consequences is warranted.

O145

Psychotropic medicine utilisation in Australian workers with back and neck injuries

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Introduction: Psychotropic medicines are frequently prescribed to injured workers. However, data on the extent and determinants of their utilisation in injured Australian workers is limited.
Aims: To characterise the psychotropic medicine utilisation and identify its determinants over three years in workers with back and neck-related conditions following a workers' compensation claim.
Methods: The utilisation of five groups of psychotropic medicines—antidepressants, gabapentinoids, anxiolytics, hypnotics/sedatives and antipsychotics—in 22,595 workers was examined. The World Health Organisation drug statistics methodology, guidelines for Anatomical Therapeutic Chemical classification and Defined Daily Dose (DDD) assignment were employed. Descriptive statistics were used to characterise the utilisation by time loss duration and temporal trend over the years. Zero-inflated negative binomial regression was employed to identify determinants of psychotropic medicine utilisation.
Results: The overall utilisation (DDD/1000 workers/day) of psychotropics for all-time loss claims was 135.4 (CI: 128.8-142.1). The highest utilisation was for antidepressants (74.2, CI: 70-78.5) followed by gabapentinoids (31.6, CI: 29.7-33.5), anxiolytics (16.1, CI: 14.7-17,6), hypnotics/sedatives (10.6, CI: 9.4-11.8) and antipsychotics (2.9, CI: 2.3-3.4). Claims with increasing time loss duration showed increasing utilisation for each major class of medicine and overall psychotropic utilisation. The incidence rate ratio on the number of DDD for overall psychotropic medicines (1.21, CI: 1.00-1.47), antidepressants (1.29, CI: 1.02-1.63) and antipsychotics (3.47: CI:1.31-9.17) was higher in the age group of 35-44 years. There was a 20.2% increase in dispensing of psychotropic medicines from 2010 to 2016, driven mainly by an increase in gabapentinoid (111.4%) and antidepressant (14.1%) utilisation.
Discussion: The utilisation of psychotropic medicines in compensated Australian workers with time loss claims for back or neck conditions appears to be high, particularly in those with longer time loss durations. There was significant variation in psychotropic medicine utilisation across some sociodemographic-related characteristics. The prescribing trend changed over time, with increasing utilisation of gabapentinoids in recent years

O146

Regular opioid use of different potency and dementia risk and neuroimaging outcomes

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Introduction:
The associations between opioid of different potency are unclear, particularly among different dementia subtypes.
Objective:
To examine the association between regular opioid (including strong and weak types) use and dementia risk and neuroimaging outcomes, compared with non-opioid use.
Methods:
This prospective cohort study was based on UK Biobank participants with non-cancer chronic pain. Regular opioid use was defined as self-reported taken weekly, monthly or three monthly by participants at baseline. Exposures were first categorized in three groups: no analgesics use, non-opioid analgesics (mainly NSAIDs and acetaminophen) use and opioid use. The opioid users were further categorized into strong and weak opioid users. The primary outcome was incident all-cause dementia and its subtypes, including Alzheimer's disease (AD) and vascular dementia (VD). The secondary outcome was brain magnetic resonance imaging measures.
Results:
Among the 197,734 eligible participants, 22,058 (11.2%) reported regular use of opioid.3,997 all-cause dementia, 1,886 AD and 987 VD incident cases were observed over a median of 13.8 years follow-up. Multivariable analyses showed that regular opioid use was associated with increased risk of all-cause dementia (fully adjusted hazard ratio [aHR] 1.14; 95% CI 1.03-1.28), AD (aHR 1.11; 95% CI 0.94-1.32) and VD (aHR 1.38; 95% CI 1.12-1.70), compared with non-analgesics user. In addition, regular strong opioid user had a higher risk of all-cause dementia (aHR 1.54; 95% CI 1.08-2.18) than weak opioid users (aHR 1.13; 95% CI 1.01-1.26). Consistently, regular strong opioid use was associated with an 18611.30 [(95% CI, 4426.21-32796.39] mm3 and 543.66 (95% CI, 299.88-1076.82) mm3 decrease in white matter and hippocampal volumes, while no significant association observed for other neuroimaging outcomes.
Conclusions:
Regular use of opioid, especially strong opioid was associated with a higher risk of dementia and lower white matter and hippocampal volume, highlighting the importance of monitoring cognitive function among patients taking strong opioid.

O147

Identifying Safety Signals for Adverse Events Causing Mortality Due to Ferric Carboxymaltose

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Background:
Iron deficiency anemia (IDA) is a global health concern, with ferric carboxymaltose (FCM) emerging as a preferred intravenous therapy for its efficacy and safety profile. Recent reports of FCM-associated mortality necessitate a comprehensive safety evaluation. This study aims to identify potential associations between FCM use and fatal adverse events by analyzing spontaneous reports and conducting an extensive systematic review.
Methods:
We conducted a retrospective case/non-case study using spontaneous reports in the FDA Adverse Event Reporting System (FAERS) from FDA approval to September 30, 2023. Disproportionality analysis was conducted by calculating the Proportional Reporting Ratio (PRR), Reporting Odds Ratio (ROR), and Information Component (IC) to identify adverse event signals for FCM (PRR ≥ 2, LB ROR > 1, IC025 > 0). We systematically searched electronic databases, including PubMed, Cochrane CENTRAL, Scopus, and Google Scholar, from inception to December 31, 2023, to support the findings of disproportionality analysis.
Results:
39 death cases were reported in FAERS on FCM. However, no signal of considerable strength was identified [PRR= 0.3 (χ2= 81.4), LB ROR= 0.2, IC025 = -2.4]. We identified significant strength for AEs such as anaphylactic shock [PRR= 5.6 (χ2= 63.5), LB ROR= 3.5, IC025 = 1.5], circulatory collapse [PRR= 15.0 (χ2= 455.5), LB ROR= 10.8, IC025 = 3.1], respiratory distress [PRR= 10.8 (χ2= 338.3), LB ROR= 7.9, IC025= 2.8], arrhythmia [PRR= 3.5 (χ2= 45.2), LB ROR= 2.4, IC025= 1.1]. In the systematic review, we identified the AEs such as anaphylactic reaction, severe hypophosphatemia, respiratory distress, hypotension, bronchospasm, and hypophosphatemia osteomalacia.
Conclusion:
Our study identifies potential safety signals associated with FCM, including anaphylactic shock, circulatory collapse, respiratory distress, and arrhythmia. These findings underscore the importance of informed decision-making and careful patient selection when considering FCM therapy, emphasizing the need for heightened vigilance in clinical practice.
Keywords: Ferric carboxymaltose, circulatory collapse, respiratory distress.

Session: Geriatric [Med-1F, Oct 14th 08:30-10:00] O200-O205

Moderators: Sri Harsha Chalasani and Yagi Tatsuya

O200

Association between Anticholinergic burden and risk of Fall and Fracture: Case-Case-Time-Control Study (Rising Star Awardee)

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Introduction
Observational studies have indicated association between recent elevated anticholinergic burden and increased risk of falls and fractures. However, this observed association may not necessarily be due to the anticholinergic burden itself but could be substantially confounded by indication.
Objective
To evaluate the association between a recent increase in anticholinergic burden and risk of falls and fractures in Taiwanese population.
Methods
We conducted a case-case-time-control study using National Health Insurance Research Database in Taiwan. We included patients over 65 who were hospitalized or admitted to emergency room due to falls and fractures from 2016 to 2020, with index date as admission date. Future cases were those occurred within 60-150 days after matched index date. We defined hazard period as 60 days before index date, with reference period randomly selected from 121 to 300 days before index date. We classified sum of Anticholinergic Cognitive Burden Scale (ACB) within each period into three groups: 0, 1-2, 3+ points. We used conditional logistic regression model to estimate effect of anticholinergic burden on risk of falls and fractures.
Results
We included 434,322 patients, with a mean age of 77 and 36% male. The crude case-crossover analysis showed that an ACB score of 1-2 points (OR 1.27, 95% CI 1.25-1.30) and 3+ points (OR 1.42, 95% CI 1.40-1.44) were associated with a higher risk of falls and fractures. The case-case-time-control analysis suggested that an ACB score of 1-2 points (OR 1.29, 95% CI 1.24-1.33) and 3+ points (OR 1.40 95%, CI 1.37-1.44) were also associated with an increased risk of falls and fractures.
Conclusion
Our findings suggest an association between recently elevated anticholinergic burden and an increased risk of falls and fractures. We recommend that clinicians monitor drugs with anticholinergic properties to prevent acute risk of falls and fractures.

Keywords: anticholinergic burden, fall and fracture

O201

Association between Recently Elevated Anticholinergic Burden and Urinary Retention: A Case-case-time-control Study

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Introduction
There is limited evidence on the association between recently elevated anticholinergic burden and the risk of urinary retention.
Aims
To evaluate the association between recently elevated anticholinergic burden and the risk of urinary retention among older adults in Taiwan.
Methods
We conducted a case-case-time-control study using data from the Taiwan National Health Insurance Research Database (NHIRD). Inclusion was older adults (65+) diagnosed with urinary retention between 2017 and 2021. We selected future cases, defined as those with urinary retention occurring within 60-150 days after the matched event date. The hazard period was defined as the 60 days preceding the diagnosis, while the referent periods were random 60-day intervals within the 121 to 300 days before the diagnosis. We used the Anticholinergic Cognitive Burden Scale (ACB) to categorize scores into three groups: 3+, 1-2, and 0. Conditional logistic regression was applied to assess the odds ratios (ORs) and 95% confidence intervals (95% CIs).
Results
Of 135,116 future cases were eligible for the case-case-time-control analysis. The average age was 78.3 years, and 73.3% were male. The crude case crossover analysis showed that an ACB score of 1-2 points (OR 1.80; 95% CI, 1.74-1.87) and 3+ points (OR 2.31; 95% CI, 2.25-2.37) were associated with a higher risk of urinary retention. The case-case-time-control analysis revealed that an ACB score of 1-2 points had an OR of 1.68 (95% CI, 1.57-1.80) and an ACB score of 3+ points had an OR of 2.12 (95% CI, 2.03-2.22), suggesting that recently elevated anticholinergic burden is associated with an increased risk of urinary retention.
Discussion/Conclusion
Older adults with recently elevated anticholinergic burden were associated with an increased risk of urinary retention. This underscores the importance of monitoring the risk of urinary retention in individuals recently receiving anticholinergic drugs.

Keywords: anticholinergic burden, urinary retention, older adults

O202

Associations Between Polypharmacy, Inflammatory Markers and biological aging among US Older Adults

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Introduction:
Polypharmacy may lead to adverse health outcomes in older adults, but the relationship between polypharmacy and biological aging remains poorly defined. This study aims to investigate the association between polypharmacy and accelerated biological aging, as well as the mediating effect of inflammatory markers.
Methods:
Participants who were 65 years of age or older and took at least one prescription medication from the National Health and Nutrition Examination Survey (1999-2018) were included in the cross-sectional study. The concurrent use of 5 to 9 medications was defined as polypharmacy, while the use of more than 9 medications was defined as hyper-polypharmacy. Biological aging was assessed from multiple perspectives, including phenotypic age, biological age, AnthropoAge, frailty index, telomere length and circulating α-klotho concentration. The degree of inflammation was quantified using four indices constructed based on blood cell counts, including the systemic immune-inflammation index, systemic inflammatory response index, neutrophil-to-lymphocyte ratio, and monocyte-to-lymphocyte ratio. Weighted multiple linear regression analysis were performed to examine the association between polypharmacy and accelerated biological aging. Mediation analysis was conducted to assess the influence of inflammatory markers on the relationship between polypharmacy and accelerated biological aging.
Results:
A total of 12,238 participants were included, of whom 4,679 (weighted percentage: 38.0%) were taking between 5 and 9 medications, while 538 (weighted percentage: 4.5%) were taking more than 9 medications. After adjustment for multiple covariates, both polypharmacy and hyper-pharmacology remained significantly associated with α-klotho, phenotypic age, biological age, AnthropoAge, and frailty index, but not telomere length. Mediation analysis revealed that the association between polypharmacy and accelerated biological aging was partially mediated by inflammatory markers, with the proportion of mediation varying from 0.69% to 19.60% (all $p < .05$).
Conclusion:
These findings suggest that polypharmacy is significantly associated with multiple biological aging measures, which may be partially mediated by inflammation.

O203

Predicting Long-Term Mortality in Elderly Using Shizuoka Hip Fracture Prognostic Score: SHiPS

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Introduction:
Hip fractures are common among the elderly and are associated with high mortality rates. Accurate prediction of long-term prognosis at the time of fracture using preoperative data is crucial for planning appropriate medical interventions and resource allocation, thereby improving clinical management and patient outcomes.
Aims:
This study aimed to create and validate the Shizuoka Hip Fracture Prognostic Score (SHiPS), a model designed to predict long-term mortality in elderly patients with hip fractures using accessible preoperative information.
Methods:
We conducted a retrospective cohort study using the Shizuoka Kokuho Database, a Japanese claims database spanning 8.5 years, which included 43,529 patients aged 65 years and older who experienced their first hip fracture between April 2012 and September 2020. Prognostic factors were identified through univariate and multivariate Cox regression analyses. Based on the hazard ratios, we developed the Shizuoka Hip Fracture Prognostic Score (SHiPS), categorizing mortality risk into four levels. The score was validated using receiver operating characteristic (ROC) curve analysis for 1-year, 3-year, and 5-year mortality.
Results:
The key prognostic factors identified included age, sex, fracture site, nursing care certification, and several comorbidities such as any malignancy, renal disease, congestive heart failure, chronic pulmonary disease, liver disease, metastatic solid tumor, and deficiency anemia. The SHiPS, with a score range of 0 to 64, demonstrated reliable predictive performance with area under the receiver operating characteristic (ROC) curves of 0.718 for 1-year, 0.736 for 3-year, and 0.758 for 5-year mortality. Notably, the predictive accuracy remained above 0.7 (AUC) for patients regardless of whether they underwent surgery, highlighting its robustness across different treatment scenarios.
Conclusion:
The Shizuoka Hip Fracture Prognostic Score (SHiPS) effectively predicts long-term mortality in elderly hip fracture patients using preoperative data. This tool can be instrumental in clinical decision-making and improving patient outcomes by enabling early risk assessment.

O204

Sedative and anticholinergic medication use in older Australians with dementia

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Introduction:
Sedative and anticholinergic medications are linked to poorer outcomes, such as worsening cognitive function, in older people, especially those with dementia. However, national population-level estimates of their use and the associated sociodemographic factors are lacking in Australia.

Aims:
To estimate the prevalence and risk factors for sedative and anticholinergic medication use in older Australians with dementia.

Methods:
This study used linked 2021 Census and Pharmaceutical Benefits Scheme (PBS) data, including people aged 65 or above. Dementia was defined as a self/proxy-reported diagnosis in 2021 and/or at least one dispensing of an antidementia drug between 2016 and 2021. Main outcomes were sedative and anticholinergic medication use, defined using the Drug-Burden Index (DBI) (at least one DBI contributing drug) and the Anticholinergic Cognitive Burden Scale (ACB) (ACB score ≥3). Prevalence was calculated by 5-year age strata. Binary logistic regression models explored associations with self-reported comorbidities and sociodemographic factors.

Results:
Of the 177,809 people with dementia, over half used at least one DBI contributing drug. Highest use was in those aged 65-69, with two-thirds using at least one DBI contributing drug. Anticholinergic burden was also highest in this age group (19%). Prevalence of DBI drug use and anticholinergic burden declined with increasing age. Those living in non-private dwellings and requiring assistance with core activities were at increased risk, while older age, higher socioeconomic status, and higher education were associated with lower risk. Antidementia medication use was associated with a lower risk of high anticholinergic burden.

Discussion:
Over half of people with dementia were exposed to sedative and anticholinergic medications, with risk higher in certain sociodemographic groups. Regular review and ongoing monitoring are necessary to ensure appropriate use of these drugs in this vulnerable population.

O205

Calcium Channel Blockers and Selective Serotonin Reuptake Inhibitors Use and Fracture Risk

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Introduction
Despite their frequent concurrent use, little is known about the safety of concomitant use of calcium channel blockers (CCBs) and selective serotonin reuptake inhibitors (SSRIs) with regard to fracture risk.

Aims
We compared risk of fractures in patients concomitantly treated with CCBs and SSRIs versus CCB-only users. Additionally, we compared the risk of fractures among concomitant CCB-SSRI users initiating cytochrome P450 3A4 (CYP3A4) inhibiting SSRIs (e.g., fluoxetin) versus non-CYP3A4 inhibiting SSRIs (e.g., citalopram).

Methods
This retrospective cohort study used IBM MarketScan® commercial claims and Medicare Supplemental database (2007-2019). We included adults diagnosed with hypertension and depression, newly initiating SSRIs while being treated with CCBs (i.e., concomitant CCB-SSRI users) and those who did not (i.e., CCB only users). Our primary outcome was the first occurrence of any fracture. We used stabilized inverse probability of treatment weighting (sIPTW) to balance baseline risk between groups. Cox proportional hazard regression modeling was used to compare fracture risk.

Results
We identified 191,352 concomitant CCB-SSRI and 956,760 CCB-only users (mean age 56 years, 50.1% males). After sIPTW, compared to CCB only users, CCBs-SSRIs users had a higher risk of fractures (hazard ratio (HR):1.43, [95% confidence interval (CI):1.22-1.66]). No difference in the risk of fractures between concomitant users of CCB-CYP3A4 inhibiting SSRIs and those of CCB-non CYP3A4 inhibiting SSRIs (HR:1.10, [95%CI:0.87-1.40]) was observed.

Discussion/Conclusions
Short term concomitant CCB-SSRI use was associated with increased fracture risk. However, concomitant CCBs and CYP3A4 inhibiting SSRIs compared to CCBs and non CYP3A4 inhibiting SSRIs use was not associated with increased risk.

Session: Cancer [Med-3F, Oct 14th 08:30-10:00] O206-O211

Moderator: Benjamin Bates

O206

Utility of electronic medical record databases for oncology pharmacoepidemiologic studies in Japan

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Introduction
Multi-institutional electronic medical record (EMR) databases, such as the Medical Information Database Network (MID-NET), have been recommended for postmarketing studies in Japan. However, their utility for cancer pharmacoepidemiology studies is not well-established.
Aims
To assess the validity of oncology-related data in EMR databases compared to those in hospital cancer registries (HCR).
Methods
Using EMR and HCR data (2011-2021) from two institutions: Site-A (a large university/teaching hospital) and Site-B (10 community hospitals from a large national healthcare system), both contributing to MID-NET, we identified incident cases for 11 cancer types using “diagnosis category” and the “initial/recurrent” variable in EMR data. We calculated the positive predictive value (PPV) and sensitivity of incident cancer in EMR using HCR as the gold-standard. Initial cancer treatments and stages were compared between EMR and HCR. We also examined the length of the available baseline period for covariate/confounder ascertainment.
Results
Among 102,735 to 472,078 patients with one of 11 cancer types in EMR, 14% (14,164) and 6% (28,542) had incident cancer in Site-A and Site-B, respectively. The PPV for EMR-based incident cancer was 85% and 83%, and the sensitivity was 79% and 68% in Site-A and Site-B, respectively. Cancer treatments and stages recorded in EMR matched HCR records exactly. Patients with baseline data available for over 180 days prior to diagnosis accounted for only 35% and 48% of all incident cases in Site-A and Site-B, respectively. Varying baseline periods from 30 to 180 days, approximately 50% of covariates captured using the 180-day period were identified using the 30-day period.
Discussion/conclusion
While 20-30% of incident cases were missed and ~15% of EMR-base incident cases were not incident in EMR, initial treatments/stages were identified with 100% accuracy. Short baseline periods are concerning for confounding adjustment, potentially missing 50% of baseline covariates using a 30-day baseline period.

O207

Heavy Metal Contamination in Drinking Water Increases Gallbladder Cancer Risk in India

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Introduction: Northern India ranks second highest globally for gallbladder cancer (GBC) cases, and there's a need for more regional studies on the link between arsenic in drinking water and GBC due to significant geographical variations.
Aim: To explore the risk and potential carcinogenic role of arsenic and other heavy metals in the drinking water of gallbladder cancer patients.
Methodology: We conducted a hospital-based observational cohort study in a tertiary care cancer specialty hospital in northeast India. Using inductively coupled mass spectrometry (ICPMS), an Agilent 7800, arsenic (As), and other 11 trace elements (Be, V, Cr, Fe, Ni, Co, Se, Sr, Cd, Hg, and Pb) were measured in urine (n=216) and drinking water (n=97) collected from histopathologically confirmed GBC patients. The USEPA model was used to assess cancer and non-cancer risks. The Incremental Lifetime Cancer Risk (CR) and Hazard Quotient (HQ) were used to determine cancerous and non-cancerous risk levels in patients with GBC. Heavy metal concentrations were expressed in parts per billion ± standard error.
Results: The mean concentration of As (20.59±2.09), Se (78.49±17.95), Sr (82.05±7.08), and Cd (4.86±0.65) exceeded the WHO limit in urine samples of GBC patients. About 61.3% of water samples exceeded the WHO limit for As in their drinking water. The health risk assessment shows that the exposed concentration of As, Cr, Ni, and Cd in the urine samples can cause cancer risk with CR values of 0.001, 0.001, 0.000089, and 0.0012, respectively. The As, Cr, Ni, and Cd (CR: 0.00007, 0.0003, 0.00044, and 0.00001, respectively) had cancer risk with the exposed concentration in their drinking water. There was a strong positive correlation in arsenic concentrations between water and urine (R2=0.84).
Conclusion: The findings reveal a significant association between arsenic, heavy metal contamination, and gallbladder carcinogenesis, warranting further investigation through individual-level observational and molecular studies.

O208

Treatment patterns and outcomes of EGFR exon20ins mutated NSCLC patients in Taiwan

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Introduction:
Epidermal growth factor receptor (EGFR) exon 20 insertion (exon20ins) is an uncommon mutation in non-small cell lung cancer (NSCLC) patients, which had poor prognosis outcome prior to the introduction of novel target agents (i.e., amivantamab). Treatment options for this population remain limited.
Aims:
To analyze treatment pattern and clinical outcomes in NSCLC patients with EGFR exon20ins.
Methods:
Electronic medical record data from Chang Gung Research Database, a multi-institutional network containing around 10% of Taiwanese patients, were extracted and transformed into a common data model specially for the EXPLORE-LC Taiwan dataset. Biomarker data were further enhanced. All newly diagnosed stage IIIB/IV NSCLC patients with EGFR exon20ins who aged 18 years or older and received first NSCLC treatment between 2016 to 2020 were included and followed up until death or December 31 2022. Patient characteristics were described descriptively. Treatment sequences and clinical outcomes were analyzed and stratified by different types of first-line systematic anti-cancer treatments (SACT). Overall survival (OS) was estimated using the Kaplan-Meier method with 95% confidence interval (CI) reported.
Results:
Among 4,445 stage IIIB/IV NSCLC patients included in the dataset, only 181 patients (4.1%) had EGFR exon20ins. Of these EGFR exon20ins mutated patients, 170 (93.9%) were non-squamous carcinoma and 42 (23.2%) had brain metastasis at diagnosis. Furthermore, eight (4.4%) and four (2.2%) patients co-mutated with ALK and ROS1, respectively. During the follow-up period, 175 (96.7%) patients received at least one line of SACT. EGFR tyrosine kinase inhibitors (EGFR-TKI; n=121, 69.1%) and platinum-based chemotherapy (n=39, 22.3%) were two main first-line SACT regimens. Patients treated with EGFR-TKI had better median OS than those receiving platinum-based chemotherapy (32.3 [95% CI: 24.9, 46.5] vs. 15.9 [95% CI: 10.0, 22.4] months).
Discussion:
The study provides additional data on the real-world characteristics, treatment patterns, and clinical outcomes of Taiwanese NSCLC patients with EGFR exon20ins.

O209

Risk of lung cancer with concomitant use of ACEi and DPP4i

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Introduction: Whether concomitant use of angiotensin converting enzyme inhibitors (ACEi) and dipeptidyl peptidase 4 inhibitors (DPP4i), both potentiating the levels of bradykinin and substance P, would further exaggerate the risk of lung cancer remains uncertain.
Aims: To evaluate whether the concomitant use of ACEi and DPP4i is associated with an increased risk of lung cancer compared with concomitant use of ACEi and SGLT2i.
Methods: Using the nationwide healthcare data of South Korea between 2010 and 2022, we identified a cohort of adults who firstly received ACEi and then identified a subset of patients firstly prescribed DPP4i or SGLT2 inhibitors (SGLT2i) during the ACEi treatment. The index date was defined as the first date of DPP4 inhibitors or SGLT2i administration. The primary outcome was incident lung cancer, defined using a previously validated algorithm with an 88.9% positive predictive value. Patients were followed from 1 year after the index date until the earliest occurrence of lung cancer, 1 year after switching between the study drug classes, death, or study end date (31 December 2022). Hazard ratios (HRs) and rate differences (RDs) per 1000 person-years of lung cancer were estimated after weighting by propensity score fine stratification method.
Results: Among a total of 42,108 eligible patients initiating ACEi, 35,990 (85.5%) initiated DPP4i and 6,118 (14.5%) initiated SGLT2i. During a 5.2-year mean follow-up, concomitant use of DPP4i vs. SGLT2i with ACEi was associated with an elevated risk of lung cancer (2.28 vs. 1.18 events per 1000 person years; HR 1.95, 95% CI 1.09 to 3.49; RD 1.10, 0.50 to 1.70).
Discussion/Conclusion: Among adults initiating ACEi, concomitant use of DPP4i was associated with an increased risk of incident lung cancer compared with SGLT2i. Thus, concomitant use of ACEi and DPP4i poses a significant drug-drug interaction, and this combination of therapy should be used with caution.

O210

Treatment modalities for primary head and neck cancer in Japan

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Introduction:
The state-of-the-art of the treatment for head and neck cancer (HNC) has evolved recently due to the development of immunotherapy and advances in radiotherapy. However, the treatment modalities applied in real-world settings in Japan are not fully described.
Aims: To investigate the initial treatment modalities of primary HNC in real-world settings in Japan.
Methods:
A retrospective cohort study using the Japan Medical Data Center (JMDC) was conducted. Adult patients with at least two diagnosis codes of the same primary HNC cancer (ICD-10-CM: C00-C14, C32) between January 2015 and March 2023 initiating HNC treatment were included. Patients were followed till the end of initial treatment, last enrollment in JMDC, or June 30th, 2023, whichever happened first. The initial treatment episode was defined as the period with the first HNC treatment before a 90-day gap. The cohort was classified into four groups based on surgery and metastasis status: resectable, unresectable without mention of metastasis (unresect-NM), unresectable with regional metastasis (unresect-RM), and unresectable with distant metastasis (unresect-DM). The treatment patterns were described for each group.
Results:
A total of 3,031 patients were included in the study with 41.1%, 36.2%, 16.5% and 6.2% in resectable, unresect-NM, unresect-RM, and unresect-DM group, respectively. Chemoradiotherapy was the most common treatment modalities among unresectable patients (unresect-NM: 54%; unresect-RM: 76%; unresect-DM: 58%), and was the second common treatment modalities among resectable patients (20%) following surgery only (62%). 29% of patients in unresect-DM group used PD-(L)1 inhibitor, however, only 3%-8% of the other patients received it. Among 1,960 patients receiving radiotherapy (resectable: 20.4%; unresect-NM: 48.5%; unresect-RM: 23.9%; unresect-DM: 7.2%), only 30 patients received advanced particle therapies such as proton therapy, heavy ion therapy, and boron neutron capture therapy.
Discussion/Conclusion: One-third of the patients in unresect-DM group received immunotherapy, but the adoption of advanced particle therapies remains low.

O211

Occurrence of Adverse Drug Reactions in Chemotherapy Patients: A Cross-sectional Study

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Introduction. Antineoplastic agents commonly cause adverse drug reactions (ADRs) in cancer patients, who are particularly vulnerable due to low tolerance. Pharmacovigilance of these drugs is limited due to significant under-reporting, making it crucial to measure the frequency and severity of ADRs in oncology patients.
Aim. We aimed to assess the frequency, types, severity, and management of ADRs in chemotherapy patients.
Methods. A 12-month cross-sectional study was conducted in a tertiary-care teaching hospital, including 327 chemotherapy patients from January to December 2023. The data was collected in a suspected ADR reporting form by the Central Drugs Standard Control Organization (CDSCO) and reported to the ADR Monitoring Centre and Vigiflow at the National Coordinating Centre (NCC). The suspected drugs were evaluated for causality using the Modified Naranjo scale, and ADR severity was assessed with the Hartwig et al. severity scale.
Results. Out of 327 patients, 230 developed ADR (70%). A total of 372 ADRs were reported, which indicated 1.6 events per patient. ADRs mainly occurred in the age group of 40-60 years (57.0%), predominantly affecting females (64.8%). Common ADRs included thrombocytopenia (11.2%), neutropenia (9.9%), and diarrhea (7.7%). Ovarian (17.3%) and breast cancer patients (15.6%) had the highest ADR incidence. Platinum-based agents and antimetabolites were the common culprit drugs. Causality assessment showed 36.1% of ADRs as ‘possible’ and 61.7% as ‘probable.’ Severity of ADRs was categorized as ‘mild’ (49.13%), ‘moderate’ (46.08%), and ‘severe’ (1.3%). All patients received corrective measures upon experiencing ADR. In addition, chemotherapy was temporarily withheld in 49 patients until the improvement with corrective measures. The therapeutic agent was substituted in two patients, and the dosage was reduced in eight patients.
Conclusion. The study emphasizes the critical need for vigilant surveillance to minimize the impact of these complications on treatment outcomes. Future studies could stratify data based on cancer stages. Developing a model for early detection of severe ADRs should also be explored to improve patient outcomes.

Session: Cardiovascular 2 [Yasuda, Oct 14th 11:30-13:00] O212-O217
Moderators: Masato Takeuchi and Kristian Filion

O212

Disease burden and treatment patterns of atherosclerotic cardiovascular diseases in Hong Kong

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Introduction:
Evidence on the clinical disease burden and lipid-lowering drug treatment choices among patients with incident atherosclerotic cardiovascular disease (ASCVD) in Hong Kong is limited.
Aims:
This study aims to describe the disease burden and treatment patterns for secondary prevention of ASCVD in Hong Kong by identifying the incidence of diseases, mortality rates, patients' LDL cholesterol levels, and treatment of lipid-lowering agents, utilising real-world data from the Hong Kong public healthcare system.
Methods:
All patients with an incident diagnosis or procedure code for ASCVD from 2010 to 2020 in a territory-wide clinical database in Hong Kong were identified. We studied the incidence, mortality rates, low-density lipoprotein (LDL) cholesterol trends, and treatments stratified by each ASCVD, age and sex groups.
Results:
A total of 243,201 cases of ASCVD were included. The three most frequent index ASCVD conditions were ischemic stroke (n= 86,251 [35.5%]), myocardial infarction (MI) (n=54,674 [22.5%]), and chronic coronary heart disease (n= 42578 [17.5%]). Incidence of all ASCVD decreased from 326 per 100,000 individuals in 2010 to 266 in 2020. Ischaemic stroke had the highest incidence during these 10 years. The all-cause mortality rate at 5 years after the index ASCVD event was the highest for MI and was greater in women than men. Over 80% of patients with ASCVD received statins in Hong Kong, with very low uptake of non-statin lipid-lowering agents (5.2%). Despite most patients starting statin prescriptions after ASCVD diagnosis for over a year, half of patients still had LDL cholesterol levels over 1.8 mmol/L after years of follow-up.
Conclusion:
The overall incidence of ASCVD decreased from 2010 to 2020. Despite high coverage of statin prescriptions in Hong Kong, the disease burden remained high with an unmet goal of optimal LDL cholesterol levels.

O213

Associations of biological aging with intraoperative hypotension during major surgery

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Introduction:
Intraoperative hypotension (IOH) is a common issue in surgeries, associated with severe postoperative complications and increased healthcare costs. Previous studies have identified various risk factors for IOH, but the role of biological age remains underexplored.

Aims:
This study aimed to evaluate the association between accelerated biological aging and the risk of IOH in surgical patients.

Methods:
A multicenter-based retrospective cohort study was conducted using electronic health records and anesthetic management system from three hospitals from April 2016 to December 2022. Patients undergoing major surgeries under general anesthesia were included. Biological age was determined using the phenotypic age (PA) approach. PA acceleration (PhenoAgeAccel) was also assessed. The primary endpoint was the occurrence of IOH, defined by mean arterial pressure (MAP) below 60 mmHg.

Results:
Out of 19,475 patients included in the study, IOH was detected in 2750 (14.1%). Patients exhibiting biological aging had a higher risk of IOH after adjusting for age, sex, and surgery type (adjusted odds ratio [aOR], 1.08, 95% confidence interval [CI] 1.03-1.13, P<0.001). More significant PhenoAgeAccel were associated with longer cumulative duration of IOH (aOR 0.44, 95% CI 0.25-0.62, P<0.001) and greater area under the MAP threshold curve (aOR 3.00, 95% CI 0.86-5.14, P=0.006). Subgroup analysis confirmed these findings, particularly in patients aging between 0-39 (aOR 1.13, 95% CI 1.03-1.24, P=0.008), males (aOR 2.75, 95% CI 2.55-2.96, P<0.001), and those undergoing non-cardiac surgery (aOR 1.11, 95% CI 1.04-1.17, P=0.001), while an inverse association was observed in cardiac surgeries (aOR 0.69, 95% CI 0.58-0.82, P<0.001).

Discussion:
The study suggested that accelerated biological aging may serve as a predictor for IOH, with higher biological aging linked to an increased risk and severity of IOH. Targeting preemptive measures and careful monitoring in patients identified with accelerated aging could potentially reduce the occurrence and impact of IOH.

O214

Influenza vaccines reduce hospitalized cardiovascular complications in Taiwan elderly: a nationwide study

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Aim/Objective:
To evaluate whether the risk of hospitalization for cardiovascular diseases (CVDs) in elderly populations declined following influenza vaccination.

Methods:
This retrospective cohort study with target trial emulation framework utilized Taiwan's National Health Insurance Research Database. Study subjects were the people aged ≥65 year from a flu season of 2019/2020. The vaccinated group was study subjects receiving an influenza vaccination in October-December 2019. Vaccinated elderly were matched with unvaccinated individuals within the same month using propensity score matching (PSM) on a series of patient baseline characteristics. Cox proportional hazard model was employed to assess the CVD risk with vaccination status.

Results:
Among 500,000 elderly individuals sampled from the season of 2019/2020, 157,272 PSM pairs of vaccinated and unvaccinated elderly were identified, with a mean age of 73.3 years old and 45.9% of male subjects. Compared with non-vaccination, having an influenza vaccination reduced risks of various CVDs by 4%-34%, including ischemic heart disease (hazard ratio [95% confidence interval: 0.96 [0.92-1.02]), hypertensive heart disease (0.85 [0.79-0.91]), cerebrovascular disease (0.84 [0.77-0.91]), heart disease (0.84 [0.80-0.89]), pulmonary heart diseases (HR [95% CI]: 0.80 [0.64-1.01]), and other heart diseases (0.66 [0.43-0.99]). Results of series of sensitivity analyses (e.g., restricting influenza events to those confirmed by principal diagnoses, negative control outcome analyses, restricting the follow-up to different peak flu months) and interaction tests for various patient characteristics (e.g., age, gender, frailty status) are consistent with primary findings, supporting study robustness.

Conclusion:
Vaccine effectiveness on CVD-related hospitalizations among the general elderly populations in real-world settings was well-corroborated.

O215

Exploring the cardiometabolic impact of antipsychotics: real-world evidence from Australia

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Introduction:
Antipsychotic medications are prescribed for various psychotic and non-psychotic disorders. Few studies have examined the cardiometabolic outcomes of antipsychotic use in a national cohort.

Aims:
To generate real-world evidence on the cardiometabolic health of patients exposed to antipsychotics in this country in 2022.

Methods:
Using a 10% representative sample of a national medication dispensing dataset, patients dispensed an antipsychotic in 2022 (exposed group) and patients without any current or previous antipsychotic dispensings (unexposed group) were identified. Their cardiometabolic burden was estimated as the proportion of subjects with dispensings for medicines to treat hyperglycemia, dyslipidemia, hypertension and thrombosis in 2022. Age, categorised into three groups (<18, 18–64, >/=65 years), and sex characteristics were compared between the two groups using Pearson's chi-square test. Logistic regression analyses estimated the odds ratios (aOR) and 95% confidence intervals (CI) for cardiometabolic medication use, adjusted for baseline differences.

Results:
Nearly 1.64 million subjects were chosen from the dataset, with 38,420 being dispensed an antipsychotic (2.4%) and the rest being unexposed. Both groups were significantly different in their baseline characteristics for age and sex (P <0.0001). The proportion of patients with any cardiometabolic outcome was 44.5% in the exposed cohort and 36.5% in the unexposed, yielding an aOR of 1.30 (95% CI 1.27–1.33). Similar results were observed for hyperglycemia (17.1% versus 9%, aOR 1.97), dyslipidemia (26% versus 21.3%, aOR 1.23) and thrombosis (9.6% versus 7.2%, aOR 1.35), while hypertension was lower in the exposed (27.1% versus 27.2%, aOR 0.87, 95% CI 0.84–0.89).

Discussion:
Antipsychotic exposure is associated with a higher likelihood of the use of medications to treat hyperglycemia, dyslipidemia and thrombosis. These findings highlight the need for metabolic monitoring of patients prescribed antipsychotics, with careful consideration in non-psychotic disorders.

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O216

Trends in the use of sodium-glucose cotransporter 2 inhibitors following hospitalisation with heart failure, New South Wales, Australia

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Introduction.
Sodium-glucose cotransporter 2 inhibitors (SGLT2i) significantly reduce risks of re-hospitalisations and deaths in people with heart failure (HF). While initially used for treating type 2 diabetes (T2D), accumulating evidence of cardiovascular benefits in people with HF regardless of T2D has resulted in expanded indications for HF. Little is known about the use of SGLT2i in Australian routine clinical practice among people with HF.
Aims.
To quantify and characterise temporal trends in SGLT2i use following hospitalisation for HF.
Methods.
Using linked administrative data, we identified adults hospitalised with HF in New South Wales during 2014-2021. We estimated the quarterly prevalence of SGLT2i use during the study period defined as having ≥1 SGLT2i dispensing in the 90 days following discharge. We assessed the sociodemographic and clinical characteristics of people with a post-discharge dispensing of SGLT2i in 2020-2021.
Results.
We identified 57,496 people hospitalised with HF during 2014-2021 (median age 80.0 years, 51.6% male, 34.8% with T2D). We observed a ~8-fold increase in the prevalence of SGLT2i use over this period, reaching 7.8% by the end of 2021 (Figure). This increase was primarily driven by increased use in people with T2D, with a 16-fold increase, up to 16.5% by the end of 2021. There was almost no use among people without T2D from 2014-2020, but this increased to 1.8% by the end of 2021. 1,057 (5.7%) people were prescribed SGLT2i in 2020-2021, with key characteristics as follows: median age 72.0 years, 67.2% male, high comorbidities prevalence (94.0% T2D, 46.8% chronic kidney disease, 36.5% obesity), 66.9% SGLT2i prevalent users, and 65.2% used ≥10 medicines.
Discussion.
SGLT2i use has increased among people hospitalised with HF, primarily in people with T2D. However, this use remains relatively low, with only one in six people hospitalised with HF with T2D in 2021 filling a prescription. Continued monitoring is required with the expanding indication for HF, to ensure clinical benefits are realised within this high-risk population.

O217

Low-dose versus standard-dose prasugrel in East Asians with acute coronary syndrome: a matching-adjusted indirect comparison using real-world data

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Introduction.
Clinical trials have shown that levels of active metabolites of prasugrel in the body were higher in East Asian populations, which may lead to an increased risk of bleeding in patients receiving standard doses of prasugrel. Whether a low-dose regimen of prasugrel provides the same treatment effect but reduces the risk of bleeding in East Asian populations is under discussion.
Aims.
To compare the effectiveness and safety of low-dose and standard-dose prasugrel in East Asian populations by an anchored matching-adjusted indirect comparison using patient-level data from Taiwan and published aggregate data from Korea.
Methods.
Using claims data from the National Health Insurance Research Database, we matched the population of Taiwan to the population of the Korean study and then adjusted 7 important covariates to balance the baseline characteristics between two study cohorts. Effectiveness outcomes were MACE, composite of cardiovascular death, non-fatal MI, stroke and vessel revascularization, and their individual components. Safety outcome was bleeding event. Fatal outcomes were all-cause death and cardiovascular death.
Results.
After matching and adjusting, no significant differences were observed between two groups across all effectiveness and fatal outcomes, either during hospital admissions or in 6 months following DAPT initiation. However, the bleeding risk of the low-dose prasugrel group was significantly lower than that in the standard-dose prasugrel group (adjusted OR, 0.34; 95% CI, 0.13-0.94). The results were consistent with the main analysis in the sensitivity analyses adjusting different covariates.
Discussion.
Due to diverse patient characteristics across studies, it is essential to account for these differences to ensure a more accurate comparison. Adjusting for cross-study differences, our results suggested similar treatment effectiveness between the low-dose and standard-dose prasugrel regimens for AMI patients, but low-dose prasugrel provided preferable for reducing bleeding events in East Asian populations.

Session: Cost Effectiveness / Economic Evaluations [Sanjo, Oct 14th 11:30-13:00] O218-O223

Moderators: Kanae Togo and Krishna Undela

O218

Real-world cost-effectiveness study of first and third generation EGFR-TKIs for advanced NSCLC

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Introduction:
Lung cancer is a leading cause of mortality globally, with EGFR-mutated metastatic non-small cell lung cancer (NSCLC) prevalent in the Asian population. EGFR-tyrosine kinase inhibitors (TKIs) are used for managing this condition. The FLAURA trial recently demonstrated the remarkable efficacy of osimertinib in the front-line setting. However, analyzing real-world effectiveness, safety, and pharmacoeconomic considerations is essential for patients to make informed treatment choices.
Aims:
This study aims to compare the clinical effectiveness and safety of osimertinib versus gefitinib/erlotinib in treating EGFR-mutated metastatic non-small cell lung cancer (NSCLC), along with a cost-effectiveness analysis.
Methods:
This prospective, single-center, open-label, parallel assignment, phase IV cohort study was conducted at a Clinical Oncology Center in the western region of India. Patients with EGFR-mutated metastatic NSCLC were recruited after obtaining informed consent and allocated into two cohorts. Cohort 1 received osimertinib, while cohort 2 received gefitinib/erlotinib. Patients were followed for 1 year. The response to EGFR-TKIs was assessed using objective response rate (ORR), disease control rate (DCR), progression-free survival (PFS), and incidence of adverse events (AEs). Incremental cost-effectiveness ratio (ICER) was calculated through a cost-effectiveness analysis.
Results:
A total of 70 patients were enrolled, with 35 patients in each cohort. The ORR for cohorts I and II was 11.11% and 25.64% (p=0.142), respectively, and the DCR was 69.44% and 82.05% (p=0.28), respectively. Osimertinib and gefitinib/erlotinib had median PFS of 8.43 months and 10.68 months, respectively. The incidence of AEs for osimertinib and gefitinib/erlotinib was 1.94 and 2.49, respectively. The ICER between cohorts I and II was 454,848 INR.
Discussion:
Osimertinib was not found to be superior to gefitinib/erlotinib in terms of clinical effectiveness and direct medical costs, particularly in a developing nation like India. Although osimertinib demonstrated a better safety profile, the higher treatment cost compared to gefitinib/erlotinib is not justifiable.

Impact of Price Changes on Economic Burden of Anemia Treatment in CKD

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Introduction:
Chronic kidney disease (CKD) imposes a substantial economic burden on many countries and patients' families due to its high morbidity and mortality rates.

Aims:
To analyze the impact of drug price changes on the economic burden of erythropoiesis-stimulating agents (ESAs) and roxadustat for treating anemia in CKD patients in China.

Methods:
We utilized national cohort data from Tianjin Inspur Healthcare Big Data. Patients with renal anemia aged over 18 who visited any hospital in Tianjin from January 2018 to June 2023 were included. Study indicators included changes in the average price of roxadustat and ESAs from 2019 to 2023, changes in drug utilization, and changes in patient costs.

Results:
A total of 130,863 patients with renal anemia were enrolled in the study cohort. The average price of traditional ESA drugs remained stable from 2019 to 2023, with minor fluctuations of less than $10. In contrast, roxadustat, a novel drug for renal anemia treatment, showed a consistent annual price decrease from $413.79 in 2019 to $134.28 in 2023. ESA usage decreased from 2019 to 2023: 727,136 (100%), 781,909 (94.8%), 74,727 (87.8%), 649,548 (77.7%), and 245,692 (72.5%). Meanwhile, roxadustat usage increased: 290 (0.0%), 42,856 (5.2%), 103,601 (12.2%), 185,982 (22.3%), and 93,328 (27.5%). Patient visit costs from 2019 to 2023 were $1.40 billion, $2.86 billion, $1.93 billion, $2.07 billion, and $1.19 billion, respectively.

Discussion:
No significant correlation was found between drug price changes and the overall financial burden of ESA and/or roxadustat for anemia in Chinese CKD patients.

O220

Cost-effectiveness analysis of combinatorial pharmacogenomic-guided treatment for major depression

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Background:
Pharmacogenomic testing has the potential to improve the efficacy and safety of antidepressant pharmacotherapy. This study aims to assess the cost-effectiveness of implementing a combinatorial pharmacogenomic testing (CPGx) approach to guide the prescription of antidepressants.
Methods:
We developed a two-stage decision tree diagram of a short-term 6-week follow up, and a lifetime Markov model with 3-month cycles. The analysis compared the current standard of care (SoC) with the alternative strategy of CPGx testing in adult patients with major depressive disorder (MDD). Clinical outcomes and utilities were obtained from published studies, while healthcare costs were estimated based on data from Hamad Medical Corporation, Qatar. The short-term outcome measure was the incremental cost-effectiveness ratio (ICER) against treatment response without side effects and without relapse, as well as against treatment response with or without side effects and without relapse. The long-term outcome assessed the ICER against the quality-adjusted life year (QALY) gained, with a 3% annual discount rate. The study adopted a public hospital perspective. One-way, multivariate, and scenario sensitivity analyses were performed to evaluate the robustness of the model.
Results:
Adopting the CPGx testing for adult patients with MDD in Qatar resulted in cost savings of Qatari Riyal (QAR) 2,289 (95% CI, -22,654-26,340) for the health system. In the short term, the CPGx testing was associated with higher response rates without side effects and without relapse (mean difference 0.10, 95% confidence interval (CI) 0.09-0.15) and higher response rates with or without side effects and without relapse (mean difference 0.05, 95% CI 0.04-0.06) compared to the SoC. For long term, the CPGx testing resulted in 0.06 QALYs gained, per person, along with cost savings of QAR 46,215 (95% CI -15,744-101,758).
Conclusion:
Implementing pharmacogenomic testing to guide antidepressant use was found to improve population health outcomes, while also significantly reducing health system costs.

O221

Productivity Burden of Cardiovascular Disease in Diabetes and Impact of Health Interventions

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Introduction.
Tackling cardiovascular disease (CVD) in type 2 diabetes (T2D) is a crucial priority. A novel measure called the productivity-adjusted life-year (PALY) has been developed to account for the productivity loss from diseases.
Aims.
To use a 10-year dynamic modeling to examine the burden of CVD resulting from T2D in terms of PALYs among the working age population, and to explore the potential impact of interventions on the burden of CVD in T2D in Qatar, 2024-2033.
Methods.
We designed models to quantify the productivity burden (using the PALY) of CVD in Qataris with T2D aged 40–65 years from 2024 to 2033. The base-case analysis was designed to quantify the burden of CVD in terms of PALYs experienced using real-world data from the Primary HealthCare Corporation (2020). The risk of first CVD events was estimated via the 2013 PCE-ASCVD. Afterward, three simulations were conducted under hypothetical scenarios to assess the potential productivity advantages resulting from enhanced control of risk factors. These scenarios included reductions in systolic blood pressure (SBP) by 17%, number of smokers by 19%, and incidence of T2D by 9.5%. To determine the productivity, we considered the absenteeism, presenteeism, and workforce dropouts.
Results.
In the base-case, the estimated total PALYs were 2.18 million, contributing US$233.03 billion to the country's GDP. Reducing the incidence of T2D by 9.5% would project gains of 113,911 PALYs, accompanied by economic gains of US$12.44 billion. Additionally, if there were a 17% reduction in SBP and a 19% reduction in smoking numbers, there would be gains of 111,677 and 108,228 PALYs, respectively. These reductions would also result in economic gains of US$12.61 billion and US$12.21 billion, respectively.
Conclusion.
CVD in T2D could have a significant impact on PALYs in Qatar. However, improved risk factors control has the potential to mitigate the impact of this condition.

O222

Cost-effectiveness of universal screening for Lynch syndrome among colorectal cancer patients in Vietnam

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Introduction.
Lynch syndrome (LS), the most prevalent hereditary condition of colorectal cancer (CRC), accounts for 2-3% of all CRC cases. Recent US and European guidelines have recommended universal LS screening or routine screening of CRC patients up to 70 years old. However, despite the clear benefits of LS screening programs, there is a lack of economic evaluations of such programs in Vietnam, where the prevalence of CRC is rapidly increasing.
Aims.
The primary objective of our study is to assess the cost-effectiveness of implementing universal screening for LS among patients with CRC from the perspective of a healthcare system. Additionally, we sought to identify critical parameters that may influence the cost-effectiveness of LS screening and warrant consideration by Vietnamese policy-makers.
Methods.
In this study, we utilized a state-of-the-art decision-analytic model to assess the cost-effectiveness of LS screening from the perspective of the healthcare system in Vietnam. Our novel approach allowed us to compare two distinct testing strategies: sequencing of all MMR genes without prior tumor analysis (Strategy 1), sequential immunohistochemistry and germline testing analysis (Strategy 2), and no testing.
Results.
Assuming a CRC incidence rate of 0.0168%, and a share of patients affected by LS equal to 6.25%, the model identified 801 newly LS diagnosed cases. Our analysis indicated that universal LS screening is highly cost-effective. Strategy 2 was the most sensitive strategy in identifying LS CRC patients (N = 801), followed by strategy 1 (N = 697). Strategy 1 was the most expensive, followed by Strategy 2. The ICERs relative to the “No Screening” strategy ranged from 3 154 USD/QALY in Strategy 2 to 8 026 USD/QALY in Strategy 1. The one-way sensitivity analysis results shown that the variables most influenced model outcomes in the both two strategies were the utility of alive after cancer and probability CRC for LS carriers.. The cost-effectiveness acceptability curves for two strategies compared to the “No Screening strategy”. Considering a threshold of 12.852 USD/QALY (3 times GDP per capita), strategy 2 had a 100% probability of being cost-effective as compared to “No Screening” and strategy 1 had around 70% probability of being cost-effective.
Discussion.
This is the first comprehensive economic evaluation of LS testing strategies in Vietnam, and our results provide compelling evidence to support the introduction of cost-effective LS screening recommendations in the country.

O223

Assessing Burden of Chronic Diseases on Health-Related Quality of Life in Taiwan

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Introduction:
Chronic diseases pose a significant and growing burden on healthcare systems worldwide. Health-related quality of life (HRQoL) is a crucial measure reflecting the overall well-being of individuals affected by these conditions.
Aims:
This study aimed to quantify the impact of various chronic diseases on individuals' HRQoL using a nationally representative survey database in Taiwan and to identify variations in HRQoL across different demographic groups and disease conditions.
Methods:
We utilized data from the 2017 National Health Interview Survey, which included 15,765 individuals aged over 20 years. The study population was divided into two subgroups using age 65 as the cutoff for analysis. HRQoL was assessed using the EQ-5D-5L index, derived from EQ-5D-5L responses based on the Taiwanese value set (range -1.03~1), and the EQ-VAS (0~100). The impact of each chronic disease on HRQoL was measured using ordinary least squares regression.
Results:
Overall, 7,844 individuals reported having at least one chronic disease. The average number of comorbidities was 0.70 (SD 1.09) for those under 65 and 2.19 (SD 1.79) for those over 65. Among the younger age group, individuals with stroke exhibited the worst HRQoL, with the lowest EQ-5D-5L index (mean ± SD: 0.7936 ± 0.3680) and EQ-VAS (65.23 ± 18.21). For the elderly over 65, those with Parkinson's disease had the lowest EQ-5D-5L index (0.4859 ± 0.5449), while those with mental disorders had the lowest EQ-VAS (61.97 ± 19.28). Multivariable regression confirmed that these diseases contributed the most significant negative impact on individuals' HRQoL when relevant demographic factors and the number of comorbidities were controlled.
Discussion:
The study quantified the disease burden in Taiwan by evaluating HRQoL scores under different chronic conditions. However, significant variations were observed in the distribution of EQ-5D-5L index and EQ-VAS scores across various chronic diseases, highlighting the need for further investigation into the discrepancies.

Session: Prenatal & Pregnancy [Ito, Oct 14th 11:30-13:00] O224-O229

Moderators: Yea-Huei Kao and Taku Obara

O224

Prenatal and infant antibiotic exposure linked to child neuropsychiatric disorder risk

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Introduction.
Antibiotics are the most commonly prescribed prenatal medications worldwide, accounting for approximately 80% of all prescription medications for pregnant women. Previous studies have shown that exposure to antibiotics in early life or prenatally is associated with neuropsychiatric disorders, including autism spectrum disorder (ASD), attention-deficit hyperactivity disorder (ADHD), sleep disorder, conduct disorder, and mood and anxiety disorders. However, some previous studies showed that antibiotic exposure during pregnancy does not appear to affect early childhood socio-emotional development.
Aims.
We aimed to investigate the potential association between prenatal antibiotics and the risk of neuropsychiatric disorders in children.
Methods.
A nationwide, population-based, birth cohort study (infants, n=3,163,206; paired mothers, n=2,322,735) was conducted in South Korea, with four designs (unmatched, propensity matched, sibling-comparison, and health-screening cohorts). Follow-up continued until the first diagnosis of neuropsychiatric disorder, 31 December 2020 (end of the study period), or the date of death, whichever occurred first.
Results.
Antibiotic exposure in both fetal life and infant age was associated with an increased risk of overall neuropsychiatric disorders in childhood (prenatal [HR=1.07, 95%CI {1.05 to 1.08}]; postnatal [HR=1.05, 95% CI {1.03 to 1.07]). There was a synergistic effect of antibiotic exposures occurring both prenatally and postnatally (HR=1.12, 95% CI {1.09 to 1.15}). The association was significant in both common and severe neuropsychiatric disorders, while it was more pronounced in severe outcomes such as anxiety and stress-related disorders, autism spectrum disorders, and mood disorders (excluding those with psychotic symptoms).
Discussion.
Prenatal and postnatal exposure to antibiotics can lead to the development of neuropsychiatric disorders, suggesting clinicians take into account the potential for adverse consequences that might not be diagnosed until childhood when assessing the risk-benefit of early-life antibiotic prescription. Our study suggests that antibiotic exposure may influence the risk of neuropsychiatric disorders, but further research is needed to confirm these findings.

O225

A national population study of preterm birth following COVID-19 vaccination during pregnancy

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- Introduction/Aims
We aimed at estimating the association of COVID-19 vaccination during pregnancy with preterm birth from a national population cohort investigation.
-Methods
Individual-level data of women who gave births between January 1, 2021, and December 31, 2022, along with their infants, were obtained from the National Health Insurance System database. Preterm births were identified based on the ICD-10 codes of preterm birth in neonates and pregnant women. We 1:4 matched mothers who received COVID-19 vaccination during pregnancy to those who did not receive any COVID-19 vaccination during pregnancy based on propensity score (PS) for COVID-19 vaccination during pregnancy. Odds ratios (ORs) for preterm birth per any COVID-19 vaccination during pregnancy were calculated, adjusting for age, residential area, employment status, level of income, presence of disability, season of delivery, and the baby gender. We further compared the OR of preterm birth between the type of vaccines among the vaccinated mothers.
-Result:
Among a total of 106,692 mother and neonate pairs, 8,966 (8.4%) mothers received a COVID-19 vaccination during pregnancy. Of these vaccinated mothers, 78.0% received the Pfizer-BioNTech vaccine, 16.8% received the Moderna vaccine, and 5.1% received the Novavax vaccine. Overall, 7,039 (6.6%) neonates were born preterm. Preterm birth occurred in 5.5% (496/8,966) of vaccinated mothers and 6.6% (2,379/35,848) of their matched controls. The association between COVID-19 vaccination during pregnancy and preterm birth was not evident (OR=0.79, 95% confidence interval [CI]: 0.71, 0.89). The odds ratio of preterm birth was not different between the Pfizer-BioNTech and Moderna vaccines (OR=1.00, 95% CI: 0.76, 1.32) or between the Pfizer-BioNTech and Novavax vaccines (OR=1.17, 95% CI: 0.72, 1.91).
-Conclusion
We observed no increase in the risk of preterm birth among mothers who received a COVID-19 vaccination during pregnancy. Our findings add to the evidence supporting the safety profile of COVID-19 vaccination during pregnancy.

O226

Pregnancy Outcomes Following COVID-19 Vaccination: Preterm, Stillbirth and Miscarriage

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Introduction:
Although pregnant women, who are vulnerable to infections, should be administered vaccines promptly during global disease outbreaks, potential concerns about harmful effects on fetuses disturb their timely vaccination.
Aims:
To evaluate preterm birth, stillbirth, and miscarriage outcomes in pregnant women who were vaccinated COVID-19 vaccine during pregnancy.
Methods:
A retrospective cohort study was conducted on pregnancy episodes of women aged 18-49 occurring between February 27, 2021, and December 31, 2022, using a linked database of the Korea Disease Control and Prevention Agency-COVID-19-National Health Insurance Service cohort (K-COV-N cohort). Each episode was defined using an algorithm validated in previous studies, which distinguishes pregnancy outcomes with both surgical and ICD-10 codes. All episodes were classified into two groups depending on whether they received the COVID-19 vaccination during pregnancy. After 1:3 propensity score (PS) matching for maternal age, residence, insurance type, parity, hypertension status, diabetes status, and last menstrual month, we calculated the relative risk (RR) and 95% confidence intervals (CI) of pregnancy outcomes using a conditional logistic regression model.
Results:
A total of 581,740 pregnancy episodes were identified among 544,649 women, consisting of 440,645 (75.8%) full-term, 15,512 (2.7%) preterm, 3,050 (0.5%) stillbirth, and 122,533 (21.1%) miscarriage episodes. During the pregnancy, 63,394 (10.9%) episodes received at least one dose, with 1,238 for preterm, 510 for stillbirth, and 10,060 for miscarriage episodes. After PS matching, the RRs of the COVID-19 vaccination were 0.61 (95% CI: 0.58-0.65), 1.89 (95% CI: 1.69-2.11), 0.66 (95% CI: 0.65-0.68) for preterm, stillbirth and miscarriage, respectively.
Discussion/Conclusion:
In our study, COVID-19 vaccination reduced the risks of preterm birth and miscarriage. However, unlike previous studies, it increased the risk of stillbirth. Further analysis based on the gestational age at vaccination and the number of doses is needed.

Keywords: COVID-19 vaccine, pregnancy, pregnancy outcome

O227

Prenatal benzodiazepines or z-drugs use and risk of psychiatric disorders in children

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Introduction
Benzodiazepines and z-drugs readily cross the placenta and fetal blood-brain barrier and may disrupt fetal central nervous system development. Yet, studies on the potential impact of benzodiazepines or z-drugs use during pregnancy on the onset of psychiatric disorders in children remain scarce.
Aims
To investigate the association between prenatal use of benzodiazepines or z-drugs and a spectrum of psychiatric disorders in children.
Methods
Using Korea's nationwide healthcare database, we identified all pregnancies resulting in live births between 2009 and 2020. Exposure was defined as ≥1 benzodiazepines or z-drugs prescription during pregnancy and unexposed (the referent group) was those without benzodiazepines and z-drugs prescriptions from 1 month before pregnancy to the delivery. The outcome of interest was psychiatric disorders in children, which were further categorized into 13 groups. Children were followed up from birth until diagnoses of psychiatric disorders, death, or end of the study period (2021). Hazard ratio (HR) with a 95% confidence interval (CI) was estimated using the Cox proportional hazard model and propensity score (PS) fine stratification was used to adjust for numerous potential confounders. We additionally conducted sibling comparison analysis and comparison with those exposed to benzodiazepines or z-drugs before pregnancy to account for unmeasured confounders.
Results
Among 3,902,522 children, 86,392 (2.2%) were prenatally exposed to benzodiazepines or z-drugs. The unadjusted estimate was elevated for psychiatric disorders (HR 1.47, 95% CI 1.44-1.50); however, after adjustment, there was no substantial association (1.08, 1.06-1.10). The weighted cumulative incidence of psychiatric disorders at age 13 years was 15.3% for the unexposed group and 16.9% for the exposed group. The results from the sibling comparison analysis (0.98, 0.93-1.03) and the comparison with the past-exposed group (1.02, 1.00-1.04) further supported no association.
Conclusions
This study suggests that benzodiazepines or z-drugs use during pregnancy is not associated with psychiatric disorders in children.

O228

Real-world drug exposure during pregnancy: Insights from the JDIIP database

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Introduction:
Ensuring medication safety during pregnancy is crucial for pregnancy pharmacovigilance (PregPV). The current adverse event reporting system tends to collect more information on cases with abnormal outcomes while underreporting cases without abnormalities. The Japan Drug Information Institute in Pregnancy (JDIIP) database, which contains data from drug treatment counseling for pregnant women, is expected to address this gap in comprehensive PregPV databases.
Aims:
To evaluate the utility of the JDIIP database by exploring the real-world implications of PregPV.
Methods:
This study included pregnant women who sought consultation with JDIIP between October 2005 and December 2017. We focused on the 2023 Clinical Guidelines for Obstetrical Practice, which serves as Japan's basic framework for obstetrical care. The guideline includes clinical questions (CQs) and their corresponding answers. To investigate the potential for capturing data on contraindicated drugs not easily collected in spontaneous reports, we selected drugs listed in CQ104-3 ("Which contraindicated drugs, if used only in early pregnancy, can be considered to have no clinically significant fetal effects?"). Using the JDIIP database, we examined the number of patients exposed to these specified drugs to assess real-world drug exposure.
Results:
Among 7,329 women consented to participate, 5,840 had confirmed pregnancy outcomes (80% follow-up rate). We visualized patient background information and drug exposure status for drugs listed in CQ104-3. Drugs such as female hormones (n = 381), fluoroquinolones (n = 353), and antiemetics (n = 313) were used in pregnant women. We confirmed that exposures to these drugs occurred before pregnancy or during the first trimester, highlighting the JDIIP database's strength in collecting and visualizing drug exposure patterns.
Discussion:
Our findings underscore the significant potential of the JDIIP database as a resource for understanding real-world drug exposure during pregnancy. The JDIIP database is a promising source for advancing PregPV initiatives.

O229

Assessment of Maternal Dietary Pattern and Its effect on Early Gestational Period

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Introduction:
Maintaining a balanced and nutritious diet during pregnancy is vital for maternal and fetal health. This study examines maternal dietary patterns and their effect on biochemical parameters in early gestation.
Aim:
To understand the impact of diet on maternal health outcomes, particularly regarding iron status and biochemical profiles.
Methodology:
A structured questionnaire was employed to collect detailed dietary intake data from pregnant women during their early trimesters. Nutrient intake was analyzed and compared to established dietary guidelines for pregnant women in India. Blood samples were collected and analyzed for various biochemical parameters, including lipid, renal, and hepatic profile parameters. A cross-sectional study design with a sample size of 85 pregnant women in their early trimesters was included. Statistical analysis was done using SPSS software.
Results:
Most participants had normal fruit, milk, and salt intake as per the RDA, but low intake of non-vegetarian food in the first trimester and low salt intake and vegetable intake in the second trimester. Lipid parameter (Total cholesterol, HDL, LDL, and triglycerides) dysfunction was persistent in the second trimester when compared to the first ($P<0.001$). Significant correlations were found between certain dietary factors and biochemical parameters in both trimesters. Iron levels were found significantly lower in patients not taking iron supplements in both trimesters ($P=0.003$ and <0.001 respectively). Furthermore, a positive correlation was found between milk intake and iron levels ($r=0.634, P=0.004$) along with salt intake and iron levels ($r=0.728, P=0.027$). In addition, higher fruit intake was associated with increased HDL levels ($r=0.490, P=0.008$) and lower milk intake was associated with higher urea levels ($r=-0.712, P=0.02$).
Conclusions:
In conclusion, this study provides valuable insights into early pregnant women's dietary patterns and biochemical parameters during early gestation. The findings underscore the importance of assessing dietary intake and preparation of standard dietary guideline for Indian pregnant women.

Session: Cancer and Others [Med-1F, Oct 14th 11:30-13:00] O230-O235

Moderators: Lei Chen and Daisuke Koide

O230

Twenty-year secular trend of thyrotoxicosis and thyrotoxic periodic paralysis in Hong Kong

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Introduction
Thyrotoxic periodic paralysis (TPP) is a rare complication of thyrotoxicosis characterized by hypokalemia, and episodic muscle weakness/paralysis, which is potentially fatal when cardiopulmonary complications occur. The lack of large TPP cohorts hinders relevant epidemiology studies.
Aims
To establish a population-based registry of thyrotoxicosis and TPP in Hong Kong, and to evaluate their secular trend during 2002-2021.
Methods
Clinical data from the electronic medical database in Hong Kong, the Clinical Data Analysis and Reporting System (CDARS), was retrieved. One hundred potential cases of thyrotoxicosis (by ICD-9-CM: 242.xx) and TPP (by ICD-9-CM: 242.xx and 359.3, plus low potassium level) were randomly selected from CDARS, followed by reviewing clinical notes, examining laboratory test records, and deriving positive predictive value (PPV) of the clinical data. A population-based registry of thyrotoxicosis and TPP in Hong Kong was established. The standardized incidence rate of both thyrotoxicosis and TPP were computed with annual percentage change (APC) for trend analysis.
Results
The PPV of clinical data in CDARS for thyrotoxicosis and TPP were 0.86 (95% CI: 0.79-0.93) and 0.97 (95% CI: 0.94-1), respectively. Population-based cohorts of thyrotoxicosis (n=83,184) and TPP (n=999) were established. The age- and sex-standardized incidence rate of thyrotoxicosis increased from 45.22 to 80.7 per 100,000 person-years from 2002 to 2021, with APC of 4.72% (95% CI: 2.02-8.05). Both sexes had increasing trend in age-standardized incidence rate of thyrotoxicosis. As TPP patients were predominantly male, the age-standardized incidence rate of TPP was stratified in both sexes. In 2002 and 2021, the incidence rate (per 100,000 person-years) in male was 1.48 and 1.28 respectively, while that in female was 0.11 and 0.13, without significant trend observed.
Discussion
This is the first study validating clinical data for TPP in electronic medical database. Its high PPV enabled establishment of the largest TPP cohort to-date, facilitating future epidemiology studies.

O231

Effect of Biological Immunotherapy for Psoriasis on the Development of Psoriatic Arthritis

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Introduction:
Psoriatic arthritis (PsA) poses a significant concern for patients with psoriasis. While previous studies have explored the impact of biological treatments on PsA progression, their ability to assess the effect of targeting specific interleukin (IL) pathways has been limited by insufficient statistical power.
Aims:
To assess the risk of PsA associated with the use of IL-23 inhibitor (IL-23i), IL-17 inhibitor (IL-17i), or IL-12/23 inhibitor (IL-12/23i) compared to tumor necrosis factor inhibitor (TNFi) use among patients with psoriasis.
Methods:
This population-based cohort study used the nationwide claims database from South Korea (2007–2022). New users of ILis or TNFis with psoriasis who did not have PsA or other inflammatory arthritis were categorized into each class of ILi use for comparison with TNFi use. The outcome was the development of PsA, assessed after a 3-month lag period to minimize protopathic bias. We calculated multinomial propensity scores and applied overlap weights to balance predifined covariates. Hazard ratio (HR) and 95% confidence intervals (CIs) were calculated using Cox proportional hazards models.
Results:
We identified 9,681 patients with psoriasis (mean age 45.1; 33.7% female), of whom 3,913 (40.4%), 2,126 (22.0%), 2,773 (28.6%), and 909 (9.3%) were respectively exposed to IL-23i, IL-17i, IL-12/23i, and TNFi. PsA occurred in 276 (2.8%) patients during 23,045 person-years of follow-up. The weighted HR for any ILi was 0.43 (95% CI 0.28 – 0.68), with specific HRs of 0.25 (0.15 – 0.43), 0.52 (0.31 – 0.87), and 0.48 (0.30 – 0.76) for IL-23i, IL-17i, and IL-12/23i, respectively. IL-23is exhibited the greatest rate difference of -2.52 (-3.99 – -1.06) incident cases of PsA per 100 person-years.
Discussion:
We found a reduced risk of PsA among patients with psoriasis using ILis, particularly IL-23is, compared to TNFis. These results support the current clinical practice, where newer ILis are the preferred biologics for managing psoriasis.

O232

Role of Rare Disease Databases in Pharmacoepidemiological Studies in India: A Review

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Introduction:
Rare disease databases act as valuable sources of epidemiological data, treatment outcomes, and demographic spread of diseases. A comprehensive data source containing real-world information about the disease and corresponding treatment data can support informed decision-making, treatment management, and the development of targeted therapeutics. Due to vast demographic and social diversity, the Indian rare disease landscape is not well-studied and it is important to address this area through effective pharmacoepidemiological studies.
Aim:
This review explores the current rare disease database scenario in the Indian context to identify the challenges associated with data collection and analysis and proposes solutions to address these to ensure effective database usage for rare disease treatment management.
Methods:
A comprehensive search was undertaken to identify relevant studies on the quality, features, and utilization of rare disease databases in India. The studies were selected based on their relevance, information, and content that can either cover the Indian landscape or can be effectively extrapolated in the Indian context.
Results:
The Indian healthcare system generates a vast amount of clinical information like clinical records, electronic health records, patient outcomes, clinician observation sheets, and insurance payout data. The Indian Council of Medical Research (ICMR) developed the National Registry for Rare and Other Inherited Disorders (NRROID) in 2019. This database can support epidemiological insight assessment, drug utilization studies, and effectiveness research. ~12,000 records have been aggregated so far, but challenges remain in source identification, infrastructure, awareness, and timely reporting.
Discussion:
Rare disease databases can play crucial role in advancing pharmacoepidemiological research in India. By developing appropriate data capture and analysis mechanisms, fostering collaborations across researchers, clinicians, and companies, and promoting public-private partnerships in developing and implementing robust technological infrastructure, the rare disease treatment landscape can be vastly improved in India thus providing a better quality of life for rare disease patients.

O233

Site-specific Cancer Incidence among Antipsychotic Users in Hong Kong: Descriptive Cohort Study

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Introduction:
Research findings on the relationship between antipsychotics (AP) and cancer is oftentimes inconsistent across cancer sites and populations.
Aims:
To estimate the incidence of site-specific cancer in patients who were first continuously prescribed antipsychotics in Hong Kong and compare it against the general population.
Methods:
A descriptive, retrospective study was performed using real world data from Hong Kong Clinical Data Analysis and Reporting System (CDARS) and Hong Kong Cancer Registry (HKCaR). The crude incidence rate of cancer and age-standardized rate (ASR) were calculated to evaluate cancer incidence. Subgroup analyses were conducted for male and female users, as well as for first-generation antipsychotics (FGA) and second-generation antipsychotics (SGA) subgroups.
Results:
For the AP users who were prescribed over 90 days or more would have more cancer risk than the general population (ASR of AP users vs ASR of general population (317.3 vs 249.1), the results reflected in all AP users and males (371.5 vs 268.7), females (275.9 vs 229.7), and FGA users (521.8 vs 249.1), but not true in SGA users (233.9 vs 249.1). The distribution of cancer among AP users exhibits both commonalities and distinct patterns compared to the general population. Major types of cancer among AP users rank similarly to those in the general population, indicating similarities in both male and female groups. Certain cancers such as lung, breast, leukaemia, and bladder cancers show higher ASR among AP users. Males have an additional higher risk of liver cancer incidence, and females have a relatively lower overall cancer risk, including a slightly reduced risk of lung cancer. Higher incidence of numerous cancer types is observed among FGA users compared with SGA users.
Conclusion:
Incidence of cancer is higher among antipsychotic users compared to the general population, and the pattern of site-specific cancer incidence varied.

O234

Aspirin Use and Mortality Following a Cancer Diagnosis: A Clone-Censoring Weighting Method

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Background
Previous meta-analyses have linked aspirin use to a 20% reduction in both all-cause mortality and cancer-specific mortality. However, failing to account for immortal time bias might impede causal interpretation.
Objectives
To evaluate the effect of post-cancer diagnosis aspirin use on the overall mortality, cancer-specific mortality, and cardiovascular mortality.
Methods
We enrolled patients aged above 20 years old with newly diagnosed cancer between 2011 to 2018. We assigned the index date as the date of the first cancer diagnosis. The death record and the cause of death were obtained by linking with the National Death Registry. In the naïve analysis (i.e., subject to immortal time bias), aspirin use was defined as any prescription record after the index date. Thus, patients were inherently immortal during the period between the index date and the prescription date to allow for the use of aspirin. We then subsequently applied clone-censoring weighting (CCW) approaches to account for the immortal time bias. Outcomes were compared between patients who received aspirin within 365 days after the index date and those who did not. We used non-parametric bootstrap with 150 samplings to estimate the 95% confidence intervals.
Results
We identified a total of 41,662 cancer patients with a mean age of 64.7 (SD 16.5) and 56.62% male. In the entire follow-up period, 4,656 (11.2%) patients with any aspirin exposure, and the median time to prescription was 390 days. In the naïve analysis, post-cancer diagnosis use of aspirin was associated with protective effect against overall mortality (Hazard ratio: 0.83; 95% CI 0.79-0.88) and cancer-specific mortality (0.84; 0.74-0.95) and cardiovascular mortality (0.89; 0.73-1.00). However, using the CCW approach, no significant benefits were observed for overall mortality (1.05; 0.72-7.05), cancer-specific mortality (1.27; 0.89-92.78), and cardiovascular mortality (1.25; 0.89-43.83).
Conclusions
Protective effect of aspirin diminished after accounting for the immortal time bias.

O235

Longevity of systematic reviews of PARP inhibitors in ovarian cancer

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Introduction:
Systematic reviews and meta-analysis are reliable sources of clinical and medical evidences. However, in rapidly evolving medical fields, their relevance can quickly diminish without regular updates. Little research has been done on update frequency and shelf-life of systematic reviews.
Aims:
To assess the frequency of updates and shelf-life of systematic reviews, to evaluate adherence to recommended update frequencies by different guidelines, and to compare the updating frequencies of academic vs industry-sponsored systematic reviews of poly (ADP-ribose) polymerase inhibitors (PARPi) in ovarian cancer (OC).
Methods:
The study was registered in PROSPERO (ID: CRD42024509536) and conducted in accordance with PRISMA guidelines. A thorough search of PubMed and Cochrane Library databases (January 2015 - December 2023) was performed to identify systematic reviews of PARPi in OC. Relevant data were extracted, and shelf-life was determined using Kaplan-Meier analysis using Excel and SPSS version 29.0.2.0.
Results:
Out of 115 systematic reviews, 43 met the inclusion criteria, with only 4.65% being updated. The median shelf-life for updating systematic reviews was 8 months due to new studies and 2 months due to new publications. The average time from search end date to acceptance of manuscript was 6 months, with publication taking an average of 10 months. Pharmaceutical companies sponsored fewer reviews compared to academia, with no significant difference in update frequency.
Conclusion:
Half of the systematic reviews of PARPi in OC were outdated pre-publication, indicating non-adherence to existing guidelines. This underscores the urgency for enhanced updating protocols to uphold systematic review reliability.
Keywords: Systematic Review; Ovarian Cancer; PARP Inhibitors; Shelf-life.

Session: Medication Access / Regulation [Med-3F, Oct 14th 11:30-13:00]

O236-41

Moderators: Helga Gardarsdottir and Chieko Ishiguro

O236

Access to Oral Childhood Cancer Medicines in High Income and LMIC Countries

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Background:
Despite a growing burden of childhood cancer globally and disparities in childhood cancer mortality rates between high income and LMICs, there is limited information on trends and disparities in access to essential medicines indicated for the treatment of childhood cancers between high income low and middle income countries (LMICs).

Aims:
1. To investigate trends and disparities in the use of oral childhood cancer medicines in high income and LMICs by geographic region between 2015-2020.

Methods:
We analyzed quarterly sales data from IQVIA's MIDAS for oral childhood cancer medicines between January 1st 2015 to October 31st 2020. We included a total of 25 oral childhood cancer medicines indicated for the treatment of common childhood cancers (i.e., leukemia, lymphoma, brain and nervous system cancers). Average quarterly sales trends of cancer medicines were expressed as standard units (SUs) or tablets per 100,000 children aged < 20 years per day.

Results:
Although the use of childhood cancer medicines increased significantly in LMICs between 2015 and 2019 (from 122 to 172 tablets per 100,000;p< 0.01), LMICs accounted for only ¼ of childhood cancer medicines in 2019. Although the use of childhood cancer medicines increased only 4.7%, use was nearly 20-times greater in high income countries (3,104 tablets per 100,000) in 2019. Use also varied substantially between and within regions of LMICs; Turkey (1,798 per-capita) and Romania (2,408 per-capita) with the highest rates and West Africa and Thailand the lowest rates (2.5 and 7.4 per-capita, respectively). In 2019, High Income Countries with the lowest number of deaths from childhood cancer had the largest volume of childhood cancer medicines.

Discussion/Conclusions:
Although access to oral childhood cancer medicines has steadily increased in LMICs since 2015, there is still widespread inequitable access to these essential medicines when compared to high income countries.

O237

Access to Monoclonal Antibody and Antibody-Drug Conjugates for Cancer Indication in Indonesia

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Introduction:
Monoclonal antibodies (mAb) and Antibody-Drug Conjugates (ADC) have revolutionized cancer therapy due to their targeted action and improved efficacy compared to chemotherapies. Many patients have benefited from these therapies since the first one was approved. Studies on which mAb and ADC are accessible for cancer treatment in Indonesia were limited.
Aims:
To investigate the accessibility of mAb and ADC-based products for cancer treatment in Indonesia based on marketing authorization data from the Indonesian Food and Drug Authority (BPOM).
Methods:
This study retrospectively identified mAb and ADC for cancer indication in Indonesia using marketing authorization data from the Indonesia Food and Drug Authority (BPOM) until 17th November 2023. Data were extracted and coded using the World Health Organization Anatomical Therapeutic Chemical (WHO ATC) classification system. Products of mAb and ADC were identified using the L01F code for monoclonal antibodies and antibody-drug conjugates. The study evaluates conformity of these products with the Indonesia National List of Essential Medicine (NLEM) 2021, Indonesia National Formulary 2021, and World Health Organization Essential Medicine List (WHO EML) 2019.
Results:
As many as 16,115 medicine products were identified from the BPOM database. Of those, there were 1,260 active ingredients. Eleven mAb were identified, namely atezolizumab, bevacizumab, brentuximab vedotin, daratumumab, durvalumab, obinutuzumab, pembrolizumab, pertuzumab, ramucirumab, rituximab, and trastuzumab. There is one ADC, namely trastuzumab emtansine. There are no mAb or ADC included in the Indonesian NLEM 2021. Two mAb, rituximab and trastuzumab was included in the Indonesia National Formulary 2021. These two were also included in the WHO EML 2019 on the complementary list.
Discussion/Conclusion:
Indonesia is improving access to targeted therapies for cancer patients as can be seen from the twelve approvals of mAb and ADC. Two of them, rituximab and trastuzumab were included in the Indonesia National Formulary and covered by the national health insurance.

O238

Descriptive analysis of outcomes in regulatory-required post-marketing database studies in Japan

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Introduction:
Post-marketing database studies (PMDS) are pharmacovigilance activities encouraged since a regulatory revision issued in 2018 by the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. However, a comprehensive review of outcomes of interest in PMDS does not exist.
Aims:
To describe and analyze outcomes of interest and types of databases being utilized in PMDS.
Methods:
All risk management plans (RMPs) listed in the PMDA website from April 2013 to December 2023 were extracted. Two researchers systematically and independently identified PMDS listed in RMPs. Outcomes of interest in PMDS were summarized according to their study objectives and were analyzed in conjunction with the databases being utilized.
Results:
Among 648 RMPs retrieved and reviewed, 85 PMDS were identified within 63 RMPs. Eighty-one out of 85 PMDS targeted 138 outcomes for safety objectives and 5 targeted 5 outcomes for effectiveness objectives. In total, 138 outcomes for safety objectives were investigated, including 122 identified as important identified risks (IR)/important potential risks (PR)/others and 16 as important missing information (MI). Of the 122 IR/PR/others, the most common targets (system organ class level of the Medical Dictionary for Regulatory Activities) were “Infections and infestations” (n=18, 14.8%), “Metabolism and nutrition disorders” (n=17, 13.9%), “Cardiac disorders” (n=15, 12.3%), and “Vascular disorders” (n=15, 12.3%). Among 122 IR/PR/others, 47 (38.5%) were investigated using the Medical Data Vision database, 23 (18.9%) used registries and 17 (13.9%) used the Medical Information Database Network (MID-NET®). Sixteen MIs included usage for patients with renal dysfunction (n=5) followed by long-term use (n=3), and safety of medication switching (n=3) mainly.
Discussion:
This is the first study to comprehensively describe and analyze outcomes of interest and data sources in PMDS conducted in Japan. Elucidated insights about combinations between outcomes of interest and databases should be informative for pharmaceutical companies to plan additional pharmacovigilance activities.

O239

Prescriptions of the acid-suppressants after withdrawal of ranitidine in Korea

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Introduction:
In 2019, ranitidine was withdrawn from the global market due to the detection of the probable carcinogen N-nitrosodimethylamine. This is expected to have led to a shift in the prescription of medications for acid-related disorders.
Aims:
To identify prescription amounts of acid-suppressants following the withdrawal of ranitidine in Korea.
Methods:
National claims data from January 2016 to May 2023 was utilized to count for the prescriptions of histamine h2 receptor antagonists (H2RA) and proton pump inhibitors (PPI) in the patients with acid-related diseases. The number of claims and the amounts of prescriptions based on defined daily dose (DDD) were calculated for each drug. An interrupted time series analysis was conducted using piecewise linear regression and autoregressive integrated moving average model to evaluate the change in prescriptions after ranitidine recall.
Results:
A total of 483,556,858 claims for H2RA and 246,946,250 claims for PPI were made during the study period. Following the withdrawal of ranitidine, the number of monthly claims for all H2RAs decreased by 4,180,035 (95% CI: 3,763,723 to 4,596,347), while the number of monthly claims for all PPIs increased by 256,275 (95% CI: 104,823 to 407,726), immediately. Among PPIs, esomeprazole and rabeprazole showed the most pronounced increases, with 16.5 and 11.0 DDD prescribed in 2022, respectively. For H2RAs, famotidine exhibited the largest increase, with 11.0 DDD prescribed in 2022.
Discussion:
There was a significant decrease in the prescription of H2RA and prominent increase in the prescription of PPI after the withdrawal of ranitidine in Korea. Given the potential harms of PPI, further research in needed to evaluate the public health implications of changes in the utilization of acid-suppressants.

O240

Decision-making Autonomy in Healthcare Utilization among Married Women and Associated Factors

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Introduction:
Women's autonomy is very important in health decision-making but most studies focused solely on fertility, children, or maternal healthcare use. Due to this reason, the magnitudes and factors associated with women's autonomy in other types of healthcare remain unclear. Therefore, this study aimed to estimate the magnitude and identify factors associated with decision-making autonomy on healthcare use among married women in Indonesia.
Methods:
A national cross-sectional study was conducted among married women using the Indonesia Demographic and Health Surveys 2017. Women's autonomy in healthcare decision-making was measured based on responses regarding the individual typically responsible for making healthcare decisions on behalf of the respondent. Potential factors, such as intrapersonal, interpersonal, community, and policy-related were obtained. Multinomial logistic regression was used to determine the associations between potential factors and outcomes. The odds ratio (OR) and 95% confidence intervals (CI) of the analysis were reported.
Results:
The respondents in this study comprised 34,467 married women across 34 provinces in Indonesia. Most of the respondents had joint health decisions with the husbands (45.7%). The result showed that several factors were associated with either women's full autonomy or jointly with the husbands in the healthcare decision-making. These factors included secondary or higher education, ownership of mobile telephones, higher household wealth index, urban living, residency in Java or Bali provinces, participation of women in decision-making, and independence in visiting a medical center.
Conclusions:
The majority of married women made joint health decisions with the husbands. Public health interventions should focus on vulnerable women, such as those who are uneducated, poor, participate less in household decision-making, face barriers in accessing healthcare services, and live in urban to increase autonomy in healthcare decision-making.

O241

Mapping five-year changes in childhood immunization in a South Indian community.

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Background:
Nationwide, childhood-immunization exhibits altered vaccine demands and uneven utilization patterns. These variabilities may stem from various internal and external factors influencing parental preferences. Regular checks and balances are necessary to ensure equal accessibility for all sections of society.
Aim:
To assess childhood vaccine usage trends over five-years (2018-2022) and monitor instances of delayed or incomplete immunization within the community.
Methodology:
This ambispective study recorded childhood-vaccine utilization trends over five-years. Immunization details from 2018-2020 were retrieved retrospectively, while data from 2021-2022 were collected prospectively through an immunization registry. Trends in vaccine utilization, delays, and incomplete vaccinations among children were analyzed and compared.
Results:
The study profiled 32,085 children who received 87,782 vaccine doses over five years. Optional vaccines were less utilized (18.12% of doses by 25.14% of children) compared to mandatory vaccines (81.88% of doses by 74.86% of children). The most utilized mandatory vaccine was Oral Polio (17.48%), and for optional vaccines, it was MMR (28.31%). Boys had higher utilization rates (55.97%), with a significant male preponderance in optional vaccine utilization ($p < 0.05$). There was a 26.12% decline in vaccine utilization in 2022 compared to 2018. Among children with delayed immunization (6.02%), 3.38% were on catch-up schedules, and 2.45% were not. The most commonly delayed vaccines were DTP boosters (30.90%), Tdap (26.19%), and MMR (20.65%). Influenza vaccines (28.08%) and varicella vaccines (20.92%) were the most partially utilized optional vaccines. Significant predictors of deviated immunization status included gender (female), age over one year, rural residence, and low to middle-income families.
Conclusion:
The study mapped the utilization trends in a South Indian community over five years, including during COVID-19. Gender inequality in the utilization of optional vaccines is a concern warranting further research and redressal. Timely childhood vaccinations are crucial for reducing susceptibility to vaccine-preventable diseases and promoting overall well-being.

Session: Machine Learning / AI & Vaccination [Yasuda, Oct 14th 16:00-17:30] O242-47

Moderators: Shintaro Hiro and Chi-Chuan Wang

O242

Machine learning for high-risk multimorbid antipsychotic user identification and cardiovascular event prediction

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Introduction:
Pre-existing multimorbidity is a known risk factor for major adverse cardiovascular events (MACE) among antipsychotic users. However, the association between multimorbidity and polypharmacy patterns and MACE remains to be clarified.
Aims:
Identify specific multimorbidity patterns and antipsychotic use associated with increased MACE risks and develop and validate a time-to-event prediction model.
Methods:
This retrospective cohort study utilized electronic health records from the Hong Kong CDARS database. Patients aged 18-65 years, with records of 2 or more chronic health conditions within three years prior to the initial date of antipsychotic intake, were enrolled. Baseline characteristics, including age, sex, chronic disease history, antipsychotic usage history, and previous one-year drug intake history, were collected. The dataset was randomly divided into training and validation subsets based on the initial year of antipsychotic prescription. A Conditional Inference Survival Tree (CISTree) was employed to classify MACE risk groups. Eight machine learning models were trained using 5-fold cross-validation for hyperparameter optimization and validated on the validation set.
Results:
27,466 patients were included. The CISTree model identified older patients (>44 years) with chronic kidney disease (CKD), cancer, hypertension, and using antianginal and antiplatelet drugs but not taking antidepressants as having the highest MACE incidence rate (173.065 per 1,000 person-years; 95% CI: [125.023, 230.990]). The Random Survival Forest (RSF) model outperformed the other seven models, identifying age, antidepressant usage, and chronic kidney disease (CKD) as the top three significant predictors. Furthermore, factors associated with a lower risk of MACE included younger age (<44 years), the use of antianginal, antibacterial, or antidepressant drugs, no usage of antiplatelet drugs or haloperidol, and the absence of CKD.
Discussion:
We identified highly specific high-risk groups in multimorbidity people using antipsychotics; prediction based on the same features demonstrates excellent power and potential in aiding clinical decisions.

O243

Artificial Intelligence Techniques for the Survival Prediction of Oropharyngeal Squamous Cell Carcinoma

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Introduction:
Oropharyngeal squamous cell carcinoma (OPSCC) is prevalent globally. Artificial intelligence techniques like deep learning and machine learning can be used for survival prediction with better accuracy than traditional models.
Aims:
This study aimed to use machine learning and deep learning techniques to develop models for identifying and visualizing significant predictors of OPSCC survival rates.
Methods:
A retrospective cohort study was conducted at a tertiary care cancer hospital in northeast India and retrieved a dataset of 1042 OPSCC patients admitted between 2018 and 2020. The dataset contained 12 predictor variables (independent variables) associated with the survival status (dependent variable) of the patients (alive or dead). Logistic regression, support vector machine (SVM), random forest (RF), and multilayer perceptron (MLP) were the prediction models used to determine the significant predictors of OPSCC survival rate. The key variables were ranked using random forest variable selection techniques. In addition to using the random forest technique, we also performed binary logistic regression to further evaluate the significance of these variables in predicting survivability. The study used various metrics to assess the classification performance of the models, including sensitivity, specificity, accuracy, precision, F1 score and Matthews' correlation coefficient.
Results:
The MLP model achieved the best performance across all evaluation metrics in this study. The MLP model was observed to have higher accuracy (83.25%; area under the curve (AUC)=0.83) and precision (0.83) than RF (accuracy=81.34%; AUC=0.80; precision=0.80), logistic regression (accuracy=77.99%; AUC=0.78; precision=0.75) and the lowest in SVM (accuracy=75.12%; AUC=0.75; precision=0.70). Variables such as age, treatment (surgery followed by radiotherapy), metastasis, T stage, and nodal status were identified as predictors of the OPSCC survival rate.
Conclusion:
A deep learning technique incorporating the clinical variable can be an excellent model for predicting survival rates among OPSCC patients. The MLP model was observed to have better predictability than other models.

O244

Computational drug repurposing for gallbladder cancer integrated with pharmacovigilance approach

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Introduction:
Over 115,000 people die from gallbladder cancer (GBC) annually, a rare yet highly fatal disease accounting for 80-95% of biliary tract cancers. Its high recurrence rate, geographic disparities, limited treatments, and drug resistance underscore the urgent need for targeted therapies.
Aims.
To identify potential targets and inverse pharmacovigilance signals associated with GBC and screen existing drugs for repurposing based on the identified targets.
Methods:
A systematic search was conducted in Gene Expression Omnibus (GEO), and microarray expression profile datasets related to GBC were downloaded. Differentially expressed genes (DEGs) between normal and GBC were identified using GEO2R and Venn diagram tools, with those displaying a log (fold change) >1 and a p-value <0.05 considered significant. A protein-protein interaction network was built using the Search Tool for the Retrieval of Interacting Genes (STRING) and analyzed using Cytoscape. The prognostic significance of the target gene was evaluated using GEPIA, and genomic alterations were investigated through the cBioPortal database. Subsequently, inverse disproportionality analysis was performed using Open Vigil 2.1 on the FAERS database (to retrieve repurposable drugs). Furthermore, molecular docking was conducted in Biovia Discovery Studio by keeping dinaciclib (CDK1 inhibitor) as a reference to investigate the target's interaction with the identified drugs.
Results:
Cyclin-dependent Kinase 1 (CDK1), significantly overexpressed in GBC, was identified as a potential target. According to the GEPIA database, overexpression of CDK1 is associated with reduced survival of GBC patients. Among 54 drugs identified from inverse disproportionality analysis, levothyroxine and folic acid were prioritized due to their highest docking score of -77.83 Kcal/mol and -73.27 Kcal/mol, respectively, followed by atorvastatin and methotrexate. These findings hold promise for the future of GBC treatment.
Discussion:
In the realm of drug repurposing, GBC is unexplored. Despite its aggressive nature, studies related to the molecular mechanism of the disease and targeted therapy are limited; our pioneering work, which takes a novel approach to drug repurposing, is the first to examine drug repurposing and identified levothyroxine, folic acid, atorvastatin, and methotrexate as promising candidates, highlighting the need for in vitro and in vivo studies.

O245

AI in Pharmacovigilance: Asia Pacific's Scientific and Public Discourse

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Introduction:
Artificial intelligence (AI) is transforming pharmacovigilance(PV) worldwide, but discussions are limited to Global North countries.
Aims:
This study explores how the public and scientific communities in Asia Pacific countries discuss AI in PV, aiming to identify potential gaps and research focus.
Methods:
We analysed online media conversations (2022-February 2024) and scientific literature from global and Asian databases to understand these discourse.
Results:
Our initial analysis of over 19,000 online conversations showed most discussions came from news sources, with limited (26 tweets) on social media platform X. These tweets focused on US FDA and South Korea collaboration on AI in medical products. Sentiment was neutral.
In the scientific literature, we found 17 relevant studies, mostly published in 2023 and originating from Japan (5), South Korea (4), and China (3). None were from South or Southeast Asian countries. The most frequently discussed AI techniques were machine learning (10/17) and natural language processing (NLP) (10/17). These studies primarily focused on using AI to detect adverse drug reactions (ADRs) (8/17), with less attention given to processing safety reports (2/17) or integrating prediction uncertainties (2/17). Challenges like data quality and management (6/17), model accuracy and adaptability (4/17), and integration with existing systems (3/17) were highlighted. Other potential applications of AI in pharmacovigilance, such as extracting drug-drug interactions, identifying high-risk patient groups, predicting side effects, and simulating clinical trials, were rarely or not at all explored. Ten studies expressed optimism about the positive impact of AI on drug safety and healthcare efficiency, while the remaining 7 acknowledged the potential but emphasized current limitations (neutral sentiment).
Conclusion:
Discussions on potential of AI in PV, public and scientific, are still limited in the Asia Pacific region, particularly in South and Southeast Asia. This lack of representation suggests potential inequities in AI-driven drug safety solutions in the region.

O246

Risk of Guillain-Barre syndrome after Influenza Vaccination in Korean Adults

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Introduction:
Previous studies on the association between the influenza vaccine and Guillain-Barre syndrome (GBS) have shown varying results by study year and region.
Aims:
To evaluate the risk of GBS following influenza vaccination among Korean adults in the 2016-2017 to 2021-2022 seasons.
Methods:
We performed a self-controlled risk interval study using vaccination registry from the Korea Disease Control and Prevention Agency and the National Health Insurance Service claims data. This study included adults aged 18 and older who received a single dose of the influenza vaccine in at least one season from 2016 to 2022, with each season defined as the period from September to April of the following year. GBS event was defined as the first hospitalization for GBS within 84 days post-vaccination and was identified using both ICD-10 code (G61.0) and codes indicating treatment for GBS, a rare incurable disease. The exposure risk intervals were defined as 1–42 days post-vaccination with the control interval set at 43–84 days post-vaccination. Conditional Poisson regression model was used to estimate the adjusted incidence rate ratio (aIRR) with adjustments for calendar time by weekly interval.
Results:
The GBS cases identified within 84 days post-vaccination during the 2016-2017 to 2021-2022 seasons were 35, 27, 35, 58, 62, and 68, respectively. Corresponding aIRRs for the 2016-2017 season were 4.09 (95% confidence interval [CI]: 0.68–24.78); for the 2017-2018 season, 0.69 (95% CI: 0.12–4.06); for the 2018-2019 season, 0.41 (95% CI: 0.08–2.01); for the 2019-2020 season, 0.69 (95% CI: 0.19–2.48); for the 2020-2021 season, 0.75 (95% CI: 0.23–2.49); and for the 2021-2022 season, 1.70 (95% CI: 0.60–4.80).
Discussion/Conclusion:
There was no evidence of an increased risk of GBS after influenza vaccination during the 2016-2017 to 2021-2022 seasons. However, the recommended vaccine strain varies by season, continuous monitoring for GBS remains necessary.

O247

Trends and predictors of zoster vaccination coverage among U.S. cardiovascular disease population

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Introduction:
Patients with cardiovascular disease have a higher risk of herpes zoster and subsequent cardiovascular events. The Centers for Disease Control and Prevention (CDC) recommends two zoster vaccines, Zostavax® and Shingrix®, for this population to prevent zoster and its complications. However, the zoster vaccination coverage and the predictors of vaccine uptake among patients with cardiovascular disease remain unknown.

Aims:
This study aimed to examine the trends of zoster vaccination and identify predictors of zoster vaccine uptake among adults with cardiovascular disease in the U.S.

Methods:
Data from the 2011 to 2022 National Health Interview Survey (NHIS) were used. NHIS is a nationally representative survey conducted annually to monitor the health of the U.S. population. The study population was adults aged ≥50 years with cardiovascular disease. Zoster vaccination was defined as respondents who self-reported having ever received the zoster vaccine. Weighted vaccination rates were estimated using NHIS survey design with clustering and stratification. Joinpoint regression was used to analyze changes in the direction and magnitude of trends. Multivariable logistic regression models were used to identify predictors associated with zoster vaccine uptake.

Results:
Zoster vaccination coverage significantly increased from 12.2% in 2011 to 40.5% in 2022 (p trend <0.01), with an average annual percentage change (AAPC) of 10.8%. One joinpoint at 2014 was identified. Predictors independently associated with zoster vaccine uptake included aged 70 years and over ($p<0.05$), females ($p<0.05$), college degree or higher education level ($p<0.05$), having health insurance ($p<0.05$), having a usual place of healthcare ($p<0.05$), and having a flu vaccination ($p<0.05$).

Discussion:
Our study indicated an increasing trend in zoster vaccination and identified several predictors of vaccine uptake among adults with cardiovascular disease in the U.S. These findings can assist healthcare providers in making informed decisions and implementing effective immunization strategies to promote zoster vaccination within this population.

Session: Molecular & Covid-19 [Sanjo, Oct 14th 16:00-17:30] O248-O253
Moderators: Simon Bell and Hiroyuki Yamamoto

O248

Association of vitamin D Status with various biomarkers in diabetic foot infection

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Abstract:
Background:
Currently, there is a paucity of evidence showing serum vitamin D deficiency affects biofilm formation and vitamin D signalling peptides like the vitamin D receptor (VDR) protein and Cathelicidin antimicrobial peptide (LL-37), which subsequently influence the therapeutic strategies in patients with diabetic foot infection (DFI).
Objective:
The study aims to determine the various factors associated with vitamin D status and the treatment strategies in DFI patients.
Methods:
A hospital-based prospective observational study was conducted with 52 DFI patients. Their serum vitamin D, VDR protein, and LL-37 levels were measured by ELISA. Biofilm formation was quantified by the tissue culture plate method. Chi-square tests and unpaired t-tests were used for statistical analysis.
Results:
The vitamin D status of 52 DFI patients showed that 22 (42.3%) were deficient, 29 (55.76%) were insufficient, and 1 (1.92%) belonged to the sufficient group. Biofilm formation ($p = 0.007$) and low LL-37 level ($p<0.001$) were significantly associated with the vitamin D-deficient group. Further, significantly lower levels of VDR protein were seen in the vitamin D-deficient group ($t43.862= -6.571$; $p<0.001$). In addition, surgical intervention-treatment strategy was significantly associated with the vitamin D-deficient group ($p = 0.012$), low LL-37 group ($p<0.001$), and lower levels of VDR protein ($t9.560= -4.212$; $p = 0.002$).
Conclusion: The lower levels of the LL-37 and VDR proteins, along with the formation of biofilm and surgical interventions, were mostly seen in vitamin D-deficient DFI patients.

O249

Nationwide Cross Sectional Study for Local Polypharmacy by NDB data during COVID-19

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Introduction:
Polypharmacy is a serious global issue, mainly for older adults in developed countries, and Japan is one of the most severe aging and depopulating countries worldwide. A periodical medical fees amendment was made in April 2020 to include reduction incentives for polypharmacy and duplicated medications during COVID-19 pandemic.
Aims:
This nationwide cross-sectional study aims to demonstrate the polypharmacy trend based on secondary medical areas (SMAs) from the NDB Open Data on annual reimbursement claims for outpatient prescription fees in Japan after the recent polypharmacy reduction policy.
Methods:
Polypharmacy proportion (PP) and polypharmacy reduction ratio (PRR) were treated as outcome variables following our previous researches, and this study defined April 2019 to March 2020 as pre-COVID and April 2020 to March 2021 as during COVID. Urban SMAs is set for a population of 1,000,000 (or a population density of 2,000 persons/km2 and above), and local SMAs is set for a population of 200,000 and above (or a population of 100,000 and above with a population density of 200 persons/km2 and above), excluding urban areas. Depopulated SMAs is defined as other areas except for urban SMAs and local SMAs.
Results:
The mean values of PP (pre-COVID) were 4.17% for total SMAs, 3.27% for urban SMAs, 3.91% for local SMAs, and 4.84% for depopulated SMAs. The mean values of PP (during COVID) were 4.16% for all SMAs, 3.37% for urban SMAs, 3.92% for local SMAs, and 4.74% for depopulated SMAs. A statistically significant decrease in PP was detected in depopulated SMAs, with 1.39% as the PRR value.
Discussion/Conclusion:
This study revealed that the effectiveness of polypharmacy reduction policies implemented during the COVID-19 pandemic were limited in reducing nationwide polypharmacy in Japan. However, further polypharmacy reduction is required in depopulated SMAs because the mean (95% CI) of PP in depopulated SMAs remained high.

O251

Metformin's impact on post-COVID-19 condition risk in overweight/obese individuals in the UK

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Introduction:
Recent clinical trial have suggested that metformin reduce the risk of post-COVID-19 condition (PCC) in overweight/obese individuals.
Aims:
This study aimed to investigate whether metformin use reduces the risk of PCC among overweight/obese patients, emulating the recent trial in the real-world setting.
Methods:
We conducted a population-based cohort study using the United Kingdom Clinical Practice Research Datalink(CPRD) Aurum. Eligible individuals were overweight/obese adults (BMI ≥ 25 kg/m2, aged ≥18) with a record of SAR-CoV-2 infection between March 2020 and April 2023. Individuals with contraindications for metformin or prescriptions for metformin within the year prior to their COVID-19 diagnosis date were excluded. The study cohort was divided into two groups: those who initiated metformin before 30 days after COVID-19 diagnosis (exposed) and those who did not (unexposed).The primary outcome was defined as having a PCC diagnostic code or having at least one of 25 WHO-listed symptoms between 90-365 days after the COVID-19 diagnosis, with no history of these symptoms 180 days before SAR-CoV-2 infection. Individuals were followed up to 1 year after their COVID-19 diagnosis date. Propensity score fine stratification was applied to balance the observed characteristics to minimise confounding between the metformin and non-metformin groups. Risk ratio(RR) and 95% confidence interval(CI) were calculated using the logistic regression model to estimate the impact of metformin on the risk of PCC.
Results:
The metformin group (n=1,105) had a significantly lower risk of PCC with 100 events compared to 141,395 events in the non-metformin group (n=615,575), with a RR of 0.39(95% CI 0.32-0.48), regardless of diabetes status. Among individuals with diabetes, the RR of PCC for the metformin group compared to the non-metformin group was 0.42(95% CI 0.33-0.54).
Discussion/Conclusion:
Our study confirms the trial findings, demonstrating that metformin has a preventive effect on long COVID in overweight/obese individuals in a real-world setting.

O252

Effectiveness of Molnupiravir and Nirmatrelvir-Ritonavir in COVID-19 Patients with Type-2 Diabetes

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Background:
Emerging evidence suggested the significantly increased risk of all-cause mortality in COVID-19 patients with type-2 diabetes. However, direct comparison on the effectiveness of molnupiravir and nirmatrelvir-ritonavir among COVID-19 patients with type-2 diabetes remains scarce.

Aims:
To compare the effectiveness of molnupiravir and nirmatrelvir-ritonavir for COVID-19 patients with type-2 diabetes in non-hospitalised and hospitalised settings.

Methods:
Target trial emulation was conducted using territory-wide electronic health databases in Hong Kong. A sequential trial approach was adopted. Adults with type-2 diabetes who had a COVID-19 infection and initiated either molnupiravir or nirmatrelvir-ritonavir within five days of infection between 16 March 2022 and 31 December 2022 were included. One-to-one propensity score matching was applied between treatment groups. Each subject was followed from index date (date of molnupiravir or nirmatrelvir-ritonavir initiation) until the earliest occurrence of all-cause mortality, 28 days from index date or the end of data availability (31 January 2023). Risk of all-cause mortality between treatment groups in non-hospitalised and hospitalised settings was compared by Cox regression adjusted with baseline characteristics. Subgroup analyses were performed with age (<70, ≥70 years), sex, Charlson comorbidity index (<4, ≥4), and number of COVID-19 vaccine doses (0-1, ≥2 doses).

Results:
17,974 non-hospitalised (8,987 per treatment group) and 3,678 hospitalised (1,839 per treatment group) patients were identified. Nirmatrelvir-ritonavir users had lower risk of all-cause mortality as compared with molnupiravir users in both non-hospitalised (absolute risk reduction [ARR] at 28 days

0.80% [95%CI 0.56-1.04]; HR 0.42 [95%CI 0.26-0.66]) and hospitalised setting (ARR at 28 days 2.83% [95%CI 1.54-4.11]; HR 0.60 [95%CI 0.42-0.85]). Findings were consistent in all subgroups.

Conclusion:
In non-hospitalised and hospitalised settings, nirmatrelvir-ritonavir was more effective than molnupiravir in reducing 28-day all-cause mortality among COVID-19 patients with type-2 diabetes. Hence, nirmatrelvir-ritonavir may be preferred over molnupiravir for patients with no contraindications to the antivirals.

O253

Irrational Consumption of Ivermectin During the COVID-19 Pandemic: Data From 67 Countries

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Introduction
To repurpose ivermectin for COVID-19 treatment has gained attention in several resource-limited countries during the pandemic.

Aims
To investigate the trends of ivermectin consumption during the COVID-19 pandemic using a global pharmacy sales database. We hypothesized that the consumption of ivermectin would increase during COVID-19 despite the limited evidence to support its use.

Methods
We analysed data from IQVIA MIDAS® Quarterly Sales Database ("IQVIA MIDAS"), including data from both retail and non-retail channels from 67 countries between 2016 and 2021. The information captured in the database includes country, corporation, manufacture, type of formulation, propriety names, active ingredients, and quarterly volume of sales. All medicines were coded using the Anatomical Therapeutic Chemical (ATC) codes defined by the European Pharmaceutical Market Research Association (EPHMRA). Standard units (SUs) were used to estimate the consumption of medicines. One SU was defined as one tablet, capsule, ampoule/vial, or 5 mL oral suspension by IQVIA. The use of anthelmintic was calculated by total consumption per 1000 population. The 2022 World Bank classification was used to define the country income level as lower-middle income, upper-middle-income, or high-income countries.

Results
We observed an increase of ivermectin consumption from 1,682 in 2015 to 11,065 thousand SUs in 2021. During the pandemic, the consumption of ivermectin increased compared to previous years, particularly in lower-middle and upper-middle-income countries but not for high income countries. Ivermectin consumption increased substantially in Egypt, Argentina, Peru, and Venezuela during the COVID-19 pandemic.

Discussion/Conclusion
Government agencies play an important role in disseminating vital information about the pandemic. Potential irrational consumption of ivermectin raises important issues about using evidence-based decisions and ensuring the governments' reactions are appropriate when there is insufficient evidence and significant social pressures to act.

Session: Medication Adherence [Ito, Oct 14th 16:00-17:30] O254-O259

Moderators: Tsugumichi Sato and Frank May

O254

Development of Novel Medication Adherence Scale for Chronic Diseases Patients In Indonesia

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Introduction: The existing scale solely evaluate nonadherence to medication without providing any understanding of specific barriers that hinder adherence, particularly barriers that occur in Low-Middle-Income-Countries (LMICs) that may differ from those found in High-Income-Countries (HICs). Thus, they offered limited utility in developing focused intervention approaches to improve medication adherence.
Aims: to develop and validate a new scale to identify patients' medication adherence and medication-taking barrier in patients with chronic diseases in Indonesia
Methods: The initial phase involved conceptualization framework and item generation. Subsequently, the items underwent preliminary evaluation, involving an Item Content Validity Index (I-CVI) assessment. The third phase encompassed the evaluation of psychometric properties and item reduction, along with an assessment of agreement with clinical outcomes and comparison with a Validated Questionnaire (MARS-5) using 447 chronic disease patients. We were using confirmatory factor analysis (CFA), goodness-of-fit index (GFI), comparative fit index (CFI), and root mean square error of approximation (RMSEA). We determined the reliability test using Cronbach's alpha and test-retest reliability using intraclass correlation.
Results: The initial draft included 35 question items, each with an I-CVI score of one. Then 12 items were selected based on factor loadings which were then grouped into 3 dimensions: patient, external, and medication-related factors. The CFA showed that the data was fit for the model (Chi-square 148.858, P<0.001, RMSEA = 0.067, CFI = 0.958, GFI = 0.948). The reliability test shows a good internal consistency (Cronbach's α 0.83) and test-retest reliability (intraclass correlation 0.76). Concurrent validity was demonstrated through correlations with MARS-5 showed moderate correlation (r 0.54; p<0.001). However, this scale did not show a correlation with clinical measures of objective measurement (r 0.14; p 0.021).
Conclusion: These 12 items demonstrated favorable validity and internal consistency and can be utilized to identify barriers to adherence across a range of chronic conditions.

O255

Association between coordinated care and adherence to antihypertensive medicines among adults experiencing polypharmacy in Australia

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Introduction.
Adherence to antihypertensives is key for blood pressure control. Most people with hypertension have several comorbidities and require multiple medicines, leading to complex care pathways. Strategies for coordinating medicine use can improve adherence, but the cumulative benefits of multiple strategies are unknown.
Aims.
To assess the effects of multiple measures of coordinated care on adherence to antihypertensives among people using a large number of medicines.
Methods.
Using dispensing claims for a 10% sample of eligible Australians, we identified adult users of antihypertensives during July/2018-June/2019 who experienced polypharmacy (≥5 unique medicines). We measured medicine use reflecting coordinated medicine management in 3 months before and including the first observed dispensing, including: the use of simple regimens for each cardiovascular medicine; prescriber continuity; and coordination of dispensings at the pharmacy. We measured adherence (proportion of days covered) to antihypertensive medicines in the following 12 months, and used logistic regression to assess independent associations and interactions of adherence with these measures of care.
Results.
We identified 202,708 people, of which two-thirds (66.6%) had simple cardiovascular medicine regimens (one tablet per day for each medicine), two-thirds (63.3%) were prescribed >75% of medicines from the same prescriber, and two-thirds (65.5%) filled >50% of their medicine on the same day. One-third (28.4%) of people experienced all three measures of coordinated care. While all measures were significantly associated with higher adherence, adherence was greatest among people experiencing all three measures (odds ratio=1.63; 95% confidence interval: 1.55-1.72). This interaction was driven primarily by the effects of prescriber continuity and dispensing coordination.
Discussion.
Coordinating both the prescribing and dispensing of medicines can improve adherence to antihypertensives, which supports strategies consolidating both the prescribing and supply of patients' medicines.

O256

Assessment Of Medication Adherence And The Impact Of Patient Education On Medication Adherence Among Polycystic Ovarian Syndrome Patients

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Introduction. Polycystic Ovarian Syndrome (PCOS) is one of the most common and prevalent endocrine diseases among reproductively active women. Assessing medication adherence and identifying barriers that lead to medication non-adherence play a crucial role in effective patient care.

Aim.
To assess the medication adherence and the impact of patient education on medication adherence among PCOS patients.
Methods.
A prospective interventional study was conducted at the Department of Obstetrics and Gynaecology in a tertiary care hospital over a period of six months to assess medication adherence amongst PCOS patients using Morisky Medication Adherence Scale 8-Item (MMAS-8) and validated barrier questionnaire for medication adherence. The effectiveness of clinical pharmacist-assisted patient counselling in enhancing medication adherence was re-evaluated by using the MMAS-8 scale; post addressing the barriers to medication adherence. A paired t-test was used to compare the difference between the medication adherence score means of baseline and follow-up.
Results.
A total of 137 participants above the age of 18 years were enrolled in the study, of which, 120[87.59%] participants were prescribed with medications. Based on the MMAS-8 questionnaire, only 32[26.67%] were highly adherent to their medication during the baseline interview. After the patient education and medication counselling, a follow-up was conducted at one month revealing an improvement in adherence, with 64[53.33%] participants showing high adherence. In comparing the mean scores from baseline[mean=6.320±1.65] to follow-up[mean=7.133±1.31], the paired t-test revealed a significant difference[(mean difference=0.813, SD=1.342); ($p<0.0001$)]. The primary factors responsible for non-adherence were consistently linked to forgetfulness[40.0%], believing that medications are not helping their condition[30.0%], and feeling that medications do not compliment their lifestyle[29.17%].
Conclusion.
This study reveals that with clinical pharmacist-led intervention, medication adherence among PCOS patients can be improved. Individualized medication counselling addressing various adherence barriers along with patient education can improve the medication adherence.
Keywords. PCOS Medication Adherence, Adherence Interventions

O257

Patterns of medication adherence to lipid-lowering therapy in primary care

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Introduction:
Even with the extensive use of lipid-lowering treatments in primary care, trajectories of medication adherence and related risk factors remain unclear.
Aims:
To identify trajectories and predictors of medication adherence for the adult population prescribed lipid-lowering treatment in Australian primary care.
Methods:
A retrospective cohort study used data from adults prescribed lipid-lowering treatment between January 2013 and March 2023. Adherence was defined as having at least one record of a prescription every six months. Group-based trajectory analyses and multinomial logistic regression were used to define medication adherence trajectories and their predictors over 5 years.
Results:
Four distinct trajectories were identified in 51,504 individuals (mean age 62 years, 53.1% males) and included persistent adherence (20%), gradual decline (10%), rapid decline (29%), and early discontinuation (41%). Compared to the persistent-adherence group, individuals in the early discontinuation group were more likely to be younger (adjusted relative risk [aRR] 0.97, 95% confidence interval [CI] 0.97, 0.97), females (aRR 0.91, 95% CI 0.84, 1.00), non-smokers (aRR 0.76, 95% CI 0.70, 0.84), urban residents (aRR 1.20, 95% CI 1.09, 1.33), with a total cholesterol ratio>4 (aRR 1.11, 95% CI 1.00, 1.22), and with no history of diabetes (aRR 0.66, 95% CI 0.57, 0.75). Similar characteristics were found in the rapid decline group, except for sex. Younger age, females, a high total cholesterol ratio, and no history of hypertension were associated with the gradual decline group compared to the persistent adherence group.
Discussion/Conclusion:
Distinct risk profiles were identified for individuals prescribed lipid-lowering treatment with different medication adherence trajectories, which can be used to implement targeted strategies to improve medication adherence and cardiovascular health in primary care.

O258

Impact of Same-Day ART on Care and Medication Discontinuation Among HIV/AIDS Patients

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Introduction:
Inconsistencies exist between real-world evidence and randomized trials regarding early initiation of antiretroviral therapy (ART) and care retention among human immunodeficiency virus (HIV)-infected patients. In line with WHO recommendations, Taiwan initiated same-week ART in 2018 and same-day ART in 2021.
Aims:
To investigate the effects of same-day versus same-week ART initiation on care and medication discontinuation among HIV-infected and AIDS patients in Taiwan.
Methods:
This population-based cohort study analyzed AIDS and HIV patients in Taiwan who began ART within 7 days of diagnosis between 2017 and 2019, using data from the National Health Insurance claims database. Care and medication discontinuation were defined as 90 days from the last clinical visit and 30 days from the last medication date, respectively. A doubly robust weighted Cox regression model estimated the average hazard ratio for same-day versus same-week ART initiation, focusing on a 12-month risk of care and medication discontinuation.
Results:
Among the study population, 83% of 1,024 HIV-infected patients and 80% of 3,452 AIDS patients received same-day ART. One-year care discontinuation rates were nearly 30% for both groups, while ART discontinuation rates exceeded 80% in both groups. Same-day ART initiation showed a statistically insignificant reduced risk of care discontinuation in both the HIV (aAHR = 0.94, 95% CI: 0.68-1.31) and AIDS groups (aAHR = 0.86, 95% CI: 0.73-1.01). However, it was associated with an increased risk of medication discontinuation in both the HIV (aAHR = 1.22, 95% CI: 0.99-1.49) and AIDS groups (aAHR = 1.06, 95% CI: 0.93-1.22).
Conclusion:
Same-day ART initiation shows varied effects on care and medication continuation. While it may enhance care retention, caution is warranted due to high medication discontinuation rates among HIV and AIDS patients, emphasizing the need to consider broader care contexts.

Keywords: same-day ART initiation, care discontinuation, medication discontinuation, HIV/AIDS

O259

Development and pre-validation of the medication treatment satisfaction instrument for children and adolescents aged 8-18 years old

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Introduction.
Medication Treatment Satisfaction (M-TS) from the patients' perspective is important for comprehensively evaluating the effect of medicines. However, there is no generic and validated instrument for paediatric patients' M-TS.

Aims.
To develop and pre-validate a self-report and generic Medication Treatment Satisfaction Instrument for Children and Adolescents aged 8-18 with chronic disease (MTSI-CA).

Methods.
A three phase, mixed-methods, observational study was performed. Patients (8-18 years old) with a chronic disease and treated with medication for more than one week were eligible to participate. Phase I involved systematic reviews and semi-structured interviews to establish a conceptual framework and item pools. Phase II utilized the Delphi method and the cognitive interview to assess the relevance, comprehensibility, and comprehensiveness of the initial instrument. Phase III involves testing the instrument on a larger sample of pediatric patients to confirm its measurement properties and feasibility.

Results.
The review identified 69 M-TS PROMs (four generic, 32 disease-specific, and 33 drug-specific; 60 for adults). We conducted semi-structured interviews with 15 patients and 11 experts (pediatricians, pharmacists, nurses, psychologists, and PROM methodologists), Delphi methods with 14 experts and cognitive interviews with 10 patients. We conducted a single-center, pre-validation study in China and recruited 113 pediatric patients met the inclusion criteria. The instrument achieved a response rate and completion rate of 100%, with a completion time of 2-8 minutes, indicating good feasibility. Exploratory factor analysis was conducted on the 22 items, resulting in a proposed model consisting of 8 domains. The instrument demonstrated sufficient content validity (high-quality evidence) and

internal consistency (high-quality evidence). Discriminate validity was demonstrated between the 25% of subjects with the lowest scores and the 25% with the highest scores. The MTSI-CA had six multi-item domains (effectiveness, safety, impact on health-related quality of life, ease and convenience, information and Involvement in treatment decision-making, and access and cost) and two single items (medication shame and global satisfaction). We are conducting further multicenter validation studies to assess the validity and reliability of the MTSI-CA.

Discussion. The MTSI-CA had good feasibility (i.e., the MTSI-CA is easy to accept and complete), content validity (i.e., the MTSI-CA can accurately reflect the purpose and content of the assessment), and internal reliability (i.e., the MTSI-CA has good internal consistency among the items within the instrument), making it useful for promoting rational medication use in pediatrics in both clinical and academic settings.

Session: Psychiatric [Med-1F, Oct 14th 16:00-17:30] O260-O265

Moderators: Toshiki Fukasawa and Yvonne Lee

O260

The use of ADHD medication and the risk of suicide attempt (Rising Star Awardee)

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Introduction
There have been rising concerns regarding the risk of suicide attempt upon use of attention-deficit/ hyperactivity disorder (ADHD) pharmacological treatments.
Aims
To examine the risk of suicide attempt among individuals treated with ADHD medication across five countries/region.
Methods
This multi! national self-controlled case series study examined the risk of suicide attempt among individuals treated with ADHD medication using electronic health records from population-based databases across Hong Kong, New Zealand, South Korea, Taiwan, and the United Kingdom. We included individuals who initiated ADHD medication and had a recorded suicide attempt during the study period (2001-2020). We calculated incidence rates for suicide attempt events in each predetermined exposure risk periods. Incidence rate ratios (IRR) in periods of exposure to ADHD medication compared with unexposed periods were calculated with conditional Poisson regression. The IRRs and their 95% confidence intervals (CIs) were estimated for each exposure risk periods.
Results
We identified 452, 4841, 313, 222, and 1058 patients from Hong Kong, New Zealand, South Korea, Taiwan, and ! the United Kingdom, respectively. Risk of suicide attempt was the highest during the pre-exposure period in all populations: Hong Kong, 90-days-pre-exposure (IRR 4.10, 95%CI 2.61-6.46), first-90-days-exposure (3.21, 1.95-5.28), post-90-days-exposure (1.24, 0.93-1.67); New Zealand, 90-days-pre-exposure (2.40, 2.10-2.75), first-90-days-exposure (1.54,1.28-1.85), post-90-days-exposure (1.06, 0.94-1.19); South Korea, 90-days-pre-exposure (2.67, 1.61-4.44), first-90-days-exposure (1.35, 0.70-2.62), post-90-days-exposure (2.22, 1.30-3.79); Taiwan, 90-days-pre-exposure (2.66,1.49-4.74), first-90-days-exposure (no events were observed), post-90-days-exposure (0.87,0.46-1.66); and United Kingdom, 90-days-pre-exposure (2.07, 1.41-3.03), first-90-days-exposure (1.47, 0.80-2.69), post-90-days-exposure (1.45, 1.08-1.94).
Conclusions
Although initiation of ADHD medication was associated with suicide attempt, the risk was the highest ! in the period immediately before ADHD medication initiation. Thus, the results of this multinational study do not support a causal association between ADHD medication use and suicide attempt.

O261

Evidence base for off-label use of psychotropic medications in adolescents with depression

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Introduction
Psychotropic medications are a common therapy for depression. Whereas, these drugs are frequently off-label used, especially in adolescents. Off-label drug use is associated with indeterminate effectiveness and increased risks of side effects, so requires evidence to support its clinical implementation.
Aims
The study aims to investigate extent of evidence for off-label use of psychotropic medications in treatment of adolescence depression.
Methods
A cohort study (2020-2022) was carried out in adolescents with the diagnosis of depression in a tertiary hospital in China. Label-adherence of psychotropic medications was determined with the reference of drug labels approved by China National Medical Products Administration. The Formulary of Off-label Use of Drugs, and The Formulary of Off-label Use of Drugs for Paediatrics were applied to examine the evidence on particular scenarios. Logistic regression models were applied to detect the association between participant characteristics and off-label use of psychotropic medications.
Results
Among 4097 adolescents using psychotropic medications, off-label use accounted for 73.6%. Common off-label use scenarios included using eszopiclone, quetiapine, aripiprazole, olanzapine, idebenone and citicoline for treating depression; and generalizing the use of fluvoxamine, trazodone, agomelatine, and escitalopram from adults to adolescents. Use of olanzapine, agomelatine and escitalopram in treatment of adolescence depression was supported with evidence, depositing bare evidence for others. Senior psychiatrists (adjusted odds ratio =1.8, 95% confidence interval =1.4-2.3) were more likely to extrapolate psychotropic drug use from adults to adolescents. But, the senior title of psychiatrists (AOR=0.7, 95% CI=0.6-0.9) was inversely associated with off-label-indication use.
Discussion
Prevalence of off-label use of psychotropic medications was high in adolescents with depression. Generally, evidence on common off-label scenarios is sparse. More high-quality studies are expected. Feasible evidence for off-label drug use should be incorporated into clinical decision support system in China. Extra cautions are required when generalizing adult use of psychotropic medications to adolescents.

O262

Suicidality and vortioxetine in adolescents and young adults: disproportionality analysis using FAERS

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Introduction:
Prevalence of antidepressant use in children and adolescents is growing in the last decade. Vortioxetine is a new multimodal antidepressant approved by the FDA for the treatment of Major Depressive Disorder and recently introduced in Europe. Whether antidepressants would increase the suicidal ideation and behavior in children and adolescents remain controversial.

Aims:
We aim to investigate the association between vortioxetine use in children, adolescents and young adults and risk of suicidality using spontaneous reporting system

Methods:
We conducted a case/non-case study with disproportionality analysis based on the FDA Adverse Event Reporting System (FAERS). We analyzed individual case safety reports of suicide, suicidal behavior or overdose related to vortioxetine in children, adolescents and young adults compared to all other medications in FAERS (1988-2023). We first compare the characteristics of cases and non-cases. Then, we calculated reporting odds ratio (ROR) with 95% confidence intervals (CI%), in overall and by age groups and limited to major depression.

Results:
A total of 85 reports describing suicidality associated with vortioxetine use in pediatric patients and young adults were identified, mostly from US and Canada and in female. We detected several strong disproportionate reporting signals for vortioxetine use in patients aged 0-24 and several suicidality events. The strongest signals were intentional overdose (ROR=7.45, 95%CI: 4.62-11.44), suicide attempt (ROR=7.34, 95%CI: 4.31-11.75) and suicidal ideation (ROR= 6.41, 95% CI: 4.21-9.40). These signals were mainly driven by those observed in young adults (18-24 years old). Only "suicidal ideation" signal was found in adolescents (12-17 years old). All the above-mentioned signals were no longer triggered if we limited to vortioxetine use for major depression.

Discussion:
Better knowledge of vortioxetine-related suicidality risk is needed to increase clinicians' awareness leading to safer prescribing of vortioxetine in pediatric patients and young adults.

O263

Self-harm and the use of leukotriene receptor antagonists and inhaled corticosteroids

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Introduction
Leukotriene receptor antagonists (LTRAs) and inhaled corticosteroids (ICS) are two classes of asthma medications. Although there have been concerns about the psychiatric side effects of LTRAs and ICS, their effects on self-harm, one of the most severe outcomes, remains unclear.

Aims
To evaluate the association between LTRA and ICS use and self-harm among patients with asthma.

Methods
Asthmatic patients aged>10 years, who received at least one prescription of ICS, one prescription of LTRA, and had at least one self-harm during 2005-2020, were identified from the UK Clinical Practice Research Datalink linked to Hospital Episode Statistics and Office for National Statistics. A self-controlled case series (SCCS) study design was used to compare the incidence rates of self-harm during the following five risk windows to baseline (in the order of precedence if they overlapped): 90-day before first LTRA use (pre-LTRA exposure), 90-day before first ICS use (pre-ICS exposure), LTRA alone, ICS alone, combination use of LTRA and ICS. Incidence rate ratios (IRRs) were calculated using conditional Poisson regression model, adjusted for age, season, and concomitant medications.

Results
Of 313,943 individuals prescribed both LTRA and ICS during the study period, 2,900 had an incident self-harm. Compared to baseline, a lower incidence of self-harm was observed during the pre-LTRA exposure period (IRR=0.74; 95%CI=0.56-0.97) but not pre-ICS exposure period (IRR=0.99; 95%CI=0.71-1.39). No increased risk was observed during ICS alone (IRR=0.83; 95%CI=0.71-0.97), LTRA alone (IRR=0.67; 95%CI=0.56-0.81), and combination use (IRR=0.65; 95%CI=0.53-0.79). Results from sensitivity analyses to check SCCS assumptions and negative control analysis supported the robustness of results.

Discussion
The incidence of self-harm was lower before exposure to LTRA and did not increase to above baseline level during exposure to LTRA or ICS. Our results do not support an association between LTRA and ICS use and an increased risk of self-harm in patients with asthma.

O264

Association of hydroxychloroquine and psychiatric disorders among patients with systemic lupus erythematosus

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Background: Psychiatric disorders are one of the common comorbidities among patients with systemic lupus erythematosus. Hydroxychloroquine is the mainstay treatment for systemic lupus erythematosus. Concern has been raised by case series regarding hydroxychloroquine could cause psychiatric side effects. To our knowledge, no large nationwide study has focused on the use of hydroxychloroquine and psychiatric disorders among patients with systemic lupus erythematosus.

Objectives: To evaluate the association of hydroxychloroquine and psychiatric disorders among patients with systemic lupus erythematosus

Methods: We included patients aged over 20 years and newly received HCQ treatment between 2010 and 2021 using Taiwan's NHIRD database. We classified patients into two treatment strategies of initiating hydroxychloroquine within three months versus non- hydroxychloroquine treatment within three months. We defined a period of three months to screen for treatment initiation and applied cloning, censoring, and weighting approach to emulate the target trial. The primary outcome of interest was psychiatric disorders. We estimated the hazard ratio, five-year absolute risks, risk differences and risk ratio with 95% confidence intervals (CIs) with pooled logistic regression.

Results: We included a total of 15,210 patients with systemic lupus erythematosus. The hazard ratio of psychiatric disorders was 2.54 (95% CI, 1.24 to 3.61). The five-year absolute risk of psychiatric disorders was 1.72% (95% CI, 0.40% to 3.51%) among hydroxychloroquine users, and 0.67% (95% CI, 0.30% to 1.18%) among non-hydroxychloroquine users, respectively. The five-year absolute risk difference and risk ratio between the two treatment strategies for psychiatric disorders were 1.13% (95% CI, 0.13% to 2.52%) and 2.55 (95% CI, 1.14 to 3.54), respectively.

Conclusion: The use of hydroxychloroquine was associated with an increased risk of psychiatric disorders among patients with systemic lupus erythematosus. Because hydroxychloroquine is the first-line treatment for systemic lupus erythematosus, vigilant monitoring of hydroxychloroquine therapy is essential.

O265

Medication Treatment Patterns for Attention-Deficit/Hyperactivity Disorder in Chinese Children and Adolescents

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Introduction:
Attention-deficit/hyperactivity disorder (ADHD) is a prevalent neurodevelopmental disorder. Chinese children and adolescents exhibit unique patterns in ADHD medication treatment compared to their Western counterparts.

Aim:
To identify medication treatment patterns for ADHD in Chinese children and adolescents.

Methods:
A retrospective study was conducted on patients aged 6 to 17 diagnosed with ADHD between January 2020 and November 2023, using electronic medical records from Jiangsu Province's Population Health Record Big Data Platform. Descriptive analysis explored demographic factors and medication prescriptions. Age- and sex-adjusted logistic regression examined the relationship between comorbidity and multiple medication prescriptions.

Results:
Of 25,637 patients aged 6-17 years diagnosed with ADHD, 25,530 (99.5%) received medication treatment, with 21,213 (83.1%) being male. The most commonly used medication was methylphenidate, prescribed to 15,421 (60.4%) patients, followed by atomoxetine with 11,987 (47.0%) patients. Among the 1,817 patients treated with both atomoxetine and methylphenidate, 1,272 (70.0%) were initially treated with methylphenidate. ADHD patients with comorbidity were more likely to receive multiple medications (adjusted odds ratio [aOR], 3.26; 95% CI, 2.75-3.84).

Discussion:
Medication treatment for ADHD is highly prevalent among children and adolescents in China. However, compared to other countries, the variety of medications is limited, with methylphenidate being the predominant treatment. Patients with comorbid psychiatric disorders may experience more severe ADHD symptoms, necessitating the use of multiple medications.

Session: Cancer – Breast and Prostate [Med-3F, Oct 14th 16:00-17:30]
O266-O271
Moderators: Keiko Asao and Kai-Li Liaw

O266

Dihydropyrimidine dehydrogenase deficiency genotyping-guided fluoropyrimidine-based adjuvant chemotherapy for breast cancer. Cost-effectiveness analysis.

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Introduction.
While standard doses of adjuvant fluoropyrimidine-based chemotherapies are generally safe for most patients, the risk of severe toxicity is increased for patients with dihydropyimidine dehydrogenase deficiency (DPYD).
Aims.
We examined the cost-effectiveness of offering DPYD pharmacogenetic-guided care versus the current standard of care (SoC) for local or metastatic breast cancer patients in Qatar.
Methods.
We developed a two-stage decision analysis, with an analytic tree model over a 6-month, followed by a life-table Markov model over a lifetime horizon. We compared the current SoC with the alternate strategy of DPYD genetic screening in Qatari patients eligible for adjuvant fluoropyrimidine therapy. Clinical outcomes and utilities were obtained from published studies, while healthcare costs were estimated from Hamad Medical Corporation, Qatar. The short-term outcome included the incremental cost-effectiveness ratio (ICER), defined as cost per survival without grade III/IV ADRs at six months. The long-term outcome was the ICER, defined as cost per quality-adjusted life year (QALY) gained, with a 3% annual discount rate. The study adopted a public hospital perspective. Sensitivity analyses were conducted to explore the impact of key input parameters on the robustness of the model.
Results.
In the short-term model, at its base case, DPYD genomic screening was dominant over SoC with a mean cost-saving of QAR 84,585 (95% confidence interval (CI), 45,270–151,657). In the long-term model, compared to the current SoC, DPYD genetic screening would result in an ICER of QAR 21,107 (95% CI -59,382-145,664) per QALY gained.
Discussion.
Based on our model, implementing DPYD genetic screening to detect DPYD mutations in breast cancer patients before therapy initiation is a cost-saving and cost-effective strategy in Qatar.

O267

Risk of endometrial cancer by endocrine therapy for breast cancer in Japan

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Introduction: Breast cancer (BC) survivors may have an increased risk of endometrial cancer due to endocrine therapy, but the risk is unknown among Japanese women, especially by type of endocrine treatment (tamoxifen, aromatase inhibitors).

Aims: We aimed to determine the risk of endometrial cancer overall and by type of endocrine treatment among BC survivors.

Methods: We conducted a matched cohort study using data from the JMDC claims database. Between January 2005 and December 2019, women aged 18–74 years with and without BC were matched with 1:4 ratio for age and entry timing to the database. We estimated and compared the risks for endometrial cancer between the groups, using the stratified Cox regression analysis further adjusting for BMI, smoking, diabetes, and oral contraceptives. In addition, we estimated the risk by endocrine treatment regimen (tamoxifen, aromatase inhibitor, tamoxifen, and no endocrine therapy) during the first year after the BC diagnosis, using the unstratified Cox regression analysis in which the reference group was women without BC, and patients were followed from one year after the matching, further adjusted for chemotherapy (anthracycline, taxane).

Results: Among 24,017 BC survivors and 96,068 matched women (mean age 50.5 years), endometrial cancer occurred among 56 and 38 women (incidence rate of 0.7 and 0.1 cases/1000 person-years, respectively), with the adjusted hazard ratio of 8.10 (95% CI 3.97–16.5). By treatment, the tamoxifen (n=10164, mean age 45.9 years), aromatase inhibitor (n=5468, 58.9 years), and no hormone therapy (n=7765, 50.4 years) groups had 26, 4, 10 endometrial cancer cases, and the adjusted hazard ratios were 6.86 (3.59–13.13), 1.45 (0.33–6.51), and 5.35 (2.37–12.09), respectively, compared to women without BC.

Discussion: Japanese BC survivors showed an increased risk of endometrial cancer than women without BC, and the risk varied by the type of endocrine therapy.

O268

Cardiotoxicity in postmenopausal breast cancer: a comparison of aromatase inhibitors and tamoxifen

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Introduction: Endocrine therapy plays a pivotal role in the management of hormone-receptor-positive early-stage breast cancer in postmenopausal women. Despite the increasing preference for aromatase inhibitors (AIs) over tamoxifen, their cardiovascular safety profile remains an ongoing concern.

Aims: This study compares the cardiovascular risks associated with AIs and tamoxifen in postmenopausal women with non-metastatic breast cancer.

Methods: A retrospective multinational cohort study was conducted using data from the US SEER-Medicare database and Taiwan's national claims database and cancer registry. The study population comprised postmenopausal women diagnosed with stage I-III breast cancer from 2010-2019 in the US and from 2011-2020 in Taiwan. Patients were divided into two groups based on their initial therapy with AIs or tamoxifen after surgery. The study outcomes were 3-point major adverse cardiovascular events (MACE) and venous thromboembolism (VTE). Covariate balance was ensured through inverse probability of treatment weighting. Cardiovascular risks were evaluated separately for each country's cohort using cause-specific hazard models.

Results: The cohorts included 36,931 US patients (89.6% AIs users) and 22,573 Taiwanese patients (71.1 % AIs users) for MACE analysis, and 31,706 US patients (89.4% AIs users) and 21,957 Taiwanese patients (71.0% AIs users) for VTE analysis. No significant increase in MACE risk was observed for AI users compared to tamoxifen users in either country (US hazard ratio [HR]: 1.13, 95% CI 0.83-1.52; Taiwan HR 1.21, 95% CI 0.85-1.70). Conversely, AI users in the US showed a lower risk of VTE (HR 0.35, 95% CI 0.27-0.45), while the pattern was not statistically significant in the Taiwanese cohort (HR 0.72, 95% CI 0.42-1.24).

Discussion: AIs do not elevate MACE risk compared with tamoxifen in postmenopausal breast cancer patients. The observed ethnic variations in VTE risks underscore potential differences in thrombotic responses to endocrine therapy, consistent with prior research indicating lower VTE risks in Asian populations.

O269

Cardiovascular Risks in Prostate Cancer Patients Using Adjunct Treatment

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Introduction: Abiraterone and enzalutamide are oral novel hormonal agents (NHAs) used in prostate cancer (PCa) management. By inhibiting androgen biosynthesis and receptor activity, NHAs can cause metabolic alterations, leading to adverse cardiometabolic events. However, data on their cardiovascular safety compared to traditional chemotherapy are scarce.

Aims: To evaluate the risk of major adverse cardiovascular events (MACE) of NHAs and chemotherapy for PCa patients in Hong Kong.

Methods: This cohort study used electronic health records in Hong Kong. Patients with PCa treated with NHAs (abiraterone and enzalutamide) between 2001 and 2019 were included in the exposed group, and those with docetaxel were active controls. Primary outcome was MACE over 10 years of follow-up. Propensity score matching (PSM) was used to control confounding factors. Cox regression was used to estimate the hazard ratios (HR) and competing risks were accounted for using the Fine-Gray method. Sensitivity analyses censored patients at drug switching and filled missing prostate specific antigen (PSA) levels using multiple imputations.

Results: Among 25,821 PCa patients, 2729 (10.57%) had used adjuvant treatments. After PSM, 617 NHA users and 317 controls were included. MACE incidence rate was 70.28 and 35.76 per 1000 person-years in NHA and docetaxel users, respectively. NHA use was associated with increased risk of MACE (HR 1.61, 95% confidence interval [CI] 1.10–2.35), supported by the Fine-Gray estimator (subdistribution HR 1.52, 95% CI 1.04-2.15) and remained consistent after multiple imputation for missing PSA values (HR 1.59, 95% CI 1.12–2.26). Censoring at drug switching showed elevated risk without statistical significance (HR 1.39, 95% CI 0.96–2.03).

Conclusions: NHA use is associated with elevated risk of MACE compared to docetaxel. Our findings emphasize the need for baseline cardiovascular risk assessment before choosing between NHA and docetaxel as adjunct treatment, and close monitoring of cardiovascular complications in patients receiving NHAs.

O270

Primary Prevention of Hormonal Treatment-related Cardiovascular Events in High-Risk Prostate Cancer Patients

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Introduction: Among men with prostate cancer, androgen deprivation therapy (ADT) therapy frequently causes adverse cardiometabolic events, but data on primary prevention using statins or metformin are scarce.

Aims: To investigate the effectiveness of statins and metformin against major adverse cardiovascular events (MACE) in high-risk ADT-treated prostate cancer patients in Hong Kong.

Methods: This cohort study used electronic health records in Hong Kong. Men with prostate cancer treated with ADT between 2004 and 2019, without a history but risk factors for atherosclerotic cardiovascular disease were included. New users of statins or metformin within one year after ADT initiation were compared with non-users using an index date one year after ADT initiation. Outcomes were MACE and all-cause mortality over 10 years of follow-up. Cox regression was used to estimate the hazard ratios (HR) and competing risks were accounted for using the Fine-Gray method to estimate subdistribution HR.

Results: Among 11,457 eligible men, 235 statin users and 129 metformin users with high cardiovascular risks were identified. After propensity score matching, incidence rates of MACE were 14.29 and 35.19 per 1000 person-years in statin and metformin new users, respectively. Neither statin (HR 0.82, 95% confidence interval [CI] 0.39 – 1.70) nor metformin initiation (HR 1.27, 95% CI 0.65 – 2.47) was associated with a reduced risk of MACE. Statin initiation was associated with reduced all-cause mortality (HR 0.53, 95% CI 0.40 – 0.68), but not metformin. Competing risk analysis showed that statin initiation was associated with a reduced risk of MACE (sHR 0.49, 95% CI 0.26 – 0.92).

Conclusions: Statin initiation was associated with reduced cardiovascular risks and improved overall survival among high-risk patients undergoing ADT for prostate cancer, but not metformin. Further investigations are needed to validate the benefits of statins against cardiotoxicities of hormonal treatment for prostate cancer.

O271

Incidence of type 2 diabetes mellitus in men initiated tadalafil

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Introduction: Tadalafil, commonly prescribed for benign prostatic hyperplasia, can be beneficial for patients with type 2 diabetes (T2DM) for glycemic markers and complications. However, evidence is lacking regarding the association between long-term use of tadalafil and incidence of T2DM.

Aims: Therefore, this study aimed to assess the impact of tadalafil on the incidence of T2DM.

Methods: We emulated a target trials of tadalafil use (5mg per day orally) and risk of T2DM using population-based claim database from 2014 to 2023 in Japan. The study cohort comprised patients who received at least two new prescriptions of tadalafil or alpha blocker for benign prostatic hyperplasia and had no history of diabetes diagnoses, no prescription of glucose lowering drugs, and no history of hemoglobin A1c ≥ 6.5%. The primary outcome was the incidence of T2DM defined using diagnostic code, prescription records, and laboratory data. Pooled logistic regression was used to estimate the adjusted risk ratios and 5-year cumulative incidence differences between tadalafil and alpha blockers using as treated approach.

Results: A total of 5,180 participants initiated tadalafil treatment and were compared with 20,049 alpha-blocker initiators. The median follow-up time for each arm was 27.2 months [interquartile range (IQR) 12.0–47.9] in tadalafil users and 31.3 months (IQR 13.7–57.2) in alpha blocker users. The incidence rate of T2DM in tadalafil and alpha-blocker users was 5.4 [95% confidence interval (CI) 4.0–7.2) and 8.8 (95%CI 7.8–9.8) per 1,000-person years, respectively. Initiation of tadalafil was associated with a reduced risk of T2DM (risk ratio 0.47, 95%CI 0.39–0.62, 5-year cumulative incidence difference −0.031, 95%CI −0.040 – −0.019).

Discussion/Conclusion:
The incidence of T2DM appears to be lower in men with benign prostatic hyperplasia exposed to tadalafil than in those receiving alpha-blockers. This, tadalafil be more beneficial than alpha-blockers in preventing the development of T2DM.

Spotlight Poster Presentations
[Ito-B1F Gallery 1, Oct 13th]

SP500

Optimizing Depression Treatment: A Cost-Effectiveness Analysis of Pharmacogenetic-Guided Therapy in Qatar

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Introduction:
Pharmacogenetic (PGx) testing has the potential to improve the efficacy and safety of antidepressant pharmacotherapy for moderate-severe major depressive disorder (MDD) by identifying genetic variations that influence medication metabolism and adjusting treatment regimens accordingly.
Aim:
This study aims to assess the cost-effectiveness of implementing a PGx testing approach to guide the prescription of antidepressants.
Methods:
From a public hospital perspective, we developed a two-stage decision tree diagram of a short-term 6-week follow up, and a lifetime Markov model with 3-month cycles. The analysis compared the current standard of care (SoC) with the alternative strategy of PGx-guided (multi-gene panel) testing in adult patients with MDD. Clinical outcomes and utilities were obtained from published studies, while resource costs were from Hamad Medical Corporation, Qatar. The short-term outcome measure was the incremental cost-effectiveness ratio (ICER) against treatment response without side effects (SEs) and without relapse, as well as against treatment response with or without SEs and without relapse. The long-term outcome assessed the ICER against the quality-adjusted life year (QALY) gained and years of life saved.
Results:
Adopting the PGx-guided testing in Qatar resulted in cost savings of Qatari Riyal (QAR) 2,289 (95%CI -22,654-26,340) for the health system. In the short term, the PGx-guided testing was associated with higher response rates without SEs and without relapse (mean difference 0.10, 95%CI 0.09-0.15) and higher response rates with or without SEs and without relapse (mean difference 0.05, 95%CI 0.04-0.06) compared to the SoC. For long term, the PGx-guided testing resulted in 0.13 years of life saved and 0.06 QALYs gained, per person, along with cost savings of QAR 46,215 (95%CI -15,744-101,758). Sensitivity analyses confirmed the robustness of the model results.
Conclusion:
Implementing PGx testing to guide antidepressant use was found to improve population health outcomes, while also significantly reducing health system costs in Qatar.

SP501

Exploring Glucocorticoid Receptor Expression in Type 2 Diabetes Mellitus Sepsis Patients

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Introduction: Sepsis, a complex and life-threatening condition, poses considerable challenges in clinical settings due to its high mortality rate. Type 2 Diabetes Mellitus (T2DM) exacerbates sepsis by impairing immune function and altering inflammatory responses. Furthermore, the impact of diabetes on glucocorticoid receptor (GR) functionality exacerbates the severity of the condition.
Aims: We aimed to investigate the association between diabetes and glucocorticoid receptor expression in a cohort of sepsis patients, shedding light on potential implications for the pathogenesis and treatment of sepsis in patients with T2DM.
Methods: Our study involved 47 adult sepsis patients, including 16 with diabetes and 31 without diabetes. Blood samples were collected, and GR expression was quantified using real-time polymerase chain reaction (RT-PCR) from peripheral blood mononuclear cell (PBMC) specimens.
Results: The RT-PCR analysis revealed a difference in GR expression between both groups. Notably, the expression of GRs in the DM group was higher than in the non-T2DM (11.27 vs. 10.85 log 10 gene copies/mL, p= 0.01). Our results also demonstrated that the T2DM group had a higher neutrophil count than the non-DM (p= 0.04). In addition, there were no differences in age distribution between the groups. Furthermore, regarding mortality, the expression of GRs was similar in the patients who experienced mortality compared to the group that survived in the sepsis cohort.
Discussion:
Our investigation revealed that patients with Type 2 Diabetes Mellitus (T2DM) and sepsis exhibited elevated glucocorticoid receptor (GR) protein expression compared to sepsis patients without T2DM. This indicated that diabetic patients may regulate the inflammation caused by T2DM through increased protein production. Targeting GR pathways could offer a promising approach to modulate the immune response and improve outcomes in this population.

SP502

Comparison of machine learning models on cardiovascular risk prediction in diabetic patients

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-Introduction
In pharmacoepidemiology, to detect early and prevent aggravation, multivariate logistic regression model has been widely applied for disease onset prediction. Tree-based ensemble models which can detect non-linear relationships and handle missing values, are also increasingly applied. Lately, the tree-based ensemble models are highlighted because of their explainability applying Shapley's additive explanatory values (SHAP).

-Aims
To compare the performance of three machine learning models, multivariate logistic regression model (LR), random forests (RF), and gradient boosting decision trees (GBDT), for cardiovascular risk prediction in type2 diabetic patients.

-Methods
The predictive models of cardiovascular events defined by ICD-10 codes, were constructed using a retrospective cohort of type2 diabetic patients (n = 12,301, events = 1,258) extracted from the RWD database between 2008 and 2021. The laboratory test values, including eGFR, creatinine, blood urea nitrogen, were available in the RWD database. LR, RF and GBDT were implemented on Python using LogisticRegression, RandomForestClassifier from scikit-learn and LightGBM Tuner from Optuna, respectively. We compared the performance of the models based on the ROC-AUC scores. Furthermore, the tree-based ensemble models were attempted to explain by means of SHAP.

-Results
The ROC-AUC scores for cardiovascular events in 2 years were 0.5617 with LR, 0.6213 with RF and 0.6464 with GBDT. The tree-based ensemble models showed slightly high performance to LR in this study. SHAP analysis showed that many features, including age, index year, and baseline eGFR, associated with both RF and GBDT. Additionally, SHAP were visualized by force plots to understand the impact of features on the models.

-Discussion
Considering the characteristics of real-world data with many features and missing values, tree-based ensemble models could be an alternative to multivariate logistic regression model in real-world data analysis.

SP504

Long term Comparative Safety of ARNi verses ACEi/ARB: A Real-World Data analysis

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Angiotensin Receptor-Neprilysin Inhibitor (ARNi) is a novel pharmacological class that needs a more comprehensive understanding of the treatment's safety profile.
The study aims to assess the long-term safety of ARNi and ACEi/ARBs after market approval from July 2015 to August 2021 using electronic medical records. The study also evaluates the difference in hospital length of stay between the groups, providing a comprehensive evaluation of the clinical outcomes associated with these drugs.

A retrospective comparative longitudinal cohort study was done using Brigham and Women's Hospital records. Patients were divided into those taking ARNis or ACEi/ARB. To reduce bias, a propensity score matching was conducted. Lab reports were analyzed to compare the incidence of adverse events (AE) between drug cohorts. We've assessed the risks of serum creatinine (Scr>1.4 mg/dl), hyperkalemia > 5.5 mmol/liter, low systolic blood pressure (SBP< 90 mmHg), as well as patient encounters to detect angioedema, and acute tubular necrosis. Additionally, HF relatedhospital stay was calculated using Mann-Whitney test .

Results showed that ARNi group had lower incidence of some AE compared to the ACEi/ARB Cohort. Specifically, the incidence of hyperkalemia (7.7% in the ARNi vs 29.8% in the enalapril), low systolic blood pressure (38.4% vs. 47.1%), and high serum creatinine levels (42.2% vs 59.4%) were all statistically significant lower in the ARNi group. However, the incidence of angioedema and acute tubular necrosis did not show statistical significance between the two groups.
Additionally, patients in the ARNi group stayed less in the hospital (median = 11 days) than patients in the ACEi/ARBs group (median = 17days). The Z-score=-6.147,p< 0.001.

These safety analyses showed that the ARNi administration may be associated with a lower risk of certain AE compared to the ACEi/ARB administration. Additionally, patients treated with ARNi spent less days in the hospital compared to patients treated with ACEi/ARBs.

SP505

Antibiotic use in Singapore pre- and post-COVID-19: a quasi-experimental approach

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INTRODUCTION: The COVID-19 pandemic affected healthcare utilisation because of lockdowns, reductions in non-elective surgeries and stay-at-home orders.

AIMS: This study assessed antibiotic use in Singapore's public healthcare sector pre- and post-COVID-19 pandemic.

METHODS: We conducted interrupted time-series analyses using aggregated public healthcare institutions' (PHIs) dispensing data (including hospitals, polyclinics) on oral and parenteral antibiotics, from January 2018 to December 2023. Defined daily doses (DDDs) per 1,000 inpatient days for hospitals and DDDs per 100 doctor visits for polyclinics were calculated and grouped by WHO Access, Watch, Reserve (AWaRe) classification. Access-to-Watch ratio was compared across time periods and care settings.

RESULTS: Overall pre-pandemic utilisation increased by 21.1 in thousand DDDs/quarter (95% CI 1.8, 44.1), mainly in hospitals. In polyclinics, pre-pandemic utilisation decreased by -0.3 DDDs/100 doctor visits (95% CI -0.7, 0.1) but was not significant. In 2020, a significant ($p<0.001$) and sudden decrease of -437.5K DDDs was observed in PHIs due to lockdowns. After adjusting for inpatient days, the decrease remained significant in the hospitals, especially in the Access antibiotics.
With the rollback of COVID-19 measures from 2021, utilisation increased from 817.8 to 895.8 DDDs/1,000 inpatient days, with a significant trend change of +26.1 (95% CI +15.5, +36.7) in the hospitals. The increase was less pronounced in polyclinics [+1.8 (95% CI +1.2, +2.3)]. Reduction in the Watch antibiotics use (e.g. clarithromycin, ciprofloxacin) post-pandemic led to increase in the Access-to-Watch ratio from 1.77 to 1.95 in the hospitals and 4.25 to 6.73 in polyclinics.

DISCUSSION: Consistent with published studies, the pandemic affected local antibiotic utilisation trends. However, the lockdown effect was more pronounced in the hospitals than polyclinics. The use of Watch antibiotics remains controlled post-pandemic, possibly due to ongoing antimicrobial stewardship in hospitals and prudent use in polyclinics. Future work should examine drivers of antibiotic trend in polyclinics.

SP506

Association between SGLT2 inhibitor exposure and risk of gastroesophageal reflux disease

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Introduction: Recent research has presented divergent conclusions regarding the potential correlation between Sodium-glucose cotransporter 2 inhibitors (SGLT2is) and gastroesophageal reflux disease (GERD).
Aims: The aim of this study was to compare the risk of GERD between SGLT2i users and non-SGLT2i users.

Methods: A cross-sectional study was conducted utilizing data from the 2021 Medical Expenditure Panel Survey (MEPS). We included patients aged over 18, had insurance, diagnosed with type 2 diabetes (T2D), and received at least one anti-diabetes medication. Logistic regressions analyses accounting for complex sampling designs were performed to calculate odds ratios (OR) and confidence intervals (CI). The covariates adjusted in this study were sociodemographics and self-reported health status. Subgroup analyses were carried out to assess differences across various variables, including age, gender, race, ethnicity, education, income, insurance and health status.

Results: The weighted subjects were divided into two groups: 2,799,050 SGLT2i users , and 20,789,424 non-SGLT2i users. Overall, SGLT2i users had higher adjusted odds of GERD compared to non-SGLT2i users (OR=1.64, 95%CI:1.13-2.39). Consistent results were found in the subgroup analyses. Use of SGLT2i was associated with significantly higher odds of GERD in male (OR=2.00, 95%CI:1.21-3.30), black (OR=2.63, 95%CI:1.19-5.82), non-Hispanics (OR=1.49, 95%CI:1.01-2.19), patients with a high school degree (OR=2.14, 95%CI:1.28-3.60), patients with low income (OR=2.11, 95%CI:1.19-3.74), patients with public insurance (OR=2.08, 95%CI:1.27-3.41), and patients with poor to fair health status (OR=2.31, 95%CI:1.32-4.05).
Discussion/Conclusion: Our study found an increased risk of GERD in SGLT2i users, which suggests that SGLT2is should be administered with greater caution among high-risk individuals. However, due to the nature of the cross-sectional design of this study, further studies are needed to clarify the causal relationship between SGLT2i exposure and risk of GERD.

SP507

Association Between Metabolic Syndrome And Chronic Periodontitis in Japanese Claims Database

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Introduction: Metabolic syndrome (MetS) is a condition caused by lifestyle and with dyslipidemia, type 2 diabetes mellitus, and hypertension. MetS is emphasized because of its association with other serious diseases like stroke. Chronic periodontitis (CP) is also caused by lifestyle and if progresses, affects non-oral diseases. Previous studies have reported interrelation with MetS, remained unclear.

Aims: To examine the association between Mets (dyslipidemia, type 2 diabetes mellitus, and hypertension) and CP in Japan.

Methods: This study used Cross Fact claims database, included from January 2010 to December 2019 and patients who met all following criteria: (1) At least one confirmed diagnosis of dyslipidemia, type 2 diabetes mellitus, or hypertension and (2) 30<= - <65 years old and (3) with 180 days of look back period. The occurrence of CP among MetS patients (%) and characteristics like age at first record of each disease, sex, and the coincidence of other MetS were analyzed.

Results: Patients enrolled in this study were 183,017 (dyslipidemia: 97,498, diabetes: 23,676, hypertension: 107,466 and if diagnosed multiple, counted in each). Patients with CP in this study population were 72,013 (73.9%, 95%CI:73.58-74.14) for dyslipidemia, 16,727 (70.6%, 95%CI:70.06-71.23) for diabetes, 76,654 (71.3%, 95% CI:71.06-71.60) for hypertension, which indicated that CP occurrence were higher in dyslipidemia patients than other two MetS. As characteristics, female showed higher CP occurrence compared to male (75.20%, 95%CI:74.94-75.53 for female, 70.6%, 95%CI:70.3-70.87 for male in study population), which previous studies have reported similarly.

Discussion: Among Mets patients, who had CP showed high proportion regardless of which MetS disease they had. Especially, the proportion of dyslipidemia patients with CP was higher than other two diseases . Further research is required to assess how MetS interact with CP, particularly to explore the factors affect high CP occurrence in dyslipidemia patients.

[Ito-B2F, Oct 13th]

SP508

Treatment Patterns of Patients with Rheumatoid Arthritis in Japanese Claims Database

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Introduction: Rheumatoid arthritis (RA) is a chronic inflammatory disorder primarily affecting joints. According to the RA treatment guidelines, Methotrexate (MTX) is the first-line treatment, however, combination therapy with biologic DMARDs or Janus kinase inhibitors (bDMARDs/JAKi) is recommended when MTX alone is insufficient. This study investigates the actual use of anti-rheumatic drugs in patients with RA.

Aims: To investigate the prescription patterns of MTX and bDMARDs/JAKi, and to examine the differences in patient demographic and clinical characteristics of each treatment pattern.

Methods: Using the claims database of Cross-Fact provided by INTAGE Real World Inc., the study included RA patients newly prescribed anti-rheumatic drugs from January 2019 to December 2023. Exclusion criteria included patients with malignancies, immunosuppressive or systemic steroid use, age under 18, certain autoimmune diseases, and a less than 3-month lookback period. The index date was defined by the first date of the prescribed anti-rheumatic drugs. Drug prescriptions and patient demographics were evaluated.

Results: A total of 7,570 eligible patients were included. 3,468 patients were initially prescribed MTX, and 587 were initially prescribed bDMARDs/JAKi. Additionally, 432 were switched to bDMARDs/JAKi from MTX. There was a higher proportion of younger patients aged 18-44 years in both the bDMARDs/JAKi initial prescription group (34.1%) and the bDMARDs/JAKi switching prescription group (33.1%) compared to the other group. There was also a higher proportion of patients treated in hospitals with 20 or more beds in both the bDMARDs/JAKi initial prescription group (68.0%) and the bDMARDs/JAKi switching prescription group (53.5%) compared to the other groups.

Discussion: In the Japanese RA treatment cohort, demographic and clinical factors influence the choice of therapy. Younger patients and those treated in larger hospitals are more often prescribed bDMARDs/JAKi, suggesting early aggressive treatment in this group.

SP509

Drug Utilization Pattern of Anticholinergic Drugs among Patients with Dementia in Taiwan

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Introduction: Anticholinergic drugs were commonly prescribed for patients with dementia. Although the long-term use of anticholinergic drugs is found to be associated with cognitive impairment in the elderly population, previous studies on the issue often excluded Asians. It is essential to evaluate the prevalence and pattern of anticholinergic drug use among patients with dementia.

Aims: The study aimed to investigate anticholinergic drug utilization patterns among patients with dementia in Taiwan.

Methods: This retrospective study utilized Taiwan's Longitudinal Health Insurance Database 2005 (LHID 2005), an administrative claims database including health and medication information among residents in Taiwan. The length of the data was from 2005 to 2018. The study population was patients aged over 65, diagnosed with dementia, and received at least one drug for dementia (cholinesterase inhibitors, memantine, and piracetam) for over 30 days. The anticholinergic drugs were categorized into groups of mild, moderate, and severe cognitive impairment based on the Anticholinergic Cognitive Burden scale. Descriptive statistics were used to present the prevalence and pattern of medication use.

Results: There were 11,379 elder patients with dementia enrolled in the study and most of them received piracetam (94.7%) and donepezil (18.2%). In terms of concurrent anticholinergic drug use, drugs with mild cognitive impairment were the most used (49.2%), followed by severe (28.6%) and moderate (22.2%). Specifically, cimetidine (13.8%), fexofenadine (8.3%), and cetirizine (7.7%) ranked as the three most frequently prescribed drugs. Regarding the classification of anticholinergic drugs, those for gastrointestinal conditions and disorders (26.5%) and antihistamines (23.4%) accounted for the majority.

Conclusion: The study showed a high proportion of anticholinergic drug use among older people with dementia in Taiwan. Anticholinergic drugs with mild cognitive impact were reported as the most common use. Future studies could further evaluate the cumulative effect of anticholinergic drug use on dementia among older patients.

SP510

Reassessment and update of the Japanese Treatment Satisfaction Questionnaire for Medication (TSQM)

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Introduction: The Treatment Satisfaction Questionnaire for Medication (TSQM) is a generic measure used to assess treatment satisfaction with medications for patients with a wide range of diseases and modes of administration. All 3 versions of the TSQM have previously been translated into Japanese. However, real-world usage of the measure has identified that the questionnaire includes wording that may be difficult to understand and is also limited to oral medications.

Aims: This study aimed to update the translation of the Japanese version of the TSQM and to reassess the psychometric properties using a sample population of patients with diabetes and migraine in Japan who were prescribed oral and injectable medications.

Methods: The translation and cultural adaptation of the Japanese version of the TSQM were conducted in alignment with the ISPOR task force guidelines. The questionnaire was finalized upon cognitive debriefing interviews with 8 patients. The psychometric properties of the Japanese version of the TSQM were assessed by analysis of Classical Test Theory and Rasch Measurement Theory using data from 512 patients.

Results: Minor modifications were made to the questionnaire following the cognitive debriefing interviews. The results from the psychometric validation found that all Japanese TSQM versions have moderate reliability and high intra-scale validity. Results from the Rasch Measurement Theory added additional support to the reliability and validity of the measures. The scale invariance was supported from differential item functioning across subgroups of patients compared by factors including disease and modes of administration.

Discussion/Conclusion: All Japanese versions of the TSQM were found to have sufficient reliability and validity. These measures were proven to be sufficient regardless of disease or mode of administration. Additional studies investigating the extent of the psychometric properties for modes of administration other than oral or injectable are required.

SP511

Myasthenia gravis following initiation of statin therapy: multinational self-controlled case series study

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Introduction

Recently, regulatory authorities worldwide have advised patients receiving statins to be aware of the potential onset of myasthenia gravis (MG) symptoms. Yet, evidence regarding this potential adverse effect were limited to case reports and disproportionality analyses.

Aims

This study aims to examine the risk of incident MG following initiation of statin therapy using multinational real-world data.

Methods

A self-controlled case series (SCCS) study was conducted using electronic medical records and claims databases from Hong Kong, Japan, and United Kingdom. Individuals aged 18 years and above with their first diagnosis of MG and first prescription of any statin during the study period were included. Conditional Poisson regression was employed for within-individual comparison of MG risks during different risk periods (up to two years after statin initiation) compared to the non-exposure period, adjusted for age. Pooled results based on meta-analysis of all study sites were reported.

Results

A total of 2267 MG cases were analysed. Combining all study sites, we observed a significantly increased risk of incident MG during the first year after statin initiation compared to the non-exposure period, with a higher risk during days 0-179 (pooled IRR [95% CI]: 2.662 [1.276-5.553]) than days 180-364 (1.407 [1.014-1.954]). No increased risk of MG was observed more than one year after

statin initiation (1.011 [0.848-1.206]). Moreover, the magnitude of MG risk elevation during first 180 days after statin initiation was more pronounced with higher intensity of statins used.

Discussion

In this multinational SCCS study, an increased risk of incident MG during the first 6-12 months after initiation of statin therapy was observed, with greater magnitude of risk elevation for higher intensity statin regimens. Monitoring for incident MG shall be warranted within the first 6-12 months after initiating statin treatment, especially for medium-to-high intensity statin therapy.

SP512

Association between SGLT-2 inhibitors and DPP4-inhibitors Use and Risk of Acute Pancreatitis

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Introduction and Aims: We utilized the Korean national health insurance claims database to investigate the potential association between the use of SGLT-2i or DPP4i and the risk of acute pancreatitis through a nationwide case-based analyses.

Methods: Study subjects were diagnosed as type 2 diabetes mellitus who had been prescribed DPP4i, or SGLT-2i at least once between January, 2018 and December, 2020. We defined incident acute pancreatitis cases based on ICD-10 code K85 in either the principal or first additional diagnosis during a hospital admission or emergency department visit. We compared the prescription status of the anti-diabetic medications during the hazard period (30 days before the event of interest), and the preceding control periods of same length with 60 days of washout periods, using conditional logistic regression adjusted for other anti-diabetic medications. When anti-diabetic medication shows a noticeable increase in the exposure trend, we employed the case-case-time-control design to adjust for the effect of the exposure trend on the risk estimate. To ensure the robustness of our findings, a nested case-control study was conducted, with the controls defined within the current type 2 diabetes mellitus cohort.

Results: A total of 7219 incident acute pancreatitis cases were included. In the case-case-time-control analysis, adjusting for the utilization trend, the risk between the acute pancreatitis and SGLT-2i (adjusted odds ratio, 95% confidence interval 0.84, 0.52-1.35) and DPP4i (0.95, 0.54-1.66) was negligible and not statistically significant. The nested case-control study further supported these results, use of SGLT-2i (1.05, 0.91-1.21), DPP4i (1.01, 0.94-1.09) within a 30-day of time window did not show increase the risk of acute pancreatitis.

Conclusion: The use of newly approved hypoglycemic drugs such as SGLT-2i or DPP4i, is not associated with an elevated the risk of acute pancreatitis in patients with type 2 diabetes after considering the trends of anti-diabetic medication prescription.

SP513

Effectiveness and Safety of First-line Chemotherapy in Elderly Metastatic Pancreatic Cancer Patients

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-Introduction
Pancreatic cancer is a highly aggressive malignancy with a poor prognosis. Current treatment guidelines for metastatic pancreatic cancer emphasize FOLFIRINOX (5-FU, leucovorin, irinotecan, oxaliplatin) or gemcitabine plus nab-paclitaxel as key first-line therapies. However, elderly populations were not the primary focus in clinical trials for these regimens, and comparative studies on their effectiveness and safety in elderly patients are limited.

-Aims
This study aims to evaluate the effectiveness and safety of FOLFIRINOX versus gemcitabine plus nab-paclitaxel in treating elderly patients with metastatic pancreatic cancer.

-Methods
This retrospective cohort study utilized data from the TriNetX Research Network, which includes 88 healthcare organizations. We identified patients aged 65 and older diagnosed with metastatic pancreatic cancer between January 1, 2012, and May 20, 2023, who received either FOLFIRINOX or gemcitabine plus nab-paclitaxel as first-line therapy. The index date was defined as the start date of first-line treatment. Propensity score matching ensured comparability between groups. Survival outcomes were analyzed using the Kaplan-Meier method and Cox proportional hazards models.

-Results
A total of 1,099 patients were identified for the FOLFIRINOX group and 388 for the gemcitabine plus nab-paclitaxel group. After propensity score matching, two cohorts of 360 matched patients each were obtained. The median overall survival was 8.7 months for the FOLFIRINOX group compared to 6.8 months for the gemcitabine plus nab-paclitaxel group, with a hazard ratio of 0.714 (95% confidence interval: 0.598 to 0.851). Incidences of adverse effects included febrile neutropenia (31.4% vs. 19.7%), diarrhea (33.6% vs. 21.7%), and anemia (20.3% vs. 29.2%) for the FOLFIRINOX versus gemcitabine plus nab-paclitaxel groups, respectively.

-Discussion/Conclusion
FOLFIRINOX demonstrated a survival advantage over gemcitabine plus nab-paclitaxel among elderly patients with metastatic pancreatic cancer. However, the higher toxicity associated with FOLFIRINOX necessitates careful consideration by clinicians to balance effectiveness against potential adverse effects.

SP514

Gender Differences in Safety of Polypharmacy in Korean Elderly

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[Introduction]
While several adverse events (AEs) are known to be associated with polypharmacy, there is a lack of study on the differences by gender.
[Aims]
To investigates gender differences in the safety of polypharmacy among the elderly.
[Methods]
We conducted a retrospective cohort study using the Korean claims data, which includes medical information from one million individuals sampled from 2013-2019. The study population included male and female aged over 65 as of 2014. Patients diagnosed with AE within 2 years prior to index date (January 1, 2015) or those who were polypharmacy patients during the year 2013 were excluded. Polypharmacy was defined as averaging 5 or more prescriptions daily over a year, while non-polypharmacy was defined as averaging fewer than 5 prescriptions daily. The average number of prescriptions per day was calculated by summing the total prescription days for each drug in 2014 and dividing by 365. The five prespecified AEs included hepatic disease, renal disease, fracture, fall, and death, identified by ICD-10 codes. Patients were followed from the date of index date until the earliest diagnosis of AE, death, or end of study (December 31, 2019). We performed 1:4 propensity score matching and estimated incidence rate ratio (IRR) using negative binomial regression model, adjusted for age, residence, Charlson comorbidity index.
[Results]
Out of 93,594 elderly individuals, 42.8% were male, with 14.2% in the polypharmacy group among males. For females, 13.9% were in the polypharmacy group. Hepatic disease (adjusted IRR: 1.11, [95% CI: 1.02-1.20]) showed a statistically significant increase in risk with polypharmacy only in males, while fall (1.80, [1.35-2.41]) and death (2.01, [1.31-3.08]) showed increased risk with polypharmacy only in females.
[Conclusions]
Our research shows that there are differences in polypharmacy safety by gender in hepatic disease, falls, and death. Further gender-specific research is necessary in polypharmacy safety studies.

[Ito-B1F Gallery 1, Oct 14th]

SP515

Performance status classification of lung cancer patients by trained machine leaning

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Introduction. The Eastern Cooperative Oncology Group Performance Status Scale (ECOGPSS, hereafter abbreviated as PS) is widely used to select appropriate patients for clinical trials. PS is also used to narrow down patients in research studies using electronic health record (EHR) sources. Patient status against PS is often not measured in clinical practice, resulting in missing records of “PS grade” in EHR sources. The missing records of PS grade leads to a diluted patient cohort due to insufficient narrow down, making it difficult for researchers to generate convincing evidence from EHR sources. We have thus tried to develop a classification model using trained machine learning (ML), which enables us to supplement the missing records of PS grade with high accuracy.

Aim. This study aims to develop ML-based models to classify the status of non-small cell lung (NSCLC) patients at initial diagnosis into PS grade.

Methods. A cohort of 10,525 patients diagnosed with stage III-VI NSCLC with one or more records of PS grade at diagnosis was identified from ConcertAI Patient360™, deeply curated, de-identified EHRs and linked claims in the US. We developed classification models to discriminate between favorable (0-1) and unfavorable (2+) PS grade using logistic regression, gradient boosting classifier (GBC), K-neighbors classifier, and etc, with 14 variables recorded before medication.

Results. As preliminary results, the classification model using GBC classified patient status into PS grade, giving an AUC-ROC of 0.59 providing accuracy of 0.80. Key variables for classification were cancer stage, Charlson Comorbidity Index, number of metastatic sites, and age.

Discussion. There is room for improvement of the model to classify patient status given the low AUC-ROC value. For better classification, further studies are underway including broader variables like medication sequence or outcomes including timing of disease progression or death.

SP516

Comparative Effectiveness of Levetiracetam versus Valproic Acid in Post-Stroke Seizure Patients

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Introduction
There is limited evidence regarding the use of levetiracetam in post-stroke seizures. Considering that inadequate seizure control for post-stroke seizure patients increases the risk of disability and mortality, it is crucial to understand whether levetiracetam can effectively serve as a suitable alternative anti-seizure drug in this population.
Aims
To evaluate the risks of seizure recurrence and mortality of levetiracetam compared to valproic acid in post-stroke seizure patients.
Methods
This retrospective cohort study was conducted using the National Health and Insurance Research Database in Taiwan. Patients who received the first inpatient seizure diagnosis between January 1, 2012 and December 31, 2020, and were newly prescribed monotherapy levetiracetam or valproic acid were included. Patients were required to have had at least one stroke diagnosis within two years before the seizure diagnosis. Levetiracetam users were the exposure group and valproic acid users were the reference group. Inverse probability of treatment weighting was applied to balance the baseline covariates between groups. Outcome measures included risks of seizure rehospitalization, all-cause mortality, and the need for switching to or adding alternative anti-seizure drugs. Outcomes between the groups were compared using Cox-proportional hazard models.
Results
We included 740 levetiracetam and 786 valproic acid users in this study. Levetiracetam was associated with lower risks of seizure rehospitalization (HR: 0.85; 95% CI: 0.72-0.99) and the need for switching to or adding alternative anti-seizure drugs (HR: 0.66; 95% CI: 0.57-0.77) compared to valproic acid. However, no significant difference in the risk of all-cause mortality was observed between the two study groups.
Discussions
Our study indicates that levetiracetam had a lower seizure rehospitalization risk and comparable mortality to valproic acid. Levetiracetam users were also more likely to persist with their medication without requiring alternative anti-seizure drugs. Therefore, levetiracetam may be a suitable option for post-stroke seizure patients.

SP517

Identification of Hypocalcemia Prognostic Factors with Romosozumab Administration: A Nested Case-Control Study

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Introduction:
The anti-sclerostin antibody drug, romosozumab, is a novel option in osteoporosis treatment. It has both bone anabolic and antiresorptive effects by inhibiting the suppression of Wnt signaling. However, hypocalcemia has been reported as an adverse effect in some patients receiving romosozumab treatment. The risk factors for romosozumab-induced hypocalcemia were not well established.
Aims:
This study aims to investigate the impact of romosozumab on hypocalcemia and factors associated with hypocalcemia upon romosozumab administration.
Methods:
Using multi- institutional databases in Taiwan, we conducted a population-based nested case-control study. We included patients with a prescription for romosozumab between November 2021 and March 2024. Patients without baseline creatinine and calcium level were further excluded due to important prognostic factors. We included patients who experienced hypocalcemia during the medication usage period or within one month after medication cessation and matched each patient experiencing an event with up to 2 control subjects. The cohort entry date and index date were defined as first date of romosozumab and occurrence of hypocalcemia, respectively. We used conditional logistic regression to assess risk factors for hypocalcemia.
Results:
There were 306 romosozumab users experiencing 97 hypocalcemia events (31.6%).
Longer cumulative romosozumab use was not associated with an increased risk of hypocalcemia (cumulative uses: OR, 0.92 [95% CI, 0.79-1.08]; more than 6 months uses: OR, 0.87 [95% CI, 0.25-3.00]). Patients with CKD were associated with an increased risk of hypocalcemia (OR: 2.46 [95% CI, 1.01-5.97])
Discussion:
This nested case-control study found that CKD was associated with hypocalcemia during romosozumab administration, and there was no significant correlation between cumulative dose and hypocalcemia. These findings demonstrate that in osteoporotic patients with CKD requiring romosozumab therapy, close monitoring of serum calcium levels and vigilance for hypocalcemia symptoms may be essential to prevent the occurrence of severe hypocalcemia.

SP518

Lithium and risk of fractures in bipolar disorder: A Population-Based Cohort Study

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Introduction: Lithium is considered to be the most effective mood stabilizer for bipolar disorder. Evolving evidence suggested lithium can also regulate bone metabolism which may reduce the risk of fractures. While there are concerns about fractures for antipsychotics and mood stabilizing antiepileptics, very little is known about the overall risk of fractures associated with specific treatments.

Aims: To compare the risk of fractures in patients with bipolar disorder prescribed lithium, antipsychotics or mood stabilizing antiepileptics (valproate, lamotrigine, carbamazepine).

Methods: A retrospective population-based cohort study was conducted using a primary care electronic health record database in the UK - IQVIA Medical Research Data (IMRD-UK). Patients with bipolar disorder who were newly prescribed lithium, antipsychotics or antiepileptics between 1993 and 2019 were identified. Risk of fractures was compared between lithium and non-lithium groups with propensity score fine stratification weighting.

Results: Among 40697 patients with bipolar disorder from 1993-2019 identified from a primary care electronic health record database in the UK, 13385 were new users of mood stabilizing agents (lithium: 2339; non-lithium: 11046). Lithium was associated with a lower risk of fractures compared with non-lithium treatments (HR 0.66, 95% CI 0.44-0.98). The results were similar when comparing lithium with antipsychotics (HR 0.72, 95% CI 0.49-1.07) and mood stabilizing antiepileptics (HR 0.75, 95% CI 0.42-1.34), respectively.

Discussion: Lithium was associated with a lower risk of fractures compared with non-lithium treatment among patients with bipolar disorder. The effect might be from the protective effect of lithium or increased risk of fractures due to other non-lithium treatments. Our findings could help inform better treatment decisions for bipolar disorder and lithium's protective effect on fractures should be taken in consideration for patients with high risk of fractures.

SP519

Comparative effectiveness of long-acting injectable versus oral antipsychotics in patients with schizophrenia

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Introduction: The details of the advantages of long-acting injectable antipsychotics (LAIs) over oral antipsychotics (OAs) in real-world setting remain unclear.

Aims: We compared the effectiveness of LAIs and OAs in treating schizophrenia, focusing on whether the benefits of LAIs over OAs are evident even in the prevalent new user design and on effect heterogeneity.

Methods: We conducted a prevalent new user cohort study using two administrative claims databases in Japan. We included patients with schizophrenia initiated on LAIs and matched patients on OAs using time-dependent propensity score matching. We compared the risks of psychiatric hospitalization and treatment discontinuation based on hazard ratios (HRs) using the Cox proportional hazards model. Effect heterogeneity was evaluated using subgroup analyses with factors of psychiatric hospitalization history and proportion of days covered (PDC).

Results: In total, 2520 patients using LAI and OA were identified as matched cohorts. LAIs were associated with a higher psychiatric hospitalization risk than OAs (HR, 1.41; 95% confidence interval [CI], 1.06–1.88) in the entire population; however, LAIs were associated with lower risk in the group with a low PDC and psychiatric hospitalization history (HR, 0.51; 95% CI, 0.30–0.89). LAIs were associated with a lower risk of treatment discontinuation than OAs (HR, 0.76; 95% CI, 0.66–0.87) in the entire population; in the subgroup analyses, a consistent trend was observed in all strata (LAIs had a lower risk).

Conclusions: Using a prevalent new user design, this study confirmed that LAIs have an advantage regarding treatment continuity. LAIs had higher psychiatric hospitalization risk than OAs in the entire population; however, this study suggested the presence of effect heterogeneity due to psychiatric hospitalization history.

SP520

Quantification and Related Factors of Oversupply of Chronic Disease Medications in Japan.

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Introduction
While medication waste may be caused by medication oversupply, the degree of medication oversupply and its related factors are unclear in Japan.
Aims
This study aimed to quantify oversupply of chronic disease medications per patient and to identify its related factors and causes.
Methods
A retrospective cohort study using a large insurance claims database was conducted for patients aged ≥ 55 years who received one or a combination of major five classes of chronic disease medications in FY 2019. Medications with the same ingredient and the same specification were treated as the same medication. Medication oversupply was defined as a medication possession ratio > 1.0. The proportion of oversupplied patients, and the excess days and costs of oversupplied medications were calculated. Logistic regression models were utilized to analyze related factors with the two cohorts, excessive oversupply (≥ 30 excess days/year) and normal supply (≤ ±15 excess days/year), for each class. Causes of oversupply were classified by reviewing history of prescription and dispensing for 50 individuals randomly selected from excessive oversupply cohort.
Results
The proportions of oversupplied patients and excessively oversupplied patients were approximately 16% and 1–2% for all medication classes, respectively. Three-quarters of the oversupplied patients had ≤ 14 excess days/year. However, there were a patient with 983 excess days/year of oversupplied medication and a patient with nearly 90000 yen/year of oversupplied medication costs.
Notable related factors for all classes were greater frequency of early supply, inpatient prescription, and greater number of ingredients taken concomitantly. The most prominent category of causes was ‘Early supply of medications prescribed by a single facility’, irrespective of classes.
Discussion
The factors and causes of oversupply could reflect unique features of Japanese healthcare system. The findings suggest the need of developing measures for reducing medication oversupply.

SP521

Telomere length, a marker of aging, based on nutritional status in women

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Introduction: Telomeres are sequences of nucleotides that maintain cell stability but shorten with each cell division. When telomeres reach a critical short length, cells stop dividing (senescence) or die (apoptosis). Telomere length is used as a marker of aging and can be influenced by factors such as stress, lifestyle, nutrition, and hormones. Women undergo hormonal changes during menstruation, pregnancy, and menopause, which can affect telomere length.

Aims: Our study aimed to examine the relationship between nutritional status and telomere length in adult women.

Methods: This cross-sectional design study, conducted in 2023, involved 93 women aged 30-45 in Padang City, Indonesia. Nutritional status was assessed by examining body weight, height, and fat percentage. Body fat percentage was analyzed by a bioelectrical impedance analyzer. Furthermore, blood samples were analyzed using O'Callaghan and Fenech's technique to measure telomere length. The data was analyzed by using one-way ANOVA test.

Results: This study found that the mean age of the subjects was 38.34 ± 4.9 years. Among the subjects, 26 had normal nutritional status (normal-weight lean, NWL), 11 had normal-weight obesity (NWO), and 56 were obese (Ob). The mean telomere lengths for NWL, NWO, and Ob subjects were 432.08 ± 205.8 bp, 412.46 ± 143.9 bp, and 401.63 ± 137.0 bp, respectively. Statistical analysis revealed no significant difference in telomere length among the three groups ($p > 0.05$).

Discussion/conclusion: Our findings demonstrated that although there were no significant differences between the three groups, there was a tendency for telomere length to decrease as nutritional status increased. Further research is needed to explore other factors related to telomere length in Indonesian women.

[Ito-B2F, Oct 13th]

SP522

Validation of claims-based algorithms for intussusception in Japan: The CLEAR Study

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Introduction:
Monitoring the incidence of intussusception after rotavirus vaccination is recommended by the World Health Organization. In Japan, the linkage of vaccination records with medical claims data covering the entire population will be developed in a few years for vaccine safety monitoring. However, there is no validated claims-based algorithm to identify patients with intussusception.

Aims:
We aimed to validate claims-based algorithms to identify patients with intussusception from Japanese claims data.

Methods:
The target population was those who visited one hospital in Japan at least once between June 2017 and August 2023. Their claims data were used to develop algorithms. Ultrasound test results data were used as the reference standard for true patients with intussusception. 'Claims-based cases' were defined by three patterns: Algorithm #1 diagnosis code ICD-10 K56.1 on inpatient claims, Algorithm #2 ultrasound test codes accompanying #1; Algorithm #3 intussusception treatment codes accompanying #2. 'True cases' were defined by diagnosis based on ultrasound test results. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) with their 95% confidence intervals were calculated for each algorithm.

Results:
The target population comprised 243,432 patients (female 54.4%, mean age 49.0 years). The number of 'true cases' from the reference standard was 17 patients (female 41.2%, mean age 1.0 years). The number of 'claims-based cases' identified by algorithms #1, #2 and #3 was 116, 51, and 27 respectively. The sensitivities and PPVs were 94.1% (82.9%, 99.9%) and 13.8% (7.5%, 20.1%) for algorithm #1, 82.4% (64.2%, 99.9%) and 27.5% (15.2%, 40.0%) for algorithm #2, and 70.6% (48.9%, 92.2%) and 44.4% (25.7%, 63.2%) for algorithm #3, respectively. All specificities and NPVs were greater than 99.9% (99.9%, 99.9%).

Discussion:
This study showed algorithms with high sensitivities and specificities, although PPVs were low. We will add data from other hospitals and continue to find more suitable algorithms.

SP523

A Prediction Model for the 5-ASA Intolerance among Japanese ulcerative colitis patients

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Introduction
The first-line agent for the treatment of ulcerative colitis is 5-aminosalicylic acid (5-ASA). About 10% of patients taking 5-ASA are deemed to develop a condition called “5-ASA intolerance,” in which they have difficulty taking 5-ASA continuously due to adverse effects. The number of patients developing 5-ASA intolerance seems to be on the rise. We can provide safer treatment if we can identify patients at high risk of developing 5-ASA intolerance.

Aims
The purpose of this study was to develop and internally validate a prediction model for the occurrence of 5-ASA intolerance among Japanese ulcerative colitis patients.

Methods
We analyzed data from December 2016 to March 2023 using the payer database held by JMDC Inc. The occurrence of 5-ASA intolerance was defined when the 5-ASA oral prescriptions were discontinued within 180 days of the initial prescription and a diagnosis of ulcerative colitis was made after the discontinuation. Predictors were selected from the candidate factors based on expert opinions and the results of univariate Cox regression analysis. A prediction model was developed using the Cox proportional hazards model, considering the nonlinearities of continuous variables and interactions between variables. Internal validity of the model was assessed from two points; 1) The model’s accuracy by a calibration plot, 2) The model’s discrimination ability by optimism-corrected c-index with bootstrapping.

Results
The sample size was 10,749 with 1,038 (9.7%) events. The selected predictors were gender, age, 5-ASA brands, and prescription dose. The developed prediction model along with its internal validity will be reported in the session.

Conclusion
In this study, a prediction model for the occurrence of 5-ASA intolerance among Japanese ulcerative colitis patients was developed and internally validated. This model can help provide safer treatment.

SP524

Erythropoiesis-stimulating agents and osteoporotic fracture in chronic kidney disease: A case-control study

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Background: Erythropoietin was linked to bone metabolism in preclinical studies, but the relationship remained inconclusive in humans. Therefore, the association between erythropoiesis-stimulating agent (ESA) use and bone metabolism needs further investigation.

Methods: Using the electronic health record from the Hong Kong Hospital Authority, we conducted a nested case-control study among patients with chronic kidney disease (CKD) using ESA between 2005 and 2022. Incidence cases of osteoporotic fracture were matched with up to 10 fracture-free controls on age, sex, and year of fracture incidence. We estimated the odds ratio (OR) and 95% confidence interval (CI) for the association of ESA with fracture risk using conditional logistic regression, adjusted for unbalanced CKD-related risk factors after matching.

Results: 959 osteoporotic fracture cases were identified and matched with 9262 fracture-free control. The duration of ESA treatment was associated with an increased risk of osteoporotic fracture [OR per year of ESA treatment: 1.27, 95% CI: 1.21-1.33, p<0.001]. An increase in accumulated ESA dose was associated with increased fracture risk, but the effect was attenuated after adjustment for ESA treatment duration. Consistent findings were observed in the spine and hip fracture subtypes. Similar results were observed in subgroup analysis stratified by age, sex, CKD stages, and dialysis history, and in the sensitivity analysis with adjusted prescription duration for iron supplementation and average haemoglobin level since initiation of ESA treatment.

Conclusion: This study suggests a potential relationship between the use of ESA and bone metabolism among patients with CKD. The management of anaemia management in CKD patients with ESA might warrant a shorter treatment duration.

SP525

Exploring Signals of Substance Use Disorder Using VigiBase

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Substance use disorders (SUD) rank among the top ten most disabling conditions globally. Additionally, drug-related issues can lead to increased morbidity and mortality, resulting in a substantial burden.

To explore signals for SUD in adults, focusing on the anatomical main group level in the Anatomic Therapeutic Chemical (ATC) Classification.

We utilized VigiBase data from January 1, 2000, to October 27, 2023. VigiBase, maintained by the Uppsala Monitoring Centre for the World Health Organization, was used to identify cases of individuals over 18 years old with Standard Medical Dictionary for Regulatory Activities Queries (SMQs) targeting “Drug abuse, dependence, and withdrawal”. Non-cases were individuals over 18 years old with any other SMQs. Drug exposure was categorized based on "suspected" and "interacting" reports, and the frequency of drugs focused on the 1st level of ATC code. The reporting odds ratios (RORs) with 95% confidence intervals (CIs) were calculated using logistic regression models.

Among 17,783,005 reports with ATC codes, 260,145 were identified as cases. Most of these cases were within the 18-44 age group (38.81%), with females accounting for 58.08%. A significant proportion of the reports (78.35%) originated from the Americas. 'Nervous system' drugs were the most frequently reported cases (27.98%), followed by ‘Dermatologicals’ (14.71%). However, ‘Antiinfectives for systemic use’ were most frequently reported among non-cases (22.16%). 'Benzodiazepine derivatives' exhibited an ROR of 4.18(95% CI, 4.09–4.27). The stratified analysis, 'Benzodiazepine derivatives' showed higher ROR in females (ROR, 3.84; 95% CI, 3.73–3.95) and individuals younger than 75 years old (ROR, 4.30; 95% CI, 4.21–4.40).

Including neurologic, dermatologic, and psychiatric drugs, further investigations for detecting novel signals of SUD are needed to enhance public health surveillance.

SP526

Pharmacoepidemiology of Tuberculosis Preventive Therapy in HIV Programs in Nigeria: Lessons Learned

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Introduction
Tuberculosis Preventive Therapy (TPT) is a life-saving treatment to prevent latent tuberculosis (TB) infection from progressing to active tuberculosis disease. Consistent monitoring of the safety and efficacy of TPT is important to ensure tuberculosis prevention goals are achieved.
Aims
The study describes a cohort analysis of safety and efficacy assessments of Isoniazid-based TPT for persons living with HIV (PLWH) in Nigeria, to provide real-world data for informed decision-making in prevention of tuberculosis.
Methods
National HIV and tuberculosis treatment guidelines were applied in Isoniazid-based TPT for eligible PLWH receiving anti-retroviral therapy (ART) across 38 hospitals in Nigeria. A total of 10,728 PLWH (18-72 years), who commenced and completed at least one course of TPT between February 2017 and February 2022, were monitored till February 2024. Adverse drug reactions (ADRs) were evaluated for TPT safety assessments. All PLWH were clinically screened for active TB at every clinic visit, to assess the efficacy of TPT. Data were analyzed by descriptive statistics.
Results
A total of 10, 348 (96%) PLWH completed TPT without interruption while 380 (4%) PLWH interrupted TPT, re-started, and later completed TPT. Factors attributed to TPT interruption were missed clinic appointments (43%), HIV stigma (37%), and ADRs (20%). ADRs (n=76) reported included gastrointestinal disturbances (41), dizziness (17), skin rashes (10), and numbness of extremities (8). All ADRs were mild, transient, and managed according to guidelines. Active TB incidences decreased from 35% (before TPT) to 10% (after TPT). Further analysis showed that 8% of the 10% active TB incidences occurred in PLWH who completed TPT but interrupted ART due to behavioral factors.
Discussion/Conclusion
The results showed that TPT is safe and efficacious in preventing tuberculosis in PLWH. However, factors responsible for TPT and ART interruptions should be considered to ensure optimization of TPT among PLWH.

Keywords: Drug safety, Drug efficacy, Tuberculosis.

SP527

Antibiotic utilization in infective endocarditis management at a teaching hospital in Vietnam

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Introduction: Infective endocarditis (IE) is a rare, life-threatening bacterial infection with high morbidity and mortality, significantly affecting patients' quality of life. There is still limited data on the use of antibiotics, as well as the epidemiological characteristics of the causative pathogens in Vietnam.

Aims: The purpose of this study was to investigate the epidemiological characteristics of pathogens isolated from patients with IE, antimicrobial therapies, and the rationality of antibiotic use in the management of IE at a teaching hospital in Vietnam.

Methods: We performed a cross-sectional study on patients diagnosed with IE from January 2020 to May 2023. Data were retrospectively collected from electronic medical records. The appropriateness of antimicrobial therapies was assessed using guidelines from the European Society of Cardiology (2023), the Japanese Circulation Society (2017), and the American Heart Association (2015).

Results: A total of 84 patients were included in the study, with a median age of 57 (49- 65) years; males accounted for 63.1% of the study population. The proportion of positive blood cultures was 61.9%. Gram-positive bacteria accounted for 58.3%, with the most common pathogens isolated being Viridans group streptococci (VGS) (38.1%). The susceptibility rates of the VGS isolates to penicillin and ampicillin were 57.1% and 66.7%, respectively. Combination antibiotic regimens were more common in empirical treatment (82.9%). The overall appropriateness of antibiotic use at admission and after the susceptibility test was 62.85% and 100.0%, respectively. Fifteen patients (17.9%) developed adverse drug reactions (mostly related to vancomycin), leading to changes in antibiotic therapy. Valvular surgery (OR=4.231; 95%CI: 1.204–14.868; p=0.024) and hospital-acquired pneumonia (OR=0.148; 95%CI: 0.040–0.552; p=0.004) were factors significantly associated with the likelihood of treatment success.

Conclusion: The results of this study emphasize the importance of selecting empirical antibiotics based on updated susceptibility data and the role of valvular surgery in the treatment of IE.

SP528

Von Hippel-Lindau disease-associated renal cell carcinoma natural history study in China

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Introduction: Von Hippel-Lindau (VHL) disease is a rare disease characterized by an increased prevalence of benign and malignant tumors, particularly renal cell carcinoma (RCC). There is a lack of epidemiological data for the Chinese population, and published information on the natural history of VHL disease in China is limited. Understanding the natural progression of the disease is crucial for contextualizing clinical trial results and informing further product development.

Aims: Evaluate the linear growth rate (LGR) of RCCs among VHL patients.

Methods: We conducted a retrospective, non-interventional study by reviewing medical records of VHL disease-associated RCC (VHL-RCC) patients at Peking University First Hospital from Jan-2010 to Jun-2021. Eligible patients included Chinese patients with confirmed VHL-RCCs during the study period, available follow-up, and no prior therapy or procedures for RCCs proximate to the index date. Each tumor was followed from the index date, defined as the first serial diameter measurement, to therapy or treatment impacting the tumor, or patient death or loss to follow-up. The diameter data was abstracted from the radiology reports. LGR was evaluated for RCCs with ≥3 CT/MRI measurements at tumor-level and patient-level using a multi-level linear mixed model regressing tumor diameter on time since the index date, accounting for dependency in patients and tumors.

Results: A total of 21 eligible patients with 31 tumors were included in the analysis. The median tumor diameter at the index date was 2.1 cm. The median tumor-level and patient-level LGR, derived from the multi-level model, were 0.353 cm/year and 0.401 cm/year, respectively. Almost all patients (90.5%) and tumors (96.8%) exhibited a positive LGR over the follow-up period.

Conclusion: Spontaneous regression of RCCs is unlikely for patients with VHL undergoing active surveillance in the absence of therapy. The study adds critical insights into the natural progression of the disease in a real-world setting.

SP529

Efficacy and safety of parpi as 1l-maintenance therapy in aoc: network meta-analysis

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Introduction: Poly (ADP-ribose) polymerase inhibitors (PARPi) have emerged as effective maintenance therapy, offering significant survival benefits in advanced ovarian cancer (AOC).

Aim: This network meta-analysis (NMA) evaluates the comparative efficacy and safety of PARPi monotherapy as first line (1L) maintenance treatment in patients with AOC.

Methods: We searched 'PubMed' and 'Embase' platform on 10th Jan 2024 for randomized controlled trials (RCTs) of FDA approved PARPi (olaparib, niraparib, and rucaparib) in newly diagnosed AOC. Bayesian NMA was conducted using the netmeta package in R studio, version 4.3.2.

Results: We identified four RCTs with 2,046 patients. PARPi significantly improved progression free survival (PFS) in overall population as compared to placebo. For patients with BRCA-mutation (BRCAm) positive, olaparib (HR: 0.35; 95% CI: 0.26-0.47), niraparib (HR: 0.4; 95% CI: 0.27-0.59), and rucaparib (HR: 0.4; 95% CI: 0.21-0.75) significantly improved PFS compared to placebo. Similarly, for patients with homologous recombination deficiency (HRd); niraparib (HR: 0.45; 95% CI: 0.36-0.57), rucaparib (HR: 0.47; 95% CI: 0.31-0.71) significantly improved PFS, olaparib data not available in HRd. Safety analysis revealed a higher risk of grade 3 or 4 adverse events (AEs) with olaparib, rucaparib, and niraparib as compared to placebo. All assessed PARPi showed an increased risk of anemia. For neutropenia, niraparib and rucaparib exhibited significant risks, while olaparib demonstrated non-significant risk as compared to placebo. Moreover, among all assessed PARPi only niraparib showed a statistically significant risk of thrombocytopenia relative to placebo. The tolerability profile, including AE leading to dose reductions were significantly higher in all three PARPi compared to placebo. Overall risk of bias in all included RCTs was low.

Conclusion: PARPi as 1L-maintenance therapy significantly improved PFS, especially in patients with BRCAm and HRd. Although the risk of grade 3 or 4 AE was significantly higher in PARPi as compared to placebo, patients tolerated PARPi.

Poster Presentations

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[Adherence]

P100

Adherence Trajectories to Aromatase Inhibitors in Postmenopausal Breast Cancer: A Five-Year Study

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-Introduction:
For postmenopausal women with hormone receptor-positive breast cancer, a five-year course of aromatase inhibitor (AI) is considered an optimal choice due to its efficacy, side effect profile, and reduction in recurrence rates. However, maintaining adherence remains a significant challenge in clinical settings.
- Aims:
This study aims to identify distinct adherence trajectory groups among nonmetastatic patients receiving AI therapy and to determine the associated factors.
-Methods:
We utilized data from Taiwan's National Health Insurance Research Database and National Cancer Registry, identifying hormone receptor-positive postmenopausal women newly diagnosed with stage 1-3 breast cancer who initiated AI therapy after surgery. Medication adherence was calculated using the monthly proportion of days covered and conducted. A five-year cohort study on adherence trajectories was conducted using group-based trajectory modeling. Multinomial logistic regressions were employed to identify factors associated with different trajectories.
- Results:
The analysis included 4760 women, and a five-trajectory model was determined based on Bayesian information criterion (BIC) and fitness criteria. The identified trajectories were: continuous optimal adherence (34.2%, n=1639), continuous suboptimal adherence (47.3%, n=2271), progressive nonadherence then discontinuation (7.3%, n=322), early nonadherence then discontinuation (5.4, n=256%), and immediate discontinuation (6.0%, n=272). Factors linked to nonadherence included age over 80, higher comorbidity burden, use of chemotherapy, and residing in northern regions.
-Discussion:
This study identifies potential factors related to medication adherence trajectories among breast cancer patients receiving AI treatment in Taiwan. These findings provide direction for healthcare professionals to develop interventions to improve medication adherence. Future research should investigate the impact of adherence trajectories on clinical outcomes.

P101

ART Adherence and its Associated Barrier Experienced by PLHIV in Mizoram, India.

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Introduction: Antiretroviral Therapy (ART) has resulted in increasing the longevity of people living with HIV infection. Despite the current era of Anti-Retroviral Therapy (ART) available with free of cost in India, Non-Adherence (NA) remains a major encounter in real-life settings. Hence, identifying barriers to measure ART adherence is essential for treatment success. Therefore, the study is conducted to find out how well people living with HIV (PLHIV) are adhering to ART and what obstacles they face in highly HIV prevalent state in India.
Aims: The aim of the study is to assess the ART adherence among PLHIV in Aizawl, Mizoram and evaluate the Adherence barrier among PLHIV in Aizawl, Mizoram.
Methods: A cross-sectional study was conducted between January 2023 to May 2024 at ART Centres, Aizawl, Mizoram, India. A pre-tested questionnaire on Adherence Barrier Questionnaire (ABQ) Scale was administered after translating in local language. Medication adherence was assessed using Visual Analog Scale (VAS). Chi-square test and Mann Whitney U test was used for statistical analysis at a significance level of $p<0.05$.
Results: There was a total of 300 participants consisting of 176 (58.7%) male and 124 (41.3%) female. The mean score of Adherence to ART is 9.48 (SD±0.920) while the mean of total Adherence barrier score is 16.64 (SD ± 2.47). There was a significantly higher adherence barrier score among participants with low adherence (Mean 18.29, SD±3.12) followed by moderate adherence (Mean 17.19, SD±3.05) and good adherence (Mean 16.31, SD±2.08) across the ABQ domain. In addition, there was significantly higher unintentional adherence barrier score among the unemployed (Mean 8.64, SD±2.28) participants compared to the participants with jobs (Mean 8.25, SD±1.95)
Conclusion: The overall adherence to ART is satisfactory in the study center, and there is a low risk of adherence barrier with respect to the total ABQ scale.

P102

Clinical Pharmacist's Intervention to Improve Medication Adherence in Patients Receiving Oral Oncolytics

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Background: Oral chemotherapy has gained popularity due to its convenience and potential to improve cancer patients' quality of life (QoL). However, ensuring medication adherence remains a significant challenge.

Aims: This study aimed to implement clinical pharmacist services and evaluate their impact on medication adherence and QoL in patients receiving oral oncolytics.

Methods: A prospective interventional cohort study was conducted at a cancer speciality hospital for a period of nine months. The study included patients aged ≥18 years receiving oral chemotherapy. The intervention group received personalized medication counselling and educational materials, while the control group received standard care. Medication adherence was assessed using the Morisky Medication Adherence Scale (MMAS-8), and QoL was evaluated using the EQ-5D-5L and EORTC QLQ-C30 questionnaires.

Results: A total of 202 participants were randomly assigned to either the intervention or control group. The intervention group demonstrated a significantly higher change in medication adherence compared to the control group [mean difference (MD) 0.66±0.09, p<0.01)]. Furthermore, the intervention had a positive and significant effect on specific aspects of functioning and QoL. The intervention group showed improvements in overall role functioning (MD 0.06±0.02, p=0.03), cognitive functioning (MD 0.08±0.03, p=0.01), and social functioning (MD 0.12±0.03, p<0.01), along with a decrease in overall pain (MD -0.06±0.05, p=0.03) compared to the control group. The analysis of self-reported questionnaires revealed important findings regarding non-adherence factors in both the intervention and control groups. The primary factors contributing to non-adherence were consistently associated with feelings of depression or being overwhelmed (98%), perceiving the treatment as complex (94%), and facing challenges in reaching the hospital easily (51%).

Conclusion: Pharmacist-led interventions have demonstrated the potential to improve medication adherence and humanistic outcomes among oncology patients. The study also highlights the importance of personalized medication counselling in addressing adherence barriers and enhancing patient understanding.

P103

Development and validation of medication adherence questionnaire for patients with chronic illnesses in Southern India

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Introduction. Assessing medication adherence is a big concern in the healthcare system. Different methods help to access medication adherence, but it is limited to certain diseases. Newly validated medication adherence questionnaire mainly focuses on patients with hypertension, diabetes, and asthma for assessing medication adherence.
Aims. To validate the newly developed medication adherence questionnaire for patients with chronic diseases in Southern India.
Methods. An extensive literature search was conducted from search engines using MeSH terms for the development of medication adherence questionnaire. The questions are designed to identify the barriers to medication adherence if the patient is not adherent to their prescribed regimen (The validated and developed questionnaire is mentioned below. Table 1). These are 8-component questions, a patient is considered adherent if the score falls < 4 and non-adherent The developed adherence questionnaire was subjected to validation with a team of 20 experts from community pharmacists, professors, associate professors, assistant professors, and lecturers from the department of clinical pharmacy. The experts are asked to rate the questions based on relevance, clarity, simplicity, and ambiguity on a scale from one to four, with four being the highest score. I-CVI and S-CVI scores for the questionnaire are above 80% and the internal consistency measured using Cronbach alfa is 0.90.
Results. The I-CVI and S-CVI scores for the questionnaire are above 80% and the internal consistency with the parameters consisting of relevance, clarity, simplicity, and ambiguity are measured using Cronbach alpha and the average is 0.90, therefore, the questionnaire is considered ‘excellent.

Discussion. The newly developed and validated questionnaire is useful in assessing patient-reported medication adherence because of its accuracy, sensitivity, and ease of use. The MAQ's data analysis gives helpful insights into how well people follow their treatment and help them if they need it, possibly predicting outcomes better than other evaluating tools. Implementing such medication adherence questionnaires helps healthcare professionals understand the extent of adherence in patients and they can aid in improving patient outcomes.

P104

Impact of CPE program on medication adherence among community pharmacists

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Introduction. Continuing Pharmacy Education (CPE) is essential for pharmacists to stay updated with the latest clinical knowledge and skills, directly impacting medication adherence practices.
Aims. To assess the impact of a CPE program on community pharmacists' knowledge and perceptions regarding medication adherence.
Methods. A prospective interventional study was carried out with 30 community pharmacists who underwent a CPE program focused on "Medication Adherence." The impact was assessed using a Knowledge, attitude, and practice (KAP) questionnaire, validated through expert review and pilot testing, achieving a Cronbach's alpha score of 0.89 for reliability. Assessments were conducted before and one month after the program. Statistical analysis included a paired t-test to evaluate significant changes in knowledge, attitudes, and practices, with significance set at $p < 0.05$.
Results. Out of the 30 community pharmacists who participated in the CPE program, the majority of the community pharmacists were males (66.7%) and were aged between 20-30 years (70%). Among them, 76.7% were employees, with Diploma (86.7%) being the highest educational degree and working experience ranging from 0-5 years (63.3%). The paired t-test was conducted on the overall knowledge (p-value = 0.0023), attitude (p-value = 0.62), and practice (p-value = 0.09) questions separately. Community pharmacists show significant improvement in the knowledge section of medication adherence from 42% to 66.3% before and after the CPE program with a p-value < 0.05 (p-value = 0.0023). The average score value before the CPE program was 15.41 (SD ±2.9) and after the CPE program, it improved to 18.55 (SD ±3.3), with a statistically significant p-value of < 0.05 (p-value = 0.0003).
Discussion. The CPE program markedly improved pharmacists' understanding and practices of medication adherence, as validated by significant post-intervention improvements in KAP scores. This emphasizes the value of continuous ongoing education in enhancing pharmacy practice and patient care outcomes.

P105

Knowledge, medication beliefs and adherence in diabetes patients: A structural equation modelling

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Introduction: Non-adherence to glucose-lowering medications is a crucial problem in type 2 diabetes (T2D) patients. Diabetes knowledge and medication beliefs including beliefs about natural remedies are likely associated with medication adherence. Studies investigating the relationship between medication adherence and those factors are a good basis to develop intervention improving medication adherence.
Aims: To determine associations between patient characteristics, diabetes knowledge, beliefs about medication, beliefs about natural remedies and medication adherence to glucose-lowering medications.
Methods: This was a multicentre cross-sectional study which was conducted in sixteen primary health care centres in Indonesia. T2D patients, aged above 18 years who were willing to participate were included in the study. Adapted diabetes knowledge questionnaire (DKQ), beliefs about medications questionnaire (BMQ) and medication adherence rating scale-5 (MARS-5) were used as assessment tools. Structural equation modelling was used to analyse the data.
Results: This study included 328 T2D patients (mean age 60.6±8.9, female 74.4%, mean duration of diabetes 7.1±6.2). The final model (CFI: 0.916; RMSEA: 0.057; SRMR: 0.055) indicated that beliefs about glucose-lowering medications in terms of necessity (B=0.152), overuse (B= -0.216) and side effects (B= -0.108) were significantly associated with medication adherence. Additionally, taking natural remedies was also significantly associated with medication adherence (B= -0.139).
Discussion: The findings demonstrate that patients are more likely to adhere to their medication when they believe the medicines are important, not overused, and not harmful. People who are natural remedy users may have lower adherence to prescribed medications. Somewhat surprisingly, knowledge about diabetes did not make a difference in adherence.

P106

Real-world persistence with second-line IL-17i and IL-23i treatment for psoriasis in Japan

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Introduction: In patients with plaque psoriasis (PsO), second-line biologic use follows first-line biologic failure, but evidence on second-line biologic experience is still largely lacking.

Aims: This study describes second-line biologic persistence in patients with PsO in Japan.

Methods: This retrospective cohort study used the Japanese Medical Data Vision database containing hospital-based claims data on 46 million patients in Japan. Study population included adults who used IL-17 inhibitors (IL-17i) or IL-23 inhibitors (IL-23i) as second-line biologic treatment for PsO (ICD-10=L40.0) between 01 January 2015 and 31 December 2022. Persistence was measured from the time of initiating second-line biologic to discontinuation, switch to another biologic, loss to follow-up or study end, whichever came first. Discontinuation was defined as a treatment gap of at least twice the biologic-specific maintenance dosing interval (IL-17i: 8 weeks for secukinumab and ixekizumab, 4 weeks for brodalumab; IL-23i: 16 weeks for guselkumab, 24 weeks for risankizumab and tildrakizumab). Persistence rate was estimated by the proportion of patients continuing second-line biologic at 6-, 12-, and 24-months after initiation. Median (IQR) persistence and persistence rates with 95%CI were reported for the IL-17i and IL-23i groups.

Results: In total, 311 PsO patients received second-line biologic during the study period; 48.6% (n= 151) received an IL-17i, and 51.4% (n=160) received an IL-23i. For patients receiving second-line IL-17i, median persistence was 5.5 (2.8-14.4) months and persistence rates at 6-, 12-, and 24-months were 61.5% (52.5-69.9%), 48.9% (39.0%-59.0%) and 33.3% (23.4-45.1%), respectively. For patients receiving second-line IL-23i, median persistence was 8.6 (4.6-20.1) months and persistence rates at 6-, 12-, and 24-months were 80.9% (73.4-86.7%), 63.6% (53.8%-72.4%) and 51.7% (39.3-63.8%), respectively.

Discussion/Conclusion: In this study, persistence was longer for IL-23i than IL-17i as second-line treatment for PsO in Japan, consistent with previous findings for first-line use.
plaque psoriasis; interleukin-17 inhibitor; interleukin-23 inhibitor; second-line biologic persistence.

P107

Statin Medication Adherence in Relation to Dyslipidemia Risk Categories

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Introduction: Ensuring medication adherence to statins, a key drug for the prevention of cardiovascular disease, is an important issue. However, the extent of medication adherence to statins is not fully understood.
Aim: This study aims to clarify the medication adherence to statins based on the risk category of dyslipidemia.
Methods: We used administrative claims data obtained from the Japan Medical Data Centre (JMDC). Out of 174,941 patients who initiated statin therapy, we excluded those without 3 months of screening and 12 months of observation periods. Finally, we analyzed 81,596 patients. Medication adherence was assessed using the Proportion of Days Covered (PDC) method, with a cut-off value set at 80% PDC. The risk categories for dyslipidemia were referred to the 2017 Japan Atherosclerosis Society (JAS) guidelines for the prevention of atherosclerotic cardiovascular diseases.
Results: Among our study patients, 91% used statins for primary prevention (n=74,363). In this group, 26.9% were classified as high risk (n=20,016). Medication adherence exceeding 80% was observed in 63.6% (12,726/20,016) of these high-risk patients. The proportion of patients with medication adherence over 80% was similar between those administered high-intensity statins and those on low-intensity statins.
Discussion /Conclusion: Our study found that medication adherence to statins is approximately 60% in patients using statins for primary prevention of cardiovascular disease. Generally, maintaining Low-Density Lipoprotein Cholesterol (LDL-C) at adequate levels requires over 80% medication adherence to statins. Our study highlights the importance of educating patients on the necessity of maintaining high medication adherence to achieve optimal therapeutic outcomes with statin therapy.

[AI and Machine Learning]

P108

Comparative evaluation of generative large language models in adverse drug reaction prediction

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Introduction:
The advent of large language models (LLMs) in generative AI has transformed text processing, but their potential for identifying adverse drug reactions (ADRs) from clinical text remains unexplored. Identifying ADRs from clinical text demands intricate cause-and-effect assessment and relation extraction. It remains uncertain if generative LLMs can effectively tackle such complex tasks.

Aims:
This study aims to assess the performance of generative LLMs in detecting ADRs from unstructured clinical text containing causally linked drug-adverse event pairs.

Methods:
Various generative LLMs are tested in their ability to correctly classify ADRs from text segments in the Medical Information Mart for Intensive Care (MIMIC-III) dataset (n=4418). LLMs are prompted to generate a probability score for each specific drug-adverse event pair in the text segment to indicate the likelihood of an ADR being present. We use F1 score to evaluate the performance of LLMs based on these probabilities. Furthermore, we benchmark the performance of generative LLMs against our in-house fine-tuned BioM-ELECTRA-large model, a LLM designed for biomedical text analysis and fine-tuned for ADR classification, to provide a comprehensive comparison of their abilities in detecting ADRs from clinical text.

Results:
Despite lacking prior training on ADR classification, Gemini 1.5 Pro and Claude 3 Opus demonstrated F1 scores comparable to BioM-ELECTRA-large (0.86, 0.78, and 0.72 for Gemini 1.5 Pro, Claude 3 Opus, and BioM-ELECTRA-large, respectively). Generative LLMs exhibited higher recall but lower precision, indicating a trade-off where LLMs captured a wider range of ADRs but with higher false positive. To address this trade-off, a hybrid framework is proposed to combine BioM-ELECTRA-large's precision with generative LLMs' recall capabilities for high-performance ADR prediction while optimizing computational costs.

Conclusion:
This study enhances the understanding of generative LLMs in ADR detection and introduces a pioneering hybrid framework for balancing performance and computational resource allocation in ADR prediction systems.

P109

ePhenotyping: machine learning approach for defining diabetic kidney disease as an outcome

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[Introduction] Outcomes in the pharmacoepidemiologic studies are used for identifying the target patients contracting the disease of interest. True condition of the patients is defined by multiple features including confirmed diagnosis, related prescriptions, medical practices, etc. This is called "ePhenotyping" when using the electronic health records, receipt data, etc. as the data sources.In the post marketing surveillance (PMS) based on the real-world data, laboratory test value (LTV) facilitates outcome definition, but currently not enough available in many databases. Taking a kidney disease in PMS for example, without the LTV, identification of patients with the true condition is difficult or become dubious.
[Aims] Here, to address this issue, we tested ePhenotyping for Diabetic Kidney Disease (DKD) if DKD patients are accurately identified without the LTV, where the patient group is often focused on as the target of the PMS.
[Methods] Firstly, 11,468 diabetic patients with eGFR < 30 were selected as a gold standard of the DKD patient from the RWD database. Similarly, 11,468 diabetic patients with eGFR > 30 were randomly selected as a non DKD patient. Then, those were divided into two datasets (training data and test data) including 5,734 of DKD and non DKD patients, respectively. Finally, prescription drugs, medical practices, and definitive diagnosis from one month before to after the date when eGFR met the criteria were incorporated into modeling the classifier for the DKD patients.
[Results] With the supervised machine learning approaches including gradient boosting decision tree, we found the DKD patients are identified at 0.83 of PPV and 0.79 of sensitivity.
[Discussion] In this study, we concluded the ePhenotyping enables us to define outcomes accurately identifying DKD patients. Clinical implications and validity for the selected variables remained to be discussed with clinicians, and the models are kept optimizing for more valid assessment for the future.

P110

Investigating NAFLD Patient Phenotypes in Southern Taiwan Using Machine Learning-based Cluster Analysis

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Introduction:
Non-alcoholic fatty liver disease (NAFLD) is a common liver disease in clinical settings, leading to the subsequent development of liver cirrhosis or hepatic cancer, decreasing patients' life expectancy and deteriorating quality of life. In recent years, machine learning has been widely used in medical research. Cluster analysis can be applied to discover group phenotypes with similar characteristics within a population.
Aims:
This study aimed to identify NAFLD patients' phenotypes using cluster analysis.
Methods:
A retrospective cross-sectional study was conducted with a multiple-center database between 2016 and 2022. Patients diagnosed with NAFLD were included. K-prototypes, an unsupervised machine learning-based cluster analysis was used to cluster the patient characteristics, including comorbidity, comedication, and healthcare utilization records in a 365-day characteristic tracking period.
Results:
During the inclusion period from 2017 to 2021, we included 6,008 patients in the NAFLD cohort. Four clusters were built according to the algorithm. Cluster 1 (n=807) comprised the oldest patients with a median age of 68.1 years. This cluster has the highest proportion of diseases, including hypertension (62.2%), type 2 diabetes mellitus (53.4%), and heart failure (9.8%). Cluster 2 (n=2,504) was the healthiest group, exhibiting the lowest comedication use. Cluster 3 (n=2,345) tended to have gastrointestinal issues, with upper (21.9%) and lower (10.2%) gastrointestinal endoscopy records and increased use of agents against reflux diseases. Patients in cluster 4 (n=352) were the youngest, however, presented with chronic viral hepatitis (16.5%), hepatic failure (4.6%), and anemias (12.5%).
Discussion:
In this study, we identified characteristics of NAFLD patients, noting disproportionate comorbidities, especially in cluster 1. Further research will measure associations between NAFLD clusters and hepatic cancer. Leveraging big data management, we navigate medical records more efficiently than traditional methods, allowing the exploration of disease development networks with more potential factors.
Keywords: NAFLD, machine learning

P111

Machine learning predicting risk of infection among patients treated with b/ts DMARDs

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Introduction: Biological and targeted synthetic disease-modifying anti-rheumatic drugs (b/ts DMARDs) are effective treatments for rheumatoid arthritis (RA). However, the use of b/ts DMARDs is associated with an increased risk of opportunistic infections.
Aims: This study aims to develop a machine-learning model to predict the risk of hospitalized infections following the initiation of b/ts DMARDs in arthritis patients.
Methods: Models were trained on RA patients newly initiated with b/ts DMARDs extracted from the Hong Kong electronic medical records (EMR) database. The primary outcome was hospitalized infection within one year after b/ts DMARDs initiation. Machine learning algorithms, including random forest, neural network, and XGBoost, were adapted to classify patients' risk of infection with performance measured by area under the receiver operating characteristic (AUROC). Predictive features included demographic, co-morbidity, co-medication, and laboratory results. Recursive feature elimination was applied to determine the most predictive set of features. Shapley values were used to explain the contribution of features to model predictions.
Results: In total, we identified 3143 patients newly prescribed with b/ts DMARDs during the study period, of whom 297 have recorded hospitalized infections during the observation period. History of infection, b/ts DMARDs mode of actions, co-prescription of prednisolone, opioid, methotrexate, age, level of red blood cell counts, and C-reactive protein and Hypertension were selected as predictive features. The neural network had the greatest AUROC of 0.76 (95%CI: 0.69-0.83) compared with random forest 0.73 (95%CI: 0.65-0.81) and XGBoost 0.71 (95%CI: 0.63-0.79). Shapley values illustrated that the top three impactful predictive features were history of infection, age, and serum level of C-reactive protein.
Discussion: We developed a predictive machine learning model for b/ts DMARDs-induced infection based on the EMR database. The developed prediction tool will be able to identify high-risk patients and support the early prevention of severe infection among patients with immunocompromised conditions.

[Asthma and COPD]

P112

Development of pulsatile drug delivery system of Bambuterol for treatment of Asthma

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Introduction: Pulsatile drug delivery systems (PDDS) offer advantages over conventional dosage forms by providing delayed, rapid, and instant drug release. This makes PDDS ideal for diseases like bronchial asthma, which has symptoms recurring at night or early morning. This study develops a pulsincap formulation targeting the gastrointestinal tract (GIT) with bambuterol hydrochloride (BHC) to optimize asthma treatment through controlled and targeted drug release.
Aim: To design and develop a pulsatile drug delivery system of bambuterol for treating Asthma.
Methods: Capsules body were treated with formaldehyde to harden them and protect them from fast dissolving, the granules of BHC were prepared by wet granulation method, and they were checked for preformulation evaluation studies. Drug-Excipient study by FTIR, evaluation of prepared DDS analysis including in vitro drug release studies.
Results: FTIR studies confirmed no interaction between the polymer and BHC, indicating component compatibility. Preformulation studies showed good flow properties of the granules. The in vitro release profile of BHC granules revealed rapid drug release, with formulation F6 (20 mg crospovidone) achieving 95.65% release within 15 minutes. The modified pulsincap formulation (F6-P5), with karaya gum and lactose, demonstrated a 5-hour lag time, achieving 91.87% drug release by the 9th hour. This study highlights the potential of BHC granules for effective GIT targeting.
Discussion: The research demonstrates the feasibility and efficacy of utilizing pulsincap technology for the pulsatile delivery of BHC to the GIT, offering a promising avenue for improving asthma management. The findings highlight the significance of lag time in achieving controlled drug release and in optimizing drug formulations for targeted delivery.
Keywords: Pulsin cap, Lag time, Gastrointestinal targeting, Formaldehyde treatment.

P113

Reliever use and asthma control among U.S. adults with asthma, 2007-2020

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- Introduction
Asthma is one of the most common respiratory illnesses in the United States. Patients with poorly controlled asthma may experience symptoms of asthma attacks, such as shortness of breath. In such cases, relievers are used to quickly alleviate patient's symptoms. However, trends in reliever use among adults with asthma have not been well-documented in recent years. Moreover, reliever use may indicate patients' asthma control status.

- Aims
To (1) examine national trends in reliever use and asthma control, and (2) identify characteristics associated with reliever use among U.S. adults with asthma.

- Methods
Data from the 2007-2020 U.S. National Health and Nutrition Examination Survey were used. Adults with asthma aged at least 18 years were included as the study population. Relievers included short-acting beta agonists, short-acting muscarinic antagonists, and inhaled corticosteroid/formoterol. Asthma control was defined by the presence of asthma attacks and emergency room visits for asthma. Joinpoint regression analysis was conducted to evaluate trends in reliever use and asthma control. Multivariable logistic regression models were used to identify factors associated with reliever use.

- Results
From 2007 to 2020, there was a significantly decreasing trend in reliever use (average annual percent change [AAPC], -10.16; 95% CI, -19.35~-3.55). Decreasing trends were also observed in both asthma attacks (AAPC, -1.34; 95% CI, -5.08~2.43) and emergency room visits for asthma (AAPC, -14.64; 95% CI, -30.27~4.11). Several characteristics, including poor asthma control, older age, former and current smoking status, and having health insurance coverage, were associated with increased odds of reliever use among U.S. adults with asthma.

- Discussion/Conclusion
There is a declining trend in reliever use among U.S. adults with asthma, which might be reflected on improvements in asthma control. Disparities in reliever use still exist across several characteristics, highlighting the need for tailored interventions in clinical practice.

P114

Trends in Use of Asthma Inhalers with High Global Warming Potential

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Introduction: In response to the Montreal Protocol and US Clean Air Act, the FDA banned the production and sale of CFC (chlorofluorocarbon) propelled metered-dose inhalers (MDIs) for asthma in the U.S. Manufacturers largely replaced these MD inhalers with hydrofluoroalkane (HFA) propellants or dry powder inhalers (DPIs). HFA inhalers, however, have high global warning potential and DPIs lack this risk. Despite ongoing global efforts to address climate change in the pharmaceutical supply chain, information on the use of asthma HFA and DPI inhalers in the U.S. is not known.

Aims: To examine trends in the use of asthma HFA and DPI inhalers in the U.S.

Methods: We used IQVIAs National Prescription Audit which captures information on all prescriptions filled at retail pharmacies between January 2018 and December 2023 in the U.S. We analyze the total number of fills per month (monthly fill rates) for all HFA and DPI inhalers overall and separately. We also report changes in the market share for HFA products and the number of new HFA (vs. DPI) generic and branded products.

Results: Between January 2018 and December 2023, the total number of monthly prescriptions dispensed at US pharmacies for asthma inhalers increased from 8.7 million fills/month to 10.4 million fills/month ($p<0.001$). This increase was largely due to the growth in the volume (from 6.6 million fills/month to 8.4 million fills/month; $p<0.001$) and share (from 76% to 79%) of HFA inhalers. In fact, the number of DPI inhalers filled per month did not change during this period (~2.1 million throughout).

Conclusion/Discussion: Efforts to strengthen efforts to increase the use of asthma inhalers that do not have a high global warming potential, such as DPIs, are needed in the U.S. Such efforts include the development of more lower emission inhalers and DPI inhalers to promote their use.

[Autoimmune]

P115

Belimumab utilization evaluation at a tertiary hospital in Taiwan

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Introduction:
Belimumab is a B-lymphocyte stimulator-specific inhibitor indicated for adult systemic lupus erythematosus (SLE) or lupus nephritis who are receiving standard therapy of glucocorticoids. It was covered by National Health Insurance (NHI) since the end of 2022 in Taiwan. Individuals under belimumab treatment should be assessed for effectiveness to receive payouts from NHI.

Aims:
To determine if current utilization of belimumab was concordant with clinical guidelines and evaluate the effectiveness and safety.

Methods:
We conducted a single-center, retrospective chart review medication utilization evaluation (MUE). Patients initiating belimumab as an add-on therapy to glucocorticoids from August 5, 2023 to March 31, 2024 were included. Data collection contained patients' basic information, diagnosis, prescription and adverse events related to belimumab. We analyzed the performance of systemic lupus erythematosus disease activity index (SLEDAI), steroid-sparing activity, and adverse reactions, which presented by descriptive statistics.

Results:
Eight patients were included with diagnosis of lupus nephritis from type III to type V. The mean age was 48 years old and 87.5% were female. All patients received 10 mg/kg of belimumab with recommended dosing interval. 50% had SLEDAI reduction at week 15-30, including one achieved disease remission (SLEDAI=0). Those without SLEDAI improvement had shorter follow-up time, ranging from 8 to 12 weeks. No one had change in renal function during the follow-up period. 62.5% had more than 50 % reduction in steroid dose at week 12-36. Among total 51 injections in all patients, four adverse events (infusion-related reaction and edema) occurred in four individuals.

Discussion:
Utilization of belimumab in clinical practice was concordant with guidelines in this evaluation. Belimumab treatment yielded improved outcomes in SLE management and steroids reduction without major adverse events leading to therapy interruption. All patients met NHI payment guidelines during the follow-up period. Long-term evaluation was suggested to increase sample size and complete regimen.

P116

Efficacy of telitacicept in the treatment of SLE: a network meta-analysis

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Introduction:
Telitacicept is developed and marketed in China for systemic lupus erythematosus (SLE), under clinical trials in the US and EU. Evidence on telitacicept efficacy is limited, especially connected with other biologics.
Aims:
To conduct a network meta-analysis, from randomized controlled trials (RCTs) and observational cohort studies, considering studies both in English and Chinese.
Methods:
We searched PubMed and China National Knowledge Infrastructure (CNKI) (updated to April 2024) and selected studies for biologics measuring SLE response index (SRI)-4, at least 24 weeks. Both the initial search and the study selection were performed by 2 researchers.
For study quality, we used Jadad scale for RCTs and Newcastle-Ottawa scale for observational studies. Publication bias was assessed by funnel plot and Egger's test. Pooled ORs of response were calculated by random-effect models. Ranking was assessed by Surface Under the Cumulative Ranking Curve (SUCRA).
Results:
Eighteen studies were included (16 RCTs; 2 telitacicept studies; 16 in English) for 10,837 patients. Two studies had high risk of bias, mainly from lack of blinding. No significant publication bias was suggested (Egger's test p=0.25).
Telitacicept and belimumab ranked the highest (SUCRA: 0.96 and 0.70) for SRI-4 response, followed by atacicept, ustekinumab, sifalimumab, anifrolumab, and rontalizumab (<0.70). Telitacicept (OR 2.16 [1.80, 2.58]), belimumab (1.42 [1.17, 1.71]), atacicept (1.27 [1.08, 1.50]), and sifalimumab (1.28 [1.02, 1.61]) showed significant response versus placebo.
When restricted to studies measuring SRI-4 at 52 weeks (11 studies), the ranking was similar.
Conclusion:
Telitacicept is effective in the treatment of SLE, as proven in direct comparisons but also in this network analysis combining multiple treatment options. It ranked higher than other biologics in terms of SRI-4. This is meaningful given the high prevalence of SLE in China and its association with morbidity and mortality.
Keywords:
Telitacicept, systemic lupus erythematosus, network meta-analysis, efficacy

P117

Forecasting the incidence and prevalence of inflammatory bowel disease in three countries

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Introduction

The global exacerbation of inflammatory bowel disease (IBD) has increased the disease burden and economic impact. Gaps remain in understanding the IBD burden in Asian and Western populations.

Aims

To estimate and compare the current and forecasted 10-year incidence and prevalence of IBD in the US, Japan, and Hong Kong.

Methods

Patients diagnosed with IBD were identified from two large employment-based healthcare claims databases in the US and Japan (2010-2022), and a population-wide electronic medical records database in Hong Kong (2003-2022). We used Autoregressive Integrated Moving Average models to predict incidence and prevalence from 2023 to 2032, stratified by age, sex, and disease subtype, with 95% prediction intervals (PI). The forecasted annual average percentage change (AAPC) with 95% confidence intervals was calculated.

Results

In 2022, the IBD incidence per 100,000 was highest in the US (39.62) compared to Japan (26.48) and Hong Kong (4.68). By 2032, the gap between the US (41.86 [95%PI: 35.65, 48.08] per 100,000) and Japan (39.03) is forecasted to narrow, while remaining substantial with Hong Kong (6.19). The fastest forecasted increase in incidence is among those under 18 in Japan (AAPC: 9.06) and the US (AAPC: 4.43), and among adults aged 18-44 in Hong Kong (AAPC: 5.78). The forecasted 2032 incidence per 100,000 in Japan (male: 44.61, female: 33.07) and Hong Kong (male: 8.90, female: 4.19) is higher for males, with the opposite in the US (male: 40.60, female: 42.96). The forecasted incidence of Ulcerative Colitis in Japan (33.28) will surpass the US (23.57) and far exceed Hong Kong (3.17) by 2032; the incidence of Crohn's Disease is expected to be highest in the US (18.31).

Discussion

The projected burden of IBD is increasing in three countries, displaying distinct patterns across age groups, sex, and disease subtypes. Targeted prevention and treatment measures are essential.

P118

Interaction of Disease Modifying Anti Rhematoid Drugs in A Public District Hospital

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Introduction. Drug-drug interactions (DDIs) due to polypharmacy can lead to detrimental conditions that might interfere therapeutic goals, and increase morbidity and mortality rates and health care costs. Rheumatoid arthritis (RA) is a joint disorder often found as a result of disruption of immune function and patients with it are often prescribed polypharmacy.
Aims. This study aimed to determine the association of potential adverse DDIs between the use of Disease Modifying Anti Rheumatoid Drugs (DMARDs) in RA patients with polypharmacy compared to those without polypharmacy.
Methods. This cross-sectional study was conducted at a District Public Hospital Banjarmasin using data from 2022-2023. Data of potential adverse DDI were inputed into Lexicomp® application and then analyzed by using binomial logistic regression test.
Results. This study showed that 815 drug-drug interactions were found in 95 patients. All prescribed DMARDs were conventional synthetic (n=569). Most of dug interaction was under category D (i.e therapy is considered to modify) by 365 drug pairs (44.79%). A combination of methotrexate and folic acid was most frequently prescibed by 207 times (25.40%) and under category A (no interaction was found) followed by a combination of leflunomide and methylprednisolon by 187 times (22.94%). The later drug might increase immunosupresant effect of leflunomide. Meanwhile, according to the level of severity most of DDIs was moderate by 534 drug pairs (65.52%). 365 (45.34%) of them were potentially harmful, but 450 (54.66%) were not. Polypharmacy was found for 759 (94.29%) drug pairs, while 56 (5.71%) were not. RA patients precribed DMARDs with polypharmacy did not have a significant different event of DDIs compared to those who were not prescribed polypharmacy (crude POR 0.634, 95%CI, 0.367-1.094, p=0.102).
Conclusion. This study demonstrates that there is no significant difference in potential adverse DDIs between DMARDs polypharmacy compared to non-polypharmacy in patients with RA.

[Cardiovascular]

P119

Aspirin for Prophylaxis of VTE: Systematic Review and Meta-analysis of Non-Randomized Studies

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Objective: Aspirin as an agent for thrombo-prophylaxis in patients with Total Hip Replacement (TKR)& Total Knee Replacement (THR) is gaining a lot of importance in preventing Venous Thrombo-embolism (VTE) complications. Current guidelines don't recommend aspirin over other anti-coagulants as the data from the meta-analysis of RCT's lacked a significant sample to draw conclusive results. The present study was aimed to carry out a systematic review and meta-analysis of non-randomized studies (NRS) to determine the effect of aspirin as prophylaxis for VTE.
Methods: A complete electronic search was conducted at PubMed, Cochrane central controlled trial register (CENTRAL), and Google Scholar for relevant articles published till March 2022. All the non-randomized, observational studies that compared the efficacy and safety outcomes pertaining to prevention of VTE between aspirin and other anti-coagulants among THR and/or TKR patients were included in the analysis. Any post-surgical VTE event (DVT and/or PE) is considered the primary outcome and adverse events as secondary outcomes. Both efficacy and safety outcomes were reported as pooled risk estimates with 95% CI with a level of significance at $P < 0.05$. A total of 21 studies were identified for the analysis.
Results: The overall risk of occurrence of VTE among the patients taking aspirin was not significantly different from anticoagulants (RR, 0.78, 95% CI, 0.52-1.15). Patients who underwent THR had a higher risk for VTE with aspirin (RR, 1.50, CI 95%, 1.35-1.61), while the patients who underwent TKR showed a lower risk of VTE with Aspirin (RR 0.80, CI 95%, 0.75-0.85).
Conclusion: Meta-analysis of NRS advocates the role of Aspirin as a prophylactic agent for VTE, especially for patients who are in need for TKR. Further RCT's are required to re-establish the role of aspirin especially in patients undergoing THR.

Key words: Aspirin, Anti-coagulants, VTE prophylaxis, THR/TKR

P120

Association between antihypertensive types and hospital stay and mortality in stroke patients

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Introduction: Hypertension is one of the risk factors for stroke, and antihypertensive agents are administered to improve outcomes in ischemic stroke patients. Appropriate use of antihypertensive types in ischemic stroke may influence stroke morbidity and mortality.
Aim: This study aimed to determine the association between the type of antihypertensive agents and the length of hospital stay and mortality in ischemic stroke patients.
Methods: The research method employed was retrospective cohort, conducted on ischemic stroke patients treated in a public hospital in Banjarmasin, South Kalimantan, Indonesia, who received antihypertensive therapy during 2018-2021. The independent variable was the type of antihypertensives, while the dependent variables were the length of hospital stay and mortality. Age, gender, education level, and comorbidities were considered as confounding variables. The association between independent variables and the length of hospital stay was analyzed using linear regression, while logistic regression was used to analyze their relationship with mortality.
Results: The study included 175 subjects, predominantly aged 18-64 years (64.6%), male (54.3%), and with low education level (41.7%). The type of antihypertensives used were combination antihypertensives (40.6%), CCBs (21.7%), ACEIs (6.9%), ARBs (25.7%), and beta-blockers or diuretics (5.1%). Administration of beta-blockers or diuretics significantly increased the risk of mortality (RR 6.30, 95% CI 1.40-28.42, p = 0.02). Higher education (regression coefficient -3.83, 95% CI 7.102-(-0.565)) and comorbidities (-3.30, 95% CI 6.59-(- 0.01)) influenced the association between the type of antihypertensives and the length of hospital stay. \
Conclusion: The type of antihypertensives is associated with mortality in ischemic stroke patients, and higher education level and comorbidities affect the association between the type of antihypertensives and the length of hospital stay in ischemic stroke patients.

P121

Blood pressure variability and risk of cardiovascular events in real-world clinical settings

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Introduction: Clinical trials and cohort studies reveal that elevated visit-to-visit variability in blood pressure (BP) is associated with an increased risk of cardiovascular events and poor outcomes. However, the real-world applicability of long-term BP variability measurements remains underexplored.
Aims: To evaluate the association of visit-to-visit BP variability collected from regular outpatient settings with the risk of cardiovascular events and all-cause mortality in an unselected patient population.
Methods: In this retrospective cohort study at a large academic medical center in Taiwan, we calculated variability independent of the mean (VIM) and average real variability (ARV) of BP using electronic health records of 16,945 adults with at least one outpatient BP measurement in three consecutive years from 2012 to 2017. The association of BP variability with the risk of cardiovascular events and all-cause mortality through 2020 was assessed using Cox proportional hazard models.
Results: Over a median follow-up of 4 years, 317 patients experienced cardiovascular events, and 582 died. The adjusted hazard ratios (HRs) for cardiovascular events increased gradually across both VIM and ARV quartiles of BP. The adjusted HRs (95% CIs) per interquartile range increase in systolic BP variability were 1.24 (1.09-1.41) for VIM and 1.11 (1.01-1.23) for ARV. For diastolic BP, the HRs (95% CIs) were 1.22 (1.09-1.36) and 1.13 (1.02-1.24), respectively. Similar results were observed for all-cause mortality, except a weaker association with ARV of diastolic BP (HR: 1.08, 95% CI: 0.99-1.17). The association between VIM of BP and risk of cardiovascular events was consistent across patient subgroups, even in those with BP levels currently considered to be the normal range.
Discussion: Our findings support the practicality of incorporating BP variability measures, which is readily available from regular outpatient settings, into real-world practice. Further investigations are needed on how antihypertensive treatments affect BP variability and cardiovascular outcomes.

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Cognitive Impairment Among Patients with Cardiovascular Diseases: Comparisons of Sex, Elderly, Education

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Introduction/Aims: Evidence showed the relationship between cognitive impairment and cardiovascular diseases (CVD), but few studies used the Montreal Cognitive Assessment (MoCA) to assess cognitive impairment. MoCA was validated and designed to detect mild impairment with higher sensitivity. This study aimed to determine the cognitive impairment and compare between sex, the elderly, and education level.
Methods: This cross-sectional study was conducted among patients with CVD at a teaching hospital in northern Thailand. Cognitive impairment was evaluated by interviewing patients using the MoCA as a tool, with MoCA score <25/30 classified as cognitive impairment.
Results: Of 113 patients (52% male, mean age of 63±14.9 years), the prevalence of impaired cognitive function among patients with CVD was 78.8%, 95% confidence interval (95% CI): 70.06-85.89. The prevalence did not differ by sex but differed by age and education. Older patients were more likely to have cognitive impairment than younger ones (≥65 years, 87.3% vs. <65 years, 70.7%; OR, 2.84 (95% CI: 1.07-7.53). Patients with low education were higher in cognitive impairment (primary school or lower, 86.2% vs. higher than primary school, 58.8 %; OR, 4.36 (95% CI: 1.63-11.61).
Discussion/Conclusion: Four-fifths of CVD patients had cognitive impairment, which was not sex-dependent but age and education-dependent. Our findings suggest the need for routine cognitive screening in patients with CVD.

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Combination therapy with sacubitril/valsartan and SGLT2 inhibitors for HFrEF with renal dysfunction

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Introduction: Previous trials have highlighted the renal benefits and overall effectiveness of sacubitril/valsartan (S/V) and sodium-glucose cotransporter 2 inhibitors (SGLT2i) in patients with heart failure with reduced ejection fraction (HFrEF) and chronic kidney disease (CKD). However, concerns have been raised about the limited applicability of these findings in clinical practice due to the relatively small number of CKD patients included in previous studies. Furthermore, there is a lack of research investigating the combined use in HFrEF patients with an eGFR below 30 mL/min/1.73 m².

Aims: We attempted to develop a model which allows us to investigate the feasibility of the optimal combination therapy across the spectrum of time-varying eGFR, specifically levels below 30 mL/min/1.73 m², and to identify the strengths of—and barriers in putting into practice—the combination therapy with S/V and SGLT2i, among real-world patients with HFrEF and CKD.

Methods: We developed a time-varying prediction model based on data retrospectively extracted from electronic health records at the National Taiwan University Hospital, with interaction terms where eGFR levels were stratified with S/V and SGLT2i. The cohort comprised 501 patients initially prescribed S/V between March 2017 and January 2020. We identified critical predictors within the time-dependent Cox regression framework using a stepwise variable selection procedure with a penalized smoothing spline method.

Results: The model—which identified 43 critical predictors—revealed that such usage was associated with enhanced survival rates in patients with HFrEF, particularly those with an eGFR below 30 mL/min/1.73 m². Maintaining a cumulative daily dosage of 180-mg S/V with SGLT2i treatment for at least three months was associated with reduced mortality. Notably, this observed benefit did not seem to be counteracted by a decline in eGFR.

Conclusion: The combination therapy using S/V and SGLT2i demonstrates promising potential in improving survival outcomes among patients with HFrEF, particularly those with compromised renal function.

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Comparative Cardiovascular Safety of Anti-Calcitonin Gene-Related Peptide Monoclonal Antibodies Versus OnabotulinumtoxinA

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Introduction: Monoclonal antibodies targeting calcitonin gene-related peptide (CGRP) or its receptor (anti-CGRP-mAbs) have emerged as promising treatment for migraine prevention. Yet, concerns remain regarding their cardiovascular safety related to blocking CGRP. There has been no comprehensive investigation into the cardiovascular safety of anti-CGRP-mAbs, particularly in high-risk populations such as the elderly and disabled.

Aims: To compare the incidence of cardiovascular diseases (CVD) between Medicare beneficiaries with migraine who initiated anti-CGRP-mAbs versus OnabotulinumtoxinA in the United States.

Methods: In this retrospective sequential cohort study, we examined a 15% national sample of fee-for-service beneficiaries in Medicare claims data from May, 2018 to December, 2020. The study included beneficiaries with migraine initiating anti-CGRP-mAbs or OnabotulinumtoxinA. We excluded those with pre-existing myocardial infarction (MI), stroke, cluster headache, or malignant cancer within the year prior to treatment initiation. To mitigate biases from new drug introductions and COVID-19 pandemic, we divided patients into five cohorts, each covering a sequential six-month period based on the treatment initiation date. We used inverse-probability-of-treatment-weighted Cox proportional hazards models to estimate the adjusted hazard ratio (aHR) of time to the first composite CVD event (MI or stroke). Secondary outcomes included hypertensive crisis, peripheral revascularization, and Raynaud's phenomenon.

Results: The study identified 5,153 anti-CGRP-mAb initiators (mean±SD age=57.8±14.0 years; female=83.6%; White=82.2%) and 4,000 OnabotulinumtoxinA initiators (age=61.9±13.7 years; female=83.8%; White=83.8%). Covariates were well-balanced between the groups. Anti-CGRP-mAbs were not associated with increased risks of composite CVD events (aHR=0.88, 95%CI=0.44−1.77), hypertensive crisis (aHR=0.46, 95%CI=0.14−1.55), peripheral revascularization (aHR=1.50, 95%CI=0.48−4.73), or Raynaud's phenomenon (aHR=0.75, 95%CI=0.45−1.24) compared to OnabotulinutoxinA. Subgroup analyses by age group or presence of established CVD (except MI and stroke) yielded consistent results.

Discussion/Conclusion: Despite initial concerns regarding the elevated CVD risk associated with CGRP blockade, our findings suggest no increased CVD risk among anti-CGRP-mAb users compared to OnabotulinumtoxinA users in Medicare beneficiaries with migraine.

P125

Different potency of statin on major adverse cardiovascular events among Taiwanese patients

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-Introduction Statin treatment has proved to be cardioprotective (e.g., lowering incidence of major adverse cardiovascular events [MACE]) compared with non-treatment. However, few evidence regarding the effectiveness of different potency of statin on MACE exist, with inconsistent findings among patients with atherosclerotic cardiovascular disease patients (ASCVD) reported.
-Aims This retrospective cohort study aimed to evaluate comparative effectiveness of high/moderate- versus low-potency of statin on preventing MACE in patients with ASCVD.
-Methods 14,748 ASCVD patients with any statin prescriptions from 2014 to 2017 were identified from the electronic health records of National Cheng Kung University Hospital in Taiwan. Statin users were categorized into high/medium-potency or low-potency groups, with a 3: 1 propensity-score matching applied for these two groups in order to ensure between-group comparability at baseline. Study outcomes included MACE and individual components (i.e., ischemic stroke, non-fatal myocardial infarction [MI]). Cox proportional hazard model analyses were performed to assess the cardiovascular risk (e.g., MACE) with statin exposure (i.e., high/medium- vs. low-potency). All analyses were separated for incident new and stable (i.e., having at least chronic prescription refill or two consecutive prescriptions with a gap<7 days) statin users.
-Results Compared with low-potency statin, the use of high/medium-potency statin was associated with insignificantly increased MACE risk (i.e., hazard ratio [HR], 95% confidence interval [CI]: 1.53 [0.86-2.75]) among statin new users, but not stable users (0.97 [0.64-1.48]). Moreover, the stable use of high/medium statin was associated with an insignificantly decreased stroke risk (0.640 [0.36-1.15]) but increased risk in new users (1.28 [0.63-2.58]). A trend of increased MI risk with use of high/medium- versus low-potency statin was observed in both new and stable users (2.35 [0.89-6.26], 1.46 [0.81-2.64]).
-Discussion/Conclusion Different potency of statin might not affect the risk of development of MACE. Future large-scale studies from other countries or races/ethnicities are warranted to corroborate our findings.

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Epidemiology of Worsening Chronic Heart Failure: A Population-based Retrospective Cohort Study

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Introduction: Chronic heart failure (HF) represents a spectrum of disease states, including periods of stability or worsening. Worsening chronic heart failure (WCHF) occurs when patients with HF experience deterioration marked by hospital readmissions, emergency department visits, or heightened treatment needs.
Aims: The study aimed to characterize the epidemiology, clinical features, and outcomes of Asian patients with WCHF, and to explore the heterogeneity within this group in terms of demographics, clinical parameters, and management.
Methods: From January 1, 2005 to September 30, 2022, adult patients with HF were included in the WCHF cohort due to HF-related hospital readmission, emergency department (ED) visits, or intravenous diuretic treatment at the outpatient department beyond a 90-day interval following index HF event. Baseline data including demographics, comorbidities, and medication were compared between WCHF and non-WCHF patients. Outcomes assessed included all-cause mortality, HF readmission, and acute care encounters.
Results: Among 12,637 HF patients, 2,326 were categorized into WCHF group. Patients with WCHF were older (77.7 vs. 74.8, P<0.001), with lower body mass index (23.2 vs. 23.6, P=0.003), and reduced left ventricular ejection fraction (57.4% vs. 58.9%, P<0.001). During a median follow-up of 1.5 years, WCHF patients had higher risks of all-cause death or HF readmission (adjusted hazard ratio [aHR], 4.64; 95% CI 4.29-5.02; P<0.001), first HF acute care encounter (aHR, 9.57; 95% CI 8.72-10.51; P<0.001) and first all-cause readmission (aHR, 2.14; 95% CI 2.03-2.26; P<0.001) compared to patients without WCHF. Among HF patients with reduced ejection fraction (HFrEF), WCHF subjects were more likely to received more guideline-directed medical therapy (GDMT) (75.8% vs. 47.6%, P<0.001).
Discussion: This population-based cohort study conducted in Asian patients demonstrated that patients with WCHF exhibited poorer prognosis and higher healthcare resource utilization. But there was a discernible deficit in the utilization of GDMT among all HFrEF patients.

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Epidemiology, characteristics, and prognosis of heart failure with partial improved ejection fraction

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Introduction:

A subset of patients diagnosed with heart failure (HF) with reduced ejection fraction (HFrEF) demonstrate partial improvement in left ventricular ejection fraction (LVEF). However, there is limited information on the epidemiology, clinical characteristics, and prognosis for these patients with HF exhibiting partially improved ejection fraction (HFpimpEF). Understanding these aspects is crucial for optimizing patient management and outcomes.

Aims:

The main objective of this study was to comprehensively assess the epidemiological aspects, clinical features, and prognosis of patients with HFpimpEF.

Methods:

Among 3,691 adults with HF who had two LVEF echocardiograms at least three months apart in Yinzhou District, 350 were initially categorized as HFrEF (LVEF ≤40%). These were further classified into subtypes: persistent HFrEF (pHFrEF) (LVEF ≤40%), HFpimpEF (LVEF 41-49%, improvement <10%), and HF with improved ejection fraction (HFimpEF) (LVEF >40%, improvement ≥10%). The primary outcome was all-cause death or first HF-related readmission.

Results:

During a median follow-up of 15.6 months, 62 (17.7%) patients were classified as HFpimpEF. Using multivariable Cox models, HFpimpEF demonstrated a lower risk of readmission or death compared to pHFrEF after adjustments (adjusted hazard ratio: 0.55; 95% CI, 0.31-0.96; P=0.037).

Discussion:

Given its unique clinical presentation, HFpimpEF should be recognized as a distinct HF subtype. This subtype is characterized by partial improvement in LVEF and generally has a more favorable prognosis compared to pHFrEF. These findings underscore the importance of identifying and managing HFpimpEF as a separate entity to improve patient outcomes.

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Evaluation of Clinical Characteristics and 90-day Outcomes amongst Heart Failure Patients: Insights from a Tertiary-care Hospital Settings

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Introduction. Heart Failure (HF) is a chronic, multi-faceted, life-threatening condition that has become a major global public health concern.
Aims. To assess clinical characteristics, prescribing patterns, and 90-day clinical outcomes of patients with HF.
Methods. A six-month prospective cohort study was carried out with HF patients aged ≥ 18, of any sex, in New York Heart Association (NYHA) Class I-III with LVEF ≤ 40% to > 50%, at a tertiary-care hospital's Cardiology department. After consenting, their complaints, past medications, and current treatments were recorded. Data were analysed using frequencies, percentages, and linear regression to identify outcome predictors.
Results. A total of 84 patients (75% male, 25% female, mean age 60.08 ± 10.11 years), 94% had heart failure with reduced ejection fraction (HFrEF), with 44% de-novo, and 48% in NYHA class III were enrolled in the study. Hypertension (HTN) and type 2 diabetes mellitus (T2DM) were prevalent comorbidities (67% and 54%, respectively). 35% were hospitalized for ischemic heart disease (IHD) and 12% for dilated cardiomyopathy (DCM). Of 685 prescribed medications (average 8.2 per patient, mean 10.54), only 37% were guideline-directed medical therapy (GDMT), with β-Blockers (89%), sodium-glucose cotransporter-2 (SGLT2) inhibitors (68%), angiotensin receptor-neprilysin inhibitors (ARNI) (67%), and mineralocorticoid receptor antagonists (MRA) (50%) most prescribed. The 90-day mortality was 2%, with a 10% readmission rate for acute decompensated heart failure (ADHF) and an average hospital stay of 4.46 ± 1.60 days. Ischemic heart disease emerged as a significant predictor for 90-day outcomes (β = 0.503 [0.113-0.573], p = 0.004).
Conclusion. IHD is one of the predictors implicating heart failure in the study cohort. The 90-day mortality was two in every ten patients and the majority of the management did not comply with GDMT, which demands drug therapy optimization in anticipation of improved clinical outcomes.
Keywords: Heart failure, Ischemic heart disease, Guideline-directed medical therapy, Acute decompensated heart failure.

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Identification of Drug-related Problems Associated with Stroke Management: A Hospital- based Observational Study

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Aims. The study aimed to identify the drug-related problems (DRPs) in patients diagnosed with stroke.
Methods. A single-center, hospital-based, prospective, observational study was carried out in the Departments of Mahavir Trauma Hospital for 6 months. Patients aged above 18 years, irrespective of any gender and diagnosed with both hemorrhagic & ischemic stroke were enrolled in the study. We followed them up till discharge.
Results. A total of 105 patients [78(74.28%)], males; 27(25.71%), females] were studied. The study population aged 41-70 years [53(50.47%)] were highly prevalent of stroke. The majority of the patients were diagnosed with ischemic stroke [66(62.85%)], followed by diagnosed with hemorrhagic stroke [39(37.14%)]. Of them, [14(13.33%)] patients had a history of stroke. Among them, 16 patients were measured with homocysteine level where [4(25%)] patients had a high level of homocysteine. A total of 91 different medications were used amongst patients, where most commonly prescribed medications include Levetiracetam [63(60.00%)], Cephalosporins [57(54.52%)], Aspirin [46(43.80%)], Enoxaparin [45(42.85%)], Labetalol [24(22.85%)] and Mannitol [37(35.23%)]. A total of 80 DRPs were found in patients which includes omission of therapeutic monitoring [18(17.14%)], followed by, administration error [16(15.23%)], drug-drug interactions [15(14.28%)], dispensing error [12(11.42%)], prescription error [10(9.52%)], adverse drug reactions [7(6.66%)], drug-food interactions [1(0.95%)] and omission error [1(0.95%)]. The most commonly observed ADRs were Mannitol induced hypotension and dry mouth. The survival rate of study participants was 72%.
Conclusion. This study helped to identify the rate and patterns of DRPs affecting the clinical outcomes of patients diagnosed with different clinical sub-types of strokes. It is believed that early detection of DRPs may improve the therapeutic outcome and survival rate of the stroke patients.

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Knowledge, Attitude & Practice of Patients Toward Cardiovascular Disorders Attending the Out-Patient Department of Cardiology

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Aims. To assess the level of knowledge, attitude, and practice (KAP) of patients toward cardiovascular diseases (CVDs) attending the Out-patient Department (OPD) of Cardiology during the study period.
Methods. A hospital-based, cross-sectional study was carried out at the OPD of Cardiology for 4-weeks. A 36-item questionnaire about the risk factors and preventive strategies of CVDs was developed, validated (Cronbach's alpha for reliability test is 0.87), and generated for participants aged ≥ 18 years. Chi-square test was used to compare categorical data and Multinomial logistic regression was used to identify the factors influencing knowledge, attitude, and practice level.
Results. A total of 112 patients [75% males, 25% females] with a mean age of 58.96 ± 13.38 years participated in the study. Out of them, 71% came from rural areas, and 40% belonged to the lower middle class of socio-economic status. The majority [102 (91%)] of the participants were diagnosed with ischemic heart disease (IHD). All three KAP scores were of poor to excellent levels. The overall knowledge score was poor [78.57%], attitude and practice scores were excellent [82.14%], and [83.93%], respectively. The CVD knowledge, attitude, and practice mean scores amongst CVD patients were 9.79 ± 5.28, 4.38 ± 1.64, and 7.12 ± 1.80, respectively. There was a significant association found between marital status and knowledge level , socioeconomic status and attitude level, and age and practice level. In Multinomial logistic regression analysis, male gender (p = 0.019) and unmarried (p = 0.000) participants were significantly associated with high attitude scores.
Conclusion. The attitude and practice level amongst the participants were adequate, but the knowledge level was poor. Therefore, there is a necessity to target specific populations with tailored health education programs regarding lifestyle modification, and reduction of risk factors associated with CVDs to ameliorate the level of knowledge.

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Long-term use of beta-blocker therapy after myocardial infarction

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Introduction: Beta-blocker (BB) therapy has been considered a cornerstone in cardiovascular disease management for years. Initially renowned for its efficacy in reducing mortality and morbidity post-myocardial infarction, contemporary evidence presents a more contradictory scene. While historical data strongly supported BB therapy's benefits, recent observational studies and randomised controlled trials (RCTs) reveal conflicting results.
Aims: This review aims to summarise and compare the existing evidence from the pre-reperfusion era and modern practice on BB therapy on different health outcomes.
Methods: a State-of-the-Art Review was performed by searching the grey literature for clinical guidelines in US, Europe, and Australia on post-MI management. The most influential randomised clinical trials (RCTs) conducted in the pre-reperfusion era were searched using CENTRAL database (1960-1980) and the current evidence was searched using CDSR, Embase, and Medline (2014 to the present).
Results: Real-world evidence, RCTs, and meta-analyses offer inconsistent conclusions regarding BB therapy's long-term effectiveness, especially in patients with preserved left ventricular ejection fraction (LVEF). Methodological limitations, such as selection bias, and heterogeneity concerning inclusion and exclusion criteria, complicate the interpretation of results. Consequently, contemporary guidelines vary in their recommendations reflecting the uncertainty surrounding BB therapy's role in modern cardiovascular care.
Conclusion: Although BB therapy has been a fundamental part of secondary prevention post-MI for decades, current evidence suggests that its long-term effectiveness in improving health outcomes is inconclusive in patients with preserved LVEF. Additionally, many questions remain unanswered that require further investigation to reach a consensus on BB therapy’s effectiveness post-MI. The possibility of discontinuing BB use in patients where there is no clear benefit could reduce polypharmacy, improve medication adherence, and lower the overall burden on patients and the healthcare system. This may simplify treatment regimens, minimise side effects, and decrease healthcare costs associated with unnecessary medications.

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Lower Limb Amputation Association with Sodium-Glucose co-Transporter-2 inhibitors: Systematic review and Meta-Analysis

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Sodium-Glucose-Cotransporter-2 Inhibitors (SGLT-2i) were approved for management of type II Diabetes Mellitus (DM II), heart failure, and chronic kidney disease. In patients with DM II, positive association of Lower Limb Amputation (LLA) among diabetic patients was shown in many meta-analysis studies but were highly sensitive to the exclusion of CANVAS Program studies. In non-diabetic patients, there were few Randomized Controlled Trials (RCTs) that reported LLAs but did not indicate a significant association.

To conduct a comprehensive systematic review and meta-analysis of RCTs to assess association of SGLT-2i and the risk of LLA regardless of the indications.

We performed a systematic search within CENTRAL, PubMed, Embase, and Google scholar databases from inception to April 31st, 2024. RCTs comparing SGLT-2i to placebo or active control were included. The primary outcome was incidence of LLA. Two authors extracted the data independently from each eligible study then crosschecked. Any discrepancies were resolved by consensus. Publication bias was assessed using forest plot. Comprehensive Meta-Analysis software (version 3.0) was used for analysis.

A total of 20 studies reporting LLA were included. Most studies reported a follow-up period of 6 months to 4 years. Due to high heterogeneity (I2>50%), a random effect meta-analysis model was performed. No significant difference in incidence of LLA between SGLT-2i users compared to the control groups regardless of the indication (OR, 1.26 [95% CI, 0.98-1.6]). In addition, the stratification by diabetes status; diabetic (OR, 1.32 [95% CI, 0.99-1.79]) versus non-diabetic (OR, 1.07 [95% CI, 0.77-1.49]) yielded similar results.

No significant difference in the incidence of LLA between SGLT-2i users and non-users was observed. The positive associations shown in previous studies were highly sensitive to the exclusion of CANVAS program studies that lack adjudication committee for LLA assessment. Due to limited studies included, results in non-diabetic patients should be interpreted with caution.

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Outcomes of PCSK9 Inhibitors users with ASCVD: a cohort study in China

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Introduction
Despite evidence from clinical trials, real-world clinical evidence on the effects of PCSK9 inhibitors on LDL-C and cardiovascular events is lacking.
Aims
To investigate the impact of PCSK9 inhibitors compared with other lipid-modifying drugs on LDL-C changes and MACE in patients with ASCVD.
Methods
A retrospective cohort study using electronic health records from The Hong Kong University - Shenzhen Hospital identified ASCVD patients with high LDL-C levels (≥2.6 mmol/L) on PCSK9 inhibitors, statins, or ezetimibe between 2015 and 2023. Using a prevalent new-user cohort design, PCSK9 inhibitor and other lipid-modifying drug users (statin or ezetimibe) were matched 1:2 based on time-conditional propensity scores. Entry into the study cohort was the date of the first PCSK9 inhibitor prescription or the corresponding physician visit for the reference group. Patients were followed for mortality and MACE (composite of cardiovascular mortality, myocardial infarction (MI), stroke, and heart failure (HF) hospitalization). LDL-C levels before and after the entry date were analyzed, and associations between PCSK9 inhibitors and MACE were assessed using adjusted Cox regression analyses.
Results
A total of 1,305 PCSK9 inhibitor users and 65,156 on statin or ezetimibe users were identified. Mean LDL-C levels in the PCSK9 inhibitor users changed from 3.10 (IQR: 2.23 to 3.85) to 1.48 (IQR: 0.79 to 1.95), while in the statin/ezetimibe users, levels changed from 3.26 (2.54 to 3.99) to 2.06 (1.41 to 2.52). 57% of PCSK9 inhibitor users and 32% of statin/ezetimibe users had an LDL-C reduction of 50% or more. Hazard ratios (HR) for the PCSK9 inhibitors users were: MACE, 0.848 (0.406–1.773); MI, 1.200 (0.200–7.188); stroke, 0.341 (0.058–2.012); HF, 0.557 (0.150–2.073); and all-cause mortality, 0.424 (0.078–2.309).
Conclusions
Patients on PCSK9 inhibitors had a greater reduction in LDL-C levels compared to those on statin or ezetimibe therapy. Effects on MACE, MI, stroke, HF, and mortality were nonsignificant.

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Prescription Patterns of Lipid-lowering Therapies in Patients with Atherosclerotic Cardiovascular Disease (ASCVD)

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Introduction. Lipid lowering therapy (LLT) is important to treat atherosclerotic cardiovascular disease (ASCVD).
Aims. To evaluate the prescription pattern of LLTs and identify the percentage of patients with ASCVD who have achieved target LDL-cholesterol levels based on various guidelines such as, ESC, ACC/AHA, and LAI guidelines.
Methods. A hospital-based, prospective study was conducted in the OPD of Cardiology from January 2024 to March 2024. Participants with a known history of ASCVD of either gender, aged ≥ 40 years receiving statin therapy, were enrolled in the study. The patients receiving statin therapy with baseline lipid profile records and completed 1 month of follow-up were analyzed.
Results. A total of 108 eligible patients (70% males, 30% females) with a mean age of 61.21±10.1 years were studied. Hypertension (HTN) and type-II diabetes mellitus (T2DM) were prevalent comorbidities (81% and 43%, respectively). The body mass index (BMI) of majority of the study population (57%) ranged from 25.0-29.9 kg/m2 i.e., overweight with an average BMI of 26.6 ± 3.31kg/m2. ASCVD patients' average baseline LDL-cholesterol levels was ranged 88.81 ± 33.3 mg/dL. Of 666 prescribed medications (average 6.1 per patient), 100% received statins, followed by 44% received Ezetimibe monotherapy or combination therapy, 14% received Bempedoic acid, and 4% received fibrates. On one-month of follow-up patients' average LDL-C level was 71.7 ± 16.5 mg/dL and non-HDL-C was 84.5 ± 18.3 mg/dL . According to the ACC/AHA and ESC guidelines for very high-risk patients having pre-existing ASCVD, non-HDL-C goal (< 100 mg/dL) was achieved after one month.
Conclusion. There is an utmost need to optimize the prescribing patterns of LTTs to attain the LDL-C goals according to the standard guidelines. Strategies to manage other comorbidities and counselling for lifestyle modification are the need-of-the-hour to minimize the risk of further events and ensure the patient safety.

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Prescription patterns of oral anticoagulants in older adults with atrial fibrillation

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Introduction: The prevalence of oral anticoagulants (OACs) in older adults with atrial fibrillation (AF), especially those on long-term care (LTC), is unclear.
Aims: To evaluate the trend of prescriptions of OACs in older adults in Japan.
Methods: This population-based study based on medical and LTC claims data obtained from Hachioji city, Tokyo, included participants aged ≥75 years, with recorded diagnoses of AF, and without recorded diagnoses of valve diseases or venous thromboembolism. Prescriptions of OACs were evaluated between during a 3-month period (from September to November) from 2014 to 2019, overall and by LTC needs (categorized into 4 groups: no LTC needs certification, support levels, care levels 1 and 2, and care levels 3 to 5).
Results: In 2019, among 3,574 participants (mean 83 years and 44% women), one-third (38%) were certified with their LTC needs, including 9% having care levels 3 or higher. The prevalence of OACs from 2014 to 2019 increased from 56% to 71% in overall and 49% to 71% in participants with care levels 3 or higher, respectively. In 2019, the prevalence of OACs (70% to 72%) was similar across different LTC needs. The proportion of participants receiving direct oral anticoagulants (DOACs) in those receiving OACs increased from 42% in 2014 to 84% in 2019, and in 2019 the proportion was not varied by LTC needs (81% to 86%).
Discussion: This study demonstrated that the increased prescriptions of OACs in older adults with AF, including those with high levels of LTC needs, which might be attributed to the increased use of DOACs. The results should be carefully interpreted by the possibility of differences in recording of AF diagnosis by year and LTC needs. Further evidence on benefit and risk assessment of OACs in this vulnerable population is needed for medication optimization.

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Real-World Characteristics, Treatment Patterns, and Outcomes in Patients with ASCVD in China

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Introduction:
Atherosclerotic cardiovascular disease (ASCVD) imposes a significant burden on the healthcare system in China. The analysis of lipid-lowering therapy in patients with ASCVD aims to provide evidence-based support for rational clinical drug use and relevant policy formulation.
Aims:
To analyze the characteristics, treatment patterns, and outcomes of ASCVD patients in China, focusing on the use of statins and PCSK9 inhibitors (PCSK9i).
Methods:
This retrospective study utilized electronic healthcare records from Jiangsu Province. Patients were included if they had ≥ 2 statin prescriptions or ≥ 1 PCSK9i prescription with an ASCVD diagnosis from July 31, 2018, to September 30, 2023, and were older than 18 years at first drug initiation. LDL-C follow-up trends and 95% confidence intervals (CI) were calculated. Patient demographic, clinical, and healthcare utilization characteristics were summarized using descriptive statistics.
Results:
The study included 86,789 patients (69,101 in the statin cohort and 17,688 in the PCSK9i cohort). The average age was 62.2 years (SD 11.44), with 38.3% of the statin cohort and 44.2% of the PCSK9i cohort being female. Patients in the PCSK9i cohort had higher outpatient visits (8.69 ± 12.99 vs. 7.10 ± 10.73) and inpatient admissions (1.42 ± 1.10 vs. 1.30 ± 1.10) compared to the statin cohort. Baseline LDL-C levels were 3.33 mmol/L (SD 1.12) in the PCSK9i cohort and 3.35 mmol/L (SD 1.10) in the statin cohort. Post-treatment, LDL-C levels in the PCSK9i cohort reduced to a median of 1.33 mmol/L (mean: 1.52 mmol/L), with a relative reduction of 56.3% (95% CI 49.7% to 56.3%), maintained over time.
Discussion:
Patients initiating PCSK9i treatment had more severe health conditions and higher healthcare utilization compared to those on statins. The effectiveness of PCSK9i underscores the importance of its use alongside other lipid-lowering therapies in ASCVD management.

P139

Risk of cancer comparing warfarin and direct oral anticoagulants

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Introduction: Previous evidence suggests a potential protective effect of warfarin against cancer, compared to non-users. However, it may be prone to immortal time bias and residual confounding.
Aim: To investigate the association between warfarin and hazard of cancer (any cancer and 16 most common site-specific cancers including female breast, prostate, colorectum, lung, bladder, stomach, oesophagus, non-Hodgkin lymphoma, leukaemia, ovary, pancreas, multiple myeloma, uterus body, brain and central nervous system, liver, and kidney) using a new-user active-comparator (direct oral anticoagulants [DOACs]) cohort design.
Methods: We conducted studies using population-based databases from England and Hong Kong (HK). People with atrial fibrillation aged ≥18 years who had first anticoagulant treatment during study period (2011.01.01-2019.12.31) were involved.
Results: Compared with DOAC use, an increased hazard of overall cancer was found in warfarin users (hazard ratio [HR] 1.09, 95% confidence interval [CI] 1.01-1.18) in England; however, no evidence supported such association in HK (HR=0.89, 95%CI=0.79-1.01). For site-specific cancers, increased hazard of colorectal cancer was observed in warfarin users versus DOAC users in England (HR=1.22, 95%CI=1.03-1.46) but not in HK (HR=1.08, 95%CI=0.81-1.44); lower hazard of female breast (HR=0.49, 95%CI=0.30-0.80), ovarian (HR=0.07, 95%CI=0.01-0.58), and pancreatic (HR=0.45, 95%CI=0.22-0.94) cancers and a higher hazard of kidney cancer (HR=3.53, 95%CI=1.62-7.69) were found, comparing warfarin with DOACs in HK, but not in England.
Conclusions: This study does not find protective effect of warfarin against cancer versus DOACs. The risks of site-specific cancers including colorectal, pancreatic, kidney and sex-specific cancers between oral anticoagulants may require further investigation in other independent datasets.

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Risk of Stroke Associated with NSAID among Osteoarthritis Patients with Atrial Fibrillation

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Introduction

A great amount of studies imply that the NSAIDs（non-steroidal anti-inflammatory drug）including COX-2 inhibitors（selective inhibitors of cyclooxygenase-2）and traditional NSAIDs are related to higher risk of vascular events such as myocardial infarction, thromboembolism and stroke. In addition, atrial fibrillation may also increase the opportunity to cause vascular events. Stroke would lay a serious burden on medical care system. Consequently, establishing the safety profile of NSAIDs is necessary.

Aims

This study aims to clarify the association between risk of ischemic stroke and use of non-aspirin NSAIDs in osteoarthritis (OA) patients with non-valvular atrial fibrillation.

Methods

A retrospective cohort study is devoted on the analysis of Taiwan National Health Insurance Database. Persons were eligible if they had diagnosis for OA with atrial fibrillation. A total of 3826 patients were included in the study. The endpoint was defined as ischemic stroke. The hazard ratio (HR) and 95% confidence interval of outcomes were calculated by cox regression models.

Results

In demographic analysis, diclofenac accounted for 28.5% and celecoxib accountd for 13.5% among all NSAIDs prescriptions in user group. Compared to non-user, some drugs were associated with increased risk of ischemic stroke such as etoricoxib (adjHR=1.897; 95%CI=0.682-5.281), diclofenac (adjHR=1.462; 95%CI=0.837-2.553), meloxicam (adjHR=1.111; 95%CI=0.63-1.958), ibuprofen (adjHR= 1.497; 95%CI= 0.365-6.152). Especially, celecoxib (adjHR=1.879; 95%CI=1.003-3.522) show higher and statistically significant risk of ischemic stroke.

Discussion/Conclusion

Our study finds that in OA patients with non-valvular atrial fibrillation, celecoxib was related to higher risk of ischemic stroke. In contrast, naproxen was associated with decreased risk. Further research is needed to clarify the relationship between NSAIDs and ischemic stroke risk.

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Sodium-glucose cotransporter 2 inhibitors and cardiovascular events across body mass index

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-Several studies have shown significant reductions in major adverse cardiovascular events (MACE) and heart failure (HF) with sodium-glucose cotransporter 2 inhibitors (SGLT2i); however, there is insufficient evidence to determine whether these reductions are not modified in populations stratified by body mass index (BMI).
-To assess whether stratification by baseline BMI modifies the measures of association between SGLT2i and the risk of MACE and HF compared to dipeptidyl-peptidase 4 inhibitors (DPP4i) among patients with type 2 diabetes (T2D).
-We used nationwide claims data of Korea (2010.01-2022.12) to construct active comparator, new-user cohort of T2D patients stratified by Asian BMI categories: Normal, 18.5 to <23 kg/m2; Overweight, 23 to <25 kg/m2; Obese, ≥25 kg/m2. New users of SGLT2i were 1:1 propensity score (PS)-matched with new users of DPP4i. The co-primary outcomes were 4-point MACE and hospitalization for HF. Patients were followed using an as-treated exposure definition. PS-matched hazard ratios (HR) with 95% confidence intervals (CI) were estimated using Cox models.
-New users of SGLT2i and DPP4i were 1:1 PS-matched (n=231,332 pairs; obese 174,675 pairs, overweight 35,372 pairs, and normal weight 21,285 pairs). The overall hazard ratio (HR) for the risk of MACE with SGLT2i vs. DPP4i was 0.90 (95% CI 0.86-0.95) with no evidence of effect modification by baseline BMI (p for homogeneity: 0.32). The risk of HF decreased in total cohort (0.53, 0.44-0.63), obese (0.47, 0.37-0.58) and overweight (0.49, 0.31-0.78) groups, but not in normal (0.86, 0.58-1.29) group, with evidence of effect modification by BMI (p for homogeneity: 0.01).
-SGLT2i improved 4-point MACE compared to DPP4i regardless of BMI status, while the decreased risk of hospitalization for HF was modified by BMI. Normal weight patients presented no significant reduction in the risk of HF, suggesting a potential role of body weight in the underlying mechanism by which SGLT2i improve heart failure.

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Statins and intracerebral hemorrhage risk: a target trial emulation study in China

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- Introduction
Statin has been shown to prevent major vascular events in a wide range of individuals, but the risk of intracerebral hemorrhage (ICH) from statin use remains unclear.
- Aims
To evaluate the impact of statins on the risk of ICH in Chinese population.
- Methods
Using 2011-2020 year data from the Yinzhou Regional Health Care Database (YRHCD), patients aged 50 years or older with no history of ICH and statin use were included. In the framework of target trial emulation. 60 sequential target trials were emulated each month from 2011 to 2015. Within each trial, patients were categorized as statin initiators or non-initiators based on their first prescription during the one-month enrollment period. Patients in different groups of each emulated trial were matched using propensity scores (PS) and then stacked together into one dataset. On this dataset, Cox proportional hazards model was used to estimate the effect of statin on ICH risk.
- Results
53,413 statin initiators and 35,033,455 non-initiators from 60 emulated trials were included into analysis. After PS matching, with a median follow-up of 6.83 (interquartile range 5.67-8.17) years, the hazard ratio of ICH of statin initiators compared with non-initiators was 1.25 (95% confidence interval: 1.09-1.43). The results are consistent across multiple subgroups and sensitivity analyses.
- Discussion/Conclusion
Increased ICH risk was found for ICH-free patients when they received statin treatment.

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Systematic review and meta-analysis of DOACs versus LMWH in Cancer-Associated venous Thrombosis

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Introduction: Cancer-associated venous thrombosis (CAT) is a condition associated with high mortality rates. However, limited evidence exists regarding the effectiveness and safety of low-molecular-weight heparin (LMWH) and direct oral anticoagulants (DOACs) for its treatment.
Aims: Using data from multiple clinical and real-world studies, we conducted a systematic review and meta-analysis to compare the effectiveness and safety of DOACs to LMWH in patients with CAT.
Methods: We conducted a systematic search of PubMed, Embase, and Cochrane Library databases up to May 31, 2023, for relevant randomized controlled trials (RCTs) and cohort studies comparing DOACs to LMWH in patients with CAT. Two reviewers independently screened the studies, assessed the risk of bias, and extracted data. Meta-analyses were performed separately for RCTs and cohort studies with a specified 6-month follow-up period. Risk ratios (RRs) were calculated and pooled using the random-effects model.
Results: The systematic review included five RCTs and 20 cohort studies. After applying the six-month follow-up criterion, 17 articles with a total of 22,941 patients were analyzed in the meta-analysis. In RCTs, DOACs were associated with a lower risk of VTE recurrence (RR 0.66, 95% CI 0.49-0.87) compared to LMWH, with no significant differences in major bleeding (RR 1.31, 95% CI 0.85-2.03) and all-cause mortality (RR 0.99, 95% CI 0.84-1.71). Cohort studies showed a lower risk of VTE recurrence (RR 0.71, 95% CI 0.62-0.80) with DOACs, no significant difference in major bleeding (RR 0.89, 95% CI 0.65-1.22), and a reduced risk of all-cause mortality (RR 0.46, 95% CI 0.25-0.85).
Conclusions: The findings from both RCTs and cohort studies indicate that DOACs significantly reduce the recurrence of VTE in patients with CAT without increasing the risk of major bleeding or all-cause mortality compared to LMWH. These results suggest that DOACs may provide a superior anticoagulation effect for CAT compared to LMWH.

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Trend of treatment patterns and lipid control for primary prevention of ASCVD

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Introduction
Evidence on treatment patterns and lipid control for primary prevention of atherosclerotic cardiovascular disease (ASCVD) in Hong Kong (HK) is limited. During the COVID-19 pandemic, it is important to investigate the prescribing patterns of lipid-lowering medication (LLM) and lipid control impacted by the pandemic and COVID-19 vaccination programme (CVP).
Aims
To estimate the prescribing trend of LLM and mean low-density lipoprotein cholesterol (LDL-C) level among patients with primary prevention of ASCVD.
Methods
Electronic health records database from the Hospital Authority in HK was used. We extracted relevant data to identify LLM and LDL-C levels between January 2020 and 31 August 2023. We extracted a cohort of primary prevention for ASCVD, defined as patients without any ASCVD diagnosis but receiving LLM in 2016-2019 and those who received LLM before their first ASCVD diagnosis in 2020-2023. We applied interrupted time series (ITS) analysis to assess the trend of monthly proportion of LLM prescriptions and mean LDL-C level before and after CVP and the fifth wave COVID-19 pandemic.
Results
The monthly proportions of LLM prescriptions fluctuated from 3.29% to 5.18%, while the monthly mean LDL-C levels fluctuated from 2.06 to 2.28 mmol/L for the patients with primary prevention of ASCVD. In the ITS analysis, no immediate change or change in the trend of the proportion of LLM after CVP were observed, while we found a marginal increase in the immediate change of monthly mean LDL-C levels (0.056, 95%CI: 0.002,0.110) after CVP. We observed a decrease in the immediate change of the proportion of LLM (-0.369, 95%CI: -0.691,-0.046), and a slight decrease in the trend of the monthly mean LDL-C levels (-0.007, 95%CI: -0.011,-0.003) after the fifth wave COVID-19 pandemic.
Conclusion
The findings indicated the latest real-world practice of prescribing trends in LLM and lipid control among patients with primary prevention of ASCVD.

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Trends in Obstructive Sleep Apnea incidence in Taiwan from 2004 to 2020

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Introduction
Obstructive Sleep Apnea (OSA) has rapidly increased in Taiwan and is linked to higher comorbidities and mortality. Therefore, updating nationwide trend analyses of OSA incidence is crucial for informing clinical management strategies.
Aims
To determine the trends in incidence of diagnosed OSA in Taiwan from 2004 to 2020.
Methods
A retrospective nationwide longitudinal study was conducted using data from Taiwan's National Health Insurance Research Database collected from 2004 to 2020. Newly diagnosed cases of OSA were identified using the International Classification of Diseases diagnostic codes. OSA incidence patients were defined as those with their first OSA diagnosis between 2004 and 2020, confirmed by a polysomnography (PSG) procedure within one year prior to diagnosis, and without prior OSA diagnosis before 2004. The incidence rates were categorized into eight age groups: 0-19, 20-29, 30-39, 40-49, 50-59, 60-69, 70-79, and ≥ 80 years, and age-adjusted incidence rates were presented by calendar year.
Results
From 2004 to 2018, the incidence rate increased annually, peaking at 95.14 per 100,000 person-years in 2018, before starting to decline in 2019 and 2020. Men are more than twice as likely to develop OSA as women. The incidence of OSA was generally higher among people aged 40 to 69 years than in other age groups. When 2007 data was used as a baseline, the relative incidence ratio for those aged 20-29 and 30-39 years in 2020 was 2.50 and 2.04, respectively, indicating that young adults aged 20-39 years saw the largest increase in incidence.
Discussion/Conclusion
This study shows that the incidence of OSA is significantly rising in Taiwan, affecting both genders and all age groups. Middle-aged people had the highest incidence, while younger people showed higher rising trends in the incidence of OSA. The elderly's relatively low incidence of OSA suggests that it may have been underestimated.

[COST- EFFECTIVNESS AND ECONOMIC EVALUATIONS]

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Evaluation of clinical and economic implications of adverse drug reactions in a tertiary care teaching hospital.

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Introduction. Adverse drug reactions (ADRs) pose significant clinical and economic challenges, affecting healthcare quality and patient outcomes. A comprehensive analysis of these reactions is essential to develop effective management strategies and optimize healthcare resources.
Aims. To evaluate the clinical and economic implications of adverse drug reactions.

Methodology. A prospective, interventional study conducted over a six-month period in the departments of General Surgery, General Medicine, Medical Oncology, and Intensive Care Units. Patients aged 18 years and older who admitted due to an adverse drug reaction (ADR) or experienced an ADR during their hospital stay. Clinical outcomes of ADRs quantified using the Modified Hartwig and Siegel Scale, which assesses severity levels. Economic impacts evaluated through the direct medical costs associated with each ADR and the management strategies utilized.

Results. 218 adverse drug reactions (ADRs) were documented from 144 patients [84 (58.3%) males and 60 (41.6%) females], with an average of 1.5 ADRs per patient. Among 1509 administered medications, 92 elicited ADRs, averaging 2.3 ADRs per medication, predominantly involving antimicrobials [24 (26.1%)] and antineoplastics [19 (20.7%)]. The distribution of ADRs across formulations revealed intravenous solutions as most common [152 (69.7%)], followed by tablets [52 (23.8%)]. ADR severity was categorized as mild [66 (28.4%)], moderate [155 (71.1%)], and severe [1 (0.4%)]. These ADRs resulted in additional medications [133 (61.0%)], prolonged hospital stays [11 (5%)], and ICU admissions [11 (5%)]. Of all ADRs, 117 (54%) were resolved at the time of reporting, with 101 (86%) resolving in under five days and 16 (14%) in over five days. The total cost for managing these ADRs was US$ 6652.61, averaging US$ 30.5 per ADR.
Conclusion. In low- and middle-income countries, the clinical and financial burden of ADRs compromises patient's well-being and trust in Health care process. The early detection and prevention of the ADRs is vital in improving overall patient outcomes.

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Examining Quality of Life in Individuals Experiencing Adverse Drug Reactions: The Application of the WHOQOL-BREF Scale for Evaluation

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Introduction. Adverse drug reactions (ADRs) are a significant concern in healthcare, often leading to increased morbidity and decreased quality of life among affected individuals. Understanding the impact of ADRs on QOL is crucial for effective patient management and improving healthcare outcomes.
Aims. To assess the quality of life (QOL) of patients post ADR using WHOQOL-BREF scale.
Methods. A prospective interventional study was conducted over a period of six months among patients admitted to the Departments of General Surgery, Intensive Care Units, General Medicine, and Medical Oncology in a tertiary care hospital who had an ADR-related admission or experienced at least one ADR during their hospital stay. The WHOQOL-BREF scale was used to assess the QOL of these patients post ADR. The questionnaire was administered 30-days after discharge. Pearson's correlation coefficient was used to determine the level of agreement between the four domains of the WHOQOL-BREF. A paired t-test was used to compare the difference between the score means of different domains. A t-test was used to investigate the association between participants' characteristics and QOL.

Results. A total of 218 ADRs were identified among 144 patients of whom 121 (89.5%) patients were administered with the questionnaire while the rest 23 (10.5%) were lost to follow-up due to deaths and unresponsive phone calls. Of the 121 participants, 69 (57%) males and 52 (43%) were females. The WHOQOL-BREF assessment revealed varying perceptions of health-related quality of life. Social Relationships score was the highest (61.46) and Environmental Health lowest (55.89), suggesting room for improvement. "Overall QOL" scored highest (4.05 ± 0.64), reflecting a positive outlook. A moderate positive correlation (0.428) between Q1 and Q2 indicated an alignment between overall quality of life and general health. Comparing WHOQOL-BREF scores with sex, age, medications, length of hospital stay, and comorbidities showed a significant correlation between sex and Social Relationship. Males showed slightly higher QOL scores in all domains compared to females in Physical Health [Males: 59.63, Females: 56.28], Psychological Health [Males: 60.86, Females: 58.38], Social Relationships [Males: 63.81, Females: 57.87], and Environmental Health [Males: 56.60, Females: 54.77].
Discussion. The study on ADRs' humanistic outcomes using the WHOQOL-BREF revealed that higher social and psychological QOL. Most patients reported moderate post-ADR QOL, underscoring the need for tailored interventions in post-ADR care, especially concerning gender-related QOL associations.
Keywords. Adverse drug reaction, QOL

P148

Cost-effectiveness analysis of the first-line treatment with nivolumab plus ipilimumab in mesothelioma

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Introduction.Malignant Pleural Mesothelioma(MPM) is an uncommon tumour known as malignant pleural mesothelioma. The NCCN guidelines recommend immunotherapy and chemotherapy for the first-line treatment of unresectable malignant pleural mesothelioma, with special emphasis on immunotherapy in patients with non-epithelioid tumors.
Aims. This study's objective was to assess the cost-effectiveness of treating MPM in China using an Nivolumab(NIV) plus Ipilimumab(IPI) regimen.
Methods. The estimated findings came from a multicenter randomised phase III trial that demonstrated enhanced survival benefits for MPM patients receiving a combination NI treatment. To calculate the Incremental Cost-Effectiveness Ratio(ICER) from the viewpoint of Chinese society, a partitioned survival model was built. One-way certainty and probabilistic sensitivity analysis are used to resolve the uncertainty in the model.
Results. When compared to platinum plus pemetrexed chemotherapy, our base case study showed that the overall cost of treatment increased from $14448.212 to $158877.930 when the NI combo regimen was used. The effectiveness of NI combination therapy increased by 0.203 Quality-adjusted LifeYears(QALYs), from 0.601 QALYs to 0.804 QALYs. With a Willingness-To -Pay(WTP) threshold of $35856.90/QALY, the incremental cost-effectiveness ratio was $711476.442, and there was a 0% chance that it would be cost-effective.
Discussion. When considered as a whole, the findings of this study indicate that, from the standpoint of Chinese payers, the combination of NI is not a cost-effective alternative as a first-line therapy option for MPM.

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Economic evaluation of medical expenses in home medical care (Zaitaku) using NDB

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- Introduction: Along with growing of a super-aging society, the number of patients with non-communicable diseases (NCDs) and its home medical care (Zaitaku) are rapidly increasing in Japan. At the same time, growing of medical expenses is big concern.
- Aims: In this study, We investigated the medical expenses of NCDs and its drug consumptions in home medical care using medical big data: the National Database of Health Insurance Claims and Specific Health Checkups of Japan (NDB).
- Methods: The databases of medical claims of outpatient and dispensing claims from the NDB Sampling Dataset (January, April, July, October of 2012-2019, and January of 2020) were linked based on patient IDs and the data analysis was performed. Patients who had the word "home (Zaitaku)" in the dispensing action code in the dispensing information record of the dispensing claims were considered to be patients receiving home medical care, and were counted based on medical expenses (insurance points). Patients who had the dispensing action code in the dispensing information record of the dispensing receipt receiving six or more kinds of medicines were extracted as patients receiving polypharmacy.
- Results: The total number of home medical care patients and the number of patients receiving polypharmacy increased year by year. The total medical expenses of home medical care patients also increased year by year, while the average medical expenses per patient with home medical care gradually decreased. It was also confirmed that the average medical expenses per home medical care patient were higher than those of home medical care patients.
- Discussion/Conclusion: In a super-aging society, the results suggested that patients with home medical care are increasing year by year, medical expenses for home medical care will increase rapidly.
- Acknowledgements: This work was supported by JSPS KAKENHI Grant Number JP22K10587.

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Health economic evaluation of self-injection of biologics in patients with rheumatoid arthritis.

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Introduction:
Biological disease-modifying antirheumatic drugs (bDMARDs) have high effectiveness in patients with rheumatoid arthritis (RA), whereas, there are concerns about their high costs. However, it has not yet been evaluated whether self-injection (SI) of bDMARDs enables patients to reduce the frequency of hospital visits and direct medical costs or not.

Aims:
To evaluate the impact of SI on medical cost in patients with RA by comparing drug cost between patients who have selected SI and those who had not.

Methods:
We conducted a retrospective cohort study using claims data from April 2014 to September 2021, which was provided from DeSC Healthcare, Inc. We defined patients with RA by both disease code and bDMARDs prescription and classified patients who have selected SI (SI group) and those who had not (non-SI group). Patients' characteristics were used to calculate a propensity score. One-to-one matching was performed, and we calculated the average of drug cost from the public healthcare payer's perspective in JPY/person/year in each group.

Results:
Total of 3,972 patients (mean age:72.5 years, female:73.3%) were matched and the total drug cost and bDMARDs cost were ¥1,020,387 and ¥939,950 (JPY/person /year) in the SI group, ¥589,712 and ¥465,175 (JPY/person/year) in the non-SI group, respectively (I USD = 110 JPY in 2021). The proportion of bDMARDs cost relative to total drug cost in the SI group (92.1%) were higher than that in the non-SI group (78.9%).

Discussion:
This study shows the higher total drug cost in the SI group compared to the non-SI group. To evaluate the health economic benefits of SI in patients with RA from the public healthcare payer's perspective, it is necessary to consider not only medical costs, but also the frequency of hospital visits and employed status.

P151

Quality of Life in Post Stroke Patients: Impact of Clinical factors.

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Aim: The study was aimed to assess the overall impact of stroke on health related quality of life (QoL) and associate it with clinical and socio-demographic characteristics of patients.

Methodology: This prospective observational study was carried out at a tertiary care hospital for a period of 2 years. Parameters like National Institute of Health Stroke Scale (NIHSS), Stroke Specific Quality of Life (SS-QoL), Modified Ranking Scale (mRS) and Mini Mental State Examination (MMSE) were used to assess the clinical aspects of stroke and correlate with quality-of-life in post stroke survivors.

Results: Among 117 stroke patients followed for a period of 6 months, with a mean age of 57.58±10.26 years, the mean SS-QoL score was found to be 202.31 (95%CI: 192.39 to 212.23) indicating a better quality of life. Several domains of QoL were affected, the most affected domains being family roles (74.7%), energy (75%), and work/productivity (75%). The least affected domains were language (89.76%) and self-care (89.2%). We observed a significant negative correlation between SS-QoL and mRS scores (r = -0.926, 95% CI: -0.95 to-0.89; p=<0.001), indicating a decreased QoL with an increased degree of disability. Similarly, QoL was again negatively correlated to severity of stroke at the time admission (r = -0.86; p=<0.001). Patients with Total Anterior Circulation infarct subtype of stroke had a significant reduction in QoL.

Conclusion: This present study observed a better quality of life among stroke survivors. We observed an inversely proportional relationship between severity of stroke at the time of admission, disability post stroke and QoL. Identifications of factors contributing to severity and disability and making any possible interventions can enhance QoL in patients with stroke.

Key words: Stroke; Stroke Specific Quality of Life; Disability; Negative Correlation.

P152

Research on the evidence development of benefit-risk in TCM formula granules

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Introduction: Traditional Chinese medicine (TCM) formula granules are extracted, concentrated, separated, dried, and granulated into granular preparations available for use in Chinese medicine clinics, which are convenient to take and suitable for industrial production, and are an important innovation in traditional Chinese medicine. In the last decade, relevant studies have mainly focused on the efficacy and safety of TCM formula granules but lacked a systematic study on their economics, especially benefit-risk.
Aims: This study will comprehensively assess the status of benefit-risk evidence development for TCM formula granules to provide an evidence-based basis for clinical selection and decision-making.
Methods: CNKI, Wanfang, PubMed, Web of Science, and Embase were searched up to 10 April 2024. Retrospective or prospective studies evaluating the cost-effectiveness of patients receiving TCM formula granules were included. We extracted data on the target patients, study design, interventions, clinical outcomes, costs and other indicators to analyze the characterization, study quality, and evidence development.
Results: 13 studies were finally included. There were 1 retrospective cohort study and 12 prospective cohort studies with a total of 1,073 patients. The CHEERS score grades were low. The evidence of clinical outcomes showed that most of the TCM formula granules had high efficacy rates. The safety evidence showed that there were no significant adverse reactions to the TCM formula granules. The TCM formula granules had a significant cost-effectiveness advantage was evident.
Discussion: TCM formula granules are being widely used in clinical practice, but there is still a need to vigorously develop evidence on the benefit-risk from the perspective of pharmacoeconomics. More high-quality evidence of benefits-risks is needed in the future to assist clinical and regulatory decision-making in TCM formula granules.

[COVID-19]

P153

Association of COVID-19 Policy Stringency on Patient Satisfaction in Chinese Community Pharmacy

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Introduction: Community pharmacy services play a crucial role in China's primary healthcare system. However, the COVID-19 pandemic has introduced unprecedented challenges, leading to compromised access and quality of pharmaceutical services. Understanding the impact of closure policies related to COVID-19 on patient satisfaction and identifying the underlying mechanisms is essential for enhancing the quality of pharmacy services.
Aims: To assess the impact of COVID-19 closure policies on patient satisfaction and evaluate the underlying mechanisms in community pharmacies in China.
Methods: Cross-sectional study conducted from April 2021 to September 2022, using an unannounced standardized patient approach in community pharmacies across China. Patient satisfaction measured using validated tools, with closure policies related to COVID-19 as the primary exposure variable.
Results: The study included 1,076 eligible visits sample of community pharmacies and patients. Results indicated that stricter closure policies had a significant negative impact on patient satisfaction ($\beta = -0.18$, $p = 0.019$). This negative effect may be attributed to worsened accessibility ($\beta = -0.12$, $p = 0.019$) and capability of pharmaceutical service providers ($\beta = -0.17$, $p = 0.002$). Subgroup analyses demonstrated a negative correlation between stricter closure policies and lower satisfaction levels with regard to accessibility, capability, and communication.
Discussion: COVID-19 closure policies in China have adverse consequences for the quality of pharmacy services. These findings highlight the urgency of addressing abrupt infectious diseases or public health emergencies. Enhancing access to pharmacy services and capability of providers are critical strategies to ensure an effective response to sudden public health crises.

P154

Effects of COVID-19 on Infectious Events in Patients with CLL in China

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Introduction:

The COVID-19 pandemic has posed unprecedented challenges to global healthcare systems, with vulnerable populations such as patients with Chronic Lymphocytic Leukemia (CLL) experiencing heightened risks of infectious complications.

Aims:

To investigate the impact of the COVID-19 pandemic on the incidence of infectious events among patients with CLL in China.

Methods:

A retrospective cohort study was conducted using patient data from multiple healthcare centers across China. The study analyzed data on CLL patients during the COVID-19 pandemic (2020-2022) and a comparable pre-pandemic period (2017-2019). The primary outcome assessed was the incidence of infectious events (fungal, bacterial, and viral infections), including respiratory infections and COVID-19-related complications.

Results:

The study included 3,635 patients who had a confirmed diagnosis and met the specified inclusion/exclusion criteria (total follow-up time: 9,258 person-years), with 2,691 patients (6,032.5 person-years) before the COVID-19 pandemic and 1,937 patients (3,225.5 person-years) during the pandemic. Throughout the follow-up period, 1,026 (28.2%) patients experienced at least one infection event, resulting in a total of 4,900 infection events among CLL patients, with an incidence rate of 52.9 per 100 person-years. The most common types of infection were viral (incidence: 4.8%, incidence rate per 100 person-years: 5.0), respiratory (19.6%, 16.3), pneumonia (11.4%, 8.4), and gastrointestinal (5.1%, 5.3). Compared to the pre-pandemic period, the incidence rates of all infection events except for viral infections (pre-pandemic: 2.7%, 4.9 vs. pandemic: 4.5%, 5.1) decreased. This decrease was observed in bacterial infection (2.3%, 1.9 vs. 1.9%, 1.5), fungal infection (2.9%, 2.2 vs. 1.8%, 1.7), and respiratory infection (21.0%, 18.9 vs. 7.6%, 11.5).

Discussion:

The study highlights the need for enhanced infectious disease prevention strategies, including vaccination and infection control measures, for CLL patients during pandemic conditions.

P155

Health equity of COVID-19 monoclonal antibodies at a US medical center

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Introduction: The equitable allocation of COVID-19 therapeutics remains a concern, with previous studies showing inequity by race/ethnicity and access to healthcare.
Aims: To describe the population of COVID-19 patients who received monoclonal antibodies (mAbs) at a quaternary medical center in the United States.
Methods: Patients ≥18 years of age with a positive SARS-CoV-2 test and received a mAb at University of California San Francisco (December 3, 2020-October 3, 2021) for treatment of COVID-19 were included. Demographic information was collected and the cohort was stratified by race/ethnicity and geographic area. The California Healthy Places Index (HPI), Healthcare Access (HA) scores, and the Social Vulnerability Index (SVI) were used to assess health status and healthcare access by geography. Higher SVI and lower HPI/HA scores reflect poorer health status/access. Statistical significance was determined at $p < 0.05$. This study was approved by the UCSF Institutional Review Board.
Results: Of 529 patients who received mAbs, White/Caucasian, Hispanic/Latinx, Asian, Black/African American (B/AA), others/unknown were 46.1, 17.4, 14.4, 10.8, 11.3%, respectively. Compared to White/Caucasian, Hispanic/Latinx and B/AA were significantly younger, unvaccinated and more likely to receive mAbs due to pre-existing conditions or obesity. Hispanic/Latinx and B/AA patients were more likely to receive mAbs in the Emergency Department; White/Caucasian patients were more likely to be seen in a clinic which may reflect differences in access to healthcare. Hispanic/Latinx and B/AA recipients had higher SVI scores and lower HPI/HA scores compared to White/Caucasian [HPI score $R^2=0.21$, $p < 0.05$].
Discussion/Conclusions: This study reflects an unbalance of COVID-19 patients who received mAbs in the early days of the pandemic. Ongoing auditing with active outreach to vulnerable populations may help decrease health inequities.

P156

Healthcare utilization and disease status of herpes zoster during COVID-19 pandemic

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- Introduction
During 2022, the COVID-19 prevalence rate soared from 0.73 per thousand person-years to 378.85, affecting over thirty percent of the population. During this time, residents avoided outside activities, and healthcare utilization decreased. However, several studies indicated that COVID-19 infection might increase the risk of herpes zoster (HZ) outbreaks.

- Aims
This study aims to understand whether there were changes in healthcare utilization and disease status for HZ before and after the pandemic.

- Methods
This study used the medical records database of a municipal hospital, collecting data on patients diagnosed with HZ from 2020 to 2023. The data were grouped by year of visit and age groups. Analyses were conducted on number of visits, department of visit, medical specialty, complication rates, and medication.

- Results
The study included a total of 1,522 HZ patients, with an average of 2.98±2.85 visits per patient. The average number of visits slightly increased since 2022 (2020-2023: 2.93±2.61, 2.84±2.50, 2.99±2.84, 3.15±3.37), with no significant difference. The prevalence rate increased after the pandemic (2020-2023: 2.9‰, 2.8‰, 3.0‰, 3.1‰). During 2022, 10 COVID-19 patients developed HZ (2.9% of HZ patients), with an average interval of 66.6±68.5 days. The next year, there were 9 (2.3%) patients with 157.2±88.1 days. Among HZ patients, the proportion of HZ with ocular complications increased during the pandemic (2020-2023: 13.9%, 17.6%, 18.2%, 17.5%), while HZ hospitalization and emergency visit rates decreased (2020-2023: 15.0%, 15.7%, 10.3%, 11.3%). The most commonly used medication was Vitamin B complex (43.3%), followed by antiviral drugs (35.8%). There was no significant correlation between medication usage trends and the year, age or COVID-19 history.

- Discussion/Conclusion
During the pandemic, the healthcare needs of HZ patients remained significant, with an increase in ocular complications. Further research may be needed to confirm whether COVID-19 contributes to this increased risk.

P157

How the Characteristics and Pattern of SARS CoV-2 Affected Their Virulence

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Corona-virus infection disease in 2019 (COVID-19) has become one of the deadliest infections during the 21st century. Clinical manifestations of the SARS-CoV-2 viral infection may vary depending on the age, sex, and immune response of infected individuals, with different disease severity. Furthermore, the mutations in this virus potentially change their characteristics and virulence. Therefore, we believe it is important to explore more about the characteristics and patterns of the virus and how these affect their virulence in humans.

This study is an exploratory descriptive with the initial stages of sample extraction using QIAamp viral RNA Mini Kit, qRT-PCR examination, and library preparation. Then, we continued with genome sequencing using the Miseq Illumina sequencing machine. The sequencing results were analyzed using the CLC Genomics Workbench app software so that the type of variance was obtained in each research sample. Data and clinical condition of patients obtained from the Center for Diagnostic and Research on Infectious Diseases, Faculty of Medicine, Universitas Andalas, Indonesia.

This study used 251 samples, with the results of variant analysis grouped into non-VOI-VOC variants (66.5%), delta variants (19.5%), and omicrons (13.9%). Sample characteristics showed that men were more infected with the delta variant (53.1%), while the non-VOI-VOC variant and the female omicron variant had a higher percentage (58.1% and 58.6%, respectively). Meanwhile, the highest infection rate was found in the age group of 20-59 years. Sample characteristics based on the degree of disease severity found the most moderate-severe category in the delta variant (16.3%).

Analysis of sample characteristics in patients infected with SARS-CoV-2 based on sex, age, and degree of disease severity influenced by the type of virus variant infecting.

P158

Impact of COVID-19 pandemic on adherence to antidepressants in Saudi Arabia

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Objective: COVID-19 has been linked to an increase in the incidence of depression and anxious symptoms, according to population studies. The current study purpose was is to analyze the adherence to antidepressant drugs before and after the COVID-19 pandemic in the Asir region of Saudi Arabia.
Methods: Using anonymized data from the Saudi German private hospital in Asir region, the medication possession ratio (MPR) was calculated for all antidepressants users. The MPR was calculated one year before COVID-19 pandemic and one year after. After confounding variables were controlled for, logistic regression analysis was conducted to predict the factors influencing adherence to antidepressants and assess whether the COVID-19 pandemic had an impact on adherence.
Results: 281 antidepressants users were included in the study. The average medication possession ratio was 67.5%, before the pandemic and 51.2% after the pandemic. The logistic regression analysis indicated that factors such as being male and being younger were significant predictors of poor adherence.
Conclusion: Poor adherence to antidepressants in the Asir region can be a result of various factors such as the stigma associated with mental illness. The COVID pandemic has further highlighted the importance of mental health and has exposed vulnerabilities in mental health care services. This study highlights the need to improve the adherence to antidepressants among patients with depression in the Asir region. This research also highlights the impact of the COVID-19 pandemic on mental health care services, and the need to provide better resources and support to patients during these difficult times.

Keywords: Antidepressants, Adherence, Covid-19, Saudi Arabia

P159

Molnupiravir for non-hospitalized adults with mild/moderately severe coronavirus disease 2019 (COVID-19)

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Aim/Objective: For insights into the antiviral drug, molnupiravir for the coronavirus disease 2019 (COVID-19), we summarized published evidence on the approved regimen (800mg twice daily over 5 days) for non-hospitalized adults with mild/moderately severe COVID-19.

Methods: We systematically searched for randomized controlled trials (RCTs) of molnupiravir for COVID-19 and included only laboratory-confirmed infections. We conducted pooled analysis of appropriate data using an inverse variance, random-effects model, and presented results as relative risk with associated 95% confidence intervals. We assessed for statistical heterogeneity using the I^2 statistic. Further, we graded and conducted trial sequential analysis (TSA) of the evidence.

Results: We included nine RCTs (30,971 persons). There was a small but significant evidence to suggest more viral clearance (of the severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]) for molnupiravir compared with no treatment/placebo (RR 1.08 [1.01 – 1.16], I^2 40.8%, 5 RCTs, 1,785 persons; moderate quality evidence). However, molnupiravir did not reduce the risk of hospitalization (RR 0.73 [0.47 – 1.14], I^2 58.3%, 5 RCTs, 28,626 persons; high quality evidence) and all-cause mortality (RR 0.51 [0.15 – 1.69], I^2 36.8%, 4 RCTs, 27,445 persons; high quality evidence). Further, molnupiravir was not associated with significantly more adverse (RR 1.02 [0.90 – 1.14], I^2 16.3%, 7 RCTs, 3,368 persons; moderate quality evidence) or serious adverse (RR 0.91 [0.71 – 1.16], I^2 0%, 5 RCTs, 27,562 persons; high quality evidence) reactions. Nevertheless, TSA suggested that more RCTs are required before any conclusions regarding viral clearance, all-cause mortality, and adverse reactions, but that more RCTs on the risk of hospitalization, and serious adverse events may be futile as the efficacy of molnupiravir for these outcomes is unlikely.

Conclusion: Molnupiravir may be promising for clearance of SARS-CoV-2, but generally does not seem better than usual care. However, more RCTs are necessary for a stronger evidence base.

P160

Nirmatrelvir-ritonavir regimen for non-hospitalized adults with mild/moderately severe coronavirus disease 2019 (COVID-19)

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Aim/Objective: Efficacy/effectiveness and safety of the approved nirmatrelvir-ritonavir regimen (300mg of nirmatrelvir with 100mg of ritonavir administered twice daily over 5 days) for treatment of non-hospitalized adults with mild/moderately severe coronavirus disease 2019 (COVID-19) remains unclear.

Methods: We conducted a systematic evidence review of published peer-reviewed randomized controlled trials (RCTs) and real-world studies [RWS] (observational) of efficacy/effectiveness and/or safety of the approved nirmatrelvir-ritonavir regimen for treatment of non-hospitalized adults (≥18-year-olds) with mild/moderately severe laboratory-confirmed COVID-19. We pooled appropriate data (for RWS, the adjusted estimates) using an inverse variance, random-effects model, and calculated statistical heterogeneity using the I^2 statistic. Results are relative risk with associated 95% confidence intervals. Further, we assessed risk of bias/study quality of the included studies, and conducted trial sequential analysis (TSA) of the evidence from RCTs.

Results: From a retrieved total 1,104 literature citations, we included three RCTs (2,774 persons) and 16 RWS (1,925,047 persons). The RCTs were of unclear risk of bias while the RWS were of good quality. Nirmatrelvir-ritonavir significantly reduced worsening COVID-19 severity (0.19 [0.06 – 0.66], I^2 54.8%, three RCTs, 2,774 persons) but increased adverse events (1.83 [1.35 – 2.48], I^2 0%, three RCTs, 2,774 persons) compared with placebo/no treatment. There was no significant difference for clearance of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and all-cause mortality although TSA suggested more sample size for these outcomes before any conclusions. Further, compared with no treatment, nirmatrelvir-ritonavir appeared to significantly reduce hospitalization (0.48 [0.37 – 0.60], eleven RWS, 1,421,398 persons) and all-cause mortality (0.24 [0.14 – 0.34], seven RWS, 286,131 persons).

Conclusion: The approved nirmatrelvir-ritonavir treatment regimen appears promising against worsening severity and suggestively, against hospitalization and all-cause mortality in non-hospitalized adults with mild/moderately severe laboratory-confirmed COVID-19. However, the evidence is generally weak. More studies are necessary for a stronger evidence base.

P161

Post-COVID19 Perception, Knowledge, and Phobia towards Corticosteroids among the General Public

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Introduction: For more than a few decades, corticosteroids (CS) have been used to treat variety of inflammatory and allergy disorders. Though the effectiveness of CS is proven, safety concern prevails. The public is now more aware of CS because of the COVID-19 pandemic, but their information sources still need to be verified.

Aim: The study investigates the general public's knowledge, experience, and fears about corticosteroids, examining their acceptance and validity, and their relationship with factors like gender, age, and education.

Methods: A cross-sectional study was conducted among the general public for a period of six months. An online questionnaire was utilized to collect the perception, knowledge, and phobia towards corticosteroids following COVID-19. People who could read and understand English were included in the study. Each participant's knowledge and phobia concerning CS were scored and graded.

Results: A total of 472 participants were enrolled in the study; the majority were females (60%) and university students (92%). Less than 32% were previously infected with COVID-19, and 33% of the total participants had used CS. The majority of them reported using it for respiratory (47.5%) and dermatological disorders (44.3%). A quarter of the samples stated that they suffered from acne and mood changes because of CS. The overall knowledge score concerning CS of the population came out to be satisfactory, but the corticophobia score was high. Moreover, their corticophobia score was positively associated with their experience of side effects and knowledge score. However, participants' educational level was negatively associated with the development of corticophobia.

Conclusion: The study found that, despite having a satisfactory understanding of CS, participants displayed a high corticophobia. Addressing this issue requires awareness campaigns, awareness programs, and patient interaction, as well as educating healthcare workers.

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Risk of mortality of COVID-19 & influenza co-infection: A clone-censor-weight study

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Introduction: In the transition to the post-COVID-19 era, it is crucial to reassess the clinical severity of COVID-19 and influenza co-infection to update the currently available evidence and provide better guidance for medical practice.

Aims: To compare the risk of 30-day all-cause mortality between patients with co-infection of influenza and COVID-19 and those with single infection.

Methods: We retrieved data from the Hong Kong Clinical Data Analysis and Reporting System. We identified patients who received test for COVID-19 and influenza using reverse transcription polymerase chain reaction (RT-PCR) between 2023-01-01 – 2024-01-31. RT-PCR-confirmed COVID-19 and influenza within 7 days were considered as co-infection. Clone censor weight method was used to reduce immortal time bias. Sex, age group, prior morbidities, were included to compute an inverse probability of censoring weights. The risk of 30-day mortality was compared between patients with co-infection and (1) COVID-19 infection or (2) influenza only. Kaplan-Meier estimates and Cox proportional hazard models were used.

Results: Out of 64,436 patients tested for with both COVID-19 and influenza, 39,148 (61%) were RT-PCR-confirmed with COVID-19 positive only, while 24,873 (38%) were RT-PCR-confirmed with influenza positive only. 415 (0.64%) patients had co-infection. From the Kaplan-Meier estimate, the 30-day mortality rates for patients with COVID-19 or influenza infection alone, compared to those with co-infection, were not statistically significant ($p = 0.83$ and $p = 0.15$, respectively). The results from the Cox model were inconclusive as the proportional hazard assumption was not met in some of the analyses.

Discussion: Our data covered a period when pandemic restrictions started to relax and addressed the recent strains of COVID-19. The risk of 30-day mortality for patients with co-infection was found similar to those with single infection. These results contradict existing meta-analyses on this topic. Further investigation is needed, particularly in subgroups defined by age and co-morbidities.

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Risk of narcolepsy after COVID-19 vaccination in Korea: self-controlled case series study

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Introduction:
Reports of narcolepsy following COVID-19 vaccination have raised concerns about potential risks. However, the association between the COVID-19 vaccine and narcolepsy remains uncertain.
Aims:
To assess the risk of narcolepsy following COVID-19 vaccination in the Korean population.
Methods:
We conducted a self-controlled case series study using a database linking nationwide COVID-19 registry data, including infection and vaccination information, with National Health Insurance Service claims data in Korea, covering January 1, 2002, to September 30, 2022. Patients who received at least one COVID-19 vaccine dose before September 30, 2021, were included. Narcolepsy patients were those diagnosed with rare incurable disease code indicating treatment for narcolepsy and cataplexy within 365 days of vaccination and prescribed stimulants within 6 months before or after diagnosis. Patients with prior stimulant prescriptions, COVID-19 infection before narcolepsy, or diagnosis of a rare incurable disease codes were excluded. We used conditional Poisson regression to estimate incidence rate ratios (IRRs), adjusted for calender time in monthly interval, and 95% confidence intervals (CI) comparing risk and control intervals. The risk window was 1-42 days after each dose. Sensitivity analyses were conducted using 14- and 21-day risk periods or ICD-10 codes for diagnoses. Subgroup analyses by sex, age, Charlson comorbidity index, and vaccine type were also performed.
Results:
Among 39,323,547 COVID-19 vaccine recipients, 412 cases of narcolepsy were identified. Of these, 239 were men (58.0%), and 240 were aged 18-29 (58.3%). The aIRR for narcolepsy risk within 1-42 days post-vaccination was 1.03 (95% CI: 0.90-1.38). Similar results were found in sensitivity and subgroup analyses.
Discussion/Conclusion:
There was no evidence of increased risk of narcolepsy following COVID-19 vaccination. Most cases occur in children and adolescents, and vaccinations for those under 18 began in Korea in October 2021. Extending the study period is necessary to gather more evidence.

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Self-medication among elderly during COVID-19 in Macao: a cross-sectional study

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Introduction
Self-medication was highly common during the COVID-19 pandemic. In elderly, the risk of self-medication is higher. Pharmacists are well positioned to provide public health education and disease prevention.

Aims
This study aims to explore the self-medication patterns and intention to seek pharmacist guidance among elderly aged 65 years or above in Macao.

Methods
A face-to-face cross-sectional survey was performed in March-April 2023 among elderly in Macao. The questionnaire was designed based on the Theory of Planned Behavior (TPB) framework. Multiple regression analyses were conducted to predict factors influencing self-medication behavior and intention to seek pharmacist guidance.

Results
In total, 412 participants completed the questionnaire. The self-medication rate was 64.2%, with the age of 85 years old and higher education being significantly associated with such behavior. The most commonly used medications were over-the-counter products and traditional Chinese medicine products. These medications were mainly obtained from widely distributed anti-pandemic packages and pharmacies. The purposes of self-medication were mainly to treat COVID-19 symptoms or prevent COVID-19 infection. While friends and family were the primary sources of information about self-medication, some participants (20.8%) also consulted healthcare professionals for advice. Further investigation about the intention of seeking pharmacist guidance on medication use showed that only 42.7% of participants were willing to seek help from pharmacists and age was a significant predictor of intentions. Of the three variables of TPB, the average scores were 3.4/5 for Attitude, 2.7/5 for Subjective Norm, and 3.6/5 for Perceived Behavioral Control. All three TPB variables were all strong predictors of intention, explaining 53% of the variance.

Conclusion
Self-medication was common among the elderly in Macao during the COVID-19 pandemic, but their intention to consult pharmacists was moderate. Public education about pharmacist's role in self-medication to manage major public health incidents should be reinforced.

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The health condition after COVID-19 infection stratified by initial disease-severity

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Aims: To stratify the severity of patients with COVID-19 infection and evaluate the risk of COVID-19-related clinical sequelae and compared age-specific differences
Methods: A retrospective cohort study were conducted using the electronic health database of Hong Kong Hospital Authority between 01 Jan 2022 to 15 August 2022. The cohort was stratified by age (≤40, 41-64, and ≥65 years old) and patients in each age-group were divided into four groups: (1)critical-group (ICU admission, mechanical ventilation support, C-reactive protein (CRP)>80mg/L or D-dimmer>2g/mL); (2)severe-group (CRP 30-80mg/L , D-dimer 0.5-2g/mL or CT value<20), (3)mild-moderate-group (COVID-19 positive-tested but not meeting the aforementioned criteria), (4)individuals without COVID-19 infection. The propensity score weighting was used to adjust the covariates among four groups. The association between COVID-19 severity and the clinical sequelae and all-cause mortality in acute and post-acute phase was estimated by the Cox proportional regression model in each age group.
Results: In ≤40, 40-64, and ≥65 age group, there were 286,114, 320,304 and 194,227 patients with mild-moderate conditions, 18,419, 23,678 and 31,505 with severe conditions, and 1,168, 2,261 and 10,178 patients with critical conditions, respectively. A general increasing trend was observed between the risk of COVID-19 related clinical sequelae and the severity of COVID-19 with advancing age, both during the acute and post-acute phases. Notably, In the acute phase, insignificant risks were observed only in mild-moderate patients aged≤40 compared to the unexposed group [e.g. mortality-risk HR (95%CI) aged≤40: 1.0 (0.5,2.0); aged 41-64: 2.1 (1.8,2.6); aged>65: 4.8 (4.6, 5.1)]; while in the post-acute phase, only patients aged over 65 were observed with a significant higher risk of clinical sequelae [aged≤40: 0.8 (0.5,1.0); aged 41-64: 1.1 (1.0,1.2); aged>65: 1.5 (1.5,1.6)].
Conclusion: The risk of health consequences after COVID-19 infection increased with increasing severity of COVID-19 infection, specifically among the elderly in both acute and post-acute phase.

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The Impact of COVID-19 restrictions on Emergency Bellwether Procedures in Asia

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Introduction: Around the time COVID-19 was declared a global pandemic, various restrictions and measures were implemented at all levels to limit disease spread and preserve healthcare capacity. Data is lacking in many low and middle-income countries on how these measures impact healthcare utilization and outcomes.
Aims: This study aims to determine the impact of COVID-19 restrictions on volumes of the 3 emergency bellwether procedures in South and Southeast Asia.
Methods: This was a retrospective cohort study of patients who underwent any of the 3 emergency bellwether procedures (Caesarean section, laparotomy and open fracture fixation) from 1 January 2018 to 31 December 2021 at one of 8 institutions in Singapore, Malaysia, Indonesia, India and Vietnam. We compared the weekly volumes, baseline characteristics and outcomes of each procedure across different time periods in each institution defined by different level of COVID-19 restrictions using selected indicators from a city-level and hospital-level response index.
Results: Weekly volumes of emergency Caesarean section decreased significantly in Guwahati Neurological Research Centre (GNRC) ($p = 5.76 \times 10^{-6}$) and Ulin General Hospital (UGH) ($p < 2.2 \times 10^{-16}$) but increased in Adam Malik Hospital (AMH) ($p = 1.45 \times 10^{-5}$). For laparotomies, volume increased in Singapore General Hospital ($p = 8.56 \times 10^{-6}$) but decreased in Military Hospital 175 ($p = 6.30 \times 10^{-7}$). The volume of open fracture fixations decreased in GNRC ($p = 1.33 \times 10^{-5}$), AMH ($p = 1.68 \times 10^{-6}$) and UGH ($p = 8.15 \times 10^{-6}$).
Conclusion: COVID-19 restrictions on the city and hospital level were associated with a decrease in surgical volumes of the 3 bellwether procedures in some of the institutions. There was some suggestion of surgical capacity limitations in UGH and MH175 during periods of more stringent COVID-19 restrictions.

Keywords: acute care surgery; pandemic preparedness; health resources, LMIC

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The Psychological Impact of the COVID-19 Pandemic on the General Population in India: Insights from a Nationwide Survey

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The Psychological Impact of the COVID-19 Pandemic on the General Population in India: Insights from a Nationwide Survey

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Introduction. A pandemic imposes restrictions in activities and changes to routine that are necessary to prevent the spread of an infectious disease, but these measures can have significant social and economic effects. Thus, this influences the mental health of the general population, as it may restrict activities, change normal routine, affect social and economic wellbeing of them.
Aims. This study aimed to assess the impact of COVID-19 pandemic on mental health of the public in India.
Methods. A cross-sectional web-based study was conducted for a period of 20 days among general population of India, through social media, emails, and online chat platforms, in the year 2020. The study used PHQ-4 and IES-6 scales to measure depression/anxiety and distress respectively. Multiple binary logistic regression was used to explore the relationship of the personal characteristics with the prevalence of self-reported psychiatric illness.
Results. The study enrolled a total of 1257 individuals with representation from all 29 states of India with a mean (SD) age of 29.3 (9.7). Based on the combined PHQ-4 scale, 13.9% (n=174) had reported a moderate-severe level of anxiety or depression. Regarding distress, nearly three-quarters (n=942) had exhibited clinical concern for distress, and more than a half (n=670) met the threshold for probable diagnosis of distress. The study found individuals who lived alone, lived in shared accommodation, or who did not have chronic illness were reported a higher prevalence of anxiety or depression, and accommodation type was associated with the distress level in comparison with their counterparts.
Discussion. Our findings can assist various healthcare professionals and government advisors in strategizing targeted interventions required for combating COVID-19 in India and across the globe. Given the higher risk of pandemic-related psychological illness and its ongoing impact on people, it is crucial for advisors and the population.

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Vaccination is protective against post-Covid-19 multimorbidity incidence: a territory-wide retrospective cohort study

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Introduction
Previous research suggests that the clinical sequalae of Covid-19 are persistent long after the infection, which may be associated with an elevated risk of multimorbidity in people with a pre-existing chronic condition.

Aims
To examine the association of Covid-19 with multimorbidity incidence among people with one chronic condition and quantify the absolute and relative incidence rates of multimorbidity after COVID-19 with or without prior full vaccination.

Methods
We conducted a retrospective cohort study with territory-wide public healthcare records from Hong Kong. From patients with only one chronic disease before January 1, 2020, we selected patients infected with Covid-19 up to January 29, 2023 as the exposed group. We randomly selected 4 patients with the same age, sex, and first chronic condition of patients without Covid-19 at that point as the comparison group. Poisson regression was used to calculate the adjusted incidence rate ratio of multimorbidity between those with or without Covid-19, as well as those who were fully vaccinated (3 does or more) before the infection. Sub-group analysis was conducted in men, women, those who were younger than 65 years, older people, and those infected with Covid-19 before or after oral antiviral drugs were made available in Hong Kong. Stratified analysis was conducted for each of the first and the second chronic conditions respectively.

Results
Overall speaking, Covid-19 was associated with 26%-increased rates of multimorbidity [95% CI 23%-29%], and Covid-19 with prior full vaccination was associated with only 8%-increased rates. Similar associations were estimated in sub-group analyses and sensitivity analyses.

Discussion
Health services should be focused on the post-Covid-19 management of patients with pre-existing chronic diseases. An early roll-out of vaccines is essential in reducing the long-term burden among those living with a chronic condition.

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Effectiveness of Nirmatrelvir-Ritonavir on Patients with COVID-19: A Nationwide Study in Taiwan

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Introduction: The combination of nirmatrelvir and ritonavir has emerged as a promising antiviral treatment for COVID-19. Despite its approval and widespread use, real-world evidence of its effectiveness based on nationwide datasets remains limited.
Aims: This study aims to evaluate the effectiveness of nirmatrelvir plus ritonavir in preventing ICU admission, ventilatory support, hospitalization, and mortality within 30 days after the confirmed diagnosis of COVID-19.
Methods: This retrospective study examines the effectiveness of nirmatrelvir plus ritonavir in patients confirmed with COVID-19 between January 1, 2022, and December 31, 2022. Data were obtained from the Taiwan National Health Insurance Research Database, linked with the National Death Registry and the National Immunization Information System. Propensity scores were estimated based on age, gender, and risk factors associated with severe COVID-19, including age ≥ 65 years, smoking, obesity, pregnancy, and underlying comorbidities such as asthma, cancer, diabetes mellitus, chronic kidney disease, and cardiovascular disease. Multivariable logistic regression was used to compare clinical outcomes between patients prescribed nirmatrelvir plus ritonavir and those who were not, using cohorts matched through propensity score matching. The logistic models also controlled the vaccination status (none, one dose, and two or more).
Results: After 1:1 propensity score matching, the nirmatrelvir/ritonavir user and non-user groups comprised 824,134 patients each. Logistic regression analysis showed that, after controlling for demographics, vaccination status, and risk factors, patients prescribed nirmatrelvir plus ritonavir had significantly lower risks of hospital admission (OR: 0.707, 95% CI 0.696 - 0.719), ICU admission (OR: 0.349, 95% CI 0.336 - 0.362), invasive ventilatory support (OR: 0.324, 95% CI 0.304 - 0.345), and mortality (OR: 0.311, 95% CI 0.298 - 0.324).
Discussion: This nationwide, population-based study provides robust real-world evidence and hightlights the significant impact of nirmatrelvir plus ritonavir in reducing the risk of adverse clinical outcomes in COVID-19 patients.

[Diabetes and Metabolic Diseases]

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Investigation of Severe Hypoglycemia Risk among Lyumjev® Treated Diabetic Patients in Japan

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Introduction: Lyumjev is a new drug formulation for patients with diabetes. Hypoglycemia is one of the major concerns in insulin therapy for patients with diabetes.
Aims: To describe the incidence proportion and rate of the first severe hypoglycemia event requiring any hospital visit, and to estimate the risk of severe hypoglycemia among adult patients with diabetes treated with Lyumjev compared to patients treated with other rapid-acting insulin analogs under routine care in Japan.
Methods: The Medical Data Vision database, a nationwide hospital-based administrative database in Japan from 1 December 2019 through 31 May 2023, was used. A comparative analysis to estimate the risk of hypoglycemia among adult patients diagnosed with diabetes who were newly treated with Lyumjev (Lyumjev cohort) or with rapid-acting insulin analogs other than Lyumjev (comparator cohort) was performed using propensity score matching method (1:5) to control for potential baseline confounding.
Results: There were 10 592 patients in Lyumjev cohort and 52 917 patients in comparator cohort after propensity score matching. The total duration of follow-up period was 2 613.8 person-years and 15 565.7 person-years for the Lyumjev cohort and the comparator cohort, respectively.The incidence proportion and rate of the first severe hypoglycemia in the matched cohort (comparative analysis) were 0.32% (95% confidence interval [CI]: 0.23, 0.45) and 1.3 per 100 person-years (95% CI: 0.2, 7.9) for the Lyumjev cohort and 0.45% (95% CI: 0.40, 0.51) and 1.5 per 100 person-years (95% CI: 0.8, 2.9) for the comparator cohort. The hazard ratio was 0.76 (95% CI: 0.53, 1.09; p-value: 0.1324).
Discussion: There was no statistically significant increased incidence or risk of severe hypoglycemia with Lyumjev compared to other rapid-acting insulin analogs among adult patients who are naive to rapid-acting insulin analogs and initiating treatment. This study did not impact the benefit-risk balance of Lyumjev.

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Prevalence and predictors of adverse events with DPP-4 inhibitors: A cross-sectional study

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Introduction: Dipeptidyl peptidase-4(DPP-4) inhibitors are widely prescribed for managing type 2 diabetes mellitus (T2DM) despite safety concerns. However, studies on the prevalence and the factors contributing to these adverse drug reactions with DPP-4 inhibitors in South India are scarce.
Aim: This study assessed the prevalence and predictors of adverse events(AEs) associated with DPP-4 inhibitors in T2DM patients.
Methods: This retrospective cross-sectional study analysed data from medical records of T2DM patients on DPP-4 inhibitors admitted to the medicine department in a South Indian tertiary care hospital from 2019 to 2021. The causality of AEs was assessed using the Naranjo algorithm and WHO-UMC criteria, and severity using the modified Hartwig and Seigel scale. We applied a Generalized Linear Model with a binary response and logit-link function to understand the parameters that best explain the AE. The best-fit models were selected based on the lowest Akaike's Information Criterion and highest Pseudo R2 and presented the odds ratio(OR) with a 95% confidence interval. All the analyses were performed in R software version 4.2.1.
Results: Among the 796 patients included, AEs were observed among 26% of the study population. A total of 212AEs were observed, with saxagliptin-associated AEs being the most prevalent(66.6%). Hepatic AEs(37.7%) were predominant, followed by gastrointestinal events(16.5%) and electrolyte imbalance(12.3%). Most AEs were possible based on WHO-UMC criteria(78.7%) and the Naranjo scale(86.7%), with 58% being moderate severity and 42% mild. In the multivariate analysis, aspartate transaminase[OR:1.013(0.006-0.020)], alkaline phosphatase[OR: 1.004(0.001-0.007)], and patients already on DPP-4 inhibitor[OR 0.191(-2.126 - -1.215)] were significant predictors for AEs with DPP-4 inhibitors.
Conclusion: The study identified a high prevalence of AEs associated with DPP-4 inhibitors and highlighted significant factors contributing to these events. These findings underscore the necessity of vigilant monitoring and risk assessment while using DPP-4 inhibitors in the Indian population.
Keywords: adverse event, DPP-4 inhibitor, predictor

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Adherence to routine medical examinations among patients with type 2 diabetes mellitus

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Introduction: Type 2 diabetes increases the risk of complications such as retinopathy, nephropathy, and periodontal diseases. Regular medical examinations are essential for early detection and management of these complications to improve clinical outcomes. Prior research has primarily focused on medication adherence, leaving a gap in understanding adherence to routine examinations.
Aims: This study aimed to evaluate adherence rates to regular medical examinations among patients with type 2 diabetes and to identify associated factors. Additionally, it compared adherence across different examination types.
Methods: We analyzed data from the 2017 National Health Interview Survey in Taiwan, focusing on individuals diagnosed with diabetes after age 20. High adherence was defined as completing at least three of the following examinations in the past year: HbA1c test, eye screening, urinalysis, and dental check-up. Evaluated factors included current age, age at diagnosis, gender, marital status, educational level, living situation, employment status, income, self-rated health, daily activity limitations, and comorbidities. Adherence rates were calculated as weighted percentages, and influencing factors were assessed using Wald chi-square tests and logistic regression models.
Results: After applying weights, the study included 1,512,815 patients, of whom 47.2% achieved high adherence. The adherence rates were 77.5% for HbA1c test, 42.9% for eye screening, 59.6% for urinalysis, and 44.1% for dental check-up. Higher adherence was significantly associated with younger age at diagnosis, female gender, higher educational attainment, being married, retirement or unemployment, and higher income levels ($p<0.05$). Age at diagnosis emerged as the most consistent factor of adherence across all examination types.
Conclusion: Approximately half of type 2 diabetes patients adhere to recommended routine examinations, with significant disparities driven by demographic and socioeconomic factors. Targeted interventions tailored to address these factors are crucial to enhance adherence and improve patient outcomes.

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Anemia and SGLT2 Inhibitors in Patients with Diabetes across Different CKD Stages

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Introduction/Aim: Sodium-glucose transport protein 2 (SGLT2) inhibitors was associated with a lower anemia incidence in patients with diabetes and CKD. However, there was limited evidence on anemia and SGLT2 inhibitors in such patients across different CKD stages.
Methods: We emulated a pragmatic target trial of CREDENCE and DAPA-CKD using a multi-institutional cohort between 2016 and 2022. We included patients with diabetes and CKD stages 1-3 newly receiving SGLT2 inhibitors or GLP-1 RAs. Patients were stratified by baseline estimated Glomerular filtration rate: CKD stages 1-2 or CKD stage 3. Propensity score with fine stratification was employed to mimic similar probability of treatment assignment. The primary outcome were anemia event occurrence and anemia treatment initiation. HR and 95% CI were derived using Cox proportional hazards models to compare the risk of anemia for two treatment strategies. We assessed the effect modification using interaction terms of SGLT2 inhibitors and CKD stages.
Results: We identified a total of 12,121 and 1,474 patients with T2D and CKD stages 1-3 newly receiving SGLT2 inhibitors and GLP-1 RAs, respectively. Patients receiving SGLT2 inhibitors with CKD stage 3 experienced a lower risk of anemia event occurrence (HR 0.70, 95% CI 0.62 - 0.79) compared to those with CKD stage 1-2 (HR 0.81, 95% CI 0.69 - 0.95), with a p-value for interaction at 0.01. Additionally, patients with CKD stage 3 were associated with a reduced risk of anemia treatment initiation (HR: 0.73, 95% CI 0.60-0.89), while not for those with CKD stages 1-2 (HR: 1.37, 95% CI 0.99 - 1.90), with a p-value for interaction at 0.0001.
Conclusion: CKD stages was associated with different anemia risks for patients receiving SGLT2 inhibitors or GLP1-RAs. For patients with CKD stage 3, physicians may consider prescribe SGLT2 inhibitors to prevent anemia.

Keywords: Target trial emulation framework, SGLT2 inhibitors, anemia, CKD

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Assessment of Treatment Satisfaction, quality of life in Type 2 DM Patients

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Introduction:
In the management of diabetes treatment satisfaction plays a crucial role in patient outcomes and adherence to medications. Research studies have shown that higher levels of treatment satisfaction is associated with better glycemic control, improved quality of life and lower healthcare costs.
Aim:
To assess diabetic treatment satisfaction and health-related quality of life in type 2 DM patients.
Methods:
Our study was conducted with meticulous care at KIMS Hospital, involving a prospective randomised interventional design. DTSQs, DTSQc, and DQOL questionnaires were administered to assess treatment satisfaction and health-related quality of life during 4 follow-ups with a month gap between each follow-up. Patients' HbA1C was monitored at baseline, and final follow-ups, whereas CBG levels were monitored at every follow-up. The results were then analysed for statistical significance at $p<0.05$ using the reliable SPSS version 29.0.2, ensuring the robustness of our findings.
Results:
A total of 400 patients were recruited and segregated into control (200) and test groups (200) using the block randomisation technique. Among the control group, 60% were males in the test group, and 55% were males. The mean age group of enrolled patients is 59.5 years. A significant improvement ($p<0.05$) in DTSQ scores in test group patients compared to Control group patients ($p=0.02$). DQOL scores were also observed, with a significant improvement ($p<0.05$) in Test group patients, demonstrating the influence of education and monitoring of the patients.
Discussion and Conclusion
Continuous monitoring of counselling has shown a significant improvement in clinical outcomes, which has a positive influence on treatment satisfaction and health-related quality of life.
Key Words
Diabetes Treatment Satisfaction, HRQoL, Pharmacist intervention

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Associated Factors of Cardiovascular Events in Diabetes Outpatients at Teaching Hospitals

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Associated Factors of Cardiovascular Events in Diabetes Outpatients at Teaching Hospitals
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Introduction. Diabetes and cardiovascular disease are significant contributors of early mortality and significantly burden healthcare costs in Indonesia. Amounts of evidence indicate that hyperglycemia plays a crucial role in the elevated risk of cardiovascular events (CVEs).
Aims. Identifying the characteristics and clinical features as contributing factors to diabetes patients developing CVEs and their medication use.
Methods. This study examined the diabetes outpatient medical records of 250 patients, aged 18–60, from two hospitals in Yogyakarta, Indonesia. Descriptive and bivariate statistics to analyse the characteristics differences between patient with and without CVEs. The multivariable logistic models to predict the impact of variables on CVEs, along with the odds ratio (OR) and the 95% confidence interval (CI) for CVEs. CVEs involved the presence of any of these conditions: hypertension, coronary heart disease, ischemic stroke, or other atherosclerosis-related problems.
Results. Compared to diabetes patients without CVEs, those with CVEs had a higher age of 53.21 vs. 48.09 years ($p < 0.001$), a BMI of 26.48 vs. 25.60 ($p = 0.101$), a female gender of 28.4% ($p = 0.139$), a diabetes duration of >5 years ($p < 0.001$), hypertension 30% ($p = 0.02$), an uncontrolled glycemic 30% ($p = 0.039$), and dyslipidemia 34.8% ($p = 0.053$). The use of associated medications in diabetes with CVEs included insulin (61.71%), antihypertensives (66.67%), and antihypercholesterolemia (61.71%). Logistic multivariate analysis affirmed that amongst clinical features involved age (OR 1.069; CI 1.033-1.106; $p < 0.001$), hypertension (OR 1.923; CI 1.117-3.310; p 0.018), and dyslipidemia (OR 1.784; CI 1.032-3.084; p 0.038) had a meaningful effect on CVEs.
Discussion. The long history of diabetes and high glucose levels are still present in diabetes with CVEs. The number diabetics who received medication related CVEs were yet incomplete. Furthermore, the uncontrolled blood pressure and lipid level had 2 fold incidence of cardiovascular problems.

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Association of metabolic comorbidities with chronic hepatitis B progression among Chinese patients

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Introduction:
The prevalence of metabolic comorbidities is increasing as a function of increasing age, which is gaining a great concern in patients with chronic hepatitis B(CHB).
Aim:
We evaluated the impact of metabolic comorbidities (diabetes and hyperlipidemia) on cirrhosis and hepatocellular carcinoma (HCC) in Chinese adult patients with nucleos(t)ide analogue (NAs) treated CHB.
Method:
This is a retrospective, observational, cohort study used electronic medical records from first-tier hospital in China. Patients with CHB receiving NAs between Jan-1-2010 to Jun-01-2020 were enrolled and followed up from the first identified NAs prescription(the index date) until last visit or study end (Dec-31-2020). The baseline period is 1 year prior to the index date. Associations between the comorbidity burden and cirrhosis/HCC were explored using Cox regression models.
Results:
Among 19,987 patients enrolled, the median age was 45 years (range 18-97), 18.10% were older than 60 years, and 64.59% were male. 20.00% had at least one metabolic comorbidity including 19.18% with diabetes only, 64.53% with hyperlipidemia only and 16.28% with both. 1594 developed cirrhosis (3.525/100 person-years) and 300 patients developed HCC over the study period (0.559/100 person-years). Compared to no comorbidity, ≥1 comorbidity was significantly associated with cirrhosis (adjusted hazard ratio [aHR]1.63, 95% confidence interval [CI] [1.46-1.82]; p<0.001) and HCC (1.72 [1.35-2.19]; p<0.001). Results were consistent across ≤60 and >60-year age groups. When comes to detail comorbidity, diabetes alone was significantly associated with cirrhosis (2.34 [1.93-2.84]; p<0.001) and HCC (2.78 [2.01-3.84]; p<0.001), as was the combination of diabetes and hyperlipidemia (cirrhosis: 1.64 [1.30-2.07]; p<0.001, HCC: 1.79 [1.16-2.76]; p=0.009). Hyperlipidemia alone was associated with development of cirrhosis (1.45 [1.26-1.65]; p<0.001), but not HCC (p=0.254).
Conclusion:
Metabolic comorbidities increase the risk of cirrhosis and HCC in Chinese NA treated CHB patients. Patients with CHB warrant thorough screening and management of metabolic risk factors to reduce this risk.

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Association of multimorbidity intervals with mortality among people with diabetes

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Introduction
Multimorbidity interval, referred to as the time interval from the first chronic condition diagnosis to the occurrence of multimorbidity. Multimorbidity is highly prevalent among people with diabetes and associated with a greater risk of mortality. However, there is little research quantifying the association of multimorbidity intervals with mortality risk among people with diabetes.
Aims
To examine whether, and to what extent, time interval between diabetes and a second chronic disease may be associated with the risk of mortality.
Methods
We conducted a territory-wide nested case-control study with data from Hong Kong. The underlying cohort included patients first diagnosed with diabetes from January 1, 2010 to December 31, 2012 and subsequently diagnosed with another chronic condition as of December 31, 2019. Patients with any chronic conditions 2 years before the diabetes diagnosis were excluded.
We extracted those who died after developing multimorbidity as case participants. We defined the time interval from the date of developing multimorbidity to the death date as survival period of case participants. We randomly selected 4 patients with the same age, sex, and second chronic condition who had not died after going through the same survival period of the case participants as the control participants.
Conditional logistic regression was used to estimate the adjusted odds ratio of death. Sub-group analysis was conducted in men, women, those aged 65 years or more, and those were younger than 65 years. Stratified analysis was conducted for each of the second chronic conditions.
Results
Overall, the risk of mortality reduces by 19% with the extension of multimorbidity interval by one year [95% CI 17%-21%]. Similar associations were estimated in sub-group analysis and stratified analysis.
Discussion
Our findings suggest that clinical management of diabetes should focus on mitigating and lowering the risk of developing multimorbidity to reduce further complications and mortality.

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Benzodiazepines use in patients with obstructive sleep apnea and diabetes mellitus

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- Introduction:
Benzodiazepines (BZDs) are one of the secondary treatments for obstructive sleep apnea (OSA), and they should be used with caution because they have the potential to worsen airway obstruction. Patients with type 2 diabetes mellitus (DM) often present with OSA and obesity. However, there is limited research investigating BZDs use in this specific population.
- Aims:
To assess the utilization of BZDs among patients having DM with/without OSA (OSA-DM and non-OSA DM).
- Methods:
We conducted a retrospective nationwide longitudinal study using the data of Taiwan's National Health Insurance for the period from 2001 to 2020. Patients with incident DM followed by a diagnosis of OSA were matched (1:1) with DM without OSA with factors of gender, age, DM diagnosis year, DM duration, and survival beyond one year after DM. We examined the use of hypnotic medications at DM diagnosis and one, two, three, or five years following diagnosis, including BZDs and non-benzodiazepines (non-BZDs).
- Results:
A total of 40,370 patients were included. At the time of DM diagnosis, 3,150 patients with OSA-DM (15.6%) were BZD users, and the trend of BZD use decreased after the first-year follow-up, with 16.4% in year one, 15.0% in year two, 15.0% in year three, and 13.2% in year five. Less than 10% of the non-OSA DM group used BZDs and stayed stable during the follow-up period. At baseline, 1,956 patients (9.69%) in the non-OSA DM group and 4,067 patients (20.15%) in the OSA-DM group used non-BZDs. Following the first-year follow-up, there was a decrease in non-BZDs use in both groups.
- Discussion:
In the OSA-DM group, BZD use was twice as common as in the non-OSA DM group, possibly due to comorbidities such as insomnia or psychiatric disorders. Non-BZDs, which have fewer respiratory depressant effects, may be preferred in OSA patients.

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Bridging the link between diabetes and chronotype: A first study in India

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Introduction. Type 2 diabetes has affected 537 million adults aged 20 to 79 worldwide, which is expected to rise to 783 million by 2045. Individuals with evening chronotype [reduced physical activities and sleep, eating habits during late hours] have a higher risk of developing diabetes due to diminished glucose tolerance, increased inflammatory markers and increasing stress on the pancreas.
Aims. This study aims to explore the link between evening chronotype and diabetes, identify new approaches and target interventions to combat the rising trend in diabetes.
Methods. Using a comparative cross-sectional study design, 200 Indian subjects satisfying the study criteria were enrolled using a simple random sampling method within 6 months in a tertiary care hospital after the consenting process. Enrolled subjects were given a morningness-eveningness questionnaire by the American Thoracic Society [determines chronotype], glycated hemoglobin test, fasting blood glucose, and postprandial blood glucose tests were performed.
Results. The population's mean age and standard deviation were found to be [46.61±11.59 years]. 52.5 % of the population were males. Further, the population was segregated into morning chronotype (score: ≤41) [diabetics: 4(2%); nondiabetics: 93(46.50%)], intermediate type (score: 42-58) [diabetics: 6(3%); nondiabetics: 18(9%)]; evening type: (score: >59) [diabetics: 77(38.50%); nondiabetics: 2(1%)]. There was a statistically significant difference between the number of diabetics in morning and evening chronotypes [p value <0.001]. The clinical pharmacists played a crucial role by providing chronotherapy in evening type patients [79(39.5)] which helped in preventing the progression of diabetes, and lifestyle counselling for intermediate type patients [18(9%)] to avoid the ramifications.
Discussion. In a study done by Iwasai et al., middle-aged males were selected and a high rate of the evening chronotype (10.9%) was identified in those with type 2 diabetes, compared with just 2.2% evening type who were non-diabetics.
Conclusion. This study implies that there is an association between evening chronotype and diabetes, hence by chronotherapy and counselling altering the chronotypes we could control the ramifications of diabetes.

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Cardiovascular Outcomes in Patients with Type 2 Diabetes and Obstructive Sleep Apnea

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Introduction
There has been limited investigation in the combined, longitudinal cardiovascular consequences of patients with type 2 diabetes mellitus (DM) and obstructive sleep apnea (OSA).

Aim
To examine the major cardiovascular outcomes (MACE) of OSA in patients with DM (OSA-DM) compared to diabetic patients without OSA (non-OSA DM).

Methods
This retrospective population-based cohort study used data from Taiwan's National Health Insurance Research Database. Newly diagnosed DM patients from 2000–2017 were identified. Patients with and without OSA were matched by sex, age, year of DM diagnosis, duration of DM, and survival at one year post-DM. The primary outcome was major adverse cardiovascular events (MACE), analyzed using a Cox regression model. These events included nonfatal myocardial infarction, nonfatal stroke, death from cardiovascular disease (CVD), hospitalization due to unstable angina or coronary revascularization, and hospitalization due to heart failure. We controlled for age, sex, comorbidities, medications, medical utilization, and the Charlson Index.

Results
The study included 40,370 patients (71.48% male, mean age = 58.1). OSA-DM subjects had higher rates of cardiovascular comorbidities, antihyperglycemic and cardiovascular medication use, and health care utilization. Patients with both OSA and DM exhibited a decreased risk of MACE compared to those without OSA (hazard ratio [HR], 0.93; 95% confidence interval [CI], 0.88–0.98; $p = 0.003$). Additionally, OSA-DM patients had a lower risk of hospitalization for nonfatal myocardial infarction (HR, 0.67; 95% CI, 0.59–0.75; $p < 0.001$) and death within 30 days of hospitalization for CVD (HR, 0.69; 95% CI, 0.62–0.77; $p < 0.001$). The rates of hospitalization for heart failure, unstable angina, nonfatal stroke, and coronary revascularization did not differ significantly between the two groups.
Conclusion
Despite higher rates of comorbidities and healthcare utilization, patients with OSA and newly diagnosed DM have a lower risk of major adverse cardiovascular events than those with DM alone.

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Cardiovascular risk of colchicine in patients with type 2 diabetes and gout

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Introduction: Clinical trials have shown that colchicine prevents secondary cardiovascular events, expanding its indications. Given the increased cardiovascular risk in patients with gout and type 2 diabetes (T2DM), evidence of colchicine's effectiveness in this population is needed.
Aims: To investigate the association between colchicine use and the risk of cardiovascular events in patients with T2DM and gout compared to nonsteroidal anti-inflammatory drugs (NSAIDs).
Methods: This population-based cohort study used the national claims database of South Korea (2010–2022). The study included patients diagnosed with T2DM who were newly prescribed colchicine or NSAIDs for gout. The outcome was major cardiovascular events (MACE), comprising stroke, myocardial infarction, and cardiovascular death. Patients were followed up using an as-treated definition of exposure from the date of first study drug prescription. We calculated propensity score (PS) incorporating over 50 demographic and clinical covariates and used 1:2 PS matching to balance the covariates between groups. Hazard ratios (HRs) were estimated using a Cox proportional hazard model. We performed subgroup analyses based on age, sex, antidiabetic treatment, and cardiovascular comorbidities. A duration-response analysis was performed with day 120 as a change point.
Results: We identified 13,019 colchicine (mean age 65.5; 35% female) and 117,156 NSAIDs (63.1; 35%) users with T2DM and gout. After PS matching, 12,908 colchicine and 25,816 NSAIDs users remained. The adjusted HR (aHR) for MACE was 1.04 (95% CI 0.73–1.49). Subgroup analyses were consistent except for patients with dyslipidemia (aHR 2.00, 1.06 – 3.79) compared to those without dyslipidemia (aHR 0.83, 0.52–1.33). The aHR was 1.67 (1.06–2.62) before day 120 and 0.82 (0.41–1.66) after day 120.
Discussion: This nationwide cohort study found that colchicine use does not significantly reduce MACE risk in a real-world population with comorbid T2DM and gout. Nevertheless, longer-term colchicine use may have a more favorable cardiovascular profile.

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Comparison of Biguanides and DPP-4 Inhibitors on Cardio-Cerebrovascular Outcomes, Complications, and Costs

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Introduction:
Western guidelines often recommend biguanides as the first-line treatment for diabetes. However, in Japan, dipeptidyl peptidase-4 (DPP-4) inhibitors alongside biguanides are increasingly used as the first-line therapy for type 2 diabetes (T2DM). There have been few studies comparing the effectiveness of biguanides and DPP-4 inhibitors concerning diabetes-related complications, cardio-cerebrovascular events, and associated costs.
Aims:
To compare the outcomes of patients with T2DM who initiate treatment with a biguanide versus a DPP-4 inhibitor, focusing on long-term complications, cardio-cerebrovascular events, and treatment costs.
Methods:
A cohort study was performed from 2012 to 2021 using the Shizuoka Kokuho Database. Patients diagnosed with T2DM were included. The primary outcome was the incidence of cardio-cerebrovascular events or mortality from the initial date of treatment. Secondary outcomes included incidences of diabetes-related complications (nephropathy, renal failure, retinopathy, and peripheral neuropathy) and the daily cost of the drugs used. The cost calculation in this study refers specifically to the medication costs of diabetes drugs. Propensity score matching was performed to compare the two groups.
Results:
The matched cohort comprised 529 patients treated with a biguanide and 2116 patients treated with a DPP-4 inhibitor. No significant differences were found in the incidence of cardio-cerebrovascular events or mortality (p=0.139) and T2DM-related complications (p=0.595) between the two groups. However, the biguanide group was significantly cheaper (mean daily cost of antidiabetes agent for biguanides group 61.1 JPY; for DPP-4 inhibitors group 122.7 JPY; p<0.001).
Discussion/Conclusion:
In patients with T2DM initiating pharmacotherapy, there were no differences in the long-term incidences of cardio-cerebrovascular events or complications between biguanide and DPP-4 inhibitor use, but biguanides were associated with lower costs.

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FINDRISC for detecting metabolic syndrome: Findings from an Indonesian national health survey

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Introduction: Existing studies with different target populations found different diagnostic accuracy of the Finnish Diabetes Risk Score (FINDRISC) tool. Therefore, the actual utilisation of the FINDRISC to detect early metabolic syndrome in the Indonesian population requires further evaluation.
Aims: This study aims to evaluate the diagnostic accuracy of the FINDRISC tool for detecting individuals with metabolic syndrome in Indonesia.
Methods: A dataset from the Indonesian National Basic Health Survey 2018 was analysed, and instances of metabolic syndrome were identified in accordance with both National Cholesterol Education Program Adult Treatment Panel III (NCEP-ATP III) and International Diabetes Federation (IDF) guidelines. Diagnostic accuracy of the FINDRISC tool was established using the Area Under the Curve of the Receiver Operating Characteristic (AUC ROC) curve, while optimal cut-off scores were determined by Youden's Index.
Results: From 24,243 participants, the mean and standard deviation of the FINDRISC score was 5.5 (SD 4.1). The prevalence of metabolic syndrome was 32.6% and 25.0% based on NCEP-ATP III and IDF criteria respectively. Based on NCEP-ATP III criteria alone, the AUC of the FINDRISC was 81.3% (80.8%-81.9%) with 73.5% sensitivity and 76.6% specificity. Similarly, based on IDF criteria, AUC was 89.3% (88.9%-89.7%) with 89.6% sensitivity and 76.9% specificity. The optimal cut-off score was 6 for both criteria, with 39.8% of total participants above the cut-off who would require further confirmation tests.
Conclusion: Metabolic syndrome is prevalent in Indonesia, and the FINDRISC tool offers good diagnostic accuracy for detecting such cases. Utilising FINDRISC as a first-instance screening modality will reduce the number of people requiring further confirmation tests. As a result, FINDRISC has the potential for use in daily clinical practice, and the cost-effectiveness of FINDRISC should be further evaluated.

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Geographic variation in SGLT2i and GLP-1RA use for type 2 diabetes

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Introduction

Sodium-glucose co-transporter 2 inhibitors (SGLT2i) and glucagon-like peptide-1 receptor agonists (GLP-1RA) improve glycaemic control and cardio-renal outcomes for people with type 2 diabetes (T2D), and are preferentially recommended as add-on therapy. Despite evidence of significant clinical benefits, uptake of SGLT2i and GLP-1RA is low. Variation in this use is not well understood.

Aims

To explore geographic and socioeconomic variation in use of SGLT2i and GLP-1RA in New South Wales (NSW), Australia.

Methods

We identified 367,829 NSW residents aged ≥40 years dispensed metformin in 2020, as a proxy for T2D. We estimated the prevalence of use of other glucose-lowering medicines among people with T2D, and prevalence of SGLT2i and GLP-1RA use among people using concomitant T2D therapy (i.e. metformin + another glucose-lowering medicine). We measured prevalence by small-level geography, stratified by age group, and characterized by remoteness and socioeconomic status.

Results

The prevalence of SGLT2i (29.7%) and GLP-1RA (8.3%) use in people with T2D aged 40-64 increased with geographic remoteness and in areas of greater socioeconomic disadvantage, similar to other glucose-lowering medicines. The prevalence of SGLT2i (55.4%) and GLP-1RA (15.4%) among people using concomitant T2D therapy varied across geographic areas; with lower SGLT2i use in more disadvantaged areas, and localized areas of high GLP-1RA use. Compared to people aged 40-64 years, prevalence of SGLT2i and GLP1-RA use was lower in older age groups, but with similar patterns of variation across geographic areas.

Discussion/Conclusion

The prevalence of SGLT2i and GLP-1RA use varied by geography, likely reflecting a combination of system- and prescriber-level factors. Socioeconomic variation in GLP-1RA use was overshadowed by localised patterns of prescribing; geographic variation in medicine use cannot be interpreted without considering the potential impact of local policies and practice. Continued monitoring of variation can help shape interventions to optimise use among people who would benefit the most.

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Risk analysis of ezetimibe and drug-induced liver injury in Taiwan

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- Introduction
In a health risk communication by Health Canada in March 2024 noted that ezetimibe may cause drug-induced liver injury (DILI). There is substantial evidence indicating a causal relationship between monotherapy with ezetimibe and the occurrence of DILI.
- Aims
This study aims to analyze the risk of DILI and other adverse effects associated with the use of ezetimibe at a regional hospital in Taiwan.
- Methods
This study retrospectively collected data from the hospital's medical system on patients who prescribed ezetimibe monotherapy from January 2022 to December 2023. The analysis included patients' basic demographic information. Liver function-related parameters, such as AST, ALT, alkaline phosphatase (ALP), gamma-glutamyl transferase (r-GT), and bilirubin levels, were evaluated to assess the occurrence of DILI.
- Results
A total of 380 patients were treated with ezetimibe monotherapy, with an average age of 62.3 years. 217 patients had abnormal ALT or AST levels, and 39 patients had abnormalities in both. One patient had ALT levels more than five times the upper limit of normal (ULN), and ten patients had more than three times ULN. One patient had ALP levels more than twice ULN combined with abnormal r-GT levels. None of the patients had diagnoses of drug-induced liver injury or related allergic reactions.
- Discussion/Conclusion
Based on the results, more than half of the patients had at least one abnormal liver function parameter. Two patients met the criteria for DILI, but their liver function abnormalities were more likely related to their comorbid conditions.
However, it is still recommended that liver function tests be considered when initiating ezetimibe therapy. Patients should also be instructed on the early symptoms of liver injury and advised to immediately inform healthcare providers if such symptoms occur. If liver injury is suspected, liver function should be tested and evaluated promptly.

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Safety of SGLT2 inhibitors in type 1 diabetes: real-world experience in Japan

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Introduction
Sodium-glucose cotransporter 2 (SGLT2) inhibitors may be prescribed as “off-label” adjunct therapies for type 1 diabetes mellitus (T1DM). Japan is one of the few countries where two SGLT2 inhibitors—dapagliflozin and ipragliflozin—have received regulatory approval for use in patients with uncontrolled T1DM. Concerns remain regarding the safety of SGLT2 use among T1DM patients.

Aims
To investigate the safety profile of SGLT2 inhibitor therapy among T1DM patients in a real-world setting.
Methods
We analyzed data from the RWD database, a multihospital database that contains patient data from 230 institutions across Japan. We selected patients with T1DM who initiated treatment with either dapagliflozin or ipragliflozin after regulatory approval, with regular care for T1DM at medical institutions participating in the RWD database. Prespecified adverse events included acute kidney injury, hypoglycemia, amputation, ketoacidosis, urinary tract infection (UTI), genital infection, and non-vertebral fracture. The newly recorded diagnoses of the aforementioned events were identified from the initiation of SGLT2 inhibitors to the last prescription date, including the days covered by the last pills.

Results
From 13, 848 patients with T1DM, we identified 393 initiators of SGLT2 inhibitors after regulatory approval; the details of patient characteristics and glycemic control dynamics are reported in 2024 ISPE Annual Meeting. The median age was 51 years (interquartile range: 42 to 63), and females accounted for 55.7%. During a total of 10,650 person-months of follow-up, 48 patients (12.2% or 4.5 cases per 1000 person-months) had at least one record of prespecified adverse events. The most common adverse event was hypoglycemia, occurring in 19 patients (4.8%), followed by UTI (4.1%) and ketoacidosis (2.3%); no records of limb amputation or non-vertebral fracture were documented.

Conclusion
Despite the limited sample size, our data offer insights regarding the safety profile of SGLT2 inhibitors when they have an expanded "on-label" indication for T1DM.

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Sodium-glucose cotransporter 2 inhibitors and suicide in patients with diabetes and depression

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Introduction Sodium-glucose cotransporter 2 (SGLT2) inhibitors may halt both neuro-inflammation and blood-brain barrier disturbance, indicating its antidepressant properties. However, no studies assessed suicide in patients receiving SGLT2 inhibitors with diabetes and depression.
Aims To evaluate the association between the use of SGLT2 inhibitors and suicide risk in patients with diabetes and depression.

Methods We emulated a target trial using data from the Taiwan National Health Insurance Research Database. Inclusion were adult patients with diabetes and depression newly receiving the SGLT-2 inhibitors or dipeptidyl peptidase-4 (DPP-4) inhibitors treatments between 2016 and 2020. We assigned the patients to the SGLT-2 inhibitors or DPP-4 inhibitors group and defined the index date as the first day of receiving those medications. Excluded were patients with a history of attempted suicide, bipolar disorder, or schizophrenia. The outcomes were the successful suicide and attempted suicide. Inverse probability of treatment weighting (IPTW) was applied to mimic randomization between groups. We used the Cox proportional hazards models to estimate hazard ratios (HRs) and 95% confidence intervals (95% CI).

Results A total of 26,775 patients with diabetes and depression newly received SGLT2 inhibitors (n=3,663) and DPP4 inhibitors (n=23,112). The mean age was 64.2 years, and 39.5% were male. We observed an increased risk of successful suicide in patients receiving SGLT2 inhibitors (crude HR 1.18 95% CI 0.64-2.18). After applying IPTW, patients receiving SGLT2 inhibitors were not associated with a reduced risk of successful suicide (HR 0.97 95% CI 0.50-1.92) or attempted suicide (HR 0.99 95% CI 0.82-1.20).

Discussion/Conclusion The Use of SGLT2 inhibitors was not associated with a reduced risk of suicide in patients with diabetes and depression. However, due to the observed increased risk of successful suicide, clinicians should continue to closely monitor their mental health.

Keywords: sodium-glucose cotransporter 2 inhibitors, diabetes, depression, suicide

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The association of SGLT2i versus DPP4i with incident anemia in Hong Kong.

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Introduction: Anemia is a common complication in patients with diabetes and impaired renal function. Sodium-glucose co-transporter 2 inhibitors (SGLT2i), one of the second line glucose-lowering agents (GLA), have been shown to increase hemoglobin levels and reduce anemia-related outcomes in recent post-hoc studies of placebo-controlled trials. However, without an active comparator, the comparative effects of SGLT2i versus other GLA is unclear. Dipeptidyl peptidase-4 inhibitors (DPP4i), another commonly used second line GLA, have also been shown to reduce the decline in hemoglobin levels among diabetic kidney disease patients in recent studies. Therefore, comparisons of the potential anemia benefits of SGLT2i and DPP4i are warranted to better inform treatment decisions.

Aims: To investigate the association of SGLT2i versus DPP4i with the risk of incident anemia events using real-world clinical data in Hong Kong.

Methods: This was a population-based retrospective cohort study using electronic medical records from the public healthcare sector in Hong Kong (the CDARS database). Clinical data of type 2 diabetes patients using SGLT2i and DPP4i between 2015 and 2018 were collected. The “prevalent new-user” design was adopted to account for the previous exposure to the comparator drugs. Propensity score (PS) matching was used to balance baseline characteristics of the two exposure groups. Hazard ratio of incident anemia was evaluated using the Cox regression.

Results: The PS-matched cohort included 6,415 SGLT2i users and 25,660 DPP4i users, with a mean age of 61 and a median follow-up of 2.6 years. SGLT2i was significantly associated with a reduced risk of incident anemia compared to DPP4i (hazard ratio: 0.40; 95% CI: 0.31-0.52; $p<0.001$).

Discussion: The association of SGLT2i with reduced anemia among diabetes patients remained with an active comparator. Compared to DPP4i, SGLT2i conferred better protection against anemia, and therefore potentially a better treatment choice for diabetes patients with an elevated risk of anemia.

[Drug Safety]

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Evaluation of the ADR Reporting System at a South Indian Teaching Hospital

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Biography:

Introduction
Good Pharmacovigilance practices are essential to minimising drug-related issues, such as adverse drug reactions, and their negative impact on clinical and economic outcomes.
Aims
To initiate and evaluate the adverse drug reaction reporting system at a tertiary care teaching hospital in South Telangana, India.
Methods
This prospective observational and interventional study conducted at the Department of Clinical Pharmacy at KIMS Hospital, Narketpalli, Telangana. All in-patients were monitored for drug safety issues. All unpleasant events were reported. Naranjo's scale was used to assess causality, Hartwig's scale was used for severity, and the modified Shumock and Thornton scale was used to assess preventability. All the reports were assessed based on drug and disease class.
Results
During the study period, 1330 Adverse events were detected. Among them, 446 were due to the coronavirus vaccine, and 884 were due to drugs. About 44.3% of males and 55.07% of females experienced adverse events. About 69% of ADRs were observed in patients with over 40 years of age. Alcohol (68%) and cigarette smoking (62%) showed an influence on precipitating ADRs. In the disease category, the majority of ADRs 397(29.84%) were seen in type 2 DM patients, followed by Hypertension (HTN) 206, and in Asthma (110). Causality scores reveal that, Definite (17%), Probable (54%) and Possible (28%). The majority of ADRs were mild (85.93%), Moderate (10.15%) and severe (3.9%) in severity, 17% of reported ADRs were preventable, and 75% of ADRs were probably preventable. The majority of ADRs reported were with Calcium Channel Blockers (5.09%) followed by Loop Diuretics (4.39%).
Discussion/Conclusion
ADRs negatively influence the clinical and economic outcomes. Properly initiated pharmacovigilance practices will prevent unwanted ADRs and help patients to get positive clinical outcomes.

Key Words
Adverse Drug Reaction, Pharmacovigilance, Causality, Severity and Preventability Assessment

P190

Assessment of Drug Information Resources for Recommendations on Renal Drug Dosage Adjustment

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Introduction: Healthcare providers use various drug information (DI) resources to select drug doses in patients with renal impairment. However, the differences among these resources in making dosage recommendations pose additional risks for drug use in this special population.

Aim: To assess the consistency of renal drug dosage recommendations among six DI resources.

Methods: We reviewed six DI resources namely; British National Formulary 85th edition (BNF-85), drugs.com (DDC), Medscape.com (MS), Micromedex (MM), Renal Drug Handbook 5th edition (RDH-5), and UpToDate® (UTD), to explore the recommendations on renal drug dosage adjustments for one-hundred drugs. The recommendations provided for each drug, in each DI resource, were carefully reviewed, documented, and then categorized as numerical, non-numerical, dosage adjustment not required, contraindicated, no advice mentioned, and not listed. Each DI resource was scored for scope by calculating the number of drugs for which the resource provided a recommendation. Fleiss' Kappa(k) score was estimated using SPSS v29.0 to measure the consistency in documented information among the DI resources.

Results: RDH-5 had the highest scope score (89%), followed by UTD (82%), whereas BNF-85 and MS had the least scope scores of 54% each. The intersource reliability test revealed Fleiss' kappa(k) score of 0.246 [CI: 0.216-0.276, p<0.001], indicating a fair agreement among the DI resources regarding information on drug use in impaired renal function. Further, the intersource reliability test according to the anatomical therapeutic chemical (ATC) classification of studied medications revealed that the DI resources had the highest consistency [k=0.289, CI:0.200-0.379, p<0.001] for the drugs acting on the nervous system, concerning information on their use in renal impairment.
Conclusion: Developing an evidence-based list of renal drug dosage adjustments based on a single scale of assessing renal impairment, will help guide rational drug use in this special population.

Keywords: Consistency, Drug information resources, Impaired renal function, Rational drug use.

P191

Bruton Tyrosine Kinase Inhibitors and Potential Risk of Drug-Induced Liver Injury

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Objective
To evaluate the potential association between Drug-induced liver injury (DILI) and the use of Bruton Tyrosine Kinase (BTK)

Methods, Results
We searched the WHO global database (VigiBase) for all reported cases between 2013 and Feb 2024 using a signal detection tool (VigiLyze). The search terms included (Acute liver injury OR drug induced liver injury OR Hepatic enzyme increased OR elevated alkaline phosphatase OR hepatocellular injury OR ascites OR hepatocellular jaundice OR Hepatic failure OR liver failure OR ALT levels increased OR ALT levels elevated OR AST levels increased OR AST levels elevated) (Preferred Term (PT) (MedDRA)) AND (Ibrutinib OR Acalabrutinib OR Zanubrutinib (substance (WHO drug)). The WHO-UMC causality assessment system performed for cases for the top 30 completeness score for each medication. Microsoft Excel 2019 used to perform the descriptive analysis.

A total of 435 DILI cases reported with BTKIs use; Of these, 384 cases with Ibrutinib use, 40 cases of Acalabrutinib use, and 11 cases of Zanubrutinib use. Among these cases, 78.16% classified as “Serious”, and 42% involved individuals aged 65 years or older. The gender distribution showed 38.10% females, and 53.10% males. Causality assessment of the included cases for Ibrutinib (n=30) resulted in one certain, nine probable, four possible, nine unlikely, and seven un-assessable cases. Positive de-challenge was observed in 12 cases, while positive re-challenge occurred in two cases. Acalabrutinib (n=30), had two possible, two unlikely, and 26 un-assessable cases. positive de-challenge observed in one case. Zanubrutinib (n=11) had one possible, two unlikely, and eight cases were un-assessable.
Conclusion
Our finding suggests that there is a potential association between DILI and the use of Ibrutinib, Acalabrutinib, and Zanubrutinib. Further epidemiological studies are needed to assess the risk of DILI with the use of these medications.

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Comparative Review: Overseas Safety Information Utilization in Japan, Australia, and the EU

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Introduction: With the globalization of the pharmaceutical industry, the need for incorporating post-marketing drug surveillance occurred in the overseas has been emphasized.

Aims: To investigate the trends in utilizing international safety information by regulatory authorities in Japan, Australia, and the European Union (EU) countries.

Methods: Japan, Australia, and the EU were selected for analysis due to their economic advancement and dominant pharmaceutical markets. Online research was conducted using keywords such as "overseas pharmacovigilance," "post-marketing surveillance," and "international drug regulation." Additionally, we sought to identify the rationales of selecting the referenced countries.

Results: Canada, the United States, and Switzerland were commonly referenced for safety information among the study countries. They share a similar economic status (relatively high per capita GDP) and continuously support the development of the pharmaceutical industry. Additionally, regulatory agencies such as the FDA in the US, Health Canada in Canada, and Swissmedic in Switzerland rigorously manage the safety and efficacy of drugs. They all operate various regulatory policies, including voluntary adverse event reporting systems, and collaborate with international organizations to adhere to global standards for drug surveillance. Besides these common countries, Japan specified the United Kingdom, France, and Germany as reference countries. Australia referred the UK and Singapore. The EU, apart from the common reference countries, also engages with Israel and New Zealand, with whom it has Mutual Recognition Agreements.
Conclusions: This study indicates that regulatory authorities are extensively monitoring and sharing safety information from overseas. The countries referenced for drug safety information are commonly characterized by their economic advancement, well-structured drug regulation systems, and large pharmaceutical markets. As regulatory authorities closely monitor overseas safety information, the quality of drug surveillance and the prompt response to adverse reactions is expected to improve further.

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Corticosteroid Adverse Effects: A Comprehensive Study on Occurrence, Severity, and Preventability

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Introduction: Corticosteroid therapy is extensively utilized for treating autoimmune diseases, allergies, and inflammatory disorders. Despite their effectiveness, corticosteroids can cause adverse effects that significantly impact patient quality of life and adherence to treatment.
Aims: This study aims to capture and analyse the adverse drug reactions (ADRs) associated with the use of corticosteroids.
Methods: This is a prospective observational study conducted in the Department of General Medicine, Nephrology and Respiratory Medicine. The ADRs observed are subjected to causality assessment, preventability and serverity. Clinical records and laboratory tests of patients were reviewed, and patient interviews were conducted to evaluate the occurrence and severity of short-term ADRs. Descriptive and inferential statistics were used to analyze the data and identify factors associated with adverse effects.
Results: In this study, we screened 360 patients and identified 102 patients receiving corticosteroid medication, with nearly equal gender distribution. A total of 55 ADRs were identified among the enrolled subjects with prevalence rate of 49.01%. The main adverse drug reactions observed were hyperglycemia (11.76%), hypokalemia (9.80%), and hypertension (3.92%). Also, rare ADRs such as epistaxis, steroid-induced leukocytosis, hypothalamic pituitary adrenal axis suppression, osteoporosis, and cushing's syndrome were also identified. These ADRs were categorized by organ system, revealing metabolic (11.76%), cardiovascular (3.92%), and electrolyte (9.80%) effects. ADRs assessed according to the Naranjo causality assessment scale were classified as probable (24.51%) and possible (75.49%), with a severity level predominantly at level 1 (56.8%) additionally, 80.39% of ADRs were identified as definitely preventable.

Discussion: The finding highlight the prevalence and variety of ADRs associated with corticosteroid therapy. One-fifth of ADRs were definitely preventable indicates opportunities for improving patient safety through enhanced monitoring and patient education. These insights can inform clinical practices and patient management strategies to mitigate the risks associated with corticosteroid use.

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Evaluation of medication safety program in ambulatory patients with chronic disease

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Introduction: Medication errors were inevitable in patient care. Massive work burden on healthcare providers hinders medication safety assessment, especially during ambulatory care context.

Aim: To evaluate the medication safety program in ambulatory patients with chronic disease.

Methods: An interventional study was carried out in an ambulatory setting of a tertiary care hospital for 6 months. Patients above 18 years of age with chronic conditions were included. The medication safety assessment program was initiated by the ambulatory pharmacist in collaboration with the general medicine outpatient department. Under this program, patients' prescriptions, and clinical findings were recorded. Obtained data screened with multiple medication safety assessment tools & drug databases. Descriptive & inferential statistics were used to analyze the data.

Results:
A total of 58 patients of age 50±11 years were enrolled, among them 45% were on (n=26) polypharmacy. The majority were diagnosed with hypertension (n=21, 36%), diabetes (n=12, 21%), and rheumatoid arthritis (n=15, 26%). During medication safety assessment, a total of 11 adverse reactions and 183 (77.5%) clinically important potential drug-drug interactions (pDDIs) were identified. Out of which 65.78% (n=155) of clinically important pDDIs & 36% (n=4) of adverse reactions were seen in patients with polypharmacy. Overall, 82% (n=150) of clinically important pDDIs and 55% (n=6) of adverse reactions were resolved with interventions led by ambulatory pharmacist under this program. A strong correlation exists between the number of medications prescribed to the patients and the number of clinically important pDDIs ($r=0.65$, $p<0.001$)*.
Conclusion:
Ambulatory pharmacist-led medication safety programs can significantly enhance the quality of care while reducing avertable healthcare costs in chronic disease patients.

Keywords: ambulatory care, drug interactions, medication safety, adverse reaction.

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EXPLORING DRUG INTERACTIONS IN A HEMATOPOIETIC CELL TRANSPLANT UNIT: A COMPREHENSIVE ANALYSIS

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Introduction: Hematopoietic Cell Transplantation (HCT) is a complex procedure necessitating multiple medications to manage graft-versus-host disease. The concomitant use of multiple drugs raises concerns about drug-drug interactions (DDIs), which could compromise treatment efficacy or lead to adverse effects.
Aim: This study investigates the prevalence of potential drug-drug interactions (DDIs) in a HCT unit.
Methods: A prospective comprehensive analysis was conducted by examining the medical prescriptions/drug charts from the pre-infusion (day -8) to post infusion (day +12) day of 19 HCT patients. Potential DDIs were analyzed using Uptodate(®)/micromedex and categorized according to levels of severity, evidence, and onset (rapid and delayed). Only interactions of major or moderate severity were included in the potential DDI analysis.
Results: Data were analysed for 19 HCT patients. The median age was 32.5 years; 57.8% (11) of the patients were male, and 42.1% (8) were undergoing autologous HCT. The patients received a median of 8 drugs each. Up to 118 potential DDIs were detected, 63.1% (12) of patients had at least 1 potential DDI and 36.8% (7) were exposed to at least 1 major potential DDI. The most commonly involved drugs were voriconazole (9, 28.1%), furosemide (8, 25%) and fluconazole (5, 15.6%). Most potential DDIs had moderate severity (98, 83.0%), a pharmacokinetic mechanism (45, 38.1%), and were classified as delayed onset (91, 77.1%). Under the category of major interactions, voriconazole interacted with fosaprepitant, cyclosporine and tacrolimus, and fluconazole with levofloxacin frequently.
Conclusions: The therapeutic complexity of the treatment resulted in a significant prevalence of possible DDIs during the HCT conditioning period. The majority of possible DDIs found in the study have the potential to cause nephrotoxicity, and cardiotoxicity, among others that could be clinically significant. Adequate observation of clinical and laboratory parameters is necessary to guarantee a successful HCT.
Keywords: Hematopoietic cell transplant, Drug-drug interactions

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Omeprazole and Potential Risk of Erectile Dysfunction

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Omeprazole, a Proton Pump Inhibitor (PPI) approved in Saudi Arabia for the management of gastroesophageal disease, peptic ulcer disease, gastric ulcers, duodenal ulcers, reflux esophagitis, Zollinger-Ellison syndrome. Erectile dysfunction (ED) adverse event is already included in the product information of other PPIs (e.g. esomeprazole, pantoprazole, lansoprazole, rabeprazole and dexlansoprazole).

To evaluate the potential association between omeprazole and ED as a part of drug class effect project.

We conducted a systematic literature search on January 2024, using PubMed, Embase, and Google Scholar, for English articles on human investigating the association between omeprazole and the risk of ED. The search terms included ‘omeprazole’ OR ‘Losec’ AND ‘erectile dysfunction’ OR ‘organic erectile dysfunction’. Moreover, we conducted a search in the World Health Organization (WHO) database “VigiBase” and in the local database of National Pharmacovigilance Center to retrieve case reports up to March 2023. Then, cases were assessed using the WHO-Uppsala Monitoring Center causality system.

Six observational studies were identified. First study found a significant association between PPIs and ED (odds ratio: 1.81 [95% Confidence Interval (CI): 1.07-3.07]. A prospective observational study showed significant reduction in testosterone levels post omeprazole with one patient developing ED. Three pharmacovigilance database analysis studies identified several cases of ED. In 2 studies, ED reporting with omeprazole was higher compared to other medications within VigiBase [Reporting Odds Ratio (ROR): 2.13, 95% CI: 1.83-2.48] and Lareb (ROR: 2.54, 95% CI: 1.52-4.25). Forty cases were assessed; 1 probably related, 19 possibly related, 1 unlikely, and 19 un-assessable. In VigiBase, 288 global cases were reported and 13 cases with completeness score one were assessed; 2 probably related, 8 possibly related, and 3 were unlikely. No local cases were reported to the SFDA.

The available evidence suggests potential association between ED and omeprazole. Further epidemiological studies are needed to investigate this potential association.

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Polypharmacy was positive associated with inflammatory makers in US older adults

Polypharmacy Was Positive Associated With Inflammatory Makers In Us Older Adults Chun Chen[1],
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Introduction: Inflammation has been reported to be associated with the aging and multimorbidity.
Aims: The objective of this study was to elucidate the relationships between polypharmacy and markers of inflammation.
Methods: Participants who were 65 years of age or older and took at least one prescription medication from the National Health and Nutrition Examination (1999-2018) were included in the cross-sectional study. The concurrent use of 5 to 9 medications was defined as polypharmacy, while the use of more than 9 medications was defined as hyper-polypharmacy. Systemic immune-inflammation index (SII), systemic inflammation response index (SIRI), neutrophil to lymphocyte ratio (NLR), monocyte to lymphocyte ratio (MLR), platelet to lymphocyte ratio (PLR), and product of platelet count and neutrophil count (PPN) were calculated from blood cell counts. Weighted linear regression analysis, subgroups analysis and sensitivity analysis were used to investigate the relationship between polypharmacy and markers of inflammation.
Results: Of 10,753 participants assessed, 4,115 (weighted percentage: 38.3%) were taking between 5 and 9 medications and 474 (weighted percentage: 4.4%) were taking more than 9 medications. After adjustment for covariates, multivariable linear regression revealed a significant correlation between both polypharmacy and hyper-polypharmacy and inflammatory indicators. Weighted β-coefficient and 95% confidence interval of polypharmacy were 0.077(0.045, 0.109), 0.102(0.070, 0.134), 0.07(0.044, 0.096), 0.064(0.042, 0.086), 0.038(0.014, 0.063), 0.045(0.016, 0.075), 0.021(0.004, 0.037), and 0.028(0.011, 0.044) for SII, SIRI, NLR, MLR, PLR, PPN, white blood cell (WBC) and C-reaction protein, respectively. The positive associations between hyper-polypharmacy and inflammatory markers were more pronounced, with the exception of WBC. The results of subgroup and sensitivity analyses demonstrated a robust, positive correlation between polypharmacy and inflammatory markers, particularly for SII, SIRI, NLR, and MLR.
Conclusion: In a population of older Americans, polypharmacy was found to significantly increase levels of inflammation, a relationship that was independent of the presence of comorbidities.

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Pulmonary Events Associated with Proteasome Inhibitors: Quantitative Signal Detection Using FAERS Database

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Introduction

Proteasome inhibitors, such as bortezomib, carfilzomib, and ixazomib, have revolutionized multiple myeloma therapy by disrupting protein degradation, halting cancer cell growth. Despite their established efficacy, concerns endure about long-term safety in broader patient populations, attributed to limited data on infrequent and delayed adverse events (AEs).

Aims

The study aimed to deepen the comprehension of proteasome inhibitors' safety profile in multiple myeloma patients through disproportionality analysis of the FDA Adverse Event Reporting System (FAERS) data.

Methods

The FAERS database, accessed via Open Vigil 2.1 MedDRAv24, was utilized, covering data up to September 2023. Signal refinement involved limiting drug roles to 'primary suspect' status. Disproportionality analysis employed the proportional reporting ratio with chi-square value and reporting odds ratio. Evans 2001 criteria, n > 2, chi2 > 4, PRR > 2, ROR_LB > 1, defined a probable association between the drug and AE.

Results

In the FAERS database, reports indicated AEs linked to Carfilzomib in 12,513 patients, Ixazomib in 18,123 patients, and Bortezomib in 43,195 patients. Notably, significant signal scores were detected in the System Organ Classes (SOCs) of 'Respiratory, thoracic, and mediastinal disorders' and 'Infections and infestations'. Even after signal refinement, the majority of these associations remained significantly associated. Significantly associated Preferred Terms (PTs) included pneumonia, respiratory tract infections, bronchitis, pulmonary sepsis, acute pulmonary oedema, etc…

Discussion

Bortezomib, carfilzomib, and ixazomib each have their own unique safety profiles, which reflects their distinct structural and mechanistic properties. The study detected significant disproportionality signals linking pulmonary events to proteasome inhibitors, underscoring the necessity for clinicians to account for patient comorbidities and concurrent medications when prescribing these agents. These findings contribute to refining the safety profile of proteasome inhibitors during post-marketing, facilitating better risk assessment and patient care.

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Risk of Drug-drug Interaction in Gout Arthritis Patients Prescribed NSAIDs

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Introduction. The risk of drug-drug interactions might increase due to polypharmacy. A chronic disease such as gout arthritis especially in the geriatric patients that is frequently accompanied by multicomorbidities is often prescribed polypharmacy, including Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) to treat a symptom of pain.
Aims. This study aimed to determine the association of potential adverse drug pair interactions from NSAIDs use in gout patients with polypharmacy compared to those whithout polypharmacy.
Methods. This analytical observational study with a cross-sectional approach was conducted at a Public Regional Hospital Banjarmasin in December 2023 using the electronic medical record. Potential drug-pair interactions of NSAIDs and the association were analysed by using Lexicomp® and the Fisher Exact test, respectively.
Results. In 13 gout patients 32 drug pair interactions were found. Among all NSAIDs, glucosamin was the most prescribed by 62 times (79.49%) followed by meloxicam by 18 times (23.08%) and diclofenac by 4 times (5.12%). According to the potency of drug-drug interaction, most of drug pairs were under category C (the benefit outweight the risks, but proper monitoring should be done) by 26 drug pairs (81.25%). Most of drug pairs were categorized to have moderate severity by 26 drug pairs (81.25%). Major interaction between meloxicam and diclofenac was found in 1 drug pair (3.13%) increasing the risk of adverse event in gastrointestinal system. Among the patients with polypharmacy, 29 (96.7%) drug-pair interactions found were not potentially harmful and only 1 (3.33%) drug-pair interaction was potentially harmful. While among patients without polypharmacy, only 2 (100%) drug-pair interactions were not potentially harmful and no potentially harmful drug-pair interactions were found (0%). The statistical test showed the p-value of 0.938.
Conclusion. This study concluded that there was no difference in adverse drug pair interactions using NSAIDs between polypharmacy compared to non-polypharmacy in patients with gout.

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Risk of Fracture Associated with Pregabalin or Mirogabalin Use: A Case-Case-Time-Control Study

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Introduction: Pregabalin, a gabapentinoid, has been used worldwide for neuropathic pain. Mirogabalin, a new gabapentinoid, was recently launched in several Asian countries, and may be as effective as pregabalin but with less dizziness and somnolence. Although cohort and case-crossover studies have shown an association between pregabalin use and fall-related injuries, these studies might suffer from residual confounding due to the lack of an appropriate comparison group in cohort studies, as well as bias from exposure-time trends or treatment persistence in conventional case-crossover studies. Additionally, findings on mirogabalin and its association with fall-related fractures are lacking.
Aims: We evaluated the risk of fracture associated with the use of pregabalin or mirogabalin while adequately addressing the aforementioned biases using a case-case-time-control design.
Methods: A case-case-time-control study was conducted using future cases as controls for current cases. Patients with incident fractures were identified in a Japanese claims database between September 27, 2014, and October 31, 2022. The fracture event date was defined as day 0. For each current case, a hazard period (day −1 to −30) and a control period (day −61 to −90) were set. Each current case was matched by age and sex to one future case with a fracture occurring 120–365 days later. Conditional logistic regression models were used to estimate odds ratios (ORs) and 95% confidence intervals (CIs) for fractures in both current and future cases, adjusting for time-varying covariates. The ORs of case-case-time-control study were obtained by dividing the ORs in current cases by the ORs in future cases.
Results: A total of 814,216 current cases were eligible, with an average age of 75.0 years. The ORs were 1.31 (95% CI, 1.21−1.41) for pregabalin and 1.57 (95% CI, 1.33−1.85) for mirogabalin.
Discussion: Given the fracture risk observed, caution is advised when prescribing pregabalin or mirogabalin in clinical practice.

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Trends in Adverse Drug Reactions in Ghana- Evidence of spontaneous reports, 2005-2021

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Introduction Adverse drug reaction (ADR) monitoring is crucial in ensuring patient and pharmaceutical safety, given the significant global issues associated with patient well-being. However, there is lack of evidence regarding the trend pattern of ADR reports in Ghana.
Aims We therefore, aimed to analyse and characterize trends in ADRs reported in Ghana over 16 years.
Methods We analysed ADR reports received by the Ghana National Pharmacovigilance Centre and entered into VigiBase from 2005 to 2021. Jointpoint regression was used to estimate age-adjusted ADR rates, stratified by sex and patient characteristics, suspected medication groups, clinical indications and the manifestation of ADRs. To evaluate trends over time, the percentage annualised estimator was used. Suspected medication groups for ADRs were coded using the Anatomical Therapeutic Chemical classification system and the Medical Dictionary for Regulatory Activities was employed to classify ADRs and indications.
Results We identified a total of 6,189 ADR reports from 2005 to 2021. The age-adjusted ADR report rates increased significantly from 2005–2019, with an annual increase of 18.6%, however, there was a downward trend from 2019–2021, although not statistically significant. Males accounted for the majority (64.3%) of ADR reports compared to females (35.7%). The medication group most frequently associated with ADRs were antiprotozoals accounting for 35.6% of all ADR reports while vascular disorders (21.0%) were the most commonly observed clinical indication in relation to ADRs. An increase in ADR report rates was noted for infections and infestation with an annual increase of 22.4% (95% CI: 9.7–36.7%; $p < 0.001$). General disorders and administration site conditions (20.1%) were the most frequently reported ADRs.
Conclusion ADRs remain a huge burden on the healthcare systems of Africa, especially Ghana, with an increasing trend of ADR-related medication use. The findings of this study call for multifaceted strategies aimed at reducing the ris

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Variation of Adverse Drug Events in Different Settings in Africa: Systematic Review

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Introduction Adverse drug events (ADEs) significantly impede the development of Africa's healthcare system as it is one of the predominant burdens it faces.
Aims This study aimed to systematically review published studies on ADEs and summarize the burden of ADEs across different settings in Africa.
Methods Studies with ADE rates reported in African settings were identified by searching PubMed, EBSCO, Science Direct, and Web of Science. Settings of ADEs included those leading to hospital admissions, developed during hospitalizations, and captured in the outpatient departments or communities. Grouped ADE prevalence rates were described using median and interquartile range (IQR). PROSPERO registration (CRD42022374095).
Results Seventy-eight studies carried out in 15 African countries were included. The median ADE-related fatality rate was 0.3%. The overall median prevalence of ADEs leading to hospital admissions was 6.3% (IQR: 1.5%–10.3%) in any patient population and the median prevalence of ADEs developed during hospitalizations was 12.8% (IQR: 6.4%–49.4%), while the median prevalence of ADEs in the outpatient and community settings were 22.9% (IQR: 14.6%–56.1%) and 32.6% (IQR: 26.0%–41.3%), respectively, with a median of 43.5% (IQR: 16.3%–59.0%) of ADEs being preventable.
Conclusion The healthcare burden of ADEs was significant in both hospital and community settings in Africa, with many being preventable. Due to limited studies conducted in the community setting, future research in this setting is encouraged.

[Drug Utilization and Adherence]

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Extra labeled use Among Pet Owners: Insights from Saudi Arabia

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Aim: The primary objective of veterinary medicine is to ensure the health and welfare of animals through appropriate therapeutic interventions, which include disease prevention, diagnosis, growth promotion, and improved feed efficiency. This study explores medication utilization and extra-labeled use among pet owners in Saudi Arabia, emphasizing the patterns and knowledge of crossover medication use.
Methods: A population-based cross-sectional online survey was conducted from December 2022 to April 2023. The survey targeted Saudi Arabian citizens and residents with at least one pet or involved in animal husbandry.
Results: The final sample included 347 participants after refining the data for completeness. The demographic analysis revealed that most participants were adults (90.2%), with a significant portion holding university-level education (63.68%). Cats (63%) and birds (30.54%) were the most common pets, with 59.65% of participants providing regular vaccinations to their animals. Veterinary doctors were the primary source of medication information (43.33%) and providers of medications (60.58%). While 40% of participants never used human medications on their pets, those who did commonly used antibiotics and topical preparations. About half (50%)of these participants adjusted the dosage when administering human medications to animals. The study also found that 52% of pet owners believed only veterinary doctors should prescribe medications for animals, whereas 42% thought both veterinarians and pet owners could use human medications in animals. Despite recognizing the dangers of human medications for animals, participants did not perceive significant risks to human health from this practice.
Discussion/conclusion : The reliance on human medications for animals, particularly antibiotics and topical preparations, raises substantial concerns about the potential for adverse reactions and the development of antibiotic resistance. The findings underscore the need for enhanced education on the risks of extra-labeled medication use and the development of clear guidelines to promote responsible medication practices among pet owners.

P207

Impact of Clinical Pharmacist Counselling on Medication Adherence among Cognitively Impaired Geriatrics

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Aims. To assess the impact of clinical pharmacists' counselling and to identify the facilitators and barriers of medication adherence amongst elderly patients with cognitive impairment

Methods. A single-centre, prospective, pre-post, cross-sectional study was performed in the Departments of Geriatrics, Neurology, and Psychiatry at a tertiary-care teaching hospital in Southern India from Aug 2024 to Mar 2024 Treatment charts of the cognitive impaired patients aged ≥ 65 years, diagnosed with Parkinson's Disease and/or dementia of either gender were reviewed. Written informed consent obtained from the patients' representatives. Patient demographic details, treatment charts, and medical orders were recorded to assess drug usage pattern. Standard Medication adherence rating scale (MARS) and pre-validated facilitators/barriers question tool consisting a few open-ended questions were administered with direct patient interview to assess patients' adherence levels towards their prescribed medications at baseline and after 30 days of follow-up.

Results. The study enrolled 156 participants with an average age of [mean±SD: 75.18 ± 8.28 years]. Among the study participants, [141 (90.38%)] of the participants completed the questionnaires at baseline and after 30 days, remaining [15(9.61%)] were lost of follow-up after 30 days. Of 156 participants, [122 (78.2%)] showed good adherence, followed by 34 (22.4%) showed poor adherence at baseline. After the counselling by Clinical Pharmacist ,medication adherence improved significantly (mean= 9.17 ±1.134) after 30 days compared to baseline (Mean = 7.75±2.281), with mean difference = -1.418,±1.856; [t (140) = - 9.074, p < 0.001]. A validated facilitators and barriers questionnaire revealed that 67.3% of patients often forgot to take medications, while 51.7% were careless. Accessing healthcare was a challenge for 77.5% patients, and 52.5% faced issues due to polypharmacy and therapy-related factors.

Conclusion. The study reported that medication adherence significantly improved from baseline to 30-day of follow-up. But, optimizing medication adherence is quite challenging amongst the cognitively impaired geriatrics.

P208

Prescription status of centrally acting muscle relaxants in Korean elderly

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Aim: We aim to expand the DUR provisions for centrally acting muscle relaxants, with strong anticholinergic effects, for the elderly population by analyzing prescription patterns of these to geriatric patients.

Methods: From 2018 to 2020, prescription patterns of centrally acting muscle relaxants in patients aged 65 years and older were analyzed using data from the Health Insurance Review and Assessment Service-Aged Patient Sample (HIRA-APS). The centrally acting muscle relaxants approved in Korea, including, afloqualone, baclofen, chlorphenesin, chlorzoxazone, cyclobenzaprine, dantrolene, eperisone, methocarbamol, orphenadrine, pridinol, tizanidine, tolperisone, were selected.

Results: From 2018 to 2020, 2,245,833 elderly patients aged 65 and over were seen, of which 880,813 patients (39.2%) were prescribed centrally acting muscle relaxants. These were more often female (61.2%) than male (38.8%), and most received prescriptions at primary care clinics (76.5%). Additionally, almost all patients received prescriptions via outpatient treatment (95.6%). Of the 12 selected drugs, eperisone was the most prescribed at 67.3%, followed by afloqualone at 9.6%, orphenadrine at 7.8%, and chlorphenesin at 6.2%. Elderly patients were most frequently prescribed these drugs in orthopedic clinics (53.9%), apart from internal medicine (13.1%) and neurosurgery clinics (10.0%). Patients received the drugs for dorsalgia (15.8%), spondylopathy (11.8%), gonarthrosis (7.5%), intervertebral disc disorders (6.0%), and shoulder lesions (5.7%), with most prescriptions being made for musculoskeletal disorders.

Discussion: Prescription of centrally acting muscle relaxants requires caution in geriatric patients due to their anticholinergic effects. A significant proportion of elderly patients had been prescribed centrally acting muscle relaxants before. DUR information for these drugs tailored to geriatric patients should be developed.

P209

Prevalence and Patterns of Drug-Related Problems Among Elderly Patients in Critical-Care Units

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Introduction: Drug-related problems (DRPs) are common among elderly patients in critical care units and can lead to adverse outcomes, increased healthcare costs, and prolonged hospital stays.
Aim: To determine the rate, pattern, and severity of DRPs among elderly patients admitted to critical care units.
Methods: A prospective interventional study was conducted over a period of 9 months in all intensive care units at a tertiary care hospital. Elderly patients (≥ 60 years) were enrolled in the study, and data on DRPs was collected. DRPs were identified and classified according to Hepler and Strand's classification. The severity of DRPs was assessed, and pharmacist interventions were recorded.
Results: A total of 137 elderly patients (mean age: 68.5 ± 7.3 years) were included, with 78.1% experiencing at least one DRP (with a total of 210 DRPs identified). The average number of DRPs per patient was 1.53 ± 0.76. The most common types of DRPs were subtherapeutic doses (37.1%) and adverse drug reactions (20.5%). Pharmacist interventions were made for all identified DRPs, with an acceptance rate of 92.4%. The severity assessment revealed that 52.4% of DRPs were major, 40.5% moderate, and 7.1% minor. Among the 43 adverse drug reactions (ADRs) identified, the most common were hypokalemia (23.3%) and hypoglycemia (11.6%). Causality assessment classified 62.8% of ADRs as possible and 37.2% as probable, while severity assessment showed that 72.1% were moderate and 4.7% severe. Preventability assessment revealed that 86.0% of ADRs were not preventable.
Conclusion: The high prevalence of DRPs among elderly patients in critical care units emphasizes the importance of pharmacist interventions in identifying and resolving DRPs to optimize patient care and improve treatment outcomes in this vulnerable population.

Keywords: drug-related problems, elderly, critical care, pharmacist interventions.

P210

Usage trends of government-subsidised cancer drugs in Australia: an analysis

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Introduction: Treatment for cancer remains a significant and escalating healthcare expense worldwide. Although annual reports on the total costs of cancer care are available in Australia, the potential impact of evolving treatment guidelines and the introduction of new drugs on future budgeting remains largely uncertain.

Aims: To examine the trends in the use of Pharmaceutical Benefits Scheme (PBS) cancer drugs subsidised by the Australian government over the past decade.

Methods: PBS codes for all PBS cancer drugs that were listed in government-endorsed treatment protocols were obtained and used to retrieve usage data. Their patterns of use, represented by the number of prescriptions (services) processed by Services Australia, were analysed for the period between 2012 to 2022.

Results: The overall prescribing of cancer drugs is outpacing Australia's population growth, primarily due to an ageing population and the accelerated rise in cancer diagnoses observed over the past decade. From 846 government-endorsed treatment protocols,142 cancer drugs were available on the PBS, of which kinase inhibitor (39 drugs) and monoclonal antibody drugs (24 drugs) had the highest increase in use during the study period: 16% and 23% respectively. Of the drug types analysed, hormonal agents (20 drugs) were the most prescribed, while the use of the drug aflibercept continued to rise despite the discontinuation of related treatment guidelines.

Discussion/Conclusion: The utilisation of government-subsidised cancer drugs is increasing faster than Australia's population growth, especially for newer, high-cost monoclonal antibody and kinase inhibitor drugs, indicating continued pressure on government spending.

[Geriatric and frailty studies]

P211

Development of Claim-Based Frailty Index in A Nationwide Database

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Objective:
To develop Claim-Based Frailty Index (CFI) by using Survey-based Frailty Index (SFI) as reference standard in the National Health Insurance Database (NHID) in Taiwan.

Methods:
The Taiwan Longitudinal Study on Aging (TLSA) survey was used to develop the SFI. And, ICD-9 codes were organized by subheadings and categorized based on prevalence into three groups: > 0.001, > 0.01, and > 0.05. The CFI was then estimated using a lasso regression model with SFI as a function of health deficit variables. Expand the ICD code subheadings to three digits and recalculating prevalence and categorization. Lasso regression was performed for each prevalence group, leading to the estimation of CFI using selected three-digit ICD-9 codes. The best approach was chosen based on C statistics from logistic regression for mortality and correlation with SFI. Finally, validation of the CFI derived from NHID 2015 was conducted by comparing it with the Charlson Comorbidity Index (CCI) in predicting mortality, 30-day readmission rates, the number of ER visits, and hospital days in 2016.

Results:
A total of 8,300 participants were interviewed in 2015 TLSA, of which 4,040 (48.7%) were male and 4,260 (51.3%) were female. The mean age was 67.6 ± 10.9 years. We choose prevalence threshold > 0.001 as our best CFI. The mean CFI was 0.039 ± 0.080. Validation results showed that after adjusted for age and sex, CFI was similar to CCI in predicting mortality (C statistic: 0.85 vs. 0.84), 30 days readmission (C statistic: 0.71 vs. 0.72) and number of ER visits (Pseudo R2: 0.17 vs 0.18) and was superior in predicting hospital days (Pseudo R2: 0.11 vs 0.08).

Conclusion:
Our CFI can be used to measure frailty in Taiwan NHID.

Keywords: Claim-Based Frailty Index (CFI), Survey-based Frailty Index (SFI), Taiwan Longitudinal Study on Aging (TLSA), National Health Insurance Database (NHID)

P212

End-of-life medication management: A Delphi consensus approach in the Western Pacific region

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Introduction. Palliative care, including end-of-life care, aims to enhance the quality of life for those with life-limiting illnesses. Older adults at this stage often face challenges due to evolving health needs, leading to polypharmacy. Polypharmacy raises concerns about potentially inappropriate prescribing. Existing tools commonly used to identify prescribing issues such as the STOPP/START criteria are tailored for aged care and may be limited in palliative settings. Previous studies have developed tools for identifying inappropriate prescribing in palliative settings. However, the Western Pacific region has not received commensurate attention. A tailored checklist for this region is needed to address these gaps and improve the quality of palliative care.

Aims. To develop a medication checklist to guide prescribing decisions for older adults in the last 6 months of life.

Methods. A Delphi expert panel, consisting of palliative care clinicians from 12 Western Pacific countries and regions, will be convened. These include Malaysia, Singapore, India, Bangladesh, Sri Lanka, Taiwan, Hong Kong, Japan, South Korea, China, Australia, and New Zealand. Panellists will be tasked with indicating their level of agreement with statements on whether medication classes should be deprescribed, continued, or initiated in older adults during the last 6 months of life via an online survey. Consensus on a medication class will be deemed achieved if the level of agreement is ≥ 75%.

Results. Descriptive statistics will be employed to summarise and analyse the collected data. An overview of participant demographics will be presented. Data from the expert panel's consensus on medication classes will be analysed to identify areas for deprescribing, continuation, and initiation during the last 6 months of life.

Discussion. This study holds significant implications for rationalising prescribing decisions and mitigating potentially inappropriate prescribing issues in palliative care, particularly for older adults at the end-of-life in the Western Pacific region.

P213

Potential drug-drug interactions in geriatric outpatients with depression in China

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Introduction. Potential dug-drug interactions (pDDIs) are associated with decrease of effectiveness, and increased risks of drug side effects. Identifying pDDIs is significant for detecting and managing the risks. However, bare research has examined pDDIs in elderly people with depression who are likely to have comorbidities and co-medications, and be more susceptible to the side effects due to drug reactions.
Aims. Aims of this study are to investigate the epidemiology of pDDIs in geriatric patients with depression, examine factors associated with pDDIs, and identify severity and preventability of pDDIs.
Methods. The presence of pDDIs were assessed via Medscape Interaction Checker on the prescriptions extracted from medical records. Clinical outcomes and management strategies for pDDIs were displayed. Logistic regressions were used to analyse the potential associations between participant characteristics and pDDIs.
Results. Medication data for 3 years were collected from 845 geriatric patients. 75.6% of the patients ever had pDDIs. Severe levels of depression and polypharmacy were positively associated with the occurrence of pDDIs (Adjusted odds ratio = 2.1, 95% confidence interval = 1.2-3.8; aOR = 47.6, 95% CI = 7.8-289.1, respectively). Frequent drug pairs with pDDIs were combining selective serotonin reuptake inhibitors (SSRIs) and trazodone (or mirtazapine), and augmenting SSRIs with olanzapine.
Discussion. Prevalence of pDDIs were high in geriatric patients with depression. Drug combinations in highest frequency and serious severity are a priority for pDDI detection and management. Special attentions are also needed for drugs with pharmacodynamic synergism, and CYP enzyme substrates and inhibitors. Patients with severe levels of depression, polypharmacy, cardiovascular diseases, and liver or renal function impairments are of special interests as they are potentially more susceptible to the risks of pDDIs.

P214

Prevalence and risk factors of potentially inappropriate medication use in older Australians.

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Introduction: Potentially inappropriate medications (PIMs) have been associated with adverse outcomes such as increased risk of hospitalisation and mortality in older adults. However, there is currently a lack of national estimates of prevalence of PIMs defined using the latest list of PIMs.

Aim(s): To estimate the prevalence and factors associated with the use of PIMs in older adults living in Australia.

Method: This study utilised data from the Pharmaceutical Benefits Scheme and 2021 Census. PIMs were defined using the 2023 Beers Criteria and the 2024 list of Australian PIMs (AUSPIM). Users of PIMs were defined as having at least one dispensing of PIMs during the three-month study period following 2021 Census (August – October 2021). People aged 65 or above were included in the study. Prevalence was calculated for 5-year age strata. Patient sociodemographic factors were included in a multivariate logistic regression model to explore factors associated with the use of PIMs.

Results: Overall, 3.8 million Australians aged 65 or over in 2021 were included in this study, with a median age of 74 (interquartile range: 69-80) years, and half were female (54%). Overall, 38% and 41% of individuals were using at least one PIM according to the Beers Criteria and AUSPIM, respectively. The prevalence was highest among those aged 90 to 94 years old, with over half of the population using at least one PIM according to the Beers Criteria (50%), and AUSPIM (52%). Older age, requiring assistance with core activities, lower education level and living in a non-private dwelling were associated with increased likelihood of using a PIM.

Conclusion: Over half of older people living in Australia use PIMs, with risk highest in those from certain sociodemographic groups. Healthcare professionals should review the use of PIMs regularly to ensure equitable and quality use of medications.

P215

Statin Therapy for Primary Prevention in Old and Very Old Adults

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Introduction
There is little consensus on initiating statins for primary prevention of cardiovascular diseases (CVDs) in adults aged 75 years or older due to the underrepresentation of this population in randomized controlled trials.
Aims
To investigate the benefits and risks associated with statin use for primary prevention in old (aged 75-84 years) and very old (aged≥85 years) adults.
Methods
Using territory-wide electronic health records, we emulated a sequence of 96 nested target trials on the elderly who were aged over 75 years and met indications for statin initiation in each calendar month from January 2008 to December 2015 in Hong Kong. Propensity score matching was used to emulate the randomization of participants at baseline. Outcomes of interest included major CVDs (stroke, myocardial infarction, heart failure), all-cause mortality, and major adverse events. Pooled logistic regression models were adopted to estimate the risk differences in the intention-to-treat (ITT) analysis, as well as the per-protocol (PP) analysis with inverse probability weighting to adjust for time-varying confounders related to treatment adherence.
Results
Of 42 680 matched person-trials aged 75 to 84 years and 5390 matched person-trials aged 85 years or older (average follow-up, 5.3 years), risk reduction for overall CVD incidence was found for initiating statins in adults aged 75 to 84 years (5-year standardized risk reduction[95%CI] - ITT: 1.20%[0.57%,1.82%]; PP: 5.00%[1.11%, 8.89%]) and in those aged ≥ 85 years (ITT: 4.44%[1.40%, 7.48%]; PP: 12.50%[4.33%, 20.66%]). The risk reduction was consistently observed for all-cause mortality and CVD subtypes. No significantly increased risks for myopathies and liver dysfunction were found in either age group.
Conclusion
Reduction for CVDs after statin therapy was observed in patients aged 75 years or older without increasing risks for major adverse events. Notably, the benefits and safety of statin therapy were consistently found in adults aged 85 years or older.

[Health Policy]

P216

Geographic Variations in Nicotine Dependency Treatment Use in Japan

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Introduction: Smoking has various health consequences. The Japanese public medical insurance covers nicotine dependency treatment, including counseling, pharmacological treatment, and the use of an electronic device application.

Aims: This study assesses the geographic variations in nicotine dependency treatment utilization in Japan.

Methods: The nicotine dependency management (NDM) fee and two medications indicated for nicotine dependency were assessed in the pooled open data of the National Database in Japan from 2018 to 2022. The standardized ratios (StdR) of the number of patients who claimed the initial NDM (type 1) and the total dose of each medication (varenicline and nicotine) were estimated using the indirect adjusted by the population stratified by age and sex in 47 prefectures. The coefficient of variance (CV) was used for the geographic variations.

Results: In the five years, a total of 458,382 patients had a claim for the initial NDM fee and 41,714,782 mg of varenicline (equivalent to 379,225 patients' dosage for a standard treatment course) and 136,229,729 mg of nicotine (equivalent to 61,782 patients' dosage for a standard treatment course) were prescribed. The StdR of the NDM, varenicline, and nicotine varied from 0.71 to 1.78, 0.73 to 1.68, and 0.49 to 1.96 among prefectures, respectively. The CV of the StdR of the NDM, varenicline, and nicotine were 0.20, 0.31, and 0.17, respectively. The correlation coefficients between NDM and varenicline, NDM and nicotine, and varenicline and nicotine were 0.96, 0.62, and 0.45, respectively. The StdRs of all three treatments assessed (NDM, varenicline, and nicotine) tended to be higher in Western than Eastern regions in Japan.

Discussion: The practice of nicotine dependency treatment varies geographically in Japan. The variation may be associated with the relevant healthcare resources available locally.

P217

"Biopsychosocial Determinants of CLBP in Northern India: A Population-Based Cross-Sectional Analysis"

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Introduction: Chronic low back pain (CLBP) is a significant cause of disability worldwide, affecting millions and posing a substantial burden on healthcare systems. The condition's multifaceted nature, involving biological, psychological, and social factors, complicates its management.
Aims: This study investigates the biopsychosocial determinants of CLBP disability in this region to inform targeted interventions and public health strategies.
Methodology: A population-based cross-sectional design was employed, covering diverse urban and rural populations in Northern India from November 2017 to February 2020. The study included adults aged 18 and above diagnosed with CLBP, using face-to-face interviews to gather socio-demographic and medical data. The biopsychosocial model guided the analysis, utilizing tools like the Multidimensional Pain Inventory, Fear-Avoidance Beliefs Questionnaire (FABQ), and the WHO Disability Assessment Schedule (WHO-DAS). Statistical analyses, including ANOVA and multiple regression, were performed to identify significant determinants of CLBP disability.
Results: The study enrolled 457 participants, with a balanced gender distribution and a mean age of 46.4 years. Key findings revealed that biological factors (age, gender, comorbidities), psychological factors (anxiety, depression), and social factors (occupational status, educational level) significantly influenced CLBP disability. Higher levels of anxiety and depression were strongly associated with lower health-related quality of life (HRQOL) and greater disability. The FABQ scores highlighted the role of fear-avoidance beliefs in chronic pain management.
Conclusion: The research highlights the complex interplay of biopsychosocial factors in CLBP. Addressing these determinants through integrated, multidisciplinary approaches involving mental health services, physiotherapy, and community support can enhance CLBP management. The findings advocate for tailored public health policies and interventions to reduce the CLBP burden in Northern India, emphasizing the need for holistic care. To generalize the results future studies should explore longitudinal data and broader geographic areas
Keywords: Chronic Low Back Pain, Biopsychosocial Model, Disability, Quality of Life

P218

Assessment of new anti-cancer biological products approved through Priority Review in China

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Introduction In recent years, the rapid development of biotechnology has made biologics a focal point for research and development by pharmaceutical companies, due to their high specificity and relatively low toxicity and side effects. In 2020, China introduced the latest version of the Drug Registration Regulation, optimizing regulatory processes for innovative biologics by establishing a priority review program to accelerate market access and better fulfill clinical demands.
Aims This study examined the differences in time to approval, efficacy, and safety between priority review and non-priority review anti-cancer biological products approved by China's National Medical Products Administration (NMPA) during the same period.
Methods We analyzed all innovative anti-cancer therapeutic biological products approved by the NMPA between January 1, 2015, and December 31, 2023, using a public database. Development and Biologics License Application (BLA) approval times for priority and non-priority reviewed antineoplastic biologics were compared using the Mann-Whitney U test and T-test. A meta-analysis was performed to pool hazard ratios for progression-free survival (PFS), response rates (RR) from single-arm trials, rates of treatment-related serious adverse events, and rates of Grade ≥3 adverse events.
Results Out of 14 innovative biologics corresponding to 25 indications approved during the study period, the drug development time (2.83 vs. 2.95 years, p=0.996) and BLA approval time (321 vs. 403 days, p=0.211) for priority-reviewed biologics were numerically shorter than for non-priority reviewed biologics. There were no significant differences in RR in single-arm trials (41.5% vs. 55.6%, p=0.576). However, priority-reviewed biologics were more likely to have a Grade ≥3 adverse reaction rate (36% vs. 20%, p=0.003) and a treatment-emergent serious adverse reaction rate (20% vs. 8%, p=0.001).
Discussion/Conclusion Priority review biologics were associated with faster approval times but had a higher likelihood of adverse reactions. However, there was no statistically significant efficacy advantage over non-priority review biologics.

P219

Community Pharmacists' Health Screening Services: Knowledge, Attitudes, Practice and Barriers

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Introduction: Patient's and customers regularly visit community pharmacies for buying medications and seeking information about medications, common illnesses and overall health issues. Health screening services if employed in the pharmacies will help to identify and prevent diseases, before symptoms appears. Health screening services for the screening of diabetes, hypertension can be made available at the community pharmacies. These services if implemented in the pharmacies helps to identify individuals who are at risk and referring them to their physicians. The services like hypertension and diabetes screening are relatively easy for community pharmacist to perform.
Aim: To understand the pharmacist knowledge, attitudes, practices, and barriers to offering health screening services in community pharmacies was the goal of the study.
Methods: This was a cross-sectional descriptive study, involving community pharmacists in Udupi district, using a structured questionnaire to assess their knowledge, attitude, practice and barriers to health-screening services. The questionnaire covered various domains including demographic traits, pharmacist knowledge, attitude, practice, and barriers to offering health screening services.
Results: A total of 71 community pharmacists from Udupi district participated in this study. The majority (76.1%) of pharmacists showed adequate knowledge and awareness of health-screening services, in addition to having a positive attitude towards health screening services. 64.8% of pharmacists, however, were against offering health screening services. Lack of training (32.4%), lack of time (26.8%), and non-payment (21.1%) for health screening services performed were cited as reasons for not providing health screening services.
Discussion/Conclusion: Due to the advantages of easily accessible health screening services in community pharmacies, which help in the early detection of illnesses in the community, pharmacists should receive training in health screening services.

P220

Comparison of Health Literacy Between Immigrants and Natives in Taiwan

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-Introduction: As of December 2023, more than 590,000 immigrants lived in Taiwan, with numbers increasing. Previous studies indicate that immigrants are at a higher risk of poor health literacy (HL). However, extrapolating these results may be problematic due to varying cultures and racial compositions across countries. Currently, research comparing HL between immigrants and natives in Taiwan is lacking.

-Aims: To compare the level of HL between immigrants and natives using the National Health Interview Survey (NHIS) of Taiwan.

-Methods: The 2017 Taiwan NHIS served as the data source for this study. We included individuals who aged ≥20 years old and completed the HL questionnaire. The key independent variable was nationality (natives and immigrants), and the dependent variable was HL. The total score of the HL questionnaire was calculated and divided into two categories: poor (scored 0-33) and good (scored 34-50) HL. Multivariable logistic regression was performed to evaluate the odds of being with low HL between immigrants and natives, adjusting for age, sex, family income, self-reported health status, cardiovascular diseases, respiratory diseases and mental diseases.

-Results: After weighting, there were 6,871,548 individuals in our study, comprising 54,674 immigrants and 6,816,874 natives. A chi-square test showed similar age distributions between immigrants and natives (p-value=0.25). Compare to natives, immigrants had lower family incomes and lower educational levels (p-value<0.01). The proportion of respondents with poor HL were 12% and 8% among immigrants and natives (p-value=0.48), respectively. Multivariable linear regression showed that immigrants had similar HL level as natives (OR: 1.57, 95% CI: 0.46-5.39).

-Discussion: Our study suggests that immigrants in Taiwan do not have a significantly poorer HL compared to the natives. However, the non-significant difference may be caused by the limited sample size of immigrants. Further studies are needed to better understand the HL of immigrants in Taiwan.

P221

Enhancing Health Equity: Evaluating South Africa's CCMDD Programme

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Aim/Objective: This study evaluates the evolution and resilience of South Africa's Central Chronic Medicine Dispensing and Distribution (CCMDD) program in improving healthcare accessibility for chronic patients amidst various challenges.
Methods: The study assesses CCMDD's operation within the National Health Insurance (NHI) framework, focusing on its expansion, patient retention strategies, and engagement with service providers. It employs gradual scaling and geographic information system (GIS) tools for targeted interventions.
Results: CCMDD significantly expands medication access, improves availability, reduces the burden on public healthcare, and enhances patient adherence. The program's vital role in managing chronic conditions is underscored, calling for further research to evaluate health outcomes and patient quality of life.
Conclusion: Clear contracts, service level agreements (SLAs), and standard operating procedures (SOPs) are crucial for scaling success. Ongoing private sector engagement, geographic diversification, and adaptability ensure patient well-being and system resilience, aligning with the goals of NHI and Universal Health Coverage (UHC).
Keywords:
CCMDD Program,Chronic Medication Distribution,Public-Private Collaboration

P223

Exploring Pharmacoepidemiology for Advancing Rare Diseases and Orphan Drug Research: Indian Perspective

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Introduction: Pharmacoepidemiological studies provide valuable insights into real-world usage of medications. However, in the case of rare diseases, limited disease prevalence, insufficient data collection and assessment challenges, and varying disease classifications make drug utilization studies challenging. Proper collection and analysis of pharmacoepidemiological data can provide important insights into treatment patterns, drug safety, and effectiveness in countries like India with a substantial burden of rare diseases.

Aims: This review assesses the current landscape of orphan drug utilization studies in India. It aims to identify gaps, challenges, and opportunities in using pharmacoepidemiology to advance rare disease research for improving healthcare and reducing treatment costs.

Methods: A review of relevant literature, encompassing scientific publications, regulatory data, and policy documents was undertaken for this study. The search of the relevant literature focussed on works related to pharmacoepidemiological studies of orphan drugs, current challenges in conducting these studies, and opportunities in improving the design and conduct of these studies especially in the Indian context.

Results: The Central Drug Standards Control Organization (CDSCO) has approved 218 orphan drugs in India between 2000 and 2022. However, there is a lack of extensive pharmacoepidemiological studies focused on drug utilization. The National Registry for Rare and Other Inherited Disorders (NRROID) by the Indian Council of Medical Research has collected 12,790 records, but information usage is largely unknown. Challenges include limited data availability, infrastructure, expertise, and underreporting.

Discussion: Pharmacoepidemiology has immense potential in rare disease research in India by providing insights about drug utilization, predicting drug safety during development, drug repurposing, evaluating drug safety and effectiveness, identifying drug targets, and assessing economic burden of healthcare system. Solutions include leveraging national disease registries, electronic health records and claims databases and fostering collaboration between researchers, clinicians, and policymakers to support research and improve treatment availability.

Keyword: Rare Disease, Orphan Drugs, Pharmacoepidemiology, India

P224

Five-year comparison of biological product approvals in Indonesia and the United States

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Introduction: Perceived delays in drug approvals have been a major concern for policymakers in Indonesia. Access to a drug is not possible until the drug has received marketing authorization from the regulatory body. Comparison of biological product approvals in Indonesia and the United States (US) is crucial in improving access to innovative therapies.
Aims: To assess the differences between Indonesia and the US in the approvals of biological products between 2019 and 2023.
Methods: We searched publicly available data from the US Food and Drug Administration (USFDA) to identify biological products approved between 2019 and 2023. Indonesian marketing authorization data was taken from the Indonesian Food and Drug Authority (BPOM) website. Data from USFDA and BPOM were coded using the World Health Organization Anatomical Therapeutic Chemical (WHO ATC) classification system. We excluded allergens and antigens for diagnostic products. Differences in approvals of biological products between Indonesia and the US were described.
Results: Between 2019 and 2023, 162 biological products which consist of 47 diagnostic products, 58 therapeutic products, and 56 vaccines approved in the US were identified. Of those, we found 58 active ingredients (34 therapeutics and 24 vaccines) with 28 out of 58 (48%) being approved in Indonesia. Most of the approved therapeutics were blood products such as coagulation factor, immunoglobulin, fibrinogen, plasminogen, and prothrombin. On the other hand, cell and gene therapy is not yet available in Indonesia. Indonesia hasn't approved vaccines for anthrax, chikungunya, Ebola, and tick-borne encephalitis. Vaccine for cholera was available but the marketing authorization expired in 2020.

Discussion/Conclusion: This study confirmed that fewer FDA-approved biological products were approved in Indonesia over the past five years. Due to limited data availability on the application submission date from the companies, we were unable to confirm the time difference between the application submission and the approval date.

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IMPACT OF AMBULATORY PHARMACIST-LED TELEPHONIC INTERVENTION ON PATIENT'S HEALTH-RELATED QUALITY OF LIFE

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Introduction: Many patients need extensive aftercare & clinical follow-ups to manage their chronic illness. Significant gaps exist in outpatient care including poor communication, inadequate follow-up, insufficient patient education, medication management issues, and financial barriers. Ambulatory pharmacist-led telephonic intervention possesses huge potential to bridge these care gaps.

Aim: To assess the impact of ambulatory pharmacist-led telephonic intervention in patient's health-related quality of life.

Methods: A pilot study is carried out in an ambulatory setting of a hospital for 6 months. Patients with atleast one chronic condition & visiting the study site are included, after obtaining written consent. The patient's medical record data, contact details, and other necessary information were collected. The ambulatory pharmacist-initiated telephonic intervention every month after evaluating the patient's needs. Under this initiative, various levels of preventive care services were delivered. Health-related quality of life assessments were performed using the EuroQoL® EQ-5D-3L instrument at baseline, 2nd month, and 4th month. The data obtained was analysed using descriptive statistics.

Results: 58 patients enrolled, among which 53% were above 50 years of age & 67% had preliminary education. Majority of them were suffering from hypertension (36%), diabetes (21%) and rheumatoid arthritis (26%). Under this initiative, 79% of patients received personalized counseling (primary-level preventive care). About 9% of patients received secondary-level preventive care in which disease & treatment-related complications were evaluated & addressed; Referrals were initiated for 3% of patients as a part of tertiary-level preventive care. The average HRQoL was 66.23±15.45 at baseline & follow-up HRQoL measures were 71.41±14.48 and 75±14.98. This initiative, enhanced patient's self-care practices.

Conclusion: Ambulatory pharmacist-led telephonic intervention has positively impacted patient's health-related quality of life.

Keywords: ambulatory pharmacist, preventive care, quality of life, telephonic interventions.

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IMPACT OF ONCO-CLINICAL PHARMACIST IN HEMATOLOGICAL MALIGNANCY CENTRE: A RE-AIM FRAMEWORK ANALYSIS

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Introduction: Management of hematologic cancer encompasses multimodal therapeutic strategies ranging from chemotherapy to Hematopoietic Cell Transplantation (HCT). These therapeutic facets demand vigilant monitoring throughout its intricate course. As an integral part of the multidisciplinary healthcare team, onco-clinical pharmacists play a crucial role in optimising the therapeutic protocols.

Aims: This study applies the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework to assess the scope of onco-pharmacists in HCT setting.

Methods: Medication management services offered by the onco-clinical pharmacist and HCT pharmacist was assessed in onco setting and HCT Unit. The drug-related problems and clinical interventions were documented on a pre-validated tool with additional focus on therapeutic drug monitoring of immunosuppressants. Data obtained was analysed using the PQA Medication Therapy Problem Categories Framework to estimate clinical outcomes. Finally, a survey was conducted in the patients/caretakers and healthcare professionals to assess the degree of satisfaction pertinent to the pharmaceutical care.

Results: Over a 9-month period, the HCT pharmacist monitored 15 allogeneic and 4 autologous patients, while 73 individuals with hematologic malignancies were cared for by onco-pharmacists. This included 72 HCT patient encounters and 219 hematology patient encounters/interactions, with an average follow-up duration of 90 days. The HCT pharmacist managed 128 medications, identifying 216 medication-related problems and providing 194 interventions, while the onco-pharmacist managed 84 medications, identifying 96 problems, and providing 108 interventions. The time in therapeutic range of immunosuppression was 67.9% under the HCT pharmacist's management. In the satisfaction survey, of the 70 patients/18 caregivers, 71(88%) were strongly satisfied with the pharmaceutical care and of the 28 health care professionals, 24(85%) were strongly supportive of the continued need of a HCT pharmacist.

Discussion: The RE-AIM framework provided a methodological approach for programmatic evaluation and generalizability. The implementation of an HCT pharmacist services and novel practice models positively enhanced the clinical and humanistic outcomes.

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Implementation of deprescribing in psychiatry: A prospective interventional study

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Biography:

Introduction: Deprescribing is an essential practice in various fields of medicine, including psychiatry. It involves reducing or discontinuation of medications with unfavorable risk-benefit ratios, thus optimizing treatment, minimizing polypharmacy, improving patient safety and treatment outcomes.
Aim: To identify and deprescribe medications that were being used inappropriately and drugs that caused adverse outcomes among psychiatric patients.
Methods: It was a prospective interventional study conducted among inpatients at the Department of Psychiatry of a tertiary care hospital in Southern India for 9 months. Data regarding potentially inappropriate medication use and adverse drug reactions were identified using tools such as the standard treatment guidelines, Beer's criteria, and drug information databases like UpToDate. Identified interventions were conveyed to the prescribing psychiatrist and upon their acceptance, the process of deprescribing was initiated. Patient satisfaction post deprescribing was assessed.
Results: A total of 170 psychiatric patients with mean age of 37.3±12.4 were enrolled in the study of which 62.4% were males. The study identified 42 potentially inappropriate medications, primarily D2 receptor antagonists (13, 28.2%) and atypical antipsychotics (7, 17.9%). The primary reason for their inappropriateness was lack of a valid indication. Adverse drug reactions were associated with 28 medications, primarily involving atypical antipsychotics (14, 50%) and benzodiazepines (7, 25%). A total of 70 medications were targeted for deprescribing, out of which 24 deprescribing were initiated by the prescriber and 46 were initiated by the pharmacist. Pharmacist-initiated interventions had an acceptance rate of 45.7%. Ultimately, 45 medications were successfully deprescribed. Patient satisfaction post-deprescribing was assessed and majority of subjects expressed positive response (61.5%).
Conclusion: Deprescribing in psychiatry proves effective in addressing inappropriate medication use and adverse health outcomes. However, successful deprescription with the involvement of both prescribers and pharmacists, emphasizes the importance of personalized medication management in improving patient care.
Keywords: Deprescribing, Potentially-inappropriate medications, Adverse outcomes.

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Improving Comprehension of Oncology Drug Related Issue after Pharmacist Education

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Introduction: Nowadays, there are more options for cancer treatment. Besides traditional chemotherapy, targeted therapy with monoclonal antibodies or orally administered small molecular drugs, as well as immunotherapy, have become the newest trends in cancer treatment.

Aims: With different types of side effects and self-care precautions, being educated by pharmacists may improve the understanding of drug-related problems.

Methods: We conducted a retrospective analysis of a questionnaire administered to patients undergoing their initial course of cancer treatment, which encompassed chemotherapy, targeted therapy, and immunotherapy. The questionnaire comprised 13 inquiries concerning fundamental self-care practices and the management of side effects. Additionally, we assessed medication adherence using the Morisky score. Data collection spanned from 2021 to April 2024.

Results: 608 patients were enrolled in this study. The predominant cancer types among these patients were breast cancer (62.1%), followed by gastric cancer (14.7%), head and neck cancer (8.5%), hepatic cancer (6.3%), and pancreatic cancer (4.4%). The remaining 4% consisted of urothelial cancer, blood cancer, and other types. The mean pre-test score prior to pharmacist education was 73.4. Following pharmacist intervention, the mean post-test score significantly increased to 94.3. While the majority of patients demonstrated good compliance, 21 patients exhibited poor medication adherence. Additional educational interventions will be provided for these individuals.

Discussion: Though cancer patients often receive education from doctors or nurses, the inclusion of pharmacists in the educational process can significantly enhance understanding of basic self-care and side effects management.

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Promoting Materiovigilance: Empowering Community Pharmacists with Sensitization Initiatives

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Introduction: Medical devices play a vital role in patient care, yet they carry inherent risks, underscoring the importance of materiovigilance in monitoring and preventing Medical Device Adverse Events (MDAEs). The occurrence of these reported events underscores the necessity for a regulated system to supervise medical device surveillance.
Aims: This study primarily aims to develop a Knowledge, Attitude and Practice (KAP) questionnaire and to assess the effectiveness of an awareness/sensitization program about medical devices among the community pharmacists.
Methods: A structured, self-administered questionnaire, derived from previous studies, was developed and validated consisting of 30 questions. The questionnaire was distributed to the community pharmacists, and their responses were collected. The normality of the data was assessed using the Kolmogorov–Smirnov test and Wilcoxon Signed Ranks test was utilized to compare pre- and post-scores of the participants.
Results: Out of 170 individuals surveyed, 150 responses were received, meeting the required sample size. Prior to the sensitization efforts, 96% of participants were unfamiliar with materiovigilance. The Kolmogorov-Smirnov test result for Knowledge, Attitude, Practice (pre-total) yielded a statistic of 0.444, 0.411 and 0.390 with 150 degrees of freedom and a significance level of 0.000 and post result are Knowledge, Attitude, Practice (post-total) yielded a statistic of 0.188, 0.354 and 0.233 with 150 degrees of freedom and a significance level of 0.000. Wilcoxon signed ranks test was conducted, revealing a statistically significant result with a p-value of <0.05.
Discussion: These changes underscore the effectiveness of educational initiatives in improving KAP related to medical device safety monitoring. By tracking changes in KAP over time, adjustments can be made to sensitization programs to ensure continuous improvement and relevance. By identifying areas of weakness or misunderstanding, interventions can be designed to address specific knowledge gaps, reshape attitudes, and promote best practices among community pharmacists.

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REAL WORLD EVIDENCE IN REGULATORY DECISION MAKING: CURRENT STATUS & FUTURE PROSPECTS

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Introduction: Real-World Evidence (RWE) stands as a pivotal factor in augmenting regulatory decision-making within the healthcare sphere. This study scrutinizes the present landscape and future trajectories of RWE integration within the regulatory frameworks of the United States (US) and the European Union (EU).
Methods: A comparative analysis was conducted, delving into regulatory documents, guidelines, and pertinent literature sourced from the USFDA and the EMA. The review honed in on data infrastructure, methodological prowess, capacity-building endeavors, and the possible opportunities and challenges in integrating RWE.
Results: The US and EU have comprehensive initiatives integrating RWE, supported by extensive data infrastructure including Electronic Health Records (EHRs), registries, and claims databases. Sophisticated resources in pharmacoepidemiology and data science bolster these efforts. The EU actively broadens data accessibility through European Health Data Space (EHDS), addressing challenges of data quality, standardization, privacy, and interoperability.
Discussion: Prospective avenues for RWE integration encompass the development of robust methodologies and analytical tools, substantial investment in capacity building, and the assurance of transparency and active patient participation. Challenges encompass tackling causality and biases, fostering collaborative endeavors to establish best practices, building trust, and aligning stakeholder expectations.
Conclusion: The US and EU stand at the forefront of RWE integration, harnessing robust data infrastructure and proficiency in methodology. The effective assimilation of RWE necessitates concerted efforts aimed at addressing data accessibility, methodological advancements, capacity building, and stakeholder engagement. Collaborative ventures will underpin the global development and regulation of safe and efficacious healthcare products.

P232

Setting research-priorities for safe and rational use of medicines in Indian context

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Background and objectives: We have constituted a National Task Force (NTF) in 2022 to explore possible solutions that could improve safe and rational use of medicines (SRUM). The objective was to identify research ideas in the field of SRUM through a survey of relevant stakeholders (Indian and International), and further to prioritize the research ideas using a pre-identified set of criteria.
Methods: This exercise was carried out using the CHNRI method which is an established research priority setting methodology. The NTF gathered research ideas from relevant Indian and global stakeholders. The ideas were checked for duplicates, re-phrased where necessary and classified into various sub-themes. Subsequently the research ideas were scored by Indian experts with relevant technical expertise.
Results and Interpretation: The final output of the prioritization process was a list of research ideas or questions, ranked by their scores. We received 852 ideas related to SRUM. After excluding ideas which were duplicate or unclassifiable, there were 209 ideas. 55 ideas were identified as priority by Indian researchers, which included ideas on rational use of antimicrobials, optimizing polypharmacy in elderly and measures to reduce environmental burden of pharmaceuticals.
Conclusion: The findings of the research priority setting exercise will help to improve SRUM in India. We will now work with partners in India to translate the prioritized research ideas into research questions, develop and test solutions that can be adopted by health systems in India. The NTF will identify policy, technological, or educational interventions that can improve SRUM.
Keywords: CHNRI, Safe and Rational Use of Medicines (SRUM), LMIC (Low-middle income countries), research priority setting exercise.

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Social media detoxification in pharmacy students: RCT study

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Introduction: Social media use was increasing, with 40% of university students found to be addicted, negatively affecting their health. A social media detox could reduce addiction.
Aim: This study compared the impact of social media detoxification between experimental and control groups, assessing SMAT scores and weekly social media usage among undergraduate pharmacy students before and after the intervention.
Method: Undergraduate pharmacy students were randomly assigned to experimental and control groups. The experimental group reduced screen time on mobile phones and tablets by 50%, while the control group continued normal usage. Both groups completed the SMAT questionnaire (0 = definitely not true to 3 = definitely true) before and after the 4-week intervention and recorded weekly social media usage. Data collection was from December 2023 to February 2024.
Results: Of 23 students, 12 were in the experimental group and 11 in the control group. Initial SMAT scores were similar (38.0±6.7 vs. 36.0±8.5; p=0.536). After 4 weeks, the study found a significant difference in the mean difference of SMAT scores between the experimental and control groups (16.8±4.9 vs. 8.5±7.3; p=0.004). Weekly social media usage decreased substantially more in the experimental group (2905.6±1608.8 to 1059.3±1591.9; p=0.012). Both groups showed significant decreases in SMAT scores pre- and post-study (experimental: 38.0±6.7 to 21.2±7.1, p<0.001; control: 36.0±8.5 to 27.4±10.1, p=0.003). Weekly social media usage decreased significantly in the experimental group (4208.8±1651.8 to 1303.2±702.5; p<0.001).
Discussion: Limiting screen time on mobile phones and tablets for social media detoxification significantly lowered SMAT scores and weekly social media usage compared to normal usage.

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Standardized Approach to Obtain Patients feedback on RMMs Shape and Content

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Introduction:

The Saudi Food and Drug Authority (SFDA) conducted a project to improve the current Additional Risk Minimization Measures (aRMMs). To the end of 2023, the SFDA has approved 303 aRMMs. Therefore, gathering the perceptions of patients on aRMMs is very important to improve the implementation of aRMMs. Their feedback is utilized to enhance the safety of medicinal products and to improve the recognized gaps in the current aRMMs.

Aims:
To obtain patients' feedback about three aRMMs, semaglutide, ranibizumab and mycophenolate in regards to design and content.

Methods:
A focus group discussion was conducted targeted patients who received patient guide of targeted medicines. These focus groups were conducted in collaboration with regional pharmacovigilance offices allocated in different hospital in Saudi Arabia. The questions were carefully designed to collect data on the effectiveness, clarity, design and content of the current aRMMs. Three medicines were selected based on specific criteria, which is Seriousness of risk and the number of Generic products marketed in Saudi Arabia. Descriptive statistics were performed to represent demographic characteristics and patients' opinions using Microsoft Excel program

Discussion:

A total of 60 patients participated in three focus group discussion conducted in three hospitals. The majority around 90% found that the Patient Guide is excellent, appropriate, and agreed that its appearance was clear and all instructions are understandable. Also, the information provided can be followed easily. In addition, number of participants agreed that excess information is provided and briefing of information is preferable. However, 10% of participants stated that the medical terms were not clear. Also, more than 90% of participants agreed that the reporting of adverse drug reactions is clear and stated that the illustrations, size, font, and color were excellent, however, 7% of the participants stated that the font is small and reporting ADRs was not clear.

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The context and perspectives for implementing a tailored pharmacist-led intervention in Indonesia

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Introduction: Medication adherence is a common problem among type 2 diabetes (T2D) patients worldwide, including low- and middle-income countries. A recent study showed that a tailored pharmacist-led intervention improved medication adherence among T2D patients in Indonesia. Identifying the opportunities and challenges in practice is useful to increase the chance of interventions being successfully adopted widely in clinical practice.
Aims: To explore the context and perspectives for implementing a tailored pharmacist-led intervention to improve medication adherence to glucose-lowering medication among people with T2D in Indonesia.
Methods: Semi‐structured interviews were performed among community pharmacists (CPs) and T2D patients focusing on the context of medication adherence and perspectives regarding a proposed intervention. All interviews were audio recorded, transcribed verbatim, and coded independently by two researchers using directed content analysis guided by the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework.
Results: Sixteen CPs and thirteen T2D patients were interviewed. Medication adherence was recognized as a problem by patients, which CPs could address. Most CPs and patients were positive about the proposed intervention. Applying the RE-AIM framework showed factors relevant for implementation of the intervention, from both the CP and the patient perspectives. For most domains, challenges were seen at the setting level, including insufficient management support and resources. At staff level, training of pharmacists was relevant, particularly to better counsel and motivate patients in taking their medication. At patient level, challenges were seen to support older adults having poor self-efficacy and for patients not having time for counseling by the CP.
Discussion: The proposed pharmacist-led intervention was considered relevant in the current healthcare context but several factors need to be addressed when planning further implementation of the intervention in Indonesia.
In further research,stakeholders at the macro level need to be involved to investigate how to address perceived barriers for implementation of the intervention.

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The Impact of Volume-based Procurement on the Spatial Accessibility of Insulin

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Introduction:
China's vast geographical landscape has led to significant regional disparities in economic development and healthcare resource distribution. In economically disadvantaged or remote areas, reduced insulin prices have not effectively increased accessibility due to high transportation costs and limited healthcare services, exacerbating health inequalities between urban and rural regions. Thus, the spatial accessibility of insulin is crucial for achieving healthcare equity.

Aims:
This study aims to assess the spatial accessibility of insulin across approximately 361 cities in China, analyzing travel times and accessibility inequalities. It evaluates how regional variations affect equitable access to insulin.

Methods:
The study utilizes pharmaceutical procurement data from 2017 to 2023, with geographical information on healthcare facilities sourced from Amap. We employed 1×1 km² scale friction maps for driving, obtained from the China National Geomatics Center, which includes detailed road networks and administrative boundaries. The analysis focuses on travel times and utilizes Gini and Theil indices to quantify spatial inequalities in insulin accessibility.

Results:
The implementation of the Volume-based Procurement (VBP) policy in 2021 significantly reduced travel times to healthcare facilities across China, with notable reductions in provinces like Beijing and Jiangsu by over 50%. Concurrently, Gini and Theil indices, indicating inequality in accessibility, substantially decreased. For instance, Shanghai's Gini index reduced from 0.0177 pre-VBP to 0.0044 post-VBP. However, regions like Qinghai saw increases in travel times, indicating uneven benefits across the country.
Discussion:
The reduction in travel times and inequality indices post-VBP implementation highlights the policy's effectiveness in enhancing insulin accessibility, particularly in regions with previously high disparities. However, the persistence of accessibility challenges in remote areas like Tibet suggests the need for targeted interventions to bridge remaining gaps. This may include the development of mobile healthcare services and improved transportation infrastructure to ensure comprehensive improvements in insulin accessibility nationwide.

[Methods]

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A Comparative Review of International Common Data Models for Vaccine Safety

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Background:The Common Data Model(CDM) is crucial for integrating multi-source heterogeneous data and supporting big data analysis for vaccine safety.
Aims:To review the key elements and technical characteristics of CDMs, providing a reference for constructing a localized CDM system for vaccine safety evaluation.
Methods:A systematic review was conducted using search strategies based on "vaccine safety" and "CDM" themes in databases like PubMed and Embase, supplemented by global surveillance platforms. Key information from identified CDMs'official documents was extracted for a systematic comparison of model overview, data structure, and ETL tools.
Results:The CDMs currently used in vaccine safety monitoring include OMOP, Sentinel, PCORnet, ADVANCE, VAESCO, and BIFAP. Technical details of ADVANCE, VAESCO, and BIFAP were not accessible:(1) Model Overview: OMOP, Sentinel, and PCORnet developed with input from regulatory agencies, healthcare institutions, and academia, These models have been updated more than ten times since their inception to expand the scope of terminology mapping, address COVID-19 data aggregation, and other reasons. (2)OMOP has 39 relational model tables, Sentinel has 20 star schema tables, and PCORnet has 23 core star schema tables with new data dimensions like patient-reported outcomes. OMOP disperses vaccine data across multiple tables, while Sentinel and PCORnet centralize immunization records.(3)ETL Process: All three CDMs emphasize standardized, traceable ETL steps and full-process quality control. OMOP uses unified standard concept systems(e.g., SNOMED CT, RxNorm) for semantic mapping to enhance interoperability; Sentinel and PCORnet balance standard vocabularies with industry codes(e.g., ICD, NDC), reducing mapping workload but facing terminology integration challenges. OMOP supports open-source ETL tools like Rabbit in a Hat; Sentinel has a comprehensive SAS package; PCORnet lacks dedicated ETL tools.
Conclusion:A localized CDM should be based on vaccine regulatory needs, leveraging international experience to enhance system specifications, optimize data collection, and develop ETL solutions. Multi-party collaboration can establish a CDM system suited to national conditions.

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A scoping review for Emulating a Target Trial in Vaccine

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Introduction: Clinical trial in Vaccine have been historically some difficulties on clinical trials, with data on the effectiveness and safety relying on observational research. Methodological concerns regarding the data sources, study designs, and outcomes used for estimating associations are still problematic in observational studies. Answering on causal inference is still more complex. Despite the increased interest in emulating target trials using observational data, little is known about this approach in vaccine.

Aims: This review aims to describe the methodology for assessing the available literature concerning emulating target trials for studying outcomes in vaccine.

Methods: We performed a systematic review. The literature search was conducted using MEDLINE, EMBASE, the Cochrane databases, and reference lists from previous related reviews. We summarized characteristics of these eligible studies. We used existing statements to identify quality gaps in the current literature. Variables related to the content for pharmacoepidemiologic research was included. The Risk Of Bias In Non-randomised Studies - of Interventions (ROBINS-I) guided the assessment of the target trial emulation.

Results: Our review of identified 46 studies reveals several unique considerations when leveraging target trial emulation for vaccine research. These challenges include aligning clinically relevant outcomes with the research questions, identifying etiologically relevant time windows, defining relevant treatment strategies, and fixing exposure, eligibility criteria, and follow-up initiation. Despite these challenges, the methodology is promising in that it bridges the gap between randomized clinical trials and observational studies by adopting a transparent and clearly defined approach.

Discussion/Conclusion: Data regarding the safety and effectiveness taken, prior to and during exposure and it was necessary to understand how we could answer these questions using rigorous methods in observational research. Through this scoping review, we intended to understand to what extent the target trial approach was used in vaccination and provide recommendations to improve its use in this field.

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Distributed learning in effect estimation using routinely collected healthcare data:a systematic review

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Introduction:Distributed learning in multicenter studies addresses the issue of small sample sizes inherent in single-center research, while ensuring data privacy. This approach enhances the representativeness and generalizability of results and is particularly suitable for studies involving rare events.
Aims:Evaluate the status and methodology of distributed learning in the medical field to provide references for multicenter medical research.
Methods:A systematic search was conducted in PubMed, Scopus, etc., using the keywords "EHR/EMR/Claim" AND "distributed/federated learning." Studies on distributed learning in effect estimation were included.
Results: A total of 31 studies were included, covering 25 iterative methods and 49 specific applications. The majority were published in or after 2019(27/31), mainly from the United States(23/31). The most common regression model used was logistic regression(16/31), followed by Cox regression(9/31), Poisson regression(3/31), and GLMM(3/31). (1)In iterative methods, the principles mainly include constructing surrogate likelihood functions(13/25) and iterative communication(7/25). 40%(10/25) used single-round communication, 12%(3/25) used 2-3 rounds, and 48%(12/25) required multiple iterations. Additionally, 56%(14/25) addressed data heterogeneity, and 32%(8/25) dealt with rare outcomes. Methods were evaluated using estimation bias and MSE, with centralized analysis as the gold standard. (2)Among the 49 applications, the most common scenario involved using artificially partitioned datasets (26/49). Research focused on COVID-19 patients(9/49) and cancer patients(9/49), with adverse drug reactions being a significant research theme(11/49). Distributed algorithms showed less estimation bias than meta-analysis, particularly in cases of high data heterogeneity or rare outcomes. CDM(7/49) or FAIR principles(3/49) are now mainstream for data standardization, but missing data is still predominantly handled by deletion(9/11). Most algorithms provided open-source code, with varying usability.
Conclusion:Distributed computing has been applied to various models for epidemiological effect estimation, demonstrating wide applications in the medical field. Recent efforts have focused on handling data heterogeneity and addressing rare outcomes. However, improvements in code usability and missing data handling are still needed.

P240

Evaluation of time-related bias with non-user control

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Introduction: In observational studies estimating the association between treatment and time-to-event outcomes, time-related biases can significantly impact results. Immortal time bias is one of the such biases, and two types are known: misclassified immortal time bias and excluded immortal time bias (Suissa 2007). Misclassified immortal time bias is caused by misclassifying the period between the time of cohort entry and the treatment initiation as a treatment group, and excluded immortal time bias is caused by excluding the period between the time of cohort entry and the treatment initiation from the analysis. These biases often arise when we inadequately set the start of follow-up (time zero), especially when non-users are used as the control group.

Aims: This study aims to illustrate time-related bias when non-users are used as the control, using both mathematical formulas and simulated data.

Methods: For simplicity, our formulation is based on the situation that there is no confounding and no treatment effect. We compare three different settings of time zero for treatment and control groups: (1) cohort entry date (CED) vs CED, (2) treatment initiation date (TID) vs CED, and (3) TID vs matched, where time zero for the non-user control is defined as the corresponding date from CED to TID of their matched treatment patient.

Results: Our simulation shows that both methods (1) and (2) exhibit large apparent preventive effects of the treatment due to immortal time bias. The magnitude of the bias is greater for the method (1) (misclassified immortal time bias) than for the method (2) (excluded immortal time bias). Conversely, method (3) shows no bias.

Discussion/Conclusion: To minimize time-related biases, researchers should use an appropriate time zero, especially when using a non-user control group.

Keywords: excluded immortal time bias, misclassified immortal time bias, time zero

P241

Lasso-type shrinkage method for the modified Poisson and least-squares regressions

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Introduction: Logistic regression has been widely used for cohort studies with binary outcomes in pharmacoepidemiology. However, when the event frequency is not low (>10%), the odds ratios fail to approximate risk ratios, and risk ratios and risk differences are preferred epidemiologic effect measures because of their straightforward interpretations. The modified Poisson and least-squares regressions have been alternative standard methods to estimate these measures with adjusting potential confounding factors.
Aims: We develop the lasso estimation for these effective regression analyses, an efficient shrinkage machine learning method that enables variable selection simultaneously.
Methods: We developed the lasso-type shrinkage and variable selection methods for the modified Poisson and modified least-squares regressions, and applied these methods to a retrospective cohort study that investigated the effects of donor killer immunoglobulin-like receptors genotype on the reactivation of cytomegalovirus after a hematopoietic stem cell transplantation. The new methods can provide effective risk ratio and risk difference estimates under small and sparse data settings. We also provide a bootstrap method to calculate the confidence intervals of the effect measures. In addition, we developed a new R package, regconfint, to implement these methods with simple commands.
Results: Through application to the hematopoietic stem cell transplantation cohort study, we showed that the lasso-type shrinkage methods could provide stable shrinkage estimates and narrower confidence intervals generally, even under the small and sparse data settings. We also showed that the lasso estimation enables effective variable selection for the risk ratio and risk difference regression models.
Conclusion: The ordinary modified Poisson and modified least-squares regressions have limitations for the accuracy of estimation in the effect measures under ill conditions, but the lasso-type estimation possibly overcomes these difficulties. The new methods also enable effective variable selections for these multivariate analysis models.

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Methods applied to assess real-world effectiveness of drugs: A scoping review

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Introduction: Real-world evidence (RWE) on drug effectiveness, i.e., understanding how drugs perform in actual clinical practice, is crucial. However, the specific methods applied in pharmacoepidemiological drug effectiveness studies, and whether these methods depend on the drug investigated, remain unclear.
Aims: This scoping review aims to collect pharmacoepidemiological studies evaluating drug effectiveness using real-world data (RWD) and to categorize them based on (i) the methods applied and (ii) the drugs and outcomes investigated.
Methods: We searched PubMed and Embase for studies published in English language in the six-month period from July 2019 to December 2019. Studies with the following characteristics were eligible for inclusion: (i) RWD-based studies investigating the exposure of one or more drugs in humans, and (ii) studies including at least one primary outcome that can be classified as an effectiveness outcome.
Results: Of 4,820 identified records, 1,129 continued from title-abstract screening. Of these, 200 were randomly selected for full text assessment, and 90 were finally included. The 90 studies used RWD from the US (n=45), European countries (n=22), Asian countries (n=14), other countries (n=5), and multiple countries (n=4). Across the studies, chemotherapy was the dominating drug exposure (n=32), and all-cause mortality/survival was the most frequent outcome of investigation (n=53). Looking at applied methods, cox regression (n=46), Kaplan-Meyer analysis (n=42), and logistic regression (n=15) were the most frequent statistical models. Moreover, 13 studies applied descriptive statistics only. To counter confounding, adjustment by multivariable models (n=55), stratification (n=38), and propensity score matching (n=23) were the dominating methods.
Discussion: Our findings indicate that pharmacoepidemiologists reach towards well-known methods in RWD-based drug effectiveness studies. To comply with the increasing need for high-quality RWE of drug effectiveness, we believe that a continued focus on suitable data sources, methods, and scientific reporting in such studies is needed.

P243

Outlier detection and influence diagnostics for dose-response meta-analysis

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Introduction: Dose-response meta-analysis has been gaining prominence in pharmacoepidemiology and health technology assessments as a method to synthesize evidence of dose-response relationships from multiple studies.
Aims: In practice of dose-response meta-analysis, “outlying” studies possibly lead to serious biases and yield misleading results. Also, there might be influential studies that have notable impacts on the overall evidence. In this study, we propose new methods of outlier detection and influence diagnostics for dose-response meta-analysis.
Methods: We developed 3 new methods, and applied them to a dose-response meta-analysis that assessed the efficacy of selective serotonin reuptake inhibitors for treatment of major depression. These methods involve leave-one-out-type influential analyses based on (1) study-level studentized residual, (2) arm-level studentized residual, and (3) generalized variance ratio statistic for the grand mean parameters of pooling model. We also developed quantification methods for statistical errors of these influential statistic using bootstrap.
Results: Through the influential analyses, a clinical study assessing the efficacy of fluoxetine was detected as a potential outlier among the 17 studies involved in the dose-response meta-analysis. The study was a phase 3 study in Japanese adults with major depressive disorder, and the efficacy of fluoxetine was not clearly demonstrated in this study. Fluoxetine has not been approved in Japan. The other studies generally showed the efficacy, and fluoxetine has been approved in US and registered in WHO Model List of Essential Medicines. Thus, the Japanese study could be detected as an outlier and this study was also shown to be influential to the overall results of the dose-response meta-analysis.
Discussion: Our new methods can provide effective statistical outcomes to circumvent erroneous evidence. These methods would also provide new insights in evidence from dose-response meta-analysis as the antidepressant study.

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Exploring Methodologies to Incorporate Patient Voice in Pharmacoepidemiology Studies

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Introduction. Patient and caregiver perspectives provide crucial information in understanding disease burden, patient journey, and unmet medical needs. Patient voices were traditionally captured using classic patient-centered market research, however patient-centered clinical effectiveness research (CER) is increasingly used to provide advanced evidence for regulators and payers. The differences between these two approaches have not been thoroughly discussed.
Aims. This study assessed both patient-centered CER and market research approaches to assist researchers to make informed decisions on how to select the fit-for-purpose study design.
Methods. A comprehensive literature search on PubMed was performed using generative artificial intelligence to identify studies from 2014 to 2024. Online desk research was also performed as a supplement. Findings related to definitions, concepts, methods for patient-centered CER and market research were captured. Similarities and differences were synthesized with a narrative synthesis approach.
Results. A total of 726 studies were screened. Analysis concluded that CER aims to generate evidence in support of medical technologies value evaluation, drug effectiveness, and/or safety for regulators and payers, whereas market research is used to generate insights for commercial purposes without the same level of scientific rigor. Both approaches use standard instruments and customized questionnaires to collect data from patients, and researchers may apply quota sampling to achieve the comprehensiveness and representativeness of research. Major process differences are identified in which CER requires study protocol and ethics review. Furthermore, CER includes multiple rounds of instrument validation including cognitive debriefing to generate reliable results to meet requirements of advanced evidence. From a statistical analysis perspective, data derived from both approaches are suitable for descriptive analysis, however CER is more robust to enable comparative or multivariate analysis.
Discussion. There is an increasing trend of patient-centered studies in the APAC region. Researchers are recommended to select a study approach based on their objectives to enable generation of fit-for-purpose data to benefit stakeholders.

[Neurology]

P245

Characteristics of Duchenne Muscular Dystrophy Patients in Taiwan: A Population-Based Study

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Introduction
Duchenne muscular dystrophy (DMD) is a rare hereditary muscle disorder with poor prognosis and quality of life. However, the nation-wide real-world data on DMD is lack in Taiwan.

Aims
The study aimed to investigate the characteristics, treatment patterns and the healthcare resource utilization (HCRU) of patients with DMD in Taiwan.

Materials and Methods
The Taiwan National Health Insurance Research Database with a data period of 2012 to 2021 was used in this population-based cohort study. Patients with initial catastrophic illness certificate (CIC) of DMD during 2013 to 2020 were identified, and the date of CIC issued was defined as the index date. Patients were followed-up for systemic steroid use, ventilator initiation, mortality and HCRU until death or end of the data period (December 2021), which ever came first.

Results
A total of 134 newly-diagnosed DMD patients were included in the study cohort. Sixty-eight patients (50.7%) were diagnosed during 2012-2015 with a median age at index date of 7 years; while 65 (49.3%) were diagnosed during 2016-2020 (median age at index date: 5 years). With a mean follow-up period of 4.4 years, 70 (52.2%) patients received systemic steroid treatment and 19 (14.2%) patients received ventilator. The median age of initiating systemic steroid and ventilator support was 6 years and 20 years, respectively. During the follow-up period, there were 159 DMD-related hospitalization events, and the mean length of stay was 6.7 (SD: 7.9) days per event. A total of 11 death events were captured, and the average age of death was 22.6 (standard deviation [SD]: 4.6) years.
Discussion
In consistent with the epidemiology studies from other Asian countries, most of the DMD patients were diagnosed before 10 years. The current study implies the increased awareness of DMD in Taiwan in recent years and highlights the potential disease burden of DMD.

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Epidemiological studies on the genetic background in the development of subacute myelo-optico-neuropathy

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Introduction: Subacute myelo-optico-neuropathy (SMON) is a neurological disorder associated with the administration of clioquinol. Although clioquinol has been used worldwide, there was an outbreak of SMON in the 1950s–1970s in which the majority of cases were in Japan, prompting speculation that the unique genetic background of the Japanese population may have contributed to the development of SMON. We compared the frequency of loss-of-function polymorphisms in ABCC4, ABCC11, SOD1, and NQO1, which we expected to be associated with development of SMON, between patients with SMON and healthy controls.
Aims: To elucidate the genetic background involved in the development of SMON.
Methods: We analyzed 125 Japanese patients with SMON. ABCC4 rs3765534 polymorphism, ABCC11 rs17822931 polymorphism, SOD1 loss-of-function polymorphisms (rs2070424, rs4998557 and rs4816405) and NQO1 loss-of-function polymorphisms (rs1800566, rs10517, rs689452, and rs689456) were evaluated. The allele frequency distribution of each polymorphism was compared between the patients and the healthy Japanese individuals (Human Genomic Variation Database and Integrative Japanese Genome Variation Database) as well as our in-house healthy controls.
Results: The frequencies of loss-of-function polymorphisms in ABCC4, ABCC11, SOD1, and NQO1, alleles in patients with SMON did not differ significantly from those in the normal control group.
Conclusion: The genetic background associated with development of SMON has not yet been identified. At the moment, we consider that drug-induced factors may be more likely to contribute to the development of SMON than the genetic factors. We plan to expand the target genes of our analysis in the future.

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Riluzole use for motor neuron disease and all-cause mortality: A time-to-event analysis

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Introduction
Motor neuron diseases (MND) are a group of neurodegenerative disorders affecting motor neurons. Riluzole is a commonly used supportive therapy for MND patients. However, due to the rarity of MND cases, there is limited research exploring the effectiveness of riluzole use on survival outcomes for MND patients.

Aims
This study aimed to estimate the risk of all-cause mortality following riluzole use for MND patients.

Methods
The study used a multi-centre analysis from Hong Kong, Taiwan, and Korea. We applied a common data model-based approach to improve the reproducibility. Incident patients with MND as the primary diagnosis were selected. A multivariable Cox regression model was conducted to estimate hazard ratios (HRs) and 95% confidence intervals for all-cause mortality. The observation period was defined from the date of MND diagnosis to the death date, the study end date (December 31, 2018), whichever came first. The covariates included were sex, Charlson comorbidity index, and hypertension. The data cleaning and analysis were performed on each site using SAS 9.4 software. The results from each site were then integrated using a random-effects meta-analysis.

Results
The numbers of MND patients for time-to-event model from Hong Kong, Taiwan, and Korea are 1,939, 11,473, and 24,450. Although the meta-analysis with a random effect model revealed a significantly elevated risk of all-cause mortality among riluzole users [HR: 1.98 (95%CI: 1.17, 3.36)], a relatively large difference in baseline comorbidities was identified. The results are similar in Taiwan and Korea, while the results in Hong Kong were insignificant [1.16 (95%CI: 0.87, 1.54)].
Discussion
Our study found a higher mortality risk among MND patients following riluzole use. However, there is potential confounder by indication, time-varying confounding and heterogeneity of the population across different sites. A traditional conditional model may be inappropriate. Further analysis is needed to verify this conclusion.

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Treatment patterns among patients with myasthenia gravis: An insurance claims database study

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Introduction: Although treatment strategies for myasthenia gravis (MG) have changed significantly in recent years, the real-world situation is not well understood.
Aims: To summarize treatment patterns focusing on dose of oral corticosteroids (OCS) over time in an observational study, using three database-derived cohorts: JMDC claims database covering the Social Health Insurances (JMDC) between 2005-2021; DeSC database covering the National Health Insurance (NHI) between 2014-2021; and DeSC database covering the Late-stage Elderly Medical Service System (LSE) between 2014-2021.
Methods: A cohort of patients with a record of MG (ICD-10 code: G70.0), starting immunotherapy at ≥16 years of age, with a serological test and having at least 180 days of MG-free baseline period was derived. Achievement of ≤5mg/day OCS was defined if at least 90 days of consecutive ≤5mg/day OCS were observed during the follow-up, without any gap longer than 60 days between two consecutive claims. The time to achieve ≤5mg/day OCS was estimated using Kaplan-Meier survival analysis.
Results: In total, 811 patients were included. Mean ages were 49 years for JMDC, 61 years in NHI, and 80 years in LSE. In JMDC, the median time to achieving ≤5mg/day OCS was significantly shorter ($p = 0.042$; log rank test) in patients included in 2015 or later (11.0 months) than in those included before 2015 (17.9 months). Among the three cohorts, median time to ≤5mg/day OCS was shorter in LSE (6.5 months) than JMDC (11.0 months) and NHI (11.7 months).
Discussion: Faster tapering of the OCS dose was observed in patients starting treatment after the publication of the 2014 Japanese clinical guidelines for MG, compared with patients starting treatment prior to this. The more cautious use of OCS in elderly MG patients in LSE may reflect awareness and perceptions of tolerability and side effects in the elderly.

P249

Valbenazine in Tardive Dyskinesia: Meta-analysis of RCTs and Retrospective Study of FAERS.

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Introduction: Tardive dyskinesia (TD) is a movement disorder induced by dopamine receptor antagonist medications. Valbenazine represents a novel, highly selective vesicular monoamine transporter 2 inhibitor approved by the US FDA for the treatment of TD.
Aims: This study integrated safety data on valbenazine in TD from randomized controlled trials (RCTs) and the FDA Adverse Event Monitoring System.
Methods: We systematically reviewed RCTs reporting adverse events (AEs) of valbenazine in patients with TD applying search on databases like PubMed, EMBASE, and ClinicalTrial.gov. The quality assessment was done using the Cochrane Risk of Bias Tool. We utilized a random effect meta-analysis to calculate Peto odds ratio (OR) with 95% confidence intervals (CI). The Open Vigil 2.1 MedDRAv24 was used to search the FAERS database, with data available until September 2023.The disproportionality was calculated using the proportional reporting ratio (PRR) and the reporting odds ratio (ROR). Signal refinement was conducted by restricting the drug roles to 'primary suspect'.
Results: For the safety meta-analysis, nine RCTs with available AEs were examined. A total of 240 AEs were found associated with the valbenazine group and 96 AEs with placebo. Valbenazine significantly increased the risk of somnolence (OR=3.42, 95% CI: 1.97-5.92, p: <0.0001) compared with the placebo. In FAERS, 1,443 patients were reported with AEs associated with valbenazine. Significant signal scores were observed in nervous system disorders, psychiatric disorders, musculoskeletal and connective tissue disorders and general disorders and administration site conditions. Few generated signals, failed to meet the signal criteria upon refinement.
Discussion/Conclusion: Despite an expanding amount of information on the novel valbenazine, there is relatively limited evidence defining the comprehensive safety profile of this medication. The current study has updated and refined the safety profile of valbenazine during its post-marketing phase, thereby aiding in the assessment and mitigation of risks to optimize patient healthcare outcomes.

[Infectious Disease]

P300

A study to assess drug related problems associated with anti-tubercular medications.

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Introduction: Tuberculosis (TB) has been a major public health concern. Achieving an optimal therapeutic outcome is hindered by many factors including, drug related, patient related, and system related. Drug-related problems (DRPs) in anti-TB treatment include adverse drug reactions, drug interactions, and non-adherence to medication. To optimize patient outcomes Pharmacists play a crucial role in addressing these issues through counselling, monitoring treatment, and managing drug regimens.
Aims: To assess Drug Related Problems associated with anti-tubercular medications.
Methodology: This prospective interventional study, conducted over 9 months at Urban Primary Health Centres and tertiary hospital in Mysore. Patients were selected based on specific criteria. Baseline details including demographic, medication history was collected, and patients were monitored on each visit. Various tools were used to assess DRPs: Hepler and Strand classification, WHO-UMC Causality Assessment, Naranjo Adverse Drug Reaction Probability Scale, Hartwig and Siegel severity assessment, Shumock and Thornton Preventability scale, and the 10-item Medication Adherence Rating Scale (MARS).
Results: Out of 230 patients, [61.30%] were males, and [30.86%] were aged 31-45 years. [97.13%] were new TB cases, and [75.65%] had no family history of TB. Detection was primarily through microbiological confirmation [62.17%], and [73.91%] resided in urban slums. Isoniazid, rifampicin, and pyrazinamide were prescribed to [above 98%] of patients. Among 445 DRPs, adverse drug reactions accounted for [46.06%], drug interactions [23.59%], and drug use without indication [5.61%]. Gastrointestinal disorders [46.82%] and hepatobiliary disorders [17.56%] were the most common adverse reactions. Barriers to adherence included fear of infecting family [87.06%], stigma and discrimination [75.43%], and income loss [72.4%]. Adherence improved over 180 days. Chi-Square test using MARS showed a highly significant relationship between adherence and non-adherence [$p < 0.0001$].
Conclusion: Clinical Pharmacists play a vital role in reducing DRPs and improving patient outcomes in TB treatment.
Keywords: Anti-Tubercular Therapy, Drug-related problem, Medication adherence, Barriers

P301

Adverse drug reaction in drug-resistant tuberculosis patients: a retrospective study

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Introduction: The high incidence of drug-resistant tuberculosis (TB) in Indonesia presents a significant public health challenge, exacerbating the difficulty in controlling and eradicating the disease. Multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) cases are rising, necessitating more complex and prolonged treatment regimens, which often come with severe side effects. Consequently, rigorous monitoring of adverse drug reactions in TB patients is crucial to ensure treatment efficacy and patient safety.

Aim: This study was conducted to assess adverse drug reactions and their management in drug-resistant TB patients.

Methods: This was a retrospective descriptive study, using data of drug-resistant TB patients who completed therapy from January 1st, 2021 to December 31st, 2023 at the Tuberculosis Outpatient unit at the PKU Gombong Hospital, Central Java, Indonesia. Data were collected from patients' medical records.

Results: There were 84 patients included in this study, 96% of them were identified having adverse drug reactions. The five most prevalent adverse effects found in this study were gastrointestinal disorders (39.02%) followed by musculoskeletal disorders (22.83%), neurotoxicity (11.27%), ototoxicity (6.07%), and blood disorder (5.78%). The strategies employed to manage adverse drug reactions involved incorporating symptomatic medications and/or modifying the treatment regimen

Conclusions: Due to the limited sample size, we cannot draw a definitive conclusion. However, the findings of this study are crucial as they provide valuable insights into the adverse effects experienced by drug-resistant TB patients in Indonesia.

Keywords: Adverse drug reactions; management; pharmacovigilance; resistant tuberculosis.

P302

Antimicrobial treatment for inpatient bacterial bloodstream infection in Hong Kong (2012-2021)

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Introduction. Bloodstream infection (BSI) is one of the leading causes of morbidity and mortality worldwide. Understanding prescribing patterns of antimicrobials for treating BSIs is imperative to improve clinical practices and particularly antibiotic stewardship programmes.
Aims. To characterize antimicrobial prescriptions of inpatients with bacterial BSIs in relation to characteristics of patients in Hong Kong in 2012-2021.
Methods. Individual electronic medical records for patients admitted into Hong Kong public hospitals from January 1, 2012 to December 31, 2021 provided by the Hospital Authority (HA) were utilized to identify BSI patients and events and to characterize related antibiotic prescribing patterns using information on patient demographics, antimicrobial prescriptions, microbiological testing result and antibiogram from antibiotic susceptibility test, etc.
Results. A total of 116,504 patients with BSI leading to 144,934 BSI events were identified over the study period, with 92.8% and 89.4% of the defined BSI events recorded of empirical and definitive antimicrobial treatment, respectively. Among empirical treated BSI events, 96.5% were prescribed with intravenous agents and amoxicillin/clavulanic acid, piperacillin/tazobactam and meropenem were mostly frequently used. There were 58,337 (43.4%) BSI events receiving monotherapy as empirical treatment. The median duration of definitive treatment was 7 (IQR, 4-13) days, with penicillins/β-lactamase inhibitors being most commonly used for BSIs with Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis and Citrobacter species. Antipseudomonal penicillins/β-lactamase inhibitors and carbapenems were also prescribed frequently for treating BSIs with various causative pathogens.
Discussion. The intensive use of broad-spectrum antibiotics in BSI inpatients warrants further investigations about the antimicrobial resistance profile of causative bacteria and the clinical impact of a plenty of antibiotic exposure on BSI patients. Appropriate recommendations could be provided after understanding antibiotic prescribing patterns to improve clinical practice guidelines for BSI treatment.

P304

Assessment of antimicrobial dosing appropriateness in chronic kidney disease patients

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Introduction: Chronic Kidney Disease (CKD) is a growing global disease burden leading to a range of systemic complications. Considering the altered pharmacokinetics in CKD patients, the standard antibiotic dosing regimen is often inadequate or unsafe in treating infections.

Aim: To assess appropriateness of antibiotic dosing in chronic kidney disease patients.

Methods: A prospective observational study was carried out after the approval of institutional ethics committee. CKD patients with age ≥18 years prescribed with antimicrobials were included in the study. Creatinine clearance or eGFR was calculated using Modification of Diet in Renal Disease (MDRD) equation. The main outcome measured was antimicrobial dosing appropriateness based on Stanford Antimicrobial Dosing guidelines.

Results: The study was carried out in 101 patients admitted to nephrology department. There was a male preponderance with 64.4 %. Hypertension was the predominant co-morbidity observed. 83% patients belonged to stage 5 CKD. The most commonly prescribed intravenous antibiotic was Cefoperazone/Sulbactam (83.2%) 1.5g BD. The gram-negative pathogens were prevalent in study site with epidemiological data supporting the antibiotic. This was followed by Meropenam (10.5%) 500mg OD and Ceftriaxone (4.2%) 750mg BD. Antimicrobial dose of 88.6% prescriptions were appropriate. Eighty-two percent of the patients converted to oral antibiotics, primarily Cefixime (61.4%) 200 mg BD.

Discussion: The hurdle of calculating creatinine clearance based on a single equation is a reality. The assessment of dose appropriateness using MDRD equation and Stanford antimicrobial dosing guidelines have shown that majority prescriptions are appropriate. Knowledge gap exists in the need of an equation with ease of calculation and reliability to address wide population variabilities.

Keywords: CKD, MDRD, Antibiotics, Appropriateness

P305

Changing trends in influenza mortality among regions from 2001 to 2022

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Introduction: According to a research in 2022, global influenza mortality rates increased from 2001–2018. However, trends in influenza mortality among regions following the COVID-19 pandemic have not been determined.

Aim: We aimed to assess the changes in regional influenza mortality trends due to the COVID-19 pandemic.

Methods: Using the vital death registration data from the WHO Mortality Database from 2001–2022, influenza mortality was analyzed by classifying WHO member countries into seven regional groups. Deaths due to influenza were defined using the International Classification of Diseases 9 and 10 codes (ICD-9:487, ICD-10: J10, and J11).
To show global trends in crude and age-standardized mortality rates, we used locally weighted scatterplot smooth curves.

Results: Seventy-six countries were analyzed. All regions, excluding Latin America and the Caribbean, showed a declining trend; Western Europe peaked at 0.68 in 2020, Eastern Europe at 0.30 in 2018, North America at 1.01 in 2017, Oceania at 0.84 in 2017, and Asia peaked at 0.30 in 2016 and has been declining thereafter. Africa has exhibited a constant downward trend since 2010. Many regions showed a similar trend, although the CR values were higher for older individuals aged ≥65 years in each region. Additionally, mortality rates of several countries may increase by 2022.
Discussion: Overall, influenza mortality has decreased since 2018, although there are regional differences. However, in some countries, the mortality rates have returned to the same level as the pre-COVID-19 pandemic period; therefore, continued observation is needed.

P306

Clinical and economic evaluation of Xuebijing injection for sepsis treatment in China

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Introduction: The combination of TCM and Western medicine in sepsis treatment can significantly improve efficacy and alleviate adverse reactions in patients. Wherein, Xuebijing injection has been strongly recommended by multiple domestic clinical guidelines and expert consensus for sepsis treatment.
Aims: From the health care and societal perspectives, this study aimed to evaluate the clinical and economic effects of Xuebijing injection for patients with sepsis in comparison to conventional treatment in real-world practice.
Methods: Data was collected from the Hospital Information System of 8 hospitals across China from September 2016 to June 2019. Patients whose primary discharge diagnosis was sepsis according to ICD-10 diagnostic coding were included and divided into two samples: exposure group (Xuebijing injection group) and control group (non-Xuebijing injection group). Comparative analysis of the cost, hospitalization duration, effective rates, mortality rates, and biochemical indicators in these two groups was conducted. A subgroup analysis was conducted on ICU sample patients. Propensity Score Matching was used to control potential confounding factors.
Results: 1759 patients were included. The exposed group was significantly ($P<0.05$) better than the control group in effective rates (68.6% VS 56.3%), mortality rates (8.0% VS 13.2%), and inflammation indicators (-1.58 VS -.111). Compared with the control group, the exposed group resulted in a decline of 0.1 hospitalization day and an incremental cost of 4634.1 yuan, the ICER was 46,341.3 yuan/Day. From the view of efficacy, the exposed group resulted in an additional 12.3% and an incremental cost of 4634.1 yuan, the ICER was 376.8 yuan/efficacy. In the ICU subgroup, the ICER was 22,256.2 yuan/day and 2,503.8 yuan/efficacy, respectively.
Conclusions: Xuebijing injection showed advantages for inpatients with sepsis compared with conventional treatment. Future studies using prospective pragmatic controlled trials can test and explore more about the effects of Xuebijing injections on sepsis.

P307

Comparative Effect of Four Antimalarial Treatments on Haematocrit in Children Southwest, Nigeria

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Aim/Objective: The aim of this study was carried out to compare the change in hematocrit following four antimalarial treatments.
Methods: Data were extracted from 313 case record forms of children that met the eligibility criteria aged 3-119 months enrolled in antimalarial clinical trials in Southwest Nigeria between 1998 and 2014. Change in haematocrit levels from baseline through 28 days follow-up period were compared among children treated with artemether-lumefantrine (82), atovaquone-proguanil (41), artesunate-amodiaquine (156) and chloroquine (34).
Repeated measures analysis was done by fitting a general linear model (GLM).
Results: The median age of the study population was 25 months and 54% were males. The mean differences (95% CI) in haematocrit from baseline were 4.7% (95% CI = 3.6, 5.8), 4.4% (95% CI = 2.7, 6.0), 3.8% (95% CI = 3.0, 4.7) and 2.4% (95% CI = 0.5, 4.4), for artemether-lumefantrine, atovaquone-proguanil and artesunate-amodiaquine and chloroquine, respectively. Using the general linear model, repeated measure analysis showed significant differences in the mean haematocrit level over the 28-day follow-up among the four treatment groups ($p<0.05$).
Conclusions: All children experienced increased haematocrit after treatment, with artemether-lumefantrine appearing to result in a greater increase in haematocrit than other antimalarial drugs. Children who are more susceptible to haemolyze during and after malarial infection such as Sickle Cell Disease and G6PD deficiency patients might benefit more from using the artemether-lumefantrine combination than the other antimalarial drugs in the Nigerian market.
Keywords: Anaemia, Haematocrit, Antimalarial Drugs

P308

Comparing Effectiveness and Safety of Conventional versus Super-Bioavailable Itraconazole in Dermatophytosis

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Introduction: The prevalence of dermatophytosis is increasing in India, with patients presenting with multiple-site lesions, extensive skin lesions, and unusually large lesions. Frequent recurrence and the chronic nature of this disease complicate its treatment. Given the evolving nature of dermatophytosis, current standard treatment options may be insufficient.
Aim: To compare the effectiveness and safety of conventional itraconazole and super-bioavailable itraconazole, along with adjuvant therapy, in patients with disseminated dermatophytosis.
Methods: This study was designed as a prospective, observational cohort study over a period of one year. Patients with disseminated dermatophytosis were recruited after obtaining informed consent. They were divided into two cohorts: one receiving oral itraconazole 200 mg once daily, and the other receiving super-bioavailable itraconazole once daily. Clinical and economic outcomes were assessed using the Physician's Global Assessment (PGA) scale and cost-effectiveness analysis, respectively. Direct medical costs were used to calculate the incremental cost-effectiveness ratio (ICER).
Results: The cure rates at 6 weeks were 73.7% (45 out of 61 patients) for cohort 1 and 68.2% (15 out of 22 patients) for cohort 2 (p=0.61), indicating that both treatments are equally effective. Patients who achieved clinical cure were subsequently monitored for clinical relapse over an additional four weeks. During this follow-up period, clinical relapses were observed in 20% (9 out of 45 patients) of cohort 1 and 6.6% (1 out of 15 patients) of cohort 2 (p=0.29). The cost-effectiveness analysis determined the ICER between conventional itraconazole and super-bioavailable itraconazole to be 265.86 INR.
Discussion: Patients with disseminated dermatophytosis treated with either conventional itraconazole or super-bioavailable itraconazole exhibit similar clinical responses and clinical relapse profiles. Both treatment groups showed significant reductions in PGA scores, indicating no superiority of super-bioavailable itraconazole over conventional itraconazole. Cost-effectiveness analysis suggests a marginal advantage for the super-bioavailable itraconazole regimen.

P309

Consumption and expenditure on fidaxomicin and oral vancomycin for Clostridioides difficile infection in 43 countries and regions

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Introduction. Current treatment guidelines recommend fidaxomicin and oral vancomycin as first-line treatments for Clostridioides difficile infection (CDI). Disparities in the prevalence of CDI and the availability of novel treatments require understanding of contemporary trends in fidaxomicin and oral vancomycin consumption at the global level.

Aims. To assess international trends in the consumption and expenditures of fidaxomicin and oral vancomycin.

Methods. We used the IQVIA-MIDAS global sales database to analyse data from 2012 to 2023 for fidaxomicin and oral vancomycin in 43 countries. We used defined daily doses per 100,000 inhabitants per year (DDD/100K) and manufacture level price (standardised in 2023 US dollars) to evaluate consumption and expenditure. Changes in consumption and expenditure were estimated using compound annual growth rates (CAGR).

Results. Average consumption of fidaxomicin across 43 countries increased rapidly from 21.68 DDD/100K in 2012 to 126.68 DDD/100K in 2023 (CAGR = 17.42%) and similar increases in expenditure (2012 = 0.07 USD/capita, 2023 = 0.34 USD/capita; CAGR = 14.96%). During the same period, oral vancomycin consumption increased from 71.61 to 120.82 DDD/100K (CAGR = 4.87%), but a decreasing trend in expenditure (2012 = 0.20 USD/capita, 2023 =0.03 USD/capita; CAGR = -15.16%). The earliest adoption of fidaxomicin in middle-income economies occurred five years later than in high-income economies. Despite higher CAGRs, consumption of fidaxomicin and oral vancomycin in middle-income economies was only 1.9% and 2.3%, respectively, of that in high-income economies in 2023. Regionally, although Northern America experienced a high increase in consumption of oral vancomycin (CAGR = 6.55%), it showed the largest decrease in expenditure (CAGR = -17.44).

Discussion. Consumption of fidaxomicin and oral vancomycin continues to increase globally. However, the global utilization of fidaxomicin and oral vancomycin exhibits significant economic and geographical disparities, showing inequitable accessibility. Efforts to improve the availability of affordable medication in non-high-income economies are essential.

P310

DRUG INTERACTIONS IN PEOPLE LIVING WITH HIV WITH COMORBIDITIES VERSUS WITHOUT COMORBIDITIES

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Introduction: Worldwide, People Living with Human Immunodeficiency Virus (PLW-HIV) adhere to Antiretroviral Therapy (ART). ART has increased risk for Drug Interactions (DIs) due to comorbidities (COs), Poly Pharmacy.
Aims: To study the pattern of DIs in HIV patients with-comorbidities (WC) versus (vs) without comorbidities (WOC).
Methods: In India, five years of retrospective data from Hospital Medical Record Department were screened for DIs in HIV patient's WC vs WOC. DIs were assessed using databases of University of Liverpool (ULP), Micromedex (MM), Epocrates (EP), for Severity and Clinical significance of DIs.
Results: Total of 1643 HIV patients were Hospitalised; 713 HIV seropositive cases were selected based on study criteria. Out of 713 HIV patients, 546 (77.1%) of HIV patients WC and 167(22.9%) WOC. Out of 713 patients, one sample t-test showed (p-value < 0.001) in 549 HIV Patients with DIs 427(78%) WC vs 122 (78%) WOC in comparison with no DDIs in 164 HIV Patients 119 (21.7%) WC vs 45 (26%) WOC. COs associated with DIs were higher in cardiovascular disease (23%) followed by Renal (12.5%). Severity of DIs as per ULP were "Red" Drugs that should not be co-administered 14(4.4%) in WC vs 2(2.7%) in WOC, "Amber" Potential clinically significant interaction 196(62%) in WC vs 32(43.8%) in WOC, "Yellow" Potential weak interaction 106(33.5%) in WC vs 39(53.4%) in WOC. MM-DIs were "Contraindicated" 12(3%) WC vs 1(1.2%) in WOC, "Major" 240(60.3%) in WC vs 57(71.2%) in WOC, "Moderate" 129(32.4%) WC vs 19(23.7%) in WOC, "Minor" DIs 17(4.3%) in WC vs 3(3.7%) in WOC. EP DIs were 'Avoid" 158(24.8%) WC vs 33 (21.4) WOC, "Monitor" 304 (47.7%) WC vs 82 (53.2%), "Caution" 169(26.5%) WC vs 39 (25.3%) WOC. Higher DIs were in TDF+3TC+EFV 308(78.8%) followed by TDF+FTC+EFV 241(70.8%).
Conclusion: Clinicians must Check for DIs while prescribing ART with Other drugs for Comorbidities.

P312

Epidemiology of serious side effects from macrolide and risk management in Thailand

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Macrolides are widely used in Thailand and they have been known for side effects such as gastrointestinal disturbances, abdominal pain and hepatotoxicity. They may also cause allergic reactions, including rash and anaphylaxis. Among existing epidemiological evidence from scientific database until year 2022 showed that the most three serious side effects from macrolides had caused more cardiac disorders or changes in liver enzymes compared to placebo. Recently, the stringent countries have introduced legal measures to reduce risk from serious effects of macrolides including strictly used in patients with underlying cardiac diseases due to its much used. The study is aimed to quantify the serious adverse events and its risk management. Methods: Retrospective study was used in surveillance database of the Thai Vigibase
The passive surveillance in Thailand between year 2021-2023 had revealed the general anti-infectives for systemic use were 18,087 events (45.32%) from total 36,259 adverse events reported from hospitals under the Ministry of Public Health. Among these were 12.5% with serious effects from widely antibiotic use. The proportion of female: male was 1.2:1. Serious adverse effects included arrythmias and hepatotoxicity were found in erythromycin and roxithromycin use. In 2024, Thai FDA has implemented the legal warnings to macrolides specified to reduce the most serious risks in cardiovascular, hepatotoxicity and skin disorders. In summary, the surveillance system has disclosed the serious risk of macrolides. The legal warnings have endorsed the safe use of macrolides in Thai patients.

P313

Evaluation of role-play to improve community health workers knowledge on antimicrobial resistance.

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Introduction:
Accredited Social Health Activists (ASHAs) are community health workers in India who serve as the first point of contact for healthcare in rural areas. However, they are under-trained to resolve community health challenges like antimicrobial resistance (AMR).
Aims: To assess the impact of role-plays on improving the understanding of antimicrobial resistance and promotion of responsible antibiotic usage in communities by the ASHAs.
Methods: A mixed-methods approach was adopted, involving 58 ASHAs from six primary health centers (PHCs). The cross-sectional quantitative component assessed the knowledge and practices towards antibiotic use using a validated questionnaire and fifty-eight in depth interviews explored the likelihood of discussing AMR, effectiveness of role plays and ASHA worker actions based on role-plays in community. A descriptive analysis was performed for the quantitative data, and a thematic analysis was performed for qualitative data.
Results:
A total of 58 participants from six primary health centres (PHCs) took part in this study. The mean age of participants was 39 ± 4 years and nearly one-half of the participants (44.8%) had 11 to 15 years of experience. About 56 (96.5%) participants strongly agreed that the role-play scenario emphasized the information on the importance of completing antibiotic courses as prescribed. A total of 52(89.6%) participants strongly agreed that they feel more informed about the risks and consequences of improper antibiotic usage after witnessing the role-play sessions. About 50 (86.2%) participants acknowledged that after the role-play, they are more equipped to discuss the topic of AMR and proper antibiotic usage with the community.
Conclusion:
ASHAs have the potential to become change agents for increasing rational antibiotic use in the community. The findings reinforce the need for ongoing education and advocacy efforts within primary healthcare systems to combat AMR effectively and promote better health outcomes through ASHAs for communities at large.

P314

Global influenza mortality trends: a joinpoint regression analysis

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Introduction: Influenza causes significant morbidity and mortality, and represents a major global health challenge. The World Health Organization (WHO) estimates that seasonal influenza causes 290,000–650,000 respiratory deaths annually. Despite its impact, few comprehensive studies have analyzed temporal trends in influenza mortality over the last decade.

Aims: This study aimed to examinerecent trends in influenza mortality rates from 2010–2022.

Methods: Influenza mortality data were extracted from the WHO mortality database. Long-term trends were evaluated for each WHO region (the Americas, Europe, Western Pacific, and others), with data available for at least seven years between 2010 and 2022. Joinpoint regression analysis was used to analyze the trends and estimate the annual average percentage change.

Results: Nineteen countries were included. The combined influenza mortality for both sexes increased in most countries, excluding Japan (-10.3%), South Africa (-10.0%), the Philippines (-2.0%), and Morocco (-1.2%). The highest increase was observed in Germany (43.5%), followed by the United Kingdom (34.6%), New Zealand (22.2%), and Thailand (20.1%), with increases of > 20%. Additionally, some countries, such as Germany, Mexico, and the Republic of Korea, showed a single joinpoint near 2016, which was the peak mortality.

Discussion: Our analysis of influenza mortality trends from 2010–2022 across 19 countries revealed diverse patterns. While most countries have experienced increasing influenza mortality rates, countries, such as Japan and South Africa, have declined. Joinpoint regression analysis highlighted trend changes, particularly in 2016. Countries, such as Germany and the United Kingdom, have seen significant increases, raising concerns about the current prevention strategies. Understanding these trends is crucial to tailor interventions and allocate resources. Continuous surveillance is essential for the implementation of effective public health policies to combat influenza.

P315

Impact of direct-acting antiviral treatment on total cholesterol metabolism in hepatitis C

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Introduction
Hepatitis C virus (HCV) replication and infection depend on host lipid metabolism. Since the HCV lifecycle requires lipoprotein particles, direct-acting antivirals (DAA) raise total cholesterol (TC) after sustained viral response (SVR).
Aims
This systematic review and network meta-analysis of cohort studies examines how DAA medicines affect TC metabolism results as TC evaluations lack length and DAA treatment follow-up.
Methods
Using Boolean operators and search phrases, we conducted a thorough literature search from PubMed, Cochrane Library, EMBASE, and MEDLINE-OVID electronic databases from inception to October 31, 2023. The search was not restricted to years of publication or language-specific literature and publications that were found using cohort study filtering. Using the Newcastle-Ottawa Scale (NOS) and random-effects models analysis using the MetaInsight v5.2.1 website, the quality of the included research has been evaluated.
Results
Out of the 4896 patients who were a part of the nine studies that comprised this assessment, four treatments were appropriate to include in our analysis: multiple DAAs (M), sofosbuvir-base (SOF), paritaprevir/ritonavir/ombitasvir (PTVr/OBV), and daclatasvir/asunaprevir (DCV/ASV).
Compared to baseline individuals, those on DCV/ASV regimens had a TC mean (MD) increase of 22.42 (95% confidence interval, CI: 9.47 to 34.25) at the post-end of treatment 4 (P4) week and a TC MD increase of 25.33 (12.74 to 37.25) at the P12 weeks.
TC increases at M-end of treatment and M-P24 weeks were 15.02 (8.91 to 22.6) and 20.57 (13.78 to 27.74) compared to baseline MD. Additionally, the SOF shows no statistically significant modifications, and PTVr/OBV P24 weeks has an MD of 27.35 (10.43 to 43.99).
Discussion/Conclusion
Post-therapy TC levels rise and peak 24 weeks later. TC levels are unaltered by medication discontinuation, especially for PTVr/OBV and various regimens, which last 48 weeks. In contrast, sofosbuvir-base is unaffected. This finding provides reference data for chronic illnesses and HCV therapy.

P316

Knowledge, attitude and practice towards tuberculosis among students at a Saudi Arabia

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Background: Tuberculosis (TB) is a bacterial infection. It mostly affects the lungs (pulmonary TB), but it can also affect other organs. This cross-sectional study evaluated knowledge, attitudes, and practices (KAP) related to TB among King Khalid University (KKU) students between October and November 2023.

Objective: The objective of this study was to investigate current TB knowledge, attitudes, and practices of students at King Khalid University in Abha, Saudi Arabia.

Methods: A self-administered, cross-sectional, descriptive, web-based questionnaire was conducted from October to December 2023 among the students of King Khalid University. We used a 29-item questionnaire with five sections. Section 1 contained five questions about sociodemographic factors, there were 13 knowledge questions in Section 2, Section 3 contained 7 attitude questions, Section 4 contained 3 practice questions, and Section 5 contained 1 source of information question. A chi-squared test was used to assess differences in participants' knowledge, attitude, and practices in relation to their demographic variables ($p < 0.05$).

Results: A total of 518 students completed the questionnaire. 53.66% were healthcare students and 46.33% non-healthcare students. The mean scores for healthcare and non-healthcare students, respectively, were as follows: knowledge 11.80 ± 4.81, 7.35 ± 4.96; attitude 6.94 ± 1.33, 5.05 ± 2.09; and practice 2.26 ± 0.85, 1.14 ± 0.87. The results of this study showed good knowledge (24.82 and 5.83% for healthcare and non-healthcare students, respectively) good attitude (67.62 and 46.25%) and good practice (45.32 and 9.58%). A total of 24.32% healthcare students and 28.18% non-healthcare students reported that most effective sources for obtaining information about TB were social networks, the internet and the radio.

Conclusion: The current study concludes that the knowledge, attitude, and practice about TB among healthcare faculty students is better than their non-healthcare counterparts.

P317

Liver Enzymes During and After Artemether-Lumefantrine Therapy with Uncomplicated Plasmodium Falciparum Infection

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Objectives: To determine the effect of artemether-lumefantrine on plasma levels of four liver enzymes, namely; alanine aminotransferase [ALT], aspartate aminotransferase [AST], alkaline phosphatase [ALP], and gamma-glutamyl transpeptidase [GGT] in children with uncomplicated Plasmodium falciparum infection.
Methods: We reviewed the records of all children who participated in a clinical trial of antimalarial drugs in Ibadan, Nigeria. A sample of 102 children with microscopically-proven Plasmodium falciparum infection; who met eligibility criteria were treated with 6-dose artemether-lumefantrine at recommended age-specific doses for 3 days. Study participants were followed up on days 0 to 3, 7, 14, 21, and 28 according to the World Health Organization recommendation for treatment of malaria therapeutic efficacy studies. Inclusion criteria included symptoms compatible with acute uncomplicated malaria, including parasite density of at least 1000/µL and absence of chronic illness or danger signs of severe malaria. The results of ALT (U/L),AST (U/L),ALP (U/L)and GGT (U/L) at baseline (day 0),on day 3, and on day 28 post-treatments were extracted and compared using Friedman tests.
Results: The median age of participants was 25 months (range = 3 to 119), and 49% were male. The mean values of ALT and AST did not change significantly throughout the 28-day follow-up from baseline (25.8 – 19.1U/L p= 0.0984 and 50.4 – 52.2U/L p= 0.1943 respectively). GGT decreased substantially between baseline 17.0 U/L (11.0 - 22.5) andday 28 15.0U/L (10.5-21.5) p= 0.0010 while ALP increased over time (baseline: 305.0U/L (216.0 – 403.5); day 28: 345.0 U/L (241.0 – 492.5) p=0.0303. Elevated ALT, AST, ALP, and GGT were observed in 8.5%, 20.0%, 20.9%, and 14.8% of participants,respectively.
Conclusions: Considerable rise in plasma levels occurred in ALP which could be indicative of liver injury occurring during antimalarial treatment among Nigerian children. Further research is needed to identify the underlying mechanism responsible for this possible drug-induced liver toxicity.

P318

Patterns of Antibiotic-Resistance and Multi-Drug Resistance in Clinical-Specimens: A Four-Year Retrospective Analysis

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Background
Antibiotic resistance has evolved into a formidable challenge, with microorganisms now demonstrating resistance to multiple drugs, presenting significant challenges to the medical profession. It is crucial to understand the prevalence and patterns of these resistant bacteria for prompt decision-making in clinical settings.
Aim: The aim of the study is to determine the prevalence of antibiotic resistance patterns by analyzing clinical specimens collected from a tertiary care hospital in a South Indian community.
Methodology: A cross-sectional study was conducted retrospectively using the microbiology laboratory registration book to understand the patterns and prevalence of antimicrobial and multi-drug resistance in a tertiary care hospital. Data on isolated organisms and sensitivity reports from the years 2020 to 2023 were compiled and compared to assess trends over time.
Results: The study analyzed 693 bacterial isolates, with 62.8% gram-negative and 37.2% gram-positive. Most isolates were from children under 5 (48.2%) and males (1.13:1 ratio). Urine samples had the most isolates (36.2%), followed by pus (27.4%) and blood (18.9%). Staphylococcus aureus was most prevalent among GPB (22.5%), while Klebsiella spp. dominated GNB (22.2%). GPB showed resistance to cotrimoxazole, penicillin G, norfloxacin, and ceftazidime. Enterobacteriaceae resisted ampicillin (92.5%), cotrimoxazole (85%), and tetracycline (85%). Non-Enterobacteriaceae resisted tetracycline (100%), cotrimoxazole (93.1%), and ampicillin (92.9%). Multi-drug resistance (MDR) was high (75.5%), with Klebsiella spp. showing the highest MDR (87.7%), followed by Enterococcus spp. (83.9%), Acinetobacter spp. (83.3%), and Enterobacter spp. (83.3%). S. aureus had the lowest MDR (57.7%), along with S. pneumoniae, Proteus spp., Salmonella spp., Shigella spp., and N. gonorrhoea (57.1%-66.7%).
Conclusion: This study underscores the high prevalence of antibiotic resistance among bacterial isolates in the South Indian community. Effective management requires antibiotic selection based on susceptibility reports.

P319

Perception of antibiotic deprescribing among physicians in a tertiary healthcare facility

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Introduction: Antibiotic deprescribing can improve patient outcomes, reduce side effects, and maximize cost-effectiveness; it is especially important in areas where antibiotic misuse is common.
Aims: To assess the perceptions of antibiotic deprescribing among physicians and to determine the various factors that influence the deprescribing of antibiotics.
Methods: A cross-sectional survey study was conducted among 71 physicians in a tertiary care hospital after obtaining institutional ethical approval. A questionnaire containing 20 items was developed and validated. The final Scale-level Content Validity Index universal agreement (S-CVI UA) average score was 1, indicating a satisfactory level of content validity. Fisher's exact test is used to determine the association between the background characteristics of physicians and perceptions of antibiotic deprescribing and related factors.
Results: Only 69% of participating physicians know antibiotic deprescribing, despite the majority (98.6%) recognizing antibiotic overuse. Time restraints (25.4%), ignorance (74.6%), side effect worries (42.3%), and patient/family reluctance (19.7%) are among the challenges. Deprescribing can be aided by facilitators such as departmental attention (54.9%), pharmacist involvement (268.8%), and recommendations (83.1%). 71.8 percent of doctors are willing to participate in deprescribing programs, indicating that they are receptive to maximizing the use of antibiotics.
Conclusion: The study assessed the physicians' perception of deprescribing of antibiotics. There are still gaps in confidence and expertise in antibiotic deprescribing. Focused teaching and assistance programs could improve deprescribing procedures, guaranteeing the prudent use of antibiotics in medical care.
Keywords: Deprescribing, antibiotics, perception

P320

Perspectives of community pharmacy staff towards antimicrobial resistance: Findings from qualitative study

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Introduction:
Community pharmacy staff play a significant role in dispensing antibiotics and can significantly influence public practices and attitudes towards antibiotic use. Understanding the knowledge and practices of pharmacy staff regarding antibiotic use and AMR is essential to identify gaps, improve training, and develop targeted interventions.
Objective: To explore the knowledge and practice of community pharmacy staff towards antibiotic dispensing and AMR.
Methods: A convenience sampling method was used to recruit 22 participants (pharmacists and non-pharmacists) at community pharmacies after obtaining written consent. A validated semi-structured questionnaire was developed to gather respondents' demographics, antibiotic dispensing practices, and knowledge of AMR. The data was coded and classified for thematic analysis.
Results: A total of 22 participants were included, predominantly male (91%) with a mean age of 37 ± 0.7 years. Out of 22 participants, 10 (45.5%) were pharmacists and 12 (54.5%) were non pharmacist dispensing staff. The four major themes that emerged were knowledge of AMR, dispensing patterns, patient behavior, and the training needs on AMR. The study findings reveal lack of AMR awareness among non-pharmacists and dispensing of antibiotics without a prescription was common among both pharmacist's and non-pharmacist. All 22 participants acknowledged that they dispense more of Watch category antibiotics as classified by World Health Organization (WHO) AWaRe classification. Dispensing of fixed-dose combinations of antibiotics that are widely available were also highlighted by the study participants. Additionally, the participants identified challenges in patient- related factors, non-adherence, inability to buy a full course of antibiotics due to cost, and lack of trust towards pharmacists' advice.
Conclusion: As the primary antibiotic gatekeepers, community pharmacy staff are key stakeholders in the reduction of AMR in India. The study findings reinforce the importance of developing and instituting an antibiotic training programme for community pharmacy staff and need for antimicrobial stewardship activities in India.

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Post-marketing study to assess serotype-specific effectiveness of Rotavirus Vaccine (ROTATEQ®) in China

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Aim/Objective: Rotavirus (RV) is the most common cause of severe diarrhea in infants and children globally. ROTATEQ® demonstrated high overall and serotype-specific efficacy against RV gastroenteritis (RVGE) in clinical trials worldwide and has been approved in China in 2018. The study objective was to assess the effectiveness of ROTATEQ® in children treated in hospitals for RVGE due to at least one of the RV serotypes G2/G3/G4 and G1/G2/G3/G4/G9 respectively in China.
Methods and results: Test-negative case-control design. A primary data collection study was conducted to prospectively identify serotype-specific RVGE Cases and RV negative acute gastroenteritis (AGE) Controls. Case Group 1 included RV G2/G3/G4 cases while Case Group 2 included RV G1/G2/G3/G4/G9 cases.
Children, age-eligible to be fully vaccinated with 3 doses of ROTATEQ® and receiving treatment for AGE were enrolled from 35 hospitals across China. Data from AGE cases admitted to the inpatient ward or from AGE cases who received continuous intravenous rehydration treatment for ≥2 days in an outpatient setting were collected from October 2020 to April 2023.
Stool samples were tested by enzyme-linked immunosorbent assay(ELISA) for group A RV antigen and ELISA-positive samples were genotyped(VP7) by multiplex RT-PCR.
Multivariate logistic regression models were fitted to obtain odds ratio for comparing the likelihood of ROTATEQ® vaccination among case and control groups.
The results will be presented during the conference.
Conclusion: This is the first post-marketing commitment effectiveness study of ROTATEQ® in mainland China. The analysis confirmed the high protection of ROTATEQ® against RVGE due to G2/G3/G4 and G1/G2/G3/G4/G9 among Chinese children in a real-world setting.

P324

Reviewing and Improving Legislations to Tackle Antimicrobial Resistance

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Introduction: Antimicrobial Resistance (AMR) is a global health threat caused by the widespread use of antimicrobials, which leads to microbes developing defense mechanisms against them. AMR emphasizes the need to implement a One Health approach to tackle AMR nationally and international. Action plans from drug regulatory agencies to tackle AMR have been implemented to minimize its spread, maintain the effectiveness of available antimicrobials, and support the development of new antimicrobials.

Aim: This study aims to review and improve the currently implemented national legislations to tackle AMR based on national data of antimicrobial use among food-producing animals and in alignment with international drug regulatory agencies in order to minimize global AMR spread.

Method: This is a literature review study of international drug regulatory agencies action plan to tackle AMR, taking into consideration, the national data of antimicrobial use among food-producing animals.
Result: The results showed that some antimicrobials classified as highly important with limited or no alternatives to treat serious infections in human are still being used in food- producing animals locally.

Discussion: To address the control use of antimicrobials, the study proposes a new classification system for veterinary antimicrobials as prohibited, restricted, and accessible. These classifications were based on the national data on antimicrobial use in food-producing animals and international categorization of antimicrobial importance for human and animal health.

Conclusion: Establishing a one health approach is needed to limit the spread of antimicrobials resistance among humans and animals. National and international actions need to be taken into consideration to maintain the effectiveness of currently available antimicrobials and develop new antimicrobials to tackle the antimicrobial resistance problem.

P325

The Profile of Glucocorticoid-Induced Leucine Zipper Protein in Sepsis Patients with Comorbidity

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Introduction: Glucocorticoid-induced leucine zipper (GILZ) represents a novel anti-inflammatory molecule with potential implications for the development of novel therapeutic strategies targeting inflammatory conditions, including sepsis. However, the effect of epidemiologic factors, notably comorbidity, on GILZ remains unclear.

Aims: This study aimed to describe the GILZ protein concentration in sepsis patients with different comorbidities.

Methods: We conducted enzyme-linked immunosorbent assay (ELISA) techniques to measure the GILZ protein concentration of sepsis patients in the intensive care unit (ICU). Furthermore, we cross-sectionally compared the GILZ protein concentration between sepsis patients with single or multiple comorbidities and those without comorbidities.

Results: We conducted a study involving 36 sepsis patients, comprising an equal number of 18 females and 18 males, with an average age of 59.61 ± 14.85 years (see Table 1). The study included 11 (30.55%) patients without comorbidities, 10 (27.78%) patients with multiple comorbidities, 6 (16.67%) patients with chronic kidney disease, 5 (13.89%) patients with acute kidney injury, 2 (5.56%) patients with type 2 diabetes mellitus, and 2 (5.56%) patients with hypertension. The ELISA findings (refer to Figure 1) indicated that there were no significant differences in the GILZ protein concentration among sepsis patients without comorbidities (0.112 ± 0.035 ng/ml) compared to those with multiple comorbidities (0.109 ± 0.029 ng/ml, p=0.944), chronic kidney disease (0.119 ± 0.036 ng/ml, p=0.920), acute kidney injury (0.095 ± 0.014 ng/ml, p=0.193), type 2 diabetes mellitus (0.087 ± 0.008 ng/ml, p=0.114), and hypertension (0.097 ± 0.017 ng/ml, p=0.430).

Conclusion: Our study findings indicate no significant differences in the GILZ protein concentration between sepsis patients without comorbidities and those with different comorbidities. Nonetheless, further research involving larger populations and more advanced techniques is necessary to gain a deeper understanding of this potential novel anti-inflammatory molecule.

Keywords: anti-inflammatory agents, comorbidity, epidemiologic factors, multimorbidity, sepsis syndrome, systemic inflammatory response syndrome

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Trends in Seasonal Influenza Mortality From 2001 to 2022 in Fourteen Countries

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Introduction: Influenza has emerged as the leading cause of death worldwide; however, there have been few studies on influenza mortality rates that take into account the COVID-19 epidemic pandemic.

Aims: To examine long-term international influenza mortality trends from 2001 to 2022.
Methods: Fourteen countries were included in the study. We analyzed the influenza mortality rates in 2001–2022 using the vital death registration data from the WHO Mortality Database. Long-term trends were assessed for the 14 countries by 2022: Armenia, Australia, Canada, Estonia, Georgia, Hungary, Iceland, Lithuania, Luxembourg, Mauritius, the Netherlands, Serbia, Singapore, and Sweden. Deaths due to influenza were considered if the International Classification of Diseases 9 and 10 codes for influenza (ICD-9: 487, ICD-10: J10, and J11) were listed as the underlying cause of death.

Results: In 2018, Estonia, the Netherlands, Canada, and Sweden had peak age-adjusted mortality rates (AR) for influenza, whereas Australia, Georgia, Serbia, and Lithuania had peak AR in 2019. The highest AR in 2018 and 2019 were 1.56 and 1.85 in Sweden and Australia, respectively.
In all 14 countries, the AR for influenza significantly declined through 2021, but the AR for influenza increased in all countries in 2022. Moreover, a similar trend was observed in the older individuals aged ≥65 years.

Discussion: Influenza mortality rates decreased from 2019–2021 in all 14 countries and showed an increasing from 2021–2022. The decrease in global influenza mortality rates by 2021 may be caused by that many countries have adopted measures to prevent COVID-19 infection.

[Kidney]

P327

Comparison of serum procalcitonin and C-reactive protein levels for diagnosis of AKI

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Aim/Objective: Compare the sensitivity and specificity of serum procalcitonin (PCT) and C-reactive protein (CRP) levels, for the diagnosis of acute kidney injury in sepsis patients.
Methods: A retrospective case-control study was conducted in Kasturba Medical College, Manipal, Karnataka at the Department of Nephrology. The study population included critically ill patients suffering from septicaemia. The cases patients were diagnosed with sepsis and AKI as per KDIGO guidelines. Whereas the control encompassed septicaemic patients who did not develop AKI. An equal number of cases and control were selected. Important clinical and laboratory variables, medical history, were collected along with PCT, CRP and serum creatinine (Sr.Cr) levels from both cases and control. A comparison of the sensitivity and specificity of PCT, CRP and Sr.Cr was done using MedCalc statistical software.
Results: Most of the patients in the case group were between the age group of 61-70 years with a percentage of 24% (n=56) compared to 23.3% (n=52) of the patients in the control group who were between 51-60 years of age. There were noticeably more males than females, with males accounting for 78.5% (n=183) in the case group and 63.5% (n=148) in the control group. Sensitivity, specificity and AUC of ROC (with 95% confidence interval) of PCT, CRP and Sr.Cr were 59.66%, 54.08%, 0.59, 46.78%, 62.23%, 0.59, 80.26%, 66.09% and 0.83 respectively.
Conclusion: Among the biomarkers compared serum creatine found to be more sensitive and specific for the diagnosis of acute kidney injury among septicaemic patients.

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Economic Burden of Anemic Chronic Kidney Disease in China

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Introduction:
Patients with end-stage chronic kidney disease (CKD) require frequent dialysis treatments to sustain their lives, imposing a substantial healthcare burden on them and their families.
Aims:
To investigate the healthcare burden of dialysis-dependent (DD) and non-dialysis dependent (NDD) CKD patients with anemia in China.
Methods:
We utilized national cohort data from Tianjin Inspur Healthcare Big Data. Patients with renal anemia aged over 18 who visited any hospital in Tianjin from January 2018 to June 2023 were included. The total population was divided into two subgroups based on dialysis status: 1) non-dialysis dependent (NDD) group; and 2) dialysis-dependent (DD) group. Average patient costs for inpatient, outpatient, and emergency care, as well as per person per month (PPPM) costs, were assessed.
Results:
A total of 130,863 incident CKD patients were identified, with 123,463 in the NDD group and 20,544 in the DD group. NDD patients with renal anemia had 334,902 hospitalizations, incurring costs in 332,840 cases. The mean hospitalization cost was approximately RMB 20,097.8, with an adjusted mean of RMB 20,598.2. The total follow-up duration was 682,783 months, resulting in a PPPM hospitalization cost of approximately RMB 13,860.5, and an adjusted PPPM of RMB 14,205.7. In contrast, DD patients with renal anemia experienced 31,764 hospitalizations, incurring costs in 31,682 cases. The mean hospitalization cost was RMB 19,959.6, with an adjusted mean of RMB 20,276.5. The total follow-up duration was 445,669.4 months, with a PPPM hospitalization cost of approximately RMB 13,369.9, and an adjusted PPPM of RMB 13,582.2.
Discussion:
The study results indicate that the economic burden of renal anemia is higher in dialysis-dependent patients compared to non-dialysis dependent patients.

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Longitudinal hemoglobin trajectories-associated major kidney outcomes in non-dialysis-dependent and dialysis-dependent CKD patients

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Introduction: Whether dynamic hemoglobin changes over time affect various clinical outcomes of patients with chronic kidney disease (CKD) is uncertain, despite substantial evidence showing undesirable consequences following greater hemoglobin variability.

Aims: To assess distinct hemoglobin trajectories and associated clinical outcomes for non-dialysis-dependent CKD Stage 5 and dialysis-dependent patients.

Methods: Patients having at least two records of eGFR≤15 ml/min/1.73m2 with an interval between two consecutive records within three to six months during 2013-2014 were identified from the linked Chang-Gung Research Database and National Health Insurance Research Database. Group-based trajectory modelling was utilized to determine distinct hemoglobin trajectories over three years, with a 6-month and 1-month interval of hemoglobin measurements analyzed for non-dialysis-dependent CKD Stage 5 and dialysis-dependent patients, respectively. Clinical outcomes included kidney events (i.e., dialysis and kidney transplantation) and death.

Results: Several hemoglobin trajectory groups were identified, namely "persistently moderate anemia" (Group 1), "mild-to-moderate anemia" (Group 2), "mild anemia with slight decline" (Group 3), "persistent non-anemia" (Group 4) among CKD Stage 5 patients, and "persistently moderate anemia" (Group 1), "persistently mild anemia" (Group 2), "mild-to-normal anemia" (Group 3), "persistent non-anemia" (Group 4) among dialysis-dependent CKD patients. In CKD Stage 5 patients, compared to Group 4 cases, the adjusted subdistribution hazard ratios (aSDHRs) (95%CIs) of Groups 1, 2, and 3 on kidney events/death were 2.3 (1.2-4.4)/12.7 (1.2-136.5), 2.3 (1.3-3.9)/6.8 (0.7-68.4), and 2.5 (1.4-4.4)/8.6 (0.8-91.4), respectively; for dialysis-dependent patients, compared to Group 4 cases, the aSDHRs (95% CIs) of Groups 1, 2 and 3 on death were 1.5 (1.0-2.1), 1.2 (0.8-1.6), and 1.0 (0.7-1.3), respectively. Sensitivity analyses with time-varying adjustment of eGFR had consistent findings with main analyses.

Discussion: Late-stage CKD patients maintaining moderate anemia might be at risk of increased mortality, irrespective of dialysis status, and CKD stage 5 patients with slightly declining hemoglobin were potentially progression to kidney dialysis/transplantation.

P330

Patient Journey of Diabetic Kidney Disease using an EMR database in Japan

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Introduction:
Diabetic Kidney Disease (DKD) is kidney damage that occurs as a result of long-term diabetes. It is one of the complications of diabetes mellitus and a major cause of renal failure in diabetic patients. Despite its diverse clinical course, there are limited examples using real-world data in Japan to describe the patient journey of DKD treatment.

Aims:
This study aimed to illustrate the treatment course of DKD. As a secondary objective, we examine if revisions in clinical guidelines are observable through Patient Journey using real-world data.

Methods:
In the RWD database, 356,478 Type 2 diabetes patients were identified. Based on glomerular filtration rate (GFR) categories, 7,621 with stage G3b (G3b group) and 6,510 with stage G4 (G4 group) were captured. Changes in prescriptions of hypoglycemic agent, antihypertensive agent, and nephroprotective medications before and after recording stage G3b or stage G4 were observed for both groups.

Results:
Focusing on the top 10 drugs administered in cases, hypoglycemic agent, antihypertensive agent, and nephroprotective medications, and cardiovascular disease medications were identified.
An increasing trend in hypertension medication was noted in both groups (G3b and G4) post-stage progression (G3b: 48% to 65%, G4: 57% to 76%), with a notable increase in furosemide, a loop diuretic.
Similarly, prescription for diabetes medications showed an upward trend (G3b: 38% to 51% G4: 42% to 57%), with a slight decrease in metformin usage in G4, where it's contraindicated.
Additionally, there was an increase in nephroprotective medication treatment in both stages.
Discussion:
These findings indicate that the patient journey in DKD treatment reflects changes in medication prescriptions consistent with clinical guidelines.
Future research will dive into prescription trends surrounding guideline revisions and their clinical implications, exploring the application of machine learning to better understand DKD treatment realities.

P331

Prevalence and Treatment Patterns of Nocturnal Polyuria in Taiwan: Findings from the National Health Insurance Research Database

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Introduction: Nocturnal polyuria (NP) is one of the three main types of nocturia. NP is a kidney-driven urine production disease, which characterized by overproduction of urine at night. The standard treatment for NP is a neuropeptide similar to endogenous vasopressin, desmopressin. Yet, the prevalence of NP and its current treatment pattern in Taiwan is understudied.
Aims: 1) to update the prevalence of NP in Taiwan 2) to identify desmopressin prescription patterns in NP patients
Methods: We use the 2016-2020 claims data from Taiwan's National Health Insurance Research Database for this study. For Aim 1, we had three definitions of NP: 1) diagnosed NP (ICD-10 codes: R35.81), 2) diagnosed nocturia but not coded urinary retention or overactive bladder, or 3) diagnosed nocturia and prescribed desmopressin or alpha-1 blockers at bedtime. In addition, we performed a subgroup analysis for the prevalence of NP in patients with LUTS. For Aim2, we identified the desmopressin usage pattern in NP patients based on the first and second definitions in Aim1. We documented the interval between the diagnosis of NP and desmopressin prescription, prescription continuity, and other combination therapies (anticholinergics, TCA, and alpha blockers) for NP.
Results. In Aim 1, we did not identify any patients having a diagnosis code of NP. With the second and third definitions of NP, the overall prevalence increased from 0.42% in 2016 to 0.58% in 2020. The prevalence in patients with LUTS increased from 11.30% to 13.57%. Regarding treatment patterns, the median interval between the NP diagnosis date and desmopressin prescription is 0 days, with an IQR that spanned from 0 to 14 days. Notably, 68.44% of NP patients received a prescription for desmopressin on the same day as their NP diagnosis. Additionally, 5.78% of NP patients continuously used desmopressin over three months. Eighty-three percent of NP patients who used desmopressin combined it with at least one other therapy for NP.
Discussion. Our results showed a low prevalence of NP in Taiwan. The low prevalence may be caused by the under-coded of NP and under-diagnose of NP. Most of the NP patients were treated with desmopressin right after diagnosed, and mostly in combination with other therapies.

P332

Real-world evaluation of sevelamer in chronic kidney disease: a retrospective cohort study

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INTRODUCTION: In October 2018, sevelamer, a non-calcium-based phosphate binder, was included on the subsidy list for patients with chronic kidney disease who are intolerant of calcium-based phosphate binders, or have persistent hyperphosphataemia despite optimising treatment with calcium-based phosphate binders.

AIMS: This study compared real-world outcomes between calcium-based and non-calcium-based phosphate binders and assessed the impact of the subsidy decision on the healthcare system in Singapore.

METHODS: Using linked national health record databases, this retrospective cohort study included patients with end-stage renal failure initiated on calcium-based or non-calcium-based phosphate binders from October 2016 to September 2020. Patient demographics, comorbidities, baseline laboratory values and concomitant drugs were balanced using propensity score matching. Cox regression estimated the hazard ratios (HR) with 95% confidence interval (CIs) for cardiovascular (CV) events and other secondary outcomes. Additionally, a Markov model was constructed to extrapolate the number of events avoided and potential cost savings from the use of non-calcium-based phosphate binders.

RESULTS: After propensity score matching, 804 comparable patients remained in each cohort. Over 80% of patients were initiated on the phosphate binder as treatment add-on or switch. Patients on non-calcium-based phosphate binders were less likely to develop a CV event (HR: 0.82; 95% CI 0.67–0.99) over a median follow-up period of 1.5 years. Subsidy listing of sevelamer led to increased utilisation, reduced drug costs from value-based pricing and potentially resulted in 383 fewer CV hospitalisations, translating to about $26 million saved over 10 years.

DISCUSSION/CONCLUSION: While most real-world studies include only new patients without prior use of other phosphate binders, most patients in our matched cohorts received the phosphate binder as second-line therapy, which aligned with the subsidy criteria and local clinical practice for non-calcium-based phosphate binders. In summary, subsidy listing of sevelamer had a significant positive impact on patient outcomes and the healthcare system.

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Travel and accessibility challenges in dialysis patients: A survey

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Introduction: Traveling or going on vacation might cause dialysis patients to miss their dialysis schedules, adversely affecting their health. Hence, facilities must help dialysis patients access information regarding dialysis centers in other locations.
Aim: To understand the challenges faced by dialysis patients regarding travel and accessibility to dialysis centers, and to identify their needs for travel, including vacations, family functions, and business meetings.
Methods: We conducted a cross-sectional questionnaire survey in which all patients on dialysis who met our inclusion criteria were enrolled. The required data was collected using a self-developed questionnaire. Frequency was used for categorical variables, and mean ± standard deviation or median and interquartile range (IQR) were used to calculate continuous variables. The chi-square test was used to assess patients' willingness to utilize holiday hemodialysis facilities based on their age and duration of dialysis treatment.
Results: Most patients (80.95%) had abstained entirely from traveling since the initiation of hemodialysis for multiple reasons. Among the remaining patients who went on vacation, the maximum duration and frequency were three days and 2-3 times a year. This was due to a lack of proper facilities to undergo dialysis at the travel destination. None of the patients in our center knew about holiday hemodialysis facilities; however, when informed, many were willing to utilize them. Their willingness was dependent on their age group as well as the duration of their dialysis treatment.
Discussion/Conclusion: Holiday hemodialysis facilities should be developed and promoted in India to provide affordable and safe travel experiences for people undergoing hemodialysis.

[Malignancy]

P334

(CAR) T cell Immunotherapies and Potential association of Secondary T-Cell Malignancies

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Introduction
Chimeric Antigen Receptor (CAR) T- cell immunotherapies are approved for treatment of refractory or relapsing large B-cell lymphoma, Multiple Myeloma and patients with B-cell Acute Lymphoblastic Leukemia.

Objectives
To evaluate the potential risk of secondary malignancies related to T-cells including T-cell lymphoma and leukemia, with CAR T-cell medicines: Ciltacabtagene Autoleucel (CARVYKTI®), Tisagenlecleucel (KYMRIAH®) and Axicabtagene Ciloleucel (YESCARTA®).

Methods
A systematic literature search was conducted from inception until January 2024, using PubMed, Google scholar, Cochrane library and Adis Insight database. In addition, searching the local adverse drug reactions database and World Health Organization (WHO) database was performed via signal detection tool (Vigilyze) using the terms “CARVYKTI®” OR “KYMRIAH® ” OR “YESCARTA®” (substance (WHO Drug) [AND] " T-cell lymphoma" OR “T-cell leukemia” (preferred term (PT) (MedDRA). Then, the causality assessment was performed using the WHO-Uppsala Monitoring Center causality system.

Result
We found one case report of patient developed CAR T-Cell Lymphoma post CARVYKTI® therapy for relapsed refractory multiple myeloma. In addition, a phase I clinical trial was reported 2 cases of T-cell malignancies associated with use of CD19 CAR therapy. The search of WHO global database resulted in 12 cases as follows: T- cell lymphoma [(KYMRIAH® (n=5), YESCARTA® (n= 4), CARVYKTI® (n=2)], one case reported T- cell leukemia with YESCARTA®. Of them, 7 (58.3%) cases were females, 4(33.3%) males. All cases were serious, most of them (60%) reported death outcome. Based on the WHO causality assessment, 2(16.6%) cases were probably associated with medications use. However, the majority of cases (n=10, 83.3%) considered un-assessable due to lack of information such as time of onset, de challenge/ re-challenge data.

Conclusion
The Available evidence suggests a potential association between secondary malignancies of T cell origin with the use of CAR T cell immunotherapies. Further epidemiological studies are needed to assess this potential association.

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Adverse events after receiving denosumab among solid tumor cancer patients in Taiwan

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Introduction:
Osteonecrosis of the jaw (ONJ), atypical femur fractures (AFF), and hypocalcemia are adverse events (AEs) of interest for all bone antiresorptive therapies. Most trial and post-marketing safety data are from non-Asian populations. Denosumab (120 mg) is indicated in Taiwan for the prevention of skeletal-related events (SRE) in patients with bone metastases from solid tumors, multiple myeloma, hypercalcemia of malignancy, and giant cell tumor of the bone.

Aims:
Using the Taiwan National Health Insurance database, we sought to describe the incidence rate of AEs among patients receiving denosumab for SRE prevention within an ethnic Chinese population.

Methods:
The study included patients with breast, prostate, or lung cancer, who initiated denosumab inclusive of 2013 through 2019. As the data source did not require bone metastasis to be uniformly recorded, patients were excluded having a diagnosis suggestive of other indicated uses for denosumab. Follow-up started at patient's initial denosumab administration and continued through the earliest date of 91 days after the last administration, switching, or end of study. AEs were defined by algorithms adapted from the literature and local clinical opinion (e.g. hospitalized hypocalcemia events defined as a primary diagnosis of hypocalcemia at hospitalization or emergency room visit). The cumulative incidence (first event) and 95%CI were calculated.

Results:
Patients (n = 18029, 58% women, mean age 64y) initiating denosumab were followed for a mean of 9.7 months. The two-year cumulative incidence of ONJ and number of patients with an event were 2.03% (1.72% - 2.40%), 140; AFF, 0.03% (0.01% - 0.10%), 5; and hospitalized hypocalcemia, 0.31% (0.21% - 0.46%), 25.

Conclusion:
Among patients initiating denosumab for the prevention of SRE, the observed incidence of AEs in ethnic Chinese was consistent with the incidence of AEs in clinical practice reported for global populations.

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Cancer Drug Use of Childhood Cancer Patients in China: A Cross-sectional Analysis

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Introduction
Cancer drugs, including antineoplastic and supportive agents, play an important role in the treatment and supportive care of cancer, especially childhood cancer. However, the population-based cancer drug use pattern of childhood cancer patients in China was unknown.
Aims
To characterize the utilization of cancer drugs among Chinese childhood cancer patients.
Methods
This cross-sectional analysis uses claim data from Chinese Basic Medical Insurance from 2015 to 2017. We identified childhood patients aged 0-19 years with malignant neoplasms. The primary outcome was the prevalence of cancer drug use, which were classified as antineoplastic agents, cancer supportive agents, and traditional Chinese medicines for cancer. The secondary outcomes were average annual direct medical and out-of-pocket costs.
Results
Among 262,287 cancer beneficiaries contained in the database, 766 childhood cancer inpatients were identified. The prevalence of cancer drug use of all sample patients was 70.6%, and 71.9% for children with hematological malignancy. Patients in economically developed areas with the lowest share of out-of-pocket expenditure (48.5%) had the highest cancer drug use (82.3%). In comparison, only 49.2% of children in the deprived area had ever used cancer drugs. Older children had a significantly higher prevalence of traditional Chinese medicines prescription than patients in the 0-4 years group (all $p<0.01$).
Discussion
Our study showed that the use of cancer drugs differed among economic groups and cancer types in mainland China. More progress in reimbursement, research and development, and approval of effective medication should be made to remove economic inequity and improve the accessibility of effective pediatric cancer treatment.

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Cardiac Injury in Non-Small Cell Lung Cancer Patients on Immune Checkpoint Inhibitors

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Introduction: Immune checkpoint inhibitors (ICI) have advanced the treatment of non-small cell lung cancer (NSCLC). However, concerns about ICI-related cardiac adverse events have arisen. Previous studies have focused on Caucasian populations, leaving a gap in understanding the cardiotoxicity associated with ICIs, particularly in Asian populations.
Aims: This study aims to epidemiologically describe the cardiac adverse events in NSCLC patients receiving ICIs in an Asian cohort, hypothesizing variations in cardiac injuries across different ICI types and treatment regimens.
Methods: The study cohort included adult patients with NSCLC at participating hospitals between 2015 and 2023. Stratification occurred into four cohorts: patients receiving chemotherapy, ICI (involving Pembrolizumab, Nivolumab, Camrelizumab, Sintilimab, Tislelizumab, Toripalimab, Serplulimab) with chemotherapy, ICI without chemotherapy, and a control group receiving no NSCLC-directed therapy. The primary endpoint was myocarditis, ascertained through patients' medical records. The secondary endpoints were abnormality in any cardiac biomarkers, including creatine kinase, creatine kinase isoenzyme, troponin I, or troponin T, or the conjoint elevation of creatine kinase, lactate dehydrogenase, alanine aminotransferase, and aspartate aminotransferase.
Results: Among 28,626 NSCLC patients, 102 underwent chemotherapy, 6,707 received ICI (3,334 with chemotherapy, 3,373 without), and 21,817 were unmanaged. The incidence of myocarditis was 8 (0.03%), with 0.07 per 100 person-years. Abnormality in any cardiac biomarker occurred in 622 (2.2%) patients, exhibiting respective incidence rates of 10.70, 9.61, 5.25, 14.10, and 4.21 per 100 person-years across subgroups. Conjoint elevation occurred in 188 (0.7%) patients, exhibiting respective incidence rates of 5.36, 3.21, 2.59, 3.86, and 1.18 per 100 person-years across subgroups. In ICI group, patients receiving Pembrolizumab or Camrelizumab had a higher risk of cardiac injury compared to patients receiving other ICIs.
Discussion: NSCLC patients who received chemotherapy or ICI without chemotherapy had a higher risk of cardiac injury. There was significant heterogeneity in cardiac injury among NSCLC patients in different treatment groups.

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Characteristics of Diffuse Large B-cell Lymphoma Patients receiving R-CHOP Therapy with/without G-CSF

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Introduction. The Japanese clinical guideline for appropriate use of granulocyte colony-stimulating factor (G-CSF) does not state strongly that the use G-CSF for primary prevention of febrile neutropenia (FN) in patients with diffuse large B-cell lymphoma (DLBCL) receiving R-CHOP therapy due to little evidence. The actual use of G-CSF in clinical practice has not been revealed in detail.
Aims. To clarify the actual use of G-CSF and to compare the characteristics of patients with/without G-CSF, by using real-world data.
Methods. We used the Japanese Medical Data Vision (MDV) database (data period: April 2008 to June 2021). The study population was hospitalized patients receiving R-CHOP therapy for newly diagnosed DLBCL. We observed annual trends in the proportion of the study population receiving G-CSF. We also conducted a nested case-control study in the study population, with G-CSF users as case and non-users as control, to compare the characteristics of them.
Results. A total of 9,941 were extracted for the study population, with 7,335 case and 2,606 control. During the data period, the proportion of G-CSF users tended to increase (38.5% in 2008 to 72.7% in 2021). Compared with control, case showed characteristics such as an older age, lower initial dose intensity of R-CHOP therapy, frailty, lower BMI (Body Mass Index), more advanced stage cancer, concurrent comorbidities, a history of various medical treatments, and a history of FN.
Discussion. The use of G-CSF has recently increased to be established as a concomitant drug for R-CHOP therapy. Based on the comparison results, overall, G-CSF users were more likely to be frail. This suggests that the criteria for G-CSF administration in clinical practice consider such as patient's age, severity of illness, and medical history, and is to some extent in compliance with the guideline, which weakly recommends administration to elderly patients or patients with comorbidities.

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Characteristics, treatment, clinical outcomes in Chinese CLL following discontinuation of BTKi therapy

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Aims: To explore the disease characteristics, treatment choices, and clinical outcomes in Chinese Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) patients following discontinuation of BTK inhibitor therapy.

Methods: This is a multicenter, retrospective, observational database study. We extracted CLL/SLL data from the electronic medical records of three Grade-A Tertiary hospitals located in Northern China between July 1, 2017, and December 31, 2021.
Results: Among the 37 eligible patients who discontinued BTKi, the mean age at the time of BTKi discontinuation was 62.67 ± 10.11 years, with the majority being male (25/37, 67.57%). The median duration from BTKi discontinuation to the last visit was 6.44 months (interquartile range [IQR] 2.04–15.67). Most patients (23/37, 62.16%) were relapsed/refractory (R/R) CLL/SLL patients, with the remaining being treatment-naïve (14/37, 37.84%). Treatment- naïve patients were significantly younger than R/R patients (56.93 ± 10.94 years versus 66.16 ± 8.16 years, p=0.005). The reasons for discontinuation included resistance (18/37, 48.65%), intolerance (12/37, 32.43%), and other factors (7/37, 18.92%). The most frequently used regimen among the first therapy after BTKi discontinuation was rituximab (R)-based (9/17, 52.90%). The disease control rate upon discontinuation of BTKi was 78.13% for all patients. The median progression-free survival (PFS) for BTKi therapy was 19.09 months (IQR 8.97–not reached [NR]), 19.09 months (IQR 15.58–NR) for treatment-naïve patients, and 14.39 months (IQR 5.88–NR) for R/R patients. The minimum median PFS (7.86 months, IQR 5.88–31.28) was observed in patients with resistance. Following discontinuation of BTKi, patients exhibited shorter PFS durations, with median PFS for the first and second treatments post-BTKi cessation at 8.87 (IQR 6.15–NR) and 5.32 (IQR 4.21–NR) months, respectively. No significant difference was observed in overall survival.

Conclusion: Our study shows inferior clinical outcomes for R/R patients who underwent BTKi discontinuation, especially in cases of resistance to BTKi.

Keywords: CLL/SLL; BTKi; Discontinuation; Multicenter Study

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Comparative Evaluation of PEG-rhG-CSF vs rhG-CSF for Febrile Neutropenia in Lymphoma

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Introduction:

Lymphoma chemotherapy patients frequently experience neutropenia, leading to high mortality rates and increased healthcare costs. The CSCO guidelines recommend PEG-rhG-CSF for preventing febrile neutropenia (FN) due to its efficacy, safety, and improved compliance compared to rhG-CSF, which is used for primary prevention of FN and covered by medical insurance. PEG-rhG-CSF, on the other hand, is used only for secondary prevention.

Aims:

To assess the effectiveness and safety of PEG-rhG-CSF versus rhG-CSF in preventing neutropenia in lymphoma patients undergoing chemotherapy. Additionally, this study aims to examine differences in patient adherence and healthcare costs between the two treatments.

Methods:

Data were retrospectively collected from the Hospital Health Information System (HIS) and the Jiangsu Province Population Health Big Data Platform. The cohort included lymphoma patients who received chemotherapy between January 1, 2019, and December 31, 2023, and who were first-time users of either PEG-rhG-CSF or rhG-CSF for preventive purposes. Basic patient information such as age and tumor stage was recorded.

Results:

This study is in the data screening stage, with established inclusion and exclusion criteria. Preliminary screening identified 74,925 cases of lymphoma patients based on hospitalization and outpatient records.

Discussion:

This research utilizes extensive datasets to compare the impacts of long-acting (PEG-rhG-CSF) versus short-acting (rhG-CSF) medications on the management and mitigation of FN. It evaluates the potential of PEG-rhG-CSF as a primary preventative strategy, providing data-driven insights to inform health policy and clinical practice. Additionally, the study aims to enhance therapeutic options for lymphoma patients, thereby reducing their financial burden.

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COMPARISON OF ADVERSE DRUG REACTIONS IN BONE MARROW TRANSPLANT AND HEMAT-ONCO SETTING

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Introduction: Bone Marrow Transplant (BMT) and hemat-oncology units are specialized medical facilities treating patients with complex conditions, often requiring intensive pharmacological interventions. Understanding and comparing adverse drug reactions (ADRs) in these settings is crucial for optimizing patient care and safety.
Aims: To compare the adverse drug reactions experienced by patients treated in BMT and hemat-oncology setting.
Methods: A prospective comparative analysis of ADRs reported in BMT and hematology unit over a nine-month period was estimated. Data were collected from electronic health records, focusing on ADR incidence, severity, implicated medications, and patient demographics. The causality of the reported ADR's was classified based on Naranjo's algorithm.
Results: A total of 234 ADRs were identified, with 167 (71%) occurring in the BMT unit and 67 (29%) in the hemat-oncology unit. The most frequently reported ADRs in both units were Vomiting (21%) and Febrile neutropenia (16%), although the distribution varied slightly between units. Severe ADRs requiring medical intervention were more prevalent in the BMT unit, whereas moderate ADRs were more common in the hemat-oncology unit. Analysis of implicated medications revealed high dose chemotherapy agents such as Fludarabine, ATG showed higher number of severe adverse drug reactions (72%), whereas corticosteroids (15%) and anti-fungals (13%) also exhibited moderately severe adverse reactions. Probable ADRs (56%) were more prevalent in the BMT setting, likely due to the intensive therapeutic regimens and compromised immune status of patients. Conversely, possible ADRs (58%) appeared to be more common in the hemat-oncology unit.
Discussion: This comparative analysis provides insights into the differences in ADR profiles between BMT and hemat-oncology units. Understanding these variations can aid in developing targeted strategies for ADR prevention, management, and pharmacovigilance in each setting, ultimately improving patient safety. Further research is warranted to explore underlying factors contributing to these differences and mitigate ADR incidences in both units.

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Differences for CLL Patients Between China and US: A Large-Scale Comparative Study

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Introduction:
The therapeutic landscape for chronic lymphocytic leukemia (CLL) has profoundly transformed recently. However, the demographic, clinical, and therapeutic differences in CLL between China and the US are not well known.

Objectives:
To enhance our understanding of the disparities in CLL between China and the US by providing a comprehensive comparative analysis of patient characteristics, therapeutic strategies, and survival outcomes.

Methods:
This cross-sectional study involves data from the Flatiron Database and a single-center hospital in China, focusing on patients diagnosed with CLL and receiving systemic therapy. The sample included patients newly diagnosed with CLL with continuous healthcare encounters.

Results:
A cohort of 18,782 CLL patients was identified from the Flatiron (n = 15,786) and Tianjin CAMS (n = 2,296) databases. Median ages at diagnosis were 66 (IQR: 59-74) and 61 years (IQR: 53-68) for the US and China, respectively. Advanced stages III-IV were diagnosed in 2,265 (25.7%) US and 915 (36.0%) Chinese patients ($p<0.001$). IGHV mutation rates were 39.0% and 67.8%, respectively ($p<0.001$). From 2017 to June 2023, the prevalence of targeted therapy in the US rose from 37.1% to 67.0%, and in China from 7.1% to 70.5%. Comparative analysis of treatment regimens revealed an initially lower uptake of first-line targeted therapy in China (23.2% vs. 41.4% in the US). Conversely, by the third line and beyond, China's targeted therapy usage (66.7%) surpassed that of the US (64.9%). Survival analysis showed no significant difference in overall survival between US and Chinese CLL patients ($p=0.73$), with median survival times of 9.7 (IQR: 8.8-10.8) and 9.4 years (IQR: 8.3-10.4), and 5-year survival rates of 70.5% and 69.2%, respectively.

Conclusions:
This cross-sectional analysis indicates that American and Chinese CLL patients have significant differences in baseline characteristics, but the gap in treatment regimens and survival outcomes is gradually narrowing.

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Disproportionality analysis on immune checkpoint inhibitors using a spontaneous adverse event reporting

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Investigation of adverse events (AEs) of immune checkpoint inhibitors (ICIs) is meaningful based on its rapid increase in the real-world utilization. We aimed to detect signals of adverse drug reaction (ADR) associated with ICIs plus chemotherapy as well as ICIs monotherapy compared to chemotherapy. We used individual case safety reports (ICSRs) between 2014 and 2022 using KIDS KAERS DB (2304A0076). We defined AEs and drug using MedDRA and the national drug code directory provided by the Ministry of Food and Drug Safety. Disproportionality analysis was performed with indices of reporting odds ratio (ROR) and information component (IC) to detect signals. The criteria for signal detection were established as follows: PRR and ROR value of 2 or more, $\chi 2$ value of 4 or more, an occurrence count of 3 or more, and lower bound of the 95% confidence interval greater than 0. We identified 206,959 ICSRs in the KIDS KAERS DB, of which 5,154 were associated with ICIs and 201,805 were associated with chemotherapy. Most reported cases were male (71.05%) and 60-69 years old (36.79%). A total of ICIs-AE combinations satisfied all three criteria of the signal: 146 were ICIs monotherapy and 63 were ICIs plus chemotherapy. Among the top 50 signals for ICIs monotherapy, the highest ROR was for radiation pneumonitis (ROR, 2313.58; IC, 5.38), vitiligo (ROR, 509.41; IC, 4.94), and thyroiditis (ROR, 356.79; IC, 5.03). The top 50 signals for ICIs plus chemotherapy were similar to ICIs monotherapy, with high RORs reported for bleeding varicose vein (ROR, 445.88; IC, 6.43) and macular oedema (ROR, 334.57; IC, 6.33) as adverse events not found in ICIs monotherapy. The study highlights an important signal of AEs associated with ICIs, both monotherapy and combination, with conditions such as radiation pneumonitis, thyroiditis, and vitiligo. These AEs should be monitored in clinical settings.

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Early-Onset Gastric and Colorectal Cancer in Japan and the US

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Introduction
The incidence of early-onset cancer is rising, with observed uncertainty in geographic variability.

Aim
This study aimed to describe patients with metastatic colorectal cancer and advanced gastric cancer in Japan and the US.

Methods
The data sources were de-identified, electronic health record-derived, Flatiron Health databases from Japan and the US. We selected patients diagnosed with colorectal or gastric cancer between 1 January 2015 and 31 December 2023, excluding those under 18 at diagnosis. The study defined ‘early-onset’ disease as a metastatic diagnosis of colorectal or gastric cancer before the age of 50. Descriptive statistics were analyzed in a trusted research environment compliant with local legal and ethical requirements.

Results
The population in Japan consisted of 811 patients (390 with colorectal cancer, 421 with gastric cancer). The median (IQR) age of patients with colorectal cancer was 61 (49-69), 58% were male, and 3.7% had an ECOG score of 2 or above at the time of their first treatment. The median (IQR) age of patients with gastric cancer at diagnosis was 66 (58, 72), 67% were male, and 4.4% had an ECOG score of 2 or above at the time of their first treatment. There was a higher prevalence of early-onset disease in Japan compared to the US: 27% compared to 15% (n=31,642), respectively, for colorectal cancer, and 14% compared to 10% (n=3,235), respectively, for gastric cancer.

Discussion/Conclusion
Compared to the US, the Japan cohort included a higher proportion of patients with early-onset disease. A strength of this study was the availability of disease stage, metastatic diagnosis date, and other clinical characteristics that were abstracted from patient charts. Further research will explore the generalizability of these findings and the survival outcomes for early-onset patients in Japan and the US, to generate robust evidence to inform targeted treatment strategies.

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Exploration of theragnostic target along the central dogma of anaplastic thyroid cancer

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Introduction:
The molecular interplay and pathogenesis of this poor prognosis disease called anaplastic thyroid cancer, is poorly understood, posing an unmet clinical need in the diagnosis and therapy of the neoplasia. Chromosomal aberrations play an important role in the pathogenesis of a disease. However, all mutations may not be transcribed, and all altered mRNAs may not be expressed due to transcriptional regulations.
It is important to screen along the central dogma to evaluate the underlying molecular pathway of pathogenesis. Theoretically, drugs approved against a disease can be repurposed for another

Aims:
1. Build an affordable actionable actionable minimum molecular diagnostic panel for ATC
2. Identify drugs that may be repurposed in ATC

Methods:
Two methods were used; (1) HuGE Navigator Database curation of literature (2) cBio Portal mutation analysis.
The Open Target Database scored the genes generated by the HuGE Navigator Database. Top ten genes were selected. Patient samples were analyzed on the cBio portal, yielding 183 mutations. EnrichR was used to demonstrate the interlinking processes of the genes found. An association connectome and information on the protein anomalies in this disease were constructed on the Cytoscape database. To acquire drug repurposing data, all the genes obtained were loaded into DrugBank. Medications that target a single gene were selected for additional examination.

Results: Out of the 622 genes from HuGE Navigator, 10 genes; PAX8, CCDC6, NCOA4, AKT1, TP53, BRAF, among others, had a high association score. 15 genetic mutations, 6 of which were in common with Huge Navigator analysis, were found in more than 5% of the patients.
Pathway analysis of the genes highlighted p53, VEGF, RAS signaling, PI3K/AKT and mTOR pathways among others. Approved drugs specific to only one identified target were found on DrugBank.

Conclusion: The identified theoretically repurposable drugs can be analyzed further using molecular docking.

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Investigating the preventive colorectal cancer screening among US adults by diabetes status

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- Introduction: Colorectal cancer (CRC) is linked to Type 2 Diabetes Mellitus (T2DM), which increases CRC risk. Despite guidelines emphasizing the importance of CRC screening for early detection, variability in screening adherence among adults with diabetes remains underexplored.

- Aims: This study aimed to 1) investigate the prevalence of CRC among US adults by diabetes status, and 2) examine preventive CRC screening patterns in adults aged 40-75 without CRC in 2021.

- Methods: Adult respondents aged between 40-75 years were the study population. Self-reported diabetes-and CRC-related questionnaires in 2021 NHIS data were used to identify diabetes and CRC status, which relied on affirmative responses to questions “Ever had diabetes”, “Colon cancer mentioned”, “Rectal cancer mentioned”, and “Colorectal cancer mentioned.” Preventive CRC screening was defined as respondents with diabetes but without CRC who answered yes to questions “Colonoscopy or sigmoidoscopy”, “Ever had colonography/virtual colonoscopy”, “Ever had home blood stool test”, and “Ever had Cologuard”. Prevalence of diabetes, CRC, and CRC screening were weighted and adjusted by the NHIS clustering and stratification sample design. Analyses included chi-square tests and multivariable logistic regression which were used to compare screening patterns and evaluate associations between diabetes and screening uptake.

- Results: There were 3,134 patients with diabetes enrolled in this study. Among adults aged 40-75, patients with diabetes had a higher CRC prevalence than patients without diabetes (0.86% versus 0.46%; $P<0.05$), consistent with the result in overall adult patients (1.06% versus 0.44%; $P<0.01$). In CRC-free patients, those with diabetes were more likely to have any CRC screening than those without diabetes (86.3% vs. 79.9%; $p<0.05$).

- Discussion/Conclusion: In the U.S., adults with diabetes had an increased risk of developing CRC. Higher preventive screening rates were observed among patients aged 40-75 years with diabetes, underscoring the necessity for continued emphasis on screening within this demographic.

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P+C+OMCT vs. TPF regimen as neoadjuvant chemotherapy in head & neck cancer

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Introduction: In head and neck cancer (HNC), docetaxel, cisplatin, & 5-fluorouracil (TPF) is widely accepted regimen in neoadjuvant settings. However, administration of this regimen is resource-consuming, and not feasible for many patients with low socioeconomic status. Oral metronomic chemotherapy (OMCT), typically utilized in palliative setup, when combined with a paclitaxel-carboplatin regimen provides synergistic effects owing to the continuous exposure of cytotoxic drugs to the tumor environment.
Aim: To compare the efficacy of P+C+OMCT vs. TPF as neoadjuvant chemotherapy (NACT) in patients with locally advanced HNCs.
Methods: This prospective, observational study included 46 patients undergoing NACT. The patients were assessed for efficacy after a minimum of 2 cycles of chemotherapy using RECIST 1.1 criteria.
Results: Out of 46 included patients, 25 and 21 patients received TPF and P+C+OMCT, respectively. Overall response rate (ORR) was 52% for TPF and 57.14% for P+C+OMCT (p=0.727). 2 patients in the TPF arm had complete response (CR). Disease control rate (DCR) was 92% and 95.23% for TPF and P+C+OMCT, respectively (p=0.652). In the post-NACT surgical evaluation, the tumors of 16 (64%) patients in TPF and 11 (52.38%) patients in the P+C+OMCT arm were found to be resectable (p=0.425).
Discussion: Compared to the TPF regimen, P+C+OMCT demonstrated comparable, if not superior efficacy in terms of response rates and resectability in locally advanced HNCs. Hence, P+C+OMCT might provide a promising alternative to the TPF regimen in patients for whom administration of TPF is not an option.

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Predict prostate cancer mortality: an application of real-world data-driven, time-inhomogeneous Markov model

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Introduction
Understanding prostate cancer progression and mortality risk is important for optimised patient management and informed medical decisions. Real-world data provide valuable evidence for model fitting and evaluation to predict mortality.
Aims
This study aims to develop a time-inhomogeneous Markov model using population-based real-world data to estimate prostate cancer progression and predict 10-year mortality risks utilizing baseline characteristics.
Methods
We developed time-inhomogeneous Markov model comprises seven health states related to prostate cancer progression (localized hormone-naive, localized castration resistance, metastasis hormone-sensitive, metastasis castration resistance, remission and death). Hong Kong territory-wide electronic medical database CDARS was the primary data source for real-world transition probability estimation, based on a 10-year follow-up of patients newly diagnosed with prostate cancer between and 2013. Age, Charlson Comorbidity Index (CCI) and Prostate-Specific Antigen (PSA) were considered for fitting the time-varying transition probability. Model performance was assessed using Mean Average Percentage Error (MAPE) by comparing expected and observed cumulative deaths in the validation cohort of patients diagnosed in 2014.
Results
We identified 3978 incident patients (mean [SD] age, 73.1 [8.80] years) with prostate cancer between 2011 and 2013 with 2037 death recorded during the 10-year follow-up. The MAPE of the 10-year cumulative death in the validation cohort was 0.17, indicating good prediction performance. The most frequently observed group of patients (aged <65, CCI 0, PSA 4-10 ng/mL) had one-year, five-year, and 10-year mortality risks of 3.4%, 22.6%, and 42.8%, respectively. In contrast, severe patients (aged >80 years at diagnosis, CCI >= 3, and PSA >= 100 ng/mL) faced significantly higher risks, with a death probability of 22.4% at year one, 64.3% at year five and 91.3% at year ten.
Discussion
The real-world time-varying Markov model can mimic the disease progression in actual clinical practice, estimate individual mortality risk, and guide early patient management plans for improved survival.

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Prevalence and trajectories of multiple medicine use in people with colorectal cancer

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Introduction
Multiple medicine use is common in Australia but little is known about its extent in people with cancer. There are concerns for people with colorectal cancer (CRC) as they receive treatment from multiple specialists, increasing risks of medication errors and inappropriate prescribing.
Aims
To estimate the prevalence of multiple medicine use amongst adults (>18 years) with CRC and detail how medicine use evolves from the year preceding diagnosis, through active cancer treatment, and into the post-treatment survivorship period.
Methods
We used dispensing claims for residents of New South Wales diagnosed with CRC between 2013 and 2017. We used group-based trajectory modelling to explore changes in the quarterly number and type of medicines used during the year preceding and five years following CRC diagnosis. We stratified our cohort by extent of cancer spread at diagnosis (local, regional, or metastatic disease).
Results
There were 7,088, 8,632, and 3,826 people diagnosed with localised, regional, and metastatic CRC, respectively, during the study period. The proportions of people dispensed five or more medicines during each year around diagnosis ranged between 35% and 65%, peaking near 75% during the first year following diagnosis for each sub-cohort. Medicine use trajectories were similarly stable for localised and regional CRC sub-cohorts, averaging 0–10 unique medicines dispensed/quarter over the study period. Metastatic patients showed more variation across six trajectory groups with half stable, averaging 2–8 medicines dispensed/quarter, and half declining as patients discontinued medicines prior to death.
Discussion
Multiple medicine use is common and more prevalent in CRC patients than in the general Australian population . Patients in all disease sub-cohorts experienced an increase in the number of dispensed medicines during the year following diagnosis, reflecting initiation of cancer therapies, however, medicine use trajectories were otherwise largely stable over the study period.

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Real-world Treatment Patterns of Trastuzumab Deruxtecan (T-DXd) in Chinese Breast Cancer Patients

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Introduction: Trastuzumab deruxtecan (T-DXd) has emerged as a promising therapy for breast cancer, yet data on its utilization among Chinese patients remain limited.

Aims: This study aimed to investigate the real-world treatment patterns of T-DXd among Chinese breast cancer patients, particularly focusing on treatment duration and dosing considerations.

Methods: A retrospective observational study was conducted among 2055 Chinese female breast cancer patients who received T-DXd treatment between 2023 and 2024. Patient demographics, treatment duration, tumor staging, medication patterns, and dosing details were analyzed.

Results: The age distribution showed a mean age of 54.8 years (SD 10.8), with a median of 55 years (IQR 47-61), and the majority of patients (71.1%) were aged between 41 and 64 years. The mean treatment duration of 5.4 cycles (SD 2.3) and a median of 4.0 cycles (IQR 4.0-8.0). Notably, 70.2% of patients received only 4 cycles, while 24.9% received 8 cycles, 4.7% received 12 cycles, and 0.1% received 16 cycles. The mean number of doses per cycle was 2.7 (SD 0.6), with a median of 3.0 doses (IQR 2.0-3.0). The majority of patients received 3 doses per cycle (59.0%), followed by 2 doses (33.7%), 4 doses (5.8%), and 1 dose (1.3%). The mean interval between medication refills was 85.1 days (SD 27.8), with a median of 86 days (IQR 67-102). Additionally, the mean dose per cycle was 4.9 mg/kg (SD 0.9), with a median of 5.0 mg/kg (IQR 4.3-5.5). Factors influencing dosage and treatment interval included age at diagnosis, cancer stage, body weight and geographic regions.
Discussion: These findings highlight suboptimal dosing of T-DXd among Chinese breast cancer patients, potentially influenced by lower-than-average patient weight and dosing practices. Understanding the factors contributing to these deviations from recommended treatment regimens is crucial for optimizing therapeutic outcomes in this population.

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Recent Review of Population-based Cancer Registries in the US, Europe, and Korea

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Introduction: While the importance of utilizing real-world data in epidemiological research is being emphasized, existing studies have rarely addressed the availability of real-world databases in the field of cancer.
Aims: To compare the latest operational availability of population-based cancer registries in the United States, Europe, and South Korea, providing foundational information for epidemiological research on cancer.
Methods: Criteria for selection included registries covering over 40% of the national population, operated by governmental institutions, and documenting more than two types of cancer. Consequently, the NPCR (National Program of Cancer Registries) and SEER (Surveillance, Epidemiology, and End Results), the ENCR (European Network of Cancer Registries) and the K-CURE (Korea-Clinical Data Utilization Network for Research Excellence) were identified. Each registry was reviewed based on topics discussed in prior study related to cancer registry design.
Results: Most registries were based on Electronic Medical Records (EMR), but the K-CURE distinctively integrates claims data. The NPCR focuses solely on cancer occurrence, whereas the others included information on cancer incidence, treatment, and prognosis. All registries, except for the recently established K-CURE, covered all cancer types. Each registry had an independent systematic quality assessment system. Access procedures were most straightforward for SEER, whereas others are more complex or restrictive. In terms of flexibility and timeliness, all registries were updated annually, maintaining consistency. Regarding terminology standardization, all of those registries utilize ICD-O-3, with K-CURE additionally using KCD.
Discussion: In conducting epidemiological research on cancer, it is crucial to consider the features, advantages, and limitations of these databases to select the most suitable registry based on the research objective and methods. This comparative analysis provides insights into the status of population-based cancer registries across various regions, laying the groundwork for advancements in cancer epidemiology research.

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Relationship between Dose Intensity and Effectiveness of Cyclin-Dependent Kinase 4/6 Inhibitors

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- Introduction
Cyclin-dependent kinase 4/6 inhibitors (CDK4/6i) combined with aromatase inhibitors have become the first-line treatment for hormone-positive(HR+)/ human epidermal growth factor receptor 2-negative(HER2-) advanced breast cancer. However, high proportion of patients required dose modification due to adverse effects such as severe neutropenia in clinical trials. As a result, the relationship between the dose and effectiveness of CDK4/6i is an important issue.

- Aims
To compare the effectiveness between low relative dose intensity (RDI) and high RDI of CDK4/6i as first-line treatment for HR+/HER2- advanced breast cancer.

- Methods
We conducted a retrospective cohort study including HR+/HER2- advanced breast cancer patients who initiated CDK4/6i as first-line therapy from September 2016 to December 2022 at our hospital. Patients were categorized into two groups based on their first 12-week dose intensity: low-RDI group(≤0.8 for palbociclib or ≤0.667 for ribociclib and abemaciclib) or high-RDI group(>0.8 for palbociclib or >0.667 for ribociclib and abemaciclib). The outcome was progression-free survival (PFS), defined as the time from initiating CDK4/6i to disease progression or death. We used Kaplan–Meier method to estimated PFS and Cox regression model to analyze hazard ratio (HR) and 95% confidence interval (CI) between groups.

- Results
Total 607 patients were enrolled and all were females. The mean age was 58 years old and body surface area was 1.58m². 278(46%) patients received palbociclib, 264(43%) received ribociclib, and 65(11%) received abemaciclib. There were 227(37%) in low-RDI group and 380(63%) in high-RDI group. PFS was similar in both groups, with median of 18.5 months in low-RDI group and 22.3 months in high-RDI group, adjusted HR(95%CI): 1.04(0.84-1.28).

- Conclusion
Dose intensity of CDK4/6i in the first 12 week had no impact on PFS in HR+/HER2- advanced breast cancer. This finding provided an evidence that dose adjustment had no negative impact on effectiveness.

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Safety evaluation of rituximab biosimilar products using real-world data in Japan

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Introduction: Rituximab biosimilar products (RTX-BS) have been introduced in Japan, but their safety in the real world has not been fully evaluated.
Aims: We compared incidences of adverse events (AE) by RTX-BS with RTX reference drug (RTX-R) using real-world data in Japan.
Methods: Using a medical information database (Medical Data Vision Co., Ltd.), a total of 46,726 patients with malignant lymphoma were selected who were RTX-naïve and treated with either RTX-R (n= 21,583), RTX-BS1 (n= 23,208) or RTX-BS2 (n= 1,938), without switching, during April 2014 to December 2023. Outcomes were defined as new records of AEs (infection, febrile neutropenia, heart and lung diseases, anaphylaxis) based on ICD-10, and leucopenia (grade 2 and higher) based on laboratory data which were available from 6,155 patients. Evaluation periods were up to 14 days after the first and the last RTX-treatment. Adjusted odds ratios (aOR) and 95% confidence intervals of each RTX-BS to the RTX-R were determined by multivariate logistic regression models using patient characteristics (age, sex, medical history, comorbidities, co-administered drugs, etc.) as covariates.
Results: Treatment durations of RTX were similar among three RTX-groups (median: 110 to 118 days). In the first RTX-treatment, slightly but significantly higher aORs (1.1 to 1.8) were observed for infection, febrile neutropenia, heart and lung diseases for RTX-BS1 and grade 4 leucopenia for RTX-BS2. Regarding the AEs in the last RTX-treatment, no significantly higher aORs were observed, except for anaphylaxis by RTX-BS1 in which significant association of history of anaphylaxis was identified.
Discussion/Conclusion: Although higher aOR of some AEs were observed in the first RTX-treatment, safety of RTX-BS seemed to be overall managed during RTX-treatment cycles to complete RTX-therapy as well as RTX-R. Consideration on risk factors identified in this study, such as history of AEs, would be important for safety management of either of RTX-therapy.

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Systemic exposure of VEGF/VEGFR inhibitors: artery dissection risk assessment using claims data

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Aim/Objective:To evaluate the possibility of artery dissection as a class effect of vascular endothelial growth factor pathway inhibitors (VPIs). Methods: We conducted a nationwide cohort study using the National Database of Health Insurance Claims of Japan (NDB), which covers over 100 million individuals. Patients prescribed any VPIs from April 1, 2012, to March 31, 2020, were included and patients without any medical records after the inclusion or patients prescribed same VPIs were excluded. The incidence rate (IR) of artery dissection in patients prescribed each VPI and the adjusted IR ratio (aIRR) compared to bevacizumab were examined. Results:In total, 503,342 patients were identified and the most prescribed VPI was bevacizumab (n=278,722) among 12 VPIs. The IR of artery dissection for bevacizumab, only VPI with artery dissection listed in the package insert in Japan, was 44.4 /100,000 person-years. The aIRR of artery dissection for each VPI compared to bevacizumab was consistently similar to or greater than 1.0. An additional analysis was conducted to compare the IR of each VPI with the natural IR of artery dissection in the general population from NDB. The natural IR was 1.66 /100,000 person-years in entire Japanese population, and the standardized IR (sex and age were standardized to the bevacizumab prescribed patient population) was 2.18 /100,000 person-years. Conclusion:Our findings indicated a possibility of a class effect of VPIs on the risk of artery dissection. The Pharmaceuticals and Medical Devices Agency conducted a safety assessment on the risk of artery dissection by VPIs based on this study as major evidence for review and other available data including adverse drug reaction reports, literature and pharmacological mechanism of action. The package inserts of all VPIs included in this study were revised on February 15, 2024 to add a precaution about the risk of artery dissection as "Clinically Significant Adverse Reactions".

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Tamoxifen and risk of uterine diseases in young women with breast cancer

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Introduction:
Evidence has shown an increased risk of endometrial cancer associated with tamoxifen use in women with breast cancer, but data for premenopausal women are scarce.
Aims:
To investigate the association between Tamoxifen treatment and risk of developing uterine diseases in women with breast cancer aged 20 to 50 years.
Methods:
We conducted a retrospective cohort study using a target trial emulation framework. Women aged 20 to 50 years, diagnosed with estrogen receptor–positive breast cancer, and who had undergone mastectomy from 2010 to 2019, were identified using Taiwan's National Health Insurance claims data linked to the cancer registry. Those with a history of hysterectomy, neoadjuvant therapy, and diagnosis of postmenopausal status and uterine diseases were excluded. Tamoxifen use was defined as receipt tamoxifen treatment only as adjuvant hormone treatment within one year after surgery. Inverse probability of treatment weighting controlled baseline confounding between the Tamoxifen treatment and non-treatment groups. Observational analogs of the intention-to-treat and per-protocol effects were estimated using pooled logistic regression models.
Results:
A total of 23,062 Tamoxifen users and 3,000 non-users were included. The mean age was 43.1 years (SD 5.2) and 42.4 years (SD 5.8), respectively. During the follow-up period, 3,888 users and 109 non-users developed uterine diseases, with 106 and 5 cases of endometrial cancer, respectively. In the intention to treat analysis, the estimated hazard ratio (95% confidence interval) was 4.15 (2.65-6.50) for endometrial polyps, 5.42 (4.09-7.18) for endometrial hyperplasia, and 2.41 (0.86-6.72) for endometrial cancer. Corresponding estimates in per-protocol analysis was 4.75 (2.55-8.86), 8.37 (5.24-13.35), and 4.20 (1.20-14.63), respectively.
Discussion:
Among women of premenopausal age with breast cancer in Taiwan, tamoxifen as adjuvant hormone therapy was associated with increased risk of uterine diseases including endometrial cancer. These findings highlight the importance of monitoring uterine diseases among tamoxifen users in this age.

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Design and synthesize the potent and less toxic HoLu-7 as anticancer agent

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Introduction: Quinazolinone, characterized by its distinctive structural features, holds significant importance in contemporary drug research due to its capacity for high-affinity binding at various binding sites and effective promotion of drug activity. Medicinal chemists usually design specific pharmaceutical agent for clinical treatment needs via several strategies. The CADD (computer-aided drug design) approach utilizes multiple computational techniques to facilitate the process of new drug discovery in designing ligands that may effectively bind to a specific biotarget.

Aims: To develop safe and effective anticancer drugs remains a critical aspect of contemporary healthcare. From clinical observation, patients usually suffer from significant toxic side effects when receiving chemotherapy. Therefore, the aim of the study is to develop novel chemotherapeutic drugs with good anticancer activity but low toxicity to normal cells.

Methods: In this study, the CADD technique was used to design novel potent quinazoline analogues with low toxicity for cancer treatment. A series of quinazoline derivatives (HoLu-1~HoLu-10) aiming at tubulin as a biotarget was designed and synthesized. These compounds were then subjected to treatment of oral CAL27, metastatic CAL27, colorectal HCT116, and normal colon epithelial FHC cells at a concentration of 10 μM for 72 hours. Cell viability was determined utilizing the sulforhodamine B (SRB)-based in vitro toxicology assay as described previously.

Results: Some of the compounds demonstrated significant cytotoxicity against various cancer cell lines. Among these compounds, compound HoLu-7 demonstrated the most potent cytotoxicity against CAL27, metastatic CAL27, and HCT116 cells, while exhibiting relatively low toxicity towards normal colon epithelial FHC cells.

Discussion: These findings suggest that compound Holu-7, with the structure of quinazoline scaffold possessing 2,4-disubstituted phenyl moiety and displaying the best geometrical conformation, exhibited selectivity by demonstrating non-toxicity towards normal cells but enhanced cytotoxicity against various cancer cell lines, and may be a promising candidate for further development as anticancer drug.

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Evaluation of Drug Utilization of Trastuzumab Deruxtecan in a Regional Hospital

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Introduction: The antibody-drug conjugate (ADC) acts as a "magic bullet" in cancer treatment, combining monoclonal antibodies' targeting ability with a cytotoxic payload. Trastuzumab deruxtecan, comprising trastuzumab and deruxtecan, is approved for advanced HER2-positive or HER2-low breast cancer, HER2-positive gastric cancer, lung cancer, and solid tumors, and became available in Taiwan in 2022.

Aims: To provide clarity on its utilization, we conducted an evaluation of the application of trastuzumab deruxtecan in a regional hospital.

Methods: We retrospectively collected data on patients who received treatment with trastuzumab deruxtecan at the regional hospital from 2022 to April 2024. We then analyzed various parameters, including cancer type, stage, treatment course, dosage, side effects, and subsequent treatment plans.

Results: In the study, twelve patients participated, with one having HER2-positive lung cancer and the remaining having HER2-positive breast cancer. Their mean age was 58.3±8.3 years, and all had an Eastern Cooperative Oncology Group (ECOG) score of 0-1. On average, patients received 6.8±5.7 treatment courses, with an average dosage strength of 62.3±19.2% compared to the recommended 5.4mg/kg dose. Most side effects were grade 1, including liver enzyme elevation, anemia, alopecia, fatigue, diarrhea, increased serum creatinine, and hypokalemia. However, some experienced grade 2 side effects such as neutropenia (8%), anemia (25%), and diarrhea (8%), necessitating treatment delay or dose reduction. There were no reported cases of interstitial lung disease. All patients continued treatment until disease progression or expiration, except for one who declined further treatment due to financial constraints.
Discussion: Our review indicates that physicians frequently favored lower-dose treatment, potentially due to financial constraints or concerns regarding toxicity. Nonetheless, our findings demonstrate that the treatment's efficacy was satisfactory, with no discontinuations attributable to toxicity. Although most side effects were mild, grade 2 neutropenia, anemia, and diarrhea warrant careful consideration.

[Medical Education]

P358

A systematic review of healthcare professionals' capacity building in regenerative medicine

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and patient medication practices for different oncology drugs.

Introduction
The application of regenerative medicine (RM) to meet clinical needs is a highly sophisticated process requiring healthcare professionals (HCPs) to acquire specialized skillset. Currently, the evidence about HCP capacity building concerning RM and its effectiveness is still unfolding.
Aims
The study aimed to summarize the current practices of developing HCP capacity in RM and to identify the effectiveness of capacity-building actions.
Methods
Four databases (PubMed, ScienceDirect, Web of Science, Scopus) were searched following PRISMA guidelines to retrieve related articles dated since 2005 till now.
Results
Twenty-seven publications were included from the 3534 records initially retrieved. HCP capacity building in RM mainly occurred through formal undergraduate/graduate education (n=15) and continuing professional development training (n=16). The training content encompassed RM-related disease knowledge (n=7), therapies (n=14), manufacturing (n=10), laboratory skills (n=11), clinical translation (n=12), research ethics (n=10), regulatory affairs (n=17) and data science (n=5). The main training approaches were face-to-face, network events, and workshops. Nine of the 27 studies were empirical studies which either surveyed 1,308 HCPs such as physicians (n=670), laboratory staff (n=182), interdisciplinary students (n=150), industry professionals (n=149), academic fellows (n=90), physician trainees (n=71), clinical scientists (n=23), or interviewed 27 stem cell network trainees investigating the availability, equity, and accessibility of training and education. Only 2 studies reported the training effectiveness among medical students in terms of improved self-perceived knowledge of translational process and patient care, increased interest in attending education activities and willingness to work in interdisciplinary teams. No study reported the RM training outcomes among practicing HCPs. Capacity building was expected to focus more on cell science, manufacturing operation management, and regulatory issues.
Conclusion
RM education has been increasingly used to enhance HCPs' knowledge, confidence, and practice in developing and using RM, but the evidence about the impact of capacity-building on clinical practice among HCPs warrants further investigation.

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Assessment of Knowledge, Attitude, Practice Towards Appropriate Medication Use

in High School

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Introduction: The growth in the number of medications available to consumers world-wide has increased medication use in children. Research conducted worldwide opined that children in general had a negative attitude towards medication. To date, there has been limited data on explored knowledge, attitudes and practices of school going children in India.
Aim: To assess the Knowledge, Attitude & Practice regarding the appropriate use of medication amongst the school going children.
Methodology: The study was a questionnaire based cross sectional observational study, carried out among the high school students in 3 urban & rural schools across Mysore. Students who met the study criteria were enrolled into the study after obtaining the informed consent. The questionnaires were administered and students were briefed about the purpose of the study before filling. Finally the collected questionnaires were evaluated to assess the KAP students.
Results: A total of 715 students were enrolled from three urban and three rural schools in our study. Higher KAP scores were observed in Females (74.4%) than Males (73.1%). In class-wise distribution, Class 8 shows higher KAP score (74.8%) than Class 9 (74.2%) and Class10 (72.1%). Urban schools show a better KAP score of 75.3% compared to rural schools (71.3%). Further assessment was performed to find out the influence of age, gender and geographical location of the school children on individual parameters of KAP.
Discussion: Geographical distribution of participants based on class and gender suggests that Class 9 was found to have maximum number of students (35%) compared to the other classes (31%, 34%). Gender-wise analysis of the data showed that female students enrolled in each school were comparatively lesser than males. children had a satisfactory knowledge about medicines and their use. Results are surprisingly good for the school curriculum which does not formally include education about rational use of medicines.

[Opioids and pain medications]

P360

A scoping review on the research landscape of Fentanyl in pediatric oncology.

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Background
The opioid use is restricted in children due to possible adverse drug reactions. Fentanyl is used in pediatric cancer for disease-related or therapy-related pain. During the drug administration, the child is kept under strict monitoring. The field of research is sparse, and the need to understand the ongoing research in the sector is important.
Aim
To identify the areas of research for Fentanyl use in pediatric oncology and the extent to which each area has been explored to date.
Methodology
A scoping review was performed using articles published till 31st December 2023. Keywords like “Fentanyl”, “Pediatrics”, and “Cancer” were used to identify the studies from PubMed, Embase, Scopus and Cochrane databases. A systematic two-step approach was used in the screening processes. Only research articles published in the English language were included. The extracted data from the studies included demographics, research country, aims and outcomes. The review followed the five-step methodological approach detailed by Arksey and O'Malley and the Joanna Briggs Institute updated methodological guidance.
Result
Of the 5701 articles screened, 24 (0.42%) articles were included. Cross-referencing further included one study. The major findings of the review were: 1) The research on Fentanyl use in pediatric oncology is limited. 2) The included publications were from 15 countries, of which the United States of America had the most (20%). 3) Intravenous/Intrathecal dosage forms (76%) were the most studied 4) Majority of the studies were themed on the efficacy (44%), safety (28%) and tolerability (12%) of Fentanyl in the population.
Discussion/Conclusion
The review highlighted the areas of research in pediatric oncology. Studies on areas like blood level estimation and genomic variability of the patients are needed to identify the possible relation between the variations of efficacy and safety profiles.

Keywords: Fentanyl; Pediatrics; Cancer; Scoping review.

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Comparative Study of Morphine versus Tapentadol in Cancer Pain Management

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Introduction:
Morphine and Tapentadol are using for the management of cancer pain and the study was designed to determine the comparative effectiveness of the both drugs.

Aim:
To assess the effectiveness of Morphine and Tapentadol in patients with cancer pain in outpatient settings.

Methods:
A longitudinal observational study was carried out after institutional ethics committee's approval. Patients, aged 18 years and above visiting outpatient department of palliative medicine of a tertiary care center in India and receiving oral Tapentadol 50mg or oral Morphine 10mg were recruited in the study. The severity of pain was assessed using the numerical rating scale (0-10). Categorical data in demographic parameters at baseline was analyzed by using 'Z' test for difference between two proportions. Continuous variables between the two treatment groups were analyzed by unpaired t-test.

Results:
A total of 390 patients participated in the study among whom, 161 patients received oral Tapentadol and 229 received oral Morphine. The mean age of the participants were 51.9 (±9.7) years in the Morphine group and 60.3 (±10.8) in the Tapentadol group. Morphine group consisted of 38% male whereas, Tapentadol included 22% male. The median duration of follow-up in days was 16 and 20 in Morphine and Tapentadol group respectively. Both the drugs were effective in reducing the intensity of pain during the end of follow-up with a mean difference of -0.68 [95% CI (-1.03, -0.32), p>0.001] in the Morphine group and -0.69 [95%CI (-1.10, -0.27), p>0.05] in Tapentadol group.

Discussion/Conclusion:
The study showed that Morphine was effective in cancer pain in routine clinical practice in outpatient patient department. Larger studies are needed for exploring the predictors and factors affecting pain.

Keywords: Pain, NRS, Tapentadol, Morphine, Outpatient

P362

The rate of naloxone use in emergency departments in the United States

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Introduction: The opioid crisis in the US has led to a significant increase in overdose incidents, necessitating effective emergency interventions. Naloxone, an opioid antagonist, is commonly administered in emergency departments (EDs) to counteract life-threatening overdoses. Understanding the characteristics and trends of naloxone use in these settings is crucial for improving response strategies and patient outcomes.

Aims: To determine the rate of naloxone use in EDs in the US.

Methods: This cross-sectional study used the National Hospital Ambulatory Medical Care Survey from 2017 to 2021. The data includes a national sample of visits to EDs in the US, focusing on visits where one or more naloxone orders were made for patients aged 15 and older. Sampling weights were applied to estimate national rates and 95% confidence intervals (95% CIs). The naloxone order rate, patient demographics, and the primary source of payment for the visit were examined.

Results: In 2017-2021, 0.5 per 100 ED visits included naloxone (95% CI 0.4 – 0.6 per 100). From 2017 to 2018, the rate decreased from 0.5 to 0.3, then increased to 0.6 and remained until 2021. Of all ED visits including naloxone, 55% were by male patients. Non-Hispanic White patients accounted for 63%, followed by non-Hispanic Black (19%), Hispanic (11%), and non-Hispanic other (7%). The average age was 45.4 years (42.5 – 48.3); however, those aged 25-34 comprised the largest proportion of naloxone use (25%). Medicaid (35%) and unknown (19%) were the most common sources of payment.

Conclusion: According to the CDC, drug overdose deaths increased by 30% from 2019 to 2020 and by 15% from 2020 to 2021. Our analysis indicates that naloxone use in EDs did not rise during this period, possibly due to the impact of COVID-19 measures. Naloxone use was more prevalent among relatively young adults and individuals with low incomes.

P363

Utilization patterns of analgesics in Indian cancer patients: systematic review and meta-analysis"

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Introduction: Effective pain management is crucial for improving the quality of life in cancer patients. Despite the availability of various analgesics, there is limited comprehensive data on their usage patterns, efficacy, and safety within the Indian population. This systematic review and meta-analysis aim to evaluate the utilization of analgesics among cancer patients in India, examining the types of analgesics used, their efficacy, and associated adverse effect.

Aim :
1) To assess the utilization patterns of analgesics in Indian cancer patients.
2) To evaluate the efficacy of different types of analgesics used in this population.
3)To analyze the prevalence and types of adverse effects associated with analgesic use in Indian cancer patients.

Methods: A systematic search is being conducted across multiple databases including PubMed, Scopus, and Cochrane Library, covering studies from January 2000 to December 2023. Inclusion criteria comprise studies reporting on the use of analgesics in cancer patients in India. Data are being extracted on study characteristics, patient demographics, types of analgesics used, efficacy outcomes, and adverse effects. Meta-analysis will be performed using random-effects models to synthesize the data.

Preliminary Results: Preliminary findings indicate that opioids are the most commonly used analgesics, followed by non-opioid analgesics and adjuvant analgesics. Early analysis suggests that opioids are highly effective in pain relief. Non-opioid analgesics show moderate efficacy, particularly in managing mild to moderate pain, while adjuvant analgesics appear effective in treating neuropathic pain. Common adverse effects noted include constipation, nausea, and sedation.

Conclusion: The ongoing systematic review aims to provide a comprehensive understanding of analgesic use in cancer patients in India. Preliminary results underscore the importance of opioid analgesics in pain management, although they are associated with significant adverse effects. The final results will inform better pain management strategies and highlight the need for improved palliative care services.

[Osteoporosis]

P364

Adverse drug reactions of Vitamin D: trends in Jiangsu and signal detection

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Introduction: Vitamin D (VD) demonstrates therapeutic benefits treating a variety of diseases in recent years. However, evidence of its adverse drug reations (ADRs) is limited.
Objestives: To examine the trends in incident rates of VD related ADR reports in Jiangsu province of China, and detect new safety signals for informed decisions.
Methods: We retrieved all VD related incident notifications between 2010 and 2019 from the spontaneous ADR reporting system in Jiangsu. The manifestation of ADRs were coded and classified using the Medical Dictionary for Regulatory Activities. We used Joinpoint to estimate change in age-adjusted ADR rates over a decade. We employed multiple signal detection algorithms including the traditional Proportional Reporting Ratio (PRR) and the advanced Bayesian Confidence Propagation Neural Network with Markov Chain sampling methods to detect and validate safety signals for VD real-world use.
Results: A total of 1310 VD related ADR reports were identified among residents in Jiangsu province. The age-adjusted ADR report rates showed an annual increase of 37.7% (95%CI:8.1-75.3%). The data mining approach identified a total of 109 safety signals, affecting 22 system organ classes (SOC). Of these signals, 30% were manifested in the package insert, and the rest 70% represented novel safety signals. Gastrointestinal disorders emerged as one of the primary sets of safety signals, comprising 22 signals and 43% of the total ADR reports for VD. Eructation, constipation, diarrhea, and abnormal product taste were detected by all nine methods. The first three signals have been already listed in the product information, whereas abnormal product taste has not been previously reported in the package insert.
Conclusions: Despite that VD brings clinical benefits, the increasing trend of ADR calls for additional investment on its safer use in the real world settings. Newly detected safety signals have the potential to improve informed clincal decisions.

P365

Bisphosphonates' Impact on Pain and Quality of Life in Osteoporosis Patients

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Introduction: Osteoporosis is a significant cause and consequences of morbidity and mortality in the elderly and an important public health issue. Bisphosphonates are the primary treatment options for osteoporosis. The administration of bisphosphonates may show better treatment efficacy, but less is known about its impacts on health-related quality of life (HRQoL), and whether the anti-osteoporosis treatment can improve HRQoL of osteoporosis patient.
Aims: We have carried out a meta-analysis to evaluate the efficacy of Bisphosphonates treatment for osteoporosis and its impact on pain and HRQoL.
Methods: Randomized controlled trials with Bisphosphonates treatment for osteoporosis were retrieved from PubMed, EMBASE and clinicaltrials.gov. The risk ratio with 95% confidence interval (RR, 95% CI) was calculated to evaluate the effect of Bisphosphonates treatment on incidence of fracture. Data on changes in HRQoL following Bisphosphonates treatment was also extracted. SPSS software was used for all the statistical analyses.
Results: Effective anti-osteoporotic drugs could improve HRQoL. After receiving treatment, patients had a significant improvement in their health conditions. The mean increases in mental component scores were 2.43 (95% CI: 1.71–3.03) and 2.52 (95% CI: 1.75–3.07), respectively, with an increase of 4.48 (95% CI: 3.71–5.25) or 4.53 (95% CI: 3.74–5.19) in the physical component scores
Conclusion: Our meta-analysis showed that Bisphosphonates treatment is beneficial to improve HRQoL of osteoporosis.

Keywords: Bisphosphonates; Quality of Life; Osteoporosis.

P366

Utilization of romosozumab in osteoporosis patients: A real-world evidence from Taiwan

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Introduction:
Osteoporosis is the most valued health issue in post-menopausal women. A new type of monoclonal antibody that binds and inhibits sclerostin, romosozumab, was approved by FDA. However, evidence about long-term utilization of romosozumab was limited in Asian population.
Aims:
This study aimed to analyze percentage change of bone marrow density (BMD) and prescription pattern of postmenopausal women receiving romosozumab.
Methods:
This was a retrospective observational study by using Chang Gung Research Database, which covers eight hospitals from different areas in Taiwan. Postmenopausal women with osteoporosis who received romosozumab for 12 months from November 2021 to March 2024 were included. The primary outcome was the percent change from baseline BMD of the spine and left hip. Paired-t test was applied to analyze the BMD change. Secondary outcomes were the prescribing pattern before and after using romosozumab. Baseline characteristics such as age, comorbidity, biochemical data, previous medication records and BMD were also collected.
Results:
A total of 397 patients were enrolled with the mean age of 75.6±9.6 and eGFR of 73.1±41.3. Baseline BMD of spine and left hip were 0.65±0.17 and 0.62±0.10, respectively. The percentage changes of BMD from baseline at the spine and left hip were both significantly increased (spine: 19.9%, 95% confidence interval [CI]: 10.0 – 29.9%; left hip: 2.5%, 95% CI: 0.1 – 5.1%). 33% of patients never use any medication before romosozumab and 30% of patients used denosumab as prior treatment. After receiving 12 months of romosozumab, 53% and 26% patients shifted their treatment to denosumab and bisphosphonate, respectively.
Discussion:
This study showed romosozumab was associated in increasing BMD at both spine and hip, and the percentage change from BMD baseline at spine was greater than hip. The results were also similar with previous pivotal trials and offered the effectiveness of real-world romosozumab utilization among Taiwanese patients.

[Others]

P367

Renal Outcomes and Mortality in DME: Aflibercept vs. Ranibizumab

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Introduction
Diabetic macular edema (DME) is a leading cause of vision impairment among diabetics. Evaluating the safety of treatments like aflibercept and ranibizumab, especially regarding renal side effects, is critical due to the high prevalence of kidney complications in diabetics.

Aims
This study compares the incidence of renal side effects—acute kidney injury (AKI) and end-stage renal disease (ESRD)—and all-cause mortality between DME patients treated with aflibercept versus ranibizumab.
Methods
We conducted a retrospective cohort analysis using the Global Collaborative Network's data on 12,628 DME patients. The groups analyzed included 9,206 patients receiving aflibercept and 3,422 on ranibizumab. Propensity score matching was used to equalize baseline characteristics across groups, including demographics and clinical profiles. The incidence of AKI, ESRD, and mortality were assessed through Kaplan-Meier survival analysis, and hazard ratios (HRs) with 95% confidence intervals (CIs) were computed to compare risks.
Results
Post-matching, each cohort consisted of 3,182 patients. The HR for ESRD was 1.032 (95% CI: 0.898-1.187, p = 0.653), indicating no significant difference between treatments. Similarly, the HRs for AKI and mortality were 0.979 (95% CI: 0.892-1.075, p = 0.660) and 0.987 (95% CI: 0.884-1.101, p = 0.811) respectively, showing no significant differences.
Conclusions
The study revealed no significant differences in the risk of renal side effects or mortality between aflibercept and ranibizumab treatments in DME patients. Both medications have comparable safety profiles regarding renal outcomes and survival. This supports flexible treatment choice based on other patient-specific factors. Further studies are recommended to investigate additional treatment efficacy and safety aspects.

P368

CFTR modulators for patients with cystic fibrosis: A Bayesian Network Meta-analysis

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chapter award – First place (2021-22)

Introduction
The development of CFTR modulators (correctors and potentiators) emerged as a promising approach, aiming to restore CFTR protein function. A lack of head-to-head randomized clinical trials (RCTs) comparing CFTR modulators leaves uncertainty regarding optimal treatment.

Aim
To estimate the relative efficacy and safety of CFTR modulators for patients with cystic fibrosis who have a phe508del CFTR mutation.

Methodology
We conducted an extensive literature search for randomized clinical trials (RCTs) in PubMed, EMBASE, Scopus, and Ovid from inception until December 2023. Eligible studies included any CFTR modulators for the treatment of children and adults with a confirmed diagnosis of cystic fibrosis with phe508del CFTR mutation. Two reviewers independently and in duplicate performed study selection, data extraction, and quality assessment. We performed a random effect Bayesian network meta-analysis (NMA) for each outcome using the gemtc package in R. Primary outcomes were change in ppFEV1, sweat chloride, CFQ-R score, and serious adverse events. The confidence in the NMA (CINEMA) framework was utilized to determine the certainty of evidence.

Results
23 studies involving 4296 patients examining 22 treatment strategies and placebo were included. Most studies were conducted for adults receiving 4 to 8 weeks of therapy. Vanzacaftor 10mg-Tezacaftor 100mg-Deutivacaftor 150mg combination therapy was superior to placebo (MD, 15.9; 95% CrI: 7.5-24.1; high certainty]) with SUCRA of 89.5% suggesting the highest probability of improving ppFEV1. Compared to placebo, Bamocaftor 400mg-Tezacaftor 100mg-Ivacaftor 150mg showed a significant reduction in sweat chloride (MD, -53.6-point reduction; 95% CrI: -64.8- -42.5; high certainty) and Vanzacaftor 20mg-Tezacaftor 100mg-Deuticaftor 150mg showed a significant improvement in CFQ-R score (MD, 27.9; 95% CrI: 15.9- 39.8; high certainty]. Safety analyses were limited by low event rates.

Conclusion
This NMA indicated that Bamocaftor-Tezacaftor-Ivacaftor and Vanzacaftor-Tezacaftor Deutivacaftor combination therapies were more effective for up to 4 to 8 weeks for treating adult patients with cystic fibrosis.

P369

Comparative Assessment of Pharmacoepidemiological studies of Rare Diseases in Japan and India

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Introduction: Rare diseases pose significant challenges to the global healthcare system due to criticality and lack of treatments. The quality of healthcare varies across countries making it difficult to undertake coherent approach to treatment management. Pharmacoepidemiological studies are crucial in understanding the real-world effectiveness and safety of rare disease treatments. This review explores the current landscape of these studies to identify key differences in treatment availability, health outcomes, and ways to improve healthcare for rare disease patients.

Aim
- Comparative assessment of orphan drug utilization studies in Japan and India
- Identifying best practices and areas of cross-adoption and collaboration to improve rare disease management

Methods: Literature focusing on pharmacoepidemiological studies in Japan and India were identified by searching scientific databases using combination of related keywords. Literature with information about orphan drugs and references to overall conduct, challenges, and best practices regarding pharmacoepidemiological studies were considered for the final review.

Results: Rare disease prevalence estimates vary between Japan and India. Japan's disease registry system (RADAR-J) is well established with various data sources for pharmacoepidemiological data, whereas registry in India (NRROID) is under development. Japan's orphan drug regulatory framework enables streamlined drug approval but available therapies are limited. A targeted orphan drug regulatory framework and classification system is absent in India and drug availability is limited. Pharmacoepidemiological data is widely incorporated in orphan drug development lifecycle in Japan, while in India focus is on case reports and small-scale observational studies.

Discussion: Understanding orphan drug utilization patterns and treatment outcomes based on pharmacoepidemiological data is key to identifying areas for improvement, and promoting adoption of best practices and collaboration. This will help in design and development of treatments to improve rare disease management and optimize orphan drug availability and usage across Japan and India.

Keyword: Registry, Comparative Assessment, Rare disease, India, Japan

P370

Efficacy and safety of stem-cell therapy in patients with muscular dystrophy

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Introduction: With a dramatic expansion in stem cell research, there is a conflict in the literature about whether stem cell therapy is effective and safe in muscular dystrophies.
Aims: We performed a systematic review to assess the efficacy and safety of stem cell therapy in muscular dystrophies and make recommendations for use in clinical settings.
Methods: An electronic search on Cochrane Library, Embase, PubMed, and Web of Science from inception to August 2023 to identify randomised controlled trials(RCTs) on the efficacy and safety of stem cell therapy compared to usual care in MD. Improvement in functional composite (using PUL), beyond 6-mo of treatment were the efficacy outcomes, while occurrence of treatment-emergent adverse events(TEAEs) were the safety outcomes. The Risk of Bias version 2 tool was applied for quality assessment of individual study, while GRADE for certainty assessment of individual outcome. The pooled estimates were reported as either as mean-difference(MD) or risk-ratio(RR) with 95% confidence interval(CI) and heterogeneity (I2).
Results: Three RCTs on Duchenne Muscular Dystrophy(DMD) with low risk of bias were included. The estimates of PUL 1.2 in HOPE-trial reported the overall unfavourable changes with intracoronary infusion of CAP-1002 as compared to usual care at 6(MD:-6.27; 95%CI:-14.15 to 1.61) and 12(-2.74; 95%CI:-7.68 to 2.20) month from baseline. However, the HOPE-2 trial reported the favourable changes with intravenous CAP-1002 in PUL 1.2(Least square mean(LSM):29.7; 95% CI:5.7 to 53.7; p=0.02) and PUL 2.0(LSM: 28.8; 95% CI: 1.5 to 56.1; p = 0.04 scores at 12-month from baseline. The pooled estimates of occurrence of serious AEs were not statistically significant(RR:3.22; 95%CI: 0.56-18.47; I2:0%).
Discussion: Considering a small number of RCTs, heterogeneity and low certainty of evidence, our systematic review suggests that stem cell therapy may have little to no difference in clinical improvement and quality of life in persons with muscular dystrophies.

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Evaluation of treatment efficacy, risk factors in paraquat poisoning: a decade-long study

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Introduction: Acute paraquat poisoning is a global health concern due to high mortality rate. Absence of an antidote or treatment guideline, poorly understood regimens of newer extra-corporeal removal (ECR) techniques further complicate patient prognosis. Thus, there is a need to identify optimal management strategies in acute paraquat poisoning for improving patient outcomes.
Aims: To investigate the clinical characteristics, treatment efficacy and factors affecting clinical improvement in patients admitted with acute paraquat poisoning.
Methods: The medical records of 222 patients admitted with acute paraquat poisoning from 1st January, 2012 to 1st March, 2023 were retrospectively reviewed. Patients were classified into two treatment groups, ECR group and Non ECR group. Primary outcomes were clinical improvement and clinical non-improvement. Secondary outcomes were days of hospitalisation, intensive care and mechanical ventilation. Chi square test was used to compare categorical variables and binary logistic regression was used to assess association of factors with clinical non-improvement. Statistical analysis was performed using SPSS software.
Results: A total of 139 (62.6%) males and 83 (37.4%) females with a median (IQR) age of 25 (11) years were included. The clinical non-improvement rate was 60.4% (n = 134). There was no significant difference between the ECR and Non-ECR treatment groups in terms of clinical improvement (p=0.88). Variables significantly associated with clinical non-improvement were mechanical ventilation (OR: 0.003; p<0.001) and development of multi-organ dysfunction syndrome (MODS) (OR: 0.081; p=0.012).
Conclusion: There was a significantly higher incidence of clinical non-improvement in cases with acute paraquat poisoning. Management approaches including ECR techniques did not significantly improve clinical outcome. Mechanical ventilation and development of MODS were associated with clinical non-improvement.
Keywords: paraquat poisoning, improvement, extra-corporeal removal, treatment

P372

Impostor syndrome prevalence and factors among northern thai university students

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Introduction: Impostor syndrome involves doubting one's accomplishments and feeling self-conscious about abilities, often rooted in low self-worth, upbringing, and aspirations for success. This condition affects both health and work performance and may lead to additional health issues.
Aim/Objective: To investigate the prevalence of impostor syndrome among undergraduate students and associated factors.
Method: Undergraduate students participate in this cross-sectional study design by completing an online self-report questionnaire between August and December of 2023. The Impostor syndrome was measured by the Clance Impostor Phenomenon Scale (CIPs) consists of twenty items, each of which is rated from 1 (not at all true) to 5 (extremely true) on a Likert scale. Total score of 60 or more shows the presence of impostor syndrome, whereas a score of less than 60 indicates the absence of impostor syndrome. Stata version 14 was used for data analysis; multivariable logistic regression was used to find association between impostor syndrome and the factors including gender, age, education year, income and satisfaction with GPA.
Results: Three hundred and twenty-two students completed the questionnaire; 66.7% were female; 52.5% were 20 years old; 33.5% were the second-year students. According to CIPs: 71.7% had impostor syndrome and 28.3% had no impostor syndrome. There was no statistically significant relationship between impostor syndrome and the variables including gender, age, years, income and satisfaction with GPA ($p>0.05$).
Conclusion: The prevalence of impostor syndrome was around 72%. Moreover, there was no significant association between associated factors and impostor syndrome.

P373

Indian traditional preparation of Liquorice in the post-operative pain management of haemorrhoids

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Introduction: Tissue damage is common during the surgical and Para surgical procedures because of which general post-operative complications like pain, inflammation, burning sensation, bleeding, etc. may occur. Ayurveda has explained about application of Liquorice (Glycyrrhiza glabra) Ghee preparation to reduce the pain, inflammation, burning sensation, bleeding pain caused by the surgery of haemorrhoids.
Aim: To evaluate and validate the suppositories of Liquorice preparation in Human subjects through an open labelled controlled randomized clinical study.
Methods: Total number of 40 Subjects suffering from Haemorrhoids were selected for the study and were randomly allotted into two groups namely Group-A and Group-B with 20 in each group. Subjects with Group-A were treated with Liquorice Ghee in the form of suppositories and Subjects of Group-B were treated with Diclofenac-sodium suppositories. Distribution of age gender, occupation, diet, appetite, age of haemorrhoids, bowel habit, nature and type of pain were recorded.
Results: Comparative analysis of effect of treatment on burning sensation, size, color and shape of wound, between Group A and Group B, the results of Group A (Liquorice treated) were statistically highly significant (P value <0.001). Further moderate improvement was observed on 4th day, marked improvement was seen after 5th day and maintained at follow up. Notably, Liquorice suppositories are on par with Diclofenac sodium suppositories in mitigating the pain. Whereas results of treatment on bleeding between Group A and Group B, was found to be statistically insignificant. It was found that Liquorice suppositories is the best line of treating post operative haemorrhoids. Group-A has better effects on the wound healing, burning sensation and bleeding.
Discussion: Group-A has better effect because of Liquorice suppositories which has analgesic, wound healing properties. It also contains phytochemicals which have anti-inflammatory properties. Most importantly, Liquorice preparation in Ghee increases the bioavailability of Liquorice extract.

P374

Isolation and quantification of miRNAs from the human saliva

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Introduction

Head and neck cancers (HNCs) are among the most prevalent malignancies in India, significantly contributing to cancer-related morbidity and mortality. Oral premalignant disorders (OPMDs) increase the risk of developing HNCs. Early detection of potential malignancies can improve prognosis; however, current diagnostic methods are expensive, invasive, and require highly skilled professionals. Micro-RNAs (miRNAs) play a fundamental role in oncogenesis pathways, and their elevated expression has been investigated as a potential early diagnostic tool.

Aim

This study aims to identify expression changes of miRNA-21 and miRNA-31 in patients with OPMDs.

Methods

The study involved testing the saliva of 25 patients with OPMDs (study group) and 25 healthy individuals (control group). miRNAs were isolated from saliva samples using miRNA isolation kits and quantified using reverse-transcriptase polymerase chain reaction (RT-PCR).

Results

Compared to the control group, patients with OPMDs showed significantly higher expression levels of miRNA-21 and miRNA-31. The mean expression levels of miRNA-21 were 3.5 times higher in the study group compared to the control group ($p<0.001$). Similarly, the mean expression levels of miRNA-31 were 4 times higher in the study group ($p<0.001$). These findings indicate a strong correlation between elevated miRNA expression and the presence of OPMDs.

Discussion/Conclusion

The elevated expression of miRNA-21 and miRNA-31 in patients with OPMDs suggests a higher likelihood of developing malignant conditions in the future. These miRNAs can serve as potential biomarkers for early detection of malignancies in patients with OPMDs. Further optimization and detailed research on this procedure can help identify individuals with OPMDs who are at higher risk of developing malignancies. Early detection of potential malignancies can significantly improve prognostic outcomes for these patients. Developing non-invasive early diagnostic techniques can revolutionize cancer detection and diagnosis, leading to better clinical management and reduced healthcare costs.

P375

Post-marketing safety of ustekinumab for psoriasis based on 14-year follow-up in Danish national patient data

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Introduction. Psoriasis, a chronic inflammatory skin disorder affecting many globally, often requires systemic treatments such as biologics. The long-term safety of interleukin (IL) inhibitors like ustekinumab remains uncertain due to limited follow-up in existing studies. Comprehensive long-term safety data are essential for managing chronic conditions like psoriasis.
Aims. This 14-year cohort study, using Danish national register data, aimed to investigate the long-term safety profile of ustekinumab concerning malignancies, major adverse cardiovascular events (MACE), serious infections, and serious hypersensitivity reactions compared to other systemic psoriasis treatments.
Methods. Utilizing Danish national register data, this study examined patients diagnosed with psoriasis (PsO) or psoriatic arthritis (PsA) treated with ustekinumab. Comparators included non-biological systemic treatments (non-biologic), tumor necrosis factor α inhibitors (TNF-α), IL-17 inhibitors (IL-17), and IL-23 inhibitors (IL-23). Study periods were 2009-2022 for non-biologic and TNF-α, 2015-2022 for IL-17, and 2018-2022 for IL-23. Patients with prior malignancies or MACE were excluded. An active comparator new user (ACNU) design with propensity score matching was used, and Cox proportional hazards regression models analyzed intention-to-treat (ITT) and continuous-index-treatment (CIT) estimands.
Results. Ustekinumab users averaged 45.1 years in age, younger than other groups. Males constituted 57.3% of the ustekinumab group. Hazard ratios indicated no elevated risks for malignancies excluding non-melanoma skin cancer (NMSC) (HR 1.36, CI 0.95-1.94), NMSC (HR 0.97, CI 0.61-1.53), MACE (HR 1.32, CI 0.86-2.02), or serious infections (HR 0.69, CI 0.23-2.05) compared to other treatments. Subgroup analyses by PsA status showed similar safety outcomes across all groups.
Discussion. This study found ustekinumab to be safe regarding malignancies, MACE, serious infections, and serious hypersensitivities over a 14-year follow-up in Danish psoriasis patients. Strengths include extensive follow-up and comprehensive data, ensuring no loss to follow-up. However, reliance on hospital-based diagnoses and potential registration discrepancies may bias results, and limited follow-up for IL-23 restricted some analyses. Overall, ustekinumab showed a favorable safety profile compared to other treatments.

[Pediatrics]

P376

Assessing the association between the combination use of diuretics and the risk of PDA-ligation among PDA infants

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Introduction. This study aims to evaluate the risk of PDA-ligation from combining furosemide with NSAIDs, focusing on NSAIDs' renal side effects in PDA infants, often requiring diuretics to manage decreased urine output.
Methods. Data were sourced from the National Health Insurance Research Database provided by the Health and Welfare Data Science Center of the Ministry of Health and Welfare of Taiwan. The study population included infants under one year old diagnosed with PDA between January 1, 2008, and December 31, 2017, identified based on hospitalization diagnoses within one month after birth. The population was divided into exposed and control groups based on furosemide use: the exposed group received at least one oral or intravenous furosemide within one month of birth and combination treatment with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). The control group consisted of infants treated solely with NSAIDs for PDA. The date of birth served as the index date, used to track PDA diagnosis and surgery. Infants were monitored from one month post-birth to one year to determine if they underwent PDA-ligation.
Propensity score matching was employed in a 1:1 ratio to address potential confounding factors such as weight, gestational age, degree of prematurity, and other diuretic agents. Multivariable logistic regression analysis was performed to evaluate the association between combined furosemide use and the risk of PDA-ligation.
Results. We identified 1,153 infants with PDA, 718 (62.3%) in the exposure group. Among these, 292 underwent PDA-ligation, including 269 from the exposure group. Combined furosemide and NSAIDs treatment significantly increased the risk of PDA-ligation (aOR = 3.45, 95% CI = 1.93-6.15). Survival analysis was not applied because the hospitalization records did not consistently specify the exact dates of surgery.
Discussion. This study found that combining furosemide and NSAIDs for PDA treatment in Taiwanese infants increased the likelihood of requiring PDA-ligation. Therefore, it is recommended to avoid combining furosemide with NSAIDs during PDA treatment unless necessary to minimize the risk of PDA treatment failure.

P377

Prolonged off-label antipsychotic therapy and cardiometabolic outcomes in children: a systematic review

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Introduction: Antipsychotic use for non-psychotic illnesses including anxiety, aggression, eating disorders, and behavioural and mood disorders is on the rise among children and adolescents. Paediatric antipsychotic treatment may be prescribed at low doses for many years along with psychotropic comedication, which is a cause for concern since safety issues have not been adequately examined in this situation.
Aims: This systematic review was conducted to investigate the cardiometabolic safety of prolonged antipsychotic use in this population with non-psychotic disorders.
Methods: A systematic search of six electronic databases was carried out. Both randomised clinical trials and observational studies with a duration of at least a year among patients aged 18 years or younger were included. Outcomes studied were hyperglycemia, dyslipidemia, hypertension, weight gain, metabolic syndrome, ischemic heart disease, and thrombosis, and any comparator was allowed. Both continuous and dichotomous measures were captured. Clinical heterogeneity necessitated data synthesis through a vote counting method and creation of an effect direction plot.
Results: There were 15 observational studies with 114,141 participants (mean age 10.93 years, 83.5% males); no clinical trials fulfilled the eligibility criteria. Autism and Tourette syndrome were studied in two-thirds of the studies. Prolonged antipsychotic treatment was associated with hyperglycemia (100%, n=6), metabolic syndrome (100%, n=2), weight gain (91.6% studies, n=12) and dyslipidemia (66.6%, n=6) as shown by the effect direction plot. Results were inconclusive for hypertension while no studies investigated ischemic heart disease or thrombosis. All studies were of moderate to high methodological quality.
Conclusions: Prolonged antipsychotic exposure in children, who are still undergoing physiological development, has the potential to disrupt metabolic processes that can have lasting repercussions. It is crucial that healthcare providers give careful consideration to safety issues in their approach to antipsychotic prescription in children and initiate metabolic monitoring in a proactive manner.

P378

Evaluating the Prognostic Value of the Status Epilepticus Severity Score in Children

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Introduction: The Status Epilepticus in Pediatric patients Severity Score (STEPSS) has been utilized to assess treatment outcomes in children with status epilepticus (SE).
Aims: This study aims to investigate the diagnostic value of STEPSS in predicting the survival outcomes in SE patients.
Methods: A comprehensive meta-analysis was conducted to address this objective. Pooled sensitivity, specificity, positive likelihood ratio (PLR), negative likelihood ratio (NLR), diagnostic odds ratio (DOR), area under the curve (AUC), Relative Risk (RR) and corresponding 95% confidence intervals (95% CI) were calculated. Subgroup analysis, meta-regression analysis and the Deek's plot were used to evaluate heterogeneity.
Results: Eight articles, comprising 918 SE patients, conformed to the inclusion criteria. The literature exhibited non-threshold effect-caused heterogeneity. Pooled sensitivity and specificity, calculated by a random-effects model, were 0.82 (95% CI: 0.71,0.90, Q = 0.12, I2 = 23.21) and 0.78 (95% CI: 0.70,0.85, Q = 60.71, I2 = 88.47), respectively. The DOR was 18 (95% CI: 8,43), and the Summary Receiver Operating Characteristic Area Under the Curve (SROC-AUC) was 0.85. The pooled result of RR showed that the accuracy of using STEPSS for SE diagnosis was 10.74 times higher than without using it (RR = 10.74, 95% CI: 6.12,18.86, I2 = 35.6). Subgroup and meta-regression analysis pinpointed geographical location (specifically, China) as a potential heterogeneity source. Deek's funnel plot did not reveal any obvious asymmetry. Discussion: Our evidence suggests moderate support for the efficiency of STEPSS in diagnosing the condition in pediatric patients with SE.

[Polypharmacy]

P379

A Pharmacist-Led Study on Utilization Patterns of Paliperidone in Polypharmacy Patients

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Introduction: Paliperidone, an antipsychotic used for schizophrenia and schizoaffective disorder, presents challenges in patients on multiple medications (polypharmacy). Real-world data on its use in this group is limited. This pharmacist-led study addresses this gap by investigating paliperidone utilization patterns in polypharmacy patients, aiming to optimize medication use and improve patient outcomes.
Aim: To investigate the utilization patterns of paliperidone and identify factors associated with polypharmacy among patients receiving paliperidone in a tertiary care hospital setting.
Methods: This was a pharmacist-led, retrospective study conducted in the department of psychiatry at a tertiary care hospital over 6 months. The data on utilization patterns of paliperidone was obtained using medical health records of psychiatric patients dispensed with paliperidone. Data on demographics, comorbidities, medications, and prescriptions of paliperidone were collected. Descriptive statistics were used to find the association between prescribing patterns and demographic characteristics.
Results: A total of 110 patients dispensed with paliperidone were observed in the study. Demographic characteristics used in the study were age, gender, and co-morbid conditions. Among 110 patients majority were male (70, 63.6%) and had a mean age of 25.6±4.6 years. Out of 110 patients, 45 (40.9%) patients were on polypharmacy with a higher prevalence of males (29, 64.4%). Among 45 patients dispensed with paliperidone were associated with the following co-morbid conditions 14 depression (31.1%), 31 bipolar disorder (68.8%), and 17 generalized anxiety disorder (37.7%) conditions.
Discussion: These findings underscore the importance of further research on paliperidone use in a population with schizophrenia. The high prevalence of polypharmacy and the dominance of bipolar disorder as a comorbidity necessitate further investigation to refine treatment strategies and improve patient outcomes in the population.

Keywords: Paliperidone, Patterns, Patients, Polypharmacy

P380

An Ecological study on Polypharmacy and Dementia using NDB open data Japan

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Introduction:
Japan population is aging at the highest rate in the world. Elderly patients often have multiple comorbidities, leading to polypharmacy. Polypharmacy seems to be associated with various problems such as increased risk of adverse events, decreased adherence, and cognitive impairment.
Aims
This study aimed to analyze the correlation between polypharmacy and dementia using National Database of Health Insurance Claims and Specific Health Checkups of Japan (NDB) Open Data in 2020.
Methods
The NDB, Japan's national health insurance claims database, covers most reimbursement claims. In this study, aggregate data by gender, age, or prefecture of NDB and data from the patient survey by the Ministry of Health, Labour and Welfare were used. Polypharmacy was defined as the number of prescriptions for seven or more medications per prescription in the NDB open data. Dementia was defined as the estimated number of patients with "vascular and unspecified dementia" and "Alzheimer's disease" in the patient survey. We conducted a correlation analysis between polypharmacy and the number of patients with dementia adjusted for gender and age. Additionally, we stratified the analysis by the median prescription amount of lifestyle-related disease (hypertension, dyslipidemia, and diabetes) medications.
Results
Polypharmacy was significantly associated with a higher prevalence of inpatients with dementia ($r = 0.644$; $p < 0.001$). There was no correlation between polypharmacy and outpatients with dementia ($r = -0.010$; $p = 0.947$). A positive correlation between polypharmacy and inpatients with dementia was shown in each region stratified by lifestyle-related disease medications ($r = 0.646$; $p < 0.001$, $r = 0.711$; $p < 0.001$ for high and low prescription regions, respectively).
Discussion/Conclusion
A positive correlation was found between polypharmacy and inpatients with dementia, suggesting polypharmacy is associated with the risk of developing more severe dementia. Appropriate intervention is required for medication therapy in the elderly.

P381

Associations of polypharmacy with oral microbiome in US middle-aged and older adults

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Introduction: Previous studies have shown that polypharmacy may influence the composition of the gut microbiota. However, the potential impact of drug interactions with the oral microbiome remains uncertain.
Aims: The aim of this study was to investigate the potential association between polypharmacy and the oral microbiome.
Methods: Participants who were 55-79 years old and took at least one prescription medication from the National Health and Nutrition Examination (2009-2010, 2011-2012) were included in the cross-sectional study. The concurrent use of 5 or more medications was defined as polypharmacy. Alpha diversity (within-sample richness and phylogenetic diversity) was measured with metrics including observed OTUs, Faith's Phylogenetic Diversity, the Shannon-Weiner index, and the Simpson index. Beta diversity (heterogeneous dispersion of oral microbiome community) was measured between all pairs of samples with metrics including unweighted UniFrac, weighted UniFrac, and Bray-Curtis dissimilarity. Weighted multivariable linear regression, principal coordinate analyses (PCoA) and multivariate analysis of variance (PERMANOVA) were employed to examine the association between polypharmacy and oral microbiome composition.
Results: Of 1,658 participants assessed, 562 were taking 5 or more medications (weighted percentage, 29.5%). After adjustment for covariates, multivariable linear regression revealed a significant negative correlation between polypharmacy and alpha diversity. The weighted β-coefficient and 95% confidence interval of polypharmacy were -8. 342(-12.487, -4.197), 0.566(-0.944, -0.189), and -0.126(-0.221, -0.030) for observed OTUs, Faith's Phylogenetic Diversity, and the Shannon-Weiner index, respectively. PCoA analysis showed a significant differentiation of oral microbiome community based on the prevalence of polypharmacy as measured by Bray-Curtis dissimilarity (R2=0.299%, P<.001), unweighted UniFrac distance (R2=0.247%, P<.001), and weighted UniFrac distance (R2=0.215%, P<.001).
Conclusion: In the middle-aged and older Americans adults, polypharmacy is associated with both oral microbiome alpha diversity and beta diversity. Further longitudinal studies are required to substantiate the impact of polypharmacy on the dynamics of the oral microbiome.

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Cardiovascular related polypharmacy and its association with liver and kidney function

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Introduction:
Most individuals with increased cardiovascular (CVD) risk require concurrent treatment with multiple medications, which may lead to polypharmacy.

Aim:
This study aimed to identify CVD risk factors associated with CVD-related polypharmacy and to investigate the association between CVD-related polypharmacy and the presence of liver and kidney dysfunction among patients receiving lipid-lowering therapy within the Australian primary care setting.

Methods:
Electronic medical records for adults prescribed lipid lowering therapy between January 2013 and December 2022 were utilised. A multi-logistic regression adjusted for risk factors (age, sex, smoking, diabetes, hyperlipidaemia, hypertension and chronic kidney disease (CKD)) was used to identify factors associated with CVD-related polypharmacy and with liver and kidney dysfunction. Liver dysfunction was defined as exceeding established reference ranges for alanine aminotransferase (ALT), aspartate aminotransferase (AST), and bilirubin levels, while kidney dysfunction was defined based on the estimated glomerular filtration rate (eGFR) as per the Australian guidelines.

Results:
Of 13,568 study participants (median age: 63 years, 54% males), 33.73% had CVD-related polypharmacy. Risk factors associated with CVD-related polypharmacy included diabetes (Odd ratio (OR)=5.40, 95% CI: 4.96-5.93), CKD (OR=2.39, 95% CI: 2.00-2.86) and hypertension (OR=1.91, 95% CI: 1.75-2.07). Compared to the 18-35 age group, individuals aged ≥80 years demonstrated a significantly higher association of CVD-related polypharmacy (OR=8.17, 95% CI: 5.47-12.21). CVD-related polypharmacy was not significantly associated with liver dysfunction (OR=1.19, 95% CI: 0.59-2.37) but was significantly associated with kidney dysfunction (OR=1.45, 95% CI: 1.30-1.62).

Conclusion:
Findings indicate a potentially heightened risk of polypharmacy which may lead to medication-related complications and adversely affect renal function. Comprehensive medication management and multidisciplinary-care are essential for the prevention of potential polypharmacy-related harm.

[Pregnancy and Maternal Health]

P383

Access to Contraceptives and Abortion Medications in High Income and LMICs

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Introduction: Retail pharmacies play an important role in promoting access to contraceptive and abortion products in the community. Yet, there is limited information on the availability of contraceptives and abortion products at the country-level, including by product type in retail pharmacies

Aims: We examine the availability of contraceptive and abortion products in retail pharmacies for HICs and LMICs at the regional and country-level between 2015 and 2020.

Methods: We used quarterly pharmacy retail sales data collected from IQVIA™ MIDAS® for 71 countries from January 2015 - September 2020. We report utilization as defined-daily-doses (DDD) per 1,000 women/girls of reproductive age (15-49), per day.

Results: Global contraceptive use declined from 2015 to 2020 (76.3 DDD to 71.9 DDD; $p<0.01$). Oral contraceptives and long-acting reversable contraceptives (LARCs) were substantially higher in HICs compared to LMICs (130.9 DDD vs. 16.8 DDD; 47.1 DDD vs. 0.7 DDD). Utilization of LARCs increased significantly in LMICs (0.2 DDD to 0.7 DDD; $p<0.01$), and emergency contraceptive use remained higher in LMICs compared to HICs (0.40 DDD to 0.18 DDD vs. 0.13 DDD to 0.16 DDD, respectively). Abortion product utilization was more common in LMICs compared to HICs (6.5 DDD vs. 1.2 DDD); use declined substantially over time in HICs (2.3 DDD to 1.2 DDD; $p<0.001$) but increased significantly in LMICs (3.6 DDD to 6.5 DDD; $p<0.001$). There were substantial variation within LMICs at the regional and country-level.

Discussion/Conclusion: There were persistent disparities between HICs and LMICs in contraceptive utilization which may contribute to worsening disparities in reproductive health. Our findings also suggest that LMICs are more likely to rely on abortion medications from retail pharmacies than HICs which may be related to limited access to contraceptives from the public sector.

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Evaluation of the Pregnancy Safety Information of Antineoplastic: The SFDA Experience

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Background
Safety of antineoplastic agents is a crucial issue faced the cancer patients during their treatment, especially for pregnant women and women of childbearing age since they usually excluded from clinical trials during the drug development process. In addition, some antineoplastic drugs remain in the blood at least 6 months after the completion of the therapy.
Objectives
To review the information on the use of antineoplastic agents during pregnancy and lactation in the current Summary of Product Characteristics (SPCs) of antineoplastic agents registered by the Saudi Food and Drug Authority (SFDA).
Methods
First, we identified a list of registered antineoplastic agents. Second, we assessed the current information regarding 'Fertility, Pregnancy, and Lactation ' of product information (PI) by crosschecking the local SPCs with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) PI. The information was assessed and classified as complete or incomplete depending on whether (or not) they provided complete description of medicine use in pregnancy and lactation. Third we conducted a comprehensive safety assessment of the antineoplastic drugs with “incomplete” information and needs further in-depth assessment.
Results
A total of 53 SFDA-registered antineoplastic agents were retrieved based on drug classes (alkylating agents, antimetabolites, and hormone antagonists) which were subjected to an initial review of Fertility, Pregnancy, and Lactation information in their SPCs. We assessed 29 SPCs as incomplete information. Of these, a total of 26 (49%) SPCs of antineoplastic agents have been updated and 3 antineoplastic agents (5.6%) were referred to comprehensive safety evaluation. The comprehensive safety evaluation was closed with no further regulatory action due to limited evidence to draw a conclusion.
Conclusion
Important information on the use of antineoplastic agents during pregnancy and lactation was lacking in the local SPCs. This project shows the importance of monitoring safety information in local PI.

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Impact of severe maternal morbidity on perinatal outcomes in the United States

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Introduction: Severe maternal morbidity (SMM) is critical threat to pregnant women, yet knowledge concerning its impact on perinatal outcomes is sparse.
Aims: To assess the prevalence of SMM in the US and its impact on perinatal outcomes.
Methods: A cross-sectional analysis was conducted on hospitalizations related to pregnancies (HRP) in the US using Healthcare Cost and Utilization Project Nationwide Inpatient Sample (HCUP-NIS) data from 2016-2020. We identified HRP, SMM, maternal physical and mental comorbidities, preterm birth (PTB), spontaneous abortion (SA), and still birth (SB) with ICD-10 codes. Prevalence of having at least one SMM (HALOS) and each of the twenty-one SMM conditions were assessed in total HRPs and across different demographic subgroups. Logistic regression model adjusted for maternal demographics and comorbidities was used to investigate the associations between SMM and each of the four outcomes (PTB, SA, SB, LOS > 2 days).
Results: We identified 19,533,050 HRPs during 2016-2020, among which an increasing trend in prevalence of HALOS was observed (2.3% in 2016 and 2.8% in 2020). During the study period, the general prevalence of HALOS was 2.5% and the most common SMM conditions included blood transfusion (1.3%), sepsis (0.4%), and acute renal failure (0.2%). Higher prevalence of HALOS was found in subgroups of age over 35 (3.1%), Black (4.2%), low-income (3.1%), publicly insured (3.1%) HRPs. Adjusted odds of PTB, SA, SB and LOS > 2 days among HRPs with SMM were 1.13 (95% CI: 1.10-1.16), 7.23 (95% CI: 6.95-7.51), 2.66 (95% CI: 2.55-2.78) and 3.16 (95% CI: 3.12-3.21) times those in HRPs without SMM, respectively.
Discussion: The older, Black, low-income and publicly insured HRPs are more likely affected by SMM. The association between SMM and adverse perinatal outcomes emphasizes the need for interventions in these populations to improve maternal health.
Keywords: Real-world evidence, Maternal health, SMM, Perinatal outcomes

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Infertility-Associated Psychological Stress: Optimizing FertiQoL Threshold Using Machine Learning Versus Biostatistical Models

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Introduction
Infertility, a growing global health concern, causes enormous stresses and substantially affects the quality of life (QoL) for women and their partners. However, evidence regarding the association between psychological stresses and QoL in women undergoing fertility treatments is scare.

Aim
This study assessed the optimal QoL threshold for classifying infertile women experiencing anxiety/depression.

Methods
Study data were collected from 11 hospitals with different accreditation levels in Taiwan during February-July, 2023. Patients' QoL and anxiety/depression were assessed using FertiQoL and PHQ-4, respectively, and repeatedly over fertility treatments. Machine learning (i.e., decision tree [DT] model) and biostatistical (i.e., generalized linear model [GLM]) models were employed to assess the association between the QoL and anxiety/depression of women. Model performance was evaluated using the Youden index (ranging 0 to 1, with higher values indicating better performance).

Results
There were 320 individuals with a total of 444 repeated measurements obtained for analysis. The DT model which considered all FertiQoL sub-items, medical institution types, gender and infertility treatment stages indicated an optimal FertiQoL score threshold of 63.60, with the Youden index of 0.48. The average PHQ-4 scores for individuals with FertiQoL scores< and ≥63.60 were 4.04 (± 2.08) and 1.75 (± 1.59), respectively. Also, the GLM which adjusted individual clinical characteristics selected via stepwise regression analyses determined the optimal FertiQoL threshold score of 69.85, with the Youden index of 0.45. The average PHQ-4 scores for individuals with FertiQoL scores< and ≥69.85 were 3.62 (± 2.10) and 1.55 (± 1.56), respectively.

Conclusion
Both the DT and GLM models yield comparable performance in identifying an optimal QoL score threshold, as supported by similar Youden index scores. Given its operational simplicity and autonomous data adaptation, the ML-based DT model is preferred for determining the best QoL threshold to facilitate timely psychological support and thereby enhance infertility treatment outcomes.

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Inhaled corticosteroids and long-acting beta2-agonists use during pregnancy and adverse fetal outcomes

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Introduction: Continuing controller therapy is necessary for pregnant women with asthma to decrease the risk of asthma exacerbation during pregnancy. However, existing evidence regarding the effects of inhaled corticosteroids (ICS) and long-acting beta2-agonists (LABA) on adverse fetal outcomes was less and old.
Aims: This study was to update and comprehend safety evidence on ICS and LABA use among pregnant women with asthma. The ICS use, the ICS dose-response effects, and the add-on therapy with LABA during pregnancy were investigated.
Methods: A population-based retrospective cohort study was conducted. The Health and Welfare Database, Birth Certificate Application, and Maternal and Child Health Database in Taiwan were used as data sources. Pregnant women with asthma who delivered babies between 2009 and 2017 were enrolled. Three independent variables, ICS, ICS dose-response effects, and LABA use during pregnancy, were evaluated separately. Adverse fetal outcomes included low birth weight, small for gestational age, preterm birth, and congenital anomalies. Propensity scores matching (PSM) and inverse probability of treatment weighting (IPTW) were used to adjust confounders, including socio-demographics, comorbidities, comedications, and asthma severity. Logistic regression models were used to calculate the adjusted odds ratio (aOR).
Results: There were 4,538 pregnant women with asthma enrolled. After PSM and IPTW, neither ICS nor LABA was significantly associated with any adverse fetal outcome. However, high-dose ICS users had a significantly higher risk of congenital anomalies (aOR: 4.46; 95% CI: 1.45-13.71) within 90 days of delivery and congenital anomalies (aOR: 3.87; 95% CI: 1.29-11.60) within one year of delivery than low-to-moderate ICS users.
Discussion: This study did not identify the increased risk of adverse fetal outcomes among ICS or LABA users during pregnancy. Nonetheless, a higher risk of congenital anomalies was observed among high-dose ICS users. Pregnant women who need high-dose ICS should be closely monitored.
Keywords: corticosteroid, long-acting beta2-agonist, pregnancy, asthma

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Maternal and Neonatal Adverse Events of Oral Anti-hypertensives in Pregnancy: Disproportionality Analysis

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Introduction: Oral anti-hypertensives are acceptable first-line agents for treating Hypertensive disorders of pregnancy (HDP) in outpatient settings. However, the maternal and neonatal safety of these drugs remains unclear.
Aim: To identify the safety signals of oral anti-hypertensive medications used in pregnancy related to neonatal and maternal adverse events
Methods: We carried out a retrospective case/non-case study using spontaneous reports in the FDA Adverse Event Reporting System (FAERS) from the date of approval by the FDA to 30th December 2023. The study employed a disproportionality analysis, calculating the Proportional Reporting Ratio (PRR), Reporting Odds Ratio (ROR), and Information Component (IC) to identify safety signals related to neonatal and maternal safety adverse events (if PRR ≥ 2, Lower Bound (LB) ROR > 1, and IC025 > 0) for anti-hypertensive drugs during the pregnancy. We also performed a signal refinement analysis by eliminating the confounding co-prescribed medications to identify the robustness of the findings.
Results: Using disproportionality analysis, 46 neonatal safety (Labetalol=27, Nifedipine=18, Amlodipine=1, Methyldopa=8, and hydralazine=2) signals of considerable strength such as neonatal respiratory distress syndrome and neonatal respiratory failure signals were observed for labetalol [PRR=27.4 ($\chi2$=849.7), (LB)ROR=19.6, IC025=3.8; PRR=15.5 ($\chi2$=40.3), LB ROR=5.0, IC025=0.3], and nifedipine [PRR=14.9 ($\chi2$=802.8), LB ROR=11.6, IC025 =3.3; PRR=10.4 ($\chi2$=58.2), (LB)ROR=4.9, IC025=1.4]. Neonatal Intraventricular hemorrhage identified for methyldopa and amlodipine [PRR=10.4 ($\chi2$=34.0), (LB)ROR=3.9, IC025=0.6; PRR=3.8 ($\chi2$=160.9), (LB)ROR=3.0, IC025=1.5]. Signals of considerable strength in maternal adverse events such as postpartum hemorrhage, pre-eclampsia signals were observed for labetalol [PRR=22.3 ($\chi2$=160.3), (LB)ROR=11.1, IC025=2.1; PRR=91.4 ($\chi2$=10179.8), (LB)ROR=77.2, IC025 =5.7], and nifedipine [PRR=4.7 ($\chi2$=17.5), (LB)ROR=2.1, IC025=0.5; PRR=21.0 ($\chi2$=1791.2); (LB)ROR=17.2, IC025 = 3.9].
Conclusion: Our analysis uncovers notable safety signals for both neonatal and maternal outcomes associated with oral anti-hypertensive medications during pregnancy, which emphasize the imperative for cautious prescription and close monitoring for adverse outcomes in hypertensive pregnant women.

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ORAL ANTI-HYPERTENSIVES IN THE TREATMENT OF PREECLAMPSIA: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Introduction: The use of oral antihypertensives (OAHs) over parenteral drugs in the treatment of preeclampsia is highly controversial. The current meta-analysis would provide conclusive evidence on the safety and effectiveness of OAHs when compared to parenteral drugs.
Aim: To assess the safety and effectiveness of OAHs when compared to parenteral drugs in the treatment of preeclampsia and adverse perinatal outcomes.
METHODOLOGY: A systematic search was conducted in PubMed, Cochrane Central Register of Controlled Trials, and Google Scholar to identify RCTs comparing OAHs with parenteral drugs. The primary outcome was a mean change in systolic and diastolic blood pressure (SBP and DBP, respectively) after one hour of administration. The quality of studies was assessed using the JADAD scale. Pooled odds ratios and standardized mean differences with 95% confidence intervals were calculated using the fixed or random-effects model, which was based on heterogeneity between studies.
Results: 19 RCTs with 2672 participants were included in the meta-analysis. The average reduction in SBP one hour after administration was significantly greater (SMD: -4.95; 95%CI: -7.21, -2.70; P < 0.0001) in patients receiving OAHs. Similarly, the mean reduction in DBP one hour post-administration was also significantly higher (SMD: -4.57; 95%CI: -6.25, -2.89; P < 0.0001) in the OAHs group. The safety of OAHs was assessed, and it was found that there was a reduction in flushing in the OAHs group (OR:0.30; 95%CI: 0.18,0.50; P<0.0001) along with other outcomes such as headache, hypotension, and postpartum haemorrhage even though the statistical significance is not observed. Moreover, fetal outcomes such as fetal distress, APGAR score <7, and perinatal death were found favouring OAH therapy, though not statistically significant.
Conclusion: Our current meta-analysis highlights the efficacy of oral antihypertensive drugs in preeclampsia. OAHs significantly reduce blood pressure with favorable safety profiles and potential benefits for maternal and fetal outcomes.

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Rheumatoid arthritis medications through before pregnancy and after delivery: JMDC Claims database

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Biography:

Aim/Objective:
There is few evidence of rheumatoid arthritis (RA) medications in pregnant although it is broadly known that uncontrolled disease activity during pregnancy poses the risk to pregnancy outcomes and the health of mother and child after delivery. Specifying safety RA medications in pregnant is these women's considerable needs since methotrexate, the anchor drug of RA, is teratogenic in human. Our objective of this study is to evaluate prescription for RA before pregnancy, during pregnancy, and after delivery in Japan.

Methods:
We used JMDC Claims database and estimated pregnant with rheumatoid arthritis. We identified infants born and linked them to their mothers by family identifiers. Next, we defined pregnancy period based on infants born year and month. We used data from pregnancy period and 6 months before and after it according to the previous studies in Japan.

Results:
Totally, 229 pregnancy cases were eligible for study. Percentage of pregnant prescribed RA drugs decreased during pregnancy regardless of drug category. Only 5 cases used Methotrexate until 1st trimester, but all stopped it after. Oral corticosteroids were the most commonly used throughout all periods. Salazosulfapyridine was the second highest percentage in before pregnancy and 1st trimester. However, in 2nd and 3rd trimester, Tacrolimus, Etanercept, and Certolizumab Pegol were more prescribed than Salazosulfapyridine.

Conclusion:
It is written Etanercept and Certolizumab Pegol are less into the fetus in guidelines for pregnant with RA in Japan. In our results, these drugs were more commonly prescribed than other Tumor Necrosis Factor inhibitors during pregnancy. This suggests the guidelines affected to the treatment strategy. In a few years, biologic agents will be more used because the latest guideline for RA (2024) says Tocilizumab and Abatacept are also acceptable for pregnant. We revealed how pregnants treat RA in Japan and provided real-world evidence about RA medications in pregnancy.

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Safety of omalizumab use during pregnancy on neonatal outcomes

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Introduction:
Asthma is prevalent during pregnancy and can adversely affect neonatal health. Omalizumab is an anti-immunoglobulin E (anti-IgE) monoclonal antibody for the treatment of poorly controlled asthma. However, evidence regarding the safety of omalizumab use during pregnancy is limited.

Aims:
To investigate the safety of omalizumab use on neonatal outcomes among pregnant women with severe asthma.

Methods:
This was a population-based retrospective cohort study with the active comparator design. The databases included the Health and Welfare Database, Birth Certificate Application, and Maternal and Child Health Database in Taiwan. Pregnant women with severe asthma who delivered babies between 2010 and 2021 were identified as the study population. The Global Initiative for Asthma (GINA) criteria were used to classify asthma severity. The use of omalizumab and inhaled corticosteroids (ICS) was the exposure and control, respectively. Neonatal outcomes included gestational age, preterm birth, low birth weight (LBW), small for gestational age (SGA), and the delivery way. Student's t-test and chi-square test were used to compare outcome differences between omalizumab users and ICS users. Multivariable logistic regression models were used to calculate the adjusted odds ratio (aOR).

Results:
Our study identified 13 (0.3%) omalizumab users among 4,995 pregnant women with severe asthma. There was no difference in gestational age (37.2 weeks vs.37.8 weeks, p=0.48) and delivery way (cesarean section: 61.5% vs. 46.4%, p=0.40) between omalizumab users and ICS users. After adjustment, omalizumab use was not associated with increased risk of preterm birth (aOR: 1.09, 95% CI: 0.29-4.15), LBW (aOR: 0.89, 95% CI: 0.19-4.22), and SGA (aOR:0.93,95% CI: 0.11-7.64) when compared to ICS users.

Discussion/Conclusion:
Our study showed no increased risk of neonatal outcomes among pregnant women using omalizumab. Further studies with a larger sample size and event number or with randomized, double-blind, placebo-controlled is needed to verify our findings.

Key words
Omalizumab, Pregnancy, Asthma

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SYSTEMATIC REVIEW OF CHINESE EPIDEMIOLOGY AND RISK FACTORS OF ADVERSE PREGNANCY OUTCOMES

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-Introduction: When a new vaccine launched to the market, active surveillance on the impact of which to pregnancy outcomes is one of common requirements from regulatory authorities as an important part of post-marketing safety evaluation, especially indication population including reproductive-age women, such as HPV vaccines. Knowledge of APOs' epidemiology is critical for designing a post-marketing study.
-Aims: To describe the epidemiology and risk factors of major APOs among Chinese women and newborns.
-Methods: We conducted a systemic literature review by reviewed APOs-related literatures published from 1st Jan 2018 to 30th Jun 2023, in PubMed, CNKI and Wanfang databases. APOs of interest including, for maternal, premature birth (PTB), spontaneous abortion (SA), ectopic gestation, therapeutic labor induction, gestational hypertension, and gestational diabetes mellitus, and low birth weight (LBW), stillbirth, birth defects (BD), small for gestational age (SGA) and macrosomia for neonatal. Literatures' quality was assessed via the Newcastle - Ottawa Scale score and Joanna Briggs Institute critical appraisal checklist.
-Results: A total of 98 studies was included, 43 on APOs' epidemiology and 61 on risk factors. The incidence rate of over-all APOs was 5.0%-25.45% across different Chinese regions. Incidence rate of maternal-APOs studied was 14.9%-17.42% for GDM, 5.2% for gestational hypertension, 0.18% - 11.79% for PTB, 2.13% - 6.89% for SA, 0.05%-0.1% for ectopic gestation, 0.11% for therapeutic labor inductio; and for neonatal, 0.13% - 5.96% for LBW, 0.06% - 2.3% for stillbirth, 0.11% - 1.88% for BD, 2.19% - 13.90% for macrosomia, and 1.8%-5.6% for SGA. Advanced maternal age (≥35 years), infection, stress, anxiety, depression, overweight/obesity, and high-risk Down's syndrome was studied main risk factors that should be considered.
-Discussion: Only a few literatures described APOs' epidemiology nationwide. It is necessary to conduct large-scale, prospective studies to fully understand the regional distribution differences and risk factors of APOs.

[Psychiatry and Cognitive Condition]

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Psychotropic medicine consumption in 83 countries and regions between 2017 and 2022

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Introduction:
There have been concerns about the potential impacts of the COVID-19 pandemic on mental health conditions since the pandemic, but global studies on this topic remain limited. The global monitoring of country-level psychotropic medication consumption trends can provide information on the availability and utilisation of psychotropic medications during the pandemic.
Aims:
To investigate trends in psychotropic medication consumption from 2017 to 2022 across 83 high- and middle-income countries according to country income level.
Methods:
We used quarterly pharmaceutical sales data of psychotropic medications from the IQVIA-Multinational Integrated Data Analysis System (IQVIA-MIDAS). Total psychotropic consumption included sales of antipsychotics, anxiolytics, hypnotics and sedatives, and antidepressants. Average annual sales trends of psychotropic medications were expressed as defined daily dose (DDD) per 1000 inhabitants per day. Compound annual growth rate (CAGR) was used to assess changes in consumption over time.
Results:
Psychotropic medication sales rose from 30.19 to 35.10 DDD per 1000 inhabitants per day from 2017 to 2022 (CAGR 3.06%). From 2017 to 2022, consumption of antipsychotics and antidepressants increased at a CAGR of 2.72% and 5.23%, respectively, while consumption of anxiolytics, hypnotics and sedatives decreased at a CAGR of -0.55% and -0.27%, respectively. From 2019 to 2020, anxiolytics (CAGR 3.04%), hypnotics and sedatives (CAGR 2.18%) observed a significant increase, but their consumption decreased from 2021 to 2022. High-income countries experienced the largest growth in consumption of psychotropic medications.
Discussion:
The overall consumption of psychotropic medications in 83 high- and middle-income countries has increased from 2017 to 2022, with the highest growth observed in antidepressants and high-income countries. The observed increase in consumption of anxiolytics, hypnotics and sedatives during the pandemic, followed by a decrease after the pandemic, indicates that there were increased anxiety and sleep difficulties during the pandemic and it's possible that these issues naturally improve after the pandemic.

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ADHD Medication Use During Pregnancy and Outcomes in Pregnant Individuals and Newborns

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[Introduction]
Despite their frequent prescription, the safety of ADHD medications during pregnancy is not well-studied.
[Aims]
To assess the risk of adverse outcomes associated with exposure to ADHD medications during pregnancy.
[Methods]
We conducted a case-noncase disproportionality analysis using VigiBase, the World Health Organization's pharmacovigilance database, which covers about 30 million safety report cases from 1967-2022. The study population consisted of women aged 12 to 44 years who were exposed to ADHD medications during pregnancy. The ADHD medications were identified by the ATC codes 'N06BA' or 'N06BX'. Adverse outcomes included abortion, stillbirth, fetal death, congenital malformation, pregnancy complications, preterm birth, neonatal complications, and delivery complications. We analyzed reporting odds ratios (RORs) with 95% confidence intervals (CIs) using logistic regression while adjusting for maternal age group and region.
[Results]
A total of 200,670 reports were analyzed. Cases were 2,536 (1.3%) and noncases were 198,134 (98.7%). In the ADHD group, the most reported age group was 18-44 years (N=196,596, 98.0%). The ROR for exposure to ADHD medication was 1.4 (95% CI: 1.2 to 1.6), indicating a 37.3% higher risk of adverse outcomes among those exposed compared to those not exposed.
[Conclusions]
This study identified an association between the use of ADHD medications during pregnancy and an increased risk of adverse pregnancy outcomes. These findings underscore the need for continuous surveillance to monitor the safety of ADHD medications in pregnant women. Further study is essential to analyze these adverse outcomes in more detail.

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Antidepressant Use for Patients with Depression and the Risk of Diabetes

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Introduction
The association between antidepressant use in patients with depression and the risk of type 2 diabetes (T2DM) has been extensively studied, but results remain inconsistent. Depression and diabetes comorbidity lead to poorer health outcomes and increased mortality risk compared to either condition alone. Therefore, preventing T2DM onset in patients with depression is crucial.
Aims
This study aimed to investigate the association between antidepressant use and the risk of type T2DM in patients with depression. Additionally, we studied the effects of switching or concomitant use of different types of antidepressants on T2DM risk.
Methods
This nested case-control study was conducted using a Japanese health insurance claims database. Patients with depression prescribed antidepressants at least once between January 2005 and June 2017 were identified. Odds ratios (ORs) and 95% confidence intervals (CIs) for T2DM risk associated with antidepressant use were estimated using conditional logistic regression.
Results
This study included a cohort of 32,988 patients treated with antidepressants between January 2005 and June 2017, with a mean follow-up of 2.5 years. During this period, 1,505 T2DM cases were identified, with an incidence rate of 1.81 per 100 person-years. The estimated ORs of T2DM risk for current antidepressant use compared to past use was 1.41 (1.24 to 1.62). Compared to past use without switching, the ORs of T2DM risk for past use with past switching, current use without switching, current use with past switching, and current use with current switching were 1.08 (0.87 to 1.34), 1.43 (1.20 to 1.71), 1.40 (1.14 to 1.71), and 1.69 (1.02 to 2.79), respectively.
Conclusions
Antidepressant use is associated with an increased risk of T2DM. However, no significant association was found between switching antidepressants and increased T2DM risk.

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Aripiprazole versus Second-generation Antipsychotic Use in Schizophrenia and Risk of Cardiovascular Events

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Introduction:
Atypical antipsychotics (AAPs) are the first-line treatment for schizophrenia but are found to be associated with an increased risk of cardiovascular diseases. Aripiprazole is considered to have a lower risk of metabolic side effects compared to other AAPs. However, there was a lack of studies directly assessing the cardiovascular risk of aripiprazole compared to other AAPs among patients with schizophrenia.
Aims:
To compare the risk of cardiovascular events (CVE) among patients with schizophrenia who were newly treated with oral aripiprazole versus other oral AAP medications.
Methods:
A retrospective cohort study with an active comparator design utilized the Taiwan National Health Insurance Database to enroll adults with schizophrenia who had initiated a single oral AAP medication from 2014 to 2019. The exposure group comprised aripiprazole users, and the control group included other AAP users. The cardiovascular outcomes included ischemic heart disease, ischemic stroke, arrhythmias, and heart failure. Propensity score matching (PSM) was used to balance covariates, including sociodemographic variables, comorbidities, comedication, and disease severity. Cox proportional hazard models were used to estimate the CVE risk between the two groups. Several sensitivity and subgroup analyses were conducted to assess the dosage effect of aripiprazole use.
Results:
The study included 5,505 new AAP users with schizophrenia, of which 943 (17.1%) were using aripiprazole. After 1:2 PSM, the findings indicated that aripiprazole did not significantly reduce the risk of CVE compared to other AAPs (aHR=1.44; 95% CI= 1.00-2.08). However, users of high-dose aripiprazole had a significantly higher risk of CVE than users of high-dose AAPs ($p<0.05$).
Discussion:
The use of aripiprazole did not decrease the risk of CVE compared to the use of AAP use among patients with schizophrenia. Patients taking high-dose aripiprazole should be closely monitored for their cardiovascular risks.

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Assessing drug utilization in cognitive impairment among the elderly population- A hospital-based longitudinal study

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Introduction. DUE in cognitively impaired geriatric patients focuses on the outcome of the patient's medication therapy.
Aims. The study aimed to assess the drug utilization pattern of cognitively impaired patients in the geriatric population
Methods. A prospective observational study was conducted at the Departments of Geriatrics, Neurology, and Psychiatry in a tertiary-care teaching hospital in Southern India from Sept 2024 to Feb 2024. Patients' demographics, treatment charts, health profiles, and medical orders were analyzed. Prescriptions containing medications for cognitive impairment used in the treatment of Parkinson's disease and/or dementia were screened to assess drug usage patterns for Parkinson's disease and dementia. The analysis included drug usage patterns for Parkinson's disease and dementia using WHO prescribing indicators and Defined Daily Dose (DDD).
Results. A total of 156 eligible patients [105(67%), males; 51(33%), females] with a mean age of 75.18 ± 8.28 years were recruited for the study after obtaining informed consent and by interacting with them and their caregivers. The majority (67%) were diagnosed with PD, followed by 25% of them diagnosed with dementia. 1087 medications were used, with an average of 7.91 per participant. Levodopa + Carbidopa accounted for 67.9% of all prescriptions, followed by Olanzapine at 23.1%. WHO's core prescribing indicators showed that, on average, 7.91 drugs were prescribed per encounter. Only 3.7% of drugs were prescribed by their generic name, while 8.75% of encounters involved antibiotics and 20.5% of injections. Levodopa+Carbidopa(8217.4 DDD) and Trihexyphenidyl(1212.7 DDD) were used for PD, and Donepezil (2473.6 DDD) and Memantine (407.25 DDD) were used for treating dementia.
Conclusion. The most commonly prescribed medications in our hospital setting are those used for PD and dementia. This study provides a framework of the prescribing pattern in the above-mentioned departments to assess drug utilization evaluation amongst cognitively impaired patients.

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Assessment of DRP associated with use of psychiatric medication among non-psychiatric patients

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Objective: to assess the psychotropic drug utilization pattern in various non-psychiatric wards of a tertiary care hospital
Methodology: A prospective interventional study was conducted in the study site for a period of six months. The patients treatment charts were analysed for psychotropic drug prescribing and the patient were closely monitored until discharge. DRPs observed were reported and pharmacists intervention was provided accordingly. The reported DRPs were documented and classified using Hepler and Strand classification. Additionally, both off-label and on-label prescribing were examined throughout the study period to determine whether the observed DRPs stemmed from on-label or off-label prescribing. The correlation between psychotropics and DRPs were analysed using Pearson Coefficient statistical analysis.
Results: 143 patients experienced DRPs during the course of study. It was found that 97.02% were drug interactions followed by ADRs comprising 6.99%. The identified drug interactions was classified as major(45.3%) moderate(51.07%) and minor(3.50%). The ADRs were classified according to Naranjos Algorithm and it was found that 50% of the ADRs were probable while the rest 50% belonged to possible category. Severity assessment of the ADRs revealed that 70% of the ADRs belonged to mild level 2 category.The preventability and predictability parameters revealed that majority of the ADRs were not preventable(60%) but predictable(60%). Pearson coefficient statistical method was employed to identify any correlation between off label prescribing and the DRPs. Pearson coefficient value was found to be 0.925 which indicated strong correlation between off label prescribing of psychotropic and DRPs.
Conclusion: this study demonstrates that by monitoring use of drugs, it allowed the clinical pharmacists to identify DRPs and propose interventions aimed at promoting rational drug prescribing, optimizing therapy and bolstering patient safety. This study highlights the need to develop guidelines and policies to ensure rational use of psychotropic drugs, especially in non-psychiatric wards hence promote patient safety.

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Assessment of Caregiver Burden among Caregivers of the Cognitively Impaired Patients

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Aim:
To assess the caregiver burden amongst the caregivers of cognitively impaired elderly patients.
Methods:
A cross-sectional, hospital-based, prospective cohort study amongst cognitively impaired patients was carried out at the Department of Geriatrics, Neurology, and Psychiatry for six months. Patients diagnosed with Parkinson's disease (PD) and Dementia; their caregivers were given consent to be included in the study. The Zarit burden questionnaire (ZBQ) was administered, and the responses were collected.
Results:
A total of 156 caregivers shared their experiences, and the results were like, 'No to mild burden. 133 (85.2) 'Mild to moderate burden' 16 (10.2) 'High burden' 7 (4.4) [males; 105 (67.3) females; 51 (32.6) patients]. On analysis after using the ZBQ scale, mild burden was highly observed in male patients [94 (89.5%)] and in female patients [43 (84.3%)]. The age group analysis showed that 70–79-year-olds showcased a high, mild burden of 42.42% [56]. Moderate burden was observed within the age group of 80–89 years old, with [6 (35.29%)], followed by [2 (28.57%)] observed in the age groups of 60–69 years, 70–79 years, and above 90 years old. with respect to the area of domicile, and it was identified that high caregiver burden was observed in the study participants belonging to the sub-urban area, with mild burden [85 (63.90%)], moderasste burden [9 (52.94%), and severe burden [3 (5.0%)]. Rural and urban areas with less caregiver burden were observed to have mild burden [01 (16.66%)] and [2 (33.33%)], moderate burden [5 (29.41%)] and [3 (17.64%)], and severe burden [18 (13.53%)] and [30 (22.55%)], respectively.
Conclusion:
With respect to the study, we found that the cognitively ill patients in a suburban area are more focused. Assessment of caregiver burden will help in identifying the social and physiological burden that should be assessed and addressed by the clinicians, understanding their challenges, and resolving them.

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Association between lithium use and stroke risk: nationwide self-controlled case series study

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Introduction
Emerging animal studies regarding the neurotrophic effect of lithium use have suggested the potential neuroprotective benefit on neurological disorders including stroke. However, the association between lithium therapy and stroke in human is not well-investigated.
Aims
To determine the effect of lithium on stroke prevention.
Methods
Patients aged≥20 years old, newly-diagnosed with stroke, using lithium during 2013-2019, without previous major mental disorders were identified from 2013-2018 Taiwan's National Health Insurance Research Database. Self-controlled case-series (SCCS) analysis was conducted for the age-adjusted incidence ratios (IRs) of stroke within-person in treatment exposure versus non-exposure and pre-exposure (i.e., 14 days before lithium initiation) periods. Analyses were also stratified by the presence/absence of comorbid diabetes and age (i.e., ≥35/<35 years old). Patients using lithium≥30 and 90 days were further classified for the analysis of long-term lithium exposure on stroke risk. A cohort study using time-dependent cox proportional model analysis was finally conducted to assess the causal relationship to corroborate the SCCS analysis findings.
Results
There were 994 lithium users developing stroke events. We found insignificant effect of lithium exposure on hemorrhagic, ischemic and composite strokes compared to non-exposure (i.e., IRs [95% CIs]: 0.93 [0.61-1.40], 1.31 [0.98-1.75], and 1.20 [0.94-2.53]). Such an insignificant effect was also found for composite strokes across patient subgroups: i.e., IRs (95% CIs) in non-diabetes: 1.58 (0.89-2.77), having diabetes: 1.14 (0.87-1.48), age≥35: 1.18 (0.91-1.53), and age<35:1.36 (0.73-2.59), with lower risks following longer lithium exposures: i.e., ≥30 days: 0.97 (0.58-1.64) and ≥90 days: 0.84 (0.54-1.30). The time-dependent Cox model analyses suggest lower but insignificant hemorrhagic/ischemic/composite stroke risks (i.e., hazard ratios [95% CIs]: 0.84 [0.55-1.26]/0.85 [0.61-1.68])/0.87 [0.67-1.14]) following lithium use.
Discussion
The potential neutral protection of lithium use on stroke is revealed as prolonging treatment exposures, highlighting the importance of patient's persistence/adherence to lithium therapy on neurological outcomes.

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Association between Social Media Addiction and Impostor Syndrome among Undergraduate Students.

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Introduction: The use of social media among university students is continually increasing; this can lead to social media addiction behavior. Social media addiction may cause low self-esteem, leading to impostor syndrome.
Objective: To investigate the association between social media addiction and impostor syndrome among undergraduated students.
Method: In this cross-sectional study design, undergraduate students participate with an online self-report questionnaire from August to December 2023. Social media addiction was measured by Social Media Addiction Test (SMAT), composing of 16 items with Likert-scale response from 0(not at all) to 3(yes). A score of above 30 indicated social media addiction, whereas a score of less than 30 indicates no addiction. Impostor syndrome was measured by Clance Impostor Phenomenon Scale (CIPs) which comprises 20 items, each scored on a 5-point Likert scale. The values of 60 or higher indicate the presence of imposter syndrome, whereas values below 60 indicated no impostor syndrome. The analysis was conducted with STATA version 14.0; logistic regression analysis adjusted with potential confounding factors was used.
Results: Of the 322 students who answered the questionnaire, 66.7% were female, 52.5% were under the age of 20, and 33.5% were second-year students. Among those who experienced impostor syndrome, 44.6 % addicted to social media, while 55.6% did not addict to social media. Social media addiction correlated with a higher of experiencing impostor syndrome compared to non-addicted students (Adjusted OR=2.33; 95%CI: 1.35-4.01; p=0.002).
Conclusion: The levels of social media addiction was found to be associated with an imposter syndrome.

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Association between the Use of Incretin-Based Therapies and the Risk of Depression

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Several studies indicated that incretin-based therapies, such as GLP-1 receptor agonists (GLP-1 RAs) and DPP-4 inhibitors (DPP-4is), reduce depression risk in type 2 diabetes mellitus (T2DM) patients. However, these studies often lacked an active comparator and did not capture depressive symptoms without a formal diagnosis.
Aims:
Examine the risk of depression and health-related quality of life (HRQoL) in GLP-1 RA and DPP-4i users compared to sodium-glucose cotransporter-2 inhibitor (SGLT2i) users.
Methods:
This was a cross-sectional study utilizing 2019-2021 data from the Medical Expenditure Panel Survey. We included patients aged 18 or older, had T2DM, and received SGLT2i, DPP4i, or GLP-1RA. Incretin-based therapies, DPP4is and GLP-1RAs, were the exposure, and SGLT2is were the reference. The primary outcome, depression, was assessed using the Patient Health Questionnaire-2 (PHQ-2) scale; a PHQ-2 score equal to or above three indicated depression. The secondary outcome, HRQoL, was evaluated using the Mental Component Summary (MCS) score from the Veterans RAND 12-Item Health Survey (VR-12), with a higher score reflecting better mental health. Logistic regression models and ordinary least-square models were estimated to assess depression risk and compare the mean MCS score, respectively.
Results:
For the primary outcome, the risk of depression was significantly lower in the DPP4i group (OR: 0.42, 95% CI: 0.23–0.80) and in the GLP-1RA group (OR: 0.56, 95% CI: 0.33–0.95) compared to the SGLT2i group. Regarding the secondary outcome, the mean of MCS scores was not significantly different between the DPP4i group (Mean difference = 0.65, p = 0.39) and the GLP-1RA group (Mean difference = 0.27, p = 0.70) relative to the SGLT2i group.
Discussion:
Our results suggest that DPP4is or GLP-1RAs were associated with a lower risk of self-reported depressive symptoms compared to SGLT2is. However, future longitudinal studies are required, as the cross-sectional design of this study cannot establish causality.

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Association of road traffic injuries with gabapentinoid treatment: a self-controlled case-series study

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Introduction
Gabapentinoid use is linked with impairment to consciousness and cognitive function, raising concerns about their safety. With a surging consumption of gabapentinoids, it is critical to investigate whether patients taking them are at an increased risk of road traffic incidents.
Aims
To investigate the association between gabapentinoids use and the risk of road traffic incidents.
Methods
We utilised data from the UK Clinical Practice Research Datalink (CPRD) linked with Hospital Episode Statistics (HES). We included individuals aged above 18 years old who had received at least one prescription of gabapentinoids and at least one hospitalisation record due to road traffic injuries between January 1, 2000, and December 31, 2022. Self-controlled case series design was employed to control for time-invariant factors. Patient-time was divided into pre-, on-, post-treatment and baseline periods. The incidence rate ratio (IRR) of road traffic injuries during different riskperiods were compared with baseline periods. Time-varying confounders such as age, season and concomitant medications were adjusted in the conditional Poisson regression model.
Results
The study identified 1,089,433 individuals who had at least one prescription of gabapentinoid within the study period. A total of 12,533 patients who had at least one road traffic incident were included in the analysis. The mean age at baseline was 44.92 years, and 6,333 (50.53%) of these individuals were female. No increased risk of road traffic injuries was identified during the treatment period (IRR, 1.05; 95% CI, 0.97-1.13). Only a slight increased risk was detected in the female subgroup (IRR, 1.13; 95% CI, 1.02-1.25). The trend remained consistent across different age groups, ethnicities, gabapentinoid types, other subgroups and sensitivity analyses.
Conclusions
Our study findings suggest that no increased risk of road traffic injuries during gabapentinod exposed period. Additional real-world studies of other outcomes are warranted to ensure safe use in the wider population.

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Barriers and Influential Factors in Quitting/Reducing E-Cigarette Use Among University Students

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Introduction: The rise in e-cigarette use among Thai youth is attributed to curiosity, peer influence, and perceptions of reduced harm compared to conventional cigarettes.
Aim: To identify barriers and influential factors affecting the cessation or reduction of e-cigarette use among university students in Thailand.
Methods: An online survey was administered from December 2020 to February 2021 to active e-cigarette users enrolled in two northern Thai universities. The questionnaire assessed five barriers and seven influential factors for quitting or reducing e-cigarette use using a 4-point Likert scale (1=strongly disbelieve, 2=disbelieve, 3=believe, 4=strongly believe). Responses were dichotomized into disbelief (1 and 2) and belief (3 and 4) categories.
Results: Of the 306 respondents (61% male, mean age 21.8 ± 3.0 years), 53% were dual users of e-cigarettes and conventional cigarettes, while 47% exclusively used e-cigarettes. Curiosity was the primary motivator for initiation (68%), with approximately 10% starting in junior high school. The top three barriers they believe in quitting e-cigarette use were: 1) required effort and determination (62%), 2) peer e-cigarette use (50%), and 3) perceived cost-effectiveness of e-cigarettes compared to conventional cigarettes (49%). The top three influential factors they believe for quitting were: 1) family requests (78%), 2) requests from significant others, such as lovers (75%), and 3) internet media highlighting e-cigarette risks (60%).
Discussion/Conclusion: The perceived barriers to quitting, such as the effort and determination required, peer influence, and cost considerations, indicate the need for comprehensive cessation programs that address these factors. Additionally, the significant influence of family, significant others, and internet media on quitting decisions suggests that interventions involving these influencers could be particularly effective. Future research could explore the effectiveness of such interventions in promoting cessation among young e-cigarette users.

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Burden of depressive disorders in Vietnam from 1990 to 2019

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Introduction: Depressive disorders are among the leading causes of disability globally. However, information on the burden of depressive disorders in Vietnam is limited.
Aims: We aimed to analyse the burden of depressive disorders in Vietnam from 1990 to 2019.
Methods: Using data from the GBD 2019, prevalence and disability-adjusted life years (DALYs) were used as indicators to analyse the burden of depressive disorders by age and sex. The average annual percent change (AAPC) in prevalence and DALY rates due to depressive disorders from 1990 to 2019 were calculated using the joinpoint regression analysis.
Results: In 2019 in Vietnam, depressive disorders comprised 2629.1 thousand (95% uncertainty interval (UI): 2233.3–3155.9) estimated cases and 380.6 thousand (95% UI: 258.9–533.8) estimated DALYs. The crude prevalence rate of depressive disorders was higher among females than among males. The DALYs of depressive disorder accounted for a higher percentage of the total all-cause DALYs in the 10–64-year age group than in other age groups. Major depressive disorder was the largest contributor to the burden of depressive disorders. From 1990 to 2019, the crude prevalence and DALY rates per 100 000 population due to depressive disorders were significantly increased, whereas age-standardised rates of prevalence and DALYs significantly decreased; the respective average annual percent changes were 0.88% (95% confidence interval: 0.87 to 0.89), 0.68% (0.66 to 0.70), -0.20% (-0.21 to -0.19), and -0.27% (-0.28 to -0.25).
Conclusion: Although the age-standardised prevalence rate was lower than that seen globally, depressive disorders were considerable mental health issues in Vietnam. This study will help governments and policymakers to establish appropriate strategies to reduce the burden of these disorders by identifying the priority areas and individuals.

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Clinical Spectrum and Management Challenges of Reflex Epilepsy: Insights from Northeast India

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Aims: To identify the clinical characteristics, treatment patterns, and outcomes of reflex epilepsy.
Methods: A prospective case series study was conducted at a multispecialty tertiary care hospital in Northeast India from October 2022 to May 2024. We collected demographic and clinical data, epilepsy characteristics, and treatment patterns data of reflex epilepsy patients. Therapeutic outcomes were categorized based on International League Against Epilepsy (2009) guidelines. Categorical data were expressed in frequency and percentage.
Results: A total of 32 cases, with a majority of males (62.5%) predominantly of young adults (65.6%). The majority of seizures (71.9%) were triggered by eating (rice consumption), followed by watching TV/mobile devices (6.3%). The majority of the patient's seizures were triggered by eating (71.9%), followed by TV/mobile watching (6.3%). Focal epilepsy was diagnosed in 62.5% of cases, and neuroimaging revealed structural abnormalities in 34.4%. Most of the patients had a history of febrile seizures and family epilepsy (18.8%), head injury, and delayed developmental milestones (9.4%). Comorbidities such as cognitive impairments, psychosocial difficulties, and psychiatric disorders were present in 15.6% of patients. Most patients (68.8%) were on polytherapy, commonly a combination of clobazam and levetiracetam (31.2%). Poor compliance was noted in 37.5%, with refractory epilepsy in 31.3%. Undefined drug responsiveness was seen in 18.8%, and 31.3% had undetermined outcomes.
Discussion/Conclusion: The study shows that young adult males with epilepsy often have seizures starting in adolescence, frequently triggered by eating, with common focal epilepsy and structural abnormalities. Polytherapy is common, but poor compliance and refractory epilepsy are significant challenges. These findings underscore the need for better treatment strategies, patient education, and support systems.
Keywords: Reflex Epilepsy; Eating Epilepsy; Refractory Epilepsy; Structural Etiology

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Effect of drug utilization review on prescription of typical antipsychotics to elderly

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Introduction: A notification issued in August 2018 in South Korea recommended caution while prescribing typical antipsychotics to elderly over 65 years.
Aims: This study aimed to determine changes in outpatient prescription volumes for elderly before and after Drug Utilization Review(DUR) provision for five of the eight typical antipsychotics.
Methods: From April 2017 to December 2019, prescription volumes of the five typical antipsychotics(schlorpromazine, levomepromazine, haloperidol, perphenazine, and pimozide) to outpatients aged 65 years or older, under the National Health Insurance Service-Senior(2002~2019)[1](NHIS-2024-2-082) were analyzed. Change in monthly averages pre and post DUR provision per 100,000 elderly people was calculated.
Results: A total of 657,959 seniors aged 65 years or older were seen in the study period, of which 639,504 (97.2%) were prescribed drugs at least once, and 2,646 (0.4%) were prescribed one of the five typical antipsychotics at least once. These were mainly women (57.6%), of which 58.0% received their prescriptions at primary hospitals and 33.7% at secondary hospitals. The most frequently prescribed drugs were perphenazine (56.0%), haloperidol (32.0%), and chlorpromazine (11.7%). The monthly averages of prescriptions per 100,000 elderly people within 16 month periods before and after DUR provision, excluding the month in which it was provided, dropped for haloperidol by 2.5% from 19.6 to 19.1. Additionally, while it increased for levomepromazine from 0.2 to 0.5, and remained static for pimozide at 0.3, the average monthly prescriptions for both was less than 1 post DUR provision. The proportion of chlorpromazine and perphenazine prescriptions increased by 7.7% from 6.8 to 7.3, and by 17.1% from 31.3 to 36.6, respectively.
Discussion: Despite no restrictions on prescribing cautionary drugs in South Korea, DUR provision on typical antipsychotics effectively reduced outpatient haloperidol prescription to elderly patients. Additional studies are essential to analyze the effect on in-hospital administration of typical antipsychotics.

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Evaluating LID Prevalence and Influencing Factors in PD Patients: A Pharmacovigilance Study

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Introduction. Parkinson's disease is a neurodegenerative disorder caused by dopamine neuron loss, leading to tremors, stiffness, etc. Levodopa, a treatment for Parkinson's motor symptoms, becomes less effective over time and can cause a complication- levodopa-induced dyskinesias (LID). Individual susceptibility to LID can vary considerably. A pharmacovigilance study on PD patients receiving levodopa therapy is crucial to address this knowledge gap.
Aims. This study aims to evaluate the prevalence and severity of levodopa-induced dyskinesia (LID) in Parkinson's disease (PD) patients on levodopa therapy and to identify disease-related, and treatment-related factors associated with LID development.
Methods. We conducted a retrospective observational study at a tertiary-care teaching hospital in Southern India over one year. Adult patients (>50 years) diagnosed with Parkinson's disease (PD) receiving levodopa therapy were included. Data on demographics (age, sex), PD characteristics (age at onset, severity), and levodopa treatment history (dosage, duration) were collected from medical records.
Results. A total of 160 Parkinson's patients [101(63%) males, 59(37%), females] with a mean age of 75.20 ± 4.28 years were recruited for the study after obtaining informed consent and by interacting with them and their caregivers. Levodopa + Carbidopa accounted for 60.0% of all prescriptions. The observation was carried out for LID developments and its treatment. Among 160 PD patients, 122(76%) patients showed LID symptoms [76 (62%) males, 46 (38%) females]. Following drugs like Rasagiline [40%], Amantadine [50%], and Levetiracetam [10%] were used for treating LID.
Discussion. This study highlights the high prevalence of LID in Parkinson's patients on levodopa therapy. The employed treatment options suggest a co-delivery approach to manage LID. Further research with larger, prospective designs can provide more definitive insights into LID development and optimal treatment strategies.
Keywords: Parkinson's disease, Levodopa, Levodopa-induced dyskinesia, Prevalence

P409

Evaluations of Mental Health Conditions among Children with and without Diabetes.

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Introduction:
Managing diabetes in children is challenging and can lead to psychiatric disorders, making it a global health issue. However, investigations on the association between mental health care and diabetes among children is limited.

Aims:
This study aimed to 1) report the prevalence of mood disorders and mental health care utilization among children with and without diabetes in the U.S. from 2019-2022 and 2) examine the association between diabetes and mood disorders as well as mental health care utilization among children.

Methods:
The U.S. National Health Interview Survey (NHIS) were used. Children aged 0-17 with and without diabetes were identified through survey questionnaires. Mood disorders were defined as self-reported anxiety or depression at least weekly in the past year. Mental health care utilization was defined as receiving mental health counseling, therapy, or medication in the past survey year. Chi-square tests were used to estimate trend changes and multivariable logistic regression models were used to evaluate the association between diabetes and mental health conditions. All analyses were weighted and adjusted by the NHIS survey design with the clustering and stratification.

Results:
There were 293,825 children with diabetes and 72,368,355 children without diabetes. The prevalence of mental health care utilization among children with diabetes decreased from 2019 to 2022 (counseling or therapy: 37.2% to 16.3%, p=0.07; medications: 27.4% to 7.9%, p=0.09). Children with diabetes were more likely to report experiencing anxious or depressed at least weekly when compared to children without diabetes (anxious: ORs: 1.87, 95% CI 1.08-3.25; depressed: ORs: 1.20, 95% CI 0.58-2.52).

Discussion:
A decreasing prevalence of mental health care utilization from 2019 to 2022 was observed among children with diabetes. Nonetheless, children with diabetes were more likely to have mood disorders than children without diabetes. Pediatric diabetes management should include psychological cares to improve overall health outcomes for children.

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Haematological malignancy following clozapine or olanzapine use in schizophrenia: retrospective cohort study

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Introduction:Recent disproportionality analyses and nationwide case-control studies have identified safety signals suggesting a potential association between the use of clozapine and haematological malignancy (HM) with little information on the associated incidence rate difference.
Aims: Our aim was to test for the association of clozapine use with HM in comparison with olanzapine users and examine the absolute rate difference, adjusting for prior other antipsychotic use within both groups.
Methods: A territory-wide public healthcare database in Hong Kong covering the entire population provided data for this study. We included a retrospective cohort of anonymized patients aged 18 or older with a diagnosis of schizophrenia who had used clozapine or olanzapine (drug comparator with highly similar chemical structure) for 90 days or more, with at least two prior other antipsychotic use records within both groups. Weighted by inverse probability of treatment based on propensity scores, Poisson regression was used to estimate the incidence rate ratio (IRR) of HM between clozapine and olanzapine users.
Results: In total, 9,965 patients were included, with 834 clozapine users. Clozapine users had a significant IRR of 2.15 (95% CI 1.50, 3.29) for HM compared to olanzapine users. The absolute rate difference between the two groups was estimated to be 49.35 (95% CI 39.22, 67.49) per 100,000 person-years. Findings were consistent across various sub-groups by age and sex in terms of effect size, although the IRR was non-significant for those aged 65 or older. Sensitivity analyses all supported the robustness of the results.
Discussion: A twofold elevated rate of HM associated with clozapine is identified. However, the absolute incidence rate difference is small with limited impact on the risk-benefit ratio of clozapine use for treatment- resistant schizophrenia.

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HbA1c Recording in Patients with Schizophrenia or Bipolar Disorder in DATuM IDEA®

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Introduction: The shortened life expectancy observed in patients with schizophrenia is primarily attributed to cardiovascular-related mortality, highlighting the importance of preventive measures against obesity and diabetes. This study investigated the real-world monitoring of HbA1c levels in patients diagnosed with schizophrenia and bipolar disorder using actual data obtained from DATuM IDEA®, a comprehensive medical information database in Japan that includes electronic medical records.

Objective: The primary goal of this study is to assess the frequency of HbA1c testing and other relevant clinical data in patients diagnosed with schizophrenia or bipolar disorder using a medical information database.

The cases of schizophrenia and bipolar disorder were identified using ICD-10 codes F20 and F31. Parameters such as age, HbA1c levels, diabetes diagnosis, and prescribed medications were taken into consideration. The data was extracted from electronic medical records of approximately 980,000 individuals registered in the DATuM IDEA® medical information database managed by TOPPAN Holdings Inc. from January 2019 to December 2022.

Results: Within DATuM IDEA®, there were 22,332 cases of schizophrenia and 2,350 cases of bipolar disorder. Among these cases, 15,924 underwent HbA1c evaluation, resulting in a total of 74,607 recorded HbA1c data. Throughout the data collection period, 9,885 patients had a maximum HbA1c value below 6.0%, while 2,559 patients had values of 7.0% or higher.

Discussion: In the cohort of 24,682 registered patients diagnosed with schizophrenia or bipolar disorder, 27.7% did not undergo HbA1c testing. It is crucial to consider the possibility of HbA1c evaluations being conducted at medical facilities not integrated into the database. Notably, 14.3% of cases with recorded HbA1c measurements showed values exceeding 7%, emphasizing the need for enhanced focus on blood sugar management in patients diagnosed with these disorders. The study confirms the feasibility of investigating HbA1c levels in patients diagnosed with schizophrenia or bipolar disorder using DATuM IDEA®.

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Medication Use Evaluation of ADHD Treatment at a Medical Center

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Introduction:
The efficacy and safety of ADHD treatment affect medication adherence and persistence. The information remains insufficiency.
Aims:
To evaluate ADHD medication usage in clinical practice by retrospectively reviewing electronic medical records (EMRs) at a medical center.
Methods:
This retrospective study enrolled patients under 18 years old diagnosed with ADHD who visited our clinics and were prescribed methylphenidate (MPH) or atomoxetine (ATX) from January 1, 2020, to December 31, 2022. We conducted a chart review using EMR to observe the initial prescription patterns of ADHD treatment at a medical center and evaluate the rationality, effectiveness, and safety of these medications. The chi-squared test and t-test were conducted to compare categorical and continuous variables, respectively.
Results:
There were 544 patients enrolled in the final analysis, with 76% being male. The majority received immediate-release methylphenidate (IR-MPH) as a first-line treatment, and the mean age of this group (7.64 ± 2.36 years) was significantly lower than those using long-acting methylphenidate (LA-MPH) or ATX. Regarding rationality, 70% of the patients underwent symptom assessment before medication use. In terms of medication dosage, over 90% of the patients followed the guidelines' recommendations. During the 90-day follow-up period, 159 individuals discontinued medication. In regards to effectiveness, approximately 80% experienced symptom improvement, with longer treatment duration observed among patients who perceived the medication as effective. As for safety, about one-third of the patients experienced adverse effects within three months. The most common side effects in our study are decreased appetite and weight loss. However, most patients showed improvement with continued observation or medication adjustment. Less than 3% of the study participants discontinued treatment due to intolerable side effects.
Conclusions:
The efficacy of medication can affect patients' willingness and ability to continue treatment over time. With appropriate monitoring and adjustment, most patients can safely and effectively receive treatment.

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Persistence and Adherence of ADHD Medications in Japanese patients

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Introduction
Attention-Deficit/Hyperactivity Disorder (ADHD) is a chronic condition that often necessitate long-term care and social support. Pharmacotherapy is recognized as an important intervention to improve not only the core symptoms of ADHD but also social outcomes. Previous studies indicated low persistence and adherence to ADHD medications in those patients.

Aims
To clarify the persistence and adherence of ADHD medications in Japanese patients.

Methods
The study population were identified in the claims database provided by JMDC Inc. Patients who received an incident prescription of target medications from May 2017 to December 2021 were included. The target medications were methylphenidate slow-release preparation, atomoxetine, guanfacine, and lisdexamfetamine, approved for ADHD in Japan. An incident prescription was defined as one with no prior prescription record of the target medications during a lookback period of 180 days or more before the prescription date. A patient was considered to be continuously using a medication from the initial to last fill date plus the days supply dispensed on the last fill date and when a subsequent prescription was issued within a 60-day gap after the days supply dispensed on the last fill date. Switching among the target medications was also considered as continuation. Median medication persistence was estimated using Kaplan-Meier method and persistence rates were estimated at 1 and 2 years after the index date.

Results
Among the 31,457 subjects, 21,081 (67%) were male, with a median age of 19 years. The median medication persistence was 221 days, with persistence rates of 40.3% at 1 year and 27.3% at 2 years after the index date.

Discussion
Low persistence of ADHD medication was observed, and early discontinuation was common, as reported in the other countries. The reasons may include ineffectiveness of medications, side effects of medications, and poor self-management skills due to ADHD symptoms.

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Pharmacists' Knowledge, Attitudes, Perceived barriers on providing medication counseling to psychiatric patients

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Introduction. Non-adherence to antipsychotic medication is a significant challenge, to long-term maintenance therapy and increasing the risk of recurrence. Pharmacist has a critical role in improving the adherence to medication in psychiatric patients. It is important to study the pharmacist's perspective in this aspect.
Aims. Evaluate the pharmacists' knowledge, attitudes and perceived barriers on medication counseling for psychiatric patients in selected hospitals and pharmacies in Colombo district, Sri Lanka.
Methods. A cross sectional study conducted using a self-administered questionnaire to 253 pharmacists in selected government and private hospitals and community pharmacies. Pharmacists between 18-60 years who had not less than six months of working experience and were registered with the Sri Lanka Medical Council fulfilled inclusion criteria were selected for the study. Participants' demographics, knowledge, attitude, perceived barriers on providing medication counseling was summarized using descriptive statistics. Relationships between those variables analyzed by Chi-square at a significant threshold of $p < 0.05$.
Results Demographic data results stated predominant pharmacists were females, 29-39 years age gap, 1-5 years of experiences, working in government hospital, certificate holders in Pharmacy. Gaps existed in knowledge with unaware of antipsychotic drugs and side effects. Majority had positive attitudes favoring medication counseling, believing it enhances compliance and job satisfaction. Time constraints, communication challenges, lack of experts were identified as barriers. Concerns about confidentiality and space shortage were mentioned. No associated factors between knowledge and attitudes with demographic data were found. Only perceived barriers with demographic data had correlations. Limited counseling time was associated with education level ($p=0.025$).
Discussion. Although Colombo district pharmacists welcome medication counselling, need for improvement in knowledge and practical issues are required. Enhancing the provision of counselling services could involve implementing strategies that optimize availability of time, expand knowledge regarding antipsychotics manage space constraints within pharmacies.

Key words: Medication counseling, Knowledge, Attitudes, Barriers

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Real-world Persistence and Adherence of Paliperidone in Adolescent Schizophrenia Patients in China

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Introduction The real-world drug utilizations of antipsychotics [AP] in schizophrenia treatment remain understudied in adolescent, especially in Asia.
Aim With paliperidone extended-release (PER) tablet as the first approved AP for adolescent indication for schizophrenia in China, this study aims to explore its real-world persistence and adherence.
Methods This 5-year retrospective cohort study utilized electronic medical records (2018-2022) from a psychiatry specialized hospital (PH) and a general hospital (GH) in China. Adolescent patients (12-17y) who prescribed PER during the study period were included. Index date was the date of first identified PER prescription. Patients initiated PER monotherapy at outpatient setting on the index date with a prior schizophrenia diagnosis (ICD-10: F20.x) were included. To ensure long enough follow-up for evaluation, patients were required to have had at least 1 visit during the second or third month following an initial month of care. Persistence was calculated from index date to discontinuation of PER (gap >60d between prescriptions). Adherence (proportion of days covered [PDC]) to PER was assessed during persistence use and stratified by patients with at least 1 to 6 months of persistence.
Results Overall, 44 (mean age: 15.4y, male 31.8%) and 43 (mean age: 15.6y, male 46.5%) patients were included in PH and GH, respectively. In PH, the persistence of PER was 172.4 (SD:180.80) days, and the overall adherence was 84.6% (SD: 15.53%). The adherence for patients with at least 1 to 6 months of persistence ranged from 75.3% to 82.1%. In GH, the persistence of PER was 165.3 (SD:159.39) days, and the overall adherence was 79.4% (SD:16.46%). The adherence for patients with at least 1 to 6 months of persistence ranged from 72.2% to 78.4%.
Conclusion This study provides evidence of PER's real-world persistence of about half year and demonstrates its good adherence in clinical practice.

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Social media addiction and behavior of social media usage in undergraduate students

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Introduction: Currently, students are increasingly using social media, which may lead to social media addiction.
Aim: This study aimed to investigate the prevalence of social media addiction, usage behaviors, and detoxification among undergraduate university students in northern Thailand.
Method: A cross-sectional study was conducted using an online questionnaire distributed to undergraduate university students in northern Thailand who were willing to complete the questionnaire. Data collection occurred from September to October 2023. Social media addiction was measured by the Social Media Addiction Test (SMAT), composing of 16 items with Likert scale responses from from 0 (definitely not true) to 3 (definitely true). Scores were categorized as follows: ≥ 30 = addicted, 20-29 = almost addicted, and 0-19 = not addicted. Additionally, the questionnaire included a section on social media detoxification practices.
Results: Of 312 students, 219 were female (70.2%). The majority were third-year undergraduate students (36.5%). The Social Media Addiction Test (SMAT) scores indicated that 39.1% of the students were addicted to social media, 38.8% were almost addicted, and 22.1% were not addicted. Instagram was the most frequently used platform in one day (32.1%). On average, participants spent 7.25±3.58 hours per day on social media from Monday to Friday and 9.63±5.77 hours during weekends and holidays. The objective of social media usage was for entertainment or relaxation. 39 students (12.5%) had experienced social media detoxification and the main method was substituting social media use with other activities.
Discussion: The study revealed that about 40% of university students were addicted to social media, primarily using it for entertainment and relaxation. Some students attempted social media detox by engaging in other activities. This study underscores the impact of social media on students' lives and indicates the necessity for balanced usage approaches.

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The Impact of Winter on the Use of Antidepressants

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Introduction:
Environmental and seasonal factors significantly influence mental health, with winter particularly affecting mood and behavior due to shorter daylight, colder temperatures, and increased isolation. This study investigates how these seasonal changes affect antidepressant usage, a subject currently underrepresented in empirical research.

Aims:
The study aims to assess the impact of winter on antidepressant use across different regions and provide empirical support for policy improvements in mental health resource allocation and intervention strategies.

Methods:
Data from the Chinese Pharmaceutical Bidding and Procurement Database (2018-2023) were used, quantifying antidepressant consumption using the WHO's Defined Daily Doses (DDDs). The study employed linear mixed-effects models to analyze the seasonal impact of winter on antidepressant usage, considering variables like temperature and year.

Results:
The analysis revealed a significant increase in antidepressant use during winter ($p < 0.001$). Temperature showed a strong negative correlation with usage ($p < 0.001$), with yearly data indicating a consistent rise in antidepressant use. Notably, the interaction between temperature and year also proved significant ($p < 0.001$), suggesting that colder years exacerbate the demand for antidepressants. Variability in usage across cities was also significant ($p < 0.001$).

Discussion:
The study confirms that winter contributes to increased antidepressant usage, with colder temperatures and reduced daylight linked negatively with mental health. This inverse relationship underscores the need for strategic policy interventions during winter months. To mitigate winter's impact, enhancing access to mental health services and increasing awareness about seasonal affective disorder (SAD) and other related mood disorders are crucial. These findings advocate for targeted mental health interventions tailored to the specific needs arising during colder months.

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The Interconnection Between Depression and Chronic Kidney Disease.

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Introduction:
Numerous studies have highlighted the bidirectional association between depression and chronic kidney disease (CKD). However, the nature of their causal relationship remains a subject of debate.
Aims:
This study aimed to explore the mutual associations between depression and chronic kidney disease.
Methods:
This retrospective cohort study utilized the Taiwan Biobank database, including a total of 189,132 Taiwanese individuals aged 20-70 from 2012-2023. After excluding 142,571 individuals without follow-up data, 46,561 participants remained for analysis. For Analysis 1, investigating CKD and incident depression, participants were excluded if they were missing baseline estimated glomerular filtration rate (eGFR) data or had depression at baseline (n=1,605), resulting in a total of 44,956 participants included for analysis. For Analysis 2, which explored the association between depression and incident CKD, subjects were excluded if they were missing follow-up eGFR data or had CKD at baseline (n=515), leaving 46,046 participants for analysis. Both Analysis 1 and Analysis 2 utilized Chi-square, Fisher's exact test, and independent t-test for baseline descriptive analysis. Cox proportional hazards regression analysis was conducted to examine the mutual relation between depression and CKD, with adjustment for several covariates.
Results:
For Analysis 1, the incident depression rate was 2.424 per 1000 person-years in the CKD group and the adjusted hazard ratios were 0.562 (95% CI: 0.230-1.371). Conversely, in Analysis 2, the incidence rate of CKD was 3.334 per 1000 person-years and the adjusted hazard ratios were 1.513 (95% CI: 0.988-2.316).
Conclusion:
The findings of the study have some important implications: depressive patients may have a higher prevalence of developing CKD, whereas CKD patients do not exhibit a significant tendency to develope depression. Longer follow-up studies are required for further validation of these findings.

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The role of antipsychotics on associations between extreme temperature and heat-related outcomes

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Introduction The associations between extreme temperature and heat-related outcomes in people with mental disorders and the role of antipsychotics in these associations are unclear.
Aim To investigate the associations between extreme temperature and heat-related illness in people with severe mental illness (SMI) and the role of antipsychotics in these associations.
Methods People with SMI between 1/1/2003 and 31/12/2019 were identified in Hong Kong population-based database (Clinical Data Analysis and Reporting System). We conducted self-controlled case series to estimate the incidence rate ratio (IRR) of heat-related illness, myocardial infarction (MI), ischemic stroke, delirium and all-cause Accident and Emergency (A&E) during 5-day pre-heatwave, heatwave, and 5-day post-heatwave periods versus all other periods (baseline) within an individual using conditional Poisson regression. We stratified the observation period into periods taking antipsychotics and periods not taking antipsychotics, respectively. We also excluded periods when they were hospitalised as sensitivity analysis as it may indicate no exposure to heatwave.
Results Among people with SMI, when we stratified by antipsychotic use, only those taking antipsychotics were observed to have a higher rate of heat-related illness (IRR:1.43 (95%CI:1.18-1.73) versus 0.79 (95%CI:0.53-1.16) for non-users but there was only weak statistical evidence for this difference (p-value interaction:0.06). After removing the period during hospitalisation, the difference widened (with antipsychotics: IRR:1.49, 95%CI:1.22-1.82; without antipsychotics: IRR: 0.73, 95%CI:0.48-1.12) and statistical evidence was stronger (p-value interaction:0.02). There was no higher risk of MI, ischemic stroke, delirium or all-cause A&E associated with heatwave versus baseline.
Conclusion We showed an increased risk of heat-related illness associated with heatwave in people with mental SMI prescribed antipsychotics. No increased risk of other outcomes was found during heatwave versus baseline.

P421

Trajectories of risperidone use for changed behaviours in people with Alzheimer's disease: a nationwide study

Danika Davis

Introduction: Antipsychotic use in people with dementia has been associated with adverse events including heart failure, myocardial infarction, stroke, fractures and pneumonia. Clinical practice guidelines recommend against routine use of antipsychotics for changed behaviours in dementia. Risperidone is the only antipsychotic indicated for changed behaviours in Australia. When prescribed, the total initial duration should not exceed 12 weeks.
Aim: To characterise 12-month trajectories of risperidone use for psychotic symptoms and aggression in people living with Alzheimer's disease in Australia.
Methods: A cohort of people who initiated risperidone for changed behaviours from July 2013 to February 2023 were identified from a 10% random sample of Australia's Pharmaceutical Benefits Scheme (PBS) dispensing data. All people who initiated risperidone and who were dispensed two or more prescriptions over 12 months were included. Group-based trajectory modelling was used to characterise medication trajectories.
Results: Of 9,156 people who initiated risperidone for changed behaviours, 6,881 were dispensed two or more prescriptions over the following 12 months. Four trajectories of risperidone use were identified: rapid discontinuation (16%), gradual discontinuation (25%), intermittent dispensing (46%) and persistent (13%).
Discussion: Despite the risk of harms outweighing the potential benefits, 44% of people who initiated risperidone for changed behaviours became intermittent or persistent users over a 12-month period. By extrapolation, over the past decade, more than 40,000 Australians with Alzheimer's disease were dispensed risperidone on an intermittent or persistent basis in the 12-month period following initiation.

P422

Umbrella Review on First-Line Therapy Options for Infantile Epileptic Spasms Syndrome

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Introduction: Recent guidelines and reviews on Infantile epileptic spasm syndrome (IESS) recommend the use of adrenocorticotropic hormone (ACTH), corticosteroids or vigabatrin, as the first-line treatment. However, a consensus on the most effective approach remains elusive. Aims: This umbrella review aims to synthesize evidence from systematic reviews and meta-analyses to evaluate the efficacy of first-line treatments for IESS.
Methods: Comprehensive searches of PubMed, Embase, Cochrane, and Scopus databases were conducted up to February 12, 2024. The methodological quality of the included reviews was evaluated using the “Assessing the Methodological Quality of Systematic Reviews (AMSTAR)” and the certainty of evidence was evaluated using the GRADE approach. Effect sizes and 95% confidence intervals (CI) of each related outcomes, was calculated using fixed effects models and risk ratio (RR). Reviews without meta-analyses were reported descriptively.
Results: Among 133 studies, nineteen were included for final assessment, published between 2010-2022. AMSTAR shows study quality ranges between “low “to “critically low”. For prednisolone versus ACTH, the OR for spasm cessation was 1.02 (CI: 0.42-2.44, I^2=71%), and for hypsarrhythmia resolution, it was 1.07 (CI: 0.54-2.13, I^2=71%). The certainty of evidence varied from moderate to very low. Electroclinical and clinical remission outcomes were graded as low, while reduction in spasms ranged from moderate to low, and adverse drug reactions (ADRs) were very low. Corticosteroids were superior in two studies, LD-ACTH was superior to HD-ACTH in four studies, and few studies showed no difference between HD-Prednisone and ACTH.
Conclusions: The findings indicate minimal differences in treatment efficacy for IESS, with evidence insufficient to make definitive clinical recommendations. The low to critically low quality of the studies underscores the need for higher-quality research to better inform clinical decisions.

P423

ADHD medication use and cardiometabolic conditions in pregnancy: A population-based cohort study

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Introduction
Use of medications to treat attention-deficit/hyperactivity disorder (ADHD) is becoming increasingly prevalent among women of reproductive age, but little is understood about their cardiometabolic effects in pregnancy.
Aims
We aimed to examine potential associations between ADHD medication use and cardiometabolic conditions during pregnancy (gestational hypertension, preeclampsia and gestational diabetes) and the pharmacological treatment thereof.
Methods
We conducted a population-based matched cohort study based on linkage of the New South Wales (NSW) Admitted Patient Data Collection with Pharmaceutical Benefits Scheme (PBS) dispensing data. We included women aged 18-55 from NSW, Australia, who gave birth between January 2014 and June 2021. We compared the prevalence of cardiometabolic conditions and new cardiometabolic medication use during pregnancy among women who used ADHD medications during pregnancy (n=366) with a 1:10 matched cohort of unexposed women, and also with women who had used ADHD medications in the 12 months before pregnancy (n=252). We used Poisson regression models adjusted for various sociodemographic and pregnancy-related factors.
Results
Compared with unexposed women, women who used ADHD medications during pregnancy had an increased risk of gestational hypertension (10.1% vs. 4.8%; aRR: 1.76, 95% CI: 1.20-2.57) and gestational diabetes (17.9% vs. 13.5%; aRR: 1.41, 95% CI: 1.09-1.82), with slightly elevated risk estimates for preeclampsia (6.3% vs. 4.0%; aRR: 1.30, 95% CI: 0.82-2.05) and new cardiometabolic medication use (10.7% vs. 6.6%; aRR: 1.40, 95% CI: 0.97-2.01). Compared with women who used ADHD medications before pregnancy, women who used ADHD medications during pregnancy had a greater risk of gestational diabetes (17.9% vs. 8.3%; aRR: 1.76, 95% CI: 1.06-2.93), but not of hypertensive disorders of pregnancy nor initiation of cardiometabolic medications.
Discussion/Conclusion
Women using ADHD medications have an increased incidence of cardiometabolic conditions during pregnancy, but it remains unclear to what extent this is attributable to the medication rather than the underlying ADHD.

[Real World Data]

P424

Assessment of Real-World Data Sources and A Hybrid Approach in Evidence Generation

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Introduction: Real-world evidence (RWE) is increasingly used for regulatory, reimbursement, and patient access decisions in Asia-Pacific. RWE has the capability to address similar evidence gaps across different countries in a single study through standardized research methodologies, which enables the results to be analyzed and presented holistically. However, the heterogeneity of real world data sources in Asia-Pacific poses a major challenge to conduct multi-country real-world research using a standardized approach.

Aims: To identify an innovative approach to utilize unharmonized data sources for multi-country research.
Methods: We evaluated data sources across Asia-Pacific countries for RWE generation and described a hybrid approach to utilize unharmonized data sources of varying levels of data maturity for multi-country research. Data sources were evaluated based on technical and operational elements: E.g. data availability; data format (charts, electronic records); completeness; access (individual, aggregate-level); consent requirements; and capacity and burden on research team and patients.

Results: We adopted a hybrid approach-Mosaic Model to harmonize data collected using different methods when a single collection method was not feasible for all data sources. In the Mosaic Model, data was directly extracted and enhanced from electronically structured data sources (e.g. electronic medical records, registries), and transformed using a common data model. For paper-based or electronically unstructured data sources, data was abstracted from medical records and subsequently transformed to the same common data model.
Discussion: The use of a common data model harmonizes the data for analysis and overcomes the challenges faced with unharmonized data sources and concerns about data privacy, while ensuring consistency and validity of the research under a single protocol, analysis, and timeline.
This hybrid approach was successfully implemented in oncology and metabolic disease studies in Asia-Pacific, enabling variables captured across different unharmonized data sources to be standardized for analysis.

P425

Bias description among pharmacoepidemiologic studies applying common data model: a systematic review

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Introduction
Converting data from multiple databases into the common data model (CDM) allows for the rapid, convenient application of different databases. However, there is a variety of biases present in the currently conducted related studies.
Aims
To systematically summarize the biases presented in the application of CDM in pharmacoepidemiologic research, and to provide insights for controlling these biases in future research.
Methods
Five English databases (PubMed, Web of Science, EMBASE, Scopus, Virtual Health Library) and four Chinese databases (CNKI, Wan-Fang Data, VIP, SinoMed) were electronically searched to collect relevant studies on applying CDM in pharmacoepidemiologic research from inception to January 2024. Two reviewers independently screened studies and extracted information on research details, CDM-related, pharmacoepidemiology-related information, and biases reported in the articles.
Results
This study included 309 studies, with 308 in English and 1 in Chinese. Among all the included articles, 76 reported selection bias (24.6%), 198 reported information bias (64.1%), and 114 reported confounding bias (36.9%). The most frequently reported selection bias was related to the vaccine safety datalink (VSD) data, which predominantly covers individuals with long-term commercial insurance, making the data potentially non-generalizable to other populations or representative of the U.S. population (31/76). The most frequently reported information bias was misclassification bias (98/198), which was due to not all exposures being recorded (e.g., vaccinations outside the VSD system or self-medication). Confounding bias mainly included unrecorded information and passively collected missing variables in the databases, such as certain laboratory test information (97/114).
Discussion
Our study extracted and summarized the spontaneously reported biases in the application of CDM in pharmacoepidemiologic research, outlining the proportion of each type of bias and describing their main content. Given the current state of inadequate data governance quality in this field, future research should pay greater attention to controlling these biases.

P426

Examination of methods for utilizing unstructured data using "Millennial Medical Record"

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【Introduction】
Health insurance claims data and diagnosis procedure combination (DPC) data are commonly used sources of medical information, but they have limitations when it comes to evaluating clinical outcomes like treatment effectiveness and safety. A database called "Millennial Medical Record" combines health insurance claims data, DPC data, and electronic health records (EHRs) data, which may allow for the evaluation of clinical outcomes using unstructured data from EHRs, such as progress notes.

【Aims】
The aim of this study is to examine methods for extracting clinical outcomes from unstructured data in the "Millennial Medical Record" and to assess their feasibility.

【Methods】
In this study, we analyzed progress notes in EHRs data to investigate the actual treatment status, including reasons for discontinuation of mite sublingual immunotherapy (SLIT). We focused on patients who took Actair® or MITICURE® between March 2019 and October 2022. We set keywords to extract progress notes, specifically focusing on reasons for discontinuation and adverse events. Keywords related to "discontinuation" and "drug suspension" were used to extract reasons for discontinuation, and the entire text containing these keywords was reviewed. Extracted text related to adverse events were then classified using the MedDRA for analysis.

【Results】
Out of the total study population of 640 patients, the reason for discontinuing SLIT could be determined from the progress notes in EHRs data for 139 patients. Adverse events were assessed in 457 patients. The latest figures and details will be presented on the same day.

【Discussion】
While progress notes in EHRs data provide detailed information about a patient's treatment status, the variation in what physicians write could pose a challenge for accurately determining and analyzing clinical outcomes. Further research will be conducted to establish methods for effectively utilizing unstructured data.

P427

The use of real-world evidence in Japan cost effectiveness analyses

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Introduction/Aims: Real-world evidence (RWE) has been used widely in many countries during Health Technology Assessment (HTA) submissions and appraisals. Japan formally implemented cost effectiveness analyses (CEA) for price adjustment (HTA system) from April 2019. This presentation assessed the use of RWE in Japan CEA.
Methods: We reviewed HTA dossiers submitted by pharmaceutical companies and appraisal reports created by the Center for Outcomes Research and Economic Evaluation for Health (C2H) published on their website until December 2023. We categorized RWE use cases based on the area supported and summarized by the type of RWE data source in those reports.
Results: Company dossiers on 13 products and C2H appraisal reports on 25 products were available on the C2H website until December 2023. From these reports, 70 RWE use cases were identified for 22 products, with multiple use cases in some products. Resource utilization estimation (health state cost, adverse event cost, complication cost) is the most common RWE use (24), followed by analytical population proportion estimation (17). Other RWE uses include epidemiology data of patient background characteristics for economic models (8), treatment costs of designated drugs and comparators (7), external comparator for single arm studies (4), health-state transition probability in economic models (4), comparative drug determination (3), effectiveness or additional benefit (3). Regarding the type of RWE data source, the most common source is the national database of health insurance claims and specific health check-ups of Japan (NDB) (23), followed by Japan commercial claims databases which include MDV, JMDC and IQVIA claims (15). Other sources include physician survey (11), patient disease registry (6) and retrospective cohort study (3).
Conclusion: These results showed that RWE was used in most HTA products with various purposes and diverse data sources in Japan and this will promote RWE use in HTA submissions and appraisals in the future.

[Surgery and Medical Devices]

P428

Elevated Respiratory Complications following Robotic-Assisted Lobectomy: A National Cohort Analysis

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Introduction: Robotic-assisted lobectomy (RL) is increasingly used nationally, but little comparative data exist on its safety compared to open lobectomy (OL) or video-assisted lobectomy (VL).

Aims: The study aimed to estimate the risk of perioperative complications for RL, VL, or OL.

Methods: Admissions were identified from the hospital administrative data collected between 2015 and 2019. Propensity score matching and inverse probabilistic weighting were used to account for selection bias. Logistic and quantile regression models were applied to determine perioperative outcome differences.

Results: We identified 26,140 cases of which 5,337 (20.4%), 12,680 (48.5%), and 8,123 (31.1%) underwent RL, VL, and OL, respectively. RL and VL were associated with lower complication rates, shorter lengths of stay, and fewer mortality risks. RL was associated with significantly elevated risks for perioperative respiratory complications (adjusted odds ratio [aOR] 1.10, p=0.010).

Discussion: Relatively low rates of perioperative complications for VL and RL, and higher respiratory complication rates in RL are concerning.

P429

Evaluating In-Hospital Outcomes of the Ross Procedure Using Real-World Data

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Introduction

Patients with aortic stenosis (AS) often require aortic valve replacement (AVR). The Ross procedure, first described by Donald Ross in 1967, replaces the damaged aortic valve with the patient's pulmonary valve. Compared to mechanical (M-AVR) and biological aortic valve replacements (B-AVR), the Ross procedure is associated with significant long-term reductions in stroke and major bleeding incidences and improved survival from cardiac and valve-related mortality. However, research on in-hospital outcomes among AS patients underwent Ross, M-AVR, and B-AVR remains limited.

Aims

To investigate in-hospital outcomes of AS patients underwent the Ross procedure compared to those underwent M-AVR and B-AVR.

Methods

Admissions of children and adults were identified from the Kids' Inpatient Database (KID) and National Inpatient Sample (NIS) collected from 2000 through 2020. Exact matching was employed to mitigate selection bias, and generalized estimating equations were applied to determine differences in in-hospital outcomes.

Results

We identified 875 pediatric AS patient cases, among which 480 (54.9%), 242 (27.6%), and 153 (17.5%) underwent the Ross procedure, M-AVR, and B-AVR, respectively. Among 1546 adult AS patients identified after exact matching, 168 (10.9%), 719 (46.5%), and 659 (42.6%) underwent the Ross procedure, M-AVR, and B-AVR, respectively. No statistically significant difference in mortality was observed among the three surgical types for both adults and children. However, the Ross procedure was associated with lower complication rates but higher acute kidney injury rates in children, especially compared to M-AVR. Adult AS patients underwent the Ross procedure exhibited worse outcomes than children regarding blood transfusions, procedural support, and acute kidney injury rates.

Discussion

Compared to M-AVR and B-AVR, the Ross procedure may be associated with increased complications but show no statistically significant difference in mortality, particularly in adult AS patients.

P430

Intraoperative Hemodynamics and Postoperative Outcomes in Type A Aortic Dissection

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Introduction:
Type A aortic dissection (TAAD) surgery carries a significant risk of acute kidney injury (AKI), exacerbated by intraoperative hypotension and venous congestion. Effective hemodynamic management is crucial to mitigate these risks.

Aims:
To assess whether intraoperative hypotension and venous congestion are significant predictors of postoperative kidney injury and other major adverse events following TAAD surgery.

Methods:
We collected demographic, laboratory, and outcome data for adults who underwent TAAD surgery from January 2016 to July 2023. Primary exposures were venous congestion, defined by central venous pressure (CVP) thresholds of ≥12, 16, or 20 mmHg, and mean arterial pressure (MAP) thresholds of ≤55, 65, or 75 mmHg. Primary outcomes were AKI and acute kidney disease (AKD). Secondary outcomes included death and stroke. We used restricted cubic spline regression and multivariate logistic regression to adjust for confounding factors.

Results:
Among 543 subjects, AKI or AKD was significantly associated with each 10-minute epoch of CVP ≥10, 12, 16, or 20 mmHg (all $p < 0.001$), and each 60-minute epoch of CVP ≥10, 12, 16, or 20 mmHg area under the curve (AUC) (all $p < 0.001$). Mortality increased by 6% to 13% for each 10-minute epoch of CVP ≥10, 12, 16, or 20 mmHg (all $p \leq 0.003$) and by 5% to 21% for each 60-minute epoch of CVP ≥10, 12, 16, or 20 mmHg AUC (all $p < 0.001$). Stroke risk increased by 5% for every 10-minute CVP AUC above 16 mmHg and by 11% for CVP AUC above 20 mmHg ($p = 0.039$ and $p = 0.031$, respectively).

Discussion:
Both CVP and MAP are associated with the risk of postoperative AKI and AKD in TAAD patients. CVP showed a direct correlation with postoperative mortality and stroke.

P431

Active surveillance of medical device associated adverse events at tertiary care hospital

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Introduction: Medical devices play a crucial role in healthcare delivery system but can also cause adverse events compromising patient safety and effecting overall outcomes.
Aims: To assess the pattern of Medical Device Associated Adverse events (MDAEs) among patients in critical care settings.
Methods: An active surveillance study was conducted over nine months in critical care units. Patients were monitored daily for MDAEs through case sheet reviews, interviews with patients and healthcare professionals. Reported MDAEs were assessed for causality, severity, and device disposition according to Materiovigilance Program of India (MvPI) guidelines version 1.2. Patterns of MDAEs were analyzed categorically, risk stratification, and nature of adverse events. Predictors associated with MDAEs were calculated using odds ratios at a 95% confidence interval
Results: A total of 242 MDAEs were reported among 180 patients, with the majority of MDAEs occurring in elderly patients (25.5%). Ventilator-associated pneumonia was higher among mechanical ventilator users [80(33.05%)], and most were non-implantable devices [203(83.88%)]. Regarding device risk classification, category C was the most frequently reported [130(53.71%)]. The causality assessment for [136(56.19%)] of the MDAEs was probable, with [195(80.57%)] being non-serious events. Almost all MDAEs [114(47.10%)] were device-associated and were disposed of within healthcare facilities [96(63.2%)]. Concerning patient outcomes, [222(91.7%)] of the study population recovered. Comorbidities and length of hospital stay were significant predictors [OR= 2.6 CI: 1.05-6.76, p= 0.039].
Conclusion: MDAEs in ICUs and in-patient wards contribute to patient distress and extended hospital stays. Continuous monitoring and reporting of MDAEs are essential to mitigate their incidence and improve patient safety.
Keywords: Materiovigilance, Medical devices, Medical Device Associated Adverse events

P433

Biological Age's Association with Postoperative Renal Outcomes After Surgery

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Introduction:
Postoperative acute kidney injury (AKI) and acute kidney disease (AKD) are significant risks, affecting up to 30% of cardiac surgery patients. Various factors contribute to these outcomes, including patient and surgical factors. Despite its potential as a predictor, biological aging remains underexplored in the analysis of postoperative AKI.
Aims:
This study aimed to describe biological aging in cardiac and noncardiac surgery patients and evaluate its association with postoperative renal dysfunction (AKI and AKD). We hypothesized that accelerated biological aging would correlate with increased risks of AKI and AKD, and assessed healthcare resource utilization linked to postoperative renal outcomes.
Methods:
Baseline demographics, stratified by phenotypic age acceleration (PhenoAgeAccel), were reported using mean (SD), median (IQR) for continuous variables, and number (percentage) for categorical variables. Outcome frequencies with 95% confidence intervals were depicted. Cox models assessed PhenoAgeAccel's association with postoperative AKI, while generalized linear models explored links with AKI stages and AKD.
Results:
A total of 23,247 patients were included. Analysis showed that patients with AKI and AKD tended to have higher phenotypic age. Patients with PhenoAgeAccel, particularly those with SD >2, were more susceptible to AKI, stage 2+ AKI, and AKD compared to those with phenotypic age deceleration. Subgroup analysis showed males (aOR 2.60) and non-cardiac surgeries (aOR 2.79) were more prone to AKI, whereas females (aOR 4.04) and non-cardiac surgeries (aOR 2.79) were more associated with stage 2 or above AKI and AKD. Non-linear regression demonstrated a rising trend, indicating an likelihood of AKI and AKD with higher SD. Cumulative incidence curves showed notably higher AKI likelihood in patients with SD >2, especially within 2 days postoperation.

Discussion:
As biological age increases, the risk of postoperative AKI and AKD escalates. This highlights the importance of considering biological age as a predictor in managing postoperative outcomes.

P434

INVESTIGATING DRUG RELATED PROBLEMS IN PATIENTS FOLLOWING CARDIAC SURGERY: A PROSPECTIVE STUDY

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Introduction:
Postoperative complications in patients following cardiac surgery remain a significant concern, with drug-related problems (DRPs) being potential contributors. Identifying and addressing these DRPs are essential for optimizing patient outcomes and reducing morbidity and mortality.
Aim:
To analyze Drug-Related Problems (DRPs) as contributors to postoperative complications in patients following cardiac surgery and interventional procedures.
Methodology:
Between December 2023 and June 2024, a prospective observational study investigated the incidence and preventability of DRPs in a single cardiac care center. DRPs were classified by Hepler-Strand Classification and scales utilized to analyze these DRP's are Naranjo causality assessment scale, Schumock and Thornston preventability scale, WHO causality assessment scales, Hartwig's severity scale, predictability scale.
Results:
A total of 103 patients were included in the analysis. DRP's occurred in 49 (47.5%) of patients. The most common DRP's were drug-drug interaction were 34 (33%), ADR in 8(7.7%), and unindicated indication in 7 (6.79%) patients. The most frequently observed adverse drug reactions (ADRs) included heparin-induced thrombocytopenia and drug-induced hypoglycemia. Additionally, untreated indications comprised two cases of respiratory acidosis, one case of lactic acidosis, and one case of anemia.
Discussion:
This study highlights the significant impact of drug-related problems (DRPs) on postoperative complications in patients following interventional cardiac surgery. Among the identified DRPs, drug-drug interactions, and adverse drug reactions (ADRs) were notable contributors.
High DRP prevalence, affecting nearly half of patients, highlights medication management complexity postoperatively. Unindicated indications emerged as significant DRPs, stressing rational prescribing and evidence-based perioperative care.
By addressing DRPs effectively, healthcare providers can optimize patient outcomes, reduce morbidity and mortality, and enhance the overall quality of care delivered to patients undergoing cardiac surgery.
Key Words: - Postoperative complication, Drug-related problems (DRPs), Cardiac surgery, Drug-drug interaction, Adverse drug reactions (ADRs)

P435

Predictive Modeling of Intraoperative Acquired Pressure Injuries

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Introduction:
Intraoperative acquired pressure injuries pose significant risks to patients undergoing surgery, impacting their physical health and postoperative recovery. These injuries not only cause discomfort but also lead to complications, prolonged hospital stays, increased costs, and diminished quality of life. The incidence of intraoperative pressure injuries in cardiovascular surgery patients is alarmingly high, emphasizing the importance of prevention in this population.
Aims:
To identify factors influencing intraoperative acquired pressure injuries and develop a reliable risk prediction model to facilitate the implementation of preventive measures.
Methods:
Logistic regression, naive Bayes, random forest, support vector machine, Extreme Gradient Boosting, and Gradient Boosting Decision Tree models were individually established for risk prediction. These models were weighted and integrated, with evaluation based on accuracy, recall, precision, AUC, and F1 Score metrics.
Results:
The integrated model demonstrated superior predictive performance and robustness (Test set: Accuracy=0.955, Precision=0.962, Recall=0.945, F1 Score=0.953, AUC=0.994; Validation set: Accuracy=0.833, Precision=0.907, Recall=0.907, F1 Score=0.907, AUC=0.725), effectively forecasting the risk of intraoperative acquired pressure injuries. Interpretive analysis using the SHAP framework highlighted gender and age as significant risk factors visually. Anesthesia duration, estimated glomerular filtration rate, and white blood cell count emerged as critical decision-making factors in the model.
Discussion:
This analysis employed an integrated approach to optimize the predictive model for intraoperative acquired pressure injuries, contributing to the advancement of research in this domain.

P436

PREDICTORS OF POST-OPERATIVE COMPLICATIONS IN PATIENTS FOLLOWING CARDIAC SURGERY: A PROSPECTIVE STUDY

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Introduction: Cardiac surgery is a crucial medical specialty that addresses a wide range of cardiovascular conditions. While technological advancements and surgical expertise have significantly improved outcomes, it is important to recognize that complications can still arise after these procedures. These complications can vary in severity and may affect different aspects of a patient's health, from the cardiovascular system to respiratory and neurological functions. Understanding and managing these potential issues is a fundamental aspect of ensuring successful clinical outcomes after surgical interventions.

Aim: This study aims to identify the risk factors for postoperative complications in patients following cardiac surgery and interventional procedures.

Methodology:

A total of 103 patients who had undergone any of the below cardiac surgeries such as Coronary-Artery-Angiography, Percutaneous transluminal coronary angioplasty, Coronary Artery Bypass Graft, Temporary pacemaker Implantation or Atrial Septa Defect, Closure/ Valve Replacement were included in the study. Suitable data collection forms were prepared to capture the patient details such as patient demographics, current medications, past medical and medication history, nursing notes, and laboratory data from patient case files.

Results: Postoperative complications occurred in 91 (88.3%) of patients. The most common complications were hyponatremia in 38 (36.8%), anemia in 33 (32%), hypertension in 33 (32%), tachycardia in 15 (14.5%), hypokalemia in 15 (14.5%), and hypophosphatemia in 10 (10.6%) patients. Commonly reported risk-factors include patient demographics (such as advanced age and gender), preoperative comorbidities (hypertension, diabetes, and renal dysfunction), anatomical complexity of surgical procedure, duration of cardiopulmonary bypass and cross-clamp time, intraoperative blood loss and transfusion requirements, and perioperative management strategies.

Discussion:

Study findings reveal a high prevalence of postoperative complications after interventional-cardiac surgery, affecting nearly 9 out of 10 patients. Common complications include hyponatremia, anemia, hypertension, tachycardia, hypokalemia, and hypophosphatemia, stemming from surgical factors, pre-existing conditions, and postoperative protocols.

Key-Letter: - Cardiac-surgery, post-operative, Complications, Risk-factors

P437

Sex-specific Roles of Early-postoperative Hemoglobin on Adverse Kidney Outcomes After Cardiac Surgery

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Introduction:
Anemia and transfusion are closely linked to critical outcomes affecting postoperative recovery and renal function in cardiac surgery. The relationship between early postoperative hemoglobin levels and adverse kidney outcomes, including acute kidney injury (AKI) and acute kidney disease (AKD), remains underexplored, particularly with respect to sex-specific differences.

Aims:
This study aims to assess the sex-specific mediating effect of postoperative hemoglobin on the relationship between preoperative anemia and postoperative outcomes.
Methods:
We conducted a multicenter retrospective cohort study including patients who underwent cardiac surgery at three medical centers in China. Hemoglobin levels were measured preoperatively and postoperatively, with anemia defined by WHO criteria. A mediation analysis framework was applied; the main exposure was early postoperative hemoglobin, analyzed using spline regression, and further stratified by sex and preoperative anemia severity. Sensitivity analyses were performed using different reference levels for postoperative hemoglobin.

Results:
Among 9,135 patients, the incidence of preoperative anemia was slightly higher in females (35.0%) compared to males (32.9%). Among non-anemic patients, males exhibited a significant increase in AKI risk with postoperative hemoglobin levels below 9 g/dL, while females did not show significant risk changes. For anemic patients, risk curves were nearly linear for both sexes, but females with moderate to severe anemia had a higher increase in AKI risk when postoperative anemia was severe. Mediation analysis revealed that the indirect effect of postoperative hemoglobin on AKI was higher in males (mediation proportion 41.1% vs. 22.3%), with mediation proportions increasing with anemia severity (39.0%-50.8% vs. 19.0%-31.4%). For AKD and LOS outcomes, similar sex-specific patterns were observed, with males showing greater mediation effects.

Discussion:
Our findings show that early postoperative hemoglobin levels mediate the relationship between preoperative anemia and adverse kidney outcomes, with stronger effects in males. This highlights the need for sex-specific anemia management strategies to improve postoperative outcomes.

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The Influence of Timing in Cholecystectomy on the Incidence of Post-ERCP Pancreatitis

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Introduction: Endoscopic retrograde cholangiopancreatography (ERCP) is a commonly used procedure for diagnosing and treating conditions of the biliary tract and pancreas. However, this procedure can also result in post-ERCP pancreatitis, a severe and potentially life-threatening complication.
Aim: To evaluate the impact of the timing and procedures of cholecystectomy relative to ERCP on the risk of developing post-ERCP pancreatitis.
Methodology: A thorough literature search was performed in PubMed, Cochrane CENTRAL, and Google Scholar from the inception of 20th November 2023. A combination of keywords, MeSH terms, and entry terms on Cholecystectomy, Laparoscopic Cholecystectomy, Pancreatitis, and Gallbladder disease was combined with Boolean operators. All randomized controlled trials (RCTs) examined mainly the influence of timing and procedures of cholecystectomy on the incidence of post-ERCP pancreatitis were included. The Random-effects model was used based on the heterogeneity identified using the I^2 statistic and Cochran's Q test.
Results: The results showed that the incidence of post-ERCP pancreatitis varied widely depending on the type of ERCP procedure performed. Out of 16 non-duplicate research articles identified through database searching, 4 studies, with 3621 patients, were included in this study. The risk of pancreatitis (OR 0.43, 95% CI: 0.26-0.72, p=0.001) was significantly lesser in the pre-ERCP procedure group than in the post-ERCP procedure group.
Conclusion: This systematic review & meta-analysis provides evidence that post-ERCP cholecystectomy is associated with a higher risk of post-ERCP pancreatitis than pre-ERCP cholecystectomy. These findings have important implications for clinical practice and may guide decisions regarding the timing and procedure of cholecystectomy in patients undergoing ERCP. Further studies are needed to confirm these results and identify the underlying mechanisms contributing to this relationship.
Keywords: Pancreatitis, Endoscopic retrograde cholangiopancreatography (ERCP), Cholecystectomy, Systematic review.

Key Words: Pemetrexed, Addison’s disease, Signal Detection, Adverse Drug Reactions

[Vaccination]

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Design and Analytical Methods for Vaccine Safety Evaluation

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- Introduction
In advancing the use of observational routinely collected healthcare databases in Japan's vaccine pharmacovigilance, it is essential to establish epidemiological evaluation methods for each step of signal management (signal detection, signal verification, and risk minimization for identified risks). Systematic discussions on methodologies for signal confirmation are insufficient, and no guidelines have been issued from Japan.

- Aims
This study presents our findings of designs and analytical methods for verification of safety signals in vaccine pharmacovigilance.

- Methods
We reviewed optimal designs and analytical methods for assessing causality in vaccine adverse events using routinely collected healthcare databases. Specifically, we first conducted a literature search on vaccine adverse events mainly using vaccine safety datalink to identify representative designs and analytical methods. Next, we summarized the characteristics of each design and analytical method, along with the statistical considerations for their application.

- Results
Cohort studies and Self-Controlled Case Series (SCCS) were identified as representative designs. Additionally, the study design and analysis methods used tended to differ depending on the "target vaccination population," "vaccination method (frequency)," and "adverse events of interest. The importance of conducting Quantitative Bias Analysis and applying appropriate sensitivity analyses was highlighted due to the many assumptions used in any design or method.

Discussion/Conclusion
We conducted a literature search on designs and analytical methods for verification of vaccine safety signals using healthcare databases and organized the statistical considerations. It is crucial to use methods tailored to disease characteristics and to quantitatively present the reliability of the results through sensitivity analyses.

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Exploring determinants of human papillomavirus vaccination initiation and completion among adult females

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Aim/Objective: Human papillomavirus (HPV) vaccination rates among females are lower than the World Health Organization target and vaccination rates specifically among adult females are even much lower.
Methods: We systematically evaluated individual socioeconomic/health-related characteristics associated with HPV vaccination initiation and completion among adult females. We performed a iterature search on December 14, 2022, and supplemented the search on August 1, 2023. We pooled appropriate multivariable-adjusted results using an inverse variance random-effects model and expressed the results as odds ratios with associated 95% confidence intervals. A point pooled significantly increased/decreased odds of 30–69% was regarded to be strongly associated, and ≥70% was very strongly associated.
Results: We included 63 cross-sectional studies. There were strongly increased odds of vaccination initiation among White women compared with Blacks or Asian women, and those with higher education, health insurance, a history of sexually transmitted infection (STI), receipt of influenza vaccination in the preceding year, not married/cohabiting, not smoking, using contraception, and having visited a healthcare provider in the preceding year. We observed very strongly increased odds of vaccination initiation among those younger and having been born in the country of study. Similarly, there were strongly increased odds of completing the vaccination series for the same variables as initiating vaccination, except for higher education, prior STI, smoking and contraception use. Additional variables associated with strongly increased odds of vaccination completion not seen in initiation were higher annual household income, being lesbian/bisexual, and having a primary care physician. We observed very strongly increased odds of vaccination completion similar to vaccination initiation, but including for White compared with Black women, higher education, and prior cervical cancer screening.

Conclusion: These individual characteristics may be the key to identifying women at increased risk of not being vaccinated against HPV and could inform targeted messaging to drive HPV vaccination.

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Hepatitis B vaccine safety: Analysis of adverse reactions based on VAERS database

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Introduction Hepatitis B vaccines (HBV) are widely used duo to their high clinical use and mild effects. However, as post-marketing data accumulate, several serious adverse events following HBV have been reported. Currently, quantitative studies based on real-world data are lacking, and information on their adverse effects is limited.

Aims Adverse reaction signals of the hepatitis B vaccine were mined and analyzed using the U.S. Vaccine Adverse Event Reporting System (VAERS) to provide a reference for the safe clinical use of this vaccine.

Methods Multiple statistical methods, including the ROR method, the MHRA method, and the BCPNN method, were utilized to identify signals of HBV-associated adverse reactions, and positive signals consistent with designated medical events (DMEs) were singled out for focused comparison and discussion.

Results Analysis of 53,277 HBV-related adverse events identified 270 positive signals across 22 System Organ Classifications (SOCs), with systemic disease and various reactions at the site of administration being the most common. Four potential positive new signals consistent with Preferred Terms (PTs) were identified in DME: aplastic anaemia, dermatitis exfoliative, haemolytic anaemia, and hepatic failure, with dermatitis exfoliative showing a relatively strong signal.

Discussion/Conclusion This study suggests that HBV has a potential risk in terms of causing aplastic anaemia, dermatitis exfoliative, haemolytic anaemia and hepatic failure. Since some subtypes of aplastic anaemia and haemolytic anaemia are autoimmune diseases, and immunization may stimulate potential autoimmune genetic predisposition, people with autoimmune diseases or a family history of hereditary immune diseases should be monitored after receiving HBV. Health professionals should be contacted to take measures to help if anaemia, palpitations, and high fever occur.

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Impact of the universal seasonal influenza vaccination policy in Manitoba, Canada

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Aim/Objective: In 2010, the government of the province of Manitoba, Canada introduced universal seasonal influenza vaccination policy (USIVP), providing free-of-charge vaccination to all registered residents of the province at least six months of age. Impact of the policy on seasonal influenza vaccine (SIV) uptake (receipt of vaccine) in Manitoba remains unclear, as there is a lack of published evaluations.

Methods: We conducted an ecological study, utilizing population-wide data from several linked de-identified Manitoba Health and Seniors Care administrative health databases. The study period was from 2000/01–2019/20 influenza seasons. The primary exposure was USIVP (five influenza seasons pre-policy [2005/06–2009/10] compared with post-policy [2010/11–2014/15]). The outcome was SIV uptake. We conducted pre/post logistic regression analysis stratified by age group (<5-, 5-17-, 18-44-, 45-64-, ≥65-year-olds) and certain population socioeconomic and health-related characteristics. Results are adjusted odds ratios with associated 95% confidence intervals.

Results: We observed significantly increased adjusted odds of SIV uptake post-policy relative to pre-policy in all age groups except ≥65-year-olds already covered from inception of the vaccination program. The adjusted odds ratios ranged from 0.76 (0.75-0.76) among ≥65-year-olds to 2.15 (2.13-2.18) among 5-17-year-olds, and were largely homogeneous within age groups across sex, income quintiles, regions of residence, and categories of number of visits to primary care physician/hospitalization one year prior to an influenza season except among <5- and 5-17-year-olds. These findings were mostly consistent irrespective of sex and region of residence although there was variability across income quintiles in Northern Manitoba region.

Conclusion: Introduction of the USIVP in Manitoba was followed by a significant increase in SIV uptake in the five years post policy among <65-year-olds, with similar increased relative odds of vaccination observed within age groups across subpopulations. The observed variations in the relative odds of vaccination across income quintiles in Northern Manitoba region requires administrative attention.

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Individual characteristics associated with adherence to seasonal influenza vaccination in Manitoba, Canada

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Aim/Objective: There is a lack of published evidence on factors associated with adherence (maintenance of cumulative vaccination) to seasonal influenza vaccination (SIV) in Manitoba, Canada. We sought to assess the associations.
Methods: A cohort study utilizing Manitoba administrative health databases. Participants received SIV in 2010/11 influenza season, remained registered Manitoba residents and received at least one SIV during the 2011/12-2019/20 seasons. We dichotomized adherence into “more adherent” (6-9 SIVs) and “less adherent” (1-5 SIVs) and used multivariable adjusted generalized estimating equation logistic regression models to assess association between adherence and socioeconomic, health-related, and primary care physician (PCP) characteristics, stratified by age group (<5-, 5-17-, 18-44-, 45-64-, ≥65-year-olds) and sex. Results are adjusted odds ratios with 95% confidence intervals.
Results: We included 152,493 individuals. Males had lower odds of being more adherent except among ≥65-year-olds (1.03 [1.01-1.05]). Compared with the lowest income quintile, those in higher income quintiles had higher odds of being more adherent. The odds mostly increased with increase in income quintile. Those with more contact with the PCP/hospitalization one year prior had higher odds of being more adherent. The odds increased with increased contact among 18-44-, 45-64- and ≥65-year-olds. Those who had PCP with more years of practice had higher odds of being more adherent. The odds increased as years of practice increased. These observations were mostly consistent irrespective of sex.
Conclusion: Female gender, and having higher income, more contact with the health system and experienced PCP may determine increased adherence to SIV in Manitoba. These findings require attention.

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Effectiveness of inactivated influenza vaccine against laboratory-confirmed influenza among Chinese elderly

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Introduction:
Evidence on the effectiveness of influenza vaccination in the elderly is limited and controversial, with few reports from China.
Aims:
To estimate the effectiveness of the inactivated influenza vaccine (VE) against laboratory-confirmed influenza-associated visits among elderly individuals in Ningbo, China, across four influenza seasons.
Methods:
A test-negative case-control study was conducted among elderly individuals (aged ≥60 years) from 2018-19 to 2021-22. Influenza-positive cases and negative controls were matched 1:1 by age, sex, hospital, and date of influenza testing. Logistic regression models were used to compare vaccination odds ratios (ORs) between cases and controls. VE was calculated as [100% × (1-adjusted OR)] with 95% confidence intervals (CI).
Results:
Out of 30,630 elderly patients tested, 1,825 influenza-positive cases and 1,825 influenza-negative controls were included. The overall adjusted VE for influenza-related visits was 63.5% (95% CI, 56.3–69.5%), varying by season. VE was 59.8% (95% CI, 51.5–66.7%) for influenza A and 89.6% (95% CI, 77.1–95.3%) for influenza B. VE for ages 60-69 was 65.2% (95% CI, 55.4–72.9%), for ages 70-79 was 69.8% (95% CI, 58.7–77.9%), but only 45.4% (95% CI, 6.2–68.2%) for ages 80 and over.
Discussion:
The standard-dose inactivated influenza vaccine provides substantial protection in elderly individuals in China, though its effectiveness decreases in those aged 80 years and older. These findings support continued vaccination efforts, with consideration for additional measures to protect the oldest age groups.

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Repeated vaccination and protective effect of influenza vaccine in the elderly

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Introduction:
The impact of repeated influenza vaccination on vaccine effectiveness in the elderly has been debated, and comprehensive studies in China are limited.
Aims:
To evaluate the effect of repeated influenza vaccination on the prevention of laboratory-confirmed influenza in elderly individuals in Ningbo, China.
Methods:
We conducted a test-negative case-control study using data from the Regional Health Information Platform. The study included individuals aged 60 and above during four influenza seasons from 2018-19 to 2021-22. Influenza-positive cases and negative controls were matched in a 1:1 ratio based on the visiting hospital and the date of influenza testing. Propensity score adjustment and multivariable logistic regression were employed to estimate risk and control for confounding factors.
Results:
Out of 30,630 elderly patients tested, 1,976 influenza-positive cases and 1,976 influenza-negative controls were analyzed. Multivariable logistic regression showed no significant increase in influenza illness risk for those vaccinated in two consecutive seasons compared to those vaccinated only in the current season (adjusted OR: 1.22, 95% CI: 0.94-1.58). However, individuals vaccinated only in the previous season had an increased risk (adjusted OR: 1.56, 95% CI: 1.15-2.10), and the risk was highest in those not vaccinated in either of the two consecutive seasons (adjusted OR: 3.39, 95% CI: 2.80-4.09).
Discussion:
Our findings indicate that receiving the current season's influenza vaccine is the most effective strategy for protecting the elderly, regardless of their vaccination history from the previous season. This supports annual vaccination initiatives for elderly populations to maintain high levels of protection against influenza.

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Validation of COPD Severity According to the GOLD Framework in Claims Database

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Background:
The assessment of chronic obstructive pulmonary disease (COPD) severity are guided by the GOLD guideline, which categorizes patients based on exacerbation history and symptoms using the modified Medical Research Council (mMRC) dyspnea scale or the COPD Assessment Test (CAT). However, these measures are unavailable in Taiwan claims database.
Objective:
We aimed to develop and validate a method to assess COPD severity using claims database.
Methods:
The study enrolled patients from the COPD pay-for-performance (P4P) program file between 2017 and 2022, using the enrollment date as the index date. The P4P file included information on lung function, forced expiratory volume in 1 second (FEV1), forced vital capacity (FVC), exacerbation frequency, CAT, mMRC, and the GOLD classification (Groups A to D), which served as the gold standard.
Further, COPD P4P file was linked to Taiwan National Health Insurance (NHI) claims database, containing medical diagnoses, procedures, and prescriptions. In claims database, three models using medical records of emergency room (ER) visit or hospitalization due to acute exacerbation (AE) with/without related medications were developed to identify COPD severity. The accuracy rate, sensitivity, specificity and positive predictive value (PPV) were reported.
Results:
Among the study subjects, 78% (35,603/45,632) were classified as having mild COPD (GOLD group A+B) according to the COPD P4P file. The model using AE hospitalization combined with related medications from the claims database demonstrated the highest accuracy rate of 78.8% for identifying mild COPD severity. This model exhibited a sensitivity of 88.3%, specificity of 45.2%, and PPV of 85.1%. However, its performance in identifying patients with severe COPD (GOLD group C+D) was lower, with a sensitivity of 45.2% and a PPV of 52.1%.
Discussion:
The model used AE hospitalization records with related medications is more effective to identify patients with mild COPD rather than those with severe COPD in claims database.

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Validation of ICD-CM codes to identify relapsed metastatic breast cancer in Taiwan

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Introduction
Reliable coding algorithms are pivotal for real-world data studies to provide high-quality evidence to assist clinical medical decision-making.
Aims
To analyze the validity of the International Classification of Diseases, Ninth and Tenth Revision, Clinical Modification (ICD-9-CM and ICD-10-CM) diagnosis codes in a multi-institutional electronic medical records (EMR) database to identify patients diagnosed with relapsed metastatic breast cancer.
Methods
This validation study included patients diagnosed with early stage breast cancer who received curative operation from January 1, 2011 to December 31, 2023. A simple random sample of 5% was selected from the original cohort of 9221 early stage breast cancer patients. Relapsed metastatic breast cancer was defined by ICD code (ICD-9-CM: 195.x to 196.x, excluded 196.3; ICD-10-CM: C76.x to C80.x, excluded C77.3) after curative therapies. Medical chart review according to AJCC 8th staging criteria and pathology-confirmed was defined as the gold standard to determine the presence of metastases. We estimated the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of ICD-CM codes in our database.
Results
A total of 391 early breast cancer patients with mean age of 54.8 (SD: 12.1) were included in our study. Among the total of 41 cases coded as metastases, 17 had met the AJCC criteria. As a result, the ICD-CM coding algorithm to define relapsed metastatic breast cancer reached a sensitivity of 73.9% (95% CI: 55.9–91.8), a specificity of 93.4% (95% CI: 90.9–96.0), and PPV and NPV of 41.4% (95% CI: 26.3–56.5), 98.2% (95% CI: 96.9–99.6), respectively.
Conclusion
Our analysis demonstrated utilization of ICD-CM codes had low PPV in identifying patients diagnosed with relapsed metastatic breast cancer in EMR database. Further additional operational definitions or algorithm needed to develop to identify relapsed metastatic breast cancer.