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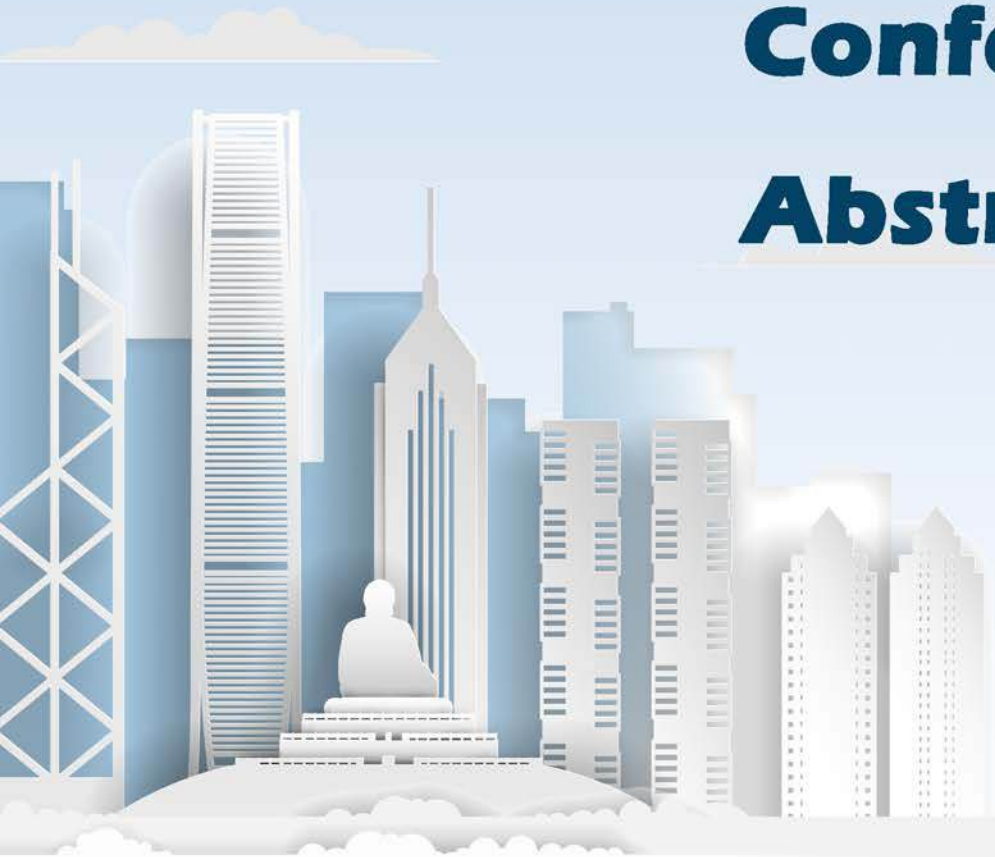

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I. Oral Presentations

Abstract #100 - 224

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Digital tools for decentralized trials and digital endpoints

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The availability of digital tools will completely revolutionise the conduct of clinical trials and future pharmacoepidemiology studies. Digital tools have allowed the creation of digital endpoints and the conduct of decentralised clinical trials (DCTs). These are poised to fundamentally reshape pharmacoepidemiology research and analysis and health research. By leveraging digital technologies—such as wearable sensors, mobile apps, and remote monitoring devices—researchers can now continuously collect high-quality, real-world data on patient outcomes directly from participants in their natural environments, rather than relying solely on clinic visits which are often episodic and infrequent. This shift enables a more authentic and granular understanding of how patients feel, function, and behave in their everyday lives, providing valuable insights into disease burden and treatment effects that previously were not visible nor accessible to researchers. For pharmacoepidemiologists, these innovations offer several key advantages. First, digital endpoints facilitate more efficient and accurate screening, earlier disease detection, and continuous monitoring, which can improve the sensitivity and relevance of outcome measures. The increased volume and diversity of data generated through DCTs also allow for more robust statistical analyses, supporting adaptive trial designs and more nuanced subgroup analyses. Decentralised approaches expand access to broader and more diverse populations, enhancing the generalizability of findings and reducing traditional barriers related to geography and clinic access. However, these advances also introduce new analytical challenges. The remote and continuous nature of data collection requires rigorous attention to data integrity, privacy, and management, as well as sophisticated statistical methods to handle missing data, variation in data quality, and potential biases introduced by remote participation. Regulatory frameworks are evolving to address these complexities. There is a need for interdisciplinary collaboration and robust infrastructure to ensure high-quality research that is responsive to the changing health needs of our populations. Digital endpoints and DCTs are the future for health research and will empower pharmacoepidemiologists to deliver more patient-centered, timely, and actionable evidence on medication safety and effectiveness. This presentation will discuss how these digital tools will help drive a paradigm shift toward real-world, data-driven insights to accelerate therapeutic innovation and improve health outcomes for all.

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Top 10 drugs most frequently associated with myocarditis and pericarditis adverse events

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Myocarditis and pericarditis are managed with various treatments, yet prior studies and case reports indicate that certain drug classes may elevate the risk for these inflammatory cardiac conditions. This research aimed to systematically identify the leading drugs most frequently associated with myocarditis and pericarditis cases.

Analyses were carried out using VigiBase from 1968 to 2024, the World Health Organization's global database of individual case safety reports. We identified the drugs most frequently reported in association with myocarditis and pericarditis, selecting the top 10 drugs based on record count, excluding those used in the treatment of inflammatory cardiac conditions to avoid potential confounding. Two statistical indicators, the information component (IC) with IC_{025} and reporting odds ratio (ROR) with 95% CI were used to conduct the disproportionality analysis in this study.

The following five drugs were consistently associated with both myocarditis and pericarditis: COVID-19 mRNA vaccine (reported in 76.2% of myocarditis cases and 88.2% of pericarditis cases), clozapine (15.3%; 2.9%), mesalazine (1.2%; 1.5%), smallpox vaccine (0.9%; 1.1%), and influenza vaccine (0.7%; 1.2%). The other leading drugs differed by condition, with nivolumab, pembrolizumab, ipilimumab, valproate, and metronidazole appearing more frequently for myocarditis, and ribavirin, sulfasalazine, methotrexate, omalizumab, and heparin for pericarditis. Each of these drugs showed a significant association with myocarditis (ROR, 83.22 [95% CI, 81.17–85.33]; IC, 3.96 [IC_{025}, 3.94]) and pericarditis (42.16 [41.19–43.16]; 3.66 [3.64]).

These findings highlight the importance of monitoring for possible adverse myocarditis and pericarditis reports when prescribing these drugs. Further studies are encouraged to investigate underlying mechanisms, assess individual patient risk factors, and explore the long-term impacts associated with drug-associated myocarditis and pericarditis.

Myocarditis and pericarditis; pharmacovigilance; Vigibase

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Short-term Risk of Urinary Retention Following Recent Elevations in Anticholinergic Burden

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Introduction: The magnitude of short-term casual effect following recent increases in anticholinergic burden remains limited quantified in older populations.

Aims: To quantify the short-term risk of urinary retention following recent elevations in anticholinergic burden and among Taiwanese adults aged ≥65 years.

Methods: We performed a case–case–time–control analysis using the Taiwan National Health Insurance Research Database (NHIRD) from 2017–2021. Eligible future cases were with urinary retention 60–150 days after a matched reference event. For each individual, the hazard period was defined as the 60 days preceding the urinary retention; two referent periods consisted of randomly selected 60-day windows within days 121–300 before diagnosis. Anticholinergic burden was quantified using the Anticholinergic Cognitive Burden Scale and grouped as 0, 1–2, or ≥3 points. We used conditional logistic regression to estimate odds ratios (ORs) and 95% confidence intervals (CIs) comparing hazard versus referent periods, with and without adjustment for population and individual trends.

Results: Among 135,116 matched individuals (mean age 78.3 ± 6.4 years; 73.3% male), short-term elevations in ACB score were significantly associated with urinary retention. In crude case-crossover analyses, ACB 1–2 yielded OR 1.80 (95% CI: 1.74–1.87) and ACB ≥3 yielded OR 2.31 (95% CI: 2.25–2.37). After controlling for population and individual trends in the case–case–time–control design, the ORs were 1.68 (95% CI: 1.57–1.80) for ACB 1–2 and 2.12 (95% CI: 2.03–2.22) for ACB ≥3.

Conclusions: Older adults with recently elevated anticholinergic burden were associated with an increased risk of urinary retention. This demonstrates the importance of timely monitoring of anticholinergic burden and prompt deprescribing of anticholinergic medications to prevent unintended outcomes.

Keywords: anticholinergic burden, urinary retention, older adults

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Patient Satisfaction and Adverse Reactions to Isotretinoin in Acne Patients

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Introduction: Acne vulgaris is a common dermatological disorder that substantially impacts patient's quality of life. Isotretinoin is an efficacious therapy for moderate to severe acne, although it is associated to several adverse drug reactions (ADRs). Although the safety and efficacy of isotretinoin have been extensively studied globally, data on patient satisfaction and ADRs in Nepal remain significantly limited.

Aims: To analyze patient satisfaction among acne patients and to characterize the adverse drug reaction profile associated with isotretinoin treatment.

Method: A prospective pre-post observational cohort study was performed with 267 acne patient. Patient demographics, acne severity assessed via the Investigator Global Assessment (IGA) scale, satisfaction ratings utilizing the Visual Analogue Scale (VAS), and biochemical data were documented at baseline and after six months of medication. ADRs reported at any point during the treatment period.

Results: The average age of participants was 22.94 ± 3.16 years, with 64.4% being female. The treatment led to an enhancement in patient satisfaction (6.82 ± 1.09 to 7.86 ± 0.51; $p < 0.001$). The incidence of at least one ADRs throughout the treatment duration was 86.5%, and they mostly appeared as mucocutaneous side effects, such as dry skin (31.5%) and dry lips (37.1%). Males had significantly lower odds of developing dry lips (OR = 0.545; 95% CI: 0.326-0.912; $p = 0.02$), nasal bleeding (OR = 0.105; 95% CI: 0.012-0.915; $p = 0.013$), and retinoid dermatitis (OR = 0.337; 95% CI: 0.133-0.857; $p = 0.018$). Males accounted for the majority of dermatosis papulosa nigra cases (7.4%; $p < 0.001$). Biochemical abnormalities included elevated triglycerides (4.5%) and LDL cholesterol (3.7%).

Conclusions: Isotretinoin treatment significantly improved patient satisfaction. Although ADRs were common, notable gender differences were identified, with males experiencing lower odds of mucocutaneous side effects.

Key words: Acne vulgaris; Isotretinoin; Adverse drug reaction; Patient satisfaction

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Non-invasive imaging of facial erythema treated with a transdermal delivery system

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Introduction: Facial erythema is a common dermatological condition, often associated with vascular dysregulation and skin hypersensitivity. Jet Peel PRO is a transdermal delivery system that enables the non-invasive infusion of active ingredients into the skin. Despite its growing popularity, there is still a lack of objective, quantitative methods to evaluate the effectiveness of such cosmetic treatments in reducing erythema.

Aim: To assess the clinical outcomes and skin effects of Jet Peel PRO treatment for facial erythema using multimodal imaging, including high-frequency ultrasound (HFUS), hyperspectral imaging, clinical photography, and GLCM texture analysis.

Methods: Thirty-six participants with persistent facial erythema underwent six weekly Jet Peel PRO treatments. Ultrasound imaging was used to confirm dermal penetration of the infused formulation. Clinical photographs were taken before, during, and after the treatment using the Fotomedicus system. Erythema severity was assessed using a Mexameter®. Hyperspectral imaging data were analyzed in the 400-1000 nm range. Texture features of the hyperspectral images were evaluated using the Gray Level Co-occurrence Matrix (GLCM), focusing on contrast and homogeneity.

Results: Post-treatment analysis revealed a significant decrease in GLCM contrast ($p < 0.01$) and an increase in homogeneity ($p < 0.01$), indicating improved structural uniformity of the skin. Hyperspectral reflectance analysis showed an increase in reflectance around 540 nm, suggesting a reduction in hemoglobin concentration, consistent with a decrease in erythema. Additionally, Mexameter® measurements demonstrated a noticeable decrease in erythema index values, confirming the clinical improvement observed through imaging.

Conclusion: Jet Peel PRO treatment reduces facial erythema. Objective imaging techniques, including hyperspectral analysis and GLCM-based texture evaluation, provide quantitative evidence of treatment efficacy. Limitations include short-term follow-up and restriction of the sample to Fitzpatrick phototypes I and II. Future research should explore long-term outcomes and efficacy across a wider range of Fitzpatrick phototypes.

Keywords: Transdermal delivery system, Facial erythema, GLCM texture analysis

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Development and Validation of Causality Assessment Tool For Adverse-Events to Medical Devices

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Introduction: Medical devices improve healthcare but pose safety risks, especially in low-resource settings. Currently, the only standardized causality assessment scale for medical device-related adverse events is the European one. The absence of region specific, user-friendly scale hampers reporting, regulatory decisions, and Materovigilance efforts.

Aim: This study aimed to produce a clear, succinct, and adaptable causality assessment tool to detect medical device-associated adverse events (MDAEs).

Method: A causality assessment scale was developed using literature review and interviews, ensuring validity and real-world relevance. Validated for face, content, and construct validity, it was compared with the European standard using 50 cases. Reliability was confirmed via Cronbach's alpha and Intraclass Correlation Coefficient (ICC) across two phases with expert raters.

Results: An improvised causality assessment scale comprising nine scored questions was developed to evaluate the relationship between medical device-associated adverse events (MDAEs) and medical devices. Each question allows responses of "Yes" (+1), "No" (-1), or "Do not know/Not applicable" (0), with total scores classifying causality as Certain (≥8), Probable (5–7), Possible (2–4), or Unlikely (<1). Validation against the European Union (EU) scale demonstrated a sensitivity of 90.95%, specificity of 83.25%, and an average area under the curve (AUC) of 0.8605, indicating strong diagnostic performance. Reliability was confirmed with a high Cronbach's alpha of 0.893, signifying excellent internal consistency. Inter-rater reliability was assessed using intraclass correlation coefficients (ICC), which showed moderate agreement among raters, improving from 0.324 in Phase 1 to 0.399 in Phase 2 following a six-week reassessment interval.

Conclusion: The new causality assessment scale improves upon previous tools by enabling more accurate and efficient evaluation of device-related adverse events, enhancing patient safety. While it shows high sensitivity and specificity, its accessibility to stakeholders would be better supported by usability testing.

Keywords: Medical devices, Causality assessment, Safety

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Barriers to Adverse-Event Reporting of Dental Devices: A Cross-Sectional Survey in India

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Introduction: Despite the increasing use of dental devices in clinical practice, underreporting of dental device-associated adverse events (DDAEs) remains a global concern. Materiovigilance systems are often underutilized in dentistry although they are essential for patient safety. Understanding the barriers that hinder reporting is critical for strengthening these systems. However, limited data are available on these barriers.

Objective: To assess barriers to reporting DDAEs among dental professionals using a validated questionnaire.

Methods: A structured, cross-sectional survey was conducted among dental professionals in a tertiary-care dental hospital in southern India. A structured cross-sectional survey was conducted among dental professionals at a tertiary-care dental hospital in South India. A validated questionnaire, demonstrating strong internal consistency (Cronbach's alpha = 0.89), comprised 20 items across four sections: Awareness and Knowledge (three items), Cognitive Barriers (6), System-level Barriers (5), and Organizational Barriers (6). The survey was administered to 100 dentists with minimum 1 year of experience, data were analyzed using SPSS version 29

Results: Key barriers to DDAE reporting included the lack of a dedicated materiovigilance coordinator (95%) in each department and insufficient training (98%) regarding the identification and reporting of DDAEs. Reporting complexity (70%) and clinical workload interference (76%) further hinder reporting. A significant proportion of normalized recurring device malfunctions were non-serious (61%), while others hesitated because of uncertainty in identifying reportable incidents (37%) or feared reputational harm (46%). Notably, only 18% found the reporting process to be easy, highlighting the need for streamlined systems and stronger institutional support.

Conclusion: This study identified critical barriers to DDAE reporting among Indian dental professionals. Addressing these issues through regular training, simplified reporting systems, and administrative support is essential to strengthen materiovigilance practices and enhance patient safety in dental settings in India.

Keywords: Medical Devices, Questionnaire, Materiovigilance

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Using Routine Clinical Data to Identify High-Risk Prediabetes for diabetes and cardiovascular-complications

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Introduction: Prediabetes elevates the risk of type 2 diabetes (T2D), premature mortality, and complications like cardiovascular disease (CVD), driven by interacting risk factors, calling for risk stratification. High-risk individuals are prime candidates for targeted and cost-effective interventions. The challenge lies in identifying those at elevated risk of progressing to T2D and related complications.

Aims: To develop an electronic health record (EHR)-based machine-learning (ML) model to predict 5-year diabetes risk in adults with prediabetes, and long-term risks of complications and mortality.

Methods: A retrospective cohort of adults with prediabetes defined by fasting plasma glucose (FPG) and HbA1c (2002–2014, followed until December 31, 2019) was used to develop a ML model with routine measures (e.g., age, FPG, HbA1c, triglyceride-to-HDL-cholesterol ratio) from the Hong Kong territory-wide EHR system. Individuals were stratified into low/intermediate- and high-risk groups using validated model-derived risk scores. Incidence rates of diabetes and complications were calculated, and associations with all-cause mortality, CVD, and heart failure were assessed using Cox-proportional hazards regression, adjusted for age, sex, and clinical covariates (e.g., FPG).

Results: The EHR-based 5-year diabetes risk model included 545,054 adults with prediabetes (mean age: 61.3±13.1 years). The high-risk group (188,735; 34.6%) had a 5-year diabetes incidence rate of 92.5 events versus 24.3 events per 1,000 person-years in the low/intermediate group. During a mean duration follow-up of 9.4 years, the high-risk group had similar all-cause mortality risk (adjusted hazard ratio [aHR]=1.01, 95% CI 0.98–1.02) but higher risks of CVD (aHR=1.14, 95% CI 1.12–1.16) and heart failure (aHR=1.14, 95% CI 1.12–1.16) compared to the low/intermediate risk group.

Conclusions: We have developed an ML model based on EHR data which effectively identifies high-risk individuals for diabetes progression with cardiovascular complications. The ML model can be integrated within the EHR system to select high-risk individuals for early prevention.

Keywords: prediabetes; diabetes; prediction.

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Target Trial Emulation in Oncology: Current Use and Future Directions

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Introduction and aims: Target Trial Emulation (TTE) has ushered popularity because of its ability to improve the reliability of causal inference from observational data. This study aimed to comprehensively master related knowledge current use, potential challenges and insights of target trial in oncology.

Methods: Systematic literature review of global oncology TTE studies based on PubMed and Embase was conducted. Time trend, basic characterizes, bias assessment, and consistency with the results of emulated RCT were analyzed.

Results: A total of 60 TTE studies in cancer areas were identified, with the annual number in 2024 being equal to the sum of rest years. Among the 35 applications in cancer treatment, registry databases (51.4%) and overall survival (80%) were predominantly used as data sources and primary endpoint, respectively. 45.8% of included TTE suffered from immortal time bias, and 48.6% from prevalent user selection bias. Among the 18 trials from 17 studies aiming to calibrate the results from preexisting RCTs, only 44.4% trials met both statistical agreement and estimate agreement. The availability of fit-for-purpose data sources and the uncertainty of concordance in results were identified as the two main hurdles for limited quantity and quality of TTE in oncology areas considering its unique challenges.

Conclusions: The application of target trial emulation in oncology has seen a significant increase in 2024, while the overall quantity and quality are still limited, which could be largely constrained by the availability of fit-for-purpose data sources and the uncertainty of concordance in results.Potential solutions were recommended for improving the feasibility and quality of oncology trial emulation, including promoting regulatory acceptance, data integration of medical rerecords and linkage with insurance claims databases, as well as best practice in trial design, including modernizing eligibility criteria, using overall survival as primary endpoint.

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Individualized treatment effect estimation in bipolar disorder: A causal machine learning approach

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Introduction: Methylphenidate (MPH) is widely used to treat attention-deficit/hyperactivity disorder (ADHD), including in patients with depression. However, concerns remain that MPH may increase the risk of manic episodes and transition to bipolar disorder (BD) in specific individuals.

Aims: We aim to estimate the treatment effect of administrating MPH on BD occurrence in patients with ADHD and depression using causal forest model with large-scale propensity scores.

Methods: We used the Health Insurance Review and Assessment Service-ADHD database (2016–2020), which contains nationwide claims data converted to OMOP-CDM. To evaluate the treatment effect of MPH on BD occurrence in adult patients with ADHD and depression, patients were divided into MPH-treated and untreated groups. Propensity scores were estimated via random forests after covariate screening using 10-fold cross-validation. A causal forest model with inverse-propensity weighting was used to estimate average and conditional treatment effects (ATE, CATE). To assess ATE heterogeneity, the validation set was divided into CATE-based quintiles, and ATEs were estimated using targeted minimum loss estimation. We identified key features of high versus low CATE groups by comparing distributions of the top 15 variables by importance.

Results: Among 28,939 patients, 19,939 were prescribed MPH and 1,881 were diagnosed with BD. A total of 4,608 baseline covariates were extracted and reduced to 4,477 after cross-validation. In the validation set, ATE was 0.018 [0.011–0.053]. ATEs by CATE quintiles (Q1–Q5) were 0.044, 0.036, 0.029, -0.002, and 0.015, respectively; Q1–Q3 showed significant effects. ATE heterogeneity among the groups was significant (χ^2_4= 17.98, p = 0.0012); indicating treatment effects of MPH differed among these subgroups. All top 15 covariates differed significantly between high and low CATE groups, except lorazepam.

Conclusions: MPH may elevate BD risk in specific populations, and CATE-based heterogeneity supports individualized treatment strategies to guide safer MPH use.

Keywords: Machine learning, treatment effect, bipolar disorder

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Methodological comparison of creatinine clearance calculation in chronic kidney disease

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Introduction: Chronic Kidney Disease (CKD) is a growing global disease burden leading to a range of systemic complications. One of the major problems in dosage adjustment of renally excreted drugs in CKD patients is lack of sufficient data to calculate creatinine clearance. Availability of different formulas with different criteria are a solution for the same but agreement among these formula remains unclear.

Aim: To evaluate agreement across three standard equations to calculate creatinine clearance in hospitalized CKD patients.

Methods: A prospective observational study was carried out in Nephrology department after approval of institutional ethics committee. CKD patients admitted in Nephrology department with age ≥18 years were included in the study. Variables included age, gender, comorbidities, height, weight and serum creatinine values. Creatinine clearance or eGFR was calculated using Modification of Diet in Renal disease(MDRD),Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) and Cockcroft-Gault. Intraclass correlation coefficient (ICC) was used to assess agreement across three standard formulas.

Results: There was a male preponderance with 63.6 % out of 101 study sample. Diabetes mellitus was the predominant co-morbidity observed. CKD stage 5 patients comprised 83% study population. An intraclass correlation coefficient (ICC) of 0.917 was observed demonstrating excellent agreement between the three-creatinine clearance estimation formula. A strong agreement with ICC of 0.948 was observed in elderly patients also. There was no gender bias as both genders showed strong agreement.

Conclusion: As there exists a strong agreement between 3 commonly used formulas with different criteria to calculate creatinine clearance, anyone of these formulas can be used for dosage adjustment of renally impaired patients. Despite the strong statistical agreement, further research and reviews are needed to ensure safe and individualized treatment in such patients.

Keywords: MDRD,CKD-EPI,Cockcroft-Gault

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Transcriptomic and Pharmacogenomic Analysis Reveals Biomarker-Guided Drug Repositioning Opportunities in DKD

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Introduction: Diabetic kidney disease (DKD) is a major contributor to end-stage renal disease worldwide, particularly in Asia, and poses significant clinical and economic challenges. Early identification of biomarkers and repurposable drug targets is essential for timely intervention and improved patient outcomes. This study aimed to uncover key molecular signatures and therapeutic candidates in DKD through integrative transcriptomic and pharmacogenomic analysis.

Methods: A publicly available glomerular transcriptomic dataset of DKD patients and healthy controls was analyzed to identify differentially expressed genes (DEGs). Protein–protein interaction (PPI) networks were constructed using STRING and functionally annotated through Gene Ontology, KEGG, and Reactome. Upstream transcription factors were predicted via ChEA, and drug–gene interactions were identified using DGIdb, with a focus on drugs with existing clinical approval. Pathways and genes were prioritized based on relevance to glomerular filtration and podocyte function.

Results: Significant upregulated and downregulated DEGs formed a highly enriched PPI network ($p < 1.0e-16$). Enriched modules were associated with extracellular matrix remodeling, proteolysis regulation, and podocyte differentiation. Notably, genes such as SERPINA3, COL6A3, and AKR1B10 were upregulated, while NPHS1, PLCE1, and IGF1 were downregulated. Transcriptional regulators included RELA, ESR1, and CJUN (upregulated) and SMAD3, SUZ12 (downregulated). Drug–gene interaction analysis identified repositionable drugs with potential nephroprotective effects, including losartan (NPHS1), hydrochlorothiazide (PLCE1), tolrestat (AKR1B10), and fomepizole (ADH1B).

Conclusion: This integrative molecular epidemiology study highlights biomarker candidates and drug repurposing opportunities in DKD, offering a precision pharmacoepidemiologic approach. The findings support further validation to accelerate biomarker-guided therapeutic strategies and inform clinical decision-making, especially in resource-limited settings.

Keywords:
biomarkers, diabetic kidney disease, drug repositioning, molecular epidemiology, pharmacogenomics, transcriptomics.

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Quasi-quantitative bias analysis of comparator choice for Denosumab in KAERS database

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Introduction: Comparator selection and observation window can distort disproportionality signals for any drug-event pair. Quasi-quantitative bias analysis (QQBA) reveals this distortion by explicitly measuring how the signal strength shifts when either the reference set or the calendar period changes.

Aims: We quantified how choice of active comparator types and recent US FDA safety communications influenced denosumab-associated hypocalcemia signals in Korean Adverse Event Reporting System (KAERS) database.

Methods: Using KAERS reports submitted from 2020 to 2024, we evaluated three drug-event pair: denosumab vs all other drugs (reference), denosumab vs zoledronic acid, and denosumab vs bisphosphonates. Disproportionality analyses were stratified into a pre-warning window (2020-2022), which preceded the boxed warning on severe hypocalcemia issued in November 2022, and a post-warning window (2023-2024). Proportional Reporting Ratio(PRR), Reporting Odds Ratio(ROR) and Information Component(IC) were computed with Haldane-Anscombe 0.5 continuity correction. Comparator bias was summarized as $\Delta = \log \mathrm{PRR\_alt} - \log \mathrm{PRR\_ref}$, where $\Delta<0$ denotes masking and $\Delta>0$ amplification.

Results: Among 3,697,274 KAERS reports, hypocalcemia was reported in 2,129 cases, 42 of which listed denosumab. With an all-drug reference set, signal showed PRR 12.34 (ROR 12.42; IC 3.60). Switching the reference to zoledronic acid lowered the PRR to 1.97 (Δ -1.83; IC 0.10), while broader bisphosphonate reference yielded PRR 3.93 (Δ -1.15; IC 0.22). Before warning, all-drug PRR was 17.91, versus 1.91 (Δ -1.87) for zoledronic acid and 16.63 (Δ +0.30) for bisphosphonates. After warning, the corresponding PRRs were 6.45 (Δ -0.65), 1.51 (Δ -2.10) and 0.86 (Δ -2.66).

Discussion/Conclusion: Signal strength can vary with different comparators or external events. Therefore, disproportionality analyses benefit from testing several comparator groups and analyzing periods before and after key events to keep bias visible.

Key words: Quasi-quantification bias analysis, Denosumab, KAERS

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Cardiovascular effects of influenza vaccination: target trial emulation using proximal causal inference

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Introduction: The substantial burden of cardiovascular diseases highlights the urgent need for cost-effective interventions. Existing evidence on the cardioprotective effect of the influenza vaccine come primarily from populations with cardiovascular comorbidities, and remain susceptible to several sources of bias, including immortal time bias and unmeasured confounding.

Aims: To assess the effect of influenza vaccination on cardiovascular events in a general older population in China while attenuating these limitations.

Methods: This is a sequentially-designed, propensity score (PS) matched, vaccine effectiveness study under a target trial emulation framework. We used data from the Yinzhou Regional Health Care Database and included older residents of Yinzhou, China. We employed a sequential trial approach in which participants were categorized as influenza vaccinees or non-vaccinees based on their vaccination regimen during the one-week enrollment period of each sequential trial from 2020 to 2022. The outcomes of interest were major adverse cardiovascular events (MACE) and acute coronary syndromes (ACS) within one year of follow-up. To address measured and unmeasured confounding, PS matching was performed in conjunction with proximal causal inference using a two-stage Poisson regression to estimate incidence rate ratios (IRRs).

Results: A total of 8,181,638 older adults were included across the 50 emulated trials. Of these, 170,011 were vaccinated against influenza, while 8,011,627 remained unvaccinated. After PS matching, all measured characteristics were well-balanced. In conjunction with the PCI approach, we found influenza vaccination was associated with decreased one-year risk of MACE (IRR: 0.86 [95% CI: 0.83-0.89]) and ACS (IRR: 0.87 [95% CI: 0.83-0.91]) compared to non-vaccination. Results were consistent across various subgroup and sensitivity analyses.

Conclusions: Influenza vaccination may reduce the risk of MACE and ACS among older adults. Our findings further support influenza vaccination as an effective public health strategy for reducing cardiovascular disease burden.

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Safety of 23-Valent Pneumococcal Polysaccharide Vaccine in Older Adults: the VENUS Study

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Introduction: Pneumonia is one of the leading causes of death among older adults. The effectiveness of the 23-valent pneumococcal polysaccharide vaccine (PPSV23) has been demonstrated, including in Asian populations. However, limited evidence exists regarding its safety in relation to adverse events among older adults in Japan.

Aims: This study aimed to examine the association between PPSV23 vaccination and adverse events among Japanese older adults. This population-based analysis also sought to generate evidence on the safety of PPSV23 to promote informed public health decision-making.

Methods: This self-controlled risk interval study utilized an administrative claims database linked to the PPSV23 vaccination registry from the Vaccine Effectiveness, Networking, and Universal Safety (VENUS) Study in Japan from January 2016 to March 2023, including adults aged 65 years or older who received PPSV23. We evaluated the risk of myocarditis or pericarditis, Bell palsy, and thrombocytopenia in inpatient settings. A conditional Poisson regression model was applied to estimate incidence rate ratios (IRRs) with 95% confidence intervals (CIs). The risk and control periods were defined as days 1–28 and 57–112 after PPSV23 vaccination, respectively.

Results: Among 138,283 older adults who received PPSV23, the median age was 75 years (25th–75th percentile: 70–80), and 61.7% were women. No meaningful associations were found for myocarditis or pericarditis (IRR: 0.50; 95% CI: 0.06-4.47), Bell palsy (IRR: 1.11; 95% CI: 0.37-3.32), or thrombocytopenia (IRR: 1.00; 95% CI: 0.55-1.81).

Conclusions: In this large, registry-linked analysis, the elevated risks associated with PPSV23 vaccination for myocarditis or pericarditis, Bell palsy, or thrombocytopenia were not evident among older adults in Japan. Further studies evaluating the safety of PPSV23 against a broader range of adverse events, including cardiovascular, neurological, and immunological outcomes, are warranted to support vaccine safety awareness among Japanese older adults.

Keywords: Vaccine safety, older adults, self-controlled risk interval analysis

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Association between antibiotic use for non-gastrointestinal infections and inflammatory bowel disease flare-ups

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Introduction: Antibiotics, through their impact on the gut microbiota, have raised concerns about their potential to trigger disease activity in patients with inflammatory bowel disease (IBD).

Aims: This study aimed to evaluate the association between antibiotic use and the risk of IBD flare-ups, and to examine whether route of administration, antimicrobial spectrum, and antibiotic class modify this risk.

Methods: We conducted a self-controlled case series study using territory-wide electronic medical records from Hong Kong. We included adults with IBD who experienced at least one flare-up and received at least one course of antibiotics for infections outside the gastrointestinal (GI) tract between 2000 and 2024, to reduce indication bias related to gastrointestinal symptoms. Conditional Poisson regression models were used to estimate incidence rate ratios (IRRs) by comparing predefined risk periods to the baseline period. Subgroup analyses were conducted by route of administration, spectrum, and class.

Results: A total of 664 patients were included (median age: 46.7 years). The incidence of IBD flare was elevated during the month preceding antibiotic use (IRR 2.97), increased further during treatment (IRR 3.74), peaked within two weeks after the prescription ended (IRR 4.76), and returned to baseline between six weeks and six months after the prescription ended, versus baseline. Increased incidences were observed for oral antibiotics during and in two weeks after treatment (IRRs 4.53 and 3.86), but not for injectable antibiotics (interaction p-values <0.01). The IRRs for broad-spectrum antibiotics were higher than those for narrow-spectrum agents from one month before to six weeks after antibiotic use, versus baseline.

Conclusions: Antibiotic use for non-GI infections was associated with a short-term increase in IBD flare risk, predominantly with oral and broad-spectrum agents. When clinically appropriate, injectable or narrow-spectrum antibiotics may have a relatively smaller impact on IBD flare-ups.

Key words: Inflammatory bowel disease; antibiotics; flare-ups

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Autoimmune disease risk after COVID-19 vaccination: a self-controlled case series

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Background: The association between COVID-19 vaccines and short-term risk of autoimmune diseases remain unclear, and there is limited evidence of different vaccine platforms.

Objective: We aim to evaluate the short-term risk of autoimmune diseases in individuals receiving COVID-19 vaccination (mRNA, adenovirus, protein).

Method: We conducted a self-controlled case series study using Taiwan's National Health Insurance Research Database and the COVID-19 vaccination registry. We included individuals receiving at least one dose of an mRNA, adenovirus, or protein-based COVID-19 vaccine between 2021 and 2022. Moreover, we excluded patients with a history of autoimmune diseases. We included the first diagnosis of autoimmune disease during the study period. The post vaccination risk period was 21 days after each dose, the pre vaccination period was 14 days before each dose, overlapping days were defined as post vaccination, and all other time served as the reference period. The observation period ended on September 23, 2022, or at death, whichever occurs the first. Conditional Poisson regression was used to estimate the adjusted incidence rate ratio (aIRR), and time-varying factors were considered such as age and different SARS-CoV-2 variant periods. The aIRR was calculated for all doses combined and separately for each dose to evaluate dose-stratified effects.

Results: We identified 191,296 eligible patients with autoimmune diseases receiving at least one dose of COVID-19 vaccination. We observe an increased risk of new onset autoimmune disease within 21 days after any of the three COVID 19 vaccine platforms (mRNA: IRR 1.52, 95% CI 1.50–1.54; adenovirus: IRR 1.81, 95% CI 1.75–1.87; protein: IRR 1.82, 95% CI 1.72–1.92). In the dose stratified analysis, all three doses showed a consistent increased risk of autoimmune disease.

Conclusions: COVID-19 vaccination was associated with an increased short-term risk of autoimmune diseases across all platforms and doses.

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Short-, medium- and long-term sequelae following COVID-19 infection: A multi-national cohort study

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Introduction: Few studies have reported the risk of clinical sequelae following COVID-19 infection in the Asia-Pacific region using multiregional data.

Aims: To obtain comprehensive evidence on the risk of clinical sequelae involving different organ systems over different time phases defined as short- (0-90 days), medium- (91-365 days) and long-term (after 365 days) period following COVID-19 infection using multi-regional databases from the Asia-Pacific regions.

Methods: A multi-regional retrospective cohort study was conducted using the electronic health records or claims data from five Asia Pacific regions, including Australia, New Zealand, Korea, Taiwan and Hong Kong. 1,169,866 individuals with COVID-19 infection and 2,553,944 comparators without infection were matched by propensity score and included in our study. Cox proportional regression was used to estimate the hazard ratio (HR) of various clinical sequelae, and all-cause mortality over short-, medium- and long-term phase following COVID-19 infection.

Results: Individuals with COVID-19 incurred a greater risk of all-cause mortality [Hazard ratio (HR) 12.78 (95%CI 3.65,44.72)] and clinical sequelae involving multiple organ systems over the short-term including respiratory [Interstitial Lung Disease: 6.01 (2.29,15.78)] and acute respiratory distress syndrome: 8.05 (5.08,12.74)] and cardiovascular disease: 1.89 (1.07, 3.33). The risk of clinical sequelae involving these organ systems largely subsided during the medium-term period [interstitial lung disease: 3.40 (1.11,10.46); all-cause mortality 2.42 (0.49, 11.87)] and long-term period [all-cause mortality 2.39 (0.33, 17.07)]. Patients aged over 65 years, or with a Charlson Comorbidity Index ≥4 have a higher risk of developing clinical sequelae compared to their respective counterparts.

Conclusions: From this multi-regional study among Asian-Pacific population, there is extensive short-term multi-organ involvement after COVID-19 infection. However, there is progressive reduction in the observed risk for most complications over the medium and long-term. The results were mainly consistent among all five Asian-Pacific regions included in our study.

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Long-Term Effects and Quality of Life: COVID-19 Versus Vaccination over One Year

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Introduction: Post-COVID-19 syndrome (PCS) and post-COVID-19 vaccination syndrome (PCVS) present overlapping clinical features, potentially stemming from naturally acquired and vaccine-induced neutralising antibodies, respectively. The comparative long-term consequences of these conditions remain insufficiently characterised.

Aims: To systematically evaluate the prevalence of long-term consequences and quality of life (QoL) among individuals recovering from COVID-19 versus those receiving COVID-19 vaccination.

Methodology: A prospective cohort study enrolled 624 COVID-19-recovered and 407 COVID-19-vaccinated participants (without prior SARS-CoV-2 infection). Clinical manifestations (encompassing general, respiratory, cardiovascular, neurological, and digestive domains) and QoL (via EQ-5D-5L) were assessed at baseline, 6-, and 12-months following discharge or vaccination. Statistical analyses included calculation of odds ratios (OR) computed as COVID-recovered/COVID-19 vaccinated with 95% confidence intervals (CI) and significance testing (p-values).

Results: At baseline, COVID-19-recovered individuals exhibited a markedly higher prevalence of at least one long-term consequence (87.3% vs 52.8%, OR=0.162, CI 0.12–0.22). Although symptom prevalence declined over time, it remained elevated in the COVID-19-recovered group at 6 months (56.7% vs 39.8%, OR=0.546, CI 0.391–0.65) and 12 months (70.8% vs 58.5%, OR=0.58, CI 0.446–0.754). Fatigue, myalgia, and chest pain persisted at significantly higher rates among COVID-19-recovered individuals throughout all time points ($p<0.05$). Cognitive symptoms, including headache and impaired concentration, were also more prevalent at 12 months post-recovery ($p<0.05$). QoL scores were consistently lower in the COVID-19-recovered cohort compared to COVID-19-vaccinated individuals at baseline (0.85±0.05 vs 0.90±0.003, $p < 0.001$), 6 months (0.90±0.04 vs 0.93±0.06, $p < 0.001$), and 12 months (0.86±0.05 vs 0.88±0.06, $p < 0.001$).

Conclusions: Recovery from COVID-19 is associated with a significantly greater and more persistent symptom burden, as well as reduced QoL, compared to post-vaccination status. These findings underscore the necessity for ongoing surveillance and targeted interventions in COVID-19-recovered individuals.

Keywords: COVID-19 recovery, COVID-19 vaccination, Post-COVID-19 syndrome (PCS) and post-COVID-19 vaccination syndrome (PCVS), Long-term consequences, Quality of life

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Real-world treatment patterns and outcomes of biologics in severe asthma in Taiwan

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Introduction: With the increasing availability of biologic therapies for severe asthma in Taiwan, it is important to assess their real-world utilization patterns and associated outcomes to inform treatment decisions and healthcare policy.

Aims: To investigate the real-world treatment retention and risk of severe asthma exacerbation (SAE) among patients with severe asthma initiating biologic therapies in Taiwan.

Methods: This retrospective cohort study utilized data from Taiwan's National Health Insurance Research Database and Cause of Death Registry (2017-2023). Adult patients with asthma who initiated a biologic—benralizumab, mepolizumab, or omalizumab—between January 2018 and November 2022 were included. The index date was defined as the date of the first biologic prescription. Generalized overlap weighting was applied to balance the baseline characteristics across groups. The 12-month treatment retention rate was estimated, and time to treatment discontinuation was analyzed using Kaplan-Meier methods. Risks of SAE within one year after the index date were evaluated using a negative binomial regression model.

Results: A total of 2,586 eligible patients were identified. After weighing, 112, 111, and 110 patients were included in the benralizumab, mepolizumab, and omalizumab group, respectively. Benralizumab users had a higher 12-month treatment retention rate (65.8%) compared with mepolizumab (61.1%) and omalizumab users (50.8%). Median time to treatment discontinuation was longest for benralizumab (716 days), followed by mepolizumab (570 days), and omalizumab (394 days). The SAE incidence rate per person-year was lowest for benralizumab 0.20 (95% CI: 0.14-0.30), compared to mepolizumab (0.36 [0.30-0.44]) and omalizumab (0.40 [0.33-0.47]). Compared to benralizumab, the incidence rate ratio for SAE was 1.80 (1.16-2.77, p<0.01) for mepolizumab and 1.96 (1.28-3.01, p<0.01) for omalizumab.

Conclusion: In this real-world cohort, benralizumab was associated with higher treatment persistence and a lower risk of SAEs compared to mepolizumab and omalizumab. Further research is needed to confirm these findings.

Keywords: Asthma, Biologics, Acute exacerbations

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Assessing ENDS impact on COPD: a systematic review and meta-analysis

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Introduction: Electronic nicotine delivery systems (ENDS) have gained widespread popularity, particularly among young adults and former smokers. While marketed as harm reduction tools, concerns exist about their long-term respiratory health impact. This review addresses the critical knowledge gap regarding ENDS use and chronic obstructive pulmonary disease (COPD) risk. Tobacco smoking remains a key confounding factor in this association.

Aims: This study aimed to evaluate the association between ENDS use and COPD risk through systematic review and meta-analysis. We specifically sought to account for tobacco smoking as a primary confounder.

Methods: A comprehensive search of PubMed, Embase and Web of Science was conducted for studies published until September 2024. Included observational studies assessed ENDS use and COPD diagnosis. Random-effects meta-analysis was performed using R software (v4.4), with tobacco smoking adjustments incorporated where available.

Results: Thirteen studies met inclusion criteria. Current ENDS users showed significantly greater odds of COPD (OR=1.488, 95% CI:1.363-1.623) compared to non-users. Former users demonstrated higher odds (OR=1.839, 95% CI:1.513-2.234). Ever-users had pooled OR=1.787 (95% CI:1.421-2.247). Sensitivity analyses confirmed robustness. Publication bias assessments showed no significant distortion.

Conclusions: ENDS use demonstrates significant association with elevated COPD risk independent of tobacco smoking. Standardized confounder adjustment methodologies are urgently needed in future research. Longitudinal studies should investigate ENDS-specific pathological mechanisms.

Keywords: electronic nicotine delivery systems, chronic obstructive pulmonary disease, respiratory health

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Nationwide serial cross-sectional study for outpatient cancer chemotherapy after new policy implementation

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Introduction: Outpatient chemotherapy enables cancer patients to maintain quality of life and to reduce the financial burden of hospitalization. In April 2022, the Ministry of Health, Labour and Welfare in Japan newly introduced incentives for outpatient chemotherapy and its side effect management (1,000 JPY for patients ≥ 15 years old).

Aims: This study analyzed the effectiveness of the newly introduced policy for enhancing the management system for outpatient chemotherapy in Japan.

Method: A nationwide serial cross-sectional study was conducted using Japan's annual reimbursement claims from fiscal years 2021 to 2022.
The primary outcome was the outpatient ratio of anticancer medications, a percentage of the prescription number of anticancer medications for outpatients in the total anticancer medication prescriptions. Another outcome was the claim counts for outpatient oncology chemotherapy Type 1 and 2. There are two types of outpatient chemotherapy, and Type 1 requires a more experienced pharmacist and dedicated treatment equipment.
The means (95% CI) of prefecture-based outpatient ratio, and claim counts of Type1 and Type2 were analyzed (n=47), and a paired t-test was performed for the outpatient ratio in FY2021–FY2022. P-value (two-sided) < 0.05 was considered statistically significant.

Result: The means (95% CI) of the outpatient ratios in 47 prefectures were 69.21% (67.26%–71.16%) in FY2021, and 71.28% (69.64%–72.91%) in FY2022. The differences of outpatient ratio were 2.06% (p<0.001) for FY2021–FY2022.
The mean (95% CI) prefecture-level increase in outpatient chemotherapy for FY2021–FY2022 was 14.31% (12.54%–16.08%) for Type 1, and -6.56% (-20.87%–7.75%) for Type 2.

Conclusion: The statistically significant increase of the outpatient ratio for oncology chemotherapy was observed in Japan after the newly introduced policy in 2022. The increase in Type 1 outpatient chemotherapy suggests improved access to specialized care, while the stagnation in Type 2 highlights potential disparities in healthcare infrastructure.

Keywords: outpatient oncology chemotherapy, policy assessment, serial cross-sectional study

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Impact of gender-affirming hormonal therapy on medication use: interrupted time series analysis

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Introduction: Trans and gender diverse people have a gender identity that differs to the one assigned to them at birth. Gender affirming hormone therapy (GAHT) is used to align physical characteristics with gender identity and improve psychosocial outcomes. Changes in medication use may serve as proxies for the health impacts of GAHT.

Aims: To perform an interrupted time series (ITS) to identify the impact of GAHT initiation on antidepressant, anxiolytic/hypnotic, antiepileptic, and cardiovascular medication use.

Methods: A 10% sample of subsidised prescriptions from the Australian Pharmaceutical Benefits Scheme was used from 2012-2024 to identify GAHT users aged ≥12. GAHT initiation was defined as: 1. Incongruent use of sex hormone (oestradiol or testosterone) with recorded sex; or 2. A change in recorded sex, and congruent sex hormone use. GAHT users were grouped into 'assigned female at birth' (AFAB) and 'assigned male at birth' (AMAB). To quantify physical and mental health impacts, a quasi-experimental ITS was performed using a Prais-Winsten regression on monthly medication use rates for 12-months pre- and post-GAHT initiation.

Results: 2519 GAHT users were identified (1032 AFAB; 1487 AMAB). Prior to GAHT initiation, an increasing trend in antidepressant use was observed for AFABs (+0.20%, 95% CI[0.08%,0.31%]) and AMABs (+0.39%, 95% CI[0.27%, 0.51%]), anxiolytic/hypnotic use for AMABs (+0.06%,95% CI[0.02%,0.10%]), and cardiovascular medication use for AFABs (+0.09%, 95% CI[0.04%,0.13%]). Following GAHT initiation, there was an immediate increase in antidepressant use in AMABs (1.60%, 95% CI[0.44%,2.76%]). There was a decline in the rates of antidepressant use after GAHT for AFABs (-0.19%, 95% CI[-0.38%,-0.01%]) and AMABs (-0.24%, 95% CI[-0.41%,-0.06%]).

Conclusions: GAHT initiation significantly impacted antidepressant use in both subgroups, suggesting positive psychological effects by nearly negating the increasing pre-intervention trend. In contrast, GAHT initiation had no significant impact for anxiolytic/hypnotics, antiepileptics, or cardiovascular medications.

Keywords: Interrupted time series, quasi-experimental, trans & gender diverse

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Impacts of dedicated budget policy on long-acting injectable antipsychotic usage in Taiwan

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Introduction: Long-acting injectable antipsychotics (LAIs) are covered by Taiwan's National Health Insurance (NHI), but their utilization remains low due to budget constraints, especially for second-generation LAIs (SGA-LAI). To promote LAI use, the NHI introduced the LAI-dedicated budget policy (LAI-DBP) in January 2022, allocating annual NT$2.7 billion. The real-world impact of this policy has yet to be investigated.

Aims: To assess the impact of the LAI-DBP on prescription rates for first- and second-generation (FGA/SGA) LAIs in patients with schizophrenia (SCZ), schizoaffective disorder (SCA) or bipolar I disorder (BPI).

Methods: Prescription data for patients aged 18 and older with SCZ, SCA, or BPI were collected from Kaohsiung Municipal Kai-Syuan Psychiatric Hospital (KSPH) electronic medical records between October 2005 and September 2024. An interrupted time-series design with Prais-Winsten regression was utilized to estimate changes in the proportion of LAI, FGA-LAI, and SGA-LAI prescriptions among antipsychotic (AP) prescriptions (LAI/AP, FGA-LAI/AP, and SGA-LAI/AP proportions) before and after the LAI-DBP implementation.

Results: Before the LAI-DBP launch, the LAI/AP proportion was 23.2%, 32.4%, and 15.1% for SCZ, SCA, and BPI, respectively. After the LAI-DBP, LAI/AP proportions increased significantly, with SGA-LAI/AP proportion rising by 74.5%, 40.7%, and 61.1%, while decreasing FGA-LAI/AP proportion by 44.0%, 27.4%, and 37.6%, for SCZ, SCA, and BPI patients, respectively. The policy had a greater impact on increasing SGA-LAI/AP proportion and decreasing FGA-LAI/AP proportion among male patients compared to females. The LAI/AP proportion among SCZ patients aged 18-35 and SCA patients aged 36-50 reaching 45% post-implementation. The policy launch shows little influence on SCA and BPI patients over 66.

Conclusions: The LAI-DBP notably boosted LAI usage, particularly SGA-LAIs, among patients with SCZ, SCA, or BPI in Taiwan. Further research is recommended to evaluate the policy's long-term impact on medication adherence and treatment effectiveness.

Keywords: schizophrenia; schizoaffective disorder; bipolar I disorder;

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A Multi-tier Regressive Markup Pricing Model for imported Medicines in Sri Lanka

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Introduction: The heavy import based pharmaceutical market in Sri Lanka follows a cost-plus pricing mechanism with a fixed supply chain markup of 65% on the Cost, Insurance, and Freight (CIF) value. This has led to affordability issues, especially for high-priced drugs. Given economic and healthcare constraints in Sri Lanka, evaluating a multi-tier regressive markup pricing structure appears practically appealing.

Aim: To develop a regressive markup pricing model to improve the affordability to patients while supporting sustainability of the pharmaceutical sector.

Method: Secondary data on 7,192 imported medicines in 2024 were obtained from the IQVIA database. A six-tier regressive pricing model was then developed by applying decreasing markup percentages to increasing CIF ranges. Annual community spending on medicines under the existing and proposed pricing regimes were then compared.

Results: The total community spending under the proposed method records a 11.68% increase compared to the current method. However, there are affordability gains for pharmaceutical products in some ranges. In particular, CIF above LKR 10,000 shows a cost reduction of 27%. Similarly, for the ranges of LKR 5,000 - 10,000 and LKR 1,000 - 5,000, the cost reduced by 18% and 9% respectively. On the other hand, LKR 1-100 and LKR 100-500 showed a cost increase of 12% and 3% respectively. Since around 59% of the total medicines fall into these low-cost categories, the increased cost supports profitability across the supply chain.

Conclusions: The proposed regressive markup eases financial pressures on high-cost medicines, supporting better affordability, despite a modest increase in overall community spendings. Future regulatory reforms may consider adopting multi-tier pricing models referenced by internal and external pricing.

Keywords: pharmaceutical pricing, maximum retail price, regressive markup

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Effect of SGLT2i treatment durations on cardiovascular outcomes: target trial emulation study

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Introduction: Sodium–glucose cotransporter 2 inhibitors (SGLT2i) have demonstrated significant cardiovascular benefits, and their use has markedly increased in recent years. However, in routine clinical practice, treatment duration is much shorter and more variable than in clinical trials, and it remains uncertain whether such abbreviated use limits the full therapeutic potential of SGLT2i.

Aims: To quantify the effect of different treatment durations of SGLT2i on cardiovascular outcomes in people with type 2 diabetes (T2D).

Methods: We emulated a hypothetical pragmatic trial using nationwide healthcare data from South Korea. Among patients who were aged 18 years or older with T2D, we compared the following treatment strategies: 1) initiation of SGLT2i with treatment durations of <1 year, 2) 1–2 years, 3) 2–3 years, and 4) >3 years. The primary outcomes of interest were major adverse cardiovascular events (MACE) and hospitalization for heart failure (HHF). We employed the cloning, censoring, and weighting method to emulate the randomization, and weighted Kaplan-Meier methods were applied to estimate 5-year absolute risks, calculated risk differences, and risk ratios (RRs). The 95% confidence intervals (CIs) were obtained from 300 non-parametric bootstraps.

Results: 1,174,088 eligible patients were included (mean age, 57.3 years; 40.5% female). Compared to patients who used SGLT2i for less than 1 year, those treated for 1–2 years, 2–3 years, and more than 3 years had progressively lower risks of MACE (RRs: 0.93 [95% CI, 0.90–0.96], 0.82 [0.78–0.85], and 0.69 [0.67–0.72], respectively), as well as HHF (RRs: 0.93 [0.90–0.97], 0.90 [0.80–0.98], and 0.74 [0.67–0.79], respectively) over a 5-year follow-up. The results remained consistent across several demographic and clinical subgroups, and in sensitivity analyses accounting for patients who discontinued treatment due to adverse effects.

Conclusions: These findings underscore the importance of sustained SGLT2i use to maximize their cardiovascular benefits.

Keywords: Target trial emulation, sodium-glucose cotransporter 2 inhibitors, cardiovascular outcomes.

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Optimal INR target for atrial fibrillation patients with and without mitral stenosis

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Introduction: The current recommended international normalised ratio (INR) in guidelines is mainly derived from trials in Western populations. The optimal INR target in Asian patients with atrial fibrillation (AF) remains unclear.

Aims: This study aims to determine the optimal INR target for Asian patients receiving warfarin with non-valvular AF (NVAF) with and without mitral stenosis (MS).

Methods: This retrospective cohort study included patients newly diagnosed with AF with and without MS between 1 January 2010 and 31 December 2023 using territory-wide electronic health records in Hong Kong. The INR-specific incidence rates of thromboembolism and bleeding were computed using the Rosendaal method. The incidence rate ratio (IRR) was calculated by conditional Poisson regression. The association between repeated INR measurements and outcomes was further evaluated using the generalised estimating equation (GEE) model.

Results: A total of 11,518 patients with AF without MS and 1,070 patients with AF-MS were identified in this study. The incidence rate of thromboembolism decreased sharply as the INR increased from 1.5-1.99 to 2.0-2.49, both in patients with AF without MS and AF-MS. The lowest bleeding incidence (2.4 events per 100 person-years) in patients with AF without MS was observed at INR of 2.0-2.49, rising to 3.4 events per 100 person-years at INR of 2.5-2.99. In patients with AF-MS, the incidence rate of bleeding remained relatively low when INR was in the range of 1.5-2.99, with a slight increase at 3.0-3.49. Both conditional Poisson regression and GEE models found a significant risk of bleeding among patients with AF without MS when INR≥2.5 but it increased among patients with AF-MS when INR≥3.

Conclusions: INR 1.5-2.5 is non-inferior to INR 2.0-3.0 for Asian patients with NVAF and an INR range of 2.0-2.49 may be an optimal target. Standard-intensity anticoagulation (INR 2.0-3.0) is still preferable for Asian patients with AF-MS.

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Prescribing Patterns and Effectiveness of PCSK9 Inhibitors in Hong Kong

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Introduction: Proprotein convertase subtilisin-kexin type 9 inhibitors (PCSK9i) are novel lipid-lowering medications (LLMs) but their real-world prescribing and response in Asian populations remain unclear.

Aims: To describe patient characteristics, concomitant treatments after PCSK9i initiation, and lipid changes in Hong Kong patients prescribed monoclonal PCSK9i.

Methods: Cohort study using electronic health records from the Hong Kong Hospital Authority of patients newly prescribed alirocumab or evolocumab between 1 August 2016 and 12 December 2024. Descriptive statistics were used to analyse patient characteristics, LLM treatment trajectories, and lipid changes at one-year of follow-up.

Results: Among 3,381 PCSK9i initiators, 3,296 met eligibility criteria (mean age 62.8 years; 70.5% male; median baseline low-density lipoprotein cholesterol [LDL-C] 2.9 mmol/L). Before PCSK9i initiation, 90.3% of patients received a LLM, 82.9% with a statin and 64.5% with ezetimibe. For longitudinal analysis, 2,195 patients had ≥1 year of follow-up (median 2.6 years; interquartile range [IQR] 1.6–4.0). 84.0% of patients initiated a PCSK9i in combination with another LLM, primarily statins and ezetimibe. Between baseline and one year after PCSK9i initiation, the use of any statin or ezetimibe declined by 5.8% and 12.5%, respectively, while high-intensity statin use declined by 11.8%. Mean relative LDL-C decreased by 44.5% (95% confidence interval [CI]: 41.8%–47.1%), and 66.9% of patients achieved an LDL-C < 1.8 mmol/L. Non-high-density lipoprotein cholesterol (non-HDL-C) decreased by a mean of 40.2% (95% CI: 38.6%-41.7%). Greater reductions in LDL-C and non-HDL-C were observed among patients receiving PCSK9i plus a statin or ezetimibe as compared with PCSK9i alone.

Conclusions: The absolute number of patients using PCSK9i in Hong Kong is low, but has increased rapidly since becoming funded in 2021. One-year follow-up in our cohort demonstrates that PCSK9i were highly effective in reducing LDL-C and non-HDL-C in clinical practice, particularly when combined with a statin or ezetimibe.

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Kidney outcomes of Dapagliflozin-10mg versus Empagliflozin-10mg versus Empagliflozin-25mg: propensity-matched cohort study

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Introduction: Sodium-glucose cotransporter-2 inhibitors (SGLT2is), including Empagliflozin and Dapagliflozin have been proven to attenuate kidney disease progression.However, head-to-head comparison data are lacking. This study addresses this evidence gap by evaluating their comparative effects on kidney function and adverse renal events.

Aims: To compare kidney outcomes among patients with type 2 diabetes (T2D) initiating Dapagliflozin-10mg (DAPA-10), Empagliflozin-10mg (EMPA-10), or Empagliflozin-25mg (EMPA-25) daily.

Methods: We analyzed a territory-wide cohort of T2D patients in Hong Kong (2000-2019) initiating DAPA-10, EMPA-10, or EMPA-25, matched 1:1:1 by propensity score. Annual post-index eGFR slopes were estimated using linear mixed-effects models adjusted for pre-index eGFR changes. The primary outcome was a composite of sustained ≥40% eGFR decline, ESKD, or cardiovascular-renal related death. The secondary outcome was hospitalization due to acute kidney injury (AKI). Risks were compared using Cox regression with intention-to-treat approach. Per-protocol analysis (excluding treatment switchers) and censoring at switching approach were adopted as sensitivity analyses.

Results: Among 20,259 patients (6,753 per group), mean age was 59.5±10.8 years with 57.6% male and median follow-up of 18 months. EMPA-10 and DAPA-10 had comparable mean (95% CI) eGFR slopes (-1.89 [-2.09 to -1.68] versus -1.77 [-1.89 to -1.65] mL/min/1.73m^2/year, fixed-effect p=0.312), whereas EMPA-25 exhibited the slowest eGFR decline (-1.35 [-1.51 to -1.19] mL/min/1.73m^2/year, fixed-effect p<0.001). Compared to EMPA-10, DAPA-10 had similar hazard ratios (HR, 95% CI) for the kidney composite endpoint (0.98, 0.84-1.15) and AKI (0.89, 0.60-1.32), while EMPA-25 reduced the risks for the respective events (0.62, 0.52–0.73 and 0.43, 0.27–0.69). These findings were confirmed by sensitivity analyses. The greater effect sizes of EMPA-25 were consistent regardless of heart failure status, KDIGO risk categories, renin-angiotensin system inhibitor use, or baseline HbA1c.

Conclusions: EMPA-25 confers greater renoprotection than EMPA-10 and DAPA-10. Further mediation analysis is needed to explain these differences accompanied by economic analysis.

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Risk of Asthma Exacerbation Among Users of Novel Antidiabetic Agents: Target-trial Emulation

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Introduction: Recent studies suggest that the use of glucagon-like peptide-1 receptor agonists (GLP-1 RAs), sodium-glucose cotransporter-2 (SGLT-2) inhibitors or dipeptidyl peptidase-4 (DPP-4) inhibitors, may reduce the risk of asthma exacerbation. However, evidence was limited when comparing these antidiabetic agents.

Aims: To compare the risk of asthma exacerbations among users of SGLT-2 inhibitors, GLP-1RAs, and DPP-4 inhibitors.

Methods: Using data from the TriNetX Global Collaborative Network from January 2016 through March 2025, we emulated three target trials to compare the risk of asthma exacerbation among patients with comorbid asthma and type 2 diabetes. The active-comparator-new-user design was implemented to minimize potential bias. We assigned patients based on their first prescription of study drugs, and propensity score matching was implemented to mimic the randomization. We defined the date of first prescription as the index date. We further examined the heterogeneity of treatment effects based on baseline BMI categories (obese: >29.9; overweight: 24.9–29.9; normal and underweight: <24.9). The study outcome was the composite asthma endpoint, consisting of exacerbation diagnoses, use of oral or injectable steroids, and use of rescue medications.

Results: There were 163,875 patients who received GLP-1 RAs, DPP-4 inhibitors, or SGLT-2 inhibitors between 2016 and the end of March 2025. Compared with DPP-4 inhibitors, the use of GLP-1 RAs and SGLT-2 inhibitors was associated with a lower risk of composite asthma endpoint, with hazard ratios (HRs) of 0.87 (95% CI: 0.85–0.90) and 0.92 (95% CI: 0.89–0.95), respectively. Effect was similar among obese patients and overweight patients, but not among those with normal or underweight.

Conclusions: Our findings indicate that the use of GLP-1 RAs and SGLT-2 inhibitors was associated with a reduced risk of asthma exacerbation. Furthermore, the effect modification by patients' baseline BMI suggests the need to individualize glucose-lowering therapy.

Keywords: Asthma exacerbation, Glucagon-like peptide-1 receptor agonists, Sodium-glucose cotransporter-2 inhibitors

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Association of pioglitazone and risk of epilepsy using the US Collaborative Network

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Introduction: Pioglitazone, approved for type 2 diabetes, showed potential anticonvulsant effects in animal studies, but its effects in real-world populations remain uncertain.

Objective: To examine anticonvulsant effects of pioglitazone among patients with type 2 diabetes.

Method: We conducted a retrospective cohort study under a target trial emulation framework using data from the US Collaborative Network. We identified patients initiating pioglitazone or DPP4 inhibitors (2004-2024), defining index date as initiation date. We applied a one-year washout period to exclude prevalent users. We also excluded patients with prior outcomes of interest or those who received both drugs on the index date. We used ICD-10-CM codes to identify outcomes of interest, including convulsions (R56), epilepsy (G40), and a composite outcome of both. We used intention-to treat analysis and 1:1 propensity score matching (PSM) to emulate treatment assignment, calculating scores based on age, sex, HbA1c, and comorbidities. We applied Cox models to estimate hazard ratios (HR) and 95% confidence interval (CI), using DPP4 inhibitors as reference. We conducted subgroup analyses by age, sex, HbA1c, and body mass index.

Results: We included 698,270 patients (185,595 pioglitazone, 526,924 DPP4 inhibitors). The mean age was 60.7 years (SD 12.0) and 61.9 years (SD 12.4), with 54.4% and 48.9% male, respectively. After PSM, 185,440 remained in each group with balanced baseline characteristics. We observed an association between a reduced risk of composite outcome (HR=0.95, 95% CI: 0.91-0.99) and individual outcomes, convulsions (HR=0.96, 95% CI: 0.91-1.02) and epilepsy (HR=0.88, 95% CI: 0.82-0.94). Results from subgroup analyses were consistent, except in patients under 65.

Conclusions: We observed an association between a reduced risk of convulsion or epilepsy and pioglitazone use, compared with DPP4 inhibitors, suggesting the potential anticonvulsant effect of pioglitazone. Further investigation is warranted to explore its anticonvulsant effect.

Keyword: pioglitazone, anticonvulsant, US Collaborative Network, type 2 diabetes.

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Aspirin in Pregnancy and Risk of Atopic and Neurodevelopmental Disorders in Offspring

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Background: Low-dose aspirin is recommended to prevent preeclampsia in pregnancies at high risk. It modulates the maternal immune system through COX-1 inhibition, raising concerns about potential risks of atopic triad and neurodevelopmental disorders in offspring. However, existing evidence on these risks remains conflicting.

Objectives: To evaluate the association of aspirin and the risks of atopic triad and neurodevelopmental disorders among pregnancies at high risk of preeclampsia

Methods: We emulated a sequence of 29 target trials of aspirin use between 0 and 28 weeks of gestation, using Taiwan's National Health Insurance Research Database from 2011 to 2021. In each sequential trial, pregnancies at high risk of preeclampsia without prior use of aspirin were eligible. Treatment strategies were aspirin use versus no-use at each gestational week. We used propensity score with IPTW to emulate randomization in the target trial. The primary outcomes were atopic triad (including atopic dermatitis, asthma, and allergic rhinitis) and neurodevelopmental disorders. The follow-up began with treatment assignment and ended at the occurrence of outcomes, delivery, or end of study period. The causal contrast of interest was intention-to-treat. We used pooled log-binomial regression models to estimate relative risk (RR) across the 29 sequential trials. We performed subgroup analyses stratified by pregnancy trimesters to assess the effect of aspirin during different biological windows.

Results: Among 58,178 pregnancies initiating aspirin and 684,245 not initiating, the mean age was 32.9 years (SD, 5.1) and 31.5 years (SD, 5.0), respectively. After propensity score weighting, we observed no association between aspirin use and the risks of atopic triad (RR: 0.97; 95% CI: 0.89-1.05) and neurodevelopmental disorders (RR: 1.02; 95% CI: 0.95-1.09). Results from different trimesters yielded consistent results to the main analyses.

Conclusion: Low-dose aspirin use during pregnancy was not associated with an increased risk of atopic triad or neurodevelopmental disorders in offspring.

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Utilization of methylphenidate and atomoxetine among children and adolescents in South Korea

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Introduction: Attention-deficit/hyperactivity disorder (ADHD) is a common neurodevelopmental disorder in children and adolescents. Despite rising global use of pharmacological treatments and growing concerns in South Korea over the potential misuse of ADHD medications as "smart drugs," comprehensive population-based utilization studies remain scarce.

Aims: To examine national trends in methylphenidate and atomoxetine use among South Korean children and adolescents using defined daily dose (DDD)-based drug utilization metrics.

Methods: This cross-sectional study used the Health Insurance Review and Assessment Service Pediatric Patient Sample database, which included patients aged 3–19 years who were prescribed methylphenidate or atomoxetine between 2010 and 2018. Medication use was assessed using cumulative DDD and standardized DDD per 1,000 patients per day. Analyses were stratified by sex, age group [preschool children (3-5 years), children (6-12 years), adolescents (13-19 years)], and geographic region [Seoul, capital region (Incheon and Gyeonggi), other metropolitan cities, and rural areas]. Monthly and annual trends were evaluated.

Results: Between 2010 and 2018, both cumulative DDD and standardized DDDs for ADHD medications increased steadily. Methylphenidate remained the predominant medication prescribed, comprising 83.2%, while atomoxetine demonstrated a consistent upward trend, increasing from 14.9% to 17.6%. ADHD medication use was significantly higher among boys, with most prescriptions in the 6–12 years (64.7%), followed by 13–15 years (22.8%), underscoring the predominance of school-aged children in the treatment population. Seoul exhibited higher standardized DDDs for methylphenidate and atomoxetine (1,474 and 626, respectively) compared to rural areas (1,244 and 553), suggesting significant regional disparities in treatment access. Monthly prescription patterns exhibited cyclical fluctuations, with distinct peaks during school semesters and declines during school vacations.

Conclusion: ADHD medication use among South Korean youth showed notable disparities by region, age group, and seasonal variation. These patterns highlight the need for continuous monitoring, as well as individual and region-specific strategies, to ensure appropriate ADHD treatment.

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Outcomes related to persistent opioid use after surgery or trauma

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Introduction: Surgery and trauma can lead to persistent opioid use (POU), characterised by continuous opioid consumption following hospital discharge. Outside the United States, there is a lack of population-based studies on POU outcomes in opioid-naive patients following these events.

Aims: To evaluate the impact of POU following surgery or trauma on health outcomes using linked data.

Methods: We included opioid-naïve patients who were dispensed opioids after being discharged following admission for surgery or trauma to any New Zealand (NZ) hospital from 2007 to 2019. Differences in outcomes between individuals with and without POU were assessed between 180 and 360 days after discharge. The primary outcome was all-cause mortality; the secondary outcomes were all-cause and opioid-related hospitalisation, and Days Alive and Out of Hospital (DAOH). Cox and quantile multivariable regression models were used to examine the association between POU and outcomes.

Results: Overall, 298,928 surgical and 206,663 trauma patients were included in the final analyses, and 17,779 (5.9%) surgical and 17,867 (8.6%) trauma patients developed POU. POU was significantly associated with increased risk of all-cause mortality (surgical, aHR=6.59; 95% CI: 5.82–7.46; trauma, aHR=2.77; 95% CI: 2.47–3.11), all-cause hospitalization (surgical, aHR=2.02; 95% CI: 1.95–2.08; trauma, aHR=1.57; 95% CI: 1.52–1.62), opioid-related hospitalization (surgical, aHR= 2.49; 95% CI: 2.24–2.76; trauma, aHR=1.89; 95% CI: 1.73–2.05) and reduced DAOH.

Conclusion: Among opioid-naive patients who received opioids after surgery or trauma, POU was associated with worse outcomes, including increased mortality. Further investigation is warranted to understand the reasons for continued opioid use beyond 90 days and the mechanisms associated with harm.

Keywords: opioid, persistent opioid use, surgery, trauma

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Association between gabapentinoid and risk of traumatic fracture a multinational observation study

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Introduction: Gabapentinoids are known to impair coordination. However, it remains uncertain whether they elevate the risk of traumatic fractures in older adults, or if this risk varies across different healthcare settings.

Aims: To investigate the association between gabapentinoid and risk of traumatic fractures among older adults in the United Kingdom and South Korea.

Methods: We performed a multinational self-controlled case series study using data from the UK Clinical Practice Research Datalink (CPRD) Aurum (linked to Hospital Episode Statistics and Office for National Statistics) and South Korea National Health Insurance Service-National Health Screening Cohort (NHIS-HEALS).Adults aged ≥60 prescribed gabapentinoids with an incident traumatic fracture were included. Four mutually exclusive risk windows were defined: 90-day pre-treatment, first 60 days of treatment period, remaining time of treatment period, and non-treatment reference period. Adjusted incidence rate ratios (aIRRs) and 95% CIs were estimated using conditional Poisson models with age, season and concomitant medications addressed as time-varying factors, and country-specific results were pooled using random effects model.

Results: 20,030 in CPRD Aurum (15,366 female [76.71%]; mean [SD] age at event, 77.85 [9.07] years) and 2,935 in NHIS-HEALS (2,007 female [68.38%]; mean [SD] age at event, 69.24 [5.73] years) were included in the analysis. The pooled results showed an increased risk of traumatic fracture during the pre-treatment period (aIRR, 2.92; 95% CI, 1.61–5.28). It then decreased to 1.31 (95% CI, 1.00–1.71) in the first 60 days of the treatment period, and further subsided in the remainder of treatment period (aIRR, 0.84; 95% CI, 0.54–1.32). Results were consistent across subgroups and sensitivity analyses.

Conclusions: Traumatic fracture risk peaked before gabapentinoid initiation and declined to non-treatment reference level during the rest of treatment period. The findings do not support a causal relationship but warrant fall and fracture prevention measures, particularly at gabapentinoid initiation.

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Comparing fracture risks following aripiprazole versus other prolactin-sparing antipsychotics after prolactin-increasing antipsychotics

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Introduction: Switching to prolactin (PRL)-sparing antipsychotics is a common strategy to reduce elevated prolactin levels for PRL-increasing antipsychotic users. Aripiprazole can effectively lower serum prolactin levels, but whether this reduces related adverse outcomes remains unclear.

Aims: This study evaluated whether switching to aripiprazole, compared to other PRL-sparing antipsychotics, reduces fracture risk as a clinically relevant adverse outcome associated with elevated prolactin levels.

Methods: We conducted a matched cohort study using the Hong Kong Hospital Authority electronic health record database. Patients aged 18–85 who used PRL-increasing antipsychotics between 2006–2020 and switched to PRL-sparing antipsychotics were included. The index date was the first switch date. 1:2 probability density sampling was used to match aripiprazole users with users of other PRL-sparing agents by sex, age, and prior follow-up duration (within 30 days). We excluded individuals with prior cancer (excluding non-melanoma skin cancer), fractures, or diabetes. Follow-up was from the index date until fractures, 365 days after discontinuation or switching of antipsychotics, the end of study (December 31, 2023), 3 years of follow-up, or death. Cox models weighted by inverse probability of treatment estimated hazard ratios (HRs) for all fractures and subtypes.

Results: Among 9,719 patients (mean age 37.7 years, 69.7% female), 3,715 aripiprazole users were matched to 6,004 other PRL-sparing users. Median follow-up was 1.09 years. Aripiprazole users had a lower risk of all-type fractures (HR: 0.45, 95% CI: 0.26–0.77, p=0.003). The HR was 0.43 (0.20–0.92) for full switchers and 0.47 (0.22–1.03) for those continuing PRL-increasing agents. Reductions were significant for spine/trunk (0.14 [0.03–0.58], 0.007) and lower limb fractures (0.50 [0.25–0.98], 0.045).

Conclusions: Switching to aripiprazole was associated with a lower fracture risk among prior PRL-increasing antipsychotic users, suggesting potential to reduce high prolactin-related adverse outcomes.

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Economic Evaluation of Antidepressants in China: Development of a Meta-Model

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Introduction: Major depressive disorder (MDD) imposes a substantial burden on global health systems, negatively impacting quality of life, cognitive function, and workplace productivity. Antidepressants are the mainstay of pharmacologic treatment, yet their cost-effectiveness varies considerably. In China, comprehensive economic evaluations comparing antidepressants remain scarce.

Objectives: To evaluate the cost-effectiveness of 16 commonly used antidepressants for MDD treatment in China and to develop a meta-model that enhances modeling efficiency and interpretability.

Methods: A decision-analytic model was constructed to simulate MDD treatment outcomes over a two-year horizon from the Chinese healthcare system perspective. The model incorporated clinical efficacy, adverse event profiles, drug costs, and utility values, drawing from published meta-analyses, health technology assessments, and national procurement data. Key outcomes included total cost, quality-adjusted life years (QALYs), and incremental cost-effectiveness ratios (ICERs). A meta-model was built using linear regression and generalized additive models (GAMs) to characterize the relationships between inputs and outcomes. Model performance was evaluated using R^2 and root mean square error (RMSE).

Results: In the base-case analysis, agomelatine emerged as the most cost-effective option, with an ICER of CNY 79,711.10 per QALY—well below China's 2023 per capita GDP threshold. Drug cost was the primary driver of uncertainty; agomelatine's price had a significant impact on its ICER. Probabilistic sensitivity analysis indicated that agomelatine had the highest probability of being cost-effective at WTP thresholds up to three times the per capita GDP. The meta-models demonstrated strong predictive performance (R^2 = 0.97–0.99); the linear model was more accurate for cost prediction, while the GAM showed slightly better performance for QALY estimation.

Conclusions: Agomelatine offers a cost-effective option for MDD treatment within the Chinese healthcare system. The use of meta-modeling enhances transparency and interpretability in cost-effectiveness analyses, supporting more efficient and evidence-based decision-making in mental health policy.

Keywords: Cost-Effectiveness Analysis, Antidepressants, Meta-Modeling

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From data to decisions: How real-world evidence transforms healthcare policy and practice

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Advances in real-world evidence (RWE) have dramatically expanded its influence on clinical guidelines, regulatory decisions, and health system policies worldwide. As the volume and rigor of RWE increase, translating these insights into tangible healthcare improvements remains a complex challenge—requiring not only scientific excellence but also effective collaboration and communication among diverse stakeholders.

Despite significant progress, persistent barriers remain. Converting nuanced, context-rich real-world data (RWD) into RWE which informs policies that are both responsive and sustainable often necessitates aligning competing priorities and demonstrating relevance in domains traditionally dominated by randomized controlled trials. The most compelling examples—where RWE has facilitated regulatory approvals, updated clinical guidelines, or influenced reimbursement decisions—highlight both the potential and complexity of translating RWD into real-world impact.

This presentation will illustrate how RWE has driven meaningful policy and practice changes, showcasing key case studies. Drawing on her leadership and experience, Dr. Ritchey will share practical strategies for overcoming translational barriers. She will emphasize the importance of stakeholder engagement, methodologic transparency, and ongoing dialogue between RWD holders, RWE generators, and decision-makers.

By reflecting on both successes and ongoing challenges, this session aims to equip RWE professionals with insights and strategies to accelerate the translation of data into improved patient outcomes and public health. Ultimately, it demonstrates how real-world research can be a powerful catalyst for sustained, meaningful change in generating actionable evidence for medical products.

II. Spotlight Poster

Abstract D1/SP01-G1 - D2/SP28-G2

D1/SP01-G1

Investigating Prevalence of OCT Genotypes and Metformin Pharmacokinetic Variability Among Indian Population

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Introduction: Metformin is the first-line oral therapy for type 2 diabetes mellitus (T2DM), but its pharmacokinetics and therapeutic response show high interindividual variability. Genetic polymorphisms in organic cation transporters (OCTs) significantly influence metformin's absorption, distribution, and elimination. OCT1 (SLC22A1), OCT2 (SLC22A2), and OCT3 (SLC22A3) mediate metformin transport across enterocytes and renal epithelial cells. Understanding these polymorphisms is crucial for optimizing therapy and advancing precision medicine.

Aim: To investigate the prevalence of OCT1, OCT2, and OCT3 genetic polymorphisms and evaluate their effect on the pharmacokinetics of metformin using a pharmacometrics approach.

Methods: The study was conducted in three phases. First, genotyping was performed to determine allele and genotype frequencies of select OCT variants. Second, plasma metformin concentrations were quantified using LC-MS/MS. Finally, a pharmacokinetic analysis was conducted using Non-Compartmental Analysis (NCA) and population pharmacokinetic (PopPK) modeling with FOCEI in PUMAS® v.1.40.1. Unpaired t-tests compared pharmacokinetic parameters between wild-type and mutant genotypes. Covariates were incorporated to explain interindividual variability.

Results: Among 230 samples, rs628031 (OCT1) showed 10% homozygous wild, 41% heterozygous, and 48.7% homozygous mutant genotypes. rs622342 (OCT1) had 22.6% wild, 53.7% heterozygous, and 23.5% mutant; rs316019 (OCT2) had 10.9% wild, 38.6% heterozygous, and 50.4% mutant; rs2076828 (OCT3) had 63.8% wild, 22.7% heterozygous, and 13.4% mutant. Metformin clearance was estimated at 97.4 L/hr and volume of distribution at 186.8 L. Incorporation of OCT2 genotype as a covariate reduced clearance variability from 55.7% to 20.2%, indicating significant influence on drug elimination.

Conclusions: OCT2 polymorphisms are significantly associated with reduced metformin clearance and volume of distribution, unlike OCT1 variants. These findings support the clinical relevance of OCT genotyping for individualized metformin therapy and warrant further validation through therapeutic drug monitoring.

Keywords: Genetic Polymorphism, Organic cation transporter, Metformin

D1/SP02-G1

SGLT2 inhibitors and GLP-1 receptor agonists for brain-related outcomes in MASLD population

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Introduction: Metabolic dysfunction-associated steatotic liver disease (MASLD) is associated with increased risks of brain-related diseases such as dementia, Parkinson's disease, and ischemic stroke. Sodium-glucose cotransporter-2 inhibitors (SGLT2Is) and glucagon-like peptide-1 receptor agonists (GLP-1RAs) have shown protective effects against these conditions, but evidence in patients with MASLD remains limited.

Aims: To compare the effects of SGLT2Is and GLP-1RAs with dipeptidyl peptidase-4 inhibitors (DPP-4Is) on the risk of brain-related outcomes in patients with MASLD.

Methods: We conducted an active-comparator new-user cohort study using the Korean healthcare database (2012-2023) among patients with MASLD, identified using a validated definition. The outcomes of interest were incident Parkinson's disease, dementia, and ischemic stroke. Two cohorts were established: one comparing SGLT2Is with DPP-4Is, and another comparing GLP-1RAs with DPP-4Is. Patients were followed from drug initiation until the earliest of outcome occurrence, death, or 31 December 2023. 1:1 propensity score matching was applied to balance covariates, and hazard ratios (HRs) with 95% confidence interval (CI) were estimated using Cox proportional hazard models.

Results: A total of 125,903 and 3,641 patient pairs were included in the SGLT2Is (mean age 52; male 72.1%) and GLP-1RAs (mean age 49; male 61.3%) cohorts, respectively, following propensity score matching. Compared with DPP-4Is, SGLT2Is were associated with lower risks of dementia (HR 0.69, 95% CI 0.64–0.74) and ischemic stroke (0.92, 0.85–0.99), with a non-significant trend for Parkinson's disease (0.83, 0.68–1.01). Similarly, GLP-1RAs were linked to a reduced risk of dementia (0.64, 0.43–0.96), but not with Parkinson's disease (0.98, 0.37–2.60) or ischemic stroke (1.05, 0.67–1.67).

Conclusion: In patients with MASLD, SGLT2Is may provide broad protection against neurodegenerative and cerebrovascular outcomes, while GLP-1RAs appear to confer outcome-specific benefits, particularly against dementia. Further studies are needed to confirm the robustness and generalizability of our findings.

Keywords: Antidiabetic medications; MASLD; Brain-related diseases.

D1/SP03-G1

Comparison of Biguanides and SGLT2 Inhibitors on Cardio-Cerebrovascular Outcomes, Complications, and Costs

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Introduction: Sodium–glucose cotransporter-2 (SGLT2) inhibitors are increasingly recommended as first-line treatment for type 2 diabetes mellitus (T2DM), but head-to-head data comparing them with metformin, the canonical biguanide, remain sparse in Japan.

Aims: To compare the long-term effectiveness and cost of initiating treatment with a biguanide versus an SGLT2 inhibitor, excluding the alternative class for 12 months but permitting other antidiabetic drugs, on a composite of major cardio-cerebrovascular events and all-cause death, and a composite of diabetic complications.

Methods: We emulated a new-user cohort trial using the Shizuoka Kokuho Database (2012–2021). Patients initiating treatment with either a biguanide or an SGLT2 inhibitor, while avoiding the alternative class during the first 12 months but allowing other glucose-lowering agents, were included. Follow-up began at treatment initiation; those who received the comparator drug within 12 months were excluded. After 1:1 propensity-score matching on demographic, clinical, laboratory, and lifestyle variables, cause-specific Cox models estimated hazard ratios (HRs). Daily medication costs were compared.

Results: After matching, 1,246 patients (623 per group) were followed for a median of 4.0 years (maximum 8.5). Cardio-cerebrovascular composite: 44/623 biguanide users (7.1%) and 35/623 SGLT2-inhibitor users (5.6%) experienced a first event (HR 0.80, 95% CI 0.51–1.24). Diabetic complications: 86/623 (13.8%) vs. 78/623 (12.5%) (HR 0.88, 95% CI 0.70–1.13). Median daily drug cost was 124.7 JPY for biguanides and 184.0 JPY for SGLT2 inhibitors ($P < 0.001$).

Conclusions: Using a large-scale regional database from Japan, we found that among adults with type 2 diabetes without prior major cardiac or renal disease, first-line treatment with an SGLT2 inhibitor did not reduce risks of cardio-cerebrovascular events, mortality, or complications compared with metformin, and cost about 50% more.

D1/SP04-G1

Impact of Liraglutide on childhood obesity: a population-based estimation

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The prevalence of US childhood obesity rose from 13.9% in 2000 to 19.7% in 2024, resulting in increased risks of severe comorbidities in adulthood. The 2024 randomized clinical trial ('SCALE Kids') demonstrated once-daily liraglutide injection (a GLP-1) efficaciously reduced BMI compared to placebo among children aged 6-11 years.

We aim to estimate the population-level effect of liraglutide use among children 6-11 years at the ≥95th percentile of age- and sex-specific obesity. We hypothesized greater uptake of liraglutide would result in greater BMI reduction and reduced effectiveness of liraglutide would result in lower BMI reduction.

We developed a population-level estimation model that varied the assumption of uptake and the effectiveness of liraglutide, after accounting for demographic, medical, and behavioral characteristics using R version 4.5.1. We utilized nationally-representative data from the 2021-2023 US National Health and Nutrition Examination Survey (NHANES) to estimate the age- and sex-specific prevalence of obesity among 6-11 year olds. We applied similar exclusion criteria to the trial: diabetes, suicidal ideation, and secondary causes of obesity.

The model estimated an overall 0.6% decrease in BMI (95% confidence interval [CI]: -1.8% to 0.6%) at 30% uptake and an overall 1.3% decrease in BMI (95% CI: -2.4% to -0.3%) at 40% uptake. Conversely, as the effectiveness of liraglutide diminished, we observed smaller reductions in BMI. The model estimated an overall 1.4% decrease in BMI (95% CI: -2.4% to -0.5%) when liraglutide effectiveness is reduced by 6% and an overall 0.8% decrease in BMI (95% CI: -1.8% to 0.2%) when liraglutide effectiveness is reduced by 4.3%.

In conclusion, a substantial number of obese children could benefit from the widespread uptake of liraglutide if its effectiveness in the real world is similar to its efficacy observed in the SCALE Kids trial. Liraglutide use among obese children could result in a population health benefit.

D1/SP05-G1

Questionnaire development and validation to assess community pharmacists' medication therapy management practices.

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Introduction: Diabetes Mellitus (DM) is a chronic condition requiring long-term care, making self-management challenging. Medication Therapy Management (MTM) is a patient-centered approach provided by pharmacists. Although assessment of the MTM practices by pharmacists (their attitudes, interests, and challenges) is needed, the lack of validated instruments hinders evaluation of pharmacists' roles.

Aims: To develop, validate, and assess the reliability of a questionnaire evaluating community pharmacists' practices, attitudes, and interest in MTM provision for type 2 DM in Karnataka, India.

Methods: A 20-item questionnaire was developed based on literature and expert input. Content validity was evaluated by eight experts (an endocrinologist, two community medicine specialists, a public health specialist, a community health nurse, a statistician, an academic pharmacist, and a pharmacoepidemiologist) for relevance and accuracy of the questionnaire. Item- and scale-level content validity indices (I-CVI and S-CVI) were calculated. The user testing method was employed to measure internal consistency (N=44) using Cronbach's alpha, and test-retest reliability (N=26) was assessed using intraclass correlation coefficients (ICC) at two time points with SPSS version 28.0.

Results: All 20 items had I-CVI values above 0.87, and the S-CVI was 0.98, indicating strong content validity. Internal consistency was acceptable across all domains: interest (Cronbach's alpha = 0.797), practice (0.811), and attitude (0.713). The overall Cronbach's alpha for the tool was 0.871. Test-retest reliability showed good consistency over time: interest (ICC = 0.821, 95% CI: 0.696–0.908), practice (ICC = 0.849, 95% CI: 0.750–0.921), and attitude (ICC = 0.833, 95% CI: 0.722–0.913). The overall ICC for the questionnaire was 0.708 (95% CI: 0.511–0.839, $p < 0.001$).
Conclusions: The questionnaire demonstrated strong validity and reliability. In the future, this tool can be used to identify training needs among pharmacists and to evaluate improvements following MTM-focused training, supporting capacity-building and quality improvement in diabetes care.

Keywords: Pharmacoepidemiology, Pharmaceutical care, Questionnaire, Diabetes.

D1/SP06-G1

Detection and resolution of DRPs in Pediatric intensive care Hospital

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Introduction: Paediatric ICUs have a high DRP risk due to polypharmacy, age-related pharmacokinetics and complex regimens in critically ill children.

Aims: The study aimed to evaluate the impact of clinical pharmacist (CP) interventions on DRPs, clinical & cost outcomes for provision of pharmaceutical care services in critically ill patients.

Methods: A prospective interventional study was conducted in the PICU in two phases—pre-intervention and post-intervention. Outcomes were assessed by using odds ratio & cost benefit analysis.

Results: A total of 449 pediatric patients were included (n=231, pre-phase; n=218, post-phase). DRP occurrence significantly reduced from 0.66 to 0.49 per patient (p=0.007). The average PICU stay was decreased from 3.90 to 2.81 days (p=0.001), and the number of drugs prescribed reduced from 9.01 to 7.06 (p=0.000). DRPs pertaining to treatment efficacy (74.93%) and safety (15.91%) were most common prevalent. Clinical pharmacist interventions led to complete resolution of 70% of identified DRPs, with 91% intervention acceptance rate and 65% fully implemented. Economically, pharmacist-led interventions result in a cost savings of INR 8,675 and cost avoidance of INR 31,813.54. After deducting service costs (INR 33,333), the net benefit was INR 7,155.54. The benefit-cost ratio was 1.24, with INR 268.13 saved per intervention and INR 185.72 per patient, reflecting cost-neutral but clinically impactful service.

Conclusion: Clinical pharmacist interventions in the PICU significantly enhanced medication safety, reduced DRP rates, shortened ICU stays, and cost benefit. Integrating pharmacists as ca key member of ICU care teams improves therapeutic outcomes and enhanced pediatric critical care delivery.

Key words: Clinical pharmacist, drug related problems, cost benefit analysis.

D1/SP07-G1

SGLT2 inhibitors and the risk of nephrolithiasis in Thai patients with diabetes

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Introduction: Nephrolithiasis is a multifactorial disease with many contributing factors varying across races, ethnicities, and sociocultural backgrounds. Diabetes is a significant independent risk factor for nephrolithiasis potentially leading to more severe complications.

Aims: We aimed to investigate the association between sodium-glucose co-transporter-2 inhibitors (SGLT2is) and the risk of nephrolithiasis in Thai patients with type 2 diabetes (T2D).

Methods: This retrospective cohort study of T2D patients used real-world data from Ramathibodi Hospital, Bangkok, Thailand. Adult T2D patients who received SGLT2is, sulfonylureas, thiazolidinediones, dipeptidyl peptidase 4 inhibitors, or glucagon-like peptide-1 receptor agonists were included. Patients who developed nephrolithiasis before or within one month of initial antihyperglycemic medication prescription were excluded. Inverse probability weighting with regression adjustment and Cox proportional hazards models were applied to estimate the effect of SGLT2is on the risk of nephrolithiasis.

Results: A total of 24,679 patients were identified between January 2015 - December 2023, of whom 5,754 received an SGLT2i. The median follow-up time was 2.2 years. Thirteen covariates associated with SGLT2i assignment (i.e., age, sex, diabetes duration, body mass index, HbA1c, eGFR, dyslipidemia, cardiovascular diseases, peripheral vascular diseases, diabetic retinopathy, renin-angiotensin system inhibitors, number of other antihyperglycemic drugs currently used, and healthcare coverage scheme) were selected for propensity score calculation. The incidence rate of nephrolithiasis was 8.4 per 1000 person-years in the SGLT2i group and 17.5 per 1000 person-years in the non-SGLT2i group. The risk of nephrolithiasis was significantly lower in patients who received an SGLT2i compared to those who did not, with a HR = 0.51; 95% CI: 0.39, 0.67.

Conclusions: Our real-world study suggested a lower risk of nephrolithiasis in Thai patients with T2D who were prescribed SGLT2is. These real-world findings provide an additional benefit related to prescribing SGLT2is in T2D patients to prevent nephrolithiasis.

Keywords: nephrolithiasis, sodium-glucose co-transporter-2 inhibitors, type 2 diabetes

D1/SP08-G2

Medication adherence to PCSK9 inhibitors in clinical practice: systematic review and meta-analysis

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Introduction: Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors are novel injectable lipid-lowering medications, but poor medication adherence in real-world settings may compromise their effectiveness. This study synthesizes evidence on medication adherence to PCSK9 inhibitors across initiation, implementation, persistence, and reinitiation phases to identify challenges and inform clinical practice.

Aims: To determine the prevalence of medication adherence to PCSK9 inhibitors in observational studies.

Methods: We searched MEDLINE, EMBASE, PsychInfo, CINAHL Plus, and medRxiv from inception to 2 August 2024 for observational studies that reported on at least one phase of medication adherence for alirocumab, evolocumab, or inclisiran. Measures were categorized into initiation, implementation, persistence, and reinitiation phases. Data were pooled using random-effects meta-analysis with multi-level models to account for measurements at multiple time points.

Results: 94 studies (101 cohorts) were included, with 56 studies (74,589 patients) contributing to the quantitative synthesis. The pooled initiation rate was 91.7% (95%CI: 83.6-96.0; I^2 = 94.2%). For implementation measures, the mean medication possession ratio (MPR) at 24 months was 86.5% (95%CI: 80.2-92.9; I^2 = 99.7%) and the proportion of days covered (PDC) at 12 months was 69.7% (95%CI: 55.9-83.5; I^2 = 99.8%). For persistence measures, proportion of persistent patients at 12 months was 81.8% (95%CI: 68.2-90.4; I^2 = 99.1%) and 12-month discontinuation rate was 12.1% (95%CI: 7.4-19.0; I^2 = 98.9%), with adverse effects being the most commonly reported reason. The proportion resuming PCSK9 inhibitor treatment after a temporary interruption was 50.4% (95%CI: 38.5-62.2; I^2 = 87.0%). Multi-level meta-analyses demonstrated a decline in MPR and persistence beyond 12 months of follow-up.

Conclusion: While PCSK9 inhibitor initiation is high, implementation and persistence decline substantially over time. Comparative real-world data for inclisiran versus monoclonal antibodies remain limited, and longitudinal studies (>24 months) are needed to clarify long-term adherence patterns.

Keywords: PCSK9 inhibitors, medication adherence, real-world evidence

D1/SP09-G2

Lipid lowering therapy use in high-risk CV patients of VESALIUS-REAL: Hong Kong

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Introduction: The benefits of lipid-lowering therapy (LLT) are being investigated in the VESALIUS-CV trial (NCT03872401) among high-risk patients without prior myocardial infarction or stroke. In parallel, the global VESALIUS-REAL study examines the burden of high-risk populations across 11 countries. Here, we provide findings from Hong Kong (HK).

Aims: To describe lipid management patterns in patients at high-risk for a first myocardial infarction (MI) or stroke in HK.

Methods: A retrospective cohort study was conducted using the HK Hospital Authority database (2010–2020). It contains electronic health records, including prescriptions, diagnoses, procedures, and laboratory test results. Patients aged ≥50 years with elevated lipids; coronary artery disease (CAD), peripheral artery disease (PAD), cerebrovascular disease (CeVD), or high-risk diabetes (DM), and other predefined high CV risk factors were selected. The earliest date when patients met all eligibility criteria was defined as the index date. Intensification was defined as a dose increase, switching to more intensive LLT, or adding drug classes.

Results: Of 118,463 patients (median age: 69 years; 47.2% were women; median low-density lipoprotein cholesterol [LDL-C]: 2.64 mmol/L), 43.6% had CAD, 8.7% had CeVD, 5.6% had PAD, and 44.9% had high-risk DM. Less than half of patients (N=54,425) were on LLT at index (94.8% on statin monotherapy and 1.2% on combination therapy). Of the 47,564 patients on LLT at index with available LDL-C measurements (mean LDL-C: 2.65 mmol/L) during the one-year follow-up period, 68.4% exceeded the LDL-C level of 1.8 mmol/L, a target commonly used by local clinicians, and only 7.9% had intensified treatment.

Conclusion: Over half of the high-risk population for first MI or stroke in HK was not on LLT, and most patients did not achieve the guideline-recommended LDL-C target during follow-up. Our results highlight a treatment gap in improving lipid management in these patients and preventing major ischemic events.

D1/SP10-G2

Regulatory Patterns in FDA Oncology Withdrawals: Spotlight on FDORA Enforcement

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Background: The FDA's Accelerated Approval (AA) pathway has enabled earlier access to oncology drugs. However, uncertainty remains over whether post-marketing confirmatory trial results are acted upon promptly, posing an ongoing regulatory challenge. The Food and Drug Omnibus Reform Act (FDORA), enacted in 2022, sought to strengthen the FDA's authority to enforce timely confirmatory trials and withdraw unsubstantiated approvals.

Aims: This study assesses whether FDORA mechanisms were applied in recent AA withdrawals and whether regulatory actions aligned with confirmatory trial outcomes.

Methods: We conducted a retrospective review of regulatory documents for five oncology drugs (Pepaxto, Exkivity, Truseltiq, Trodelvy, and Aloqopa) withdrawn from the AA pathway in 2024. Truseltiq was excluded from in-depth analysis due to its withdrawal for business reasons. For the remaining four, we compared regulatory history, withdrawal rationale, and confirmatory trial outcomes. Safety risk ratios (RR) were calculated based on adverse event data from confirmatory trials that led to approval withdrawal.

Results: Despite FDORA's provisions, four of the five accelerated approval withdrawals in 2024 were initiated voluntarily by sponsors, without formal FDA enforcement. Pepaxto was the only case withdrawn following a formal FDA-initiated process under FDORA, based on hematologic toxicity and lack of efficacy. Across the four analyzed drugs, confirmatory trials failed to show survival benefit, and their risk–benefit profiles raised concerns. Safety analyses revealed elevated risks of serious treatment-related adverse events, with RR for grade ≥4 or serious TRAEs ranging from 1.39 to 1.87.

Conclusion: Among the oncology drugs withdrawn in 2024 following accelerated approval, Pepaxto remains the only FDA-initiated withdrawal under FDORA. This highlights the critical importance of timely, rigorous confirmatory trials and benefit–risk reassessment in post-approval surveillance of accelerated oncology therapeutics. To ensure consistent regulatory enforcement, clearer criteria and operational triggers for FDORA-driven withdrawals should be articulated and standardized.

Keywords: Accelerated approval, regulatory withdrawal, confirmatory trials

D1/SP11-G2

Evaluating Institutional Medication Use Safety-Program in Ambulatory Settings for Chronic Disease Management

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Introduction: Ensuring patient safety in outpatient settings poses unique challenges for both providers and patients. The overwhelming workload faced by healthcare providers directly hinders the effective assessment of medication use safety, particularly in ambulatory care settings. Clinical pharmacists have huge potential to address this contextual concern.

Aim: To evaluate the medication use safety assessment program in ambulatory patients with chronic disease.

Methods: An interventional study was carried out in an ambulatory setting of a tertiary care hospital for a period of 12-months. Patients above 18 years of age with chronic conditions and visiting the study site were included. The medication safety assessment program was initiated by an ambulatory pharmacist in collaboration with the general medicine outpatient department. Under this program, patients's prescriptions and clinical findings were recorded using a structured data collection tool. Obtained data screened with multiple medication safety assessment tools & drug database. Descriptive & inferential statistics were used to analyze the data.

Results: A total of 402 patients of age 52.78±12.04 years were enrolled; among them, 30% were on polypharmacy (n=121). The majority were diagnosed with hypertension (n=192, 47.76%), diabetes (n=124, 30.84%), and rheumatoid arthritis (n=77, 13.8%). During the medication safety assessment, a total of 88 adverse reactions and 533 (73.9%) clinically important potential drug-drug interactions (pDDIs) were identified. Out of which 93.3% (n=112) of clinically important pDDIs & 18.3% (n=22) of adverse reactions (ADRs) were seen in patients with polypharmacy. Gender, age, comorbidity burden, medication burden, adherence status, and betel nut-user show statistically significant correlations with clinically significant pDDIs; however, only age and comorbidity burden show statistically significant correlations with ADRs.

Conclusion: An ambulatory pharmacist-led medication use safety program can significantly enhance the quality of outpatient care. Implementation of such a program will significantly improve patient safety.

Keywords: ambulatory care, adverse events, drug interactions, medication safety.

D1/SP12-G2

Development Of Novel Poison Severity And Mortality Scale: Optimizing Emergency Clinical Outcomes

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Introduction: Poisoning remains a major medical emergency and public health concern, especially in low- and middle-income countries with limited healthcare access. Early severity assessment is vital to reduce mortality. Developing accurate, practical scoring system for poisoning cases is crucial for timely treatment, guiding clinical decisions, improving outcomes, and optimizing healthcare resource use.

Aims: To develop a novel poison severity and mortality scale for assessment of poisoning cases.

Methods: An ambispective study was conducted over 7 months at a tertiary care hospital in India, analyzing 151 retrospective poisoning cases to identify key clinical parameters from patient medical records. Novel scale was developed through standardized process, which included domain determination, item development, and scale formulation. Suggestions of expert panels, statistical methods like descriptive statistics, Content Validity Ratio (CVR), Content Validity Index (CVI), Scale-CVI (S-CVI), modified Kappa coefficient, and Intraclass Correlation Coefficient (ICC) were used to evaluate the validity and reliability of the improved scale.

Results: A total of 151 retrospective poisoning cases were analyzed (mean age: 29.46 years), mostly from urban areas, pesticide poisoning being most common (36%). An initial 71-item scale (26 mortality domain, 45 severity domain) was reviewed by 25 experts from emergency, intensive care unit, and general medicine departments. Items with CVR < 0.37 and CVI < 0.78 were removed, retaining 37 items. The average S-CVI was 0.90, and the modified kappa for all items was found to be more than 0.80, depicting excellent reliability. Face validity showed unanimous expert agreement, and ICC was 0.894, indicating excellent consistency and reliability.

Conclusions: Poisoning remains a significant public health challenge. While the scale demonstrates strong reliability for acute cases, its single-center design limits generalizability. Future studies should be multicenter, include pediatric and geriatric groups, and address all exposure types for broader clinical relevance.

Keywords: Poisoning, Severity and Mortality Scale, Content Validation

D1/SP13-G2

Comparison of clinical practice guidelines for ADHD patients with comorbidities across countries

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Introduction: Attention-deficit/hyperactivity disorder (ADHD) frequently co-occurs with various psychiatric comorbidities, complicating pharmacological treatment planning and clinical decision-making. National clinical guidelines differ significantly in their recommendations, particularly regarding comorbidity-specific pharmacotherapy strategies.

Aims: This study aimed to compare and evaluate pharmacological treatment recommendations for psychiatric comorbidities by systematically analyzing national ADHD guidelines from seven countries.

Methods: A structured literature search was conducted to identify national ADHD guidelines published between 2015 and 2024 in OECD countries. Guidelines were considered eligible if they included pharmacological recommendations addressing psychiatric comorbidities. Two reviewers independently extracted relevant data using a standardized extraction form covering 18 predefined comorbidities. Key components extracted included treatment prioritization (ADHD vs. comorbidity), recommended first- and second-line medications, contraindications, and safety considerations. Guideline quality was evaluated using the AGREE II instrument, which assesses six domains including rigor of development and applicability.

Results: Among 942 records identified, 548 remained after deduplication. Following title and full-text screening, seven national ADHD guidelines from Korea, Germany, the United States, the United Kingdom, Ireland, Canada, and Australia were included. The number of psychiatric comorbidities with pharmacological treatment recommendations varied considerably, ranging from 2 (UK) to 16 (Canada). Canada, the United States, and Australia addressed over 80% of the 18 comorbidities, while the others covered fewer. Substance use disorder was the only comorbidity addressed by all guidelines. Canada and the United States provided condition-specific recommendations, while Australia and the UK offered more general principles. Germany required additional clinical interpretation. Korean and Irish guidelines included only limited recommendations. AGREE II results showed high clarity but low scores for development rigor and applicability, revealing significant variability in guideline quality.

Conclusions: Substantial variation exists in pharmacological recommendations for psychiatric comorbidities in ADHD across countries. These findings highlight the need for clearer, harmonized guidelines to promote consistent, evidence-based care.

Keywords: ADHD; Comorbidities; Pharmacological Treatment

D1/SP14-G1

Validation of diagnostic coding for chronic kidney disease using Japanese hospital-based database

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Introduction: The validity of International Classification of Diseases 10th Revision (ICD-10) codes related to chronic kidney disease (CKD) in Japan has not been evaluated.

Aims: To assess the validity of ICD-10 codes related to CKD.

Methods: We used the JMDC hospital-based database, which includes claims and laboratory data from over 1,000 medical institutions in Japan. Patients who underwent two serum creatinine measurements between April 2014 and August 2022 were identified; the second measurement was obtained between 90 and 365 days after the first. The estimated glomerular filtration rate (eGFR) was calculated. As the gold standard, CKD was defined according to the Kidney Disease: Improving Global Outcomes (KDIGO) criteria—specifically, an eGFR < 60 mL/min/1.73 m^2 on both measurements. We identified patients assigned ICD-10 codes related to CKD (N183, N184, N185, N189, N19, E102, E112, E142, and I120) within 365 days of the initial serum creatinine measurement. Subsequently, we calculated the positive predictive value (PPV), sensitivity, specificity, and negative predictive value (NPV).

Results: A total of 618,208 patients were included. Among these patients, 59,139 were assigned ICD-10 codes related to CKD, and 172,657 met the KDIGO criteria for CKD. Overall, the PPV, sensitivity, specificity, and NPV were 57.9%, 19.8%, 94.4%, and 75.2%, respectively. Notably, the PPVs for ICD-10 codes such as N183, N184, N185, and N189 were high, all exceeding 80% (80.9%–99.1%), whereas the sensitivities were low (0.7%–12.7%).

Conclusions: In the Japanese setting, the PPV of ICD-10 codes for CKD was 57.9%, which is slightly lower than previously reported values in the U.S. (86.1%) and Canada (60.1%). In contrast, the PPV of N183, N184, N185, and N189 was more than 80%, suggesting that these codes may be useful for accurately identifying patients with CKD, despite their limited sensitivity.

Keywords: Chronic Kidney Disease, hospital-based database, positive predictive value

D2/SP15-G1

Effect of ARB on the development of chronic diabetic complications: TTE study

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Introduction: RCTs suggest that angiotensin-receptor blockers (ARB) may limit the onset and the progression of nephropathy and retinopathy in patients with type 2 diabetes (T2DM). However, high-dose Olmesartan may be linked to increased cardiovascular risk. Real-world evidence remains limited, and results are inconsistent.

Aims: This study aimed to conduct a target trial emulation study to evaluate the effect of ARB initiation on chronic complications in T2DM patients with hypertension.

Methods: We used a Chinese regional health care database OMOP CDM to emulate a sequence of target trials including T2DM patients with hypertension who initiated ARB or not between 2012 and 2022. The effects of ARB initiation on new onset of diabetic retinopathy (DR), diabetic peripheral neuropathy (DPN), and cardiovascular mortality and morbidity were analysed in both intention-to-treat (ITT) and per-protocol (PP) approaches. A time-discrete dataset was constructed by month for each eligible person-trial, where the marginal structural model was adopted to estimate the causal effect accounting for time-varying variables. Pooled logistic regression approximated hazard ratios (HR).

Results: A total of 8,682 person-trial initiators (8,682 individuals) and 941,073 person-trial non-initiators (19,987 individuals) were included. In ITT analysis, ARB initiation was associated with a reduced risk of DR (adjusted HR: 0.81; 95% CI: 0.51–1.27) and cardiovascular death (adjusted HR: 0.97; 95% CI: 0.79–1.19), though not statistically significant. No association was found for DPN (adjusted HR: 1.27; 95% CI: 0.94–1.72). However, a significantly increased risk of cardiovascular morbidity was observed (adjusted HR: 1.32; 95% CI: 1.26–1.39). PP analysis results were consistent.

Conclusions: ARB initiation may offer modest protection against DR and cardiovascular mortality in T2DM patients with hypertension, but these associations were not statistically significant. Importantly, ARB use was associated with higher cardiovascular morbidity risk, highlighting the need for vigilant CV monitoring in clinical practice.

Keywords: ARB; T2DM complication; Target trial emulation

D2/SP16-G1

A Machine Learning-Based Predictive Model for Assessing QTc Prolongation in Hospitalized Patients

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Introduction: QTc prolongation is a significant concern in hospitalized patients due to its association with life-threatening arrhythmias. Accurate risk prediction is essential for early intervention. However, existing QTc risk models often lack generalizability across diverse populations and clinical settings.

Aims: This study aimed to develop and validate a machine learning model that integrates both structured and unstructured EHR data to predict QTc prolongation and derive a simplified risk score (QTc Risk Index for Hospitalized Patients, QTRISK-H) for clinical use.

Methods: We conducted a nested case-control study using data from a tertiary hospital, including patients aged ≥45 years with at least two electrocardiograms (ECGs) recorded on different days during hospitalization. Structured data included demographics, comorbidities, medications, QTc values, and laboratory results. Unstructured data from ECG and echocardiography reports were extracted using rule-based natural language processing. Six machine learning models were developed, and performance was assessed using the area under the receiver operating characteristic curve (AUROC) and Brier scores.

Results: A total of 17,081 patients were included in the final analytic cohort, with 13,426 assigned to the training/testing set and 3,655 to the temporal validation set. Among the testing set, the extreme gradient boosting (XGBoost) model achieved the highest AUROC (0.772). QTRISK-H was developed using a logistic regression model, which achieved comparable performance (AUROC 0.758). Key predictors included hypokalemia, number of QT-prolonging medications, myocardial ischemia, and intensive care unit stay. QTRISK-H outperformed existing risk scores in temporal validation.

Conclusion: The XGBoost model demonstrated the best performance, and QTRISK-H offers a clinically practical and interpretable tool for predicting QTc prolongation. Nevertheless, external validation in independent cohorts is warranted to confirm whether it can support risk-informed monitoring and prescribing decisions, thereby helping to prevent QTc prolongation and reduce the risk of serious arrhythmias.

Keywords: QTc prolongation, predicted model, machine learning

D2/SP17-G1

Depression in rheumatoid arthritis patients initiating JAKi versus TNFi: Target Trial Emulation

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Introduction: Depression is a common comorbidity in patients with rheumatoid arthritis (RA), affecting treatment prognosis and quality of life. Janus kinase inhibitors (JAKi) and tumor necrosis factor inhibitors (TNFi) are widely used in moderate-to-severe RA and have been suggested to offer psychiatric benefits. However, direct comparisons of their effects on depression remain scarce.

Aims: To compare the risk of depression among RA patients initiating JAKi versus TNFi.

Methods: We conducted a population-based cohort study using 2017–2023 Korean National Health Insurance claims data, applying a target trial emulation framework. Eligible participants were RA patients aged ≥20 years who newly initiated JAKi or TNFi. The outcome was incident depression occurring ≥6 months after treatment initiation. Patients were followed from drug initiation until the earliest of outcome occurrence, treatment discontinuation, switching, death, or December 2023. Stabilized inverse probability of treatment weighting based on baseline propensity scores was used to adjust for confounding. Weighted Cox models estimated adjusted hazard ratios (aHRs).

Results: Among 8,181 patients (3,847 JAKi users; 4,334 TNFi users), most were female and aged 45–64 years. The incidence rate of depression per 1,000 person-years was 13.1 for JAKi users and 9.9 for TNFi users. JAKi use was not significantly associated with depression compared to TNFi (aHR 1.27, 95% CI 0.92–1.76). However, subgroup analyses revealed higher risks among patients without prior statin use (aHR 1.46, 95% CI 1.02–2.10), without benzodiazepine use (aHR 1.79, 95% CI 1.15–2.80), with intermediate RA-related visit frequency (aHR 1.72, 95% CI 1.01–2.93), and among upadacitinib users (aHR 1.70, 95% CI 1.04–2.77).

Conclusions: Overall, depression risk did not differ significantly between JAKi and TNFi, but JAKi may be less favorable in certain subgroups. These findings highlight the importance of considering psychiatric benefits in clinical decision-making.

Keywords: rheumatoid arthritis, JAKi vs TNFi, depression

D2/SP18-G1

Examining the necessity of subgroup-based Rapid Cycle Analysis: Lessons from COVID-19 vaccine

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Introduction: Robust safety surveillance is essential when introducing new vaccines. In Japan, a nationwide registry linked to claims database will be established in 2026, making real-time safety signal monitoring system an urgent priority. Rapid Cycle Analysis (RCA) is usually conducted in overall population, which can mask safety signals if there is an effect modification. The investigation on the necessity of subgroup-based RCA is limited.

Aims: We aim to compare how quickly safety signals are detected in overall population versus subgroups. We illustrate mRNA COVID-19 vaccine (wild-type) on myocarditis/pericarditis.

Methods: COVID-19 vaccination program in Japan was initiated on February 17, 2021. We compared vaccinated cohort (t0=vaccination date, tend=21 days after vaccination) and historical cohort (t0=January 1st 2019, tend=December 31st 2019) using the VENUS study (vaccine registry and insure-based claims data provided from 10 municipalities; 8 have historical data). Eligible individuals in each cohort were >12 years old, enrollees of health insurance, and had no history of myocarditis/pericarditis (defined by ICD-10 codes) at t0. We applied a Poisson-based Maximized Sequential Probability Ratio Test from February 2021 to December 2023, which monthly evaluates rate ratios (RR) between these cohorts for the overall population and several patterns of subgroups defined by sex and/or age (young:12–39, middle:40–64, old:≥65 years).

Results: We identified 859,880 individuals in historical cohort (mean age:68.38, female:58%). Among 981,606 vaccinated individuals (72.65, 58%), 74 outcomes emerged (2.19/100,000 doses). No signals were detected in the overall population (observed vs. expected cumulative events:74 vs. 63.52; RR:1.16 as of December 2023). Signals were detected in young-male (2 vs. 0.17; RR:11.76) in August 2021 and young subgroup (5 vs. 0.6; RR:8.33) in September 2021. No signals emerged in the other subgroups.

Conclusions: Much earlier detection highlights the importance of subgroup-based RCA. Further consideration is required for computational requirements and other outcomes.

Keywords: rapid cycle analysis, mRNA vaccine, subgroup analysis.

D2/SP19-G1

Live zoster vaccination and chronic respiratory disease: An emulated target trial

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Introduction: Live zoster vaccination (LZV) reduces the incidence of herpes zoster and its complications. Recent evidence suggests additional benefits, including lower risks of cardiovascular disease and dementia. However, its effect on chronic respiratory diseases remains unclear. Given that herpes zoster induces strong immune activation, potentially exacerbating chronic inflammation, evaluating whether vaccination mitigates respiratory disease risk is warranted.

Aims: We evaluated whether LZV is associated with reduced risk of chronic respiratory diseases, including COPD, asthma, and interstitial lung disease (ILD).

Methods: We conducted a target trial emulation using a nationwide, population-based cohort of 2,207,784 individuals aged ≥50 years in South Korea. Health insurance claims, national health screening data, and immunization records were integrated to identify exposure to LZV between January 1, 2012, and December 31, 2021. The outcomes were newly diagnosed and hospitalized cases of COPD, asthma, and ILD. After 1:1 exposure-driven propensity score matching, we used Cox proportional hazards models to estimate adjusted hazard ratios (aHRs).

Results: The matched cohort included 431,266 individuals per group (mean age, 61.13 years; 47.70% male). LZV was associated with significantly reduced risks of COPD (aHR, 0.67 [95% CI, 0.67–0.68]), hospitalized COPD (0.65[0.61–0.68]), asthma (0.68[0.67–0.69]), hospitalized asthma (0.58[0.53–0.64]), ILD (0.80[0.74–0.87]), and hospitalized ILD (0.67[0.55–0.83]). The protective effects were more pronounced in non-smokers and were strongest within 1–3 years post-vaccination, persisting up to 7 years.

Conclusions: LZV was associated with a reduced incidence of chronic respiratory diseases and related hospitalizations. These findings support broader implementation of zoster vaccination in older adults and highlight potential benefits beyond herpes zoster prevention. Although our study focused exclusively on the live attenuated vaccine, both live and recombinant zoster vaccines may modulate systemic inflammation. Therefore, further research is needed on the respiratory benefits of recombinant zoster vaccination.

Keywords: chronic respiratory disease; herpes zoster; LZV, target trial emulation, vaccine effectiveness.

D2/SP20-G1

Gallbladder Cancer Risk Factors in Northeast India: A Mixed-Methods Sequential Explanatory Analysis

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Introduction: Gallbladder cancer (GBC) incidence varies significantly by geography, with Northeast India being a high-risk region. The relevance of globally identified risk factors within this distinct population is underexplored.

Aim: To delineate the GBC epidemiological profile in Northeast India by integrating regional patient data with an umbrella review of global evidence.

Methods: A mixed-methods sequential explanatory study was conducted. For the quantitative phase, we collected risk factor data from confirmed GBC patients (N=445) from a tertiary care cancer hospital in Assam, India, following ethical permission. For the qualitative synthesis, a systematic search was conducted in PubMed, Embase, Scopus, and Epistemonikos from inception to 30th June 2025 to identify global risk factors, and the quality of the included meta-analyses was assessed using the AMSTAR-2 tool. To ensure robust triangulation, consistency between regional findings and global evidence was compared with our effect sizes to the prediction intervals derived from the meta-analyses.

Results: Our global evidence synthesis identified over 120 risk associations from 51 meta-analyses, with strong links to gallstones, infections, and certain genetic polymorphisms. Triangulation with our regional cohort confirmed the risk of high parity (mean: 3.38 births), consistent with global data. However, critical divergences emerged: while smoking was rare (80.5% never-smokers), use of smokeless tobacco (58.6%) and betel nut (58.6%) were highly prevalent regional risk factors. Unique regional exposures included the near-universal use of mustard oil (96%), reliance on underground water (68.6%), and proximity to rivers (77.3%). In line with global findings on genetic susceptibility, the absence of Rh-negative blood groups suggests a regional genetic predisposition.

Conclusion: In Northeast India, GBC is influenced by both global risk factors and distinct regional exposures, including specific oral habits and environmental contaminants. Future research should prioritize molecular validation of genetic polymorphisms and toxicological analysis of regional water and food sources.

D2/SP22-G2

Use of Surrogate endpoints and Real-world evidence in recent oncology NICE submissions

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Introduction: Surrogate endpoints are used in oncology to faster regulatory and reimbursement decisions. Real-world evidence (RWE) has emerged as complementary data in health technology assessment (HTA).

Aims: To evaluate the use and validity of surrogate endpoints and assess how RWE was utilized in oncology HTA.

Methods: We reviewed all oncology-related NICE Technology Appraisals published between February 1, 2022 and January 15, 2025 (n=130). Terminated appraisals (n=27) were excluded, and three were further excluded: two symptom managements and one with insufficient evidence.
For each appraisal, we extracted information from the committee papers regarding: (1) the primary endpoint, (2) the maturity of overall survival (OS) data, (3) the level of surrogate validity and (4) the use of RWE. Fisher's exact test was conducted to examine whether the use of RWE differed according to OS maturity and the use of surrogates.

Results: Of the 100 appraisals, 78% relied on surrogate endpoints. The most used surrogates were progression-free survival (32%) and overall response rate (26%), with validation lacking in 76% and 95% of cases, respectively. In contrast, all uses of recurrence-free survival, disease-free survival, event-free survival were supported by full validation (100%). RWE was used in 48% of appraisals, primarily to support clinical effectiveness (21%), as external control data (20%), or for OS validation (10%). Although the difference was not statistically significant ($p = 0.39$), RWE was less frequently used for clinical effectiveness when surrogate endpoints were used than when they were not. The use of RWE was not associated with OS maturity (OR = 0.95, $p = 1.00$).

Conclusions: Surrogate endpoints are commonly used in HTA; however, their validity remains limited. No significant association was found between RWE use and either OS maturity or surrogate use, suggesting limited alignment between RWE application and trial uncertainty.

Keywords: Surrogate endpoint, Health technology assessment, Real-world evidence

D2/SP23-G2

Effectiveness of academic detailing for type 2 diabetes care in Ontario, Canada

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Introduction: Academic detailing (AD) is a one-on-one evidence-based educational outreach for healthcare providers. AD has been effective in improving prescribing behavior in various contexts, however, its impact on diabetes care in Canada remains underexplored.

Aims: We aimed to compare diabetes prescribing and care patterns between physicians who received AD and those who did not.

Methods: We conducted a population-based matched cohort study using health administrative databases in Ontario, Canada. We included primary care physicians with active billing status from September 2020 to September 2022. Each AD physician was matched to a maximum of four controls based on index year, region, sex, years in practice, and proportion of patients with diabetes. We assessed patient clinical outcomes monthly from 12 months pre- until 18 months post-intervention using mixed-effects modelling to account for matching and repeated measures, and to adjust for physician and patient characteristics.

Results: The cohort included 372 AD and 1450 control physicians, with balanced demographics. AD physicians saw fewer patients (1292 vs. 1526) but delivered more appointments per patient (4.2 vs. 3.0). Both groups had 15% of patients with diabetes. Post-intervention, biosimilar insulin use increased more sharply in the AD group compared to controls (average 9.0% vs. 5.6% of patients monthly). Patients of AD physicians consistently had higher B12 testing among those using metformin (76.5% vs. 60.0%) and greater use of SGLT2 inhibitors or GLP-1 receptor agonists (40.1% vs. 31.5%). Patient A1C control (defined as <8%) remained similar across groups (~80%). Time x group differences were significant for biosimilar insulin and SGLT2/GLP-1 prescribing ($p<0.001$), but not for B12 testing ($p=0.790$) and A1C levels ($p=0.815$).

Conclusions: AD was associated with improved diabetes prescribing patterns but did not affect other outcomes of interest. AD's success in improving diabetes care underscores the need to maximize physician engagement.

Keywords: diabetes, quality improvement, primary care

D2/SP24-G2

Digital Solutions in Materiovigilance for enhanced safe use of Medical Devices

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Introduction: Medical devices are essential tools in modern healthcare, playing a critical role in diagnosis, monitoring, and treatment. Additionally, to further advance meteriovigilance, integration with electronic health systems and predictive technologies in necessary.

Aim: To develop and validate machine learning based tool for the prediction and structured analysis of Medical Device Adverse Events

Methodology: A machine learning-powered tool was developed. Random Forest algorithm was used as the predictive model for detecting potential risks. Further to evaluate the tool functioning, data of MDAEs by active surveillance method were collected from departments of Intensive Care Unit, Pulmonology, Urology, Nephrology, Neurology, General medicine, Surgery, and Paediatrics of a tertiary care hospital after patient consent. The collected data was uploaded and was assessed for its Tool functionality. Both manually and machine learning-powered tool Reported MDAEs were assessed for causality, severity, and device disposition according to Materiovigilance Program of India guidelines version 1.2.

Results: During the study period, a total of 1857 patients were reviewed, out of them 122 patients developed MDAEs during the hospital stay. MDAEs reported were IV cannula-associated thrombophlebitis (46.72%), catheter-associated urinary tract infections (18.85%), and central line-associated bloodstream infections (14.75%). Most devices were single-use (83.6%), assistive (74.59%), and invasive (91.8%). Causality assessment revealed 90.98% of cases as probable. Serious events accounted for 33.6%, and the recovery rate was 89.34%. Infants were identified as a statistically significant high-risk group for MDAEs (OR: 12.5, p = 0.0159). The developed ML tool accurately predicted risk patterns, aiding proactive MDAE monitoring and overall report generating. The Random Forest technique used in the current study successfully predicted and categorized MDAEs.

Conclusion: The finding supports the integration of machine learning technology in into active surveillance frameworks and call for increased awareness for better report practice and stronger regulatory machines to enhance patient Safety

Keywords: Medical devices, MDI

D2/SP25-G2

Cardiovascular risk of romosozumab versus teriparatide: cohort study using Japan's national database

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Introduction: Disproportionality analyses suggested a cardiovascular risk signal for romosozumab, while statistically significant associations were not found in real-world database studies in Japan. However, their main study population did not include patients with a history of major adverse cardiovascular events (MACE), and databases used in these studies captured small population of Japanese patients with osteoporosis. Therefore, a larger comparative study was necessary to examine this risk.

Aims: This study aimed to compare the cardiovascular risks of romosozumab with those of teriparatide in the overall population and in groups with a history of MACE.

Methods: A new user cohort study was conducted using Japan's national claims database. Patients aged ≥40 years who initiated romosozumab or teriparatide between March 2019 and March 2023 were analyzed. A multivariable Cox proportional hazards model was used to estimate the adjusted hazard ratios (aHR) for MACE. Subgroup analyses were performed based on MACE history.

Results: A total of 251,219 romosozumab and 500,445 teriparatide users were analyzed (most common age group was 80–89 years for both drugs; male: 9.33% for romosozumab and 14.14% for teriparatide). MACE occurred in 1,853 romosozumab and 3,427 teriparatide users, with incidence rates of 1.09 and 1.22 per 100 person-years, respectively. The aHR (95% confidence interval [CI]) for romosozumab compared to teriparatide was 1.00 (0.94–1.06). In subgroup analyses based on MACE history, the aHRs (95% CI) for no history, for the one-year period leading up to t0, and for more than one year before t0 were 1.01 (0.95–1.08), 0.93 (0.72–1.21), and 1.00 (0.85–1.18), respectively.

Conclusion: In conclusion, no statistically significant difference in MACE risk was observed between romosozumab and teriparatide in Japan's national claims database, regardless of MACE history.

Keywords: Romosozumab, Cardiovascular risk, Nation-wide observational study

D2/SP26-G2

Potential interactions between SSRIs and DOACs: population-based cohort and case-crossover study

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Introduction: Bleeding is a known side effect of direct oral anticoagulants (DOACs) and selective serotonin reuptake inhibitors (SSRIs). However, it is unknown whether their concomitant use would further exacerbate bleeding risk.

Aims: To compare the hazard of bleeding in patients with concomitant use of DOACs and SSRIs versus non-SSRI antidepressants.

Methods: We performed a population-based cohort and case-crossover study using primary care data from the UK Clinical Practice Research Datalink(CPRD) Aurum between 1/1/2011 and 31/3/2021. The outcomes were intracranial, gastrointestinal, and other bleeding. We used a cohort design to estimate hazard ratios (HRs) using propensity score weighting, comparing DOAC+SSRI and DOAC+non-SSRI antidepressant users. We also conducted a 6-parameter model case-crossover design comparing odds of exposure to different drug initiation patterns for outcomes in hazard vs referent window within an individual to eliminate time-invariant confounding and repeated the analysis using non-SSRI as negative control precipitants.

Results: We included 35,782 DOAC users co-prescribed SSRIs and 39,745 co-prescribed non-SSRIs. There was no difference in risk of bleeding outcomes in the cohort design (intracranial bleeding: HR1.16, 99% confidence interval [CI] 0.62-2.20; gastrointestinal bleeding: HR1.09, 99%CI 0.83-1.41; other bleeding: HR1.01, 99%CI 0.78-1.29). In the case-crossover design, we observed an odds ratio (OR) of 1.64 (99%CI 1.14-2.35) for other bleeding associated with initiation of SSRI while taking DOAC, which was greater than that observed for SSRI monotherapy (OR1.06; 99%CI 1.01-1.11; p for Wald test=0.002), but greater odds ratio was not observed in patients initiated non-SSRI while taking DOAC (p for Wald test=0.83).

Conclusions: We found no evidence of increased risk of intracranial and gastrointestinal bleeding when DOACs were used with SSRIs versus non-SSRIs. However, when analysing specific order of exposures, we found a higher risk of other bleeding associated with initiating SSRIs when taking DOACs.

Keywords: direct oral anticoagulant, drug-drug interaction, selective serotonin reuptake inhibitor

D2/SP27-G2

Clinical Comparison of Magnesium versus traditional bone implants in fracture fixation

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Introduction: Magnesium-based orthopaedic implants are emerging as promising alternatives to traditional bone implants like Titanium. These implants are biodegradable, offer the potential to reduce stress shielding, eliminate the need for implant removal surgery and allow clearer Magnetic resonance imaging (MRI). Traditional implants, though effective, are associated with surgical complications and MRI artefacts. This study explores whether magnesium bone implants can match or outperform the clinical outcomes of traditional implants in real-world surgical settings.

Aims: This study aimed to evaluate the clinical performance of biodegradable Magnesium implants (screws) in comparison to Titanium implants, focusing on healing, complication rates, implant removals and imaging outcomes.

Methods: A qualitative case study approach was used to review two published randomised clinical trials involving Magnesium and Titanium screws for distal metatarsal osteotomies in hallux valgus correction. Both trials followed 26 patients, equally split between the two implant groups. The case studies were assessed based on reported healing times, pain function scores, radiological findings, MRI clarity and any need for implant removal. The goal was to interpret real-world clinical evidence in a controlled surgical setting.

Results: In both studies, patients with Magnesium and Titanium screws experienced similar healing within 6 months. No significant differences were observed in functional scores or pain relief. There were no implant-related complications in either group. By 3 years, Magnesium implants remained stable and gradually degraded without compromising bone integrity. MRI scans showed notably fewer artefacts in the Magnesium group, enhancing visibility of the surgical site. Importantly, none of the Magnesium screws required removal, unlike Titanium screws.

Conclusions: Magnesium screws showed similar short and mid-term clinical results compared to Titanium screws, with clear benefits in imaging and avoiding secondary removal surgeries. These findings support ongoing evaluation of their use in low-load orthopaedic procedures.

Keywords: Magnesium implants, biodegradable screws, case study review

D2/SP28-G2

Study on prevalent CYP2C19 variants driven sertraline PopPk in South Indian patients

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Introduction: Sertraline is principally metabolized by the CYP2C19 pathway, and South Indians exhibit an unusually high frequency of CYP2C19 loss-of-function alleles. Consequently, standard dosing may lead to overexposure and toxicity in this population. Population pharmacokinetic (PopPK) analysis enables quantification of such genetic effects at the bedside. Understanding this interaction is essential for precision dosing of antidepressants in resource-diverse settings.

Aim: This study aimed to quantify the prevalence of CYP2C19 poor-metabolizer genotypes in South Indian sertraline users and to determine how these variants affect sertraline PopPK parameters.

Methods: This study was approved by the IEC, JSSMC, Mysore. This is an open-label study conducted at JSSMC, Mysore, on 104 South Indian adults receiving steady-state sertraline provided serial plasma samples. Sertraline and desmethyl-sertraline concentrations were measured by validated HPLC, and CYP2C19 *2/*3 alleles were detected by RFLP genotyping. Sampling times, doses, demographics, and genotypes were modeled in NONMEM® using one-compartment structure with first-order absorption; covariates were selected by forward-addition/backward-elimination (α = 0.05). Model stability was confirmed by bootstrap and VPC.

Results: Poor-metabolizer genotypes (*2/*2 or *3/*3) were detected in 13 of 104 patients (12.5%). The final PopPK model estimated typical oral clearance (CL/F) at 76.8 L h^{-1} (relative standard error 8%) and volume of distribution (V/F) at 1870 L. Age and CYP2C19 status significantly reduced clearance (ΔOFV = -37; $p < 0.001$), with poor metabolizers showing a 35% lower CL/F versus extensive metabolizers. Correspondingly, the parent-to-metabolite ratio at C_max fell by 42–48% in poor metabolizers ($p = 0.002$).

Conclusions: The notable 12.5% prevalence of CYP2C19 poor-metabolizer genotypes among South Indians meaningfully slows sertraline clearance, supporting a 25-50% empirical dose reduction—especially in elderly patients. The validated PopPK model offers practical tool for genotype-guided sertraline dosing and underscores the value of pharmacogenomics in regional precision psychiatry.

Keywords: Sertraline, CYP2C19 polymorphism, Population pharmacokinetics

III. Poster

Abstract D1/P100 - D2/P410

D1/P100

Comparing GBTA, HMMs, and Process Mining for Medication Use Patterns

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Introduction: Longitudinal analyses of medication-use trajectories are critical for understanding adherence, switching, and discontinuation patterns in pharmacoepidemiology. Group-Based Trajectory Analysis (GBTA) is widely used for its intuitive group-level summaries. However, emerging machine learning approaches, such as mixture Hidden Markov Models (HMMs) or process mining, offer alternative frameworks for capturing complex, real-world prescribing behaviours.

Aims: We aim to conduct a comparative evaluation of three longitudinal clustering approaches to evaluate its use in exploring medication use patterns.

Methods: We conducted a comparative evaluation of three longitudinal clustering approaches using general practice electronic medical records and administrative dispensing data to classify patient medication-use phenotypes. GBTA modelled continuous or count-based outcomes (days covered, switch counts) as polynomial trajectories, assigning individuals to latent adherence groups. Mixture HMMs represented medication use as transitions between discrete states (e.g., on/off medication), estimating subgroup-specific transition matrices and covariate effects on both group membership and transition probabilities. Process mining reconstructed prescribing pathways from time-stamped medication events, enabling visualisation of treatment sequences (first, second, and third-line medications). Each method was assessed for its ability to capture adherence, switching, and discontinuation behaviours, as well as interpretability and suitability for covariate modelling.

Results: GBTA effectively summarised adherence patterns and identified discontinuation timepoints, with the added benefit of incorporating risk factors via multinomial logistic sub-models. Mixture HMMs offered a unified probabilistic framework, capturing dynamic transitions, switching patterns, dwell times, and covariate effects. Process mining revealed rich, real-world pathway variants, including non-linear switching, but required separate clustering and lacked built-in uncertainty quantification or parametric inference.

Conclusions: While GBTA remains foundational for adherence and discontinuation analysis, mixture HMMs provide a robust framework for modelling switching dynamics and covariate effects. Process mining offers valuable exploratory insights into real-world treatment pathways. Method selection should align with study objectives, data structure, and desired interpretability.

Keywords: Time-series clustering, Medication Patterns

D1/P101

Validation of the P-CARDIAC: a risk model for cardiovascular events

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Introduction: Cardiovascular disease (CVD) is a major cause of mortality and comorbidity in Hong Kong. To alleviate the healthcare burden and improve CVD prevention, we developed P-CARDIAC, a population-based risk model incorporating over 120 risk factors. Validation of P-CARDIAC in local clinical settings is essential for its feasibility.

Aims: The objective of this study is to evaluate the accuracy of the P-CARDIAC. We anticipate that the findings will provide valuable insights for effective service mapping.

Methods: We conducted a prospective population-based cohort study in a cardiac specialist outpatient clinic under Hospital Authority. Eligible participants, aged 18 to 80 years with prior CVD events, were recruited. Their electronic health records were extracted to observe recurrent CVD outcomes and calculate P-CARDIAC scores. P-CARDIAC scores at CV event occurrence, with and without CV-related treatment, were compared. A one-way ANOVA was performed to compare the scores.

Results: The preliminary results of this study were updated till mid-April, 2025, and included data with a mean age of 65.8 years among 859 participants. There were 33 participants experienced recurrent CVD events among 503 with prior CVD event records. All participants were undergoing at least three polypharmacy treatments during both the period before and after their recurrent CVD date. Among the participants with recurrent CVD events, 93.9% were male, with coronary heart disease being the most common type of recurrent event (72.7%). P-CARDIAC scores in both previous and recurrent CVD dates were statistically significant higher than those scores at times without a CV event. Participants receiving treatment showed lower estimated risk.

Conclusions: P-CARDIAC scores were significantly higher for participants with CVD events, demonstrating its sensitivity to event occurrences. We expect P-CARDIAC to be a frontline tool to stratified different risk patients and enable cost-effective allocation of healthcare resources.

Keywords: Cardiovascular disease, Risk prediction tool, Recurrent CVD event

D1/P102

Development and validation of 10-year cardiometabolic risk prediction models in prediabetic adults

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Introduction: Prediabetes elevates cardiometabolic morbidity and mortality risk. Early identification of high-risk individuals is crucial for preventing disease progression; however, long-term prediction models in this population are scarce. This study addressed the need for accurate 10-year risk prediction models for cardiometabolic outcomes in prediabetic patients.

Aims: To develop and validate 10-year risk prediction models for five outcomes: cardiovascular disease (CVD), hypertension, type 2 diabetes mellitus (T2DM), chronic kidney disease (CKD), and all-cause mortality in prediabetic adults defined by glycated hemoglobin (HbA1c) or fasting plasma glucose (FPG).

Methods: This retrospective, population-based cohort study utilized anonymized data from the Clinical Management System in Hong Kong. Two prediabetic cohorts (HbA1c 5.7-6.4% [N = 66,378] or FPG 5.6-6.9 mmol/L [N = 237,717]) were identified (2008-2012), with the first prediabetic diagnosis as the index date and follow-up until 2022. Patients with prevalent hypertension, T2DM, or CKD were excluded from analyses of each relevant outcome. Stepwise Cox regression was applied to a derivation cohort (2/3 of data), using routinely available demographic, physical, laboratory, and medication use variables. Model performance was assessed in the remaining validation cohort.

Results: HbA1c and FPG cohorts had 10-year cumulative incidence of CVD (20.0%; 19.5%), hypertension (26.6%; 32.3%), T2DM (22.1%; 29.0%), CKD (21.9%; 17.1%), and mortality (15.9%; 15.8%). Significant predictors included age, gender, smoking status, Charlson comorbidity index (CCI), and body mass index (BMI). We observed non-linear and interaction effects for CCI (hypertension/T2DM) and BMI (mortality). Adding laboratory results significantly improved the predictive performance for T2DM. All models demonstrated good discrimination (Harrell's C-statistic >0.7 except T2DM) and calibration.

Conclusions: We developed and validated robust 10-year risk models for cardiometabolic outcomes in prediabetic populations. These models, based on routinely available variables, can aid in the early risk stratification, enabling individualized preventive strategies for high-risk patients.

Keywords: prediabetes, risk prediction, cardiometabolic outcomes

D1/P103

Bayesian Dosage Adjustment of Tacrolimus in Kidney Transplantation: A Systematic Review

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Introduction: Tacrolimus is a first-line immunosuppressant used in renal transplant patients but exhibits a narrow therapeutic index and high inter-individual variability. While therapeutic drug monitoring using trough concentrations (C0) is common, it may not consistently reflect true drug exposure. Area under the concentration-time curve (AUC) is a more realistic metric, and Bayesian estimation methods often improved precision for AUC estimation using priori pharmacokinetic knowledge.

Aim: To focus on the reliability in using Bayesian approaches over other traditional therapeutic drug monitoring approaches for the estimation of AUC and thereby recommending the Tacrolimus dosage adjustment in renal transplant patients.

Methods: We conducted systematic literature search on PubMed, Scopus & Embase from inception to August 2024, for studies utilizing Bayesian approaches for estimating Tacrolimus exposure in renal transplant patients. Studies were included if they employed Bayesian techniques for AUC estimation or dose adjustment using population pharmacokinetic (PopPK) models or limited sampling strategies. Data was extracted, appraised using the CACPK tool, and summarised.

Results: A total of 30 articles were included. The majority reported that Bayesian methods, particularly Maximum a Posteriori Bayesian Estimation (MAP-BE), provided superior AUC prediction compared to traditional methods. Tools such as ISBA and software like NONMEM were frequently used. Most studies supported the inclusion of trough and post-dose samples >2 hours for accurate predictions.

Conclusion: Bayesian approaches demonstrate enhanced accuracy and efficiency in tacrolimus dose adjustment for renal transplant patients, outperforming conventional TDM strategies and showing potential for broader clinical application.

Keywords: Bayesian Approach, Tacrolimus, Renal Transplantation, MAP-BE

D1/P104

Improving UTI diagnosis using clinical symptoms and laboratory tests using machine learning

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Introduction: Urinary tract infections (UTIs) are common bacterial infections that affect millions worldwide, posing challenges in timely diagnosis. Although they are common, achieving prompt and precise diagnosis remains a significant hurdle. This study explores the potential of artificial intelligence (AI) and machine learning (ML) to enhance diagnostic accuracy for better patient outcomes.

Objective: To develop and validate machine learning algorithms for early UTI diagnosis using clinical symptoms and laboratory parameters, and evaluate their performance for potential integration into clinical decision-making systems.

Methods: A mixed retrospective-prospective observational study was conducted in a tertiary-care teaching hospital with 330 adult patients (18–80 years) with suspected UTIs. Patients were selected using systematic sampling from multiple departments. Clinical data, including demographics, symptoms, comorbidities, and laboratory parameters, were collected. An external-validation dataset comprising 80,000 UTI cases was utilized. Predictor variables were identified using logistic regression and Chi-square tests. Random Forest and Decision Tree algorithms were evaluated using standard performance metrics.

Results: Among 330 patients, females comprised 62.7% ($p = 0.0025$), and patients aged ≥60 had significantly longer hospital stays ($p = 0.010$). Key clinical symptoms included fever (59.7%), malaise (35.15%), and chills (33.94%). Prevalent comorbidities were diabetes (56.97%), hypertension (53.03%), and chronic kidney disease (18.78%). E. coli was the predominant pathogen (27.27%). Specific drugs associated with UTI included SGLT2 inhibitors, anticholinergics, calcium channel blockers, and furosemide. Random Forest outperformed Decision Tree with 82% accuracy, 86% precision, 90% recall, and 88% F1-score. External validation yielded 50% sensitivity and 70% specificity. Clinical feedback indicated 73.3% clinician support, highlighting the need to improve sensitivity.

Conclusion: ML algorithms, particularly Random Forest, demonstrate potential in enhancing UTI diagnostic accuracy. Integrating clinical symptoms and laboratory parameters provides a promising framework for early diagnosis, though optimization of sensitivity remains crucial for widespread clinical adoption.

Keywords: Urinary tract infection, Machine learning, Clinical symptoms

D1/P105

Predicting ischemic stroke risk in patients with atrial fibrillation with drug–protein–disease network

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Introduction: Ischemic stroke (IS) is a major complication in atrial fibrillation (AF) patients, but current risk models often ignore complex drug-protein-disease interactions, reducing their accuracy. We developed ABioSPath, an interpretable deep learning model, to predict one-year IS risk in AF patients by integrating biological pathways with clinical data. This addresses the need for precise, data-driven risk assessment without costly biomarkers.

Aims: The objective is to create ABioSPath to predict one-year IS risk in AF patients accurately. It aims to identify key molecular pathways and provide individualized risk profiles using routine clinical data.

Methods: We conducted a retrospective cohort study using electronic health records from 7,859 AF patients across 43 Hong Kong hospitals (January 2008–December 2009). ABioSPath employs a multilayer network of gene, protein, and chemical interactions, analyzed via graph convolutional networks, LSTM, and attention mechanisms. Patients with confirmed AF were included, excluding those with incomplete records.

Results: ABioSPath outperformed baseline models, achieving an AUROC of 0.7815 (95% CI: 0.7346–0.8283), positive predictive value of 0.430, negative predictive value of 0.870, sensitivity of 0.500, specificity of 0.885, average precision of 0.409, and Brier score of 0.195. Cohort analysis identified key proteins (CRP, REN, PTGS2) in prevalent pathways. Individual analysis highlighted PIK3/Akt and cytokine/chemokine signaling pathways and revealed IS risks linked to drugs like prochlorperazine maleate, demonstrating robust, interpretable predictions.

Conclusions: ABioSPath provides an effective, interpretable tool for IS risk prediction in AF patients, with potential for broader disease screening. Its use of routine data enhances accessibility, and pathway insights aid drug development. Future work should validate the model across diverse populations and diseases.

Keywords: Ischemic stroke, Atrial fibrillation, Deep learning

D1/P106

Unsupervised Learning for Novel Cardiac Surgery Phenotyping via Multimodal, High-dimensional Perioperative Data

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Introduction: Heterogeneity in baseline conditions, clinical characteristics, and intraoperative management may predispose patients to differential risks for adverse postoperative outcomes. Understanding this phenotypic heterogeneity is crucial for trajectory pattern analysis and for tailoring individualized perioperative care strategies.

Aims: This study aimed to identify distinct cardiac surgery patient phenotypes from multimodal, high-dimensional data to enhance risk stratification.

Methods: We conducted a multicenter, retrospective study included 10,847 adult patients undergoing cardiac surgery with cardiopulmonary bypass at three tertiary hospitals in eastern China (2013-2024) and an external cohort from a publicly available research dataset (2011-2020). A high-dimensional dataset was constructed by integrating demographic and surgical information, clinical features, and high-resolution intraoperative vital signs, resulting in a comprehensive feature set composed of 1,006 key parameters. Phenotypes were derived via unsupervised agglomerative hierarchical clustering, validated across three external datasets.

Results: Five distinct phenotypes were identified from the derivation cohort and clinically confirmed by expertise, with median ages ranging from 52 to 67 years and female representation varying from 24.8% to 44.0%. Phenotypes A (stable perfusion) and B (mild stress response) represented healthier subsets with stable intraoperative profiles, and phenotype A had the lowest risk of acute organ injury. Phenotype C (cardiovascular compromise), despite comprising older patients with extensive coronary artery disease, exhibited milder hemodynamic stress and lower risk of organ injury. Phenotypes D (coagulopathy and inflammation) and E (severe hemodynamic instability) were associated with significantly higher incidences of 7-day acute kidney injury (46.0% and 66.9%) and 48-hour acute liver failure (37.9% and 38.8%), greater mortality risk and prolonged ICU/hospital stays.

Conclusions: Data-driven phenotyping revealed distinct subgroups within heterogeneous surgery patients, each exhibiting unique characteristics linked to adverse outcomes. The integration of dynamic intraoperative vital signs with perioperative data enhances risk stratification and supports individualized perioperative management strategies.

Keywords: clinical phenotyping, unsupervised learning, multimodal data

D1/P107

Identification of HLA Alleles in Thailand Using Long-Read Sequencing for Pharmacogenomics Applications

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Next-generation sequencing (NGS) tools facilitate high-resolution genotyping of Human Leukocyte Antigen (HLA) genes in clinical settings, contributing to precise results and the advancement of personalized medicine. Pharmacogenetic variability, particularly in the HLA class I and II genes, affects how individuals respond to medication. The objectives of our study were to perform high-resolution sequencing of HLA class I and II genes for 537 samples at a Thai Pharmacogenomic Personalized Medicine Centre using Third-Generation Sequencing (NGS) technology at a 3-field resolution. This approach aimed to reduce ambiguities in achieving accurate typing and exploring the lengths of reads, subsequently comparing the frequencies of these variants with those in other populations. The study sequenced 537 samples using NGS with the Pacific Biosciences (PacBio) platform, identifying 233 distinct alleles out of 6444 detected variants. The highly frequent HLA alleles in six genes were HLA-A*11:01:01 (24.9%; 95% CI: 22.3-27.5), HLA-B*46:01:01 (9.9%; 95% CI: 8.1-11.7), HLA-C*01:02:01 (17.2%; 95% CI: 14.9-19.5), HLA-DRB1*12:02:01 (17.4%; 95% CI: 15.3-19.8), HLA-DQB1*03:01:01 (20.9%; 95% CI: 18.6-23.5), and HLA-DPB1*05:01:01 (23.6%; 95% CI: 21.1-26.2), The prevalence of these variants was found to differ statistically among populations ($p < 0.05$). Remarkably, the detection of some variants with distinctions in exon synonymous mutation regions, for class I variations such as A*11:01:01/43, B*51:02:01/02, B*51:01:01/02 and C*03:04:01/04 as well as for class II genes DPB1*02:01:01/02 and DRB1*15:02:01/02 based on 3-field call reads in high resolution was considerable. The study successfully sequenced HLA alleles in a 3-field high resolution to assess the diversity of HLA alleles within the Thai population. The results accentuate the importance of enhancing HLA typing screening, which could significantly improve patient clinical outcomes. Additionally, the findings provide valuable data for studies on human genetics in populations, HLA matching, transplantation techniques, HLA-associated disorders, and implications for personalized medicine.

Keywords: Human Leukocyte Antigen (HLA) genes; Next-generation sequencing; Pharmacogenomics

D1/P108

Genes, Beliefs, and Behavior: A Factor-Analytic Study on Pharmacogenomic Acceptance in Depression

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Introduction: Treatment-resistant depression (TRD), defined as the failure to respond to at least two adequate antidepressant trials, presents a significant burden in psychiatric care. Poor medication adherence, misconceptions about antidepressant therapy, and limited awareness of emerging tools like pharmacogenomic testing may contribute to treatment failure. Understanding patients' knowledge, attitudes, and practices (KAP) can inform targeted interventions to improve treatment outcomes in Major Depressive Disorder (MDD).

Aims: This study aimed to assess the KAP surrounding antidepressant therapy and pharmacogenomic testing among individuals with MDD and to identify behavioral and perceptual domains that influence treatment resistance.

Methods: A cross-sectional study was conducted between January and March 2025 involving 144 adults diagnosed with MDD attending outpatient psychiatric clinics in South India. Participants completed a validated KAP questionnaire covering antidepressant knowledge, adherence practices, and perceptions of genetic testing. Exploratory Factor Analysis (EFA) using Principal Component Analysis (PCA) with Varimax rotation was performed to extract latent constructs. Internal consistency was measured using Cronbach's alpha, and regression analysis examined associations between factor scores and self-reported treatment resistance.

Results: The mean participant age was 36.7 years (SD = 10.9), with 59% female. Only 28% demonstrated high knowledge about antidepressant use, and 41% reported full adherence. Awareness of pharmacogenomic testing was low (14%), but 62% showed interest in its future use. Four latent factors were identified, explaining 68.4% of the total variance: (1) antidepressant knowledge, (2) adherence behaviors/barriers, (3) attitudes toward pharmacogenomics, and (4) trust in healthcare providers. The KAP scale showed strong internal consistency (Cronbach's alpha = 0.87). Higher knowledge and attitude scores significantly predicted better adherence ($\beta = 0.39$, $p < 0.001$) and reduced likelihood of TRD ($\beta = -0.27$, $p = 0.008$).

Conclusions: This study emphasizes the need for education on genetic testing to address behavioral barriers and promote pharmacogenomic testing awareness for precision therapy.

D1/P109

Genome-Wide Association Study of TKI-Induced Hepatotoxicity in All of Us

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Introduction: Tyrosine kinase inhibitors (TKIs) are targeted therapies that block aberrant signaling pathways often activated in cancer cells. Although TKIs provide clinical benefits in cancers like chronic myeloid leukemia and non-small cell lung cancer, they are also linked to adverse drug reactions, particularly hepatotoxicity. Identifying genetic factors in TKI-induced liver injury is key to personalized treatment.

Aims: This study aimed to identify genetic variants associated with TKI-induced hepatotoxicity using large-scale genomic data.

Methods: We utilized data from the All of Us Research Program. Participants with available whole genome sequencing data, documented TKI exposure, and recorded liver enzyme levels were included. The observation window was defined from the first to the last TKI exposure date. A phenotype file was created, and genome-wide association analyses were performed using PLINK, adjusting for age, sex, and genetic principal components. Significant associations were visualized using Manhattan and QQ plots.

Results: Among 805 individuals with available liver enzyme data within 60 days after TKI initiation, we identified 98 cases with hepatotoxicity and 707 controls without. Genome-wide association analysis was conducted based on this case-control classification. Eight single nucleotide polymorphisms (SNPs) exceeded the suggestive threshold of $P < 1\times10^{-5}$. The lead SNP, rs72734306, showed an odds ratio (OR) of 3.73 ($P=4.18\times10^{-7}$). Other significant associations included rs71425326, associated with EML5, a gene involved in microtubule organization and immune function (OR=9.86); rs35928059, associated with CFH, a key regulator of the complement system (OR=4.43); and rs190933696, located between ERLEC1 and GPR75-ASB3, genes related to endoplasmic reticulum stress and immune response (OR=9.46).

Conclusion: These findings highlight immune regulation and ER stress–related genes, particularly CFH and ERLEC1, as potential contributors to TKI-induced hepatotoxicity. This study offers new insights into genetic susceptibility and supports personalized approaches to managing TKI-related adverse effects.

Keyword: Tyrosine kinase inhibitor, Hepatotoxicity, Genome-Wide Association Study

D1/P111

Reduction of psychiatric hospitalization after revisions for Mental Health and Welfare Act

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Introduction: Japan faces a serious issue of remarkably long psychiatric hospital stays, with an average hospitalization period of 299 days in 2022, a duration notably longer than other countries. In response to this situation, the Mental Health and Welfare Act and related legislation were revised in 2022. These revisions were conducted to shorten hospital stays in psychiatric beds.

Aims: This study evaluated the effectiveness of the 2022 revisions to the Mental Health and Welfare Act and related legislation.

Method: A nationwide serial cross-sectional study was conducted using publicly available data from the Japanese Mental Health and Welfare Survey (630 Survey). The analysis was conducted based on patient counts annually for 4 years (June 2021 to June 2024). Long-term hospitalization was defined as continuous hospitalization for one year or more in this study, and the reduction rate of long-term hospitalized psychiatric patients was set as the outcome. The mean percentage (95% confidence interval) of reduction rate for long-term hospitalized psychiatric patients by prefecture (n=47) were calculated. Paired t-tests were performed to confirm the difference of long-term hospitalized psychiatric patients between 2021-2024. P-value < 0.05 was considered statistically significant.

Result: From 2021 to 2024, there has been a decreasing trend, with the number of long-term hospitalized psychiatric patients across Japan decreasing by 8.97% (164,196 people in 2021 and 149,462 people in 2024) over the four years.
Additionally, means (95% CI) of the number of long-term hospitalized psychiatric patients in 47 prefectures are 3,421 people （2,700 people-4,141 people） in 2021 and 3,180 people (2,526 people-3,834 people) in 2024, a statistically significant decrease were observed.

Conclusion: A substantial decrease in the long-term psychiatric hospitalization rate was observed in Japan after the revision of the Mental Health and Welfare Act and related legislation in 2022.

Keywords: long-term psychiatric hospitalization, policy assessment, serial cross-sectional study

D1/P112

Drug utilisation evaluation of antipsychotics at a tertiary care hospital

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Introduction: Psychiatric disorders rank as the fourth leading cause of disability-adjusted life years, affecting 2–3% of India's population and around 10% of adults globally. Drug Utilisation Evaluation (DUE) studies help us assess how medications are prescribed and used, as well as their medical and social impact.

Aim: The present study was conducted to assess the antipsychotic drug use patterns at a tertiary care teaching hospital.

Methods: This prospective study was conducted over 12 months at the outpatient department of Psychiatry, following Institutional Ethics Committee approval. A total of 150 psychiatric patients receiving antipsychotic treatment were included, and their prescriptions were assessed against the standard therapeutic guidelines. Descriptive analysis was performed using Microsoft Excel, and the results were expressed in numerical values and percentages.

Results: A total of 428 drugs were prescribed across 150 prescriptions, including 302 (70.6%) antipsychotics and 126 (29.4%) concomitant medications. Female patients made up 54%, and males 46%. The most common diagnosis was schizophrenia (38%), followed by bipolar affective disorder (20%), alcohol dependence psychosis (14%), and others at 28%. The frequently used atypical antipsychotics were risperidone (31.1%), olanzapine (23.2%), amisulpride (20.2%), quetiapine (11.6%), aripiprazole (8.6%), and clozapine (5.3%). About 77.5% of patients received polytherapy, while 22.5% received monotherapy. The average number of antipsychotics per prescription was 2.01. Prescribing by generic name was at 100%. Use of drugs from the WHO and National Essential Medicines Lists was 68.2%. No injectables or fixed-dose combinations were prescribed.

Conclusion: This study's findings conclude that the atypical antipsychotics are the most prescribed antipsychotics. Most prescriptions were complete and followed rational prescribing principles, highlighting the need for a drug utilisation evaluation (DUE) to improve patient outcomes.

Keywords: Antipsychotics, Drug Utilisation Evaluation, Atypical Antipsychotics

D1/P113

Has Mental Healthcare Reached the Grassroots? Evidence from Psychotropic Drug utilization

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Introduction: In China, most psychotropic drugs are not strictly regulated and thus allowed in primary healthcare institutions (PHIs). Yet, uneven resource allocation has led to persistent gaps in drug availability and service capacity between PHIs and non-Primary Healthcare Institutions (nPHIs). With rising mental health needs, evaluating primary-level drug access is vital for evidence-based policy planning.

Aims: This study investigates disparities in psychotropic drug availability between PHIs and nPHIs in Shandong Province, aiming to assess whether access has shifted downward and whether PHIs are equipped for basic pharmacological interventions, thereby informing policies on service integration.

Methods: Procurement data from all public healthcare institutions in Shandong Province (2016–2024) were analyzed, covering four psychotropic drug classes: antipsychotics, anxiolytics, hypnotics/sedatives, and antidepressants. Coverage was defined as the proportion of institutions procuring each drug within the corresponding facility level. Temporal trends were assessed using statistical methods.

Results: Between 2016 and 2024, psychotropic drug coverage in nPHIs increased significantly from 56% to 92% (5.15% per year, $P < 0.001$), while PHIs rise from 50% to 52% (0.46% per year, $P < 0.001$). The largest disparity occurred in antipsychotic drug coverage (2024: 78% in nPHIs vs. 16% in PHIs), while anxiolytics showed the narrowest gap (85% vs. 41%). Most psychotropic drugs had coverage rates below 10% in PHIs, except benzodiazepines such as diazepam (31%) and alprazolam (34%). In contrast, coverage in nPHIs exceeded 50% for most drugs, including chlorpromazine (53%), olanzapine (62%), diazepam (80%), and midazolam (55%).

Conclusions: Over half of PHIs lack essential pharmacological capacity, falling short of the WHO's 75% coverage benchmark. Drug accessibility has improved mainly in nPHIs, while PHIs remain constrained by structural limitations—offering primarily anxiolytics, in contrast to the broader all psychotropic spectrum available in nPHIs. Strengthening primary-level capacity may require enhanced provider training and improved distribution incentives.

D1/P114

Vitamin D deficiency-related factors influence surgical management strategy in diabetic foot infection

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Aim: To determine the association between vitamin D status, VDR protein, and LL-37 levels with various treatment strategies in DFI patients.

Methods: A hospital-based cross-sectional study involving 169 DFI patients was conducted in a tertiary care facility in South India. Patient demographics and details of the treatment (surgical or only medical) administered was collected from the hospital's medical records. Serum vitamin D levels were measured using an electrochemiluminescence immunoassay. VDR and LL-37 were estimated in serum using ELISA kits. Data were analysed using Jamovi software version 2.4.8.0.

Results: Among the 169 patients with DFI, 139 (82.2%) received surgical interventions, while 30 (17.8%) were managed conservatively with medications. Patients who underwent surgical management showed lower median levels of vitamin D, VDR, and LL-37 in comparison to those who received drug therapy (13.2 ng/mL, 0.704 ng/mL, and 1.29 ng/mL vs. 25.1 ng/mL, 1.34 ng/mL, and 2.46 ng/mL, respectively). Additionally, in former patients a significant increase in levels of HbA1c, C-reactive protein, neutrophil-lymphocyte ratio, and systemic immune-inflammatory index, along with an extended duration of hospital stay ($p < 0.001$). Furthermore, levels of vitamin D, VDR, and LL-37 were lower in patients who underwent amputation ($p < 0.001$).

Conclusion: Our findings indicate that patients with DFI who received surgical management exhibited a significant decrease in vitamin D, VDR protein, and LL-37 levels compared to patients who received only drug therapy.

D1/P115

Assessment of factors affecting self-management practices among type 2 diabetes mellitus patients

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Introduction: Effective management of Type 2 Diabetes Mellitus(T2DM) depends on self-care practices, including glucose monitoring, dietary management, physical activity, and emotional well-being. However, sociodemographic, therapeutic, and psychological factors often hinder glycemic control and reduce quality of life.

Aims: This study evaluates self-management practices using the Diabetes Self-Management Questionnaire (DSMQ) and emotional distress associated with diabetes using the Problem Areas In Diabetes scale (PAID-5). It also aims to identify influencing factors, and to provide targeted counselling to patients with low DSMQ scores.

Methods: A prospective observational study was conducted using DSMQ questionnaire. Sociodemographic and therapeutic data were collected through interviews and medical records. DSMQ scores categorized as adequate (≥6) or inadequate (<6). Emotional distress was evaluated using the PAID-5, with scores ≥8 indicating distress. Patients with low DSMQ scores received physician-supervised counselling and were followed up via telephone after three months to reassess self-management.

Results: The analysis of 140 T2DM patients revealed significant associations between self-management practices and several factors, including age group 40–59 years ($p = 0.032$), urban residence ($p = 0.029$), private-sector employment ($p = 0.041$), middle socioeconomic status ($p = 0.018$), regular exercise ($p = 0.001$), and absence of comorbidities ($p = 0.047$), which were linked to higher DSMQ scores. No statistically significant associations were found for gender, BMI, education, dietary habits, smoking, alcohol, or type of diabetes medication. Targeted counselling led to significant improvement in DSMQ scores at three months.

Conclusions: This study highlights the need to assess sociodemographic, therapeutic, and emotional factors to improve self-management in T2DM patients. Targeted counseling significantly improved self-care and glycemic control in patients with low DSMQ scores. Limitations include its single-center design and small size, limiting generalizability. Future studies could include longer follow up and integrate digital health tools to monitor self-management behaviors.

Keywords: Type 2 diabetes mellitus, DSMQ, PAID-5, Self-management

D1/P116

Sacubitril/valsartan and SGLT2 inhibitors in HFrEF with renal dysfunction: time-dependent Cox's models

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The presence of chronic kidney disease (CKD) among patients with heart failure with reduced ejection fraction (HFrEF) often leads to conservative uptitration or underutilization of sacubitril/valsartan and sodium–glucose cotransporter-2 inhibitors (SGLT2i). This hesitancy stems from their pivotal trials that largely excluded patients with severe CKD, with those having an estimated glomerular filtration rate (eGFR) of <30 mL/min/1.73 m2 being particularly underrepresented, thus limiting their real-world applicability and clinical impact.

To address these gaps, this study evaluated the risk-benefit tradeoffs of sacubitril/valsartan and SGLT2i coadministration in patients with HFrEF across the spectrum of time-varying eGFR.

Time-dependent Cox's models were developed using a counting process framework to accommodate time-varying covariates and interaction terms. Data were retrospectively extracted from electronic health records at National Taiwan University Hospital, comprising 501 patients initiated on sacubitril/valsartan between March 2017 and January 2020, with follow-up until September 2022. Stepwise variable selection was applied, and penalized smoothing splines were used to model nonlinear trends and optimize dose-response thresholds.

A total of 59,814 time-dependent observations were captured, including medication use, echocardiographic parameters, and laboratory findings. The results indicated that patients with HFrEF and an eGFR of <30 mL/min/1.73 m2 derived significant benefits from sacubitril/valsartan (with a cutoff dose of >194 mg daily) and SGLT2i coadministration, regardless of whether renal dysfunction was preexisting or developed during treatment. Model robustness was confirmed by a generalized R2 of 0.45 and an exceptionally high concordance index (0.9340), indicating strong predictive accuracy.

This study challenges outdated treatment hesitancy and provides compelling real-world evidence advocating aggressive yet tailored S/V and SGLT2i coadministration in this high-risk population; these findings call for a shift in clinical practice, ensuring that renal dysfunction is no longer a contraindication but rather an indication for optimized therapy to improve survival outcomes.

Keywords: heart failure with reduced ejection fraction, sacubitril/valsartan, sodium–glucose cotransporter-2 inhibitors

D1/P117

Glucose monitoring effectiveness in non-insulin dependent T2DM patients: An umbrella review

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Objective: To evaluate the impact of self-monitoring blood glucose (SMBG), continuous glucose monitoring (CGM), and flash glucose monitoring (FGM) alongside non-insulin glucose-lowering medications on glycaemic control in adults with non–insulin-dependent T2DM.

Methods: An umbrella review was conducted following the Cochrane Handbook and PRISMA 2020 guidelines (PROSPERO: CRD420250628416). Searches were performed across MEDLINE, Cochrane Library, Embase, and Scopus. Reviews were eligible if they included adults with non–insulin-dependent T2DM using glucose monitoring and reported HbA1c outcomes. Two reviewers independently conducted study selection, extraction and quality appraisal using AMSTAR 2. A random-effects meta-analysis was undertaken. Publication bias and study overlap were assessed, and subgroup analyses explored potential effect modifiers.

Results: Sixteen systematic reviews comprising 81 unique studies and 23,657 participants were included. SMBG versus no monitoring showed significant HbA1c reduction (–0.23%; 95% CI: –0.29 to –0.18; I^2 = 20.9%). CGM demonstrated superior benefit over SMBG (–0.30%; 95% CI: –0.35 to –0.25; I^2 = 0%). FGM showed no statistically significant advantage over SMBG (–0.26%; 95% CI: –0.57 to 0.05) with substantial heterogeneity (I^2 = 73.9%). Egger's and Begg's tests indicated no publication bias (p = 0.80; p = 0.685). Overlap analysis identified a total of 205 citations and a mean of 2.53 citations per study, indicating moderate overlap.

Conclusion: Glucose monitoring interventions consistently demonstrated statistically significant improvements in glycaemic control among adults with non–insulin dependent T2DM. While SMBG offers measurable benefits over no monitoring, CGM provides superior HbA1c reductions compared to SMBG, supported by robust evidence and minimal heterogeneity. The moderate overlap in included studies strengthens the reliability of this synthesis. These results underscore the importance of structured and evidence-based monitoring in personalised diabetes care.Integrating these strategies into routine practice may significantly improve long-term outcomes and enable proactive, data-driven approaches to chronic disease management.

Keywords:
Type 2 diabetes, glucose monitoring, glycaemic control

D1/P118

Safety and efficacy of chiglitazar for treating T2D in China: a meta-analysis

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Introduction: Chiglitazar is a PPAR agonist used for treating type 2 diabetes (T2D). It was developed in China and has been marketed in China since 2021. Systematic review evidence on chiglitazar is lacking.

Aims: To evaluate study quality and describe the safety and efficacy of chiglitazar.

Methods: A systematic review was conducted in PubMed and China National Knowledge Infrastructure (CNKI) (through April 2025). Randomized controlled trials (RCTs) and observational studies in English and Chinese were identified by searching "chiglitazar" (or its Chinese name) and selecting studies evaluating safety, efficacy or effectiveness of chiglitazar. Both the initial search and study selection were performed by 2 independent researchers. Study quality was assessed by Jadad scale (for RCTs) and Newcastle-Ottawa scale (for observational studies). Random-effect models were used for meta-analysis.

Results: Thirteen studies were identified (all in China; 7 in English and 6 in Chinese; 1 observational and 12 RCTs [including 9 post-approval RCTs]). Treatment duration ranged from 4-24 weeks. Five studies were low quality, primarily due to blinding and withdrawal issues.
Eight studies (1402 patients) reported safety (all RCTs). The pooled RRs for AEs and SAEs were 1.00 (95% CI: 0.95, 1.06) and 0.98 (95% CI: 0.91, 1.06), respectively, for 7 placebo-controlled studies; one study showed similar AE/SAE frequencies between chiglitazar and sitagliptin. Among 5 post-approval studies, the pooled RR for AEs was 0.97 (95% CI: 0.87, 1.07) versus placebo. Six studies reported hypoglycemia and 5 studies reported edema (all <5%).
Chiglitazar demonstrated better efficacy (fasting blood glucose and/or HbA1c) versus placebo (7 studies; including 2 pre-approval studies) and was non-inferior or superior to active comparators (sitagliptin, pioglitazone, semaglutide) (6 studies; including 1 pre-approval study).

Conclusions: Chiglitazar is safe and effective for T2D treatment, though study quality varied. Future studies should employ rigorous methodology to strengthen these findings.

Keywords: Chiglitazar, safety, efficacy

D1/P119

Hepatic effectiveness of empagliflozin versus dapagliflozin in metabolic dysfunction-associated steatotic liver disease

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Introduction: While both empagliflozin and dapagliflozin are known to improve hepatic steatosis and liver enzyme levels, robust Phase III trial evidence for improving steatohepatitis and fibrosis is currently exclusive to dapagliflozin. Therefore, a head-to-head comparison between two agents is warranted.

Aims: To compare the hepatic effectiveness of empagliflozin versus dapagliflozin in metabolic dysfunction-associated steatotic liver disease (MASLD).

Methods: Using nationwide Korean claims data, we constructed a new-user cohort of adults with MASLD—defined as having T2D and a fatty liver index (FLI) ≥ 60—who initiated empagliflozin or dapagliflozin between May 2016 and December 2023. The index date was the first prescription of empagliflozin or dapagliflozin, with follow-up based on an on-treatment exposure definition. Co-primary outcomes were MASLD improvement (achieving FLI < 30) and decompensated hepatic events (ascites, variceal bleeding, hepatic failure, liver transplantation). After 1:1 propensity score (PS) matching, hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated using Cox models. Analyses stratified by low (empagliflozin 10 mg; dapagliflozin 5 mg) and high (empagliflozin 25 mg; dapagliflozin 10 mg) doses were further conducted.

Results: Among 265,098 new users of empagliflozin and dapagliflozin, 101,495 pairs were 1:1 PS matched (mean age 54.3 years; male 71.2%). Compared with dapagliflozin, empagliflozin was associated with a higher likelihood of MASLD improvement (HR 1.05, 95% CI 1.00-1.11; p=0.0557), although the result was not statistically significant. The risk of decompensated hepatic events was comparable (HR 1.01, 95% CI 0.96-1.06). Dose-stratified analyses yielded consistent findings, with no significant differences observed in either MASLD improvement (low dose: HR 1.02, 95% CI 0.76-1.80; high dose: 1.06, 0.94-1.20) and decompensated hepatic events (low dose: 1.02, 0.79-1.31; high dose: 1.09, 0.98-1.21).

Conclusion: Use of empagliflozin and dapagliflozin showed comparable effectiveness in MASLD improvement and risk of decompensated hepatic events.

Keywords: Sodium-glucose cotransporter 2 inhibitors; metabolic dysfunction-associated steatotic liver disease; hepatic decompensation.

D1/P120

Change in antihypertensive use after initiation of second-line oral antidiabetics in Korea

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Introduction: Hypertension and diabetes are increasingly prevalent chronic diseases. Although prior studies examined the effects of oral hypoglycemic agents (OHAs) on blood pressure, their impact on antihypertensive drug use in real-world settings remains unclear.

Aim: To evaluate the changes of antihypertensive drugs, use before and after the initiation of second-line OHAs —including sulfonylureas (SUs), dipeptidyl peptidase-4 inhibitors (DPP-4is), thiazolidinediones (TZDs), and sodium-glucose cotransporter-2 inhibitors (SGLT2is).

Methods: The retrospective cohort study was conducted using the Korean Health Insurance Review and Assessment database. Patients aged ≥50 years with newly diagnosed type 2 diabetes mellitus in 2019 who initiated a second-line OHA within six months of diagnosis were included. Eligibility required ≥ 90 days of OHA use and ≥180 days of follow-up. Changes in the number of antihypertensive drugs were assessed by comparing the proportions of patients with increased versus decreased use across OHA classes. Initiation and discontinuation rates of specific antihypertensive drug classes, with 95% confidence intervals (CIs), were estimated.

Results: Among 2,566,086 eligible patients, 8,085 initiated a second-line OHA in 2019. The cohort included 5,604 DPP-4i users, 3,014 SU users, 1,045 SGLT2i users, and 775 TZD users. Following initiation of second-line OHAs, the number of antihypertensive drugs increased in the DPP-4i (22.6% increase vs. 20.4% decrease) and SU groups (23.6% vs. 20.3%), decreased in the SGLT2i group (24.3% vs. 16.3%), and showed no net change in the TZD group (20.8%). Among SGLT2i users, significant discontinuation rates were observed for ARB/ACE inhibitors (OR: 1.45, 95% CI:1.12–1.87), CCB (OR: 1.57, 95% CI: 1.19–2.07) and thiazide diuretics (OR: 1.76, 95% CI: 1.17–2.63).

Conclusions: Using real-world data from Korea, this study demonstrated that the previously reported blood pressure-lowering effects of SGLT2 inhibitors significantly influenced the discontinuation and adjustment of antihypertensive prescriptions, differentiating them from other second-line OHAs.

Keywords: SGLT2 inhibitors, Real-world evidence, Cohort

D1/P121

Synergistic association of RAAS inhibitors and SGLT2 inhibitors on major hepatic events

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Introduction: Emerging evidence suggests potential hepatic benefits from both renin-angiotensin-aldosterone system inhibitors (RAASi) and sodium-glucose cotransporter 2 inhibitors (SGLT-2i), but their combined effect is unclear.

Aims: To evaluate the synergistic association of concomitant RAASi and SGLT-2i therapy with the risk of major hepatic events.

Methods: We utilized nationwide claims data (2014-2023) of Korea to establish two active-comparator cohorts of patients with type 2 diabetes and hypertension. In Cohort 1, RAASi users initiated either SGLT-2i or dipeptidyl-peptidase 4 inhibitor (DPP4i). In Cohort 2, SGLT-2i users initiated either RAASi or calcium-channel blocker (CCB). After inverse probability of treatment weighting, we used weighted Cox models to estimate hazard ratios (HRs) and 95% confidence intervals (CI) for a composite of major hepatic events (ascites, variceal bleeding, hepatic failure, or liver transplant) under an as-treated approach.

Results: In Cohort 1, among 1,533,726 patients receiving RAASi, 244,702 initiators of SGLT-2i and 1,289,024 initiators of DPP4i were identified. Adding SGLT-2i to existing RAASi therapy was associated with a lower risk of major hepatic events compared to adding DPP4i (HR 0.66, 95% CI 0.63–0.69). In Cohort 2, among 49,239 patients receiving SGLT-2i, 39,979 initiators of RAASi and 9,260 initiators of CCB were identified. Adding RAASi to SGLT-2i therapy showed a non-significant risk reduction versus adding CCB (HR 0.81, 95% CI 0.64–1.04). However, a subgroup analysis of Cohort 2 revealed that the addition of angiotensin receptor blocker (ARB) was associated with a reduced risk (HR 0.78, 95% CI 0.61–1.00; p=0.047), whereas angiotensin-converting enzyme inhibitor (ACEi) was not (HR 1.77, 95% CI 1.08–2.89).

Discussion: The combination of SGLT-2i and RAASi therapy was associated with a reduced risk of major hepatic events. This benefit was most pronounced when adding SGLT-2i to ongoing RAASi therapy and when ARB, specifically, was added to ongoing SGLT-2i therapy.

D1/P122

UTI Risk & Treatment Outcomes with SGLT2 Inhibitors in T2DM: Retrospective Study

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Introduction: Sodium-glucose co-transporter 2 (SGLT2) inhibitors have proven benefits in the management of Type 2 Diabetes Mellitus (T2DM) but concerns regarding an increased risk of urinary tract infections (UTIs) persist.

Aims: To assess and compare the incidence and clinical profile of UTIs among T2DM patients receiving SGLT2 inhibitors versus those on other anti-diabetic therapies.

Methods: A retrospective observational study was conducted based on medical records of 1,129 T2DM patients treated between January 2020 and December 2023. Patients were categorized into the SGLT2 inhibitor group (n = 541) and non-SGLT2 group (n = 588). Data on UTI incidence, patient demographics, comorbidities, microbial patterns, and clinical outcomes were analyzed.

Results: UTI incidence was significantly higher in the SGLT2 inhibitor group (45.84%) compared to the non-SGLT2 group (27.21%) ($p < 0.0001$). HbA1c levels were significantly lower in the SGLT2 group (mean 6.90±1.27) compared to the non-SGLT2 group (7.20±1.56; $p = 0.001$). Male patients in the SGLT2 group had a higher rate of UTI (54.43%) than those in the non-SGLT2 group (41.25%; $p = 0.0093$), while females in the non-SGLT2 group showed a higher UTI incidence. Common comorbidities included hypertension (74.66%), chronic kidney disease (70.15%), and ischemic heart disease (48.36%). Escherichia coli was the most frequently isolated pathogen. Most UTI cases were uncomplicated and responded well to standard antimicrobial therapy. No significant differences were observed between groups regarding UTI severity, recurrence, hospitalization rates, or renal complications.

Conclusions: The study found a significantly higher incidence of UTI among T2DM patients using SGLT2 inhibitors compared to those on other anti-diabetic therapies, although most infections were uncomplicated and manageable. SGLT2 inhibitors remain a valuable therapeutic option, but careful monitoring for UTI symptoms is recommended, particularly in high-risk patients.

Keywords: SGLT2 inhibitors; Type 2 Diabetes Mellitus; Urinary Tract Infections

D1/P123

Weight loss effects of semaglutide in normal-weight adults: a meta-analysis of RCTs

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Introduction: Glucagon-like peptide-1 receptor agonists, including semaglutide, are widely used to manage type 2 diabetes and obesity. Although their effects on individuals with obesity are well documented, evidence regarding their impact in individuals with normal weight is limited. Some randomized trials have included participants with body mass index (BMI) below 25 kg/m^2, but outcomes in this group remain under-investigated. To address this gap, we evaluated semaglutide's weight loss effect in normal-weight adults.

Aims: This study aimed to assess the weight loss effect of semaglutide in normal-weight adults through a meta-analysis of randomized controlled trials (RCTs).

Methods: We conducted a systematic review on April 24, 2024, using PubMed, Embase, and the Cochrane Library, yielding 1,157 records. After screening and eligibility assessment, four RCTs comprising ten treatment arms were included. Trials were eligible if they reported weight outcomes for participants with BMI < 25 kg/m^2 and included placebo control arms. Separate meta-analyses were performed by dosage (0.5 mg and 1.0 mg) using a random-effects model.

Results: In trials using pure placebo comparators (SUSTAIN-1 and Ikushima et al.), the 0.5 mg and 1.0 mg groups showed pooled mean differences in weight of −2.87 kg (95% CI: −4.53, −1.20) and −4.23 kg (95% CI: −7.67, −0.79), respectively. When all eligible placebo-controlled trials were assessed, some of which allowed the use of background antidiabetic medications, the 0.5 mg group showed −3.14 kg (95% CI: −4.41, −1.87) and the 1.0 mg group −3.37 kg (95% CI: −4.87, −1.86). Between-study heterogeneity was minimal (I^2 = 0–25.8%).

Conclusions: Semaglutide significantly reduced weight in adults with BMI < 25 kg/m^2. These findings provide clinical insight into semaglutide's effect across BMI ranges and support the need for further research on its use in non-obese populations.

Keywords: Semaglutide, weight loss, meta-analysis

D1/P124

Effects of vitamin D supplementation in diabetes or prediabetes: an umbrella review

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Introduction: Emerging evidence suggests vitamin D (VD) may influence glucose metabolism and insulin sensitivity, offering potential benefits in preventing the development of diabetes and its complications.

Aims: To evaluate the effects of VD supplementation on multiple health outcomes in diabetes or prediabetes.

Methods: We conducted this review strictly following the PRISMA guidelines. A comprehensive search of PubMed, Cochrane, and Embase was conducted for systematic reviews with meta-analyses of RCTs published from inception up to January 2024. Studies were included if they evaluated the effect of VD interventions on any health outcomes in prediabetes, type 2 diabetes mellitus (T2DM), or diabetic nephropathy (DN), with placebo as the control. For meta-analyses, summary effect estimates with 95%CIs were extracted. Methodological quality and certainty of evidence were assessed using AMSTAR2 and GRADE respectively.

Results: A total of 2,614 articles were retrieved and finally 34 publications with 60 meta-analyses of RCTs were included in this review. Methodological quality was high to moderate in 15% and low to very low in 85% of the included publications. The certainty of evidence was rated as moderate for 28%, low for 20%, and very low for 52% outcomes. Results from meta-analyses indicated that in T2DM, VD supplementation significantly reduced fasting blood glucose levels (MD-5.02 mg/dL, 95%CI -6.75, –3.28) and insulin levels (SMD-0.49, 95%CI -0.68, -0.31). In prediabetic populations, VD supplementation was associated with a reduced risk of progression to T2DM (RR0.89, 95%CI 0.80, 0.99). Among patients with DN, VD supplementation significantly reduced the urinary albumin to creatinine ratio (SMD-0.49, 95%CI -0.90, -0.08) and hs-CRP levels (MD-0.69 mg/L, 95%CI -0.86, -0.53). Additionally, VD showed potential benefits in lowering blood pressure, blood lipids, and inflammatory markers.

Conclusions: VD may benefit patients with prediabetes, T2DM, or DN, though the overall certainty of evidence remains low.

Keywords: vitamin D, diabetes, umbrella review

D1/P125

Real-world impact of funding decisions on SGLT2i utilisation and prescribing in Singapore

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Introduction: Dapagliflozin received funding in September 2022 for treating heart failure (HF) with reduced ejection fraction and chronic kidney disease. However, following a revised pricing proposal, empagliflozin was funded in November 2023 while dapagliflozin was delisted in August 2024 due to unfavourable cost-effectiveness compared with empagliflozin.

Aims: To evaluate the impact of drug listing changes on SGLT2i utilisation and prescribing among HF patients.

Methods: An interrupted time series analysis of public healthcare institutions' drug dispensing data was used to evaluate changes in SGLT2i utilisation before and after listing changes. Segmented regression models assessed level changes (LC) and trend changes (TC) in defined daily doses (DDDs), accounting for autocorrelation and excluding two "phase-in" months for anticipatory policy responses. Prescribing patterns in adult HF patients were compared using linked national health records with prevalent and incident SGLT2i use in 2021 and 2023. Prescribing rates between these years were compared, with rate ratios (RR) calculated from Poisson regression models.

Results: After dapagliflozin listing in September 2022, its use increased [LC +73.5K DDDs/month (95% CI 14.6K, 132.4K)] while empagliflozin use declined [LC -116.0K DDDs/month (95% CI -185.8K, -46.3K)]. The utilisation shifted significantly towards empagliflozin after its listing in November 2023 [LC +106.0K DDDs/month (95% CI 35.1K, 176.8K); TC +105.4K DDDs/month (95% CI 95.0K, 115.7K)], with corresponding decreases in dapagliflozin [LC -164.2K DDDs/month (95% CI -225.6K, -102.8K); TC -100.1K DDDs/month (95% CI -108.9K, -91.3K)], partly due to early notice of dapagliflozin's delisting as well. SGLT2i prescribing rates in HF patients increased by 109% [RR 2.09 (95% CI 2.04-2.15)] for prevalent users and 59% [RR 1.59 (95% CI 1.52-1.65)] for initiators.

Conclusions: Drug listing changes significantly impacted SGLT2i utilisation and prescribing, underscoring the role of drug pricing policies in shaping funding decisions and medication use in the public healthcare sector.

Keywords: SGLT2i, drug utilisation, prescribing patterns

D1/P126

Development, validation of KAP questionnaire for tuberculosis patients with type-II diabetes mellitus

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Introduction: Dapagliflozin received funding in September 2022 for treating heart failure (HF) with reduced ejection fraction and chronic kidney disease. However, following a revised pricing proposal, empagliflozin was funded in November 2023 while dapagliflozin was delisted in August 2024 due to unfavourable cost-effectiveness compared with empagliflozin.

Aims: To evaluate the impact of drug listing changes on SGLT2i utilisation and prescribing among HF patients.

Methods: An interrupted time series analysis of public healthcare institutions' drug dispensing data was used to evaluate changes in SGLT2i utilisation before and after listing changes. Segmented regression models assessed level changes (LC) and trend changes (TC) in defined daily doses (DDDs), accounting for autocorrelation and excluding two "phase-in" months for anticipatory policy responses. Prescribing patterns in adult HF patients were compared using linked national health records with prevalent and incident SGLT2i use in 2021 and 2023. Prescribing rates between these years were compared, with rate ratios (RR) calculated from Poisson regression models.

Results: After dapagliflozin listing in September 2022, its use increased [LC +73.5K DDDs/month (95% CI 14.6K, 132.4K)] while empagliflozin use declined [LC -116.0K DDDs/month (95% CI -185.8K, -46.3K)]. The utilisation shifted significantly towards empagliflozin after its listing in November 2023 [LC +106.0K DDDs/month (95% CI 35.1K, 176.8K); TC +105.4K DDDs/month (95% CI 95.0K, 115.7K)], with corresponding decreases in dapagliflozin [LC -164.2K DDDs/month (95% CI -225.6K, -102.8K); TC -100.1K DDDs/month (95% CI -108.9K, -91.3K)], partly due to early notice of dapagliflozin's delisting as well. SGLT2i prescribing rates in HF patients increased by 109% [RR 2.09 (95% CI 2.04-2.15)] for prevalent users and 59% [RR 1.59 (95% CI 1.52-1.65)] for initiators.

Conclusions: Drug listing changes significantly impacted SGLT2i utilisation and prescribing, underscoring the role of drug pricing policies in shaping funding decisions and medication use in the public healthcare sector.

Keywords: SGLT2i, drug utilisation, prescribing patterns

D1/P127

Association between DPP-4 inhibitor use and Parkinson's disease risk in T2DM

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Introduction: Parkinson's disease (PD) is a progressive neurodegenerative disorder with rising prevalence in type 2 diabetes mellitus (T2DM). Previous studies suggest that certain antidiabetic drug classes, such as GLP-1 receptor agonists, SGLT2 inhibitors, and DPP-4 inhibitors, may have neuroprotective effects beyond glycemic control, potentially lowering PD risk.

Aims: The relationship between dipeptidyl peptidase-4 (DPP-4) inhibitors and Parkinson's disease (PD) risk remains unclear. Therefore, we aimed to examine the association between DPP-4 inhibitor use and PD incidence in South Korean adults with type 2 diabetes mellitus (T2DM).

Methods: Using the Korean National Health Insurance Service-National Sample Cohort (2002–2019), we conducted a retrospective cohort study. Patients with T2DM initiating DPP-4 inhibitors were propensity score-matched 1:1 with controls by age, sex, Charlson Comorbidity Index, and index year. Each cohort included 3,961 patients. Statistical analyses included t-tests, chi-square tests, and Cox proportional-hazard models to estimate hazard ratios (HRs) with 95% confidence intervals (CIs).

Results: During follow-up, Parkinson's disease occurred in 17 patients (0.43%) in the DPP-4 inhibitor cohort and 69 patients (1.74%) in the matched control cohort. DPP-4 inhibitor users had a significantly lower risk of PD than matched controls (HR = 0.573, $p<0.05$). Cardiovascular disease (CVD) was associated with increased PD risk (HR=2.785, 95% CI=1.783–4.350), as was peptic ulcer disease (PUD; HR=2.272, 95% CI=1.473–3.505). Meglitinide use was also linked to higher PD risk (HR=10.517, 95% CI=1.410–79.946). Other antidiabetic classes, such as SGLT2 inhibitors and GLP-1 receptor agonists, showed no significant associations.

Conclusions: DPP-4 inhibitor use was associated with lower PD incidence in patients with T2DM., suggesting potential neuroprotection. Comorbid CVD, PUD, and meglitinide use were associated with increased PD risk. Prospective studies are needed to confirm these findings and clarify underlying mechanisms.

Keywords: DPP-4 inhibitors, Parkinson's disease, type 2 diabetes mellitus

D1/P128

Oral antidiabetics impact on COPD exacerbations in type 2 diabetes: Network Meta-Analysis

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Introduction: Type 2 diabetes (T2DM) and chronic obstructive pulmonary disease (COPD) frequently coexist, increasing morbidity and mortality. Antidiabetic agents may modulate respiratory outcomes via pleiotropic anti-inflammatory effects relevant to COPD pathogenesis. Their comparative impact on exacerbations remains unclear. This network meta-analysis (NMA) addresses optimal management of coexisting T2DM/COPD by evaluating oral glucose-lowering therapies' effects on exacerbation risk.

Aims: To compare the effects of oral antidiabetic agents on overall and severe COPD exacerbations using network meta-analysis, based on their potential mechanistic links to inflammation and respiratory outcomes. To rank treatments by efficacy for exacerbation prevention.

Methods: Following PRISMA-NMA guidelines, we searched PubMed, Embase, Cochrane Library, and Web of Science until March 2025 for observational studies and randomized controlled trials (RCTs) in adults with confirmed T2DM and COPD. Outcomes were overall and severe COPD exacerbations. Risk ratios (RRs) with 95% CIs were pooled using random-effects NMA models. Treatments were ranked using the Surface Under the Cumulative Ranking curve (SUCRA). Heterogeneity was assessed via I^2 statistics.

Results: Eleven studies (n=482,314 participants; all observational studies) were included. Compared to sulfonylureas, SGLT-2 inhibitors significantly reduced overall exacerbations (RR 0.71, 95% CI 0.66-0.77), as did GLP-1 receptor agonists (RR 0.77, 95% CI 0.71-0.84). DPP-4 inhibitors (RR 1.05, 95% CI 0.97-1.13) and meglitinides (RR 1.13, 95% CI 0.93-1.36) showed non-significant increases. For severe exacerbations, SGLT-2 inhibitors (RR 0.42, 95% CI 0.38-0.46) and GLP-1 receptor agonists (RR 0.46, 95% CI 0.42-0.51) demonstrated the strongest reductions.

Conclusions: SGLT-2 inhibitors and GLP-1 receptor agonists significantly lower COPD exacerbation risk in patients with T2DM and COPD compared to sulfonylureas. These findings support considering these agents for managing patients with coexisting T2DM and COPD. Future randomized trials are needed to validate these associations.

Keywords: Hypoglycemic Agents, COPD exacerbations, Type 2 Diabetes Mellitus, Network Meta-Analysis.

D1/P129

Alcohol and Drug Abuse in Patients with Diabetes Receiving GLP-1 Receptor Agonists

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Introduction: Preclinical evidence indicates that glucagon-like peptide 1 receptor agonists (GLP-1 RAs) may reduce alcohol and drug abuse. However, large scale real world evidence is lacking, highlighting the need to estimate treatment effects specifically among those receiving GLP 1 RAs.

Aims: To evaluate the effect of alcohol and drug abuse in patients with diabetes receiving GLP-1 RAs.

Methods: We emulated a target trial emulation from the National Health Insurance Research Database (NHIRD). We included patients diagnosed with diabetes receiving GLP-1 RAs or dipeptidyl peptidase 4 (DPP-4) inhibitors between 2013 and 2021. We assigned them at the date of their first prescription, which was defined as the index date. Propensity scores with fine stratification weights were used to generate similar probability of treatment assignment between groups. Specifically, we calculated the average treatment effect on the GLP-1 RA weights. The primary outcomes were alcohol or drug abuse. Additionally, the secondary outcome was bipolar disorder. Cox proportional hazards models were used to estimate the effect of GLP 1 RAs, generating hazard ratios (HRs) and 95% confidence intervals (CIs).

Results: Of 493,788 patients receiving GLP-1 RAs or DPP-4 inhibitors, the mean age was 46.11 ± 12.84 years and 55.4% male. Use of GLP 1 RAs was associated with a trend toward reduced risk of alcohol abuse (HR 0.60; 95% CI 0.36–1.02) and drug abuse (HR 0.34; 95% CI 0.06–3.77). Furthermore, GLP-1 RAs was associated with a reduced risk of bipolar disorder (HR 0.82; 95% CI 0.48–1.38). These results remained consistent across subgroup and sensitivity analyses, further strengthening the possible causation.

Conclusions: Our findings suggest that treatment with GLP 1 RAs may be associated with a reduced risk of alcohol and drug abuse, as well as bipolar disorder, compared with DPP 4 inhibitors.

Keywords: GLP-1 RAs, alcohol and drug abuse, bipolar disorder

D1/P130

Optimising renal function monitoring intervals for type 2 diabetes patients

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Introduction: Current recommendations for eGFR monitoring intervals in type 2 diabetes mellitus (T2DM) patients are largely consensus-based, with limited empirical evidence.

Aims: To investigate the appropriate eGFR monitoring intervals for T2DM patients at various CKD progression risk levels.

Methods: 180,984 T2DM adults (2009–2015) were stratified into low, moderate, and high CKD progression risk groups based on ADA and KDIGO guidelines. A target trial was emulated in each group to assess the impact of different eGFR monitoring intervals (2–8, 9–15, and 16–24 months for low and moderate risk; 2–4, 5–8, 9–15, and 16-24 months for high risk) on renal function decline and ESRD. Hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated using pooled logistic regression. Follow-up continued until the earliest occurrence of an outcome event, death, or December 31, 2021.

Results: In the low-risk group, extending the eGFR monitoring interval from 2–8 to 16–24 months did not significantly increase the risk of renal function decline (HR [95% CI]: 1.021 [0.771, 1.351]) or ESRD (HR [95% CI]: 1.048 [0.863, 1.272]). In the moderately increased risk group, a 16–24-month interval (vs 2-8 months) was significantly associated with a higher risk of renal function decline (HR [95% CI]: 1.03 [1.002, 1.06]), but not ESRD (HR [95% CI]: 1.092 [0.921, 1.296]). For the high-risk group, extending the interval from 2–4 to 9–15 months increased the risk of renal function decline (HR [95% CI]: 1.044 [1.005, 1.085]). Monitoring every 16–24 months (vs 2–4 months) was also associated with a higher risk of ESRD (HR [95% CI]: 1.269 [1.085, 1.484]).

Conclusions: For low-risk T2DM patients, eGFR monitoring intervals can be safely extended to 16–24 months. Annual assessments are recommended for those with moderately increased or high risk of CKD progression.

Keywords: Long-term care based on risk stratification, eGFR monitoring, type 2 diabetes mellitus

D1/P131

Use of Dipeptidyl Peptidase-4 Inhibitors and Risk of Acute Pancreatitis: Trend-in-Trend Design

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Background : There are conflicting findings regarding the risk of acute pancreatitis (AP) associated with use of dipeptidyl peptidase-4 (DPP-4) inhibitors among prior studies, primarily due to influence of confounding factors.

Objectives: To evaluate the risk of AP associated with use of DPP-4 inhibitors using trend-in-trend (TiT) design.

Methods: We conducted the study using data derived from the National Health Insurance Database. We applied TiT design to evaluate the risk of AP associated with the use of DPP-4 inhibitors. Patients with any diagnosis of type 2 diabetes mellitus (T2DM) between 2013 to 2021 were enrolled. Index date was defined as either the date of the first DPP-4 inhibitors prescription or a randomly assigned date for patients without exposure to DPP-4 inhibitors. TiT is a hybrid epidemiologic-ecologic research design that examining trends in the frequency of the outcome of interest as a function of trends in exposure. TiT method has been shown to estimate the causal effect without being influenced by unmeasured confounders. Propensity score (PS) overlap weighting, adjusted for measured confounders, was employed for comparison with TiT analysis. Sensitivity analyses included suicide attempts and acute kidney injury as negative control outcomes.

Results: We identified 2,089,710 T2DM patients with 536,284 patients exposed to DPP-4 inhibitors during the study period. Under TiT analysis, use of DPP-4 inhibitors was not associated with AP (odds ratio: 0.57; 95% CI: 0.54–2.02). Results from the PS approach indicated a higher risk of AP (1.36; 95% CI 1.30–1.42). Additionally, under the same approach, DPP-4 inhibitors were associated with increased risk of suicide attempts (1.33; 95% CI 1.24–1.42) and acute kidney injury (1.76; 95% CI 1.71–1.82).

Conclusions: Our findings did not suggest an increased risk of AP following the use of DPP-4 inhibitors. Potential unmeasured confounders should be considered and controlled using appropriate methods.

Keywords: Trend-in-Trend, Confounder, DPP-4 inhibitors

D1/P132

Risk of diabetic retinopathy with GLP-1RA, SGLT2i, and DPP-4i: a real-world study

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Introduction: Diabetic retinopathy (DR), a primary microvascular complication of diabetes mellitus, is leading a cause of new-onset blindness among adults in developed countries, imposing significant economic and societal burdens. The risks of DR associated with glucagon-like peptide-1 receptor agonists (GLP-1RA), sodium-glucose cotransporter 2 inhibitors (SGLT2i), and dipeptidyl peptidase-4 inhibitors (DPP-4i) remain unclear based on findings from large-scale randomized controlled trials.

Aims: This study aimed to compare the effects of GLP-1RA, SGLT2i, and DPP-4i on the risk of DR in patients with type 2 diabetes mellitus (T2DM).

Methods: We conducted a retrospective cohort study using data from the Ningbo Regional Health Information Platform (NRHIP), which includes approximately 2.1 million diabetic patients in Ningbo, China. An active comparator, new-user cohort design was employed to perform pairwise comparisons among new users of GLP-1RA, SGLT2i, and DPP-4i. Propensity score matching (1:1) was used to balance baseline characteristics, including demographics, comorbidities, medication use, and laboratory results. Cox regression models were used to calculate hazard ratios (HRs) and 95% confidence intervals (CIs) for DR.

Results: Three cohorts were established: SGLT2i (n=37,070), GLP-1RA (n=9,596), and DPP-4i (n=56,711). After propensity score matching and multivariate Cox regression analyses with DPP-4i as the reference, GLP-1RA significantly reduced the risk of DR (HR=0.86, 95% CI: 0.75–0.98, p=0.024). Similarly, SGLT2i was associated with a reduced DR risk (HR=0.90, 95% CI: 0.85–0.97, p=0.007). No statistically significant difference in DR risk was observed between GLP-1RA and SGLT2i (HR=0.98, 95% CI: 0.85–1.13, p=0.766).

Conclusions: Our retrospective cohort study of adults with T2DM suggest that the use of GLP-1RA and SGLT2i was associated with a lower risk of developing DR compared to DPP-4i. Clinically, GLP-1RA and SGLT2i can be recommended to reduce DR risk, although regular monitoring is necessary to identify potential vision-threatening complications.

Keywords: Diabetic retinopathy; GLP-1RA; SGLT2i

D1/P133

Readmission and safety outcomes of leadless vs transvenous pacemakers

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Introduction: Transvenous pacemakers (TV-VVI) are widely used but carry risks related to intravascular leads and subcutaneous pockets. Leadless pacemakers (LPM) were developed to minimize such complications, yet randomized comparisons with TV-VVI are lacking, and real-world evidence remains limited.

Aims: To compare 30-day readmission and procedural complication outcomes between leadless and single-chamber transvenous pacemakers in older adults using a nationally representative database.

Methods: We analyzed data from the National Readmissions Database (2016–2022) to identify patients aged ≥65 years who received either LPM or TV-VVI implants, as captured by ICD-10 procedural codes. High-dimensional 1:1 propensity score matching was applied to adjust for baseline confounders. Multivariable logistic regression was used to assess differences in readmission rates, procedural complications, and other outcomes.

Results: A total of 49,852 patients were included, with 44.8% receiving LPMs. After matching, LPM recipients had significantly lower odds of device-related complications (adjusted odds ratio [aOR]: 0.45; 95% CI: 0.30–0.65), revision or replacement procedures (aOR: 0.20; 95% CI: 0.11–0.36), implant-related complications (aOR: 0.58; 95% CI: 0.34–0.97), and device infection/inflammation (aOR: 0.48; 95% CI: 0.26–0.85). Conversely, LPMs were associated with higher odds of arteriovenous fistula (OR: 12.09; 95% CI: 2.01–232.52), vascular pseudoaneurysm (OR: 2.19; 95% CI: 1.08–4.58), and pericardial complications (OR: 1.74; 95% CI: 1.28–2.36). No significant differences were observed in 30-day readmission rates (15.5% vs. 15.9%; OR: 1.05; P = 0.079), in-hospital mortality (aOR: 0.94; P = 0.881), or prolonged hospitalization (aOR: 0.62; P = 0.107).

Conclusions: In this large national cohort of older adults, leadless pacemaker implantation was associated with fewer device-related and infectious complications compared to transvenous pacemakers. However, certain vascular and pericardial risks were elevated. These findings highlight the need for continued comparative research to guide optimal pacemaker selection.

Keywords: Leadless pacemaker; Readmission; Procedural complications

D1/P134

Optimizing Refractory Epilepsy Treatment Through Structured Seizure Monitoring: A Prospective Cohort Study

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Introduction: Epilepsy is a chronic neurological disorder affecting 23 million people in Asia, with 30-40% having drug-resistant epilepsy.

Objective: To study clinical characteristics and therapeutic outcomes in refractory epilepsy using self structured seizure tracking chart.

Methods: Prospective cohort study at JSS Hospital, Mysuru (August 2024-January 2025) using a Seizure Tracking Sheet.

Results: A total of 122 patients with refractory epilepsy were enrolled, including 68 males (55.73%) and 54 females (44.26%). The largest age group was young adults (19–44 years), accounting for 36.06% of cases (n=44).

Seizure timing showed a marked morning predominance (53.28%), followed by evening (25.41%), afternoon (24.59%), and night (20.49%). Seizure durations varied: 20.49% experienced 1-minute seizures, 31.15% had 2-minute episodes notably among11% pediatric and 4% geriatric patients on valproate and levetiracetam, while 37.70% had seizures exceeding 5 minutes—these cases frequently involved pediatric (17%) and geriatric (5%) populations treated with fosphenytoin and midazolam.
The most common clinical manifestations were body tremors (68.8%), blank stares (34.4%), falls (33.6%), tongue biting (14.7%), up-rolling eyes (13.1%), and frothing (11.4%). Leading seizure triggers included sleep deprivation (50.8%), psychological stress (47.5%), missed medications (31.9%), and sensory stimuli such as flashing lights (8.2%). Global developmental delay was reported in 8.2% of cases.

Post-ictal symptoms were predominantly drowsiness (69.7%) and confusion (60.7%), along with sensory changes (29.5%), speech difficulty (14.8%), and behavioral alterations (13.9%).
Refractory periods varied widely: 26.2% of patients were seizure-free for 6–12 months, 24.6% for 1–3 months, 22.1% for over a year, 10.7% for 3–6 months, while 16.4% experienced recurrence within 48 hours.

Levetiracetam was the most prescribed anti-seizure medication (72.95%), followed by sodium valproate (36.88%) and phenytoin (34.42%). Clobazam was commonly used as an adjunct therapy, particularly in cases with prolonged episodes.

Conclusion: Study validates structured tracking for personalized anti-seizure medication optimization in refractory epilepsy management

keywords: Refractory Epilepsy, Drug-resistant epilepsy.

D1/P135

Beliefs and experiences of opioid users in New Zealand: a cross-sectional study

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Introduction: Epilepsy is a chronic neurological disorder affecting 23 million people in Asia, with 30-40% having drug-resistant epilepsy.

Introduction: Opioids are potent analgesics commonly used for acute and cancer pain. However, they are being increasingly used for long-term non-cancer pain, which is associated with adverse outcomes.

Aims: To determine the association between patients' beliefs and persistent opioid use (POU: opioid use for & >90 days).

Methods: An anonymous online survey was administered between June 2024 and November 2024, to recent opioid users (within 12 months of study participation) in New Zealand, without a prior diagnosis of opioid misuse or dependence. All participants were asked for information related to demographics, patterns of opioid use, the Beliefs about Medicines Questionnaire (BMQ-specific), and agreement on experiences from opioid therapy. The BMQ-specific was analysed via the necessity-concern differential (NCD, -4 to 4).

Results: Of 777 responses, 686 responses were included in the analysis, with 61.0% (n=419) considered to be POU. We found that for every point increase on the NCD, there was an increased association of POU (aOR= 1.25; 95% CI: 1.01-1.55, p=0.036). A total of 619 participants completed the section on experiences from opioid therapy, nearly half of the participants agreed that they have experienced a side-effect, with around one in four agreeing that opioids impaired their ability to drive or operate machinery. In addition, approximately one in ten participants agreed that opioids may have resulted in taking time off work or school.

Conclusion: This is the first NZ study to demonstrate a significant association between patient beliefs and POU. Overall, the study highlights a reduction in treatment concerns with ongoing opioid use, which may drive future addiction and dependence on opioids. Our study further described how patients' adverse experiences related to opioid use may impact areas outside of health.

Keywords: opioid, medication beliefs

D1/P136

Changing GLD Patterns in Australian: General vs Neurodegenerative Populations (2015–2024)

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Introduction: Emerging evidence for benefits beyond glycaemic control for new glucose-lowering drugs (GLDs), such as Sodium-Glucose Cotransporter-2 inhibitors (SGLT2i) and GLP-1 receptor agonists (GLP-1RA), has transformed the landscape of GLD use. However, the trends and patterns of GLD use in dementia and Parkinson's disease (PD) populations remains underexplored.

Aims: To examine the trends and patterns of GLD use in Australia (2015-2024), focusing on individuals with dementia and PD.

Methods: We analysed prescription claims for people aged 50–99 using a 10% sample of the Australian Pharmaceutical Benefits Scheme data. Annual prevalence and incidence were calculated for each GLD class across the general population, and within the dementia and PD cohorts, defined using prior dispensing of dementia- and PD-specific medications, respectively. Log-binomial regressions were used to assess predictors of GLD initiation by cohort in 2024.

Results: Between 2015 and 2024, we identified 196,573 prevalent and 162,539 incident GLD users. The prevalence and incidence of SGLT2i use increased markedly (incidence; general population: 4.6→16.1/1,000 people; dementia: 3.5→15.9/1,000; PD: 12.5→ 25.2/1,000), with similar trend for GLP-1RA (general population: 1.0→6.9/1,000; dementia: 0.9 →4.7/1,000; PD: 3.0→9.7/1,000). In contrast, sulfonylurea and thiazolidinedione use declined across all groups. In 2024, compared to the general cohort, individuals in the PD cohort were more likely to initiate DPP-4 inhibitors (RR=1.2, 95% CI: 1.1–1.4) and GLP-1RA (RR=1.2, 95% CI: 1.1–1.4); those in the dementia cohort were less likely to initiate GLP-1RA (RR=0.8, 95% CI: 0.6–0.9) and SGLT2i (RR=0.9, 95% CI: 0.8–1.0).

Conclusion: Overall, GLD use has shifted toward newer GLDs, but the pattern of GLD use in people with dementia or PD differed from the general population. These findings highlight the urgent need for examining drivers of these differences and potential guideline implementation tailored to neurodegenerative populations.

Keywords: Glucose-lowering drugs; Dementia; Parkinson's disease

D1/P137

Comparing the risk of dementia and Parkinson's disease between abiraterone and enzalutamide

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Introduction: Abiraterone and enzalutamide are widely used agents for advanced prostate cancer (PC). Compared to abiraterone, enzalutamide is known to have higher blood-brain barrier permeability, raising concerns about potential neurocognitive risks. However, comparative real-world evidence remains limited.

Aims: To compare the risk of dementia and PD between patients treated with abiraterone versus enzalutamide.

Methods: We retrospectively analyzed South Korean nationwide claims data using a new-user, active-comparator design. Individuals aged 40-80 years with PC, who newly initiated either abiraterone or enzalutamide (but not both) between 2018 and 2020 were included. Patients with prior dementia, PD, or cerebrovascular disease from one year before to six months after the index date (first prescription date) were excluded. Propensity score matching (1:1) was employed to balance baseline characteristics, using the following covariates: age, type of National Health Security program enrollment, Charlson comorbidity index, medical history (hypertension, diabetes, dyslipidemia, cardiovascular diseases, peripheral vascular disease, chronic obstructive pulmonary disease, asthma and liver diseases) and concomitant medications (statins, antiplatelet agents, and anticoagulants). Cox proportional hazards models were employed to estimate the risk of dementia and PD, with mortality considered as a competing risk. Models were adjusted for use of anticholinergics, antidepressants, antipsychotics, and chemotherapy.

Results: The matched cohort included 2,692 patients (1,346 per group) with well-balanced baseline characteristics. Adjusted hazard ratios (aHRs) for abiraterone versus enzalutamide (reference) were: all-cause dementia, aHR 0.91 (95% confidence interval [CI]: 0.54-1.54); Alzheimer's disease, 0.83 (0.45-1.53); vascular dementia, 1.41 (0.08-25.39); other dementias, 0.82 (0.32-2.14); and PD, 2.83 (0.45-17.93).

Conclusions: No statistically significant differences in dementia or PD risk were observed between abiraterone and enzalutamide. Further large-scale studies with longer follow-up are needed to validate these findings.
This research was supported by a grant from Korea Institute of Drug Safety and Risk Management in 2023.

Keywords: Prostatic Neoplasm; Abiraterone; Enzalutamide; Dementia; Parkinson's Disease;

D1/P138

Dementia risk associated with blood-brain-barrier-crossing versus non-crossing angiotensin-converting enzyme inhibitors

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Introduction: Growing concern exists that blood–brain barrier (BBB)-crossing angiotensin-converting enzyme inhibitors (ACEis) may impair cognitive function by inhibiting brain ACE, an enzyme that degrades amyloid-β peptides, thereby potentially increasing the risk of dementia. However, current evidence on this association remains inconclusive.

Aims: To investigate the association between BBB-crossing ACEis and dementia risk compared to non-BBB-crossing ACEis.

Methods: We conducted a retrospective cohort study using the National Health Insurance Service–Health Screening Cohort (2002–2019) of South Korea. We identified individuals aged ≥ 40 years who newly started BBB-crossing or non-BBB-crossing ACE inhibitors during the period from January 1, 2003, to December 31, 2018, and maintained therapy for over 6 months were included. The outcome was incident dementia. Follow-up continued until outcome occurrence, death, or December 31, 2019, whichever came first. Propensity score (ps) 1:1 matching was used to balance the covariates between treatment groups. Incidence rates (IRs) per 1,000 person-years and their 95% confidence intervals (CIs) were estimated. Cox proportional hazards models were applied to estimate hazard ratios (HRs) and their 95% CIs among matched populations.

Results: 9,524 BBB-crossing (mean age 62.9 years; 66.5% male) and 10,747 non-BBB-crossing ACEis users (mean age 62.0 years; 59.4% male) were included. After 1:1 PS matching, 6,705 patients remained in each group, and all covariates were well balanced between groups. During a median 11.7-year follow-up, the IRs of dementia were 11.14 (95% CI, 10.40–11.94) and 10.74 (95% CI, 10.02–11.51) per 1,000 person-years, corresponding to an HR of 1.04 (95% CI, 0.95–1.15).

Conclusions: In this retrospective cohort study, BBB-crossing ACEis use was not associated with an increased risk of dementia compared to non-BBB-crossing ACEis use. Despite prior concerns, our population-based cohort study found no elevated risk of dementia associated with BBB-crossing ACEis.

Keywords: ACEis, blood–brain barrier, dementia

D1/P139

Anti-seizure drug-related problems in Patients with Refractory Epilepsy

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Introduction: In recent decades, there has been a significant increase in drug-related problem (DRP)-associated hospital admissions, primarily due to undesirable outcomes such as frequent outpatient visits, prolonged hospital stays, and increased healthcare costs. DRPs are a major concern as it negatively impact patient health outcomes. Clinical pharmacists can help ensure safer and more effective treatment plan and play a significant role among the healthcare team.

Aim: To provide safe and effective treatment by identifying and managing drug-related problems in patients.

Methods: Concurrent hospital-based cohort study was conducted at JSS Hospital, Mysuru during August 2024 to January 2025. Total of 122 patients of all ages and genders diagnosed with refractory epilepsy were included. Data were collected from case sheets, treatment charts, and patient or caregiver interviews. Hepler and Strand's classification, World Health Organisation - Uppsala Monitoring Centre Causality Assessment, Naranjo ADR Probability Scale, Modified Hartwig and Siegel ADR Severity Assessment, and criteria for determining ADR predictability and preventability (Modified Shumock and Thornton) tools were used for the study.

Results: Total of 320 DRPs were identified: 190 (59.3%) were drug-drug interactions (DDIs) and 108 (33.75%) were adverse drug reactions (ADRs). Of the DDIs, 80.4% were accepted, 19.4% were not; 50% required a change in frequency, and 82.6% were of moderate significance. Among the ADRs, 60.19% occurred in males, 28.7% were due to levetiracetam, and 62.96% were of moderate severity (Level 3). Based on assessments, 90.74% were predictable, 62.04% were not preventable, 66.66% were classified as "possible" by WHO-UMC, and 51.85% by Naranjo. Overall, 53.13% of DRPs were resolved.

Conclusion: This study highlights the role of clinical pharmacists in optimizing therapy and reducing irrational prescribing. Although personalized care can reduce prescription volume, improper DRP management contributes to longer hospital stays and poorer health outcomes.

Keywords: Anti-seizure drugs, Drug-drug interaction, Drug-related problems, Refractory epilepsy

D1/P140

Prescription opioid dose change and risk of ED visits: a case-crossover study

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Introduction: Opioid deprescribing is recommended to reduce opioid-related harms; however, no Australian studies have assessed the clinical outcomes of opioid dose reductions.

Aims: This study aims to determine if opioid dose changes are associated with mental health-related or substance use-related emergency department (ED) presentations.

Method: This self-controlled case-crossover study used POpulation Level Analysis and Reporting (POLAR) primary care data linked with data from three metropolitan hospitals in Victoria, Australia. People who had an ED presentation between April 2018 and May 2022 and had received ≥four opioid prescriptions in the 12 months preceding their ED presentation were included. Adjusted odds ratios (aOR) for ED presentations were estimated using conditional logistic regression, comparing opioid dose change in the 30 days prior to ED presentation to that in five corresponding sets of control periods of equal length not immediately preceding an ED presentation.

Results: Of the 1,458 eligible patients, 75.9% experienced a >25% reduction in their prescribed opioid dose in the 30 days before ED presentation. Compared with receiving no opioid prescriptions in the 30 days prior, >25% reduction in prescribed opioid dose (aOR: 1.78; 95% CI: 1.44-2.21) or opioid discontinuation (aOR:2.04; 95% CI: 1.48-2.82) was linked to higher odds of ED presentation whilst 10-25% reduction (aOR:0.15; 95% CI: 0.10-0.23) and stable or increased dose (aOR:0.01; 95% CI: 0.008-0.022) was associated with lower odds of ED presentation.

Discussions and Conclusions: Larger opioid dose reduction or discontinuation is associated with increased risk of subsequent mental health-related and substance use-related ED presentations.

Keywords: opioid dose change, case-cross over, emergency department presentations

D1/P141

Trends in gabapentinoid prescriptions among opioid users for pain management in Malaysia

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Background: Gabapentinoids, such as gabapentin and pregabalin, are widely recognized as first line therapies for managing neuropathic pain. Despite their benefits, these medications pose safety concerns, including sedation, dizziness, and cognitive impairment.

Aim: To evaluate the prescribing trends for gabapentin and pregabalin among patients taking opioids for their pain management.

Method: This cross-sectional study was conducted from 2010 to 2020 using the prescription databases of a tertiary hospital in Malaysia. All prescriptions for gabapentinoids that were issued to patients treated with opioids for their pain management during the study period were included. Annual number of prescriptions and prescriptions per patient were measured in repeat cross-sectional estimates. Descriptive statistics and linear trend analysis were performed using Stata version 15. Ethical approval for this study was secured from the Medical Research Ethical Committee, Ministry of Health Malaysia (NMRR-16-2135-33068).

Results: A total of 6.7% (n=2363/35237) of opioid patients were prescribed with gabapentinoids during the study period. These patients were issued with 10676 gabapentinoid prescriptions (gabapentin: 89.2%, n=9527/10676 and pregabalin 10.8%, n=1149/10676). Gabapentinoid prescriptions increased from 479 in 2010 to 1367 in 2020, representing a 185.3% increase (P<0.001). A similar trend was observed for gabapentin alone (from 468 in 2010 to 1115 in 2020, 135.5% increase, P<0.001) and pregabalin alone (from 11 in 2010 to 252 in 2020, 2190.9% increase, P<0.001).

Conclusion: Gabapentinoid prescriptions among opioid users in Malaysia significantly increased from 2010 to 2020, with gabapentin remaining the most prescribed medication, while pregabalin use rose sharply. These trends highlight the need for careful monitoring and call for action to ensure safe prescribing practices.

D1/P142

Characteristics, determinants, and antibiotic usage associated with Gram-negative infections in pediatric patients

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Introduction: Gram-negative infections in children are increasingly associated with longer hospital stays, high morbidity, and mortality. Pediatric studies that relate bacterial etiology, clinical presentations, and outcomes are few.

Aims: To study clinical characteristics, antibiotic utilization, risk factors, and outcomes of pediatric patients with Gram-negative infections.

Methods: A retrospective study was conducted in patients aged between one month and 18 years with culture-confirmed Gram-negative infections from January 2022 to December 2023 in a tertiary care teaching hospital. Demographics, clinical characteristics, bacterial etiology, and antibiotic utilization were collected from medical records. Data were analysed using SPSS v.20, and logistic regression was used to identify the risk factors.

Results: There were 227 gram-negative isolates from 209 patients, including 114 males and 95 females with a mean age of 6.34±5.97. The common conditions recorded were urinary tract infection (59.81%), sepsis/septic shock (24.40%), bloodstream infections (10.53%), and pneumonia (5.26%). The common isolated pathogens were E.coli (46.89%), Klebsiella (25.84%), and Acinetobacter (9.57%). Among these, multidrug-resistant (MDR) (16.27%), extensively drug-resistant (XDR) (5.26%), and pandrug-resistant (PDR) (5.74%) pathogens were observed. Aminoglycosides (19.88%), 3rd generation Cephalosporins/β-lactamase inhibitors (19.13%), and Sulphonamides (11.90%) were the commonly prescribed antibiotics. Furthermore, there was an increase in the average length of stay and overall mortality rates with the resistant isolates as compared to the sensitive isolates (18.25±13.07 Vs 9.04±6.80 ($p<0.01$), and 13 (23.63%) Vs 5(3.24%) ($p<0.01$), respectively). Age (OR=1.629, $p = 0.001$), mechanical ventilation (OR=15.61, $p=0.037$), central venous catheter (OR=22.48, $p<0.01$), malignancy (OR=17.36, $p<0.01$), and autoimmune diseases (OR=32.31, $p=0.010$) were identified as risk factors for the development of gram-negative infections.

Conclusion: Gram-negative pathogens cause severe infections, causing increased mortality and hospital stay in children. Understanding the epidemiology of Gram-negative infections at institutional and regional levels is essential for improving management decisions and treatment outcomes.

Keywords: Gram-negative infections, pediatrics, antibiotic usage

D1/P143

Outpatient antibiotic prescribing in early life: Analysis of Swiss health claims data

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Introduction: Appropriate antibiotic prescribing is crucial to prevent both, adverse effects and the development of antimicrobial resistance.

Aims: We aimed to assess the quantity and quality of outpatient antibiotic prescribing in children aged 0 to 2 years in Switzerland.

Methods: We conducted a drug utilization study using data from a Swiss health insurance (Helsana) with approximately 16% population coverage. The study population comprised children born between 2014 and 2021. We calculated the median time from start of insurance period to a child's first outpatient antibiotic prescription, the prescription prevalence and the rate of antibiotic treatment episodes in the first two years of life. Furthermore, we assessed the quality of antibiotic prescribing, considering the first antibiotic dispensed.

Results: We included 106'036 children. At the beginning of the study period, the median time to the first outpatient antibiotic stayed at around 33 to 34 months before rising sharply to 44 months (in birth-cohort from 2018), followed by a subsequent decline to 37 months (2020). The prescription prevalence ranged from 43% (2014) to 32% (2019). The rate of antibiotic treatment episodes in the first two years of life declined from 427 to 277 episodes per 1000 person-years. Amoxicillin was the most frequent first-ever dispensed antibiotic throughout the study period and the proportion of the World Health Organization's Access group (i.e. first-choice antibiotics) increased from 86% to 93%.

Conclusions: In our sample of Swiss claims data, children received antibiotics markedly later and less frequently than in a previous study with data from Germany and Denmark. Quality indicators were slightly poorer in Switzerland compared to Denmark, but more favourable than in Germany. These discrepancies may be partially explained by different national guidelines. Temporal trends indicate an improvement in the prescribing quality.

Keywords: antibiotics, young children, drug utilization research

D1/P144

Sex-specific reporting patterns of suicide-related adverse drug events in children and adolescents

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Introduction: While sex differences in suicidal behavior and drug response are known, sex-specific patterns in suicide-related adverse drug events (ADEs) among children and adolescents remain insufficiently characterized.

Aims: To investigate sex-specific differences in the reporting patterns of suicide-related ADEs in children and adolescents.

Methods: We compared female and male reports of suicide-related ADEs among individuals aged 2–17 years in VigiBase from 2000 to 2024. vigiPoint is a data-driven pharmacovigilance method that highlights distinguishing features of a data subset using shrinkage-adjusted log-odds ratios (logORs). Assessed features included age group, region, report type, reporter, subtypes of suicide-related ADE and drug. Features with 99% two-sided Bayesian credibility intervals of shrinkage-adjusted logORs exceeding ±0.5 were identified as key. Drug categories with sex-specific reporting differences identified by vigiPoint were further assessed through disproportionality analysis for potential safety signals. Signals were defined when reporting odds ratio or proportional reporting ratio ≥ 2, chi-square ≥ 4, and information component 95% confidence intervals ≥ 0.

Results: Among 31,881 suicide-related ADE reports, 64.8% were reported for females and 32.3% for males. Suicidal attempt (73.4% vs 50.6%) was more frequent in female reports, whereas suicide ideation (14.6% vs 33.8%) was less frequent. Of the drugs identified with sex-specific differences in suicide-related ADEs, paracetamol (9.1% vs 2.9%) and ibuprofen (4.5% vs 2.2%) were more reported in females, while atomoxetine (1.2% vs 7.8%), isotretinoin (2.5% vs 8.1%), methylphenidate (1.2% vs 4.7%), montelukast (2.3% vs 6.4%), and risperidone (1.4% vs 2.7%) in males. Disproportionality analysis detected signals for atomoxetine, isotretinoin, montelukast, and paracetamol in both sexes, and methylphenidate in males only.

Conclusions: A signal for methylphenidate in relation to suicide-related ADEs was detected only in males. Further study is needed to evaluate the potential association between methylphenidate and suicide in male children and adolescents.

Keywords: Pharmacovigilance, Suicide-related adverse drug events, Sex-specific differences

D1/P145

Risk Prediction Models for Adverse Drug Reactions in Pediatric: A Systematic Review

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Introduction: Pediatric patients face elevated ADR rates due to developmental pharmacokinetics, limited clinical data, and prevalent off-label drug use. Hospitalized children show 16.4% cumulative ADR incidence, with anti-infective-related ADRs at 38% (vs. 14.9% in adults), causing prolonged hospitalization and increased costs. Prediction models are critical to identify high-risk children and prevent harm, especially given 20% of pediatric ADRs are preventable. Despite existing systematic reviews assessing ADR prediction models for adult inpatients and older patients, pediatric-specific ADR prediction models lack systematic evaluation.

Aims: To identify published ADR prediction models for pediatric patients and secondarily evaluate their methodological quality.

Methods: Embase, PubMed, CNKI, Wanfang, VIP, and SinoMed were systematically searched from inception to January 9, 2025. Two independent reviewers conducted screening, full-text review, and data extraction, with disagreements resolved by consensus or third-author arbitration. Methodological quality was assessed using the Checklist for Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies (CHARMS), the Prediction Model Risk of Bias Assessment Tool (PROBAST) for bias risk, and the Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD) adherence. Predictive ability (AUROC, sensitivity, specificity) were reported.

Results: From 12,667 screened studies, 7 articles (describing 10 models) met the inclusion criteria. Logistic regression was the primary modeling method, with one study using machine learning. Common methodological limitations included unreported handling of missing data and univariable predictor screening. Models predicted heterogeneous ADRs across diverse settings, discrimination (AUROC) ranged from 0.63 to 0.97, with sensitivity and specificity between 52.0%-98.5% and 33.3%-98.8%, respectively. TRIPOD adherence varied from 62.16% to 86.49%. Critically, no models underwent external validation.

Conclusion: This review reveals an urgent need for validated pediatric ADR prediction models. Pervasive methodological limitations and absent external validation preclude clinical use. Prioritizing development and rigorous validation against TRIPOD/PROBAST standards is essential.

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Association of Dexamethasone Prescription with Acute Kidney Injury among Hospitalized Children

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Introduction: Acute Kidney Injury (AKI) affects approximately 26% of hospitalized children globally, contributing to prolonged hospitalization and increased mortality. Dexamethasone, a potent corticosteroid widely used for inflammatory conditions, exhibits conflicting renal effects: preclinical studies suggest it worsens renal injury via tubular epithelial cell injury, while clinical evidence links it to renal protection in some cohorts. This discrepancy necessitates real-world evidence in pediatric cohorts.

Aims: To examine the association between dexamethasone and AKI risk in hospitalized children, and identify clinical risk factors and high-risk subgroups for AKI post-dexamethasone exposure.

Methods: This retrospective cohort included hospitalized children (1–18 years) with ≥2 hospital days in 2022. AKI was defined according to the KDIGO criteria (2012). Follow-up spanned admission to AKI onset/discharge/death (median 15 days, IQR 9–24). Patients without available serum creatinine (Scr) tests or with severe renal impairment on admission were excluded. Baseline characteristics were balanced using inverse probability weighting (IPW) based on propensity scores. Multifactorial logistic regression was used to assess the association between the use of dexamethasone and the risk of AKI. Subgroup analyses and propensity score matching-based sensitivity analysis were conducted using all covariates. Variables with ≤5% missing data were multiply imputed, while those exceeding 5% missingness were excluded.

Results: Among 1,978 patients (685 dexamethasone-exposed, 1,282 non-exposed), AKI incidence was 14.0% (96/685) vs. 6.6% (84/1,282). Dexamethasone was an independent protective factor (IPW-adjusted OR 0.47, 95% CI 0.32–0.69, P<0.01). Subgroup analysis identified male sex, younger age, low baseline Scr, diuretic use, and absence of fever/pulmonary infection as factors associated with reduced AKI risk (P<0.05). Sensitivity analysis confirmed protection (Adjusted OR 0.54, 95% CI 0.29–0.99, P=0.05).

Conclusions: Dexamethasone may reduce AKI risk in hospitalized children, challenging preclinical safety assumptions. Large-scale prospective studies are warranted to validate these findings.

Keywords: Dexamethasone; Acute Kidney Injury; Hospitalized Children; Inverse Probability Weighting

D1/P147

Sex-specific associations between habitual drug use and suicide-related behaviors in Korean adolescents

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Introduction: Adolescent suicide is the leading cause of death in South Korea, with habitual drug use identified as a significant risk factor for suicide-related behaviors (SRBs). Understanding sex-specific differences in the association is essential for developing targeted prevention strategies.

Aims: To investigate sex differences in the association between habitual drug use and SRBs among Korean adolescents.

Methods: This cross-sectional study utilized data from the 2024 Korea Youth Risk Behavior Web-based Survey of adolescents aged 14 to 19. Habitual drug use was defined as self-reported habitual or intentional use of drugs (e.g., tranquilizers, stimulants, opioid analgesics) or inhalants (e.g., glue, cannabis, cocaine). SRBs, including ideation, planning, and attempts, were assessed based on experiences within the past 12 months. Descriptive statistics for adolescent characteristics were presented as unweighted frequencies and weighted percentages. Adjusted odds ratios (aORs) and 95% confidence intervals (CIs) were calculated using sex-stratified multiple logistic regression with adjustment for covariates.

Results: Among 54,653 adolescents, 1.2% of males and 1.6% of females reported habitual drug use. The prevalence of SRBs was higher among females than males, with rates of suicidal ideation (16.2% vs. 9.4%), planning (6.0% vs. 3.7%), and attempts (3.3% vs. 2.2%). Habitual drug use was significantly associated with an increased likelihood of SRBs in both sexes. Specifically, males with habitual drug use exhibited higher aORs for suicidal ideation (2.04 [1.49–2.79]) and suicidal attempts (3.38 [2.29–5.01]) than females (1.80 [1.42–2.28] for ideation; 2.35 [1.77–3.11] for attempts). Conversely, females had a slightly higher aOR for suicidal planning related to habitual drug use (2.66 [2.02–3.50]) than males (2.37 [1.72–3.26]).

Conclusions: Both males and females who used drugs habitually showed a significant increase in SRBs, although the strength of these associations varied by sex. These findings underscore the need for sex-specific strategies for suicide prevention.

Keywords: Habitual Drug Use, Suicide-Related Behaviors, Adolescents

D1/P148

Relative-age effect on ADHD diagnosis and pharmacologic treatment in children

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Introduction: Studies have shown that younger children in a classroom are more likely to be diagnosed with and treated for ADHD. However, the magnitude and implications vary across countries, reflecting differences in educational systems, diagnostic criteria, and prescribing practices. In a Canadian context, previous research on relative age effect has focused exclusively on elementary-school aged students and predated DSM-5.

Aims: This study investigates whether relative age continues to influence ADHD diagnosis and treatment in the DSM-5 era and examines whether this effect emerges during preschool-age and persists into high-school age among boys and girls.

Methods: We included British Columbian children aged 3-17 at any point between Jan 1, 2014, to Dec 31, 2023. We estimated period prevalence of ADHD diagnosis and treatment by birth month and calculated the absolute and relative risk of diagnosis and treatment for children born in December vs. January, stratified by age group: preschool (3-5), elementary school (6-12), and high school (13-17).

Results: 2,112,662 children were included in the cohort, and 51.4% were boys. Elementary and high school boys born in December were more likely to receive ADHD diagnosis (relative risk [RR] 1.27, 95% confidence interval [CI] 1.21, 1.32, RR 1.28, 95% CI 1.21, 1.27, respectively). Meanwhile, when comparing girls born in December vs. January, the relative-age effect was stronger in elementary school (RR 1.36 95% CI 1.27, 1.47), but became weaker in high school (RR 1.18, 95% CI 1.11, 1.26). This effect was not present among preschool-aged children. Similar relative-age effects were observed for the use of ADHD pharmacological treatment.

Conclusions: Relative-age effect in ADHD diagnosis and treatment persisted into high school among boys while declining among girls. Future ADHD assessment should carefully avoid overdiagnosis due to misinterpretation of immaturity related to younger relative age in the classroom.

D1/P149

Colistin Monotherapy vs Combination in Pediatric MDR Gram-Negative Infections: Propensity Analysis

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Introduction: The use of older antibiotics like colistin has been revisited to combat multidrug-resistant Gram-negative bacterial (MDR-GNB) infections. However, the comparative efficacy of colistin monotherapy versus combination therapy remains unclear in pediatric care.

Aims: To evaluate the clinical efficacy and safety of colistin monotherapy compared to combination therapy in pediatric patients with MDR-GNB infections.

Methods: This retrospective cohort study included pediatric patients under 18 years diagnosed with MDR-GNB infections and treated with intravenous colistin at Chiang Mai University Hospital between 2014 and 2024. Inverse probability weighting (IPW) was used to balance baseline characteristics between monotherapy and combination therapy groups. The primary outcome was 30-day mortality. Secondary outcomes included clinical response, end-of-treatment mortality, and microbiologic response. Univariate and multivariable logistic regression analyses were performed after IPW adjustment.

Results: A preliminary analysis of 128 pediatric patients (45 on monotherapy, 83 on combination therapy) was conducted. The median ages were 3.65 years (range, 0.71–13.19) in the monotherapy group and 2.12 years (range, 0.57–7.37) in the combination therapy group. After IPW adjustment, baseline characteristics were balanced. No significant differences were observed in 30-day mortality (adjusted odds ratio [aOR], 0.22; 95% confidence interval [CI], 0.01–4.07; p = 0.311), end-of-treatment mortality (aOR, 0.49; 95% CI, 0.06–4.35; p = 0.525), clinical response (aOR, 2.02; 95% CI, 0.23–17.85; p = 0.525), or nephrotoxicity (aOR, 1.18; 95% CI, 0.39–3.56; p = 0.764) between groups. However, microbiologic response was significantly higher with combination therapy (aOR, 31.39; 95% CI, 1.34–737.20; p = 0.032).

Conclusions: Colistin-based combination therapy improved microbiologic outcomes but showed similar mortality, clinical response, and nephrotoxicity rates compared to monotherapy. These findings suggest that colistin monotherapy may be as effective as combination therapy. However, future studies with larger sample sizes or prospective randomized controlled trials are needed to determine optimal treatment strategies in pediatric patients.

Keywords: colistin, pediatrics, MDR-GNB

D1/P150

Drug targets for attention deficit hyperactivity disorder: A proteomic-wide Mendelian randomization study

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Introduction: Attention-deficit hyperactivity disorder (ADHD) is a prevalent neurodevelopmental disorder in children contributing to significant socioeconomic burden. However, novel drug targets for ADHD remain limited. Given its early onset age, elucidating how protein perturbation impacts ADHD risk can help identify putative modifiable targets for drug development in disease prevention.

Aims: We aim to identify specific proteins as potential drug targets for ADHD prevention.

Methods: We conducted a two-sample Mendelian Randomization (MR) study leveraging protein quantitative trait loci (pQTLs) associated with 443 childhood plasma proteins (N = 2,147; ages 5 - 20 years, in standard deviation [SD]) as genetic instruments. Summary statistics from an ADHD genome-wide association study (Ncase = 38,691, Ncontrol = 186,843) were used as outcome datasource. Inverse-variance weighted method was used as the main analysis for estimating possible causal effects, with false discovery rate to account for multiple comparison. Colocalization analysis was performed to assess whether identified associations were driven by shared causal variants.

Results: Amongst 443 proteins, we identified five potential protein drug targets for ADHD. Genetically predicted higher coagulation factor XIII B chain (OR: 1.04; 95%CI: 1.01-1.06) and extracellular matrix protein 1 (OR: 1.03; 95%CI: 1.01-1.04) were associated with increased ADHD risk, and higher haptoglobin (OR: 0.96; 95%CI: 0.93-0.98), vitamin D-binding protein (OR: 0.94; 95%CI: 0.92-0.97), and sonic hedgehog protein (OR: 0.96; 95%CI: 0.94-0.98) were inversely associated with ADHD risk. However, evidence for genetic colocalization was only evident for extracellular matrix protein 1 (coloc.susie-PPH4 = 0.998).

Conclusion: Our study suggested extracellular matrix protein 1 is a promising candidate for preventing ADHD during childhood. Whether existing medications which reduce extracellular matrix protein 1 (e.g. captopril) can potentially be repurposed for ADHD prevention should be further explored using randomized controlled trials or real world evidence from electronic health records.

Keywords: attention-deficit hyperactivity disorder; mendelian randomization; childhood proteomics.

D1/P152

GLP-1 receptor agonists in children: A FAERS analysis of adverse events

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Introduction: Use of glucagon-like peptide-1 receptor agonists (GLP-1 RAs) for diabetes and/or obesity also disseminates into pediatric populations, notwithstanding their poorly established safety profile compared to better characterization in adults. Understanding spontaneous adverse event (AE) patterns appears critical for guiding clinical practice.

Aims: We aim to describe potential safety signals of GLP-1 RAs in FDA Adverse Event Reporting System (FAERS) in children.

Methods: We included AE reports where GLP-1 RA was the sole suspected active ingredient in children aged 6 to 17 years, submitted up to 31 March 2025 to the FAERS. We evaluated demographic characteristics, drug distribution, reporter qualifications, and the seriousness of AEs. These were classified according to the MedDRA version 28.0 hierarchy at the System Organ Class and Preferred Term levels.

Results: We identified 159 pediatric cases where liraglutide (37.1%) and semaglutide (28.3%) were the most frequently reported agents. Female patients constituted 71.5% of cases, and the median age was 15 years (IQR:14–17). Around half of the reports (52.2%) were submitted by healthcare professionals, and 55.3% involved serious AEs; 1.9% of cases included fatal outcomes. Semaglutide had the highest rate of serious outcomes (75.6%), which was significantly higher compared to non-semaglutide GLP-1 agonists (p=0.001). Among the 159 cases, a total of 414 distinct adverse events (AEs) were reported. Gastrointestinal disorders were identified in 37.7% of the cases, while the most frequently reported individual AE, off-label use, was observed in 18.9%. Suicidal and self-injurious behaviors were reported in 6.3% of all cases, with the highest proportion observed in semaglutide-related reports (11.1%), followed by liraglutide (5.1%).

Conclusion: A substantial portion of reported AE in children using GLP-1 RAs were serious, with semaglutide showing a notably higher rate. These results emphasize the need for cautious use and monitoring in pediatric populations.

Key words: FAERS, Glucagon-like peptide-1 (GLP-1) receptor agonists, pediatrics

D1/P153

Consumption patterns of ADHD medication in mainland China: 2015-2023

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Introduction: The use of attention-deficit/hyperactivity disorder (ADHD) medications is on the rise globally. However, there is a lack of evidence concerning the specific drug classes, geographic distribution, economic levels, hospital types, and the impact of COVID-19 on medication consumption in the Chinese market.

Aims: To evaluate the consumption pattern of ADHD medication in mainland China.

Methods: This is an observational study utilizing aggregated medication sales data from the China Medical Economic Information (CMEI) database, covering the period from 2015 to mid-2023. The impact of the COVID-19 pandemic on medication consumption was examined using interrupted time series analysis.

Results: This study investigated ADHD medication consumption in mainland China. Monthly DDDs/TID exhibited both seasonal fluctuations and a consistent upward trend (changing rate from the linear regression model: +2.54%, 95% confidence interval [CI]: +2.36% to +2.71%). Methylphenidate demonstrated higher consumption and growth rates compared to atomoxetine. Tertiary hospitals had higher consumption values, while secondary hospitals showed a greater monthly change rate. Consumption rates corresponded to economic levels, with high-income areas having the highest DDDs/TID but the second-lowest growth rate. During the initial eight months of the COVID-19 pandemic, ADHD medication consumption was lower than expected but gradually recovered thereafter.

Conclusions: This research firstly uncovers the increasing patterns of ADHD medication consumption in mainland China, the correlation between economic status and medication consumption rates, and the short-term impact of the COVID-19 pandemic on medication consumption. It emphasizes the importance of raising awareness and providing support for ADHD, particularly in regions with lower income levels. Furthermore, it offers valuable insights for further management of ADHD during pandemics.

Keywords: attention-deficit/hyperactivity disorder, medication, consumption, COVID-19, China

D1/P154

Medication Treatment Patterns and Persistence in Chinese Children and Adolescents With ADHD

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Introduction: Attention-deficit/hyperactivity disorder (ADHD) is one of the most common neurodevelopmental and neurobehavioral disorders among children and adolescents. Pharmacological treatment is considered a first-line therapy in many countries, including China. However, real-world study on medication treatment patterns and persistence in the Chinese pediatric population remain limited.

Aims: To examine the pharmacological treatment patterns, one-year medication persistence, and factors associated with treatment discontinuation among children and adolescents with ADHD in China.

Methods: This retrospective cohort study utilized electronic health records from the Jiangsu Provincial Health Information Platform. Patients aged 6–17 years with a diagnosis of ADHD who initiated pharmacological treatment between January 2020 and November 2023 were included. Treatment discontinuation was defined as a ≥180-day gap without medication during the one-year follow-up period. Descriptive statistics characterized demographic and treatment variables. Multivariable logistic regression was used to identify factors associated with treatment discontinuation.

Results: A total of 11,152 patients met the inclusion criteria, with a mean age of 9.02 years; 1,803 (16.17%) were female, and 429 (3.85%) had baseline psychiatric comorbidities. The most commonly prescribed initial medications were methylphenidate (54.38%) and atomoxetine (44.39%). During the one-year follow-up, 5,166 patients (46.32%) maintained pharmacological treatment, while 5,986 (53.68%) discontinued. Patients initiated on atomoxetine had a significantly higher risk of treatment discontinuation compared to those initiated on methylphenidate (adjusted odds ratio [aOR], 1.94; 95% CI, 1.79–2.11). Older age was also associated with a greater likelihood of discontinuation (aOR, 1.08; 95% CI, 1.06–1.10).

Conclusions: In this large real-world cohort of children and adolescents with ADHD in China, methylphenidate and atomoxetine were the predominant treatment choices. However, overall treatment persistence was low. Atomoxetine initiation and older age were significant predictors of treatment discontinuation. These findings highlight the need for targeted interventions to improve long-term adherence and optimize treatment outcomes in this population.

Keywords: ADHD, medication persistence, China

D1/P155

Applying hierarchical clustering of patient characteristics in Japanese patients with plaque psoriasis

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Introduction: Choice of biologic therapy for plaque psoriasis (PsO) requires simultaneous consideration of various patient characteristics. However, their complexity and diversity render understanding patient characteristics and making informed decisions on biologic choice challenging.

Aims: To identify PsO patient groups based on similarities in characteristics using hierarchical clustering.

Methods: This study utilized data from Medical Data Vision, Japan, an administrative database, spanning 2015.01.01 to 2022.12.31. Adult patients with PsO (ICD-10=L40.0) initiating biologics (TNF-α, IL-12/23, IL-17, and IL-23 inhibitors) were included. Patient characteristics encompassed demographics (age, sex), treatment history (topicals, systemic agents, phototherapy) and comorbidities. Hierarchical clustering (Gower distance, Ward's criterion) based on patient characteristics was performed. Pearson's Chi-square test was used to compare initial biologic therapies across clusters.

Results: Overall, 3787 eligible patients (mean age 56.4 years, 68.2% male) were grouped into four clusters, comprising 19.5%, 43.6%, 30.2% and 6.7% of patients, respectively. Clusters 1 and 2 include younger patients (mean age 52.3 and 55.3 years), while those in Clusters 3 and 4 were older (59.0 and 63.1 years). The proportion of male patients was lowest in Cluster 2 (54.6%) and higher in others (>70%). Treatment history varied, with Cluster 1 receiving minimal (no topical; 15.2% systemic), Cluster 4 moderate (76.7% topical; 31.2% systemic), and Clusters 2 and 3 substantial topical treatment (>95% topical; 23.1% and 87.0% systemic, respectively). Comorbidities were most prevalent in Cluster 4 (75.5%) and less prevalent in others (6.1%-31.9%). Initial biologic therapies varied significantly (p=0.026), with Cluster 1 preferred IL-17 inhibitors (39.4%), whereas others favored IL-23 inhibitors (39.9%-41.8%).

Conclusions: We identified four distinct clusters based on demographics, treatment history, and comorbidities. Hierarchical clustering consolidated multiple patient characteristics, thus simplifying their diversity and offering an innovative, holistic perspective for understanding biologic therapy decision making for PsO patients in a real-world setting.

Keywords: Hierarchical clustering, Biologics, Plaque psoriasis

D1/P156

Utilization Patterns of Advanced Therapies in Inflammatory Bowel Disease in South Korea

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Introduction: With the growing availability of biologics and small molecule therapies, treatment options for inflammatory bowel disease (IBD) have expanded considerably. Understanding real-world utilization patterns of advanced therapies is essential to inform clinical decision-making.

Aims: To describe patient characteristics and treatment patterns of advanced therapies in IBD.

Methods: We conducted a descriptive cohort study using South Korea's national health insurance claims database. Adults aged ≥19 years newly diagnosed with IBD between January 2014 and December 2022 were identified. Patients were stratified by IBD subtype—ulcerative colitis (UC) or Crohn's disease (CD). We assessed baseline characteristics at initiation of first advanced therapy, treatment persistence, and switching patterns.

Results: Among 53,552 patients (UC: 40,288; CD: 13,264), 8,847 (UC: 4,044; CD: 4,803) initiated advanced therapies. The median age at initiation was 43 years (IQR 30–56) for UC and 29 years (IQR 23–38) for CD. Median time-to-initiation was shorter for CD (9.6 months; IQR 3.0–27.3) compared to UC (16.9 months; IQR 6.0–36.5). In both subtypes, infliximab was the most frequently used first-line agent (UC: 42.3%, CD: 55.9%), followed by adalimumab (UC: 19.8%, CD: 24.6%). Vedolizumab (21.0%) and ustekinumab (14.6%) were also commonly used in UC and CD, respectively. Persistence with initial therapy was longer in CD (33.2 months; IQR 18.0–58.1) than in UC (23.4 months; IQR 11.2–43.6). Upon switching to second-line therapy, most patients transitioned to a different class (UC: n=256, 67.2%; CD: n=178, 71.5%). The most frequent second-line agents were tofacitinib in UC (24.9%) and ustekinumab in CD (40.2%).

Conclusions: TNF-α inhibitors remain the most widely used advanced therapies, largely due to their early introduction to the market. However, recent approvals of additional biologics and small molecule agents have expanded options. As the therapeutic landscape evolves, further studies are warranted to guide optimal treatment selection for initiating patients.

Keywords: Drug utilization; IBD; advanced treatment

D1/P157

Clinical and healthcare burden of difficult-to-treat rheumatoid arthritis in Japan

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Introduction: Difficult-to-treat rheumatoid arthritis (D2T RA) is defined by poor disease control despite standard therapies and poses a growing public health challenge. In aging populations like Japan, with rising multimorbidity, understanding the clinical profile and burden of D2T RA is essential. While the European Alliance of Associations for Rheumatology (EULAR) definition of D2T RA has gained international consensus, data on DT2 RA in Asian populations remains scarce.

Aims: This study aimed to compare the clinical characteristics, functional status, and comorbidity burden of D2T and non-D2T RA patients in Japan.

Methods: We conducted a retrospective observational study using electronic health records from a Japanese tertiary care center (2022–2025). RA patients with ≥12 months of follow-up were classified as D2T or non-D2T based on EULAR criteria. Data on demographics, laboratory measurements, disease activity, radiographic and functional status, and comorbidities were analyzed. Statistical comparisons were made using Welch's t-tests and Fisher's exact tests.

Results: Of 1,581 RA patients (D2T: n=102; non-D2T: n=1,479), D2T patients were more often female (90% vs. 78%, p=0.002) and diagnosed at a younger age (48 vs. 53 years, p=0.005). On average they exhibited higher disease activity (DAS28-CRP: 3.11 vs. 2.01, p<0.001; clinical disease activity index (CDAI): 13.0 vs. 5.2, p<0.001) and greater functional impairment (HAQ-DI: 0.88 vs. 0.49, p<0.001). Inflammatory markers (CRP, RF), renal function (eGFR), advanced radiographic stage (IV: 42% vs. 15%, p<0.001), and severe functional class (III–IV: 16.9% vs. 5.3%, p<0.001) tended to be worse in D2T patients. History of comorbid lymphoproliferative disorders (16% vs. 5.9%, p=0.007) was more common.

Conclusions: D2T RA patients in Japan are more likely to have younger disease onset, higher inflammatory activity, worse functional status, and greater comorbidity burden. These findings emphasize the need for early identification and tailored intervention strategies for RA patients.

Keywords: rheumatoid arthritis, difficult-to-treat RA, Japan

D1/P158

Real-world persistence with Ustekinumab treatment for psoriasis in Japan and China

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Introduction: Ustekinumab (UST) is an established treatment for the long-term management of plaque psoriasis (PsO), providing a reliable balance between effectiveness and safety. In real-world clinical practice, persistence of UST is an important indicator of therapeutic success influenced by efficacy, safety and patient satisfaction.

Aims: This study aims to describe persistence of UST in patients with PsO in Japan and China.

Methods. This retrospective cohort study utilized Japanese Medical Data Vision database (MDV) and Japan Medical Data Center (JMDC) claims data, and electronic medical records from Ruijin Hospital (Ruijin) in China. The study population included adults treated with UST for PsO (ICD-10=L40.0) from 01 January 2012, in Japan and 01 January 2021, in China, through 31 May 2024. Persistence was measured from UST initiation to discontinuation as indicated by a 24-week gap after the last UST prescription. Persistence was assessed using Kaplan-Meier methods, treating discontinuations as events, and loss to follow-up or study end as censoring. Median persistence was reported when 50% of patients remained persistent. Persistence probabilities with 95%CI were estimated at 3-months, 1- and 2-years post UST initiation.

Results: Among 904 MDV, 208 JMDC, and 119 Ruijin patients, 95% were persistent with UST at 3-months. For the MDV and JMDC cohorts, median persistence was 30.0 (27.7-34.0) and 26.2 (20.5-32.5) months, respectively; 1-year persistence probabilities were 73.5% (70.4%-76.3%) and 71.0% (64.1%-76.8%), and 2-year probabilities were 57.7% (54.2%-60.9%) and 51.9% (44.5%-58.8%). Median persistence was unavailable for the Ruijin cohort, as 60% of patients remained persistent until the end of follow-up after 24 months. The 1-year and 2-year persistence probabilities were 71.9% (61.2%-80.1%) and 64.2% (51.0%-74.7%), respectively.

Conclusions: UST showed comparable outcomes of persistence across various types of databases in Japan and China, demonstrating both short-term and long-term benefits for PsO patients in real-world clinical practice.

Keywords: Plaque psoriasis; Ustekinumab; Persistence.

D1/P159

Temporal trends in biosimilar prescriptions in Japan

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Introduction: Biosimilars are cost-saving alternatives to original biologics, but their uptake remains limited in Japan. Understanding prescription and switching trends is key to promoting biosimilar use.

Aims: To describe the temporal trends in the prescription of biologics in Japan, with additional analysis focusing on switching from original biologics to biosimilars.

Methods: Using the JMDC claims database (Jan 2005-May 2024), we identified patients who received at least one prescription for 17 biologics (original biologics or biosimilars). We examined monthly trends in the proportions of original biologics vs biosimilars. Furthermore, we assessed the proportion of patients by usage pattern: original-only, biosimilar-only, and switchers. Biosimilar adoption by medical institution type was also estimated.

Results: Temporal trends in the proportions of original biologics and biosimilars varied widely. In May 2024, the proportion of biosimilar prescriptions was 13.6% for somatropin and 92.5% for filgrastim. At the individual level, the proportion of patients switching from original biologics to biosimilars was low (1.2–14.0%), indicating that switches do not often occur within the same patient, while more recent new users of biologics start biosimilars. At the institutional level, university-related hospitals were more likely and clinics were less likely to introduce biosimilars than public and other types of hospitals.

Conclusion: Temporal trends and switching patterns of biosimilars vary by the type of biologics. The type of medical institution influences biosimilar use and should be considered in assessments. Further research and strategies are needed to promote biosimilar use in clinics.

Keywords: biological products, biosimilar pharmaceuticals, pharmacoepidemiology

D1/P160

Comparative efficacy between bepotastine and olopatadine for the treatment of allergic conjunctivitis

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Introduction: Allergic conjunctivitis (AC) is a common ocular inflammatory condition triggered by IgE-mediated hypersensitivity to environmental allergens. Second-generation H1 antihistamines, such as Bepotastine and Olopatadine, are widely used. However, comparative efficacy data are limited. This meta-analysis evaluates their effectiveness in managing AC symptoms, including itching, hyperemia, and ocular discomfort.

Aims: To compare the efficacy of Bepotastine besilate 1.5% and Olopatadine HCl 0.1% in relieving AC symptoms using standardized clinical outcomes.

Methods: A systematic search of PubMed, Embase, Web of Science, and Google Scholar (January–March 2025) identified randomized controlled trials (RCTs) comparing the two drugs in patients with allergic conjunctivitis. Eligible studies were RCTs involving patients with allergic conjunctivitis, Studies using validated symptom scores, and providing data suitable for meta-analysis. Six RCTs (N = 320) met the inclusion criteria.

Efficacy outcomes included the Total Ocular Symptom Score (TOSS), a composite score assessing itching, redness, tearing, and foreign body sensation, as well as individual scores for conjunctival hyperemia, itching, watering, and discomfort. Meta-analysis was performed using a random-effects model. Heterogeneity was assessed using the I^2 statistic.

Results: Bepotastine demonstrated significantly greater improvement in TOSS at Day 14 (Mean Difference [MD]: −0.35; 95% CI: −0.53 to −0.18; $I^2 = 0\%$; $p < 0.001$), Itching at Week 8 (MD: −0.40; 95% CI: −0.60 to −0.20; $I^2 = 12\%$; $p < 0.001$), and ocular discomfort at Week 8 (MD: −0.28; 95% CI: −0.45 to −0.12; $I^2 = 0\%$; $p = 0.001$). Hyperemia and watering outcomes favored Bepotastine but were not statistically significant.

Conclusion: This meta-analysis suggests that Bepotastine offers superior relief of itching and discomfort compared to Olopatadine in AC. These findings are specific to RCTs and should not be generalized to other study designs. Further large-scale trials are warranted.

Keywords: Allergic conjunctivitis, Bepotastine, Olopatadine, meta-analysis, antihistamines

D1/P161

Establishing Skin Prick Test Concentrations for Diagnosing Immediate Drug Allergies

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Introduction: Drug hypersensitivity reactions (DHRs) are unpredictable adverse drug reactions that range from mild skin rashes to severe anaphylaxis. Accurate diagnosis is crucial but challenging due to lack of standardized testing for many commonly used drugs beyond penicillin. Skin prick testing (SPT) is a reliable tool for diagnosing immediate, IgE-mediated drug allergies.

Aim: To develop and clinically validate an in-house SPT method for identifying drug allergies to selected drugs: Paracetamol, Diclofenac, Aceclofenac, and Levofloxacin.

Methodology: A five-year prospective study was conducted at a 1200-bed teaching hospital in Southern India. Healthy volunteers (n=25) and atopic individuals (n=10) were enrolled to identify non-irritating SPT concentrations for the selected drugs. Serial dilutions were prepared from pure active compounds, avoiding commercial excipients. Positive (histamine) and negative (50% glycerin) controls were used. Wheal reactions were observed every 5 minutes for 45 minutes. The validated non-irritating concentrations were tested in 10 patients with a known history of drug allergy. ROC analysis was used to evaluate diagnostic performance.

Results: The identified non-irritating concentrations were: Paracetamol (0.5 mg/mL), Diclofenac (0.2 mg/mL), Aceclofenac (0.2 mg/mL), and Levofloxacin (0.1 mg/mL). Optimal reaction times were between 15–25 minutes. ROC analysis showed moderate diagnostic accuracy (AUC ~0.70). Validation in patients showed 70% concordance with clinical history. One negative case was found to be non-IgE mediated.

Discussion: The study successfully established standardized, safe SPT concentrations for selected drugs. Use of pure compounds minimized false positives. This method enhances diagnostic accuracy for immediate-type drug allergies and may reduce mislabeling, unnecessary drug avoidance, and inappropriate substitutions in clinical practice.

Conclusion: This validated SPT protocol offers a reliable, safe, and cost-effective method for diagnosing immediate drug allergies and can improve clinical decision-making in routine practice.

Keywords: Drug hypersensitivity, skin prick test, drug allergy, paracetamol, diclofenac, levofloxacin, aceclofenac, ROC analysis, IgE-mediated reaction.

D1/P162

Recognizing Warm Autoimmune Hemolytic Anemia: a study from 3 hospitals in China

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Introduction: Warm Autoimmune Hemolytic Anemia(wAIHA) is a rare disease categorized into primary(pwAIHA) and secondary wAIHA(swAIHA). Due to its rarity, treatment often relies on physician experience, resulting in significant uncertainty surrounding its characteristics and management in China.

Aim: This study aims to describe the clinical features of adult wAIHA patients.

Method: This retrospective, observational cohort study utilized electronic health records from three hospitals in Shanghai. Adult patients hospitalized with wAIHA between January 2014 and March 2024 were included. Patients exhibiting evidence of acquired or hereditary causes of hemolytic anemia were excluded. Follow-up phone calls by physicians were conducted until death or November 15, 2024, whichever occurred first.

Results: A total of 202 wAIHA patients were identified, with 51.5% classified as pwAIHA. The median age at diagnosis was 59.0 years for pwAIHA and 56.0 years for swAIHA, with 58.7% and 59.2% female, respectively. Notably, 63.5% of pwAIHA and 100.0% of swAIHA patients had comorbidities, primarily hypertension. Severe or very severe anemia(Hb ≤ 60 g/L) was present in 28.8%of pwAIHA and 50.0% of swAIHA patients. Most presented elevated reticulocytes (≥4%)(85.3% of pwAIHA and 85.1% of swAIHA), total bilirubin(≥17.1 μmol/L) (91.2% and 78.3%), and lactate dehydrogenase(>250 U/L) (84.5% and 84.1%), indicating increased red blood cell destruction. In swAIHA underlying disease, autoimmune diseases accounted for 43.9%, hematological diseases for 26.5%, infections for 13.3%, and drug-induced cases for 8.2%. Among pwAIHA patients, 94.2% received corticosteroids as first-line treatment, with 18.3% combining immunoglobulins. The overall response rate was 94.6%, but half of the patients experienced relapse after a median of 130 days(IQR 47.5–480.8). During median follow-up of 31.6 months, complications occurred in 61.5% of patients, with infections and steroid-induced diabetes being the most common treatment-related complications.

Conclusion: This study enhances the understanding of wAIHA's clinical characteristics, emphasizing the need for improved medical interventions and support for affected populations in China.

D1/P163

The relationship between event-free and overall survival of head and neck carcinoma

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Introduction: Overall survival (OS) is often considered gold standard outcome in clinical trials for oncology treatments in patients with locally advanced (LA) head and neck squamous cell carcinoma (HNSCC). However, the need for long-term follow-up significantly increases the duration of the trials and thereby delaying patient access to new treatments. Using event-free survival (EFS) as an early clinical endpoint would potentially be more efficient than OS. Therefore, there is a need to evaluate the relationship between EFS and OS.

Aims: To describe and compare the EFS and OS patterns of LA HNSCC by different stages at diagnosis and by resectable/unresectable diseases, and to evaluate the correlations between EFS and OS using patient-level real-world clinical data.

Methods: This is a retrospective cohort study using electronic health records in Hong Kong. Patients with LA HNSCC and started primary treatment between 2006 and 2017 were included. The patients were followed for 5 years. Events for OS included all-cause deaths, while events for EFS included locoregional progression, recurrent, distal metastasis, and all-cause deaths. Patterns for EFS and OS were evaluated using Kaplan–Meier curves, and correlations between EFS and OS (in days) were measured by correlation coefficient, R.

Results: A total of 1,811 eligible patients was included. EFS and OS showed similar survival patterns: better survival was observed in patients with lower stages at diagnosis, or with resectable tumours (log-rank test $p<0.05$). EFS showed good correlation with OS ($R=0.86$). Subgroup analysis considering only either locoregional progression, recurrent, or distal metastasis events showed good correlation between distal metastasis-free survival and OS, but moderate correlations for the other two.

Conclusions: EFS showed good correlation with OS, suggesting that it could potentially be used as an early endpoint in trials for LA HNSCC.

Keywords: locally advanced head and neck squamous cell carcinoma, event-free survival, overall survival

D1/P164

Translating Potential Drug-Drug Interactions into Clinically Actionable Insights in Hematological Malignancy Patients

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Introduction: Patients with haematological malignancies (HM) are at high risk for drug–drug interactions (DDIs) due to complex treatment regimens and frequent antibiotic use. Not all drug interactions shown by databases results in clinically significant outcomes. Differentiating actionable interactions from theoretical alerts is essential for optimizing therapeutic decisions through antimicrobial stewardship.

Aim: To evaluate the frequency, severity and clinical significance of potential antibiotic-drug interactions and to implement targeted interventions in HM patients.

Methodology: A prospective observational study was carried out in oncology wards for the duration of two years (January 2023-December 2024). DDIs were identified using Micromedex database. Data was analyzed using descriptive statistics and Man-Whitney U test.

Results: Among the 393 HM patients. A total of 1,712 DDIs were identified, of which 604 (35.2%) involved at least one antibiotic. Of these: 76.9% (n=465) were classified as major, 18.3% (n=111) as moderate, 4.4% (n=27) as minor, and 0.1% (n=1) as contraindicated. The most frequently observed high risk combinations included: Azithromycin–Ondansetron (n=48) associated with QT prolongation, Trimethoprim-sulfamethoxazole–Fluconazole (n=17) associated with cardiotoxicity risk. A total of 12.5% (n=76) antibiotic drug interactions were diagnostically validated and clinically managed. The median length of stay was significantly higher among patients with diagnostically validated drug interactions compared to those with possible interactions (Mann–Whitney $U = 3.5$, $Z = -6.88$, $p < 0.001$).

Discussion: Diagnostic validated antibiotic-drug interactions had a notably longer hospital stay. These findings indicates that although interaction databases identify many potential DDIs only a portion of this results in actual clinical consequences. The prolonged length of stay may reflect the impact of adverse effects, diagnostic work-up, therapeutic changes, or complications arising from interaction-related toxicity. This study highlights the importance of distinguishing clinically actionable interactions and reinforce the role of prospective validation and antimicrobial stewardship in optimizing patient outcomes.

Keywords:
Antibiotic interactions, drug-drug interactions, antimicrobial stewardship

D1/P165

Population-based GWAS of immune checkpoint inhibitor-induced hepatotoxicity

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Introduction: Immune checkpoint inhibitors (ICIs) have become integral in cancer therapy but are associated with immune-related adverse events such as hepatotoxicity. The genetic factors underlying ICI-induced hepatotoxicity are not well understood. Identifying these factors could improve risk prediction and patient management.

Aims: This study aimed to identify genetic variants associated with ICI-induced hepatotoxicity using a large-scale genomic dataset. The objective was to uncover candidate loci for further investigation.

Methods: Patients receiving ICIs were identified from the All of Us Research Program, a large-scale, population-based genomic and health database designed to reflect diverse ancestries. Hepatotoxicity was assessed using laboratory data (ALT, AST, ALP, total bilirubin) and classified according to the Common Terminology Criteria for Adverse Events (CTCAE). Cases were defined as patients with grade ≥2 hepatotoxicity, and controls were defined as patients without clinically significant hepatotoxicity. Genome-wide association analyses were performed on array genotype data using PLINK, with quality control and adjustment for population stratification.

Results: A total of 553 patients were analyzed at the 60-day observation window following ICI initiation, including 74 cases and 479 controls. No variants reached genome-wide significance (p<5E-08). However, several loci demonstrated suggestive associations (p<1E-05). Notably, rs16957038 in CLYBL was associated with hepatotoxicity (OR=9.1, p=1.90E-06). Additional loci included rs1257300 (OR=0.36, p=3.68E-06) and rs76857861 (OR=6.8, p=6.03E-06).

Conclusions: This exploratory GWAS identified potential genetic signals for hepatotoxicity in ICI-treated patients. Larger cohorts and functional validation are needed to confirm these findings and elucidate their biological relevance.

Keywords: Immune checkpoint inhibitors, hepatotoxicity, GWAS

D1/P166

CAR T-cell therapy for acute myeloid leukemia: a systematic review and meta-analysis

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Introduction: While several studies have been conducted to investigate the effects of chimeric antigen receptor (CAR) T-cells, the overall impact of these remained unclear.

Aims: This study investigates the effects of CAR T-cells in patients with relapsed or refractory (R/R) acute myeloid leukemia (AML).

Methods: A comprehensive search of PubMed, Cochrane CENTRAL, EMBASE, ClinicalTrial.gov, and Scopus from inception to January 31, 2025 identified relevant studies. Evaluated outcomes included complete response (CR), partial response (PR), overall response rate (ORR), relapse, overall survival (OS), stable disease (SD), progressive disease (PD), persistence, post-hematopoietic stem cell transplantation (post-HSCT), myelosuppression, cytokine release syndrome (CRS), and immune effector cell-associated neurotoxicity syndrome (ICANS). A random-effects model meta-analysis was performed.

Results: Twenty-three studies were included, and the meta-analysis revealed that 68% (0.68 [95% CI: 0.52, 0.84]) of patients achieved CR, while none (0.00 [95% CI: 0.00, 0.08]) showed PR. The ORR was 73% (0.73 [95% CI: 0.57, 0.86]); however, approximately 41% (0.41 [95% CI: 0.25, 0.58]) of patients experienced relapse, and the OS was 59% (0.59 [95% CI: 0.41, 0.77]). Additionally, 31% (0.31 [95% CI: 0.20, 0.42]) of patients exhibited PD, while 27% (0.27 [95% CI: 0.11, 0.45]) demonstrated SD. CAR T-cell persistence was reported in nearly all patients (97%) (0.97 [95% CI: 0.79, 1.00]), and 40% (0.40 [95% CI: 0.23, 0.58]) received post-HSCT. Myelosuppression was observed in most patients (95% [0.95 [95% CI: 0.75, 1.00]), CRS occurred in 91% (0.91 [95% CI: 0.73, 1.00]), and ICANS was detected in 5% (0.05 [95% CI: 0.00, 0.13]).

Conclusions: Although CAR T-cell therapy demonstrated measurable anti-leukemic efficacy in R/R AML, the high incidence of treatment-related toxicities underscored the imperative for further clinical trials.

Keywords: Acute myeloid leukemia; Chimeric antigen receptor; Systematic review

D1/P167

Hypomethylating agent versus venetoclax combination for Asian patients with Acute Myeloid Leukaemia

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Introduction: Elderly patients with acute myeloid leukaemia (AML), ineligible for chemotherapy, usually receive hypomethylating agents (azacitidine or decitabine). The combination of venetoclax and azacitidine was observed with a survival advantage over azacitidine alone among patients with AML in a pivotal randomised controlled trial. However, the small sample size in the Asian subgroup means we cannot confirm a comparable survival benefit in this population.

Objective: We aimed to compare overall survival and healthcare resource utilisation in elderly patients newly diagnosed with AML receiving combination therapy (venetoclax with hypomethylating agents) versus monotherapy (hypomethylating agents alone).

Methods: Elderly patients (≥60 years old) newly diagnosed with AML during 2018 and 2023 were identified from territory-wide electronic medical records in Hong Kong. Patients were excluded if they had certain previous prescriptions, e.g., chemotherapy, or diseases, e.g., malignant neoplasm. A target trial emulation was conducted with 1:1 propensity-score matching, balancing the baseline characteristics. Kaplan-Meier curve and Cox regression compared overall survival, and negative binomial regression assessed healthcare resource utilisation with time offset. Subgroup analysis was performed based on the age of 75 years.

Results: The matched cohort included 159 patients per arm with a median follow-up duration of around 12 months. The combination therapy significantly improved overall survival compared to monotherapy [hazard ratio with 95% confidence interval (HR)=0.72 (0.57, 0.93), p=0.01], with pronounced benefit in patients ≥75 years [HR=0.68 (0.47, 0.98), p=0.04]. The combination therapy arm required fewer packed cell transfusions [26.98 vs. 35.20 units/person-year; incidence risk ratio with 95% confidence interval (IRR)=0.70 (0.56, 0.87), p=0.001], and also in patients ≥75 years [IRR=0.72 (0.53, 0.98), p=0.04].

Conclusion: Compared to hypomethylating agent alone, venetoclax plus hypomethylating agent benefits elderly patients with AML on overall survival and healthcare resource utilisation, especially among patients aged ≥75 years old.

Keywords: Acute myeloid leukaemia, Venetoclax plus hypomethylating agent, Asian patients

D1/P168

Efficacy and safety of first-line ICIs for advanced NSCLC: NMA of RCTs

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Introduction: Immune checkpoint inhibitors (ICIs) have revolutionized first-line therapy for advanced non-small cell lung cancer (NSCLC). With emerging PD-1/PD-L1 agents, we excluded bevacizumab—an anti-VEGF confounder—to present the latest network meta-analysis (NMA) focused solely on immunotherapy efficacy and safety, aiming to guide personalized treatment decisions across all PD-L1 levels.

Aim: To compare the efficacy and safety of first-line ICI-based treatments for advanced NSCLC across all PD-L1 expression levels.

Methods: This systematic review and frequentist network meta-analysis (NMA) were conducted following PRISMA guidelines and registered in PROSPERO (CRD42024616245). Phase II/III trials were identified through PubMed and Embase. Primary outcomes were overall survival (OS) and progression-free survival (PFS), while secondary outcomes include the objective response rate (ORR) and adverse events (AEs). Treatments were ranked by Surface Under the Cumulative Ranking (SUCRA) and validated by a league table. Bias assessment done via funnel plot, Egger's test, and Risk of Bias 2 (ROB2) tool.

Results: Thirty-one studies involving 15,172 patients were included, assessing 21 ICI-based regimens regardless of PD-L1 expression. In OS and PFS analyses, Prolgolimab+chemotherapy (hazard ratio [HR]: 0.51, 95%CI: 0.35–0.74; SUCRA:0.91) and Penpulimab+chemotherapy (HR: 0.43, 95%CI: 0.32–0.58; SUCRA:0.91) showed the best efficacy outcomes, respectively, across non-selective PD-L1 expression levels. Compared to chemotherapy, Pembrolizumab+chemotherapy (odds ratio [OR]: 3.10, 95%CI: 2.18–4.41; SUCRA:0.86) showed superior ORR. In OS subgroup analysis, Prolgolimab+chemotherapy ranked best for PD-L1 expression ≥50% and ≤1%, while in PFS, Penpulimab+chemotherapy and Serplulimab+chemotherapy ranked highest for PD-L1 ≥50% and ≤1%, respectively. However, Atezolizumab monotherapy was the safest option regarding any AE and grade ≥ 3 AEs.

Conclusions: Our comprehensive analysis suggests that prolgolimab and penpulimab regimens offer superior survival benefits compared to chemotherapy alone, although the combination therapies have higher AEs. The optimal treatment strategy depends entirely on patient characteristics and PD-L1 expression.

Keywords: Immune checkpoint inhibitors, non-small cell lung cancer, network meta-analysis

D1/P169

Patient-Reported Outcomes of Pharmacist-Led Topical Steroid Use in Breast Cancer Radiotherapy

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Background: Radiation dermatitis is a common adverse effect in breast cancer patients undergoing chest wall radiotherapy post-mastectomy, significantly impacting quality of life.
Aim: This study evaluates the efficacy of prophylactic topical corticosteroids—Betamethasone 0.3% cream—in mitigating radiation-induced dermatitis using Functional Assessment of Cancer Therapy-Breast (FACT-B) scores as patient-reported outcomes.

Methods: A randomized controlled trial was conducted with 12 post-mastectomy breast cancer patients undergoing chest wall radiotherapy. Participants were randomized into two groups: intervention (Betamethasone 0.3% cream, n=6) and control (no topical corticosteroid, n=6). FACT-B scores were recorded at baseline and weekly for 5 weeks.

Results: At baseline, the intervention group had a slightly higher mean FACT-B score (45.83 ± 20.69) compared to the control group (40.67 ± 12.66). The intervention group showed a significant increase in mean score during the 1st week (72.50 ± 21.20), indicating early improvement in patient-reported quality of life. However, the benefit declined over the following weeks, with scores dropping to 45.67 ± 17.64 by the 5th week. In contrast, the control group demonstrated a gradual but consistent increase in scores, peaking at 68.67 ± 0.52 in the 5th week. Variability in response was higher in the intervention group, especially between the 2nd and 4th weeks, suggesting inconsistent patient response or potential rebound effects.

Conclusion: Prophylactic use of Betamethasone 0.3% cream resulted in early symptomatic relief as evidenced by improved FACT-B scores in the first week. However, the sustained benefit was not observed over five weeks, and a higher variability was noted. While initial outcomes were promising, the long-term impact appears limited. A larger sample size and extended follow-up are warranted to validate the clinical significance of prophylactic corticosteroid use in managing radiation dermatitis

D1/P170

Risk Factor Analysis for Immediate Hypersensitivity Reactions in Chemotherapy Patients

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Background: Immediate hypersensitivity reactions (IHRs) to systemic cancer therapies are influenced by both patient-specific and treatment-related factors. Identifying these risks is vital for safer chemotherapy delivery.

Objective: To evaluate demographic, clinical, and regimen-related risk factors associated with the occurrence and severity of IHRs in hospitalized chemotherapy patients.

Methods: A retrospective review was conducted on 71 cancer patients (43 females, 28 males) who developed IHRs during systemic therapy under clinical pharmacist supervision. Variables analyzed included age, sex, BMI, comorbidities (hypertension, diabetes, renal impairment), and chemotherapy regimens. Reactions were graded using CTCAE v5.0 criteria.

Results: The median age of IHR cases ranged from 49–73 years, with older adults (60–74 years) showing a higher incidence of Grade II/III reactions—particularly among males receiving ECF or Rituximab-based regimens. While IHRs were more frequent in females, males experienced a higher proportion of severe (Grade III) reactions, especially when comorbidities were present.
BMI distribution showed 60% of patients were of normal weight and 40% overweight/obese, but no direct correlation with reaction severity was found. However, severe reactions occurred across BMI categories in patients with additional risk factors. Hypertension (20% females, 34% males) and type 2 diabetes (10% males) were linked to higher reaction severity. Renal dysfunction was observed in a few male patients with moderate reactions.
High-risk regimens included Paclitaxel ± Carboplatin (females), ECF, and Rituximab (males), while FOLFOX and Oxaliplatin regimens caused mostly mild reactions. Most IHRs occurred within 30 minutes of infusion initiation.

Conclusion: Advanced age, comorbidities, and certain multi-agent regimens increase IHR risk. BMI alone was not predictive, but overlapping risks worsened outcomes. Clinical pharmacist oversight enhanced early detection. A pre-infusion checklist assessing age, comorbidities, and regimen type is recommended for safer administration.

Keywords: Hypersensitivity, chemotherapy, risk factors, age, comorbidities, paclitaxel, rituximab, hypertension, pharmacist intervention.

D1/P171

Delayed withdrawal of Boxed Warning-labeled oncology drugs under Accelerated Approval

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Introduction: The FDA's Accelerated Approval (AA) program grants early access to therapies based on surrogate endpoints, requiring confirmatory trials to verify clinical benefit. A Boxed Warning (BW) is the FDA's strongest safety alert, highlighting the risk of serious adverse effects. Drugs labeled with a BW are more likely to fail confirmatory trials, potentially delaying regulatory decisions and AA withdrawal.

Objective: To compare the period from AA approval to the final regulatory decision (withdrawal vs traditional approval) and assess the impact of a Boxed Warning on regulatory outcomes.

Methods: Oncology drugs granted AA between 1992 and 2024 were identified using the FDA's Drugs@FDA database. Information on Boxed Warnings was obtained through the FDA Label Search. Drugs were categorized into two groups based on regulatory outcome: (1) AA Withdrawn and (2) converted to traditional approval. Duration was defined as the interval between AA approval and final regulatory decision. Non-parametric statistical tests were applied due to non-normal data distribution.

Results: A total of 144 oncology drugs were analyzed: 30 were withdrawn, and 114 received traditional approval after confirmation of clinical benefit. Among the withdrawn, 10 had a Boxed Warning and 20 did not. The median duration to regulatory decision was longer in the withdrawn group (1,378 vs. 1,196 days; $p = 0.059$). Cumulative incidence analysis showed a trend toward delayed decision in the withdrawn group ($p = 0.099$). Within this group, drugs with a Boxed Warning had the longest median duration (1,953 days), indicating prolonged market presence without confirmed clinical benefit.

Conclusion: Oncology drugs granted Accelerated Approval remained on the market for extended periods without confirmed clinical benefit, despite being labeled with a Boxed Warning.
The delayed regulatory action raises concerns about prolonged patient exposure and highlights the need for timely oversight in the post-approval setting.

Keywords: Accelerated Approval, Boxed Warning, Regulatory Withdrawal

D1/P172

Safety signals of concomitant immune checkpoint inhibitors and corticosteroids in VigiBase

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Introduction: With the expanding use of immune checkpoint inhibitors (ICIs) and the increasing reliance on corticosteroids to manage immune-related adverse events, safety data on the concomitant use of corticosteroids with ICIs remain insufficient.

Aims: To identify safety signals of ICIs when used concomitantly with corticosteroids in VigiBase.

Methods: The Individual Case Safety Reports (ICSRs) for anti-PD-1, anti-PD-L1, and anti-CTLA-4 inhibitors were extracted from VigiBase through December 2024. We performed a preferred term level disproportionality analysis, comparing reports with ICIs co-administration with corticosteroid against ICI alone as the main analysis. Concomitant use was defined by suspected, interacting, or concomitant events in the report. Signals were defined when having at least three reports and any of the following criteria were met: proportional reporting ratio or reporting odds ratio ≥ 2 with chi-square ≥ 4, or information component 95% confidence intervals ≥ 0. Detected signals were grouped by the system organ class (SOC). The subgroup analyses were performed by ICI monotherapy versus ICI combination therapy.

Results: Among the 445,721 ICSRs for ICI, 55,050 (12.3%) were reported concomitantly with corticosteroids. Concomitant users were more likely to be male (56.9% vs 53.8%), aged 45–64 years (31.1% vs 25.9%), and had serious events (86.2% vs 77.5%). Disproportionality analysis identified 300 signals for concomitant use, and the most frequently reported SOC was “infections and infestations”, followed by “gastrointestinal disorders and Respiratory”. In the subgroup analysis, the leading SOC remained consistent with the main analysis, but the next most common SOC differed with “Respiratory, thoracic and mediastinal disorders” for monotherapy and “Nervous system disorders” for ICI combination therapy.

Conclusion: Concomitant use of ICIs and corticosteroids may modify the overall safety profile. These findings demonstrate the need for additional research to confirm the safety of concomitant ICI and corticosteroids.

Key words: Immune checkpoint inhibitors, VigiBase, Corticosteroids

D1/P173

Colchicine use for gout and risk for cancer

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Introduction: Preclinical studies have suggested that colchicine, a medication widely used for gout, can inhibit tumor cell proliferation, migration, and metastasis across various cancer models. Nevertheless, evidence regarding the reduced cancer risk of colchicine in a real-world setting remains limited.

Aims: To investigate the association between colchicine use and the risk of cancer in patients with gout compared to non-steroidal anti-inflammatory drug (NSAID) use.

Methods: We conducted a target trial emulation study using the Korean National Health Insurance Service-National Sample Cohort (2002–2019). We compared new users of colchicine and NSAIDs for gout in an active comparator, new-user design to emulate random assignment. Follow-up began one year after treatment and continued until cancer diagnosis, all-cause death, or the end of the study (December 31, 2019). The outcome was overall cancer, and analyses were based on an intention-to-treat approach. We used propensity score fine stratification weighting to control confounding. Incidence rates per 1,000 person-years and 95% confidence intervals (CIs) were estimated using Poisson regression, and hazard ratios (HRs) with 95% CIs were estimated using Cox proportional hazards models.

Results: We identified a total of 5,255 patients with gout, including 1,189 colchicine users and 4,066 NSAIDs users. Colchicine users had a mean age of 50.54 years and 78.97% were male, while NSAID users had a mean age of 52.04 years and 68.25% were male. Over a mean follow-up of 12 years, the weighted IRs for overall cancer were 9.36 (95% CI, 7.79–11.14) per 1,000 person-years among colchicine users and 9.50 (95% CI, 8.66–10.40) among NSAIDs users. The crude and adjusted HRs were 0.95 (95% CI, 0.78–1.16) and 0.99 (95% CI, 0.81–1.20), respectively.

Conclusions: Despite preclinical findings suggesting anticancer potential of colchicine, our real-world analysis over a 12-year follow-up period did not support an association between colchicine use and cancer risk in gout patients.

Keywords: Gout, Cancer, Colchicine

D1/P174

Association between CDK4/6 inhibitors and risk of cardiotoxicity in breast cancer patients

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Introduction: CDK4/6 inhibitors have significantly improved survival in patients with hormone receptor-positive (HR+) advanced breast cancer. As their use expands and treatment durations increase, concerns about potential cardiotoxicity have emerged. It not only impairs quality of life but may also offset survival gains by increasing the risk of cardiovascular-related mortality. However, real-world studies assessing the cardiotoxicity of CDK4/6 inhibitors remain limited.

Aim: This study aims to estimate and compare the risk of cardiotoxicity associated with different CDK4/6 inhibitors.

Methods: This retrospective cohort study was conducted at a tertiary medical center in Taipei, Taiwan, utilizing electronic medical records from July 1, 2017, to September 30, 2024. Women with HR+ breast cancer who initiated CDK4/6 inhibitors were included. Cardiotoxicity was defined as any occurrence of cardiomyopathy, takotsubo syndrome, pericardial disease, heart failure, arrhythmias, QT prolongation, acute coronary syndrome, or venous thromboembolism. An as-treated analysis was performed, and a multivariable Cox proportional hazards model was used to estimate the risk.

Results: The study included 175 patients treated with palbociclib, 175 with ribociclib, and 74 with abemaciclib. The incidence rates of cardiotoxicity were 6.83, 15.15, and 6.44 per 100 person-years, with median follow-ups of 312, 336, and 186 days, respectively. Compared with palbociclib, ribociclib was associated with a significantly higher risk of cardiotoxicity (adjusted hazard ratio [aHR] 2.20; 95% confidence interval [CI], 1.14–4.25), whereas abemaciclib did not show a significant difference (aHR 0.66; 95% CI, 0.21–2.10).

Conclusion: Ribociclib was associated with a higher risk of cardiotoxicity, particularly cardiac rhythm abnormalities, consistent with patterns observed in prior trials. As CDK4/6 inhibitors expand into early-stage breast cancer treatment, these findings underscore the need for cardiovascular monitoring to ensure patients' long-term safety and treatment success. Given the single-center nature of this study, further multi-center research is warranted to confirm these observations.

Keywords: breast cancer, CDK4/6 inhibitors, cardiotoxicity

D1/P175

Immunosuppressant use among organ transplant patients: a single-center study in Vietnam

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Introduction: The balance between rejection prevention and immunosuppressants (IS) related adverse drug events (ADEs) is crucial, as most transplant patients require IS throughout their entire life.

Aims: To investigate the IS use and the occurrence of ADEs, especially infections, during the first six months using IS in organ transplant patients.

Methods: We performed a cross-sectional study on patients who received organ transplantation and were subsequently followed up at University Medical Center Ho Chi Minh City from 01/2018 to 04/2024. Data was collected from medical records including patient demographics, IS use, acute rejection and ADEs especially infection. Factors associated with infections were identified using univariable logistic regression analysis.

Results: There were 77 patients - 66 adults, 11 children - in the study, including 41 kidney and 36 liver transplant recipients. At the end of follow-up period, most kidney recipients maintained a steroid-tacrolimus-mycophenolate regimen (87.8%). In liver transplantation, tacrolimus-mycophenolate was predominant in adults (52.0%) while tacrolimus monotherapy was more common in children (63.6%). The tacrolimus concentration achieved target range most frequently in the first month (63.6-80.0%) and decreased thereafter. The most common ADEs in kidney recipients, adult and pediatric liver recipients were endocrine-metabolic disorders (65.8%), nervous system disorders (80.0%) and infection, respectively. Infection incidence was 34.1% in kidney; 48.0% in adult liver and 90.9% in pediatric liver recipients. Liver transplantation (OR=3.385; 95%CI: 1.323-8.659; p=0.011), age ≥ 18 (OR=0.061; 95%CI: 0.07-0.505; p=0.010), time in intesive care unit (OR=1.216; 95%CI: 1.045-1.415; p=0.012) and time in hospital (OR=1.048; 95%CI: 1.014-1.083; p=0.006) were significantly associated with infection.

Conclusion: These results emphasize the role of closely monitoring patients post-transplant to manage ADEs and intervene promptly. Optimizing IS therapy, particularly in the therapeutic drug monitoring, is also essential.

Keywords: Organ transplantation, immunosuppressants, infection

D1/P176

PD-L1 expression modulates frontline ALK-TKI response in ALK-rearranged NSCLC: target trial emulation

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Background: ALK inhibitors are standard treatment for ALK-rearranged NSCLC, but their efficacy in patients with concurrent PD-L1 expression remains uncertain. This study compared outcomes of first-line alectinib in ALK-rearranged NSCLC patients with variable PD-L1 expression levels.

Methods: This retrospective study conducted target trial emulation to compared Time to Treatment Failure (TTF) and overall survival (OS) in patients had ALK-rearranged NSCLC with variable PD-L1 expression levels receiving alectinib, based on the Flatiron Health database (2011-2025). Propensity Score Matching (PSM) balanced baseline characteristics. Time-to-first-event analysis was performed using Cox proportional hazards and Kaplan–Meier survival analysis, with the hazard ratio and 95% confidence interval calculated.

Results: 292 ALK–rearranged NSCLC patients were enrolled, with 171 in PD-L1–negative and PD-L1-low group (PD-L1 expression < 50%) and 121 in PD-L1-high group (PD-L1 expression ≥50%). After PSM, 101 patients remained in each group. Median 5-year TTF was not reached in PD-L1–negative and PD-L1-low group versus 24.1 months in PD-L1-high group. Median 5-year OS was 46.9 months (PD-L1–negative and PD-L1-low versus 43.4 months (PD-L1-high). PD-L1–negative and PD-L1-low showed a significant trend toward improved TTF (HR 0.39, 95% CI 0.23-0.67, p=0.274) and showed no significant difference in OS between groups (HR 0.91, 95% CI 0.59-1.42, p=0.68).

Conclusion: For ALK-rearranged NSCLC patients, high PD-L1 expression is associated with worse TTF among those receiving alectinib as first-line treatment.

D1/P177

Disease context matters: real-world correlation between surrogate endpoints and survival in oncology

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Introduction: While surrogate endpoints have expedited the evaluation of anti-cancer drugs, their correlation with overall survival (OS) remains uncertain. In real-world settings, pragmatic endpoints—time to next treatment (TTNT), time to treatment discontinuation (TTD)—are increasingly utilized as alternative indicators of OS.

Aims: To investigate the association between surrogate endpoints and OS in patients receiving biologics using real-world data.

Methods: A retrospective cohort study utilized the Korea-Clinical Data Utilization Network for Research Excellence registry database (2013-2021). Patients with advanced breast (BC), colorectal (CRC), and gastric cancer (GC) who received biologics (trastuzumab, cetuximab, or bevacizumab) were identified. Candidate surrogate endpoints included TTD/TTNT were defined respectively as the time from treatment initiation to discontinuation or death, and to the commencement of the next line of therapy or death. The primary outcome was patient-level correlation between TTD/TTNT and OS.

Results: A total of 550 BC, 490 GC, and 1902 CRC patients were identified. Median OS was longest in BC at 56.0 months (49.0-64.0), followed by CRC (bevacizumab: 21.0 months, 21.0-22.0; cetuximab: 26.0 months, 25.0-28.0), and GC (13.0 months, 11.0-14.0). TTNT generally presented higher correlation than TTD, though both showed weaker correlations in cancers with longer survival durations for both TTNT/TTD. Despite using the same biologic (trastuzumab), the correlation between surrogate endpoints and OS was weak in BC (TTNT Spearman $\rho = 0.230$, 0.143-0.315) and relatively strong in GC ($\rho = 0.772$, 0.716-0.820). In CRC, moderate correlations were observed irrespective of biologic types (bevacizumab: $\rho = 0.456$, 0.427-0.489; cetuximab: $\rho = 0.637$, 0.595-0.680).

Conclusions: The correlation between surrogate endpoints and overall survival appeared to be driven more by disease characteristics than specific treatment. Our findings suggest that the surrogacy reliability may be limited in cancer with longer survival, highlighting the importance of reassessment of drugs approved based on surrogate endpoints.

Keywords: surrogate endpoints, real-world data, oncology

D1/P178

Chemotherapy toxicity and intolerance assessed by CARG-TT scores in Chinese elders

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Introduction: Chemotherapy toxicities are prevalent in older adults with cancer and often compromise treatment tolerance. The Cancer and Aging Research Group Chemotherapy Toxicity Tool (CARG-TT), developed in 2011, is recommended to assess risks of severe (G3–5) toxicities, but its applicability in older adults in mainland China under current treatment practices is limited.

Aims: This study examined associations between CARG-TT scores and chemotherapy toxicity and intolerance in Chinese patients aged ≥70 years with cancer to provide preliminary evidence for its predictive value.

Methods: In this ongoing prospective cohort study, we enrolled 238 patients aged 70 years or older who initiated new chemotherapy regimens at a single cancer center in Shanghai from December 2024 to June 2025, with a planned 6-month follow-up. Baseline CARG-TT scores were obtained through face-to-face interviews prior to chemotherapy. Outcomes included G3–5 toxicities and chemotherapy intolerance, defined as a composite of discontinuation, dose reduction, delay, or missing doses. Associations between CARG-TT risk groups and outcomes were analyzed using chi-squared tests.

Results: The median age was 74 years (range 70–88); 30.7% were female, 63.4% had gastrointestinal cancer, and 62.2% had stage IV disease. Overall, 78.2% received reduced-intensity chemotherapy; 34.0% received immunotherapy, and 36.6% targeted therapy. Based on CARG-TT, 20.2% were low risk, 55.0% medium, and 24.8% high risk. Overall, 46.2% experienced G3–5 toxicities (including 8 deaths), and 26.1% did not complete planned treatment due to intolerance. G3–5 toxicities occurred in 39.6%, 48.1%, and 47.5% of low-, medium-, and high-risk patients, respectively (P=0.5852). Chemotherapy intolerance occurred in 25.0%, 29.8%, and 18.6%, respectively (P=0.2660).

Conclusions: Patients classified as medium or high risk by CARG-TT appeared more likely to develop severe toxicities, while statistical significance was not observed. Further follow-up is needed to assess the predictive ability of CARG-TT.

Keywords: Geriatric oncology, Chemotherapy toxicity, Tolerance

D1/P180

Habitual aspirin use and liver fat and inflammation: UK Biobank study

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Introduction: Steatotic liver disease is the most prevalent chronic liver condition, affecting one-third of the adult population. Habitual aspirin use is common among older adults.

Aims: To investigate the relationship between aspirin use and liver fat accumulation and inflammation.

Methods: We used data from the UK Biobank, including participants who underwent liver MRI. Liver fat percentage was assessed using proton density fat fraction (PDFF), and liver inflammation was measured using corrected T1 (cT1). Aspirin use was self-reported and participants were categorized as habitual users or others. Covariates included age, sex, socioeconomic status, lifestyle, and cardiometabolic risk factors. We used multivariable linear regression to examine associations between aspirin use and PDFF and cT1 values. Logistic regression was used to assess the association with steatotic liver disease (PDFF > 5%).

Results: A total of 36,404 participants (mean age 64.5 ± 7.6 years; 51.4% female) were included, of whom 3,530 (9.7%) reported habitual aspirin use. Compared with non-users, aspirin users were more likely to be male, older, consume more alcohol, and have higher BMI, waist circumference, blood pressure, diabetes/pre-diabetes, high triglycerides, and low HDL. They were less likely to be physically active or highly educated. Aspirin users had higher unadjusted liver fat (5.4% vs. 4.9%) and cT1 (715 ms vs. 699 ms). However, after adjusting for covariates, aspirin use was associated with lower liver fat (β (95%CI):−0.41 (−0.55, −0.27); $p < 0.01$) and higher cT1 (β (95% CI): 5.9 (4.0, 7.8); $p < 0.01$). Aspirin use was also associated with lower odds of steatotic liver disease (OR (95% CI): 0.77 (0.71, 0.84), $p < 0.01$).

Conclusion: Habitual aspirin use was associated with reduced liver fat but higher liver inflammation. Further research is needed to explore potential prospective dose–response relationships and underlying mechanisms.

Keywords: aspirin; liver fat; liver inflammation

D1/P181

Assessing volume-based procurement effects on lipid-lowering drugs in Jiangsu with mixed-effects model

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Introduction: Volume-based procurement (VBP) policy reshapes drug markets, yet its differential impact across hospital levels is unclear. Understanding VBP's effects on lipid-lowering drug procurement patterns is critical for healthcare policy refinement. This study addresses variations in policy implementation efficiency across healthcare settings in Jiangsu Province.

Aims: We evaluated VBP-induced changes in procurement expenditures, utilization, and costs across hospital tiers. Our objective was to inform drug policy optimization.

Methods: Procurement data (October 2019–September 2023) were analyzed using defined daily doses (DDDs) and defined daily cost (DDC). Mixed-effects models compared pre- and post-VBP changes, adjusting for covariates.

Results: Statins dominated the market in Jiangsu Province (rosuvastatin DDDs: 748 million). Post-VBP, expenditures and DDC decreased by 53.9% and 35.4%, respectively, with primary hospitals showing the largest expenditure reduction (61.6%) and secondary hospitals the greatest DDC decline (53.9%). DDDs increased significantly in primary care settings (e.g., pitavastatin +239.8% in secondary hospitals) but decreased for some drugs in tertiary hospitals (amlodipine/atorvastatin -7.3%). Mixed-effects models confirmed that VBP significantly reduced expenditures (OR = -1.07, $p < 0.001$) and DDC (OR = -2.70, $p < 0.001$). After covariate adjustment, expenditure reductions for rosuvastatin and atorvastatin narrowed, ezetimibe expenditures increased (OR = 0.13, $p = 0.002$), and pitavastatin usage declined (OR = -0.10, < 0.001). Changes in amlodipine/atorvastatin and ezetimibe lacked statistical significance due to short VBP implementation periods. Tertiary hospitals demonstrated the strictest policy adherence with the largest reductions ($p < 0.001$).

Conclusion: Jiangsu's lipid-lowering drug structure aligns with guidelines (statin-based, moderate-intensity preference). VBP reduced costs with tier-specific variations where tertiary hospitals prioritized generics while primary hospitals showed cost-driven shifts. Continuous tier-specific optimization is recommended to provide insights for healthcare reform.

Keywords Lipid-lowering drugs, Drug utilization, Defined daily dose system, Defined daily cost, Mixed effects model

Keywords: aspirin; liver fat; liver inflammation

D1/P182

Real-world evaluation of ticagrelor in acute coronary syndrome: a retrospective cohort study

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Introduction: In January 2019, ticagrelor, a P2Y12 inhibitor, was added to the subsidy list for preventing thrombotic events in adult patients with acute coronary syndrome (ACS).

Aims: This study compared real-world outcomes between ticagrelor and clopidogrel and assessed the impact of the subsidy decision on the healthcare system.

Methods: This retrospective study utilised linked national health record databases, and included adult patients with a ACS-related hospital admission, who were initiated on ticagrelor or clopidogrel between January 2017 to December 2020 and on aspirin concurrently. Propensity score matching was employed to balance patient demographics, comorbidities, baseline laboratory values and concomitant medications. Poisson regression was used to estimate incidence rate ratio (IRR) with 95% confidence interval (CIs) for major adverse cardiovascular events (MACE), including acute myocardial infarction (AMI), stroke or transient ischemic attack (TIA), and all-cause death, and secondary outcomes.

Results: After propensity score matching, 3475 patients remained in each cohort. Ticagrelor was associated with a 14% reduction in the incidence of MACE compared to clopidogrel at 1-year follow up [IRR 0.86 (95% CI 0.74, 0.99)], primarily driven by a significant reduction in all-cause mortality among ticagrelor patients [IRR 0.59 (95% CI 0.45, 0.76)]. The incidence of AMI and stroke/TIA for ticagrelor were numerically lower but did not reach statistical significance [IRR 0.96 (95% CI 0.81, 1.14)]. For safety outcomes, no significant differences were observed in bleeding events [IRR 0.87 (95% CI 0.64, 1.17)] or dyspnea [IRR 0.95 (95% CI 0.61, 1.48)] between the two cohorts.

Conclusions: Ticagrelor was associated with a lower risk of MACE compared to clopidogrel, primarily due to a significant reduction in all-cause mortality. These findings align with the results of the pivotal trial and other real-world studies, suggesting ticagrelor as a more effective treatment option in this patient population.

Keywords: Ticagrelor, acute coronary syndrome, real-world outcomes

D1/P183

Real-world effectiveness of PCSK9i in hyperlipidemia patients with different ASCVD risk

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Introduction: According to previous evidence, many atherosclerotic cardiovascular disease (ASCVD) patients fail to achieve optimal lipid-lowering targets despite using oral hypolipidemic agents, and the addition of proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9i) is recommended. However, the real-world evidence remains unclear whether Asian population can achieve treatment goals within one year after receiving PCSK9i therapy.

Aim: This study was aimed to assess the lipid control rate among different ASCVD risk patients with PCSK9i uses.

Methods: We conducted a retrospective cohort study by using the largest multi-institutional electronic medical records in Taiwan. We included patients with hypercholesterolemia who newly received PCSK9i between 2017 and 2023. To outcome assessment, patients without baseline or follow-up LDL-C levels were further excluded. According to ESC guidelines, we defined patients into very high-risk, high-risk, moderate or lower-risk categories based on factors such as blood pressure, cholesterol levels, and the presence of conditions like ASCVD, diabetes mellitus, and chronic kidney disease. The above risk factors were defined by ICD-10-CM code, ICD-10-PCS and laboratory data.

Results: This study included a total of 215 people. Of whom, the average age was 57.0 years (SD: 13.2) and 68.8% were males. The average total cholesterol and LDL were 233 mg/dL, and 153 mg/dL, respectively. Among the patients receiving PCSK9i, 60.5% were categorized as very high risk, 17.7% as high risk, and 21.8% as moderate or low risk. After one year of follow-up, 37.7% of patients in the very high-risk group, 47.4% in the high-risk group, and 55.3% in the low-risk group successfully achieved their treatment goals.

Conclusion: These findings suggest that, in real-world practice, PCSK9 inhibitors used as adjunctive lipid-lowering therapy demonstrate limited effectiveness in patients at very high and high ASCVD risk. Enhanced lipid management strategies may be necessary for these populations.

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Peripheral edema following the use of amlodipine and celecoxib: a case-crossover study

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Introduction: Peripheral edema is a common adverse reaction to amlodipine and celecoxib, but whether the risk increases when both drugs are used simultaneously is unknown.

Aims: To estimate the effect on edema of amlodipine and celecoxib, odds ratios (ORs) and relative excess risk due to interaction (RERI) were obtained by the case-crossover method.

Methods: We used a Japanese claims database (JMDC 2005-2021). Cases used amlodipine and celecoxib at least once during a 180-day period before newly starting furosemide (used as a surrogate for peripheral edema) after >365 days of non-use of furosemide. The odds ratios (ORs) for edema from amlodipine only (OR1), celecoxib only (OR2), and both amlodipine and celecoxib (OR3) compared to no amlodipine/celecoxib, and RERI and their 95% confidence interval (CI) were estimated by standard conditional logistic regression (SCL) and a recently proposed weighting method for multiple exposures (ICPE 2025 Washington DC). Exposure status was determined on the last day of each period.

Results: We identified 1014 cases. When the time window for control periods=120 days and 1 period=10 days, OR1=1.9 (95% CI: 1.5, 2.4), OR2=2.7 (1.9, 3.8), and OR3=4.7 (3.6, 6.2), and RERI=1.2 (0.0, 2.4) by the SCL method, while OR1=1.5 (1.2, 1.9), OR2=2.2 (1.6, 3.2), and OR3=3.2 (2.5 4.2), and RERI=0.5 (-0.9, 1.8) by the weighting method. When the length of 1 period was varied between 2 to 60 days, point estimates were OR1=1.6 to 2.0, OR2=2.0 to 3.1, OR3=3.4 to 5.8, and RERI=0.8 to 1.7 by SCL, while OR1=1.5 to 1.5, OR2=1.9 to 2.4, OR3=3.1 to 3.2, and RERI=0.4 to 0.7 by the weighting method.

Conclusion: Estimates of the risk of edema due to amlodipine and celecoxib using SCL were higher and more unstable than the weighting method. Significant RERI was suggested by SCL but not by the weighting method.

Keywords: Peripheral edema, Case-crossover study

D1/P185

Effect of PCSK9 inhibitors on major adverse cardiovascular events in patients with atherosclerotic cardiovascular disease: a population-based study using target trial emulation

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Introduction: The FOURIER trial demonstrated that evolocumab reduces cardiovascular events. Chinese dyslipidemia management guidelines advocate initiating therapy with statins and stepwise intensification, adding a cholesterol-absorption inhibitor and/or a PCSK9 inhibitor when needed.

Aims: This study aimed to evaluate, among patients with atherosclerotic cardiovascular disease (ASCVD), the association between use of PCSK9 inhibitors and the risk of three-point major adverse cardiovascular events (3P-MACE), providing real-world evidence to inform clinical practice.

Methods: Using the Ningbo Regional Health Information Platform and a target trial emulation framework, we applied an active-comparator new-user design with ezetimibe (EZE) initiators as the comparator. We included adult ASCVD patients who initiated a PCSK9 inhibitor or EZE between January 1, 2019 and June 30, 2025 while concurrently receiving statin therapy. Propensity scores were constructed from demographics, lifestyle factors, comorbidities, and medication history, followed by 1:1 matching to emulate randomization; Cox proportional hazards models were then fitted in the matched cohort to estimate the hazard ratio (HR) and 95% confidence interval (CI) for the association between PCSK9 inhibitor use and 3P-MACE.

Results: The final cohort included 4,591 new users of PCSK9 inhibitors and 4,591 new users of EZE. Over a median follow-up of 1.93 (1.89 - 1.97) years, 437 and 684 events occurred in the PCSK9 inhibitor and EZE groups, respectively. In the matched cohort, multivariable Cox models showed a significantly lower risk of 3P-MACE in the PCSK9 inhibitor group [HR (95% CI): 0.85 (0.75 - 0.96)]. Subgroup and sensitivity analyses supported the primary findings.

Conclusions: Among patients with ASCVD, initiation of PCSK9 inhibitors was associated with a reduced risk of 3P-MACE, supporting their clinical benefit in routine practice.

Keywords: PCSK9 inhibitors; target trial emulation; ASCVD; MACE; regional healthcare big data.

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Heterogeneity in Statin Efficacy for Primary Cardiovascular Prevention: A Meta-analysis

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Introduction: Evidence on the heterogeneity in the efficacy of statins for the primary prevention of cardiovascular disease (CVD) remains limited.

Aims: To identify the sources of heterogeneity in the efficacy of statins for the primary prevention of CVD.

Methods: Studies were systematically identified from a previous systematic review and searched in Medline, Embase, and Cochrane. Randomized controlled trials (RCTs) in adults without a history of CVD that investigated statin treatment were included. A meta-analysis was conducted to pool risk ratios (RR) and 95% confidence intervals (CI) for major adverse cardiovascular events [MACE], myocardial infarction [MI], stroke, and cardiovascular death. Univariate meta-regression analyses were conducted to assess the impact of trial-level covariates on the effect sizes ,using the ratio of risk ratios (RRR). Subgroup analyses were conducted by pooling ratio of effect sizes.

Results: 24 RCTs were included. Compared to no statin treatment, statin treatment was associated with a reduced risk of MACE (RR, 0.73[95% CI, 0.67, 0.80]), MI (RR, 0.68[95% CI, 0.60, 0.77]), stroke (RR, 0.76[95% CI, 0.65, 0.89]) and cardiovascular death (RR, 0.81[95% CI, 0.71, 0.95]). Univariate meta-regression indicated that higher baseline of total cholesterol (RRR, 1.29 [95% CI, 1.07, 1.57]), higher low-density lipoprotein cholesterol (LDL-C) (RRR, 1.31 [95% CI, 1.07, 1.62]), higher triglycerides (RRR, 1.81 [95% CI, 1.17, 2.81]) and lower statin intensity (RRR, 0.74 [95% CI, 0.59, 0.94]) were significantly associated with reduced efficacy of statins in stroke prevention at trial-level. While the statistical significance was borderline, the subgroup differences indicated a potentially greater benefit of statin therapy in males and participants without metabolic syndrome.

Conclusions: Statin therapy exhibited consistent efficacy in preventing CVD across diverse populations, but for individuals with elevated levels of total cholesterol, LDL-C, or triglycerides, more intensive treatment beyond statins may be necessary for effective stroke prevention.

Keywords: statins, cardiovascular disease, meta-analysis

D1/P187

Apolipoprotein A-I does not associate with cardiovascular outcomes at any LDL-cholesterol

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Introduction: Exploratory post-hoc subgroup analyses in the AEGIS-II trial suggested that the efficacy of CSL112 – human apolipoprotein A-I (apoA-I) intravenously infused in disc-shaped high-density lipoprotein (HDL) particles – may be influenced by baseline low-density lipoprotein cholesterol (LDL-C) levels.

Aims: To genetically evaluate the potential role of LDL-C in apoA-I and cardiovascular outcome associations.

Methods: We performed drug-target Mendelian randomization analyses in 339,390 European-ancestry participants from the UK Biobank. We leveraged the cis-acting variant (rs12225230) within APOA1 to mimic the pharmacological effects of apoA-I infusion (CSL112). Outcomes included ischemic heart disease, myocardial infarction, stroke, and their composite. To address potential horizontal pleiotropy and quantitative inference limitations, we applied the Katan approach. Four analyses were performed: 1) Primary associations of rs12225230 (apoA-I) with cardiovascular outcomes; 2) LDL-C stratification (≥ 100 mg/dL vs < 100 mg/dL), mirroring the AEGIS-II trial post-hoc design; 3) Evaluation of LDL-C effect modification via an interaction term (rs1222530 × LDL-C), adjusting for potential collider bias and power preservation; and 4) Statin use stratification to address residual confounding.

Results: The instrument (rs12225230) demonstrated significantly increased circulating apoA-I and HDL-C levels, but no concomitant association with any cardiovascular outcome, including the LDL-C stratified analyses (≥ 100 mg/dL vs < 100 mg/dL). These genetic results directly contradict the AEGIS-II's post-hoc signal of reverse association. Consistent null associations were observed in interaction models (rs1222530 × LDL-C), and statin use strata. The comprehensive genetic evidence therefore coherently indicates that the effects of apoA-I are independent of LDL-C.

Conclusions: These analyses provide consistent genetic evidence that circulating apoA-I concentrations do not associate with any of the cardiovascular outcomes, even when baseline LDL-C ≥ 100 mg/dL. The protective effects attributed to CSL112 infusion in AEGIS-II's post-hoc subgroup analysis are likely reflecting residual confounding rather than causal LDL-C modulation.

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Association of Dietary and Circulating Micronutrients with NAFLD: Meta-Analysis of Observational Studies

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Introduction: Non-alcoholic fatty liver disease (NAFLD) is the most prevalent chronic liver disorder worldwide and is increasingly recognized as a significant public health challenge. While metabolic risk factors are well established, association of calcium (Ca), magnesium (Mg), phosphorus (P), and selenium (Se) with NAFLD risk remains insufficiently characterized. Understanding these associations could inform targeted nutritional strategies for NAFLD management.

Aim: To systematically evaluate and quantify the association between circulatory and dietary Ca, Mg, P, and Se with risk of NAFLD

Methods: A comprehensive literature search was conducted in PubMed, Embase, and Web of Science from inception through June 2025 to identify observational studies (cross-sectional/case-control) published in English, examining associations between micronutrient levels and NAFLD reported multivariable-adjusted odds ratios (ORs). Study quality was assessed using the Newcastle-Ottawa Scale. Random-effects meta-analyses were performed using R. Sensitivity analyses were conducted using leave-one-out methods, and potential publication bias was assessed using funnel plots and Egger's test.

Results: 17 studies comprising 103,242 participants were included from 3303 screened records. The overall pooled OR was 1.05 (95% CI: 0.86–1.28), with substantial heterogeneity (I^2 = 88.7%). Subgroup analyses indicated that elevated blood calcium levels were associated with an increased risk of NAFLD (pooled OR = 1.32; 95% CI: 1.00–1.75), while higher dietary magnesium intake was inversely associated with NAFLD risk (pooled OR = 0.59; 95% CI: 0.39–0.91). A borderline inverse association was observed for lower serum calcium. No significant associations were identified for phosphorus, selenium, or the Ca/Mg ratio. Sensitivity analyses supported the robustness of the findings, and no significant publication bias was detected (Egger's test: t = 1.71, p = 0.0992).

Conclusion: Elevated blood calcium appears to confer increased risk, while dietary magnesium may offer protective benefits. These findings may inform future dietary recommendations and preventative strategies in NAFLD management.

Keywords: NAFLD, Micronutrients, Risk assessment

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Effectiveness of sodium intake among athletes: A comprehensive systematic review

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Introduction: Though many studies support sodium intake among athletes for various reasons, evidence of its effectiveness remains inconclusive. Sodium plays a vital role in fluid balance and thermoregulation, and its depletion during intense or prolonged exercise can lead to serious outcomes such as exercise-associated hyponatremia. This systematic review evaluates current evidence on sodium intake to better understand its role in preventing performance decline and heat-related illness in athletic populations.

Aim: To clarify the role of sodium products among athletes.

Methods: A comprehensive literature search was conducted in PubMed, Scopus, Embase, and Cochrane from inception to January 2025. Interventional and observational studies assessing the effect of sodium or its products in any type of athlete were included. Improved athletic performance and reduced heat-related illness were primary outcomes, while adverse effects were secondary. The Cochrane Risk of Bias Tool-2 and Newcastle-Ottawa Scale were used for quality assessment of RCTs and observational studies. Findings were analyzed by sport type to identify potential variations in efficacy.

Results: A total of 19 out of 792 screened studies met inclusion criteria, comprising 12 randomized controlled trials and 7 observational studies. The majority investigated endurance sports (cycling, running), where sodium supplementation consistently improved performance outcomes like race completion times and cycling velocity. In contrast, studies of other sports (swimming, wrestling) showed minimal benefits. Among endurance athletes, sodium intake demonstrated protective effects against heat-related illness, though certain formulations (particularly sodium bicarbonate) were associated with increased gastrointestinal complaints. The observational studies generally supported these findings but with less consistent effect sizes compared to RCTs.

Conclusions: Sodium supplementation benefits endurance sports most clearly, enhancing performance and reducing heat risks. Effects are limited in other sports. Sport-specific approaches considering individual tolerance are recommended. Further research is needed to refine guidelines on optimal sodium use across different sports.

Keywords: athlete, sodium, sports

D1/P190

Statin and risk of amyotrophic lateral sclerosis: An active-comparator, new-user cohort study

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Introduction: Amyotrophic lateral sclerosis (ALS) is a progressive and fatal neurodegenerative disorder. Elevated circulating low-density lipoprotein (LDL) cholesterol is associated with an increased risk of ALS onset. Previous studies have explored the relationship between statin use and ALS onset. However, findings have been conflicting, possibly due to methodological limitations, such as confounding by indication and failure to account for baseline differences in LDL cholesterol levels. Robust comparative studies are warranted to clarify the role of statins in ALS onset.

Aims: To evaluate the effect of statin use on ALS onset in patients with hypercholesterolemia.

Methods: We conducted an active-comparator, new-user cohort study using two Japanese administrative claims databases from April 2012 to February 2024. Patients with hypercholesterolemia who initiated statins or ezetimibe after at least 365 days of baseline observation and without prior ALS diagnosis were included. The outcome was incident ALS defined as a first definitive diagnosis of ALS. A Cox proportional hazards model was used to estimate the hazard ratio of statins versus ezetimibe. Inverse probability of treatment weighting using propensity scores was applied to adjust for confounding. A fibrate user cohort was analyzed for benchmarking.

Results: The study included 607,292 statin users, 26,963 ezetimibe users and 114,871 fibrate users. The incidence rate per 100,000 person-years of ALS was 6.8, 15.9, and 4.3, respectively. The adjusted hazard ratio for statins compared with ezetimibe was 0.42 (95% CI, 0.19–0.92). Prior to treatment initiation, mean LDL cholesterol levels exceeded 160 mg/dL equally in both the statin and ezetimibe users.

Conclusions: This study suggests that statins lower the risk of ALS onset compared with ezetimibe in patients with hypercholesterolemia. This potential protective effect of statins may not be solely attributable to their lowering effect on circulating LDL cholesterol.

Keywords: Amyotrophic lateral sclerosis; statins; administrative claims database

D1/P191

Factors associated with improved patient reported outcomes in coronary artery disease

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Introduction: Coronary artery disease (CAD) remains a leading cause of death and loss of Disability Adjusted Life Years in India and globally. Despite therapeutic advances, patients often experience symptoms that affect their quality of life. Traditional clinical markers do not fully capture patient experiences, making patient reported outcome measures (PROMs) essential for understanding treatment outcomes from the patient's perspective. To our knowledge, this study is the first to assess the percentage improvement in angina symptoms after medication using PROMs.

Aims: To identify factors associated with improvement in PROMs among patients with CAD.

Methods: A prospective cohort study was conducted from November 2022 to April 2023 in hospitalised patients with CAD. The 19-item Seattle Angina Questionnaire (SAQ) was administered through face-to-face interviews at baseline and via telephone at one-month follow-up. Patients who did not provide consent were excluded. The SAQ scores were compared before and after therapy to assess changes. A total of 117 pre-specified variables—including socio-demographic, clinical, medication-related factors, potential drug-drug interactions, and drug-related problems—were selected based on literature and clinical relevance. These were analysed using chi-square tests and multivariable linear regression to identify predictors of PROMs improvement.

Results: Of the 61 patients, 98.24% showed improvement in SAQ scores, with a mean (SD) increase of 30.17 (13.9)%. Regression analysis identified occupational status [r^2=0.126, p<.01], use of beta blockers [r^2=0.11, p<.05], and use of gastrointestinal medications [r^2=0.12, p<.05] as significant predictors. Together, these explained 30.4% of the variance in PROMs improvement [r^2=0.30, p<.01].

Conclusions: Occupational status and medication use, particularly beta blockers and GI medications, significantly influenced PROMs in patients with CAD. These findings underscore the need to consider socio-clinical factors in treatment evaluations. Further studies should explore causal mechanisms underlying these associations.

Keywords: coronary artery disease, patient reported outcome measures, Seattle Angina Questionnaire.

D1/P192

Effect of concomitant use of statins and direct oral anticoagulants

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Introduction: The potential for clinically relevant drug-drug interactions between direct oral anticoagulants (DOACs) and statins in atrial fibrillation management remains uncertain.

Aims: This study aimed to evaluate the risks of clinical outcomes associated with DOACs plus statins in patients with atrial fibrillation.

Methods: We conducted a cohort study and a six-parameter model case-crossover study, using electronic health records from the Hospital Authority of Hong Kong between 1 Jan 2011 and 31 Dec 2023. The cohort study compared hazards of hospitalised and emergency adverse outcomes (major bleeding, cardiovascular diseases, all-cause mortality) in DOACs plus CYP3A4/P-glycoprotein-inhibiting statins (interacting) users with DOACs plus non-interacting statins users. The case-crossover study compared the odds of exposure to different drug initiation patterns associated with adverse outcomes in the hazard period with the referent period.

Results: Of 145,394 people with atrial fibrillation, 31,466 co-prescribed DOACs and interacting statins and 2,822 co-prescribed DOACs and non-interacting statins. In cohort design, we observed no difference in the hazard of bleeding and cardiovascular diseases but a higher hazard of all-cause mortality in DOACs plus interacting statins users (hazard ratio with 99% confidence interval: 1.36 (1.02-1.82), compared to DOACs plus non-interacting statins users. In the case-crossover design, odds ratios for all outcomes in drug-interaction-related initiation patterns were not higher than initiating DOACs-monotherapy or statins-monotherapy patterns.

Conclusions: We found no evidence of higher risks of bleeding and cardiovascular diseases associated with DOACs plus interacting statins versus DOACs plus non-interacting statins. The results of the case-crossover study suggested that residual between-people confounding is likely to explain the elevated hazard of all-cause mortality observed in the cohort design.

Keywords: direct oral anticoagulants, statins, drug-drug interactions

D1/P193

Evaluating the Impact of Anticholinergic Burden on Fall and Fracture.

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Introduction: Observational studies have shown association between recent elevated anticholinergic burden and a higher risk of falls and fractures, while this association may not be directly attributable to the anticholinergic burden itself, but the underlying indication for which the medications were prescribed.

Aims: To evaluate the association between a transient increase in anticholinergic burden and risk of falls and fractures.

Methods: We conducted a case-case-time-control study using National Health Insurance Research Database in Taiwan. We included individuals over 65 who were hospitalized or admitted to emergency room due to falls and fractures, using admission date as index date. Future cases were those occurring 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 categorized the sum of Anticholinergic Cognitive Burden Scale (ACB) into three groups: 0, 1-2, 3+ points, using conditional logistic regression to estimate effect of anticholinergic burden on risk of falls and fractures. We also conducted subgroup analysis by osteoporosis, dementia, Parkinson disease and comedications related to fall and fracture, including alpha blocker, benzodiazepines and antiacids.

Results: We included 434,322 patients, with a mean age of 77 and 36% male. 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 associated with an increased risk of falls and fractures. Results of subgroup analysis were consistent with the main findings.

Conclusions: Our findings suggest an association between recently elevated anticholinergic burden and an increased risk of falls and fractures. We recommend that clinicians monitor cumulative effects from multiple drugs with anticholinergic properties to prevent acute risk of falls and fractures.

Keywords: anticholinergic burden, fall and fracture

D1/P194

Diabetes-Medication Use and Dementia at End-of-Life in the United Kingdom and Australia.

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Introduction: People living with dementia and Type 2 Diabetes (T2D) are predisposed to an increased risk of adverse drug events (ADEs) from T2D medication. Deprescribing or de-intensifying T2D medication regimens in this population could reduce the risk of ADEs and is often recommended in those approaching end-of- life.

Aims: To investigate the prevalence of T2D medication use in the last year-of-life in people living with dementia and the patient-level factors associated with discontinuation in the 6-months prior to death.

Methods: We used linked hospital and administrative data for individuals in the United Kingdom (UK) and Victoria, Australia. The cohort included individuals with data available for at least 12-months prior to death between July 2012 and June 2018. Logistic regression estimated the association of co-variates such as age, sex, cardiovascular disease, chronic kidney disease (CKD) and cancer with discontinuation of T2D medications.

Results: 10,016 individuals from the UK and 6,436 from Australia were identified. Those aged 85+ made up 55.8% of the UK and 37.7% of the Australia cohort. In both datasets there was little reduction in use of T2D medications, the largest change was observed in prevalence of insulin supply with a 25.6% (UK) and 43.5% (Australia) reduction in use in the last 3-months-of-life compared to use at 12-months. CKD was associated with higher odds of discontinuing metformin in the UK (OR 1.05, 95% CI 1.03–1.07) and Australia (OR 1.60, 95% CI 1.15–2.12). Those aged 85+ had an increased likelihood of discontinuation for sulfonylureas in Australia (OR 1.67 95% CI 1.16–2.40).

Conclusions: Despite observing some discontinuation of T2D medications, over half of individuals were supplied one or more of these mediations in the final 3-months-of-life. To increase comfort and minimise potential ADEs, strategies to facilitate deprescribing of T2D medications near end-of-life need to be explored.

Keywords: multi-database, dementia, type-2-diabetes

D1/P195

Serial Cross-sectional Analysis for nationwide polypharmacy reduction after policy implementation during COVID-19

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Introduction: Polypharmacy is a global health issue among older adults, and Japan is not an exception. In March 2021, operational instructions to introduce polypharmacy management systems in hospitals were released. Additionally, revisions to the medical reimbursement system, including provisions related to polypharmacy, were enacted by the Ministry of Health, Labour and Welfare (MHLW) in April 2022.

Aims: This study aimed to analyse the nationwide polypharmacy reduction in Japan after newly implemented national policies during the COVID-19 pandemic.

Methods: This study employed a serial cross-sectional design using annual prescription-based reimbursement claim data from a national database covering fiscal years (FY) 2020 (April 2020–March 2021), 2021 (April 2021–March 2022), and 2022 (April 2022–March 2023). Older adults were defined as 75 years and older, according to the academic definition in Japan. The primary outcome was the polypharmacy proportion (PP), calculated as the percentage of annual prescriptions containing seven or more medications out of the total number of annual prescriptions. Data from 335 secondary medical areas (SMAs), officially designated by the MHLW as regional healthcare units, were used as samples.

Results: The mean (95% CI) PP across all SMAs (n=335) was 4.16% (4.04–4.27) in FY2020 and 3.86% (3.76–3.97) in FY2022. A statistically significant decrease was observed ($p < 0.001$, paired t-test), and the reduction ratio of PP is 7.21% from FY2020 to FY2022.
Stratification analysis by sex and age group showed that the PP decreased from FY2020 to FY2022 among males (4.14% to 3.90%), females (3.31% to 2.96%), and those aged 75 years and older (6.41% to 6.04%), respectively.

Conclusions: A significant reduction in nationwide polypharmacy was observed after the implementation of new policies during the COVID-19 pandemic in Japan.

Keywords: polypharmacy, policy, COVID, older adults

D1/P197

Clusters of psychotropic and health service use in Australian living with dementia

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Introduction: Psychotropics are commonly used in people with dementia. Health service utilisation is important in managing both dementia-related symptoms and multimorbidity. However, patterns and clusters of psychotropic and health service utilisation among people with dementia remain poorly understood in the Australian context.

Aims: To identify factors associated with different clusters of psychotropic and health service use, and assess their association with mortality in Australians with dementia.

Methods: This cohort study utilised linked 2021 Census, death registration, Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Scheme (MBS) data. People with dementia aged ≥65 years in Australia were included in the study in 2021. Latent class analysis involving 16 variables, including different classes of psychotropics (antipsychotics, opioids, antidepressants, antiepileptics, benzodiazepines and Z-drugs), chronic health service use (such as chronic disease management plans and medication review), mental and physical healthcare (such as allied health and psychiatrist visits). Binary logistic regression was used to identify factors associated with class assignment. Association with 12-month mortality was assessed using Kaplan Meier curves.

Results: Overall, 177,809 people with dementia were included. A five-class model was selected with groups described as (1) low psychotropic use, high chronic disease management (35.4%), (2) low psychotropic use, low health services use (33.9%), (3) high psychotropic use, high chronic disease management (13.4%), (4) high psychotropic use, low health service use (14.5%) and (5) high psychotropic use, high mental health service use (2.8%). People with dementia residing in remote/regional areas were less likely to belong to classes with high health service utilisation. Despite high psychotropic use, the class with high mental health service use was associated with the lowest mortality ($p < 0.001$).

Conclusions: Health services have the potential to improve mortality outcomes in individuals with dementia; however, significant disparities in access to these services persist across Australia.

Keywords: Psychotropics, People with dementia, healthcare utilisation

D1/P198

Antipsychotics and risk of falls/fractures in dementia: a systematic review and meta-analysis

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Introduction: Dementia is a neurodegenerative condition that impairs daily functioning. Antipsychotics (APs) are frequently prescribed to manage behavioral symptoms in dementia; however, their potential role in increasing fall and fracture risk remains unclear due to inconsistent evidence.

Aims: To investigate the risk of falls and fractures associated with AP use in dementia people.

Methods: PubMed, Scopus, Cochrane Library, and ClinicalTrials.gov were searched up to January 23, 2025. Randomized controlled trials (RCTs) and observational studies reporting fall or fracture risk in dementia people using APs versus placebo or non-use were included. Pooled risk ratios (RRs) and 95% confidence intervals (CIs) were calculated using a random-effects model, with RCTs and observational studies analyzed separately.

Results: Twenty-four studies (10 RCTs and 14 observational studies) met the inclusion criteria. Findings from the RCTs indicated that AP use did not significantly increase the risk of falls compared to placebo (pooled RR=1.01, 95% CI: 0.84-1.21, p=0.952, I^2=0.0%), which was consistent with the results from observational studies (pooled RR=1.10, 95% CI: 0.79-1.51, p=0.575, I^2=80.5%). However, subgroup analysis revealed that typical APs were significantly associated with increased risk of falls (pooled RR=2.08, 95% CI: 1.32-3.26, p<0.001, I^2=0.0%). For fractures, RCTs showed no significant increase in risk (pooled RR=0.88, 95% CI: 0.25-3.09, p=0.847, I^2=46.6%). In contrast, observational studies demonstrated a significant association between AP use and increased fracture risk (pooled RR=1.44, 95% CI: 1.27-1.64, p<0.001, I^2=96.6%), including both typical (pooled RR=1.57, 95% CI: 1.03-2.41, p=0.04, I^2=26.7%) and atypical APs (pooled RR=1.23, 95% CI: 1.07-1.43, p<0.001, I^2=0.0%)

Conclusions: Overall, APs were not associated with increased fall risk, except typical APs. Observational data suggested a higher fracture risk with both typical and atypical APs. These findings underscore the need for cautious prescribing of typical APs and further studies to assess long-term safety of APs in dementia people.

Keywords: Dementia, Antipsychotics, Fractures

D1/P199

Feasibility study on polypharmacy using a deprescribing payment scheme in Japan

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Introduction: Multimorbidity and polypharmacy are nowadays prevalent in many countries. Deprescribing based on medical advice could be a countermeasure for polypharmacy, but identification of deprescribing from the healthcare database is often challenging. In 2020, Japan introduced a financial incentive for deprescribing focusing on hospitalized patients who lived with polypharmacy, with its real-world application understudied.

Aims: To characterize the profiles of patients assigned a reimbursement code for deprescribing in the claims-based database.

Methods: We analyzed an employee-based health insurance claims database (> 10 million individuals) in Japan from 2020 to 2022, in which prescriptions were traceable across all medical institutions. We identified patients assigned a reimbursement code for deprescribing at hospital discharge, and summarized medication usage at the 4-digit ATC level. Only oral medications prescribed at outpatient visits were included for analysis. In this study, regular or chronic medication use was operationally defined as a total of ≥28 days within 6 months prior to deprescription.

Results: A total of 73 patients were identified. Among them, 59% were male, and the median age was 58 years (range: 13–74 years). We unexpectedly found that only 8 patients (11%) were regularly prescribed ≥5 medication classes. As post-hoc analyses, we varied the ATC classification level and changed the definition of regular use, but the results remained largely unchanged. Finally, when the threshold for regular use was lowered to “a total of ≥7 days”, 61 patients (84%) had prescriptions from ≥5 medication classes.

Conclusions: In our study population with a limited sample size, deprescribing under Japan’s national health insurance system was mostly applied to medications with relatively short-term use. These findings suggest that there may be limited opportunities to study chronic polypharmacy through the current payment scheme for deprescribing.

D1/P200

Marijuana use accelerates biological aging among adults: Mediating role of blood cadmium

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Background: Marijuana use is rising globally amid expanding legalization. Although prior studies suggest potential epigenetic effects, its relationship with systemic biological aging remains unclear. This study aimed to investigate the association between marijuana use and accelerated biological aging, and to preliminarily explore the mediating role of metal exposure.

Methods: We analyzed data from 12,806 U.S. adults aged 20–59 years from the 2005–2018 NHANES. Marijuana use was self-reported via structured interviews. Biological age (BA) was estimated using two validated algorithms, PhenoAge and KD-BioAge. Biological aging acceleration was then defined as the difference between BA and chronological age (CA), with positive values indicating accelerated biological aging (e.g., PhenoAge delta = PhenoAge – CA). Survey-weighted linear regression models, subgroup and joint exposure analyses, and mediation models assessing serum and urinary metals were performed.

Results: Current marijuana use was significantly associated with accelerated biological aging for both PhenoAge delta (β = 0.72, $P < 0.001$) and KD-BioAge delta (β = 0.36, $P = 0.002$), independent of demographics, lifestyle, and clinical factors. Subgroup and joint exposure analyses supported consistent associations, with additive effects observed among concurrent marijuana and tobacco users. Mediation analysis identified blood cadmium as a partial mediator, accounting for 15.6% and 8.3% of the total effects on PhenoAge and KD-BioAge acceleration, respectively.

Conclusions: This study provides robust epidemiological evidence linking marijuana use to accelerated biological aging, with cadmium exposure as a potential mechanistic contributor. These findings underscore the need for greater public health attention to the long-term physiological impacts of marijuana consumption.

Keywords: Marijuana; Biological aging; Serum cadmium; Mediating effect

D1/P201

Statin Therapy for Primary Prevention in Older Patients with Chronic Kidney Disease

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Introduction: Chronic kidney disease (CKD) increases the risk of cardiovascular disease (CVD), particularly in older adults. However, there is controversy in statin use in older adults with CKD due to their underrepresentation in clinical trials. The effectiveness and safety of statins for primary prevention in elderly CKD patients require further investigation.

Aims: This study aimed to evaluate the effectiveness of statin therapy in reducing CVD and all-cause mortality among older CKD patients. It also assessed the safety of statins by examining the risk of major adverse events.

Methods: We analyzed electronic health records from Hong Kong, identifying 22,565 CKD patients aged 75–84 years and 8,811 aged ≥85 years with elevated LDL-C (≥2.6 mmol/L) between 2008 and 2015. Target trial emulation was used to estimate associations between statin use and incidence of CVD, all-cause mortality and major adverse events. Pooled logistic regression models were used to estimate intention-to-treat (ITT) and per-protocol (PP) effects.

Results: Statin therapy significantly reduced the risk of overall CVDs among patients aged 75–84 years (ITT: HR 0.94 [95% CI: 0.89–0.99]; PP: 0.86 [0.80–0.92]). A substantial risk reduction in all-cause mortality was also observed in this age group (ITT: 0.87 [0.82–0.91]; PP: 0.78 [0.72–0.84]). Among patients aged ≥85 years, statin use was similarly associated with lower CVD risk (ITT: 0.88 [0.79–0.99]; PP: 0.81 [0.71–0.92]). All-cause mortality was likewise reduced in this older cohort (ITT: 0.89 [0.81–0.98]; PP: 0.80 [0.71–0.91]). No significant increase in the incidence of myopathies or liver dysfunction was observed in either age group.

Conclusion: Statins are effective and safe for primary prevention of CVD and all-cause mortality in CKD patients aged ≥75 years, including those ≥85 years. Further research could be conducted to investigate the effects of statins on kidney function in this population.

Keywords: chronic kidney disease, elderly, statins

D1/P202

Polypharmacy, Influencing Factors, and Adverse Outcomes in Elderly Patients with Heart Failure

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Introduction: Elderly patients with heart failure (HF) often present with multiple comorbidities and complex medication regimens. However, research on polypharmacy and potentially inappropriate medication (PIM) in Asian population with HF remains insufficient.

Aims: To provide scientific evidence for improving clinical medication safety in elderly patients with heart failure.

Methods: The research studied elderly patients with HF (≥65 years) from the Ningbo Yinzhou District medical database from 2011 to 2022. We categorized them into four groups based on the number of drug types recorded during the 90-day period following their diagnosis: non polypharmacy (<5 drugs), polypharmacy (5-9 drugs), hyperpolypharmacy (10-14 drugs), and super hyperpolypharmacy (≥15 drugs). PIM was identified based on the 2019 Beers Criteria from inpatient and outpatient records. The primary outcome was a composite of cardiovascular death or HF hospitalization, while secondary outcomes included HF exacerbation, all-cause mortality, and hospitalizations.

Results: The research included 7,361 elderly patients with HF, 82.3% were prescribed five or more medications, and 53.2% had PIM. No significant differences were found between the polypharmacy and control groups, but the hyperpolypharmacy and super hyperpolypharmacy groups showed a 22% (OR, 1.22; 95% CI, 1.01-1.48) and 53% (OR, 1.53; 95% CI, 1.26-1.87) increased risks on a composite of cardiovascular death or HF hospitalization, respectively. For secondary outcomes, the super hyperpolypharmacy group had a 26% increased risk of HF exacerbation (OR, 1.26; 95% CI, 1.01-1.56), a 64% increased risk of recurrent HF hospitalizations (OR, 1.64; 95% CI, 1.27-2.12), and a 25% increased risk of recurrent all-cause hospitalizations (OR, 1.25; 95% CI, 1.09-1.44).

Conclusions: Polypharmacy and PIM use are prevalent among elderly HF patients in China. Hyperpolypharmacy and super hyperpolypharmacy are associated with worse cardiovascular and hospitalization outcomes. Interventions to optimize medication regimens—beyond eliminating PIMs—are urgently needed to improve safety in vulnerable population.

Keywords: heart failure, polypharmacy, potentially inappropriate medication

D1/P203

Evaluating Comparability Using Negative Control Outcomes in Osteoporosis

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Background: Comparability of two treatment assignments can be evaluated using negative control outcomes (NCOs); however, differing criteria for defining NCOs may lead to misinterpretation of comparability.

Objective: We aim to evaluate comparability using NCOs, applying different assessment criteria.

Method: We selected 50 negative control outcomes (NCOs) based on previous studies and clinical expertise and applied two criteria to assess comparability: (1) fewer than 5% of NCOs should be non-null, with null defined as an effect estimate crossing 1.0; and (2) fewer than 5% of NCOs should be non-null, with null defined as an effect estimate crossing the broader range of 0.75–1.3. Only NCOs with at least 100 events were included to ensure sufficient statistical power. We conducted a new user cohort study in the TriNetX US Collaborative Network comparing vertebral fracture risk between denosumab and bisphosphonates, including patients with DEXA T scores ≤–2.5 and incorporating DEXA results into 1:1 propensity score matching to address confounding by indication. Moreover, we compared our findings with a trial under a similar scenario to evaluate whether the less stringent criterion could ensure comparability. We hypothesized that, even with this less stringent criterion, our results would remain consistent with the RCT while improving comparability.

Results: After 1:1 propensity score matching, 2,195 patients were included in each group with all balanced covariates. Denosumab was associated with a lower risk of vertebral fracture (HR 0.60, 95% CI 0.43–0.85), similar to the RCT (HR 0.42, 95% CI 0.18–0.96). Using the first criterion, 2 of 16 (12.5%) NCOs were non-null, indicating lack of comparability. With the second criterion, 0 of 16 NCOs were non-null, suggesting improved comparability.

Conclusions: Applying multiple NCOs with less stringent criteria may reduce the risk of misinterpreting treatment comparability and, at the same time, enhance data usability.

D1/P204

Real-World Evidence in Drug Approval and Medical Affairs: Integration and Industry Insights

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Introduction: Real-world evidence (RWE) becomes increasingly important in regulatory and medical affairs in pharmaceutical industry, complementing randomized controlled trials (RCTs) by addressing gaps in long-term safety and effectiveness. This summary reviews how major regulatory agencies evaluate RWE during drug review, and clarifies the specific, practice-driven functions that RWE serves within Medical Affairs.

Aims:
1. Compare the roles of RWE as supportive or primary evidence across major regulatory frameworks.
2. Identify the functions of RWE in Medical Affairs and summarize methodological and procedural enablers for its adoption in routine practice.

Methods: We conducted a structured review (2018–2025) of RWE guidelines and approval records from major regulatory agencies, including the U.S. FDA, EMA, NMPA, PMDA, and HSA. The analysis examined each agency's use and approval trends of RWE, and primary applications in Medical Affairs. Quantitative data were sourced from published systematic reviews and agency reports.

Results: Regulatory frameworks now accept RWE as both supportive and, in defined scenarios, primary evidence. Between 2019 and 2021, 116 FDA approvals cited RWE; 88 influenced benefit–risk decisions and five used RWE as the primary evidence. EMA reported RWE in 40% of 2018–2019 marketing applications, supporting safety and effectiveness. NMPA's Boao Lecheng and Greater Bay Area pilots led to 13 RWE-supported approvals by 2023, formally recognizing RWE as primary, or extrapolated evidence. PMDA and HSA have also issued actionable RWE guidance. In Medical Affairs, RWE supports local evidence generation planning and gains insights from real-world practice. These impacts are enabled by strong organizational planning and effective collaboration across stakeholders.

Conclusions: RWE is now globally recognized as supportive and primary evidence in drug approval, with adoption accelerating in Asia into routine decision-making. This shift doesn't only impact regulatory pathways but also reshapes the way Medical Affairs teams drive scientific communication with stakeholders.

Keywords: RWE, drug approval, medical affairs

D1/P205

Data transportability as an underutilised method to bridge evidence gaps in Asia

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Introduction: Data transportability is a metric of external validity involving extrapolating results from a source population to a distinct target population. By incorporating real-world evidence (RWE), transportability methods can allow randomised controlled trial (RCT) findings (e.g. from Europe/US) to be applied to broader/external populations across geographies (e.g. Asia, often under-represented in pivotal RCTs), to reduce research burden and accelerate healthcare decision-making.

Aim: To review the application of data transportability in studies using Asian populations as the source and/or target.

Methods: An update to a published global review of transportability studies was conducted via MEDLINE and Embase searches in June 2025 to identify studies specifically using data from patients in Asia. Data were extracted on key study objectives and findings.

Results: A total of 10 studies were identified. Most (8/10) were proofs-of-concept, with the primary objective to demonstrate/test novel statistical methods. RWE was used most often to characterise covariates in the target population. Nine studies used RCTs as source data. Seven aimed to transport treatment effect (TE) estimates of interventions from RCTs to real-world (RW) target populations, including two studies transporting US findings to Asia (Japan, Thailand), another generalising findings from a Chinese RCT to the RW China population, and one using a Chinese source trial to predict results in European populations. The remaining three studies transported findings from multinational RCTs with trial sites in Asia to France/US RW populations. Except one methods-only paper, all noted successful transport/generalisation processes, while highlighting caution in the interpretation of transported outcomes, as some modelling assumptions may not be valid in the RW.

Conclusions: Data transportability analyses have been successfully applied using various methods, and appear particularly promising for transporting TE estimates. As there were limited examples where data transportability methods were used to bridge data gaps in Asia, future studies should investigate this application.

D1/P206

Enhancing RWE Reliability: Data Source Selection in China

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Introduction: Real-world data (RWD) is essential for generating robust real-world evidence (RWE) supporting clinical and regulatory decisions. Diverse RWD sources are available in China, such as electronic health records, claims data, and disease-specific cohorts. However, choosing the optimal data source remains challenging and impacts study quality. We address how to optimize RWD source selection to enhance RWE generation within the Chinese healthcare setting.

Aims: We aim to systematically assess China's real-world data sources and develop practical selection guidance, enhancing the reliability and applicability of real-world evidence for informed healthcare decision-making.

Methods: We summarized key elements for evaluating databases and proposed a framework to guide fit-for-purpose data source selection, highlighting critical considerations throughout. Two case studies demonstrate practical application based on specific research questions and study requirements.

Results: We catalogued an overview of the RWD landscape in Chinese Mainland and Hong Kong by identifying and characterizing widely used sources. Our evaluation covered data coverage, longitudinality, data types, information flow, and key elements vital for addressing diverse research questions.

We developed a tailored data assessment workflow to guide fit-for-purpose RWD source selection based on specific study objectives, enabling researchers to assess cases individually and identify data best suited for each research question's unique requirements.

We presented two case examples illustrating the application of this framework in selecting appropriate data sources based on study design and target population. The first example features a retrospective study utilizing regional electronic health record (EHR) database from Chinese Mainland, while the second leverages data from a Hong Kong database.

Conclusion: Our proposed framework offers a structured way to navigate China's complex RWD landscape, helping researchers align data selection with study objectives and speed feasibility assessments. Demonstrated through case studies, this approach enhances high-quality, relevant real-world evidence for healthcare.

Keywords:
Real-world data, Data source selection, China healthcare

D1/P207

Methodological considerations of knowledge-based surveys in evaluating effectiveness of risk minimization measures

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Introduction: Early-stage risk communication and knowledge adoption by target populations are essential for evaluating the effectiveness of risk minimization measures (RMM) within 12-24 months of regulatory implementation, enabling timely adjustments in healthcare practices. Knowledge-based surveys, which provide quantitative measurements of dissemination methods, perceptions of RMM, and intended actions for risk minimization, are frequently used to identify dissemination barriers and knowledge gaps. However, there is little research on recently conducted post-authorization safety studies (PASS) that focus on general principles and methodologies related to RMMs assessment through knowledge surveys.

Aims: This review aims to describe the study characteristics of recent PASS that evaluate effectiveness of RMMs through knowledge-based surveys for healthcare professionals (HCPs).

Methods: PASS evaluating the effectiveness of RMMs conducted in 2022-2024 were identified through the HMA-EMA Catalogue. Titles and full-texts were screened and study characteristics were extracted.

Results: Seventeen studies out of 720 PASS in 2022-2024 were eligible for this review. The majority of PASS were category 3 (required in the Risk Management Plan to investigate safety concerns or evaluate the effectiveness of risk minimization activities; 12/17, 70.6%), with the remaining (5/17, 29.4%) requested by regulators outside the European Union (EU). Six studies (35.3%) evaluated the effectiveness of RMMs within the GVP Module XVI recommended time window (12-24 months) following the launch or regulatory implementation of RMMs. In addition to assessing knowledge outcome (included in all studies), 11 (64.7%) studies evaluated HCPs' awareness or receipt of RMMs, 6 (35.3%) assessed RMMs utilizations, and 4 (23.5%) evaluated self-reported behaviors related to risk minimization. Among seven studies were finalized, five (71.4%) drew conclusions based on pre-defined thresholds for determining RMM effectiveness.

Conclusions: Clear understanding of methodological and data source limitations, and sources of biases is warranted to design survey studies for assessing RMMs dissemination and risk knowledge.

Keywords: PASS, RMM, survey

D2/P300

Comprehensive evaluation of maternal drug exposures and offspring autism: From nationwide database

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Introduction: Autism Spectrum Disorder (ASD) prevalence is rising globally. Prenatal medication exposure has been linked to ASD risk, but most research has focused on a narrow range of drug classes.

Aims: To perform a hypothesis-free screen of maternal Level-3 ATC drug classes and assess their associations with ASD in offspring.

Methods: Using Japan's JMDC claims database, we identified mother–child pairs with ≥1 year of maternal history before delivery and ≥2 years of child follow-up. Oral medications were classified at ATC Level 3; exposure was defined as ≥2 prescription claims during the 3-month pregnancy period. ASD at ≥2 years (ICD-10 F84) was the outcome. Multivariable logistic regression estimated odds ratios (ORs) and 95% confidence intervals (CIs): Model 1 adjusted for maternal age and child sex; Model 2 additionally for maternal psychiatric and neurological disorders; Model 3 further for indication-specific comorbidities (e.g., diabetes, hypertension, thyroid disease). Sensitivity analyses used 36- and 32-week gestational windows.

Results: Among 227 247 children, 11 872 (5.2 %) were diagnosed with ASD. In Model 1, 27 drug classes, including antipsychotics, thyroid-related, and gastrointestinal agents, showed elevated ORs. Most estimates were reduced by 10–30 % in Model 2. In fully adjusted Model 3, persistent associations remained for antiepileptics (N03A; aOR 1.30, 1.00–1.68), antithyroid agents (H03B; aOR 1.30, 1.00–1.68), laxatives (A06A; aOR 1.10, 1.01–1.20), and systemic adrenergic respiratory drugs (R03C; aOR 1.60, 1.06–2.40). Associations with psychotropic drugs attenuated to null after adjusting for maternal psychiatric history.

Conclusions: We re-confirmed the elevated ASD risk associated with antiepileptic drugs and identified novel associations with antithyroid agents, gastrointestinal motility drugs, and bronchodilators. The absolute risk attributable to these medications was very low, indicating no need for altered clinical practice. This is the first systematic evaluation of these associations and will guide future studies using causal-inference methods.

Keywords: Autism, Pregnancy drugs, Hypothesis-free screening.

D2/P301

Safety of Early Pregnancy Use of GLP-1 Receptor Agonists and SGLT-2 Inhibitors

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Introduction: The prevalence of type 2 diabetes among women of reproductive age is increasing, resulting in greater exposure to antidiabetic medications during pregnancy. Glucagon-like peptide-1 receptor agonists (GLP-1RAs) and sodium-glucose cotransporter-2 inhibitors (SGLT-2is) are commonly used non-insulin agents, but their safety during pregnancy remains uncertain. Though not recommended during conception and pregnancy due to potential risks, unintentional early exposure does occur.

Objectives: To evaluate maternal and neonatal outcomes after early pregnancy exposure to GLP-1RAs or SGLT-2is, compared to insulin or metformin, among women with type 2 diabetes.

Methods: We conducted a retrospective cohort study using data from 2019 to 2024, including pregnant women aged 12–55 years with type 2 diabetes and exposure to antidiabetic medications within 90 days before the last menstrual period and during the first 97 days of pregnancy. Descriptive statistics were used. Hazard ratios (HRs) and 95% confidence intervals (CIs) were calculated for selected outcomes.

Results: Among 777 participants, miscarriage rates were 26.0% for GLP-1RAs and 29.0% for SGLT-2is, higher than in the insulin/metformin group (9.7%). SGLT-2i exposure was associated with a significantly increased risk (HR = 1.83, 95% CI: 1.19–2.79). Preterm birth was less common in the GLP-1RA (9.8%) and SGLT-2i (8.9%) groups versus controls (15.6%), with a significant reduction for SGLT-2i (HR = 0.54, 95% CI: 0.32–0.92). No increase in major birth defects was observed. Glycemic control and neonatal birth weight were similar across groups.

Conclusions: Early exposure to GLP-1RAs or SGLT-2is may increase miscarriage risk, particularly with SGLT-2is, but does not appear to raise risks of preterm birth or birth defects. These findings suggest that unintended early pregnancy exposure may pose lower risks than previously assumed.

Keywords: Type 2 diabetes, early pregnancy, GLP-1 receptor agonists, SGLT-2 inhibitors

D2/P302

Safety of medications prescribed during pregnancy for birth outcomes: an umbrella review

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Introduction: Pregnant women frequently experience health issues; in severe cases, medications are often used, though their risks for infant health remain unclear.

Aims: To evaluate the potential effects of analgesics, antibiotics, antiemetics, and progesterone, commonly prescribed during pregnancy, on infant birth anomalies.

Methods: Systematic reviews and meta-analyses were identified through a comprehensive search. Reviews assessing associations between these medications and specific congenital anomalies or birth outcomes (e.g., low birth weight, congenital heart defects, cerebral palsy) were included. Methodological quality was assessed using AMSTAR2, and reporting quality was evaluated by the PRISMA checklist. Pooled estimates of association were extracted from each meta-analysis and evaluated by medication and outcome using the GRADE criteria.

Results: Twenty-five meta-analyses were included. Nonsteroidal anti-inflammatory drugs (NSAIDs) were associated with eight congenital anomalies. Aspirin was linked to congenital heart defects and gastroschisis. Indomethacin was associated with an increased risk of bronchopulmonary dysplasia. Acetaminophen was associated with a reduced risk of low birth weight. Antiemetics were linked to ten distinct birth anomalies. Antibiotics were associated with gastrointestinal and cardiac malformations, congenital hydrocephaly, cerebral palsy, and epilepsy. Whereas progesterone showed no significant associations with outcomes. Although most reviews met the majority of PRISMA criteria, protocol registration, handling of missing data, and assessment of the certainty of evidence were frequently unreported. Using the AMSTAR2 criteria, there were 12 high-quality reviews, 4 medium, 7 low, and 2 critically low. All significant associations between drug type and outcomes were moderate (n = 18) and high (n=1) across the GRADE criteria.

Conclusions: This umbrella review identified associations between medications and birth outcomes. While those were identified, inconsistencies between specific drugs and outcomes, selection bias, and missing protocol registration limited certainty. Potential risks to infant health should be considered when making decisions on medication use during pregnancy.

Keywords: Pregnancy, medication safety, umbrella review

D2/P303

Establishment of algorithms for identifying Potential Immune-Mediated Diseases and Pregnancy Outcomes

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Introduction: Potential immune-mediated disorders (pIMDs) and adverse pregnancy outcomes (APOs) bring significant public health burdens. However, efficiently and accurately identifying these complex cases within regional healthcare databases requires specifically developed and validated algorithms.

Aims: To enable accurate identification of pIMDs and APOs from real-world clinical data by refining a fuzzy retrieval-based diagnostic algorithm.

Methods: We conducted a validation study using data from the Xiamen Health and Medical Big Data Center (Sep 1, 2016–Dec 31, 2022). A fuzzy retrieval algorithm using Chinese diagnostic terms or ICD-10 codes was applied to identify suspected cases. A 10% random sample underwent manual chart review by two clinicians, with adjudication by a third if needed. Cases were classified as confirmed, not confirmed, or insufficient information. Positive predictive values (PPVs) were calculated as the proportion of confirmed cases among those reviewed. and refinement strategies were evaluated based on visit type, hospital level, visit frequency, and precise case retrieval strategy specificity.

Results: The PPV-optimized algorithm for identifying pIMDs cases was the presence of three hospitalizations or physician claims for pIMDs during the study period. Compared with the pre-optimization period, the number of pIMDs with PPVs >70% increased from 2 to 6. The remaining 4 pIMDs conditions demonstrated lower validity. The optimal algorithm for identifying APOs cases was Clear Chinese diagnostic name and Fuzzy Chinese diagnostic name AND ICD-10 code. Compared with the pre-optimization optimization period, the number of APOs with PPVs >70% increased from 10 to 25, while the remaining 3 APOs conditions demonstrated lower validity.

Conclusions: The initial fuzzy algorithm showed limited validity for several conditions. Refinement based on clinical encounter frequency and diagnostic specificity improved case ascertainment. These findings support the feasibility of using structured real-world data for safety signal detection in large-scale database studies.

Keywords: Potential immune-mediated disorders; adverse pregnancy outcomes; Positive predictive values

D2/P304

Refining GA Estimation in Claims-Based Pregnancy Algorithms in Korea

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Introduction: A recently developed Korean claims-based pregnancy algorithm, based on pregnancies with systemic lupus erythematosus, may enhance the identification of pregnancy episodes for observational research. However, its applicability has not yet been validated in the general pregnant population.

Aims: To evaluate and refine the performance of the existing Korean claims-based pregnancy algorithm.

Methods: The nationwide claims database from the Korean National Health Insurance Service between February 27, 2021, and December 31, 2022, was used to identify pregnancy outcomes. Gestational age (GA) was estimated based on the dates of prenatal healthcare utilization, including codes of four types of ultrasound. The Original algorithm prioritized the date from the second-or third-trimester targeted scan (TS), whereas the Modified algorithm prioritized the date of the first-trimester TS. Algorithm performance was evaluated based on the following three criteria: first, the agreement between the estimated GA and the GA included in a PB code among delivery episodes; second, comparison of estimated PB (ePB) rates with national statistics reported by the Korean Statistical Information Service (KOSIS); third, changes in ePB rate according to ultrasound code priority.

Results: Of 456,157 delivery episodes, those with a GA of less than 37 weeks were classified as ePB, with rates of 39.7% in the Original algorithm and 11.9% in the Modified algorithm. In delivery episodes with PB codes that included specified GA ranges, the Modified algorithm demonstrated higher agreement with the specified GA compared to the Original algorithm (96.4% vs. 75.2%). The ePB rate estimated by the Modified algorithm was also more consistent with the 9.4% reported by KOSIS (12.0% vs 39.8%). Algorithms that prioritized first-trimester ultrasound code estimated the lowest ePB rate.

Conclusion: The Modified algorithm, which prioritized first-trimester TS codes, improved GA estimation accuracy and reduced the GA underestimation observed in the Original algorithm.

Keywords: Algorithms, Pregnancy, Gestational age

D2/P305

First-Trimester Exposure to Specified Antifungal Medications and Major Congenital Malformations in Infants

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Introduction: Vulvovaginal candidiasis is highly prevalent among pregnant women, and its treatment is crucial. However, there is a lack of evidence regarding the risks to fetal outcomes associated with the use of antifungal medications during the first trimester of pregnancy.

Aim: This study examined the association between antifungal use during the first trimester of pregnancy and the risk of major congenital malformations (MCMs) in infants.

Methods: We conducted a cohort study using a pregnancy cohort nested in JMDC Claims Database from Japan, including women who gave birth between 2010 and 2019. Among the antifungal medications frequently dispensed or prescribed during the first trimester of pregnancy in this cohort, miconazole, oxiconazole, and isoconazole were assessed for the risk of MCMs, using clotrimazole, an antifungal medication with established safety during pregnancy, as a reference. Propensity score overlap weighting was applied to adjust for covariates, including maternal age, delivery year, maternal comorbidities, number of diagnoses and prescribed medications, and exposure to suspected teratogenic medications.

Results: Among 4,072 women who were diagnosed with vulvovaginal candidiasis and exposed to clotrimazole, oxiconazole, isoconazole, or miconazole, the overall prevalence of MCMs was 5.8% (n = 237). After applying propensity score overlap weighting, no increased risks of MCMs in infants were observed in pregnancies exposed to oxiconazole, isoconazole, and miconazole compared to clotrimazole (odds ratio [95% confidence interval]: 0.875 [0.599-1.277], 1.001 [0.611-1.640], and 0.887 [0.497-1.581], respectively).

Conclusion: There was no significant association between exposure to oxiconazole, isoconazole, and miconazole during the first trimester of pregnancy and the risk of MCMs in infants.

Keywords: vulvovaginal candidiasis, antifungal medications, malformation

D2/P306

Insulin glargine for gestational diabetes is associated with macrosomia compared with detemir

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Introduction: Insulin detemir is widely used for gestational diabetes mellitus (GDM) due to its favorable safety profile. Insulin glargine, however, has been used cautiously because of concerns about elevated insulin-like growth factor-1 and potential fetal overgrowth. Despite recent studies suggesting comparable safety, evidence on their differential effects on birth weight remains limited.

Aims: This study aimed to compare birth weight outcomes, including macrosomia (birth weight > 4,000g) and low birth weight (LBW; birth weight < 2,500g) in offsprings of mothers with GDM treated with insulin detemir or glargine.

Methods: This retrospective cohort study utilized the South Korean National Health Insurance Service (NHIS) mother-child linked database. Children born to mothers with a diagnosis of GDM were included, and outcomes were compared between those whose mothers received glargine and those who received detemir during 2010-2022. We used multivariable logistic regression to estimate propensity scores and applied overlap weighting to address potential confounding. We estimated risk ratios using Poisson regression and assessed mean differences in birth weight using linear regression.

Results: The study included 1,192 children (1,142 mothers) in the glargine group and 10,431 children (9,767 mothers) in the detemir group. Glargine was associated with a higher risk of macrosomia (10.4% vs. 7.5%) and a lower risk of LBW (7.7% vs. 10.3%), compared to detemir. After adjustment, glargine remained associated with an increased risk of macrosomia (RR=1.23, 95% CI: 1.01–1.49), but not with LBW (RR=0.89, 95% CI: 0.69–1.14). The weighted mean birth weight was higher with glargine (3,302 g vs. 3,248 g) ($p<0.001$).

Conclusion: Insulin glargine use during GDM was associated with a higher risk of macrosomia and increased birth weight compared with insulin detemir. The findings support maintaining detemir as the preferred basal insulin in GDM management.

Keywords: Gestational diabetes mellitus; Insulin treatment; Birth weight

D2/P307

Does treating genital herpes infection during pregnancy reduce placenta previa?

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Introduction: Placenta previa (PP) is a major risk factor for maternal morbidity and mortality including peripartum hemorrhage. However, strategies to prevent PP remain largely absent.Placental inflammation due to intrauterine infections is known to increase PP risk. However, specific maternal infections and their treatment effectiveness in reducing PP have not been well-investigated. Emerging literature has shown that pregnant women with genital herpes simplex virus (GHSV) infection are at higher risk of placental inflammation.

Aims: To determine whether treating women with GHSV infection during pregnancy reduces PP.

Methods: A prospective cohort study was conducted among 88,205 pregnant Kaiser Permanente Northern California members. Four cohorts were established based on GHSV infection and treatment status, treatment timing and presence/absence of symptoms during pregnancy. Cox proportional hazards regression was used to estimate the risk of PP associated with GHSV infection and its treatment, while accounting for different gestational ages at outcome (PP), timing of initial treatment, and potential confounders.

Results: Pregnant women with GHSV infection had 2.6 times higher PP risk compared to women without GHSV infection (adjusted hazard ratio [aHR]=2.62, 95% CI=2.31-2.98). Treating GHSV infection during pregnancy was associated with a 65% reduced PP risk compared to untreated GHSV infection (aHR=0.35, 95% CI=0.26-0.47).Starting treatment early in pregnancy (< 20 weeks of gestation) was more effective (aHR=0.32, 95% CI=0.23-0.44) than starting treatment after 20 weeks (aHR=0.75, 95%CI=0.36-1.58). Women with symptomatic (active) GHSV infection during pregnancy were at particularly higher risk of PP (aHR=4.99, 95% CI=4.15-6.00) than women with asymptomatic GHSV infection (aHR=1.89, 95% CI=1.59-2.23). Consequently, treating symptomatic GHSV infection was more effective, an 83% reduction in PP risk (aHR=0.17, 95%CI=0.12-0.25) than treating asymptomatic GHSV infection (aHR=0.58, 95% CI=0.35-0.97).

Conclusions: GHSV infection increases PP risk and treating GHSV infection, especially early in pregnancy and for symptomatic GHSV, is highly effective in reducing PP risk.

D2/P308

Impacts of Extreme Temperature Events on Intraoperative Hypotension: A Multicenter Cohort Study

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Introduction: Extreme temperature events (ETEs)—such as heat waves and cold spells—are becoming increasingly frequent due to climate change and are known to affect human health. However, their association with intraoperative hypotension (IOH), a modifiable risk factor for postoperative complications, remains poorly characterized. Understanding this relationship is critical for informing climate-adaptive perioperative strategies.

Aims: To assess the association between ETE exposure and both the occurrence and duration of IOH in patients undergoing major surgery.

Methods: We conducted a retrospective cohort study of 276,515 adult patients who underwent major surgery between 2015 and 2023 at three academic medical centers in China. ETEs were defined using percentile-based thresholds of daily ambient temperature over consecutive days. The primary outcome was IOH, defined as a mean arterial pressure (MAP) <65 mmHg sustained for ≥10 minutes. Multivariable logistic regression and generalized linear models were used to estimate associations.

Results: Of the total cohort, 48,023 patients were exposed to heat waves and 42,615 to cold spells. Exposure to heat waves was associated with significantly reduced odds of IOH lasting [10,15) minutes (3.56% incidence; adjusted odds ratio [aOR]: 0.89, 95% confidence interval [CI]: 0.85–0.94; P < 0.001), [15,20) minutes (2.34%; aOR: 0.89, 95% CI: 0.84–0.95; P < 0.001), and ≥20 minutes (11.88%; aOR: 0.88, 95% CI: 0.85–0.91; P < 0.001). Conversely, cold spell exposure was associated with an increased risk of IOH lasting ≥20 minutes (14.42%; aOR: 1.06, 95% CI: 1.03–1.10; P < 0.001). Stratified analysis indicated that younger female patients undergoing non-cardiac surgery were particularly vulnerable to prolonged IOH during cold spells.

Conclusions: ETE exposure is significantly associated with IOH, particularly when sustained for longer durations. These findings highlight the importance of integrating environmental risk factors into perioperative planning to improve patient safety under changing climate conditions.

Keywords: Intraoperative hypotension, extreme temperature events, perioperative risk

D2/P309

Modeling Seasonality and Ambient Temperature-Humidity Interaction Effects on Macrolide Use Patterns

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Introduction: Macrolide antibiotics are commonly prescribed for respiratory and other infections, with usage often influenced by seasonal and environmental factors. However, evidence on how temperature and precipitation affect antibiotic consumption in tropical settings remains limited.

Aim: This study aimed to investigate the relationships between seasonality, temperature, humidity, rainfall, and macrolide antibiotic use over three years among patients at a University hospital in Southern Thailand.

Methods: We analyzed 2,517 macrolide prescriptions from 2021 to 2023 at a university hospital in southern Thailand. Total Defined Daily Doses (DDDs) were modeled using a Generalized Additive Model (GAM) with a Gamma distribution and log link to handle non-normality and overdispersion. Predictors included cyclic month effects, year, total rainfall, biweekly average temperature, humidity, and lagged biweekly temperature. Climate data were sourced from Google Cloud and NASA Prediction of Worldwide Energy Resources, then linked to patient insurance registration areas. A Distributed Lagged Non-Linear Model was applied for sensitivity analysis to capture lagged temperature effects over 0–4 biweekly periods.

Results: Higher rainfall quintiles (Q3–Q5) significantly reduced macrolide use: Q3 IRR=0.45, Q4 IRR=0.41, Q5 IRR=0.38. Extreme weather events were associated with higher usage (IRR=59.1, $p<0.001$). Compared to 2021, usage was significantly lower in 2022 (IRR=0.23) and 2023 (IRR=0.13). Smooth terms for month and climate interactions were significant, suggesting seasonal and bioclimate modulation of use. Lagged temperature effects (0–4 weeks) on total DDDs of macrolides were not statistically significant--there was none of delayed temperature impact. Short-term temperature changes, therefore, did not influence macrolide consumption in this model.

Conclusions: Seasonal and bioclimatic factors, particularly the interactions between humidity and temperature, significantly influenced macrolide consumption over time. Therefore, these findings highlight the complex climatic impacts on antibiotic consumption in the context of environmental pharmacoepidemiological studies.

Keywords: Macrolide, Seasonality, Environmental Pharmacoepidemiology

D2/P310

Gastric acid suppressants and peritonitis in peritoneal dialysis: a target trial emulation

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Background: Gastric acid suppressants, including proton pump inhibitors (PPIs) and histamine H_2-receptor antagonists (H_2RAs), are widely prescribed. However, evidence regarding their association with peritonitis risk in peritoneal dialysis (PD) patients remains inconsistent.

Objectives: To evaluate the association between incident PPI or H_2RA use and peritonitis risk among PD patients, compared to non-users, employing a target trial emulation framework with sequential analyses.

Methods: We conducted a cohort study with target trials frame with sequential emulating monthly initiation cohorts from January 2006 to December 2019 using a PD cohort identified in Hong Kong. Exposure was defined by PPI or H_2RA prescription in the index month. A multinomial logistic regression model estimated propensity scores for exposure group (PPI, H_2RA, non-user), incorporating age, sex, comorbidities, and anticoagulant/antiplatelet use. Inverse probability weighting was used to balancing baseline characteristics. Peritonitis risk and mortality risk at 5 years, both risk ratio and risk difference were estimated using pooled logistic regression. 500 bootstrapping was used for 95% confidence interval (95% CI). Subgroup analyses by sex and age (<65 vs. ≥65 years) were performed.

Results: 240,431 person-trials were analysed, with 0.8% (n=2,113) for PPIs and 1.5% (n=3,654) for H_2RAs. IPW balanced most covariates (SMD<0.1), except diabetes and pre-baseline drug use. Both PPIs and H_2RAs users were associated with significantly increased peritonitis risk compared to non-users: H_2RA (RR: 1.36, 95% CI: 1.23–1.51) and PPI (RR: 1.87, 95% CI: 1.60–2.18). All-cause mortality risk was similarly elevated: H_2RA (HR: 1.42, 95% CI: 1.34–1.51) and PPI (HR: 2.32, 95% CI: 2.16–2.50).

Conclusions: PPIs or H_2RAs was associated with higher peritonitis and all-cause mortality risk in PD patients compared to non-use, with PPIs demonstrating greater risk. These findings highlight the critical need for judicious prescription and risk-benefit assessment of gastric acid suppressants in this vulnerable population.

D2/P311

Lithium Discontinuation Lowers Chronic Kidney Disease Risk: UK Case-Control Study

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Introduction: Lithium is a first-line medication for the treatment of bipolar disorder. Previous studies indicated that long-term use of lithium would lead to an increased risk of chronic kidney disease (CKD). There is a notable absence of population-based studies examining the impact of lithium discontinuation on CKD. Investigating the discontinuation effect of lithium on the risk of CKD would inform clinical decisions.

Aims: This study aimed to investigate the association between lithium discontinuation and the risk of developing CKD.

Methods: A nested case-control study was conducted using data from IQVIA Medical Research Data (IMRD) database, which covers a representative number of general practices and individuals in the United Kingdom. Individuals aged 18 or above with lithium prescriptions of over 90 days were identified, and two groups were compared: individuals who had developed CKD as cases; and individuals who had not developed CKD as controls. The discontinuation duration was included as a continuous exposure variable, adjusting for prior lithium use duration.

Results: There were 969 case participants and a total of 9,574 control participants matched for analysis, with similar mean ages between cases and controls (57.03 years vs. 56.69 years). The analysis showed that lithium discontinuation was significantly associated with lower risk of CKD, with an adjusted odds ratio (aOR) of 0.79 (95% CI: 0.77-0.80). Notably, comparing age groups, the most significant impact of lithium discontinuation on CKD risk was observed in individuals aged over 70, with a risk reduction by one-fourth for each additional year since the date of discontinuing lithium (aOR: 0.72, 95% CI: 0.67-0.77).

Conclusions: The findings suggest that discontinuation of lithium significantly lowers the risk of CKD. Close monitoring of renal functions during the use of lithium use is warranted.

Keywords: Affective mood disorder; Pharmacoepidemiology; Psychiatric epidemiology

D2/P312

Stroke risk for peritoneal dialysis patients on oral anticoagulants: a sequential TTE

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Background: Oral anticoagulants (OACs) are commonly used for stroke prevention in atrial fibrillation (AF), but their effectiveness and safety in individuals with peritoneal dialysis (PD) remain uncertain due to limited and conflicting evidence.

Objectives: To assess the association between OAC use and stroke risk in PD patients using a target trial emulation framework.

Methods: Using territory-wide electronic health records from Hong Kong (2005–2019), the adults with chronic kidney disease on PD with an incident diagnosis of AF were included. A sequential trial emulation approach compared OAC initiators to non-initiators, with monthly eligibility assessment from January 2006 to December 2019. Primary outcomes were a composite stroke (ischemic/haemorrhagic/all-cause mortality) and major bleeding (haemorrhagic stroke, gastrointestinal bleeding and other bleeding events). A logistic regression including baseline covariates (age, sex, CHA_2DS_2-VASc score, comorbidities, antiplatelet use, etc) was used for propensity score (PS). PS matching (1:10) were used to emulated randomization in the target trial. Pooled logistic regression with 500 bootstraps estimated 3-year risk differences (RDs) and 95% confidence intervals. Subgroup analyses by sex and age were prespecified.

Results: Among 8,230 eligible PD patients with AF, only 81 (0.98%) initiated OACs. After matching, 81 initiators and 806 non-initiators were analysed (median follow-up: 357 days). No significant difference was observed in the 3-year cumulative incidence of: composite stroke (RD: −0.03%, 95% CI: −0.18% to 0.11%), major bleeding (RD: −0.01%, 95% CI: −0.15% to 0.12%). Subgroup analyses (age, sex) and sensitivity analyses yielded consistent null associations.

Conclusions: In this population-based study of peritoneal dialysis patients with AF or AFL, OAC initiation did not reduce stroke, mortality, or bleeding risk in PD patients with AF. These findings suggest that the benefits of OACs in this high-risk population remain uncertain.

D2/P313

Prevalence and risk-factors of CKDu in Udupi district, Karnataka: cross-sectional follow-up study

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Background: Chronic kidney disease of unknown etiology (CKDu) is emerging as a critical public health concern in several regions, with a concerning rise in incidence by 15-20%.

Objectives: This study aimed to determine the prevalence and risk factors of CKDu in Udupi district of Karnataka, with a particular focus on occupationally vulnerable populations ie., fishermen, labourers, drivers, and farmers. It also aimed to assess disease progression over a one-year follow-up period.

Methodology: A community-based, prospective-cross-sectional study was conducted using a two-stage cluster sampling technique across five outreach centres. Individuals with a history of diabetes (RBS>200mg/dl) or hypertension requiring medications were excluded. After obtaining informed consent, participants were interviewed in their preferred language (English or Kannada) using a pre-validated questionnaire. Anthropometric data were collected and biological samples were obtained for analysis of urinary albumin, glucose, and serum creatinine. Participants with an estimated eGFR<60ml/min/1.73m2 were re-evaluated after 3 and 12 months to monitor disease progression. Multivariate logistic regression was used to identify independent risk factors, with all analyses performed using SPSS vs 20.

Results: The overall prevalence of CKDu was 4.7% among the 1359 screened individuals. The majority of participants were labourers (32%,n=435), followed by fishermen (28%,n=381) and drivers (25%,n=340). Significant associations were observed between CKDu and several exposures, including high pesticide use [OR:1.52(1.23-1.89)], reliance on home remedies for common illnesses [OR:1.24(1.17-1.68)], lack of sub-protective measures during outdoor work [OR:1.87(1.37-2.65)], use of well water as the primary drinking source [OR:2.1(1.58-2.90)]and frequent use of aluminium cooking vessels [OR:1.32(1.04-1.78)]. These risk factors remained consistent among follow-up participants. Loss to follow-up was minimal (0.3%).

Conclusion: The study reported a 4.7% prevalence of CKDu in the Udupi district in the high-risk occupational group. Modifiable environmental and occupational exposures were significantly associated with CKDu. The findings suggest an urgent need for public health interventions and community awareness.

D2/P314

Nationwide expansion of home dialysis after new policies in 2022 and 2023

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Introduction: Chronic kidney disease (CKD) and its progression to end-stage kidney disease (ESKD) represent major global public health concerns. Home peritoneal dialysis (HPD) and home hemodialysis (HHD), although cost-effective and beneficial for patients quality of life (QOL), remains underutilized in Japan, with only about 3.1% for HPD and 0.2% for HHD of entire dialysis patients. In response, the 2022 revision of the medical fee introduced ICT-based measures to enhance the quality of HPD (1,150 JPY). In 2023, CKD management guidelines were updated, and the importance of home dialysis were emphasized for patient QOL.

Aim: This study analyzes the effectiveness of new policies in 2022 and 2023 in expanding the nationwide use of HPD in Japan. Differential trends across predefined age cohorts were then analyzed.

Methods: A serial cross-sectional study design was adopted using open data from the National Database (NDB). Data from fiscal year (FY) 2021 (April 1, 2021 – March 31, 2022) through FY2023 (April 1, 2023 – March 31, 2024) were extracted. The number of the HPD management fee (40,000 JPY) and the number for HHD management fee (100,000 JPY) were defined as outcomes. Subgroup analyses by age group (20–44 years, 45-64years, 65-74years and ≥75 years) were performed, and year-over-year percentage changes were calculated.

Results: HPD claim counts increased from 114,553 in FY2021 to 122,424 in FY2023 (6.9 % up), and HHD claim counts rose from 9,276 to 9,655 over the same period (4.1 % up). In stratification analysis, the ≥75 years group of HPD claims increased from 27,227 to 31,377 claims (15.24 % up), representing the highest growth among age groups.

Conclusion: Substantial expansions were observed for home dialysis after the new incentives for HPD in 2022 and home-dialysis promotion by CKD guidelines in 2023.

Keywords: Home peritoneal dialysis (HPD), Home hemodialysis (HHD), National Database (NDB)

D2/P315

Assessment of Clinical Pharmacist Intervention on Drug-Related Problems in Neurological Patients

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Background: Drug-related problems (DRPs) are prevalent safety concerns for patients with neurological disorders due to complex medication regimens.

Objective: To assess DRP rates and patterns in patients with neurological disorders through clinical pharmacist integration and describe recommendation acceptance rates.

Methods: Six-month prospective interventional study in Neurology Department of a tertiary care hospital. Patients aged ≥18 years, >24-hour hospitalization were monitored for DRPs and ADRs using a patient-centric clinical pharmacist intervention model involving daily medication review and therapeutic recommendations.

Results: Among 200 patients reviewed (112 males, 88 females; mean age 52.3±16.7 years), 310 prescriptions were analyzed, identifying 306 DRPs. A total of 174 patients (87%) experienced at least one DRP, averaging 1.75 DRPs per patient: 89 patients (51.1%) had one DRP, 52 patients (29.9%) had two DRPs, and 33 patients (19.0%) had three or more DRPs.

Drug-drug interactions comprised 254 cases (83%), ADRs 12 cases (4%), drug duplications 9 cases (3%), inappropriate drug selection 15 cases (4.9%), dosing problems 10 cases (3.3%), and therapeutic duplication 6 cases (1.8%). Among 254 DDIs, 144 (56.69%) were pharmacokinetic and 110 (43.3%) pharmacodynamic. Pharmacokinetic interactions included 113 metabolic changes (78.47%), 18 absorption changes (12.5%), and 13 distribution/elimination changes (9.03%). Pharmacodynamic interactions showed 50 synergistic (45.45%), 35 antagonistic (31.82%), and 25 additive effects (22.73%).

Common conditions included stroke (78 patients, 39%), epilepsy (45 patients, 22.5%), Parkinson's disease (32 patients, 16%). ADRs included hyponatremia (4 cases, 33.3%), nausea/vomiting (3 cases, 25%), dizziness (2 cases, 16.7%). Causality assessment: 7 possible (58.3%), 3 probable (25%), 2 definite (16.7%). Severity: 5 mild (41.7%), 4 moderate (33.3%), 3 severe (25%).

Clinical pharmacists achieved 89.97% (275/306) recommendation acceptance, leading to therapeutic modifications in 245 patients (89.1%).

Conclusion: Substantial DRP burden, particularly DDI, demonstrates the value of collaborative clinical pharmacist interventions in optimizing neurological patient safety.

Keywords: DRP, DDI, Clinical Pharmacist intervention, ADR

D2/P316

Impact of medication information exposure on adherence to antihypertensive medication

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Introduction: Effective management of hypertension requires consistent and long-term therapy. In Indonesia, the effect of exposure to medication information on medication adherence has not been investigated. Understanding the effects of medication information exposure is essential, as informed patients are more likely to follow prescribed treatments, leading to better health outcomes.

Aims: This study investigates the relationship between exposure to antihypertensive medication information and adherence among hypertensive patients in Indonesia.

Methods: This study used secondary data from the Indonesian Health Survey 2023. Medication non-adherence, exposure to antihypertensive medication, and potential confounders such as gender, age, education level, marital status, occupation, and island of residence were assessed through self-reported single-item measures. The association between the lack of information and medication non-adherence was evaluated using multinomial logistic regression after adjusting for confounders. Odds ratios (ORs) and 95% confidence intervals (95% CIs) were reported.

Results: The 2023 Indonesian Health Survey included 877,531 individuals aged 15 years and above. However, 823,863 of these individuals did not have hypertension and were therefore excluded, resulting in a final sample of 53,668 patients with hypertension for this study. Among 53,668 patients, most were female (66.3%), married (77.4%), aged over 35 years old (95.3%), and unemployed (40.9%). The majority (68.1%) had received information emphasizing the need for regular antihypertensive medication. After adjusting for age, education, marital status, occupation, islands of residence, and duration of hypertension, not receiving information about the continuous use of antihypertensive medication was significantly associated with medication non-adherence (AOR=5.05; 95% CI=4.84–5.26; p-value = 0.000).

Conclusion: This study demonstrates a strong association between a lack of exposure to information regarding long-term antihypertensive medication and non-adherence among hypertensive patients in Indonesia. Therefore, there is a need for improved communication strategies between patients and healthcare providers to improve long-term medication adherence.

Keywords: Antihypertensive, Medication adherence, Indonesian Health Survey

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A study on drug-related problems in critical care patients receiving antimicrobial agents

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Introduction: Critically ill patients are particularly vulnerable to drug-related problems (DRPs) due to complex pharmacotherapy, polypharmacy, and altered drug metabolism. These DRPs including adverse drug reactions, drug interactions, and inappropriate dosing can lead to treatment failures, prolonged hospitalization, and increased mortality. The current study focused on assessing the prevalence, types, and clinical impact of DRPs in critical care to enhance medication safety and optimize therapeutic outcomes.

Aim: To identify and resolve DRPs among critical care patients.

Methods: A six-month prospective observational study was conducted in a tertiary care teaching hospital's critical care units. Patients (≥18 years) receiving ≥1 antimicrobial agents were included (n=280); patients who were non-cooperative, referred, or terminally ill were excluded. Data were collected from case sheets, treatment charts, and interviews with patients/caregivers. DRPs were classified using Hepler & Strand's framework; adverse drug reactions (ADRs) were assessed via WHO-UMC causality and Naranjo's algorithm.

Results: A total of 433 DRPs were identified among 280 patients [155 males (55.3%) and 125 females (44.6%)], out of which 132 (30.48%) were DDIs and 103 (23.7%) were ADRs. Out of the 132 DDIs, severity analysis showed moderate drug-drug interactions (DDIs) predominated [n = 74 (56.06%)]. In the 103 ADRs, 46.6% were male and 53.39% were female. The most reported severity level was 'moderate' (Level 3) at 59.2%. It was observed that 41.75% of the ADRs were predictable and 88.35% were not preventable. Using the WHO probability scale, 53.39% were 'probable'; using Naranjo's algorithm, 76.69% were 'probable'. The outcomes of the DRPs revealed that [n = 176 (40.6%)] cases were successfully resolved.

Conclusion: DRPs, particularly moderate DDIs and ADRs, are prevalent in critical care, with low resolution rates (40.6%). Improved antimicrobial stewardship and proactive monitoring are needed to enhance patient safety and rational drug use.

Keywords: Medication safety, Drug-related problems, Critical Care Units.

D2/P318

Translation and validation of the Pharmacy Services Questionnaire in a Chinese population

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Introduction: The Pharmacy Services Questionnaire (PSQ) was developed to measure patient satisfaction with pharmaceutical care. However, it has not been translated into Cantonese-Chinese and validated in the Hong Kong population.

Aims: To develop and validate a Cantonese-Chinese-translated PSQ among native Chinese patients who have used pharmacy services at community pharmacies in Hong Kong.

Methods: The PSQ was developed and translated into Cantonese-Chinese using iterative forward-backwards translation. Subjects were recruited by convenience sampling at three community pharmacies. Internal consistency, construct validity, discriminant validity, known-group comparison and Confirmatory Factor Analysis (CFA) were performed to confirm that the Cantonese-Chinese-translated PSQ is a valid measure of its intended constructs. Qualitative think-aloud interviews were carried out to test for comprehension and content validity. The subjects' views and interpretation of each questionnaire item were also explored to determine the relevance, comprehensiveness, and adequacy of the response options.

Results: A total of 236 adult subjects were recruited to complete the Cantonese-Chinese PSQ and the Chinese 5-Level EuroQol 5-Dimension (EQ-5D-5L HK) questionnaire. Additionally, think-aloud interviews were carried out with 15 subjects. Most subjects were able to understand and interpret the Cantonese-Chinese PSQ with relative ease. The internal consistency of Cantonese-Chinese PSQ was excellent (Cronbach's $\alpha > 0.96$) for the full-scale, Friendly explanation (FE) subscale and Managing therapy (MT) subscale. CFA confirmed the hypothesised two-factor structure of the Cantonese-Chinese PSQ. Individuals with higher education levels showed statistically significantly higher satisfaction levels in the overall PSQ score and MT scale score compared to those with lower levels of education. Additionally, there was no statistically significant correlation between the Cantonese-Chinese PSQ and EQ-5D-5L HK scores, demonstrating discriminant validity.

Conclusion: The Cantonese-Chinese translation of the PSQ is a validated, reliable, and semantically equivalent instrument used to assess satisfaction towards services provided by community pharmacies.

Keywords: Satisfaction, Community pharmacy, Validation

D2/P319

Raising Awareness:The Role of Health Education in Breast Cancer Prevention Among Women

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Introduction: Breast cancer health education is an effort in our study to raise awareness and mitigate the effects of breast cancer via education on risk factors, symptoms, barriers to seeking medical help, and regular practice of BSE, with the hope that vast understanding will guide to sooner detection of the disease and to achieve high survival rates.

Aims: To evaluate the Health Education Intervention among these women after imparting education on the above aspects of breast cancer.

Methods: The study was a descriptive, cross-sectional study conducted during the year of 2017-2023 in Bengaluru. A validated questionnaire was used Pre and post intervention phase. Women within the age group of 15-65 years were included and a total of 3100 were considered for this study . The same group of individuals were analyzed before and after the health educational intervention.

Results: Almost 45.30% of participants had poor knowledge, at baseline regarding BC. This improved up to 71.90% of the subjects having good knowledge after the health education. The data also acknowledged that participants with poor knowledge of signs & symptoms of BC dropped from 45.10% to 1.5% which proves tremendous & positive impact of health education.Post-intervention the participants with good knowledge of BSE screening and practice had increased from 22.7 % to 80.3% which was almost a 4-fold rise after the education program compared to baseline.

Conclusions: This study had given the evidence that supports the improvements in women's knowledge and compliance with BSE, after health educational intervention. Hence, Health education intervention was effective in improving women's behavior and commitment to breast self- examination as a preventive measure for the breast cancer.

Keywords: Health Education, Intervention, Breast Self-Examination

D2/P320

Pharmacist-led education in acute coronary syndrome: Systematic review and meta-analysis

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Background: Medication adherence is critical in preventing recurrent events following acute coronary syndrome (ACS), yet up to 50% of patients discontinue at least one cardioprotective medication within 12 months post their cardiovascular event. Non-adherence contributes to hospital readmissions, which occur in 20% of patients within 30 days post-discharge. Pharmacist-led medication education interventions may improve adherence and reduce adverse cardiovascular outcomes.

Aims: To evaluate whether pharmacist-led medication education improves medication adherence and cardiovascular outcomes in patients following ACS.

Methods: We conducted a systematic review and meta-analysis of studies assessing pharmacist-led education interventions in adults with ACS. We searched four databases - Embase, Scopus, MEDLINE, and PsychINFO - from January 2018 (date of last review) to October 2024. Eligible studies included randomised controlled trials (RCTs), cohort studies, and quasi-experimental designs. Outcomes included medication adherence, hospital readmissions, major adverse cardiovascular events (MACE), mortality, and patient-reported outcome measures. Risk of bias and certainty of evidence were assessed.

Results: Nine studies (n = 3,946) were included in the review. Meta-analysis of three observational studies demonstrated improved long-term medication adherence (pooled OR: 1.62; 95% CI: 1.14–2.31; I^2 = 0%). Three RCTs also suggested adherence benefits, though the duration of effect varied across studies. Meta-analyses showed significant reductions in short-term (OR: 0.48) and long-term (OR: 0.47) hospital readmissions ($p < 0.01$ for both; I^2 = 0%). MACE outcomes were mixed, with one study reporting reduced cardiac-related mortality.

Conclusion: Pharmacist-led education improves medication adherence and reduces hospital readmissions in ACS patients. While mortality benefits remain inconclusive, these interventions offer a promising model for secondary prevention. A feasibility or cluster-based study is warranted to assess implementation, scalability, and cost-effectiveness to inform future policy and system integration.

Keywords: Pharmacist-led education, acute coronary syndrome, medication adherence

D2/P321

Reliability and harmonisation of DDI checkers for chronic disease: a scoping review

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Introduction: Drug-drug interactions (DDIs) pose significant risks in chronic disease management, where patients often complex polypharmacy occurs. DDIs can lead to adverse events, reduced therapeutic efficacy, and increased healthcare costs. Although digital DDI checking tools are widely recommended, concerns persist regarding their reliability and clinical validity, as supported by unharmonious DDI tool classifications.

Aim: To evaluate the reliability and harmonisation of DDI checking tools used in chronic disease and polypharmacy management.

Methods: Following PRISMA-ScR guidelines, we searched MEDLINE, Embase, Scopus, Web of Science, Google Scholar, ACM, and IEEE Xplore databases for studies published between January 2015 and April 2025 that compared ≥2 DDI checkers in chronic disease settings. Methodological quality and validity used tailored versions of QUADAS-2 and QUADAS-C. Reliability was evaluated via inter-rater reliability metrics and descriptive statistics. Data were reported descriptively.

Results: Thirty-nine studies met the inclusion criteria. The most frequently assessed tools were Micromedex, Drugs.com, LexiDrug, Medscape, Epocrates, and UpToDate, (median: 3 tools per study). Inter-rater reliability was generally low indicating limited agreement between tools (Fleiss' Kappa: –0.055 to 0.695; Cohen's Kappa: –0.065 to 0.644; Gwet's AC1 was similarly low). A few studies used Kendall's W and Kruskal-Wallis tests, reporting significant differences in identified DDIs ($p < 0.05$). Eleven studies relied solely on descriptive statistics. Many studies focused on consensus of tools, with limited studies using a reference standard such as specialised clinicians, FDA labels, or clinical outcomes. High risks of bias were identified in medication selection, reference standard quality and index comparability.

Conclusion: DDI checking tools show limited reliability and validity, with minimal consensus, raising concerns about the clinical interpretation and classification of DDIs and the validity of supporting evidence. Standardised evaluation frameworks, greater algorithm transparency, and benchmarking against clinical outcomes are needed to improve tool accuracy and harmonisation.

Keywords: drug-drug interactions, drug-drug checkers, medication safety

D2/P322

The impact of telemedicine use on adherence to antihypertensive in elderly Indonesians

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Introduction: Hypertension remains a significant public health issue. In Indonesia, hypertension is increasing among older adults, with challenges like mobility issues and limited healthcare access hindering consistent care. Telemedicine, as the use of technology to deliver remote healthcare services, including consultations, diagnosis, monitoring, and treatment, has emerged as a potential solution to enhance access to healthcare, allowing patients to manage their conditions remotely.

Aims: This study aims to investigate the impact of telemedicine usage on adherence to antihypertensive among elderly subjects with hypertension in Indonesia.

Methods: This cross-sectional study utilized data from the Indonesia Health Survey 2023, which represents the Indonesian population, focusing on subjects aged 60 years and older with hypertension. Data on medication adherence, telemedicine usage (telemedicine is the use of electronic information and communication technologies to provide and support clinical care when distance separates the participants), and potential confounders (gender, education, residence, and blood pressure monitoring) were collected via self-reported measures. The association between telemedicine usage status and medication non-adherence was evaluated using multivariate logistic regression after adjusting for confounders. Odds ratios (ORs) and 95% confidence intervals (95% CIs) were reported.

Results: Total of 21,351 elderly subjects with hypertension. The majority were female (60.87%) and lived in urban areas (61.04%). Additionally, 70.68% received information about antihypertensive use, 39.88% graduated from elementary school, and 49.61% regularly checked their blood pressure. However, 98.43% had never used telemedicine. Multivariate analysis showed a significant association between non-use of telemedicine and lower medication adherence (aOR: 1.984654; 95% CI 1.486283-2.650135; p-value 0.000).

Conclusion: Most elderly subjects with hypertension in Indonesia have never used telemedicine, which is linked to lower medication adherence. Improving medication adherence is crucial, and telemedicine offers a promising solution. Enhancing digital literacy and accessibility for the elderly, along with training programs supported by family members, can help increase telemedicine use.

D2/P323

Assessment of factors affecting self-management among type 2 diabetics: tertiary hospital study

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Introduction: Type 2 Diabetes Mellitus (T2DM) presents a significant health burden in India, necessitating strong self-management practices for optimal glycemic control. These practices encompass lifestyle modifications and psychosocial adjustments, as emotional distress and poor adherence can impair self-care and worsen outcomes. International studies on self-management often miss psychological factors affecting adherence and lack follow-up or interventions for poor self-care. This study addresses these gaps by assessing self-management in T2DM patients with validated tools, identifying related factors, and offering counseling and follow-up as needed. Understanding how sociodemographic, therapeutic, and emotional elements influence self-management is vital to improving diabetes care.

Aims: To assess factors influencing self-management among T2DM patients using Diabetes Self-Management Questionnaire (DSMQ) and Problem Areas in Diabetes (PAID-5) scales. To provide counselling for those with low DSMQ scores and evaluate outcomes.

Methods: This prospective study enrolled 140 T2DM patients from a tertiary care hospital in Bangalore, India. Baseline data on demographics, therapy, and emotional distress were collected. The DSMQ and PAID-5 scale were used for assessment. Participants with low DSMQ scores received structured counselling. A three-month follow-up assessed changes in self-care behaviors.

Results: Among 140 patients, better self-management practices were associated with age 40–59 years ($p=0.0046$), urban residence ($p=0.00027$), private-sector employment ($p=0.029$), middle socioeconomic status ($p=0.00077$), regular exercise ($p=0.031$), and absence of comorbidities ($p=0.0027$). No significant associations were found with gender, BMI, education, diet, smoking, alcohol use, or type of medication. Follow-up showed improved DSMQ scores post counselling, indicating positive behavioral changes.

Conclusions: The study found that self-management in type 2 diabetes is significantly influenced by age, urban residence, employment, socioeconomic status, exercise, comorbidities and emotional distress; while factors like gender and medication type showed no impact. Targeted counselling and interventions targeting at-risk populations improved self-management, demonstrating its effectiveness in diabetes care.

Keywords: Type 2 diabetes mellitus, DSMQ, PAID-5

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Enhancing Informed Decision-Making in Gender-Affirming Care Through Patient-Centered Education on Hormonal Therapies

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Background: Access to comprehensive, evidence-based education on the risks and benefits of sex hormone therapy (SHT) is fundamental for empowering gender minority individuals to make informed decisions about their healthcare. Equally, it equips healthcare providers with the knowledge required to offer safer, more effective, and person-centered care. In the Indian context, particularly in regional and semi-urban settings, such as Mysuru, there is a significant lack of structured guidance and educational support around gender-affirming hormone therapy. Many transgender individuals initiate SHT without formal medical supervision, which can result in inconsistent follow-up, underreported side effects, and a poor understanding of long-term health implications.

Aim: This study sought to explore the demographic and clinical characteristics of transgender individuals undergoing SHT in Mysuru and to assess their awareness, understanding, and perception of the therapy's associated risks and benefits. The goal was to identify key gaps in knowledge and clinical literacy that could hinder safe and effective hormone use.

Methods: A mixed-methods approach was employed. Twenty-three participants (20 transwomen and 3 transmen) were selected using purposive sampling. Data were collected through structured, self-administered questionnaires, capturing demographics, details of hormone use, onset year, and the type and frequency of perceived adverse effects.

Results: Most transwomen began SHT between 1991 and 2000 using oral estradiol formulations. Transmen typically used injectable or transdermal testosterone preparations. Psychiatric symptoms—especially forgetfulness—were frequently reported among transwomen, while transmen highlighted masculinizing physical changes such as hair growth. Notably, comorbidities like hypertension and diabetes were either underreported or poorly managed, indicating gaps in patient education and monitoring.

Conclusion: The findings underscore the urgent need for targeted health literacy programs and communication strategies. Culturally appropriate educational interventions are essential to ensure that gender minority individuals can safely navigate the complexities of long-term hormone therapy.

Keywords: Patient education, Gender minorities, Hormonal risk awareness, Transgender medicine

D2/P325

Pharmacy-Based Predictors of Non-Adherence and Non-Persistence in Patients with Multimorbidity

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Introduction: Multimorbidity, significantly impacts patient outcomes, often leading to adherence challenges. This study aimed to evaluate medication non-adherence and non-persistence in patients with multimorbidity and to identify associated factors.

Methods: A retrospective observational cohort study was conducted using pharmacy claims data in Lisbon from 15,944 patients with multimorbidity, collected between 2011 and 2017. Medication adherence was assessed using the Medication Possession Ratio, while persistence was evaluated using refill-sequence analysis with a 90-day grace period, both calculated based on "any-medication". Logistic regression and Kaplan-Meier analyses were employed to identify factors associated with adherence and persistence, respectively.

Results: Overall medication adherence was 68.8%. Females patients (OR1.28 95% CI 1.178– 1.39), patients with initial diagnoses of respiratory disease (OR1.94 95% CI 1.51–2.48), cardiovascular disease (OR1.79 95% CI 1.49–2.14), hypertension (OR1.64 95% CI 1.40–1.91), those with >5 total diseases (OR2.26 95% CI 1.47–3.45), 3 diseases (OR2.00 95% CI 1.82–2.20), 4 diseases (OR1.56 95% CI 1.33–1.83), and those taking >10 medications (OR 116.50 95% CI 67.47 – 201.17), 7-9 medications (OR18.12 95% CI 14.72 – 22.29), and 4-6 medications (OR5.04 95% CI 4.54 – 5.59). were associated with non-adherence medication. All p-values were< 0.001. Moreover, almost half of multimorbidity patients (41.2%) have a non-persistence. Patients with first diagnosed cardiovascular disease (1.39 95%CI 1.23–1.56; p-value <0.001) and hypertension (1.25 95%CI 1.12–1.39; p-value <0.001) had a higher likelihood of medication non persistence compared to those with diabetes mellitus, while first diagnosed bone disease patients had a lower likelihood (0.39 95%CI 0.25–0.54; p-value <0.001).

Conclusion: This study demonstrates that medication adherence and persistence are significantly compromised in patients with multimorbidity. Factors associated with medication adherence were distinct from those influencing persistence. This suggests that interventions and strategies to improve medication-taking behavior must be tailored specifically to the phase of adherence being addressed.

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Assessment of drug-related problems in prescriptions arriving to community pharmacy

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Introduction: Drug-related problems (DRPs) refer to issues in drug therapy that may disrupt health outcomes, negatively impact patients, increase healthcare costs, and lower quality of life.

Aims: This study identifies and categorizes DRPs such as incorrect dosages, inappropriate indications, duplicate prescriptions, and drug-drug interactions. It also examines associations between DRPs and factors like gender, age, and physician specialization.

Methods: A six-month prospective cross-sectional study was conducted in two community pharmacies after Institutional Ethics Committee approval (Ref No. IEC2-540/2024). Random prescription samples were assessed using case record forms (CRFs). DRPs were categorized as per the Pharmaceutical Care Network Europe (PCNE) classification system, and drug interactions were identified using Micromedex®. DRP frequencies and associations were analyzed using the Chi-square test. Data entry and statistical analysis were performed using IBM SPSS v20.0.

Results: Among 620 prescriptions reviewed, 120 (19.3%) contained at least one DRP. The mean patient age was 46.58 years, with DRPs being more prevalent in males (73 cases; 60.8%) and those aged >55 years. General medicine prescriptions had the highest DRP proportion (62 cases; 51.7%). The most common DRP was drug-drug interactions (118 cases; 98.3%), followed by inappropriate indications (1 case; 0.8%) and dosing times (1 case; 0.8%). A statistically significant association ($p<0.042$) was observed between male gender and DRP occurrence.

Conclusions: Drug-drug interactions were the most prevalent DRP, especially among elderly males. Strengthening prescription review processes may reduce these risks and improve patient safety.

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Development and Validation of Self-Administration Medication Error (SAME) tool

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Introduction: Medication errors, particularly in self-administration, are a significant risk to patient safety, leading to adverse drug events (ADEs). Studies indicate that medication errors occur in 5% to 10% of hospital inpatients, with self-administration errors contributing substantially. Existing assessment tools focus mainly on provider-administered medications, overlooking patient-administered errors. The Self-Administration Medication Error (SAME) tool was developed to address these challenges.

Objectives: To develop and validate the SAME tool in patients of a tertiary care hospital

Methods: This cross-sectional, quantitative study was conducted at Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Pondicherry, from May 2023 to April 2024. The tool was developed through a literature review and patient interviews, resulting in ten items evaluating various aspects of self-administration. Content validity was assessed by four experts using a 4-point Likert scale, and the Content Validity Index (CVI) was calculated. The tool was then tested on 100 adult patients with chronic diseases (e.g., diabetes, hypertension, cardiovascular diseases, epilepsy) attending the JIPMER pharmacy. Internal consistency was measured with Cronbach's alpha, and Pearson product-moment correlation analysis was used to assess validity.

Results: The SAME tool demonstrated strong content validity, with all items achieving a CVI of ≥0.88 and an overall Scale-Level CVI (S-CVI) of 1.0. Cronbach's alpha was 0.815, indicating good internal consistency. Pearson correlation coefficients for individual items ranged from 0.492 to 0.740, all statistically significant ($p < 0.05$), confirming the tool's validity. The estimated prevalence of self-administration errors among participants was 17%, emphasising the need for effective assessment tools.

Conclusion: The SAME tool is a reliable and valid for identifying self-administration errors, highlighting its potential to enhance patient safety and improve medication management. Future research should explore its application across diverse healthcare settings.

Keywords: Self-Administration, Medication Errors, Tool Development, Patient Safety.

D2/P328

Guideline-directed medical therapy adherence in heart failure management: Real-world data from India

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Introduction: Heart Failure (HF) contributes to morbidity and hospitalization in India. Despite the availability of Guideline-Directed Medical Therapy (GDMT), real-world adherence to these recommendations is suboptimal. This study evaluated GDMT adherence in an Indian tertiary care setting, quantified deviations from evidence-based therapeutic protocols, and identified barriers for non-adherence. The analysis is particularly relevant owing to the evolving HF pharmacotherapy landscape, including the recent integration of Sodium-Glucose Co-transporter-2 Inhibitors (SGLT2) into standard management protocols.

Aim: To assess adherence to GDMT in HF and identify barriers contributing to deviations in an Indian tertiary care setting.

Method: This prospective observational study was conducted at a tertiary care hospital which included 85 patients diagnosed with HF. Data were collected from hospital records, including discharge summaries and medication charts. The prescribed drug classes in HF patients were analyzed for their adherence with American Heart Association (AHA) GDMT. Further, barriers to adherence were identified by interviewing providers, stakeholders, and patients.

Results: Adherence to AHA-GDMT was identified in only 28% of patients, indicating significant deviation. Diuretics were the most frequently prescribed agents (80%), followed by beta-blockers (64.6%), SGLT2 inhibitors (38.5%), mineralocorticoid receptor antagonists (30.8%), and angiotensin receptor-neprilysin inhibitors (24.6%). Prescription rates for ACE inhibitors, ARBs, ivabradine, and inotropes were below 8%. Key barriers contributing to GDMT deviation included financial constraints, polypharmacy, and limited prescriber familiarity with newer therapies. Additionally, GDMT was deferred unless NT-proBNP levels were significantly elevated, displaying reliance on biomarker thresholds.

Conclusion: The study highlights suboptimal adherence to GDMT in HF management. Limited prescription of key drug categories, particularly SGLT2 inhibitors and angiotensin receptor-neprilysin inhibitors, signifies gaps in clinical practice. Financial barriers, prescriber unfamiliarity, and reliance on NT-proBNP levels hinder optimal treatment. These findings emphasize the need for focused strategies to improve GDMT adherence.

Keywords: Heart Failure, Guideline-Directed Medical Therapy, SGLT2 Inhibitors.

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Assessment of patient perceptions towards chronic diseases and medication adherence

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Introduction: In the current scenario, patient perceptions of diseases are frequently poor due to inadequate communication and a lack of patient-centered treatment, which leads to decreased trust in clinicians and, ultimately, poorer health outcomes such as treatment failure and lower medication adherence. This study examines how people perceive their illnesses and how effectively they follow their prescribed medications.

Aim: To assess differences in patient perceptions and medication adherence across various chronic diseases.

Methods: A prospective observational study was conducted at a tertiary care hospital in Southern India for 6 months among patients with hypertension (HTN), diabetes mellitus (DM), and rheumatoid arthritis (RA). Patient perception scores were assessed using the Brief Illness Perception Questionnaire, consisting of eight questions graded on a scale of 1 to 10. The Morisky Medication Adherence Scale (MMAS-8) was used to assess adherence, consisting of eight questions, each with a yes or no answer. MMAS-8 values of 8 indicate high adherence, 6-7 moderate adherence, and <6 low adherence.

Results: A total of 200 patients were included in the study: 104 (52%) males and 96 (48%) females. Patients' perception scores were lowest for treatment control in HTN and DM. For the other questions, patients had moderate levels of perception. Among MMAS-8 scores, 54 (27%) were low adherers, 99 (49.5%) were moderate adherers, and 47 (23.5%) were high adherers.

Conclusion: Patients demonstrated moderate levels of perception, except in the treatment control domain of HTN and DM, indicating a balanced understanding of their condition. The majority of individuals were moderate adherers, suggesting inconsistent medication use. Hence, pharmacists can play a key role in enhancing these outcomes by providing patients with education and guidance about their disease, which could empower them to take an active role in their care.

Keywords: Chronic Diseases, Perception, Adherence

D2/P330

Assessing the Effect of Pharmacist-Led Education on Medication Adherence in HIV-Positive Patients

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Introduction: Human Immunodeficiency Virus (HIV) is an infectious disease that decreases CD4 count, weakens persons immune system and further causes opportunistic infections, if left untreated. Most of the patients are still non-adherent because of pill burden, forgetfulness, stigma and lack of knowledge. Therefore, adherence is a key component in optimizing patient's therapy. Educational intervention can be an effective method in improving patient's adherence.

Aim: The objective of the study was to evaluate the impact of educational intervention on medication adherence among HIV positive patients.

Methodology: This study was conducted at two ART centers of which we included HIV positive patients above 18 years of age. Patients were randomized into two groups i.e., Control and Intervention (leaflet) group. A standard questionnaire-Medication adherence rating (MARS) scale and Drug Attitude Inventory (DAI) scale was used to assess the adherence and attitude towards the medications at baseline, 1st month, 2nd month, and 3rd month. Statistical analysis was done using SPSS software version 22.

Results: A total of 397 patients were included in the study. Results showed that at baseline there was no significant difference in the MARS and DAI scores between the two groups however, statistically significant difference was observed between the control and interventional groups at third month follow up (P-value < 0.05). The common barriers for non-adherence in control group was forgetfulness and lack of knowledge whereas in intervention group it was forgetfulness and stigma.

Conclusion: There was a significant difference in the scores of MARS and DAI between the patients of control and interventional group which showed that Patient Information Leaflet (PIL) could be an effective method in improving the adherence and attitude towards the medication in HIV patients.

Key words: HIV/AIDS, Medication Adherence, Drug Attitude, Patient Information Leaflet

D2/P331

Effect of home-based educational visits on antibiotic use among Sri Lankan mothers

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Introduction: Inappropriate antibiotic use and disposal contribute to antimicrobial resistance (AMR), particularly in low- and middle-income countries (LMICs). In Sri Lanka, mothers are primary caregivers and significantly influence household antibiotic practices, although misconceptions and improper disposal persist.

Aims: To assess the impact of home-based educational visits on mothers' KAP regarding antibiotic use and disposal in the Boralesgamuwa Medical Officer of Health area.

Methods: This study explores the effectiveness of home-based educational visits in improving mothers' knowledge, attitudes, and practices (KAP) regarding antibiotic use. A quasi-experimental study was conducted among 110 eligible mothers (aged 18–50, Sinhala/Tamil/English-speaking), divided into intervention (n=55) and control (n=55) groups. Full randomization was not feasible due to household availability and willingness. The control group received no intervention. Mothers with mental illness or sensory impairments were excluded. A pre-tested, adapted KAP questionnaire (15 knowledge: 10 use, 5 disposal, 7 attitude, 5 practice questions) was used. The intervention involved home visits, leaflets, and weekly calls. KAP changes were assessed using paired and independent t-tests via SPSS v25.

Results: The intervention group showed a statistically significant improvement in knowledge (mean score from 6.5 to 8.9; $p = 0.001$), attitudes (from 4.1 to 6.3; $p = 0.003$), and practices (from 2.7 to 4.5; $p = 0.004$). In contrast, the control group showed no significant improvement: knowledge (6.4 to 6.6, $p = 0.108$), attitudes (4.2 to 4.4, $p = 0.097$), and practices (2.8 to 2.9, $p = 0.152$). Correct disposal methods, such as pharmacy returns and burning, increased from 9.1% to 38.2%. In contrast, the control group showed minimal improvement and persistent misconceptions.

Conclusion: Home-based educational visits effectively improved mothers' antibiotic-related KAP, particularly in proper disposal practices. This low-resource, culturally acceptable approach can be integrated into national public health initiatives to mitigate AMR in Sri Lanka.

Keywords: Antibiotic, home-based educational visits, mothers

D2/P332

Mobile Diary as a tool for patient-centered rare disease management

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Introduction: Patient-reported outcomes (PROs) focus on the patient's experience and perspectives, rather than solely relying on clinical assessments. PROs provide a valuable tool for understanding the patient's voice and are increasingly considered in drug approval and reimbursement decisions, especially in lack of robust clinical and real-world evidence.1 Hereditary angioedema (HAE) is a rare genetic disorder characterized by unpredictable and heterogeneous attacks that require individualized management. While prior real-world studies have described HAE attack patterns globally and in Asia, there are limited insights on the individual attack profiles.2-4 Additionally, earlier studies typically relied on the documentation of HAE attack episodes and characteristics during physician consultations, which may introduce recall bias, resulting in an underestimation of attack frequency.4

Aims: To empower patients with HAE to describe their attack profiles and treatment patterns and provide physicians with insights on the patients' real-world setting.

Methods: A mobile application, "MyHAE Story" was developed and patients enrolled in an existing HAE patient support program were invited to access the application. The application enabled patients to record their individual attack-related and treatment details.

Results: The mobile diary enabled the capture of attack profile details, including attack location, severity, prodromal symptoms, and treatment. The diary serves as a platform for patients to record and view their past attack profiles, enabling physicians to review the records and tailor individualized treatment plans. While reminders to use the application were sent to registered users, patients were not required to use the diary. Over 200 attacks were recorded over a 12-month period.

Conclusion: While similar web-based and mobile diaries have been piloted for HAE patients, this is the first known study using mobile application-based de-identified patient-reported data to provide real-world insights into HAE attack profile and treatment patterns in Asia. With proper implementation, there is potential to be adapted for other patient groups to support patient-centered care.

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Barriers and enablers to cardiovascular medication adherence: a qualitative evidence synthesis

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Background: Cardiovascular disease (CVD) remains a global health burden. Despite the benefits of pharmacological therapy, medication adherence remains poor. Understanding the barriers and enablers across diverse settings is essential for developing effective, context-specific interventions.

Objective: To explore barriers and enablers to cardiovascular medication adherence across diverse populations using qualitative evidence synthesis.

Methods: A systematic review was conducted in accordance with PRISMA guidelines (PROSPERO registration ID: CRD42024588402). Studies were sourced from Medline, Embase, PsycINFO, and CINAHL. Purposive maximum variation sampling was used to examine key population groups: low-income countries, underserved communities, rural populations, and primary vs. secondary CVD prevention settings. Framework analysis, based on the World Health Organization's adherence model, guided the synthesis approach. Sub-framework analysis identified cross-group similarities and differences.

Results: Of 145 eligible studies, 27 were sampled. Common barriers included fear of medication side effects, limited symptom awareness, negative beliefs about medication, and poor communication with providers. Enablers included strong provider relationships, a clear understanding of treatment purpose, simplified drug regimens, and social support. Key differences emerged: individuals in primary prevention settings often reported non-adherence due to the absence of symptoms, which led to a low perceived urgency or necessity for medication. In contrast, those in secondary prevention, having experienced a cardiovascular event, expressed a stronger perceived need for medication. Structurally disadvantaged groups; including low-income populations, rural residents, and Indigenous communities, faced additional barriers such as mistrust in the healthcare system, financial hardship, travel-related burdens, and limited access to providers.

Conclusion: Improving cardiovascular medication adherence requires context-specific strategies that address systemic barriers. These findings inform the design of future interventions by emphasising the need for co-designed, patient-centred approaches that reflect diverse lived experiences. They also provide actionable insights for research, clinical practice, and health policy, supporting the development of sustainable and equitable solutions across diverse populations.

Keywords: Medication-adherence, multimorbidity

D2/P334

Stewardship of medication errors in a developing country's scenario: Clinical pharmacist's role

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Introduction: In developing countries, limited resources, understaffing, and underdeveloped reporting systems increase the risk and impact of medication errors (MEs). Clinical pharmacists play a critical role in addressing these challenges through active involvement in medication safety and error prevention.

Objectives: This study aimed to establish a medication error reporting and monitoring program in a tertiary care teaching hospital in South India.

Methods: A prospective cohort study was conducted over three years among hospitalized patients aged ≥18 years. Daily interviews with patients, caregivers, and healthcare professionals (HCPs), along with medical record reviews, were used to identify MEs and assess outcomes using the NCC MERP classification and prevention standards. Root cause analysis was performed for each error and findings were shared with relevant HCPs to reduce recurrence.

Results: Among 20,256 hospitalized patients, 1,310 MEs were reported, yielding an incidence rate of 6.4%. The most frequent types were administration errors (38.2%), followed by prescribing/transcribing (28%), and dispensing/procurement errors (17% each). Clinical pharmacists reported the majority of errors (51%), followed by nurses (31%) and doctors (17%). Most errors were classified as Category A (33%) and Category B (32%). Key root causes included distractions (472 cases), workload (422), and communication gaps (341). The most commonly implicated drug classes were analgesics (19.4%) and antibiotics (15.7%). Significant risk factors for MEs included prolonged hospital stay (OR 2.31), polypharmacy (OR 2.30), comorbidities (OR 1.79), and work shifts (OR 2.36), all at 95% confidence interval.

Conclusions: The implementation of a structured medication error reporting system led by clinical pharmacists enhances patient safety in resource-limited settings. Encouraging a non-punitive, collaborative approach among all healthcare stakeholders is essential. Clinical pharmacists are vital in sustaining this system by providing continuous surveillance, education, and system-level interventions in partnership with the healthcare team.

Keywords: Medication Errors, Clinical Pharmacist, Stewardship, Patient Safety

D2/P335

Improving comprehension of OTC drug instructions through visualization

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Introduction: Traditional over-the-counter (OTC) drug instructions are often difficult to understand due to their complex text structure, which can lead to medication errors. Enhancing the efficiency and comprehensibility of drug information is crucial for public health. This study aims to solve this problem through information visualization to improve user comprehension.

Aims: This study aimed to design, develop, and evaluate an innovative visual drug instruction leaflet. The primary objective was to validate whether the design could significantly improve the speed of information retrieval and the overall user experience while maintaining information accuracy.

Methods: This study first systematically analyzed an official over-the-counter drug database to establish a taxonomy for drug instructions. We then collaborated with pharmacy experts to develop a visual prototype through an iterative design process based on this taxonomy. Finally, a controlled user study compared the effectiveness of the visual version to the traditional text version.

Results: The visual version significantly reduced information retrieval time compared to the text version while maintaining comparable comprehension accuracy. The visual design achieved a significantly higher System Usability Scale (SUS) score, indicating better usability. Subjective feedback from participants was also more positive, as they perceived the visual design as more intuitive and easier to understand. The proposed taxonomy and design solutions were also endorsed by the consulting experts.

Conclusions: This study confirms that well-designed visualization is an effective tool for enhancing the communication efficiency and user experience of over-the-counter drug information. The proposed taxonomy and design principles can be generalized to a broader range of drugs, providing a practical reference for future drug information design.

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Trends in the Utilization, Expenditure, and Costs of Non-Insulin Glucose-Lowering Drugs

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Introduction: Diabetes mellitus is a major public health concern in the United States, with increasing prevalence and treatment costs. Over the last 15 years, new non-insulin glucose-lowering drugs (GLDs) have entered the market, offering improved outcomes but at higher prices. The rising use and cost of these medications present important implications for public health spending.

Aims: This study aimed to examine national trends in the utilization, expenditure, and average cost of non-insulin GLDs from 2008 to 2023.

Methods: We conducted a retrospective trend analysis using 2008–2023 data from the National Medicaid State Drug Utilization database. All non-insulin GLDs were categorized and analyzed for prescription volume, reimbursement amount, and average cost per prescription. Total annual figures were calculated, and drug prices were computed by dividing reimbursement by prescription counts. Data analysis was performed using Excel and SAS 9.4.

Results: Non-insulin GLD prescriptions increased by 305% from 12.9 million in 2008 to 52.3 million in 2023. Metformin dominated utilization (53%) and remained low-cost ($11/prescription in 2023). Medicaid spent $2.8 billion on metformin and $1.2 billion on sulfonylureas. In contrast, GLP-1 receptor agonists and SGLT2 inhibitors showed significant utilization growth, with combined Medicaid expenditures reaching over $50 billion. The average prices of GLP-1 receptor agonists rose to over $1,100/prescription by 2023. SGLT2 inhibitors also increased sharply in cost, reaching over $770/prescription. Total Medicaid expenditure on non-insulin GLDs surged from $746 million in 2008 to $20.4 billion in 2023.

Conclusions: While metformin and sulfonylureas remain the most prescribed and affordable non-insulin GLDs, there has been a clear shift toward newer, costlier drug classes. These trends may have substantial implications for future diabetes care spending in the United States.

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Clinical and cost-effectiveness of NSTEMI management with kidney-impairment during the COVID-19 pandemic

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Introduction: People with reduced kidney function experience worse outcomes following non-ST elevation myocardial infarction and are largely excluded from relevant clinical trials. Thus, there is clinical uncertainty about the benefits versus risks of early invasive versus conservative NSTEMI management in this population, and to what extent management strategies changed during the COVID-19 pandemic.

Aims: To evaluate variation in NSTEMI management during the COVID-19 pandemic, and use this variation to study the clinical and cost-effectiveness of early invasive versus conservative NSTEMI management among people with reduced kidney function.

Methods: We used data from the British Heart Foundation Secure Data Environment (English primary and secondary care) to describe variation in NSTEMI management during the COVID-19 pandemic. This variation was used to compare the clinical and cost-effectiveness of NSTEMI management in an instrumental variable analysis to reduce the risk of unmeasured confounding. Our primary clinical outcome was all-cause death at 1-year. We triangulated our results with other analytical methods (including clone-censor-weighting) to consider other biases (namely, immortal time bias).

Results: We included 16,655 adults who presented with NSTEMI between Nov-2019 and Dec-2024 and who had an estimated glomerular filtration rate <60ml/min/1.73m2. Using the hospital's tendency to manage early invasively vs conservatively as an instrumental variable, amongst those who survived the first 7 days of the admission, there was no evidence of a benefit of early invasive management on 1-year all-cause mortality (Hazard Ratio (HR) 0.84, 95% Confidence Interval (CI) 0.46 to 1.44), and uncertain cost-benefit (-£243, 95% CI -£4,386 to £3,900). The clone-censor-weighted analysis (addressing immortal time bias) was biased by unmeasured confounding (HR 0.65, 95% CI 0.63 to 0.67).

Conclusions: In patients with NSTEMI and reduced kidney function, there is no evidence that a strategy of early invasive management improves survival or lowers costs compared to using a conservative management strategy.

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Prices and affordability of essential medicines in Sri Lanka after economic crisis

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Introduction: The 2022 economic crisis in Sri Lanka raised uncertainty regarding prices and affordability of essential medicines (EMs).

Aims: This study aimed to assess the impact of the economic crisis on the prices and out-of-pocket affordability of selected EMs in private pharmacies in Sri Lanka.

Methodology: The World Health Organization/Health Action International methodology was adopted to assess the prices and affordability of EMs in private pharmacies across six provinces in Sri Lanka. Price data for Originator Brands (OBs) and Lowest Priced Generics (LPGs) of 67 selected EMs were collected in January 2025. The Median Price Ratio (MPR) was calculated by dividing the median local price by the last updated International Reference Price (IRP) following inflation adjustment. The results were compared with prices from price control gazettes and 2015 historical data. Out-of-pocket affordability was estimated using the median price and the lowest paid government worker's daily wage in Sri Lanka.

Results: The MPRs of LPGs ranged from 0.1427 to 9.6875, while originators ranged from 0.4956 to 37.1131. A total of 26/67 LPGs and 3/23 originators recorded MPRs <1, and 19.40% of LPGs and 43.48% of originators exceeded two. Comparative MPR analysis with 2015 showed rising trends (LPGs: 45.45%, OB: 50%). Several EMs showed improved pricing, dropping closer to IRPs. Forty-four medicines included in price-control gazettes revealed conformity (97.42%) to the price ceiling. Notably, majority median prices were below the ceiling price, with percentage differences ranging from -0.02% to -1122.46%. Most LPGs (54/67) were affordable except amoxicillin oral suspension, warfarin sodium, sodium valproate and acyclovir tablets.

Conclusion: Our study indicates that although some medicine prices declined, many medicines had increased prices post-economic crisis, but were still affordable. This is likely influenced by government-introduced price control measures for EMs in 2019.

Keywords: Essential Medicines, Medicine Price, Affordability

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Investigating health insurance disparities and their impact on medicine access

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Introduction: In India, where healthcare is dominated by out-of-pocket spending, health insurance can have a huge impact on whether individuals can pay for the medicines they require. However, much research simplifies insurance coverage to a binary yes-or-no variable, without considering the more profound inequalities embedded in the system. This research looks more closely at how income, gender, and social demographics affect who is insured, and what implications this has for equitable access to necessary medicines.

Aim: To examine disparities in health insurance coverage across socio-demographic groups using multinomial logistic regression and evaluate their implications for medicine access.

Method: Secondary analysis was conducted using NFHS-5 data (N = 842,425). Predictors included wealth quintile, religion (Hindu, Muslim, Christian and others), region, residence, and education, adjusted for age and gender. Survey weights accounted for complex sampling. Multicollinearity was not detected. Sensitivity analyses using stratified and unweighted models confirmed robustness.

Results: Among participants, 34% had no formal education, and 48% lived in rural areas. Insurance coverage varied widely: the richest quintile had higher odds of private insurance uptake than the poorest (North: aOR = 5.13, 95% CI: 4.95–5.32; South: aOR = 3.36, 95% CI: 3.22–3.51). Muslims and Christians had much lower chances of any coverage than Hindus (Muslims: aOR = 0.71, 95% CI: 0.69–0.73; Christians: aOR = 0.79, 95% CI: 0.76–0.82). Education did not remain a significant predictor after adjustment.

Conclusion: Indian health insurance coverage mirrors entrenched structural inequalities. These disparities most probably lead to postponed or forgone treatment and medication underuse. Strategies need to tackle religious, regional, and economic barriers to make pharmaceuticals accessible in an equitable manner.

Keywords: Health equity, pharmacoepidemiology, health insurance utilization.

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Improved access without savings: Real-world impact of trastuzumab biosimilar in South Korea

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Introduction: The introduction of trastuzumab biosimilars—the first anticancer biosimilars in South Korea—marked the onset of biosimilar competition in oncology, underscoring its policy significance. While biosimilars are intended to improve affordability and access, their real-world impact on trastuzumab utilization and healthcare expenditures remains unclear.

Aims: To assess the impact of trastuzumab biosimilar introduction on utilization and healthcare expenditures among HER2-positive breast cancer patients in South Korea.

Methods: We conducted a retrospective cohort study using the K-CURE national claims database, a 10% sample of breast cancer patients with linked data on staging. We identified two cohorts of patients newly diagnosed with HER2-positive breast cancer: pre-biosimilar cohort (diagnosed in 2013–2014), and post-biosimilar cohort (diagnosed in 2018–2019). After 1:1 propensity score matching based on clinically relevant variables—including age, stage, and comorbidities—526 patients were included in each cohort. Outcomes included trastuzumab usage, time to initiation, and per-patient healthcare expenditure. Subgroup analyses were conducted by insurance premium decile. Group comparisons used independent t-tests when the F-test supported equal variances, and Mann–Whitney U tests otherwise ($p<0.05$).

Results: Following biosimilar introduction, per-patient trastuzumab use increased by 7.8% ($P<0.0001$). Median time from diagnosis to first dose and to peak utilization both decreased in the post-biosimilar cohort (–56.8 days; $P<0.0001$). Trastuzumab use increased among lower-income groups (+18.21%) but declined among higher-income patients (-5.03%). Average per-patient healthcare costs rose from $50,472 to $60,828 ($P<0.0001$); breast cancer-related costs rose from $46,652 to $55,829 ($P=0.0071$). Costs within one year of diagnosis also increased ($P<0.0001$).

Conclusion: Biosimilar introduction improved timely access to trastuzumab, especially among lower-income patients, but did not reduce overall healthcare costs. These findings suggest that South Korea's current price-linking policy may be insufficient to curb rising expenditures, underscoring the need for complementary measures to fully achieve the economic benefits of biosimilar competition.

Keywords: Biosimilar, Trastuzumab, Healthcare cost

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Effect of Educational Intervention on Caregivers to Improve Malnutrition in Tribal Children

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Introduction: Malnutrition and worm infestation remain significant contributors to poor health among tribal children in India. The Koraga tribal community in South India faces unique socio-cultural and economic challenges, further worsening the risk of undernutrition. Limited parental knowledge and suboptimal practices further exacerbate the condition.

Aim: To improve parental knowledge, attitude, and practice (KAP) through a structured educational program and evaluate its impact on the nutritional status of children aged 5-10 years of Koraga tribal community.

Methods: A quasi-experimental pre-post study was conducted among caregivers of the Koraga tribal community in rural villages of Udupi district, Karnataka. Baseline KAP was assessed among 122 families, and those scored below average (n=26) were recruited for the pilot WINS educational program. The intervention included an audio-visual module, pictographic food charts and bi-monthly home visits over six-months. Pre- and post-intervention assessments measured parental KAP, children's anthropometry, haemoglobin (Hb) levels, stool analysis, and health-related quality of life (HRQoL) using PedsQL 4.0. Data was analysed using paired t-tests to evaluate intervention effects.

Results: Parental KAP scores improved significantly ($p<0.001$) after six months. Children's mean Hb increased from 9.39±0.75g/dL to 10.38±0.75g/dL ($p<0.001$), eliminating severe anaemia and reducing moderate anaemia from 92.3% to 23.1%. Nutritional indicators like BAZ-scores improved from -1.14±1.09 to -0.88±0.95 ($p=0.004$), WAZ scores from -2.64±1.21 to -2.51±1.11($p=0.007$), while HAZ scores slightly declined from -2.75±1.05 to -2.83±0.98 ($p=0.002$) due to the short follow up period. HRQoL improved significantly, with child self-reported scores increasing from 43.56±6.73 to 52.34±8.36 ($p<0.001$) and parent proxy-report scores rising from 39.96±8.25 to 50.29±8.24 ($p<0.001$). Importantly, no child tested positive for worm infestation.

Conclusions: The WINS educational intervention significantly improved parental KAP and children's nutritional and health outcomes in Koraga tribal community. Future studies with longer follow-ups are recommended to sustain these improvements.

Keywords: Health education intervention, Koraga tribe, Malnutrition

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Public Health and Pharmaceutical Equity: Availability of Essential Medicines in Public Hospitals

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Public Health and Pharmaceutical Equity: Availability of Essential Medicines in Public Hospitals

Introduction: Ensuring access to free essential medicines is a vital aspect of universal health coverage. National Essential Medicines List (NEML) enhances the accessibility and utilisation of essential medicines within healthcare systems.

Aims: A study was conducted to evaluate the availability of essential medicines, inventory management, and the quality of storage facilities in public sector healthcare establishments.

Methods: The current research was carried out in 40 public health facilities across the Suryapet district in Telangana state using the ELM approach. The study included six Community Health Centres (CHCs), 26 Primary Health Centres (PHCs), four Urban Primary Health Centres (UPHCs), and three BDKs. The district's drug procurement processes were assessed through document analysis and in-depth interviews with key stakeholders. Stock registers were examined to gather data on the availability of a selection of essential medicines at the PHC level (92), CHC level (132), and tertiary care level (District Hospital/Medical College)(160).

Results: The overall percentage of medicine availability is 45.2%. Anti-hypertensive medicines are available (60%), and anti-diabetic medicines (44%). Every category of medicines, including analgesics/antipyretics, anthelminthics, antispasmodics, antiemetics, antihypertensives, and uterotonics, had at least one drug that was almost always available in public sector facilities. In contrast, medicines such as thrombolytics, anti-cancer agents, and endocrine treatments were found in fewer than 30% of public sector facilities. Among the medicines not stocked during the survey, approximately 60% had been out of stock for 3 to 6 months, while 8% had been unavailable for more than 6 months.

Conclusion: Ensuring access to free essential medicines reduces out-of-pocket expenses, providing a sustainable approach to achieving universal health coverage in India.

Keywords: Essential medicines, Public sector, Generic, Anti-hypertensive, Procurement, Universal health care

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Cost-Effectiveness Analysis of Statins, Berberine, and Combination for Cardiovascular Disease Primary Prevention

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Introduction: Statins are the cornerstone treatment for the primary prevention of cardiovascular disease (CVD), but intolerance and side effects can hinder adherence. Berberine, with promising lipid-lowering effects and good tolerance, presents a potential alternative for statin-intolerant patients.

Aims: To estimate and compare the cost-effectiveness of statins, berberine, and their combined use for primary CVD prevention.

Methods: The Scottish CVD Policy Model was used to predict long-term health and cost outcomes in Scottish adults aged 40 years or older without pre-existing CVD. Intervention and cost inputs were sourced from published literature and health service cost data. The primary outcome measure was the lifetime incremental cost-effectiveness ratio (ICER), evaluated as cost per quality-adjusted life year (QALY) gained. The intervention strategies of no intervention, atorvastatin 20 mg per day ("statins"), berberine 1000 mg per day ("berberine"), simvastatin 20 mg plus berberine 1500 mg per day ("combined intervention 1") and simvastatin 20 mg plus berberine 900 mg per day ("combined intervention 2") were analyzed for individuals with ASSIGN risk scores ≥20% and ≥10%.

Results: All intervention strategies were cost-effective (statins: ICER £1,260.7/QALY, 95%CI: £-2,528.6/QALY ~ £2,305.5/QALY; berberine: ICER £6,192.4/QALY, 95%CI: £4,655.7/QALY ~ £11,387.0/QALY; combined intervention 1: ICER £5,506.5/QALY, 95%CI: £4,506.8/QALY ~ £10,732.0/QALY; combined intervention 2: ICER £3,846.4/QALY, 95%CI: £3,107.0/QALY ~ £5,270.1/QALY), compared to no intervention, at the threshold of ICER of £20,000 per QALY. Compared to statins, berberine was less cost-effective, but the combination remained cost-effective (£10,198.6/QALY [95%CI: £6,740.4/QALY ~ £58,473.3/QALY]; £6,362.8/QALY [95%CI: £5,187.7/QALY ~ £12,499.2/QALY]) at the threshold of £20,000/QALY. Notably, when using drug costs from China, berberine and combined interventions were preferable to statins alone.

Conclusions: Statins, berberine, and combined interventions are all cost-effective options for primary CVD prevention. Berberine could be considered a valuable complementary therapy, particularly if its price decreases below that of statins.

Key words: statins; berberine; combination; cost-effective

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Inclisiran-Linked Adverse Event Detection Using FAERS Disproportionality Metrics: Exploratory Study

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Background: Inclisiran is a small interfering RNA therapeutic approved for lowering LDL cholesterol in patients with hyperlipidemia. Diverticulitis is a condition where small bulging pouches (called diverticula) that can form in the walls of the colon become inflamed or infected. Pharmacovigilance using spontaneous reporting systems such as the FAERS database is critical for identifying previously unrecognized adverse drug reactions (ADRs).

Objective: This study aimed to identify potential safety signals associated with Inclisiran using disproportionality analysis of data from the FAERS database.

Methodology: FAERS data were analyzed for Inclisiran-related adverse events using standard signal detection algorithms. The Reporting Odds Ratio (ROR) and Proportional Reporting Ratio (PRR) values are obtained from OpenVigil database. Signals were considered positive if AE >3, PRR ≥2, Chi-square >4, and ROR lower bound >1. Key metrics including PRR, ROR, and confidence intervals were extracted and assessed.

Results: As of early 2025, the FDA Adverse Event Reporting System (FAERS) has accumulated over 35 million Individual Case Safety Reports (ICSRs), documenting adverse drug reactions from both domestic and international sources. Among these, Inclisiran-related reports were identified and analyzed for disproportionality. Diverticulitis was identified among Inclisiran-related entries. It showed a PRR of 2.73 (1.55, 4.80), ROR of 2.76 (1.645; 5.111), and a Chi-square value of 10.46, surpassing the thresholds for signal detection. Although the absolute number of reports was modest, the strength of the disproportionality metrics suggests a potential link between Inclisiran and the onset of Diverticulitis.

Conclusion: The results revealed that Inclisiran may cause Diverticulitis. These findings have to be confirmed, and further pharmacoepidemiologic research is required to increase the accuracy of the prevalence and/or risk factors of these events.

Keywords: Inclisiran, Diverticulitis, Signal Detection, Adverse Drug Reactions, FAERS, Pharmacovigilance

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Development of drug safety information in Korea: Lidocaine (injection) and anaphylactic reactions

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Introduction: The Korea Institute of Drug Safety and Risk Management (KIDS) conducts monthly pharmacovigilance activities to manage serious adverse events (SAEs) and generate drug safety information.

Aims: To identify and evaluate safety signals from reported SAEs and inform regulatory decision-making on the basis of the findings.

Methods: SAEs were extracted from individual case safety reports submitted to the Korea Adverse Event Reporting System in July 2023. Three complementary methods are used for the monthly evaluations. All cases involving death or congenital anomalies are reviewed individually to determine whether a causal relationship can be excluded. To minimize the risk of rare but serious adverse events being overlooked, a qualitative assessment is applied to designated medical events (DMEs). Quantitative analysis is also conducted using data mining techniques to detect statistically significant safety signals. Drug–DME combinations with potential safety concerns are managed as accumulations. When a causal relationship cannot be ruled out through both qualitative and quantitative analyses, further investigation and long-term monitoring are conducted. On the basis of these results, KIDS may propose safety labeling changes to the Ministry of Food and Drug Safety (MFDS).

Results: During the monthly evaluation of drug–DME combinations from reported cases, KIDS reviewed reports of SAEs of anaphylactic reactions in patients receiving lidocaine as a local anesthetic. A causal relationship between lidocaine injection and the anaphylactic reactions could not be excluded. Therefore, on the basis of the findings of this review and international regulatory information, including product information from the USA, Japan, and other countries, KIDS submitted a proposal for new safety information to the MFDS.

Conclusions: In May 2025, the product information for lidocaine was updated to include the risk of anaphylactic reactions.

Keywords: lidocaine, anaphylactic reactions, Korea Adverse Event Reporting System

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Overview of patient-reported outcome measures in post-marketing surveillance across Asia Pacific

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Introduction: Patient-reported outcome measures (PROMs) capture patient-centric insights are increasingly used in regulatory decision-making. However, the integration of PROs in post-marketing surveillance (PMS) is gaining traction and varies by Asia-Pacific (APAC) markets.

Aims: This study reviewed the extent of PROMs utilization in PMS across Australia, China, Japan, Korea, Singapore, and Taiwan.

Methods: A targeted PubMed literature search (2020–2025) was conducted to identify PMS studies including PROMs in these markets. Data on PROM collection methods, therapeutic indications, and outcome measures were extracted from eligible publications and analyzed using narrative synthesis.

Results: We identified 43 studies (4% of 1,029 screened publications) that included PROMs in PMS. Most were conducted in Japan (67%), followed by Korea (16%), China (9%), Australia (5%), and multi-country studies (2%). PROMs were used in a range of therapeutic areas, most commonly immunology (19%), rheumatology (7%), and urology (7%). Nearly one-quarter (23%) of the studies used a PROM as a primary endpoint; PROMs were primarily applied to assess treatment effectiveness (74% of studies), followed by quality of life (30%) and safety (12%). In prospective studies (42 out of 43), the most common PROM collection method was a validated scale embedded in an electronic case report form (79%), then custom questionnaires (19%), interviews (2%). Only one study was cross-sectional, utilizing a one-time patient survey.

Conclusions: PROMs are being incorporated into PMS studies across APAC, yet the extent of their use in regulatory decision-making remains unclear. The variation in how PROMs are utilized highlights the need for region-specific guidance to help stakeholders align these patient-centered endpoints with regulatory requirements. Moreover, some PMS studies with PROM components may remain unpublished as agencies may not make the associated PMS reports publicly accessible; thus, current literature could underestimate the true extent of PROM use in this context.

Keywords: Post-marketing surveillance; patient-reported outcome measures; Asia-Pacific

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Association between proton pump inhibitors and gout risk in a cohort study

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Background: Gout is a chronic inflammatory arthritis caused by monosodium urate crystal deposition, leading to severe pain and joint damage. Recent studies suggest that proton pump inhibitors (PPIs) may increase gout risk. PPIs inhibit gastric H^+/K^+ ATPase activity, leading to adenosine triphosphate accumulation, which is metabolized to uric acid and may trigger gouty arthritis.

Aim: This study evaluated the association between PPI use and gout risk among South Korean adults. We hypothesized that PPI exposure would increase gout incidence.

Methods: We analyzed data from the Korean National Health Insurance Service database (2002–2019). The control cohort was generated using inverse probability of treatment weighting (IPTW) based on age, sex, Charlson Comorbidity Index score, and index year. Baseline balance before and after IPTW was assessed using standardized mean differences (SMDs), with SMD <0.1 indicating adequate balance. Cox proportional hazards models estimated adjusted hazard ratios (aHRs) and 95% confidence intervals (CIs) for gout.

Results: After IPTW, baseline covariates were well balanced between exposure and control groups. PPI use was significantly associated with an increased risk of gout compared with controls (aHR = 1.806; 95% CI, 1.763–1.850). Additional factors linked to higher risk included anti-tubercular drugs (aHR = 1.961), and angiotensin-converting enzyme inhibitors (aHR = 1.799). Conversely, female sex (aHR = 0.690), congestive heart failure (aHR = 0.757), and cerebrovascular disease (aHR = 0.823) were associated with a lower risk of gout. The proportional hazards assumption was satisfied, supporting the robustness of the Cox model estimates.

Conclusion: PPI use was independently associated with an increased risk of gout in this large nationwide cohort. These findings suggest that PPI therapy may contribute to the development of gout and underscore the need for careful prescription and further prospective studies to confirm causality.

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Age-specific signals for duloxetine using the Korea Adverse Event Reporting System Database

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Introduction: Antidepressant use has recently increased across all age groups. Older adults are more vulnerable to adverse reactions due to metabolic decline. Duloxetine is prescribed for depression and pain, but evidence on age-specific adverse event (AE) profiles remain limited.

Aims: To analyze duloxetine-related signals using the Korea Adverse Event Reporting System (KAERS) and compare signals focusing on older adults.

Methods: We conducted retrospective analysis of antidepressant-related spontaneous reports (2013-2022) from the KAERS database. Reports with duplicates, follow-ups, missing sex/age, or age under 20 were excluded. Age groups were categorized as young (20–39), middle-aged (40–64), and older adults (≥65). Frequency analysis of major System Organ Classes (SOCs) was conducted and data mining indices —including proportional reporting ratio (PRR), reporting odds ratio (ROR), and information component (IC) were calculated. AEs were standardized to preferred-terms per MedDRA version 28.0. We identified age-specific signals and unknown signals; AEs not listed in antidepressant labels in either the United States or Korea. Signals were compared across groups by RORs.

Results: Of 20,963 total reports, duloxetine-related reports were 388(14.8%) of 2,624 cases in young, 2,331(24.5%) of 9,511 in middle-aged, and 2,067(23.4%) of 8,828 in older adults. Gastrointestinal disorders were the most reported SOC in older adults, while psychiatric and nervous system disorders were most in young adults. Signal detection identified 13, 20, and 13 signals in young, middle-aged, and older adults, respectively, including 1, 8, and 2 unknown signals and 8, 14, and 7 age-specific signals. Hematuria and neutropenia were more common in middle-aged groups: relative ROR of 0.16 (95% CI: 0.02–0.98) and 0.41 (0.21–0.76), respectively. Both AE were unknown signals.

Conclusions: Age-specific variations in duloxetine signals, including unknown ones, were identified. These findings support the need for age-tailored monitoring to improve Korea's age-stratified drug safety surveillance.

Keywords: Duloxetine, Adverse events, Age-specific signal detection, Older adults, Korea

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Evaluating post-marketing regulatory impact on hypocalcemia safety signals of Denosumab in VigiBase

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Introduction: Denosumab was placed under EMA additional monitoring (AM) in April 2013 and received an FDA black box warning (BBW) in January 2024 for severe hypocalcemia in patients with chronic kidney disease. The impact of these regulatory actions on adverse event (AE) reporting patterns and signal detection remains unclear.

Aims: To evaluate changes in hypocalcemia reporting patterns for denosumab and detect signals before and after regulatory interventions by the FDA and EMA, using VigiBase.

Methods: A disproportionality analysis was conducted using VigiBase from May 26, 2010 to June 1, 2025. Bisphosphonates—alendronate, risedronate, ibandronate, and zoledronate—were used as comparators. AEs of interest were hypocalcemia and calcium metabolism disorders. Reports with only denosumab or bisphosphonates as suspected drug were analyzed using Poisson regression across phases;before AM (Phase 1), between two regulatory actions (Phase 2), and after BBW (Phase 3). Signal detection was performed per phase using Proportional Reporting Ratio (PRR), Reporting Odds Ratio (ROR), and Information Component (IC), with thresholds PRR≥2, ROR≥2, IC05>0, and $\chi 2 \geq 4$, requiring ≥3 reports.

Results: In total, 2,374 hypocalcemia reports for denosumab and 773 for bisphosphonates were identified. Among denosumab reports, 8.1% were reported in Phase 1, 78.5% in Phase 2, and 13.4% in Phase 3. Compared to Phase 1, hypocalcemia reporting declined in Phase 2 (RR=0.64; 95% CI: 0.57–0.72) and rose in Phase 3 (RR=8.24; 95% CI: 7.13–9.53). Disproportionality analysis showed consistent signals, strongest in Phase 1 (PRR=25.15; ROR=25.82; IC=3.23), and still above thresholds in Phases 2 and 3.

Conclusions: Regulatory actions may influence AE reporting patterns. Signal strength peaked after initial approval. Reporting declined in Phase 2, possibly due to limited awareness as AM did not specify hypocalcemia and rose in Phase 3 after a targeted warning. These findings highlight the need to consider regulatory context when interpreting signals.

Keywords: Signal detection; Real-World Data; Denosumab;

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Subgroup disproportionality analysis of methylphenidate adverse events in VigiBase and KAERS database

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Introduction: Methylphenidate is widely prescribed for attention-deficit/hyperactivity disorder, yet its adverse drug reaction (ADR) profile may differ by age, sex, or region due to biological factors and differences in drug use. Evidence for these subgroup risks is limited. Disproportionality analysis can identify subgroup-specific risk for the same medication.

Aims: To detect subgroup-specific safety signals of methylphenidate using disproportionality analysis.

Methods: Disproportionality analyses were conducted on individual case safety reports from the WHO-UMC global database (VigiBase) and the Korean Adverse Event Reporting System (KAERS) for 2015–2019. Reports listing any drug as suspected or interacting were included, while vaccine-related reports were excluded. ADRs were coded using MedDRA preferred terms. Subgroups were defined by sex; seven age groups; and geographic region across six WHO regions (VigiBase only). For signal detection, the Bayesian disproportionality metric Information Component (IC) was calculated for each drug–event pair, with its 99% lower bound ($IC_{99}LB$) applied to the methylphenidate subgroup and its 95% lower bound ($IC_{95}LB$) to the full dataset. Differential IC (ΔIC) quantifies disproportionate ADR reporting in subgroups. Signals were defined as: $IC_{99}LB > 0$ within subgroup; $IC_{95}LB \leq 0$ overall; $\Delta IC > 1$; and subgroup reports ≥10. Of these, signals from subgroups contributing ≥80% of methylphenidate or ADR reports were excluded, and identification as known or previously unrecognized ADRs was based on Micromedex.

Results: In VigiBase, 62 subgroup-level signals for methylphenidate were identified: 16 age-specific, 18 sex-specific, and 28 region-specific. Most of these were previously known ADRs. The strongest signal was “feeling abnormal” in children aged 2–11 years (n=82; $IC_{99}LB$=1.08; ΔIC=2.61). In contrast, no qualifying subgroup-level signals were detected in KAERS.

Conclusions: Subgroup disproportionality analysis in VigiBase identified distinctive signals for methylphenidate that were absent from national data. These findings highlight the importance of large databases like VigiBase for subgroup-specific pharmacovigilance.

Keywords: Methylphenidate, Subgroup Analysis, Pharmacovigilance

D2/P351

FAERS flags nebivolol induced melaena: A newly identified adverse event

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Introduction: Nebivolol, a selective beta-1 adrenergic receptor blocker, is commonly prescribed for the management of hypertension and heart failure. While its safety profile is well established, rare and serious adverse drug reactions (ADRs) may remain undetected until post-marketing surveillance. Signal detection and disproportionality analysis are essential tools to uncover such potential ADRs.

Aim: This study aimed to identify and evaluate the signal of melaena associated with nebivolol use, as reported in the USFDA Adverse Event Reporting System (FAERS) database.

Methodology: An in-depth case/non-case retrospective disproportionality analysis was conducted in the publicly available FAERS database for Nebivolol. Nebivolol was approved by FDA on 17 December 2007. All the reports of Nebivolol were analyzed. The investigation delved into the USFDA adverse event reporting system database, employing the top 2 data mining algorithms in widespread use for signal detection such as Reporting Odds Ratio (ROR) and Proportional Reporting Ratio (PRR) from the OpenVigil database. A value of PRR≥2 and ROR-1.96SE>2 was considered as positive signal.

Results: Among the total 30,668,520 FAERS reports, 4,685 were related to Nebivolol. The Nebivolol reports (4,487) were classified as serious, and many fatal reactions were reported. The total number of adverse events reported for Melaena is 97 on OpenVigil. On analysis, data mining algorithms showed the results as ROR of 6.22(5.092; 7.602) and PRR of 6.19 (5.07; 7.558). The ROR and PRR confirmed the occurrence of the adverse reaction cachexia for Nebivolol.

Conclusion: This analysis suggests that melaena may be a potential adverse reaction in patients receiving nebivolol. Healthcare professionals should be vigilant for signs of gastrointestinal bleeding in patients treated with nebivolol. Further epidemiological studies are warranted to validate this signal and clarify its clinical significance.

Keywords: Nebivolol, Signal detection, Melaena, FAERS, Disproportionality analysis

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Real World Data of Drug Induced Cerebral Hemorrhage: Disproportionality Analysis Using FAERS

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Introduction: Drug-Induced Cerebral Hemorrhage (DICH) or Drug-Induced Hemorrhagic Stroke (DIHS), is a sudden bleeding in the brain tissues or ventricles with drug use. Studies have identified antithrombotic medications as common agents causing DICH. Despite drugs from various other classes being linked to DICH, a comprehensive study on them has not been established.

Aims: This study aims to systematically assess the adverse event signals of therapies inducing DICH using the U.S. FDA Adverse Event Reporting System (FAERS) database, employing disproportionality analysis (DPA) methods.

Methods: Data from FAERS (1988 to Q1 2025) was extracted and analyzed using frequentist statistics. After data standardization, two disproportionality methods were used: Reporting Odds Ratio (ROR), Proportional Reporting Ratio (PRR). Reports coded with the preferred term 'Cerebral Hemorrhage' were extracted and drug-event pairs with ≥10 reported cases were included. A drug-event pair was considered a positive signal if it met all the following thresholds: PRR ≥ 2; $\chi^2 \geq 4$ and ROR > 1 with 95% confidence interval.

Results: From 1998 to 2025, 33,888 adverse event reports were recorded, identifying 650 drugs associated with cerebral hemorrhage. Of these, 378 drugs reported ≥10 cases and met the predefined criteria for positive disproportionality signals. Antithrombotic agents accounted for the most frequent and strongest signals, including clopidogrel bisulfate (PRR 15.8), rivaroxaban (PRR 13.56), clopidogrel (PRR 10.32), warfarin (PRR 8.79), aspirin (PRR 6.45) and apixaban (PRR 6.35). Among the top 15 DICH-linked drugs, commonly used non-antithrombotic agents were bisoprolol (PRR 5.2), furosemide (PRR 2.59), metoprolol (PRR 2.26) and amlodipine (PRR 2.01). Identified drugs exhibited χ^2 values from 346 to 24,347, confirming statistically significant disproportionality.

Conclusions: The findings reveal signals from both expected antithrombotics and non-antithrombotics like bisoprolol, furosemide, metoprolol and amlodipine. Thus, emphasizing the need for adequate/routine drug safety monitoring of these medications.

Keywords: Cerebral Hemorrhage; Disproportionality Analysis; Pharmacovigilance

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FAERS Signal Detection of Tirzepatide Adverse Events via Disproportionality Evaluation

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Background: Tirzepatide is an FDA-approved drug that works through dual incretin-based mechanisms to manage blood sugar levels and promote weight loss in individuals with Type-2 Diabetes Mellitus. Signal detection is used to identify previously unrecognized adverse drug reactions associated with a medication.

Objective: The study aimed to identify the newly reported signal associated with Tirzepatide in the USFDA Adverse Event Reporting System (FAERS) database.

Methodology: In this study, data from the FDA Adverse Event Reporting System (FAERS) was analyzed to identify a potential novel adverse event associated with Tirzepatide. The Reporting Odds Ratio (ROR) and Proportional Reporting Ratio (PRR) were obtained from the OpenVigil database. A signal is considered positive if the number of adverse events (AE) exceeded 3, PRR was ≥2, the lower limit of the 95% confidence interval for ROR (ROR – 1.96SE) >2, and the chi-square value was greater than 4.

Results: The database contains a total of 30,668,520 reported adverse events. Among these, 55,341 were associated with Tirzepatide following its approval by the USFDA in 2022. According to OpenVigil data, there were 29 cases of intermenstrual hemorrhage and 38 cases of postmenopausal hemorrhage linked to the drug. The analysis revealed a PRR of 2.792 (95% CI: 1.936–4.026) and an ROR of 2.793 (95% CI: 1.937–4.028) for intermenstrual haemorrhage. For postmenopausal haemorrhage, the PRR was 6.7 (95% CI: 4.854–9.248) and the ROR was 6.704 (95% CI: 4.856–9.255). These findings indicate the presence of a statistically significant positive signal. Though the incidence of intermenstrual and postmenopausal hemorrhage reports is currently low ie.,15 and 27 respectively, the observed disproportionality suggests a potentially emerging pharmacovigilance concern

Conclusion: The results revealed that Tirzepatide may cause Abnormal uterine haemorrhage. The genes and proteins showed association between Tirzepatide and Abnormal uterine haemorrhage.

Keywords: Tirzepatide, Intermenstrual hemorrhage, Postmenopausal hemorrhage, Signal Detection, Adverse Drug Reactions

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Unravelling Drug-Safety: Blockchain-Powered Pan-Asian Network - Decentralised Pharmacovigilance, Real-Time Adverse Event Insights

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Introduction: Asia, with its rapidly developing pharmaceutical markets and heterogeneous healthcare systems, faces significant challenges in adverse drug event (ADE) surveillance. These challenges include under-reporting, late detection, and inefficient cross-border information sharing. Conventional, centralised pharmacovigilance systems often fail to provide real-time, population-relevant safety information.

Aim: The objective of this research is to conceptualise and propose a blockchain- and federated AI-powered decentralised pharmacovigilance network. This network aims to facilitate real-time detection of ADEs, secure data exchange, and risk stratification at the individual level among Asian healthcare systems.

Methods: A trilateral pilot scheme involving India, Singapore, and South Korea will be developed. This scheme will incorporate the following components:
- Blockchain (Ethereum-based smart contracts): These will ensure immutability, security, and transparency in event reporting.
- Federated learning: This technology will enable AI-based signal detection on privacy-protected, decentralised datasets.
- Genomic information and mobile health data inputs: These will provide patient-specific ADE prediction capabilities.
- Regulator, hospital, pharmacy, and patient community stakeholder nodes: These will facilitate communication and collaboration within the network.

System Performance Simulation and Assessment: System performance metrics, including signal lag, false positive rate, and latency, will be simulated and assessed to evaluate the network's effectiveness.

Expected Results: The network is anticipated to reduce reporting latency by 60%, enhance the identification of rare ADEs, and enhance public trust in drug safety systems. Genomic profile-guided personalised alerts will facilitate proactive pharmacovigilance.

Conclusion: This research redefines pharmacovigilance as a smart, decentralised system that enables real-time, ethically controlled drug safety monitoring in Asia. The proposed model sets the foundation for a future where ADE prediction is not an option but a policy-driven norm.

Keywords: Pharmacovigilance, Decentralised Artificial Intelligence (AI), Real-Time Adverse Event Detection (ADE),

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Association between hair loss medications and psychiatric AEs: a dual-source pharmacovigilance review

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Introduction: Alopecia is a common dermatological condition, and the safety profiles of its primary pharmacological treatments—finasteride, dutasteride, and minoxidil—have raised ongoing concerns. Reports began to emerge of suicidal ideation and completed suicides among men using finasteride, promoting attention from regulatory bodies. Despite increased investigation, the psychiatric safety of these medications remains incompletely understood.

Aims: To address this gap, we conducted a pharmacovigilance study using real-world data to evaluate the association of suicidality and depression with finasteride, dutasteride and minoxidil.

Methods: We analyzed adverse event (AE) reports from two major pharmacovigilance databases: the U.S. Food and Drug Administration Adverse Event Reporting System (FAEAS, Q1 2004 to Q1 2025) and the Japanese Adverse Drug Event Report (JADER, Q1 2004 to Q2 2025). Disproportionality analyses were conducted using the reporting odds ratio (ROR) to detect safety signals. Subgroup analysis were also performed.

Results: After deduplication, a total of 4,007 AE reports were included (FAERS: 3,984; JADER: 23). Significant disproportionality signals were observed for suicidality (FAERS: ROR = 6.51 [95% CI: 6.15–6.90]; JADER: ROR = 5.42 [2.99–9.82]) and depression (FAERS: ROR = 9.71 [9.33–10.10]; JADER: ROR = 7.98 [4.40–14.47]) among finasteride users. In FAERS, dutasteride was also associated with a significant signal for depression (ROR = 2.14 [1.68–2.74]), but no signal was identified for minoxidil. Subgroup analysis in FAERS revealed elevated RORs for suicidality among younger patients (<45 years) (ROR = 1.37 [1.17–1.60], $P < 0.05$) and those using finasteride for alopecia (ROR = 1.27 [1.06–1.53], $P < 0.05$).

Conclusions: Finasteride use was significantly associated with increased reports of suicidality and depression, particularly in patients under 45 years treated for alopecia. These findings highlight the importance of ongoing pharmacovigilance, the need for further confirmatory studies, and consideration of safety label updates for finasteride.

Keywords: finasteride, suicidality, pharmacovigilance

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Disproportionality analysis of Methotrexate using the FDA adverse event reporting system database

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Introduction: Methotrexate(MTX) is an antimetabolite drug used to treat various conditions by inhibiting the Dihydrofolate reductase(DHFR) enzyme. The adverse events(AEs) associated with MTX therapy should be considered to reduce their severity with subsequent doses. Here, disproportionality analysis using the FDA adverse event reporting system(FAERS) databases helps to identify potential signals related to MTX therapy in pediatrics.

Aim: This study aims to find the AEs associated with MTX in children and identify and characterize associated signals.

Method: The Open Vigil 2.1 platform was used for extraction, cleaning, and standardization of data from FAERS to retrieve AEs of MTX reported from Q4 2004 to Q4 2024 in children aged 1 to 17 years. The inclusion criteria were set to reports with a frequency greater than three and were deduplicated. The study assesses the Disproportionality through Reporting odds ratio (ROR), Proportional reporting ratio (PRR), and Chi-square test. A signal was detected if ROR >1, PRR≥2, and chi-square >4 were observed in the Frequentist data. Data analysis and visual interpretation were carried out using R-Software v 4.4.1.

Results: A total of 30111 AEs were reported with MTX, with a higher occurrence in males, 15619(51.9%), than in females, 13470(44.7%). More cases were reported in the age group of 1-10(52.22%). Canada(22.3%) is ranked first among the reported countries, followed by the United States(19%). A total of 981 Preferred terms were included, and 508 signals were identified. Pseudostroke(PRR=334.164) and Pneumonia(PRR=290.577) were the strongest signals. Febrile neutropenia-FN(n=741) and Neurotoxicity(n=323) were the most frequently reported cases.

Conclusion: Our comprehensive study identified the significant safety signals associated with MTX and revealed that Pseudostroke and pneumonia were the strongest signals with MTX therapy, FN and Neurotoxicity were the Most reported AEs. This study warrants careful clinical consideration.

Keywords: Disproportionality analysis, Methotrexate, Adverse events

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Ferric Carboxymaltose-Induced Serious Adverse Events: Disproportionality Analysis and Systematic Review

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Introduction: The increasing incidence of serious adverse events (SAEs) and fatalities linked to Ferric Carboxymaltose (FCM) necessitates a rigorous re-evaluation of its safety profile, highlighting an urgent public health concern.

Aim: This study aimed to comprehensively assess the safety of FCM by identifying and characterizing its associated SAE signals using extensive pharmacovigilance data and a systematic review of case reports.

Methods: A retrospective case/non-case study was conducted utilizing FDA Adverse Event Reporting System (FAERS) and VigiBase data from Q4 2003 to Q4 2024. Signal detection employed Proportional Reporting Ratio (PRR), Reporting Odds Ratio (ROR), and Information Component (IC). Concomitant medication influence was refined using OpenVigil 2.1. A systematic search of PubMed, Scopus, and Google Scholar (inception to April 12, 2025) identified FCM-induced adverse event case reports.

Results: While 46 deaths were reported in FAERS, no significant death signal was detected (PRR=0.3, lower bound (LB) ROR=0.2, IC025=-2.3). However, significant safety signals emerged for SAEs including anaphylactic shock (PRR=3.9, LB ROR=2.3, IC025=1.0), circulatory collapse (PRR=14.6, LB ROR=10.5, IC025=3.1), respiratory distress (PRR=9.6, LB ROR=7.1, IC025=2.6), hypophosphatemia (PRR=520.7, LB ROR=530.1, IC025=8.0), and arrhythmia (PRR=3.3, LB ROR=2.2, IC025=1.0). These signals remained robust after adjusting for concomitant medications. VigiBase data similarly revealed 42 fatal cases and potential signals for hypersensitivity (PRR=4.5, LB ROR=4.4, IC025=2.1), anaphylactic shock (PRR=2.3, LB ROR=1.9, IC025=0.9), circulatory collapse (PRR=7.2, LB ROR=6.0, IC025=2.5), respiratory distress (PRR=6.9, LB ROR=5.7, IC025=2.5), and hypophosphatemia (PRR=245.1, LB ROR=234.8, IC025=7.5) with Ferinject. Eleven systematic review case reports further corroborated these SAE associations.

Conclusions: This study definitively reveals that FCM is associated with SAEs. Healthcare providers must exercise heightened vigilance, meticulously weighing the therapeutic benefits against patient-specific risks when prescribing FCM.

Keywords: Disproportionality Analysis; Ferric Carboxymaltose; Serious Adverse Events; Systematic Review.

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COVID-19 vaccines and mortality risk: comparison of estimates from self-controlled case series

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Introduction: Self-controlled case series (SCCS) are frequently used in vaccine safety studies, but is ill-suited for outcomes that affect future exposure or censor observation period, such as mortality. We aimed to compare estimates from three design options: the modified SCCS developed for this situation, the standard SCCS, and the unidirectional SCCS.

Methods: Using Malaysia's nationwide data from 2021-2022, we analysed deaths (all-cause deaths, non-COVID-19 deaths, cardiovascular deaths) among individuals aged ≥5 years. Exposure was vaccination with BNT162b2, CoronaVac, or ChAdOx1. Modified SCCS model was used for primary analysis, and compared with two other models: standard SCCS and SCCS unidirectional (follow-up starts at vaccination). Incidence rate ratio (IRR) and 95% confidence interval (CI) were computed using conditional Poisson regression for risk of deaths 21-day after vaccination versus referent window.

Results: The modified SCCS model showed that the risk of all-cause deaths in the 21-day focal window was not significantly increased following vaccination (all doses: IRR 0.60; 95%CI 0.59-0.61). The IRRs were below 1 across vaccine doses (doses 1, 2, and 3) and vaccine types. Estimates from the standard SCCS model were slightly increased (all doses: IRR 1.04; 95% CI 1.02-1.05) with dose-specific IRRs ranging from 0.97 to 1.17. The unidirectional model yielded lower estimates than the standard SCCS (all doses: IRR 0.74; 95%CI 0.73-0.76) and IRR ranged from 0.66 to 0.84. Similar results were observed for non-COVID-19 deaths and cardiovascular deaths.

Conclusion: As expected, the standard SCCS may overestimate the effect of vaccination on an outcome like mortality that violates key design assumptions. Both the modified SCCS and the unidirectional SCCS appear viable alternatives that address this issue. However, estimates from the modified model were lower than those of the unidirectional model. These findings support the favourable safety profile of these COVID-19 vaccines, with no evidence of increased mortality following vaccination.

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Psychiatric and neuropsychiatric sequelae of COVID-19 within 2 years: a multinational study

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Introduction: Concerns have been raised regarding the potential psychiatric and neuropsychiatric complications following COVID-19 infection.

Aims: We aimed to investigate short-, medium-, and long-term risks of psychiatric and neuropsychiatric disorders following COVID-19 infection in five countries.

Methods: This population-based multinational cohort study used electronic medical records from France, Italy, Germany, and the UK and claims data from the USA. Individuals with COVID-19 between 01/12/2019 and 01/12/2020 were included as targets. Ten comparators without COVID-19 for each target were selected using the propensity score matching approach. All individuals were followed from the index date until the last record. Cox models were fitted to estimate risks of incident diagnosis of depression, anxiety disorders, alcohol misuse or dependence, substance misuse or dependence, bipolar disorders, psychoses, personality disorders, self-harm and suicide, sleep disorders, dementia, and neurodevelopmental disorders within the first 6 months (short-term), 6 months to 1 year (medium-term), and 1 to 2 years (long-term) post-infection.

Results: A total of 303,251 individuals with COVID-19 and 22,108,925 without COVID-19 from five countries were included. Within the first 6 months, individuals with COVID-19 had a significantly higher risk of any studied disorders in all databases, with HR ranging from 1.14 (95% CI, 1.07–1.22) in Germany to 1.89 (1.64–2.17) in Italy. Increased risks were consistently observed for depression, anxiety disorders, and sleep disorders across almost all countries. During the medium- and long-term periods, higher risks were observed only for depression (medium-term: 1.29, 1.18–1.41; long-term: 1.36, 1.25–1.47), anxiety disorders (1.29, 1.20–1.38; 1.37, 1.29–1.47), and sleep disorders (1.10, 1.01–1.21; 1.14, 1.05–1.24) in France, and dementia (medium-term: 1.65, 1.28–2.10) in the UK.

Conclusions: Our study suggests that increased risks of psychiatric and neuropsychiatric outcomes were observed only within, and not after, the 6-month period across all databases, except for certain conditions in specific countries.

Keywords: Long-COVID; Psychiatric disorders; Neuropsychiatric disorders

D2/P360

Association of Penicillin Allergy Label with Post-COVID-19 Condition and Subsequent Clinical Outcomes

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Introduction: Penicillin allergy is common and has been linked to worse outcomes in acute COVID-19. However, its association with post-COVID-19 condition (PCC) and subsequent clinical outcomes (≥90 days post-COVID Diagnosis) including nonfatal stroke, myocardial infarction, and all-cause mortality remain unknown.

Aim: To evaluate whether penicillin allergy labelling is associated with an increased risk of PCC and subsequent clinical outcomes, and to assess whether PCC mediates this relationship.

Methods: We conducted a population-based retrospective cohort study using UK primary care data from the CPRD Aurum database (March 2020–July 2023). Adults (≥18 years) with confirmed SARS-CoV-2 infection between March 2020 and March 2023 were included, excluding those with less than one year of prior GP records. The primary outcome was PCC, defined by a PCC diagnostic code or at least one WHO-listed symptom occurring 90–365 days post-infection, without the same symptom recorded in the previous 180 days. The secondary outcome was a composite of subsequent clinical events. Adjusted hazard ratios (aHRs) and risk differences (RD) were estimated using multivariable models controlling for baseline factors. Mediation analysis assessed whether PCC mediated the link between penicillin allergy labeling and subsequent clinical outcomes.

Results: Among 1,587,288 individuals, 36,350 had a penicillin allergy label. The allergy-labelled group had a 10.8% higher 1-year risk of PCC (aHR=1.09, 95% CI: 1.07–1.12), with consistent results across subgroups. Penicillin allergy was also associated with an increased risk of subsequent clinical outcomes (aHR=1.10, 95% CI: 1.01,1.21), although PCC did not mediate this association.

Conclusion: Penicillin allergy labelling was associated with increased risks of PCC and adverse outcomes, though PCC did not mediate this relationship. These findings underscore the importance of accurate allergy assessment and de-labelling.

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Patterns of persistent healthcare use among people with long COVID

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Introduction: While some individuals diagnosed with long COVID require sustained healthcare support, there is limited evidence identifying who experiences persistently high healthcare needs. Understanding these patterns is essential for planning and allocating future services.

Aims: To characterize patterns of healthcare use and identify factors associated with persistently high utilization at least two years after a long COVID diagnosis.

Methods: We used data from the British Columbia COVID-19 Cohort, including individuals diagnosed with COVID-19 before December 31, 2022, and identified as having long COVID using a validated algorithm. Participants were followed for two years. We assessed daily healthcare encounters including medical visits, emergency department visits, hospitalizations, and classified individuals into four utilization categories: (1)Never high- not in the top 10% in either year; (2)Temporarily high- top 10% in year one only; (3)Incidentally high- top 10% in year two only; (4)Persistently high- top 10% in both years. We used Bayesian multinomial logistic regression to identify factors associated with each category, with the "never-high" group as the reference.

Results: Among 54,846 individuals with long COVID (62% female; 46.5% aged ≤49), those in high utilization groups were more likely to be older adults, and have more severe acute illness and comorbidities. Women had lower odds of high utilization across all categories of healthcare use (OR ~0.85–0.9). Hospitalization during acute illness was associated with higher odds of persistent (OR 1.37, 95% CI: 1.25–1.50) and temporary high use (OR 1.80, 95% CI: 1.64–1.97). Comorbidities such as problematic alcohol use, cancer, kidney and liver disease, heart disease, diabetes, immunosuppression, stroke, hypertension, and substance use were also associated with higher utilization.

Conclusion: Older age, severe acute illness, and specific comorbidities are associated with sustained high healthcare use among people with long COVID. Identifying these high-need groups is essential for planning and delivering long-term care services.

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Long-term risk of dementia following COVID-19: a retrospective cohort study in Korea

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Introduction: While the acute neurologic complications of COVID-19 are relatively well characterized, its long-term neurological risks for a progressive condition, including dementia, remain unclear.

Aims: To investigate the long-term risk of new-onset dementia following COVID-19 infection.

Methods: In this retrospective cohort study using a nationwide linked database of COVID-19 registry and health insurance claims data, we identified adults (≥18 years) who had a COVID-19 diagnosis between January 2020 and December 2022. Two control cohorts were established; a contemporary group with acute upper respiratory infection (AURI) diagnosis during the same period and a historical group with AURI before the pandemic. Individuals with a prior diagnosis of dementia or with a COVID-19 or AURI diagnosis inconsistent with their assigned cohort were excluded. COVID-19 patients were 1:1 matched to controls using propensity scores considering age, sex, insurance type, income, SARS-CoV-2 variant period, and dementia-related comorbidities. Hazard ratios (HRs) and 95% confidence intervals (CIs) for dementia defined by diagnosis were estimated using Cox proportional hazards models. The maximum follow-up period was until December 2024.

Results: A total of 1,592,234 COVID-19 patients (mean age 47.3 years [SD 16.6]; 39.3% female) were identified. Compared to the contemporary control group, there was no significant increase in dementia risk (HR 1.45; 95% CI 0.98–2.15), but risk was elevated in those aged ≥65 years (HR 1.60; 95% CI 1.06–2.41). Individuals who remained unvaccinated prior to COVID-19 exhibited a higher risk of dementia (HR 5.00; 95% CI 1.10–22.81), whereas no significant association was observed in vaccinated individuals (HR 1.28; 95% CI 0.84–1.93). Findings were consistent with the historical control analysis.

Conclusion: Our findings indicate that COVID-19 infection was not associated with an increased long-term risk of dementia, however, an elevated risk was observed among unvaccinated individuals, suggesting potential differences in long-term risk by vaccination status.

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Inpatient Antibiotic Utilization Before and During COVID-19 in an Indonesian Hospital

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Introduction: The World Health Organization (WHO) has reported a global increase in antibiotic use during the COVID-19 pandemic, raising concerns about inappropriate prescribing and contributing to the rise of antimicrobial resistance. In Indonesia, there is limited data on inpatient antibiotic utilization trends during this period.

Aims: This study aimed to evaluate inpatient antibiotic utilization patterns before and during the pandemic using data from a state-owned enterprise hospital.

Methods: We conducted a cross sectional study using inpatient pharmacy claims data from 2019 to 2020. Systemic antibiotics were identified using WHO Anatomical Therapeutic Chemical (ATC) codes J01 and classified according to ATC classes and AWaRe (Access, Watch, Reserve) categories. Utilization was quantified using Defined Daily Doses (DDDs) per 100 patient days. Patient days were calculated based on hospital admission and discharge dates.

Results: A total of 8,354 antibiotic prescriptions were analyzed from 1,214 inpatients. A total of 650 patients (53.54%) were female. The mean age was 54.15 ± 19.09 years, with majority (69.19%) in the 18-65 years age group. Total antibiotic use for two years was 25.66 DDD/100 patient days. Yearly breakdown showed higher utilization in 2019 (28.76 DDD/100 patient days) and a decrease in 2020 (22.13 DDD/100 patient days). Parenteral formulations accounted for the majority of antibiotic use (76.81%). Third-generation cephalosporins, particularly ceftriaxone, were the most frequently prescribed agents (40.02%). Antibiotics categorized under WHO Watch group predominated across both years, representing 83.56% of all prescriptions. Four specific antibiotics demonstrated increased use during the pandemic period (2020): azithromycin, clindamycin, gentamicin, and levofloxacin.

Conclusion: Overall inpatient antibiotic utilization declined in 2020 compared to 2019. Ceftriaxone had the highest level of utilization on both years. High use of watch group antibiotics in both years and increased use of specific agents from the watch categories (azithromycin and levofloxacin) highlights the concerns for antimicrobial resistance risk.

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Multi-organ involvement of clinical sequelae following COVID-19 infection: a multinational cohort study

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Introduction: The existing evidence on post-COVID-19 sequelae were predominantly based on findings from single database, with under-representative study populations.

Aims: This study aims to generate comprehensive evidence on the risk of clinical sequelae over the short-, medium-, and long-term, spanning up to two years following COVID-19 infection through leveraging population-based electronic medical records and claims data from five countries.

Methods: This multinational retrospective cohort study utilized electronic medical records from the US, UK, France, Germany and Italy standardised to the Observational Medical Outcomes Partnership Common Data Model. 303,251 individuals with a COVID-19 infection between December 01, 2019 and December 01, 2020 and propensity score matched non-COVID-19 comparators from 22,108,925 eligible candidates. The incidence of 73 clinical sequelae involving multiple organ systems including the respiratory, cardiovascular, dermatological and endocrine systems over the short (0-6 months), medium (6-12 months) and long-term (1-2 years) following COVID-19 infection. The hazard ratio (HR) and 95% confidence interval (95% CI) of individual disease outcomes were estimated using Cox proportional hazard regression.

Results: Individuals with COVID-19 incurred a greater risk of clinical sequelae involving multiple organ systems including respiratory [France HR 2.23, 95%CI (2.10,2.37) to Italy 13.13 (11.80,14.63)], cardiovascular [Germany 1.39 (1.30,1.50) to US 1.79 (1.74,1.85)] and dermatological [UK 1.13 (1.01,1.25) to Italy 1.77 (1.42,2.21)] disorder over the short-term. Whilst the risk of clinical sequelae has largely subsided during the medium-term, the risk of cardiovascular [US 1.16 (1.11,1.21), France 1.10 (1.01,1.19)] and endocrine [US 1.18 (1.12,1.24), Germany 1.15 (1.03,1.29)] related complications may continue to persist for up to two years.

Conclusion: Through a network of multinational healthcare databases, this study generated comprehensive and robust evidence supporting the extensive multi-organ involvement of post-COVID-19 condition over the short-term period and the subside in risk for most complications over the medium and long-term.

Keywords: COVID-19; Post-COVID-19 conditions; Long COVID

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Trends in influenza vaccine uptake before and during the COVID-19 pandemic

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Introduction: Influenza vaccination remains the most effective public health measure to reduce influenza-related morbidity and mortality. However, the coronavirus disease 2019 (COVID-19) pandemic disrupted routine healthcare services and may have influenced preventive care behaviours, including influenza vaccine uptake. While several studies have explored this issue, findings on the impact of the COVID-19 pandemic on influenza vaccination coverage in the United States have been inconsistent. Understanding these patterns is critical for informing strategies to maintain or improve vaccine coverage during future public health emergencies.

Aims: To investigate trends of influenza vaccine uptake before and during the COVID-19 pandemic in the United States and explore the associated factors.

Methods: Using self-reported data from the National Health Interview Survey during 2014-2021 (response rates ranging from 50.7-70.1%), we estimated influenza vaccine uptake. Log-binomial regression models were used to test uptake changes with adjustment for and stratification by demographic and health factors.

Results: We included 58,249 children (mean age: 8.7 years; male: 51.1%) and 205,034 adults (mean age: 47.6 years; male: 48.2%). The prevalence ratio (PR) of uptake change comparing the intra- (2020-2021) to the pre-COVID-19 period (2014-2019) was 0.72 among children with a 10.7% reduction. Uptake changes were found across subgroups with higher reduction among those aged 0-2 years, non-Hispanic Black and Hispanic ethnicity, from South and West regions, and with lower household income. For adults, uptake increased before and during COVID-19 (PR=1.15, 95% CI: 1.12-1.18) but a 2.3% reduction was found among healthcare personnel (PR=0.95, 95% CI: 0.90-0.997).

Conclusions: Influenza vaccination decreased during the COVID-19 pandemic among children and healthcare personnel. Structure inequality to influenza vaccination warrants measures to improve vaccine uptake among vulnerable groups.

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Risk of Type 1 Diabetes and mRNA-based COVID-19 Vaccines in Young Adults

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Introduction: Public interest in mRNA vaccines has grown since their rapid COVID 19 rollout in late 2020, but concerns have arisen about potential autoimmune effects, including a possible link to type 1 diabetes. However, assessing a potential causal link between mRNA based COVID 19 vaccines and type 1 diabetes in young adults is challenging and may be affected by unmeasured confounding.

Aims: To evaluate the risk of type 1 diabetes who received mRNA-based COVID-19 vaccines in young adults.

Methods: We emulated a target trial using multi institutional electronic health records (2021–2023), including young adults (≤40 years) receiving their first dose of either an mRNA based or adenoviral vector–based COVID-19 vaccine. We assigned individuals according to the vaccine type they received for their first dose, and the date of that dose was defined as their index date. Propensity score matching balanced baseline characteristics, and Cox proportional hazards models with negative control outcome calibration estimated adjusted hazard ratios (HRs). We further conducted animal models to explore biological plausibility by assessing pancreatic β cell stress after mRNA based vaccination.

Results: Among 27,849 vaccine recipients (36% male; mean age 29 years), mRNA-based COVID-19 vaccination was associated with a two-fold higher risk of incident type 1 diabetes compared with adenoviral vector vaccines (HR 2.00; 95% CI 1.06–3.77). These results remained consistent after controlling for unmeasured confounders (HR: 1.98; 95% CI: 1.05-3.75). Evidence from animal studies indicated that mRNA based vaccination intensified hyperglycemia and impaired glucose tolerance in β cell dysfunction models.

Conclusions: Even after we controlled all confounders, mRNA-based COVID-19 vaccines were associated with an elevated type 1 diabetes risk in young adults, with support from animal models indicating β-cell impairment.

Keywords: mRNA vaccination, type 1 diabetes, negative control outcome calibration, animal models

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Impact of COVID-19 restrictions on estimating causal effects: Fluoroquinolones and tendon rupture.

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Introduction: It is unclear whether changes in diagnostic recording due to COVID-19 pandemic restrictions could lead to measurement errors, that affect estimates of causal effects of treatments on outcomes.

Aims: To assess potential measurement errors due to changes in diagnostic recording during pandemic restrictions

Methods: We replicated a published cohort study using data from UK Clinical Practice Research Datalink Aurum linked with Hospital Episode Statistics between 1/1/2006-31/3/2023. We estimated absolute rate differences (RD) and hazard ratios (HR) for tendon rupture comparing fluoroquinolones vs. cephalosporins, using propensity scores (PS) for confounder adjustment. We estimated treatment effects using pre-pandemic data only and compared that with combining all data, and with using post-pandemic data only. Study start year was varied to examine the impact of including different proportions of study time covered by the pandemic.

Results: Using pre-pandemic data (1/1/2006-15/3/2020), PS-weighted HR for tendon rupture was 1.78 (95%:1.34-2.38) and RD of 0.72/1000 person-year, comparing fluoroquinolones with cephalosporin, consistent with the published study. Using all data (1/1/2006-31/3/2023), results were similar with a RD of 0.72/1000 person-year and HR of 1.77 (95%:1.35-2.32). The HR of the interaction term between treatment and a binary indicator of pre-pandemic vs. during/post-pandemic was 0.86 (95%CI:0.38-1.97). Using post-pandemic data (17/4/2022-31/3/2023), the HR was 3.80 (95%:0.74-19.46) and RD was 0.90/1000 person-year.
Varying the study start year from 2007 to 2012, HRs slightly reduced ranging from 1.65 (95%CI:1.24-2.20) to 1.62 (95%:1.08-2.41), with small variations of RDs from 0.69/1000 to 0.8/1000 person-year. Results were imprecise when the study start year was from 2013-2023.

Conclusion: Combining pre-, during, and post-pandemic data did not meaningfully affect effect estimates investigating effects of fluoroquinolones on tendon rupture. Future research with a longer study period is recommended to assess whether the HR based on pre-pandemic data remains consistent with that based on post-pandemic data.

Keywords: electronic health records;COVID-19;bias

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Nationwide serial cross-sectional study for antimicrobial drug usage during COVID-19 pandemic

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Introduction: Misuse and overuse of antimicrobial drugs can cause an acquisition of antimicrobial resistance (AMR), and proper antibiotics use is needed to minimize the risk of AMR. In April 2020, the national medical fees were revised in Japan, and instructions to monitor antibiotics usage were added. Additionally, COVID-19 pandemic enhanced preventive actions such as wearing masks for both bacteria and viruses.

Aims: This study analyzed the trend of antimicrobial drug usage after policy implementation during COVID-19 pandemic.

Method: A nationwide serial cross-sectional study was conducted using the open data from the national database (NDB). This study extracted the antibiotic prescription data of all oral medicine and injection for both inpatient and outpatient based on the therapeutic category. The antimicrobial usage was calculated as DDD (Defined Daily Dose) per 1,000 inhabitants per day (DID). Research periods were fiscal year FY2019 (April 2019-March 2020) and FY2020 (April 2020-March 2021). The means (95% CI) for DID were analyzed with data of 47 prefectures, and paired t-tests were performed. P-values (two-sided) < 0.05 was considered statistically significant.

Result: The nationwide total DID was 13.60 in FY 2019, and 10.48 in FY2020 with approximately 23% reduction. Additionally, the reduction rate of DID was 33% in the 0-19 age group, 24% in the 20-74 age group, and 13% in those aged 75 years and over during FY2019-2020. The means (95% CI) of DID based on prefectures (n=47) are 13.51 (13.13-13.89) for FY2019 and 10.56 (10.26-10.87) for FY2020, and the statistically significant difference was observed ($p<0.001$).

Conclusion: A substantial reduction of nationwide antimicrobial drug usage was observed after policy implementation during COVID-19.

Keywords: antimicrobial stewardship, COVID-19 pandemic, serial cross-sectional study

D2/P369

Study of utilization and evaluation pattern of antimicrobials in critical care units

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Introduction: Antimicrobial resistance (AMR) remains a growing concern, particularly in critical care settings where high antibiotic usage is prevalent. Utilization studies play a crucial role in informing antimicrobial stewardship (AMS) programs by identifying prescribing trends, promoting rational use, and guiding interventions to minimize resistance.

Aim: To ensure effective treatment, prevent resistance, support stewardship efforts.

Methods: A prospective observational study was conducted over six months in the Critical Care Units of JSS Hospital, Mysuru. Antimicrobial prescriptions for prophylactic, empirical, and definitive purposes were reviewed. Data were collected from treatment charts and medical orders. WHO core indicators—Defined Daily Dose (DDD) and Antimicrobial Utilization Density (AUD)—were used to quantify usage. Patient demographics (age, gender, diagnosis, duration of stay) and prescription characteristics (drug name, dose, route, frequency, generic use) were analyzed

Results: Among 280 critically ill patients, piperacillin-tazobactam had the highest DDD (2,490,444.44), followed by colistin (1,764,000) and cefoperazone (340,616.66). In AUD, piperacillin (9685.0) was most frequently used, followed by cefuroxime (8523.5), colistin (7840), clindamycin (3273.1), and ceftriaxone (2528.5). Meropenem (775.6) and linezolid (241.5) showed relatively lower usage. These patterns reflect a high reliance on broad-spectrum antibiotics, emphasizing the need for enhanced stewardship strategies.

Conclusion: The study provides a comprehensive overview of antimicrobial utilization in a critical care setting, identifying agents with high usage and highlighting opportunities for targeted stewardship interventions. These findings can inform policy and guide AMS efforts to optimize therapy and prevent antimicrobial resistance.

Keywords: Utilization pattern, Stewardship efforts, critical care units.

D2/P370

Performance of electronic algorithms for dengue and severe dengue detection

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Introduction: Dengue is prevalent and endemic in Singapore, with the number of cases ranging from 5261 to 35266 between 2019 and 2021. Dengue vaccines are under development but given the safety concerns of the first dengue vaccine DENGVAXIA, the World Health Organization and dengue experts have recommended that subsequent dengue vaccine development programs should include post-licensure evaluation of vaccine safety.

Aims: The aim of this study was to evaluate data sources within a public healthcare cluster in Singapore as being "fit-for-purpose" for pharmacoepidemiologic studies related to dengue, specifically developing and validating electronic algorithms for detection of dengue and severe dengue (SD).

Methods: This was a retrospective database cohort study of patients diagnosed with dengue at a tertiary adult hospital, a pediatric hospital and a group of polyclinics from 1 Jan 2018 to 30 Jun 2022. Dengue was defined as having a positive test for the dengue virus, virus antigen or virus specific IgM, and/or a dengue diagnostic code. Three SD algorithms were developed among those within the dengue algorithm based on different combinations of disposition (death, ICU admission) and diagnostic codes. The performance of each algorithm was evaluated in each institution using positive predictive values (PPV) based on a sample of 25 dengue cases and 10 from each SD algorithm (total n=30), validated against manual review of relevant clinical documents and laboratory test results by clinicians.

Results: A total of 8603 dengue episodes were detected over the study period. The PPV of the dengue algorithm ranged from 76 – 100%, and that of the SD algorithms ranged from 10 – 90% in the 2 hospitals.

Conclusions: Dengue can be detected with reasonable PPV using the electronic databases. However, the detection of SD is more variable by institution and algorithm.

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Rifampicin for hypervirulent Klebsiella pneumoniae infections: a systematic review

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Introduction: Hypervirulent Klebsiella pneumoniae (HvKp) is linked to invasive syndromes, including liver-abscess and meningitis. Its hypermucoviscosity-phenotype, driven by capsular regulators like rmpA and magA, makes standard antibiotics less effective. Rifampicin, a transcriptional-inhibitor, shows potential antivirulence activity but remains under-investigated in HvKp-infections.

Aims: To assess the impact and outcomes of rifampicin regimens for HvKp-infections.

Methods: We conducted a systematic search across PubMed, Embase, Scopus, and Cochrane from inception-to-June 2025. Due to the limited volume of high-level evidence, we included in-vitro, in-vivo studies, and case-reports evaluating rifampicin against confirmed HvKp-infections. Extracted data included dose, timing, co-administered agents, and clinical outcomes. Study quality was assessed using the SYRCLE risk-of-bias tool for animal studies and the JBI checklist for case-reports.

Results: Seven studies met inclusion: one in-vivo murine study, two mechanistic in-vitro studies, and four case-reports. In-vivo, rifampicin combined with zidovudine led to complete bacterial clearance and 100% survival. Mechanistic in-vitro studies demonstrated that rifampicin suppressed mucoviscosity via downregulation of rmpA/magA. Among the four clinical-cases the HvKp strains were was defined by hypermucoviscous phenotype (string-test +ve), three patients recovered following early rifampicin use (within 3–5 days), administered at 450–600 mg/day. These were used in combination with meropenem/cefoperazone+sulbactam, with symptomatic improvement within 3–7 days. One case involving emphysematous pyelonephritis responded to rifampicin with meropenem and levofloxacin. A fourth case, involving a severely immunocompromised patient with delayed rifampicin initiation (>21 days), resulted in deterioration and scummed to death. None of the cases reported rifampicin-associated toxicity.

Conclusions: Rifampicin may exert antivirulence effects in in-vitro and murine models and appears to offer adjunctive therapeutic benefit when initiated early in HvKp-infections. The apparent synergy with agents like meropenem or zidovudine warrants further investigation. Given the reliance on low-powered, non-randomized designs, these findings should be interpreted cautiously. Controlled trials are essential to validate efficacy, define optimal use, and evaluate safety.

D2/P372

Pharmacist vital allies in pediatric care: evaluating KAP of immunization in public

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Introduction: Vaccination plays a vital role in reducing childhood mortality from infectious diseases. However, suboptimal vaccination rates persist due to parental hesitancy, misinformation, and access barriers. Parents' knowledge, attitudes, and practices (KAP) critically influence vaccination uptake. Understanding these factors is essential for improving vaccine acceptance and coverage.

Aims: To assess parental knowledge, attitudes, and practices toward pediatric vaccination and to explore the potential of a digital reminder system to reduce missed vaccinations.

Methods: A hospital-based cross-sectional survey was conducted among 93 parents at KIMS Al Shifa Hospital and Government District Hospital, Perinthalmanna. Data were collected via an 18-item KAP questionnaire across immunization departments offering daycare and outpatient services.

Results: Most children were aged 0–6 months (38.7%). Knowledge was highest for polio (25.8%) and BCG (18.3%), with limited awareness of other vaccines. Most parents (88.2%) considered vaccines safe, 91.4% supported routine and booster vaccinations, and 93.5% were open to vaccination with more information. While 83.9% knew their child's vaccination schedule, 51.6% had missed doses—mainly due to lack of awareness. Most believed reminders were effective (91.4%), and 63.4% used digital tools. Only 44.1% contacted providers after missing a dose.

Conclusion: Though attitudes toward vaccination were positive, knowledge gaps and inconsistent practices persist, largely due to insufficient provider communication and lack of structured follow-up. The findings highlight the need for improved health education and digital reminder systems to enhance vaccination coverage.

Keywords: Immunization, KAP survey, Pediatric.

D2/P373

Aseptic Meningitis Induced By Antibiotics: A Disproportionality Analysis

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Introduction: Antibiotic utilization has been streamlined in various countries because of the national stewardship programs. Besides the efficacy component of antibiotics, the safety profile is a predominant area that requires special consideration in real-world settings. Many adverse events from antibiotics are unnoticed, detrimentally affecting the patients' treatment outcomes.

Aim: To identify aseptic meningitis induced by antibiotics (AMA) through disproportionality analysis.

Methods: A retrospective case/non-case disproportionality analysis was performed in the FAERS database using OpenVigil 2.1, a web-based pharmacovigilance tool, to identify AMA. The data from 2004 to the end of 2024 were extracted by using the preferred term, i.e, aseptic meningitis, of MedDRA terminology and the drug terms under the category of antibiotics. Frequentist techniques assessed the degree of association between aseptic meningitis and antibiotics. A signal is identified when the Proportional Reporting Ratio (PRR) > 2, the Reporting Odds Ratio (ROR) lower bound > 1, and the Chi-Square > 4.

Results: The study had 56% reports of AMA in the female population. The patients on sulfamethoxazole (n=74) and trimethoprim (n=73) had the highest report of aseptic meningitis, which was from the US. Aseptic meningitis was also reported in patients on amoxicillin, ampicillin, azithromycin, cefazolin, cefepime, cefotaxime, ceftriaxone, ciprofloxacin, clarithromycin, colistin, meropenem, metronidazole, minocycline, and vancomycin. A potential signal for AMA was reported in patients on cefcapene (PRR: 360.35), followed by garenoxacin (PRR: 45.39), ceftibuten (PRR: 32.03), colistin (PRR: 27.94), cefotaxime (PRR: 26.685), and amoxicillin (PRR: 22). Hospitalization (n=511) was the most prominent outcome reported in AMA patients.

Conclusions: Several occurrences of aseptic meningitis were reported with antibiotics. However, a well-designed study is required to confirm the association of aseptic meningitis with different antibiotics.

D2/P374

Incidence trend for extended Carbapenem-Resistant Enterobacteriaceae colonisation: an Interrupted time series analysis

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Introduction: Carbapenem-resistant Enterobacteriaceae (CRE) are resistant to most antibiotic drug classes and are also resistant to carbapenem, one of the "last resort" antibiotic classes.

Aims:
1. To examine the trend of CRE colonisation pre-, during and after the COVID-19 pandemic in Hong Kong.
2. To describe the duration of CRE colonisation.

Methods: We collected data from the Hong Kong Hospital Authority (HA) electronic health record, for patients aged >18 at onset, during a period from 2017/01/01--2023/06/30, for CRE laboratory tests using either genotypic or phenotypic methods.
We examined the changes in CRE monthly incidence before, during, and after the COVID-19 pandemic (i.e. 01/02/2020 – 28/02/2023) in an interrupted time series using quasi-poisson regression model. CRE colonisation duration was categorized into short-term (0-3 months), prolonged (4-6 months), and persistent (6-12 months).

Results: We identified N=65,879 episodes from 63,488 adult patients (aged ≥18) had ≥1 CRE test during the study period. Among which, N=16,122 episodes (24%) had ≥1 CRE positive result. Patients aged ≥85 contributed to the largest share of episodes by N=19,321 (29%).
About half of the episodes (N=34,690, 53%) occurred during the COVID-19 period. The CRE test positive incidence trend showed an increasing pattern with seasonality each year before the start of the COVID-19 pandemic in February 2020. The CRE incidence started to increase rapidly during the COVID-19 (p=0.008) pandemic period in 2021-22, while it exhibited a steeper growth after the pandemic in March 2023.
Among all CRE positive episodes, short-term colonisation made up 26% (N=4,123), while prolonged was 5.2% (N=837), and persistent was 7.6% (N=1,225), while the rest were indeterminate duration (N=9,937, 62%).

Conclusions: The observed growing trend in CRE incidence may be attributed to increased surveillance efforts in public hospitals, and the percentage of CRE positives warrants further investigation to account for testing trends.

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Understanding inpatient antibiotic prescribing: a synthesis of evidence on determinants and interventions

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Background: Due to the complexity of infection types, high resistance risks, and severe clinical consequences, there is an urgent need to optimize antimicrobial prescribing in hospital environment. However, key determinants on physician prescribing behavior remain divergent, evidence on the effectiveness of interventions is controversial.

Objective: This study aims to clarify the determinants on physician antimicrobial prescribing in the inpatient environment and assess intervention effectiveness to optimize prescribing.

Methods: We searched PubMed, Embase, Cochrane Library, and Web of Science up to July 5, 2025, to identify evidence on determinants of and interventions for antibiotic prescribing practices. We categorized determinants into prescriber, patient, and environment factors, then, through a single-arm meta-analysis to quantify the influence of determinants on the prescription behavior. We used a random-effects model to analyze the effect of interventions on prescription outcome. Interventions were categorized by Behavior Change Techniques (BCTs), with Effectiveness Rates (ERs) calculated.

Results: Fifty-nine studies (20 qualitative and 39 quantitative) were included. Study indicated that 81%, 80%, and 65% of participants acknowledged the influence of environmental, prescriber, and patient factors, respectively. The intervention improved rational antimicrobial prescribing by 21%, reduced antimicrobial prescribing by 50%, and reduced antimicrobial consumption by 25%.BCT analysis showed that “behavior feedback” was most effective (ER=3.5).

Conclusion: This study confirms that physician antimicrobial prescribing in the inpatient environment is influenced by multiple factors and the interventions effectively improved prescribing practices. However, the effectiveness of the intervention was not sufficiently evaluated in resource-limited settings, and further research should optimize antimicrobial prescribing practices in low- and middle-income countries.

Keywords: Antimicrobial prescribing;Determinants;Interventions

D2/P376

Probiotic supplementation improves ATT-related safety in tuberculosis patients: a prospective cohort study

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Introduction: Probiotics supplementation has gained importance in various medical conditions due to their capacity to improve gut health, modulate immune responses, and mitigate antibiotic-associated side effects.

Aims: This study aimed to assess the effect of probiotic supplementation on multiple dimensions of tuberculosis (TB) care, including clinical, humanistic, and safety outcomes.

Methods: This study is a prospective observational study. Data were collected for TB treatment outcome, haematological inflammatory indices, anti-tuberculosis treatment (ATT) induced adverse drug reactions (ADRs), and health-related quality of life (HRQoL) using the EuroQol 5-Dimension 5-level questionnaire to evaluate the effect of probiotics supplementation.

Results: 177 drug-sensitive pulmonary TB (PTB) patients were enrolled. TB treatment success rates between the study group (SG) and the reference group (RG) were 85.1% and 84.6%, respectively (p= 1.000). Among haematological inflammatory indices, only the systemic inflammation response index (SIRI) showed a statistically significant reduction after probiotic supplementation (p= 0.048). No significant changes were observed in HRQoL scores at various time points. ATT-induced ADRs were significantly lower in SG than RG (14.8% vs. 61.3%; $p < 0.001$).

Conclusion: Probiotic supplementation did not significantly influence TB treatment success or HRQoL outcomes but demonstrated a favorable impact on systemic inflammation and a significant reduction in the incidence of ATT-induced ADRs, especially gastrointestinal side effects. These findings suggest a potential role for probiotics as a supportive adjunct to ameliorate ATT-induced ADRs. Future studies should focus on assessing long-term supplementation effects to investigate humanistic outcomes.

Keywords: Pulmonary tuberculosis, probiotics, drug safety

D2/P377

Evaluation of Antibiotic Prescription in Community Pharmacy based on WHO AWaRe classification

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Introduction: Antimicrobial resistance is a growing threat to public health systems across the world, making harder to treat infectious diseases. To address this the WHO introduced the AWaRe framework, serving as a surveillance and policy tool in 2017, categorizing antibiotics into Access, Watch and Reserve groups to promote rational antibiotic use and guide antibiotic stewardship efforts.

Aim: To evaluate the antibiotics prescription in community pharmacy as per the AWaRe classification and to identify the prescribing factors associated with the AWaRe class of antibiotics.

Methodology: A prospective cross-sectional study was conducted at Radha Medicals, a community pharmacy in Udupi, Karnataka, India over ten months period. Random prescription samples were collected, allowing us to estimate the prevalence of AWaRe class of antibiotics in community pharmacy prescriptions. Antibiotics were classified based on WHO AWaRe Classification (2023). The frequency and association between patient demographic characteristics, specialization of the physician with AWaRe classification were analysed.

Results: Out of a total of 634 prescriptions reviewed, majority (58.8%) contained antibiotics from the WHO Watch category, followed by the Access (39.1%) and Reserve (2.1%) categories. The mean age of the patients were young adults aged 18 to 35 years, making up about 60.7% of the group, followed by middle-aged adults. In terms of gender, there were slightly more males (52.8%) than females. Majority of prescriptions originated from doctors with MBBS and MD qualification, who are prescribing antibiotics across all three AWaRe categories, indicating their significant role in antibiotic selection.

Conclusion: A high proportion of prescriptions from the Watch category is a concern, as overuse can make them less effective due to increased resistance. To address this issue, the study calls for strong antibiotic stewardship programs to guide prescribers and pharmacists on proper antibiotic selection, dosage, and duration.

Keywords: AWaRe Classification, Antimicrobial resistance, Antimicrobial Stewardship Program, Community pharmacy, Prescription

D2/P378

Evaluating illness severity and prescribing trends in paediatric respiratory tract infections

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Introduction: Severe paediatric respiratory tract infections (RTIs) lead to a major global health burden causing approximately 740,000 deaths in children under five. Accurate assessment of RTI severity is critical to guide timely clinical interventions. This study addresses a critical gap by jointly evaluating RTI severity and drug utilization in low resource hospital settings.

Aims: To determine the severity of RTIs through PRESS scoring system and examine prescription patterns using WHO drug-utilization indicators in hospitalized children.

Methods: A six month prospective, cross sectional study was conducted in the paediatric ward of a tertiary care hospital. Children aged 0–12 years admitted with any RTI were enrolled. A structured Case Report Form was developed to record demographics, lab values, diagnosis, medications prescribed, and the five PRESS score parameters, which guided clinical severity assessment. All prescribed medications including route, antibiotic use, and brand versus generic status were evaluated using WHO prescribing indicators. Data were analysed using descriptive statistics and chi-square tests and interpreted graphically.

Results: A total of 123 children (mean age 4.2±3.1 years; 54% male) with various respiratory tract infections were enrolled. Lower RTIs were predominant (83.7%), with 69.9% of admissions in children under five. According to PRESS scoring; most of the cases (42.3%) were mild. Analysis of prescribing patterns revealed that 58.3% of all drugs were administered parenterally; antibiotics accounted for 34.7% of drug encounters. A significant discrepancy was observed between prescribed daily doses and recommended standards ($p < 0.05$).

Conclusion: The study highlights a high burden of lower RTIs in young children with frequent use of parenteral and branded antibiotics, and notable dosing inconsistencies. These findings from a comprehensive DUE, underscore the need for enhanced antibiotic stewardship and adherence to dosing guidelines.

Keywords: RTI, PRESS, DUE

D2/P379

Economic outcomes of consumption and resistance of restricted antibiotics in a hospital

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Introduction: Overuse of antibiotics can lead to resistance and increased healthcare costs by affecting therapy outcomes, disease incidence, length of hospital stay, and overall hospital expenses. While antimicrobial stewardship programs (AMS) address these issues, the economic impact of antibiotic consumption and resistance is rarely investigated.

Aim: This study aimed to compare monthly economic outcomes of restricted antibiotic consumption and resistance between two hospital wards, focusing on: excess costs from unauthorized dispensing of restricted antibiotics, hospital stay costs, and culture sensitivity test costs.

Methods: A retrospective cross-sectional study reviewed 1,928 dispensing records from two adult wards in a government hospital (March 2019–February 2020). Monthly per-patient costs were analyzed for: over-dispensed restricted antibiotics, hospital stays, and culture sensitivity tests. Restricted antibiotics included 4th generation cephalosporins, aztreonam, carbapenems, colistin, vancomycin, and linezolid. Cost outcomes were compared between Ward 1 (with a pharmacist) and Ward 3 (without a pharmacist) using statistical analysis.

Results: One-year costs of over-dispensed restricted antibiotics were significantly lower by 60% in Ward 1 vs. Ward 3 ($p = 0.0356$). Average monthly costs for hospital stay and laboratory tests were also lower in Ward 1, but not statistically significant ($p = 0.5822$ and $p = 0.3989$, respectively). Both wards showed declining use of piperacillin-tazobactam. Levofloxacin was most prescribed in Ward 3 (350.2 DDD/1000 PD), while ciprofloxacin was more used in Ward 1 (23.3 DDD/1000 PD). Acinetobacter baumannii resistance to these antibiotics was significantly lower in Ward 1 by about 20% ($p = 0.0328$, $p = 0.0165$, $p = 0.0173$, respectively).

Conclusion: The presence of pharmacist in Ward 1 played a crucial role in monitoring restricted antibiotics, leading to improved patient outcomes and cost savings. Reduced consumption of restricted antibiotics in both wards highlights the AMS program's importance in minimizing unnecessary antibiotic use.

Keywords: Antibiotic consumption, antibiotic resistance, restricted antibiotics

D2/P380

Evaluating the ADR-Associated Hospitalisation Burden in PLHIV: 72-Week Prospective Cohort Study

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Background: Adverse drug reactions (ADRs) significantly impact global health, contributing to a substantial proportion of hospital admissions (0.2% to 59.6%) and a 1.8% fatality rate, particularly affecting low- and middle-income countries (LMIC). The Medication Regimen Complexity Index (MRCI) is a measure of medication regimen complexity, which takes into account factors such as dosage forms, frequencies, and administration routes. It reflects the challenges faced in managing medication regimens, particularly in populations with chronic conditions like HIV.

Objectives: To determine the correlation of MRCI in PLHIV with the hospitalisation rate.

Methodology: enrolled 285 adults (PLHIV) between August 2019 and November 2021, with a 78-week follow-up. Demographic profiles, ADRs, clinical and MRCI data were collected and analysed using EpiData and SPSS Version 11. The MRCI tool consists of three parts: A assesses pharmaceutical formulation, B evaluates drug administration frequency, and C examines medication administration directions. Each section is scored independently, and the total MRCI score is calculated by summing scores.

A median ART duration of 6 years (IQR, 4–9). Clinical data were collected, validated using EpiData, and analysed with SPSS version 11.

Results of objects completed till date: In this study of 285 participants, 48% were female. A median ART duration of 6 years (IQR, 4–9).Nine (3%) participants were lost to follow-up.
Statistical analysis using the Chi-Square test ($\chi^2 = 6.233$, df = 1, p = 0.013) and Spearman's rank correlation coefficient ($\rho = 0.148$, p = 0.012) revealed a significant association between Medication Regimen Complexity Index (MRCI) and Hospitalisation due to Adverse Drug Reactions (ADR).
Specifically, as the MRCI increases, there is a corresponding increase in the likelihood of hospitalization due to ADR.

Conclusion: This finding suggests that a more complex medication regimen, as measured by MRCI, may be associated with a higher risk of experiencing adverse drug reactions leading to hospitalisation.

D2/P381

Prevalence, clinical profile, and outcomes of low-level viremia among HIV-1 adults

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Introduction: HIV has become a manageable chronic disease with universal access to antiretroviral therapy(ART), targeting immune reconstitution and viral suppression. However, some patients experience low-level viraemia(LLV), i.e, low but detectable HIV RNA levels, associated with increased risk of virologic failure, opportunistic infections, and non-communicable diseases (NCDs). Limited data exist on how ART regimens like TLE(Tenofovir+Lamivudine+Efavirenz) or TLD(Tenofovir+Lamivudine+Doutegravir) affect LLV occurrence and outcomes.

Aims: To assess the prevalence, clinical profile, and outcomes of LLV among HIV-1 infected adults on TLE and TLD regimen.

Methods: This retrospective study at an HIV-care centre included adults with LLV between 1/1/2021 and 31/12/2022. Participants were on TLE/TLD for ≥6 months, ≥95% adherence, and had at least two viral-load reports. Follow-up continued until viral suppression, virologic failure, death, or the latest clinic visit. Chi-square test and descriptive analysis were used.

Results: Among 773 records screened, 62 patients (Prevalance-8%) had LLV. High-LLV was significantly associated with cryptococcosis (p = 0.026). TB occurred in 3.2%, all on TLE. Diabetes was the most common NCD(9.6%), more frequent among TLE patients. Immune discordance occurred in 8%, mostly on TLE(80%). Virological failure(1.6%) occurred in one patient who developed LLV after switching from TLE to TLD. Viral suppression was achieved in 93.5%, and persistent LLV occurred in 1.6%, both mostly among those on TLE. Two deaths(3.2%) occurred, one each in TLE and TLD groups.

Conclusion: High-LLV in our study was associated with cryptococcosis, suggesting ART initiation during advanced HIV with larger viral reservoirs. LLV was more common in TLE patients, with improved suppression after switching to TLD. This may suggest resistance from prolonged TLE exposure, though lack of resistance testing limits interpretation. Higher NCD rates in TLE patients likely reflect longer ART duration. Larger studies with resistance testing are needed to clarify LLV's impact on TLE/TLD.

Keywords: Low-level viremia, ART, TLE/TLD regimen

D2/P382

Characteristics and Safety of RSV Vaccines Based on the US VAERS Data

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Introduction: The GSK (Arexvy), Pfizer (Abrysvo), and mResvia (Moderna) respiratory syncytial virus (RSV) vaccines are both indicated for adults aged ≥60 years, but only Abrysvo is approved for use in pregnancy.

Aims: This descriptive study examined characteristics and outcomes of adverse event (AE) reports of marketed RSV vaccines to the United States FDA Vaccine Adverse Event Reporting System (VAERS).

Methods: This retrospective analysis examined VAERS reports between May 1, 2023 and February 28, 2025 and focused on AE reports related to RSV vaccines. Patient characteristics (age and sex) and AE outcomes (death, life-threatening illness, emergency room visits, hospitalization, disability, and birth defect) were summarized. The top 15 most frequently reported AEs for Arexvy and Abrysvo were described.

Results: Significant numbers of RSV vaccines were administered to individuals <18 years old [Arexvy (n=13, 0.3%), Abrysvo (n=58, 2.8%), mResvia (n=1, 3.0%), and unknown brand (n=2, 2.9%)] and those aged 18-59 (Arexvy (n=288, 5.9%), Abrysvo (n=294, 14.0%), and mResvia (n=5, 15.2%)]. Higher proportion of RSV vaccines were administered to females [Arexvy (66.0%), Abrysvo (63.0%), mResvia (75.8%)]. A total of 7088 AE reports related to RSV vaccines were identified: Arexvy (n=4882, 68.9%), Abrysvo (n=2105, 29.7%), mResvia (Moderna, n=33, 0.5%), and unknown brand (n=68, 1.0%). Hospitalization [Arexvy (4.0%), Abrysvo (8.8%)], life-threatening illness [Arexvy (1.0%), Abrysvo (8.8%)], disability [Arexvy (1.2%), Abrysvo (1.9%)], and death [Arexvy (0.6%), Abrysvo (0.8%)] were reported. The top 15 most frequently reported AEs for Arexvy and Abrysvo were similar including pain and fatigue. However, significant proportions of AEs for Arexvy were Exposure During Pregnancy (6.7%) and Wrong Product Administered (5.3%). About 5.0% of AEs for both Arexvy and Abrysvo were Product Administered to Patients of Inappropriate Age.

Conclusions: Preventable administration errors related to RSV vaccines are observed in clinical practice, which calls for proper education and training among healthcare professionals.

D2/P383

No excess risk of mortality or multimorbidity following hemorrhagic stroke after mRNA-vaccination

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Introduction: While the risk of hemorrhagic stroke following COVID-19 mRNA vaccination remains inconclusive, hemorrhagic stroke occurring shortly after vaccination raises important questions about its prognosis. Inspired by milder prognosis observed in vaccine-related myocarditis, we hypothesized that transient vaccine-related mechanisms (e.g., thrombocytopenia) might lead to a more favorable prognosis than naturally acquired cases.

Aims: This study aimed to compare the prognosis of postvaccination hemorrhagic stroke and historical conventional cases.

Methods: A retrospective cohort study was conducted using a territory-wide electronic public healthcare database in Hong Kong, linked with population-based vaccination records. Since the roll-out of mRNA Vaccines (BNT162b2), patients aged 18 years or older hospitalized with hemorrhagic stroke within 28 days after mRNA vaccination were compared with conventional hemorrhagic stroke recorded between 2016 and 2017. The two-year follow-up period began from the diagnosis of hemorrhagic stroke. All-cause mortality and multimorbidity were examined using Cox proportional hazards models, with 95% confidence intervals (95%CIs) derived from bootstrap resampling (1,000 iterations).

Results: A total of 2,578 patients were included for analysis: 110 in the postvaccination group and 2,468 in the conventional group. Over the two-year follow-up period, all-cause death occurred in 27.27% (30/110) of the postvaccination group versus 29.78% (735/2,468) in the conventional group. Multimorbidity was observed in 63.64% (70/110) of postvaccination cases and 73.14% (1,805/2,468) of conventional cases, respectively. Adjusted analyses showed no significant differences in all-cause mortality (adjusted Hazard Ratio [aHR]=0.93, 95%CI:0.64–1.28) or multimorbidity risk (aHR=0.85, 95%CI:0.66–1.05) between the two groups.

Conclusion: This study demonstrated that hemorrhagic stroke following mRNA vaccination had a long-term prognosis similar to conventional cases. These findings suggested that postvaccination hemorrhagic stroke does not have a worse prognosis and may follow a clinical course similar to conventional cases, reinforcing mRNA vaccine safety assessments.

Keywords: mRNA vaccine, hemorrhagic stroke, multimorbidity

D2/P384

Assessing Point-of-Care Testing accuracy for differentiating Gram-Negative/Gram-Positive infections: A combined quantitative analysis

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Introduction: Critically ill patients are highly susceptible to infections caused by Gram-negative (GN) or Gram-positive (GP) bacteria, necessitating rapid and accurate differential diagnosis to guide targeted antibiotic therapy and mitigate antimicrobial overuse. Point-of-Care testing (POCT) facilitates prompt diagnosis; however, its precision in distinguishing GN from GP infections warrants rigorous evaluation.

Objective: This study aims to assess the diagnostic accuracy of POCT methods, including biomarkers, molecular detection techniques based on pathogens, omics, and clinical symptoms, for differentiating GN and GP infections in critically ill patients.

Methods: A systematic search was conducted across PubMed, Embase, Web of Science, and Cochrane Library for studies published from May 2005 to May 2025 evaluating the diagnostic accuracy of POCT for GN/GP infections. The quality of studies was assessed using the QUADAS-2 framework. Pooled sensitivity, specificity, and area under the curve (AUC) were calculated employing a bivariate random-effects model.

Results: Of 87 studies included, 68 underwent quantitative analysis. Procalcitonin (PCT, 3.0–5.0 ng/mL) exhibited a pooled sensitivity of 0.84 (95% CI 0.62–0.95), specificity of 0.83 (95% CI 0.70–0.91), and hierarchical summary receiver operating characteristic (HSROC) AUC of 0.90 (95% CI 0.87–0.92). Other biomarkers (n=26) demonstrated that the pooled sensitivity ranges from 0.72 to 0.76, and the pooled specificity ranges from 0.61 to 0.80. Molecular diagnostics, including matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS) and polymerase chain reaction (PCR), achieved sensitivities and specificities of 91–98%. Clinical symptom-based assessments yielded low accuracy (AUC 0.62–0.68), whereas omics-based approaches showed moderate performance (AUC 0.75–0.84).

Conclusion: Among biomarkers, PCT (3.0–5.0 ng/mL) demonstrates robust diagnostic accuracy in differentiating between GN/GP infections, while molecular diagnostic methods provide superior precision through direct pathogen detection. Future investigations should focus on integrated host-pathogen diagnostic models to enhance the rational use of antibiotics.

Keywords: Gram-Negative/Gram-Positive bacteria; Point-of-Care testing; Diagnostic accuracy

D2/P386

Characterization of disease burden associated with bacterial bloodstream infections, Hong Kong, 2012–2021

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Introduction: Previous studies from various countries and regions have demonstrated that bloodstream infections (BSIs) pose a substantial disease burden. However, most studies are limited by incomplete clinical characterization, lack of distinction between infection-related and unrelated mortality, and a narrow focus on specific BSI types without considering host-pathogen interactions.

Aims: To comprehensively assess the burden of disease attributable to BSIs across entire clinical trajectories, stratified by different criteria.

Methods: To better characterize the clinical trajectories of BSIs, electronic medical records of patients discharged from all public hospitals in Hong Kong between 2012 and 2021 were utilized to identify bacterial BSI events. Each BSI event was temporally defined by identifying the entire duration of infection over time and subsequently categorized according to the causative pathogens and targeting antimicrobial resistance (AMR) patterns. Combined with patient demographics and clinical characteristics, the disease burden of BSI was estimated by evaluating the incidence, BSI-associated mortality, case fatality risks (CFRs), and the clinical course of infection.

Results: During our study period, a total of 143,776 BSI events finally identified. The overall incidence and BSI-associated mortality rates were 101 events per 100,000 person-years and 28 deaths per 100,000 person-years after age standardization, with a CFR of 14.6% (95% CI, 14.4-14.7%). The median course of infection per BSI event was 11 (IQR, 6-18) days. Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa and Acinetobacter species are major contributors to the disease burden of BSIs, with our targeting AMR strains associated with a consistently higher burden compared to their susceptible counterparts.

Conclusion: Our study characterizes the variations in the disease burden of BSIs among hospitalized patients, highlighting the influence of both patient characteristics and pathogen-related factors. These findings underscore the importance of individualized risk assessment and the implementation of targeted prevention and treatment strategies to reduce the overall impact of BSIs.

D2/P387

Tertiary healthcare-based study on QoL and dialysis events using dialysate analysis.

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Background: Chronic kidney disease (CKD) is a progressive, non-communicable disease that often advances to end-stage renal disease (ESRD), requiring renal replacement therapy. Patients on maintenance hemodialysis experience considerable morbidity, making health-related quality of life (HRQoL) a vital outcome measure. Evaluating QoL can help identify treatment-related complications and guide improvements in care.

Objectives: -To assess the quality of life in hemodialysis patients at a tertiary healthcare hospital.
-To determine dialysis fluid-related complications
-To conduct causality assessments of those complications.
-To evaluate the relationship between electrolyte imbalance and dialysis-related complications through chemical analysis of dialysate.

Methods: A cross-sectional study was conducted from December 2024 to May 2025 at KIMS Al Shifa Hospital, Kerala. A total of 98 adult patients undergoing maintenance hemodialysis were enrolled based on predefined criteria. Quality of life was evaluated using the KDQOL-36 tool. Dialysis-related complications were documented, and dialysate samples were chemically evaluated for sodium, potassium, calcium, and magnesium deviations. Causality assessments were conducted using WHO-UMC criteria. Data analysis was performed using Jamovi software version 2.6.26, employing descriptive statistics, independent t-tests, and ANOVA ($p < 0.05$).

Results: Among the 98 patients, 91.8% experienced at least one complication. The most common were muscle cramps (40.8%), fatigue (38.8%), hypertension (30.6%), numbness (22.4%), and hypotension (21.4%). Mean QoL scores were PCS: 39.8 ± 8, MCS: 42 ± 8.8, and Burden of Kidney Disease: 38.8 ± 19.8. Causality assessments found 83.7% of complications as “possible” and 9.2% as “probable.” Dialysate analysis showed mild deviations in electrolyte concentrations, aligning with complication reports.

Conclusion: Dialysis-related complications significantly impaired QoL. Findings suggest that dialysate electrolyte balance is a modifiable factor influencing patient outcomes. Optimizing fluid quality may enhance safety and well-being in hemodialysis patients.

D2/P388

Materiovigilance Integrating into Clinical Curriculum-Observational Study of Medical Device Adverse Events

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Introduction: Materiovigilance is vital for ensuring medical device safety and performance. The study evaluated healthcare professionals' knowledge, attitudes, and practices (KAP) regarding monitoring of implantable and other devices in Perinthalmanna, Kerala. The study investigated device-associated adverse events, analyzed device failure causes, and reported findings to the IPC-NCC.

Materials and Methods: A multicentre observational, cross-sectional study was conducted from November 2023 to October 2024 at tertiary care Hospital and affiliated healthcare centres in Kerala to identify medical device-associated adverse events (MDAEs) and evaluate healthcare professionals' knowledge and attitudes towards materiovigilance. A sample size of 109 was determined using standard proportion-based calculations. Data were collected using a validated form and Materiovigilance Programme of India (MvPI) reporting tools. The study involved phased implementation: device selection, inpatient and outpatient monitoring, causality assessment, committee reviews, ophthalmology module development, and dissemination of findings. All MDAEs were reported to MvPI, contributing to the national safety database.

Results: A total of 109 medical device adverse events (MDAEs) were identified, with 60.6% occurring in females and predominantly affecting adults aged 19–65 years. The ophthalmology department accounted for the majority of events (59.6%), followed by dentistry (27.5%) and cardiology (12.8%). Posterior capsular opacification and contact dermatitis were the most frequently reported adverse events. Devices classified as moderate-high risk (Category C) and invasive devices were commonly implicated.

A significant association between profession and knowledge was observed ($p = 0.034$). The study facilitated enhanced awareness and reporting compliance, underscoring the necessity for mandatory MDAE reporting to improve patient safety and medical device oversight.

Conclusion: The study highlights the critical need for enhanced awareness and reporting of medical device-associated adverse events (MDAEs) across healthcare settings. Tailored interventions and strengthened surveillance systems are necessary to ensure patient safety, promote a culture of accountability, and advance the quality of healthcare delivery.

D2/P389

Flatline warnings: materiovigilance of implantable pacemaker pulse generator events via MAUDE database

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Introduction: Implantable pacemaker pulse generators are critical for managing cardiac arrhythmias, but device-related adverse events (AEs) can lead to serious harm. Identifying patterns of these complications is key to improving device safety. The FDA's Manufacturer and User Facility Device Experience (MAUDE) database provides essential post-marketing surveillance to detect safety signals and emerging trends.

Aim: This study aimed to evaluate the frequency, type, and reporting characteristics of AEs related to Implantable pacemaker pulse generators reported in the MAUDE database over a 10.5-year period.

Methods: This retrospective study analyzed AEs associated with an implantable pacemaker pulse generator reported in the MAUDE database between January 21, 2015, to June 30, 2025. Data were extracted using a specific product code (DXY), downloaded, and analyzed to identify event type, trends, and insights into the safety of these medical devices.

Results: During the study period total of 10,600 AEs associated with implantable pacemaker pulse generators were reported. Adverse events such as injury accounted for 52.187%, followed by malfunction 39.793%, and death 5.784%. Device problems such as oversensing 3.811%, Failure to capture, interrogate, or backup charge with 3.745%, signal artifact 3.63%, and premature discharge of battery 2.93%. The highest number of AEs was reported in the year 2018 (29.7%), 2017 (21.17%), and 2015 (16.50%). The majority of reports originated from the United States(50%), followed by Germany(18%) and Japan(12%). Reporter occupations were primarily physicians(42%), followed by healthcare professionals(27%), and manufacturers(21%).

Conclusion: The analysis highlights recurring device issues and underscores critical areas for safety improvement. Continuous monitoring through materiovigilance systems like MAUDE is essential to mitigate risks and enhance the reliability of implantable cardiac devices. These insights can guide manufacturer improvements, and strengthen regulatory oversight to ensure long-term patient safety.

Keywords: Implantable Pacemaker Pulse generator, MAUDE database, Materiovigilance

D2/P390

Clinical risk assessment and standardization of dental device use: A materiovigilance initiative

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Introduction: Dental devices play a critical role in delivering quality oral healthcare, but are not without risk. Adverse events associated with dental devices (DDAEs) can compromise both patient safety and clinical outcomes. Traditional pharmacovigilance strategies, such as spontaneous reporting, often underrepresent device-related events, especially in dentistry, due to underreporting, lack of awareness, and limited follow-up mechanisms. By contrast, a prospective approach may provide more comprehensive and systematic data on device safety.

Aim: To determine the prevalence, severity, causality, and characteristics of DDAEs through a structured prospective materiovigilance system and develop safety guidelines for commonly used dental devices.

Methods: This prospective observational study was conducted over 6 months at a tertiary care dental hospital. Data on DDAEs were collected, analyzed, and classified using standardized tools and criteria for severity and causality. Comparisons were made considering the limitations of spontaneous reporting systems.

Results: In a cohort of 6,000 dental outpatients, 526 instances of DDAEs were recorded, indicating a prevalence of 8.77%. Events were more frequent among females (56%), pediatric (29.46%), and geriatric (13.7%) groups. Most DDAEs were linked to low/moderate-risk devices (57.6%), and 6.27% involved high-risk devices. Serious adverse events occurred in 18% of the patients. Invasive and sterile devices contributed to 50.7% and 15% of the DDAEs, respectively, and 55.5% involved single-use devices. The causality assessment revealed 59.5% related and 31.9% probable associations. SOPs were developed for the top 100 dental devices, from procurement to disposal.

Conclusion: Prospective materiovigilance identified a higher prevalence of DDAEs than that typically captured by spontaneous reporting, demonstrating the value of proactive surveillance. The implementation of SOPs and materiovigilance training can strengthen reporting systems, promote early detection, and enhance patient safety in dental practice.

Keywords: Medical Devices, Adverse events, Materiovigilance

D2/P391

Evaluating device-related adverse events in tracheal tubes: a materiovigilance-based MAUDE study

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Introduction: Tracheal tubes are critical medical devices used to secure airway patency during surgery, intensive care, and emergencies. Evaluating adverse events (AEs) through materiovigilance approach, is vital to enhance safety, performance. Retrospective data was collected from the FDA's Manufacturer and User Facility Device Experience (MAUDE) database, a comprehensive repository of real-world reports that compiles details of device-related events.

Aim: This study aimed to evaluate the frequency, event type, and reporting characteristics of AEs related to tracheal tubes reported in the MAUDE database over a 10 year period.

Methods: This retrospective descriptive study investigated AEs related to tracheal tubes reported in the MAUDE database from January 1, 2015, to June 30, 2025. Relevant data were extracted using appropriate FDA product code (BTR) and downloaded within the selected period. Detailed analysis was conducted to identify patterns in device-related problems, event types, providing insights into the safety, performance of tracheal tubes.

Results: Over a 10-year period, the MAUDE database documented 12,602 unique AEs reports related to tracheal tubes. The most frequently reported device issues include use-related problems (13%), inflation problems (9.99%), leak/splashes (5.13%) and material split/cut/torn (2.74%). Among reported event types, (78.30%) were malfunctions, (18.43%) involved injuries, and (1.12%) reported deaths. The highest number of events was reported in 2024 (22.99%), followed by 2019 (12.34%), and 2021, 2023 (9.32%). Majority of reports originated from the United States (51.72%), followed by Japan (14.36%), Switzerland (7.98%) and France (5.94%). Health care professionals (86.92%) were the primary reporters, with contributions from respiratory therapists (34.21%), physicians (28.37%), and nurses (24.34%).

Conclusion: These findings highlight the need for enhanced materiovigilance to reduce tracheal tubes related AEs. Recognizing failure modes support safer device safety. This study offers guidance for clinicians, and regulatory authorities in improving patient outcomes.

Keywords: Tracheal tube safety, Materiovigilance, MAUDE adverse event reporting

D2/P392

Approval Process of High-Risk Medical Devices in India, USA, Europe and Australia

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Introduction: A medical device is any instrument, apparatus, appliance, software, implant, or other article intended to be used, alone or in combination, for a medical treatment purpose. Regulations for High-risk medical devices vary across countries, and necessary to understand the differences to meet healthcare priorities and administrative requirements.

Aims: To study the Approval Process of High-Risk Medical Devices in India, USA, Europe and Australia.

Methods: Approval process of high-risk devices (Class C & D devices) was evaluated using the Central Drugs Standard Control Organization (CDSCO) in India, the Food and Drug Administration (FDA) guidelines for Class III devices, in the European Union through the Medical Device Regulation (EU MDR 2017/745), and Australian Register of Therapeutic Goods (ARTG) for Class III and Active Implantable Medical Devices.

Results: Approval Process of High-risk medical devices vary from country to country. The minimum waiting period for approval of the medical devices varies from 9 months (India), Australia (12 months) the EU (18 months), to 24 months (the USA). The approval pathway includes import & manufacturing licence process in India, premarket approval in the USA, conformity assessment by CE in EU and ARTG in Australia.

Conclusions: The approval processes for high-risk medical devices vary significantly across India, the USA, Europe, and Australia in terms of regulatory frameworks, timelines, and evidence requirements. While the USA and Europe have well-established, stringent pathways focusing on clinical data and risk-benefit analysis, India and Australia are evolving toward more harmonized and streamlined systems. Overall, global alignment and increased transparency could enhance patient safety and foster innovation in the high-risk medical device sector.

Keywords: High Risk Medical Devices, CDSCO, FDA, EMA, TGA.

D2/P393

Adverse Event Trends in Cochlear Implants: An Analysis from the MAUDE Database

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Introduction: Cochlear implants have significantly improved lives of individuals with severe to profound hearing loss by restoring hearing and enhancing communication. As Class III high-risk medical devices, they warrant careful monitoring due to the potential for serious adverse events. With increasing global usage, post-market surveillance is essential. The FDA's MAUDE database provides valuable real-world data on adverse events, helping identify complications, device issues, and emerging safety concerns.

Aims: To analyze MAUDE reports on Cochlear implants, identifying complications, device-related issues, and assessing patient safety profiles.

Methods: This review analyses adverse events related to Cochlear implants reported in the MAUDE database from May 2023 to May 2025. Using specific search terms and filters, all relevant AE reports were retrieved and categorized based on significant variables and frequencies. The underlying causes and occurrence of AEs were examined to identify patterns and high-risk areas. This comprehensive evaluation provided valuable insights into the safety, performance, and potential areas of improvement for cochlear implants

Results: An analysis of 500 adverse event reports related to Cochlear implants for 2 years revealed that 63.6% cases were classified as injuries (318 cases), while 37% involved malfunctions (185 cases). The most frequent device issue was Mechanical Problem, comprising 123 cases, followed by impedance problem 83 cases and expulsion 48 cases. Patient-related problems which are highly prevalent were headache 187 cases followed by failure of implant 73 cases. Reports were predominantly from the U.S. The COCHLEAR LTD was identified as the manufacturer in 253 reports.

Conclusions: Cochlear implants play vital role in restoring hearing and improving quality of life for individuals with severe hearing loss. MAUDE data shows cochlear implants are generally safe, but risks persist. Continued monitoring, adherence to best practices, and patient education are essential until further studies clarify long-term outcomes and help improve implant safety and performance.

D2/P394

Adverse Events associated with Spinal Fusion Implants: A 10-Year MAUDE-Based Analysis

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Introduction: Spinal fusion implants are widely used to manage various spinal disorders, but adverse events (AEs) can compromise patient safety and outcomes. This study utilizes the FDA's Manufacturing and User Facility Device Experience (MAUDE) database to evaluate reported complications and assess device safety. Recognizing the significance of device-related complications is essential for informed clinical decisions.

Aims: The aim of the study was to evaluate the type, frequency and trends of AEs associated with spinal fusion implants using real-world data.

Methods: AE reports were retrospectively extracted from the Manufacturer and user facility device experience (MAUDE) database using product code KWQ from January 1, 2015 to July 10, 2025. Data included event types, patient and device problems, reporter type and country of origin. Descriptive statistical analysis was conducted to determine the most frequent complications and annual reporting trends.

Results: A total of 4,454 AE reports were documented, with reports peaking in 2021 (13%), 2015 (12%), and 2016 (11%). The United States accounted for highest reports (34.7%), followed by Japan (10.19%) and Switzerland (8.14%). Geriatric patients (77.6%) were most frequently affected, followed by adults (22.4%). Manufacturers (94.6%) were the predominant reporters, followed by physicians (5.4%). In event type, injury was most common (54.4%), followed by malfunctions (45.3%), and death (0.22%). Top device-related problems included unknown adverse event (31.5%), breakage (24.5%), migration or expulsion (16.9%), fractures (11.6%), and dislodgement or dislocation (3.1%). The most common patient-related problems involved implant failure (13.6%), pain (10.6%), injury (9.5%), and hematoma (7.8%).

Conclusions: Spinal fusion implants present ongoing safety challenges, especially among elderly patients. Improved materiovigilance and standardized clinical protocols could improve patient safety and device efficacy. These findings can guide clinicians in risk-based decision-making and support regulatory bodies and manufacturers in enhancing device design and post-market surveillance.

Keywords: spinal fusion, MAUDE database, implant safety

D2/P395

A MAUDE- based analysis of adverse-events associated with transcatheter aortic valve device

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Introduction: A transcatheter aortic valve replacement (TAVR) device is used to treat severe aortic stenosis in high-risk patients through a minimally invasive approach; however, despite its benefits, it may also lead to complications. Materiovigilance helps monitor and evaluate such adverse events (AEs) to improve safety. The FDA's Manufacturer and User Facility Device Experience (MAUDE) database is a key resource for analyzing these post- market device issues.

Aim: This study aimed to evaluate the frequency, type, and reporting characteristics of AEs related to TAVR reported in the MAUDE database over a 10.5-year period

Methods: This study examined adverse events linked TAVR devices reported in the MAUDE database between January 1,2015 and June 30,2025. Data were collected using specific FDA product code (NPT) relevant to TAVR. The analysis focused on identifying device-related complications and event patterns.

Results: Over a 10.5-year period, the MAUDE database documented a total of 62,667 unique adverse event reports involving TAVR devices. The most common device-related issues were, adverse event without perivalvular leak (27.6%), fluid/blood leak (7.23%), degraded(4.51) and dyspnea (4.25%), material deformation (4.05%). Among the reported event types, malfunction accounted for 14.08%, injuries for 75.49%, and deaths for 10.11%. the highest number of adverse events was reported in 2024(10.74%), followed by 2023(9.86%), 2022(7.68%) of the total reports. Most reports originated form United States (42.7%), followed by Japan (17.60%), and Italy (11.05%). Reports were primarily submitted by other physicians, with additional contributions from other healthcare professional and manufacturers.

Conclusion: The findings emphasize the importance of strengthening materiovigilance to minimize TAVR device-related complications. Understanding reported issues can aid in refining device design and informing clinical practice for better patient safety

Keywords: TAVR, MAUDE database, Materiovigilance

D2/P396

Integrating Epidemiologic methods to evaluate safety and regulatory gaps of neuro-devices

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Introduction: Neuro-medical devices are used to diagnose and treat complex neuro disorders, such as Neurostimulation implants and Deep Brain Stimulators. However, the regulatory vary across the global markets, challenges in ensuring post-market safety and digital risk mitigation. The framework varies across different region which hinder effective surveillance and benefit-risk assessment.

Aims: This study evaluates the integration of epidemiologic approaches to identify regulatory gaps, to enhance harmonization strategies for neuro-medical device safety and post-market safety risks in neuro-medical devices across global markets.

Methods: Epidemiologic methods were applied to analyse regulatory data and post-market surveillance reports from the US, EU, and India, focusing on approval processes, adverse event reports, and studies from 2017–2025. Comparative and statistical analyses identified common risks and gaps. Tools such as signal detection and safety trend analysis assessed data quality, surveillance gaps, and harmonization efforts.

Results: Regulatory approval timelines for neuro-medical devices varied from 6 to 30 months across the US, EU, and India. Signal detection highlighted software malfunctions (35%) and cybersecurity breaches (22%) as dominant safety risks, with underreporting rates between 30–45%. Real-world data integration was lowest in India, compared to 44% (US) and 28% (EU), exposing longitudinal surveillance gaps. Analysis of 250+ adverse event records in USA revealed challenges in tracking device performance. Adoption of ISO and IMDRF frameworks improved harmonization by 25%, underscoring the importance of unified standards and structured oversight for enhanced safety and global regulatory convergence.

Conclusions: Integrating epidemiologic methods into neuro-medical device regulation enhances risk detection, surveillance, and global safety alignment. The Regulatory gaps and underreporting highlight the need for harmonized evidence standards and collaborative oversight. Strengthening real-world data integration and international regulatory convergence is essential to improve patient outcomes and accelerate safety-driven innovation.

Keywords: Neuro-medical devices, regulatory harmonization, post-market surveillance.

D2/P397

Medical device adverse events in geriatric ICU: A cross-sectional materiovigilance study

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Introduction: Medical devices are extensively used in Intensive Care Units (ICUs), particularly among geriatric patients who often present with multiple comorbidities and physiological decline. This group is more susceptible to complications from device use. Adverse events related to medical devices can increase morbidity, prolong hospitalization, and compromise patient safety. The need for targeted Materiovigilance in this population is paramount.

Aims: To assess the pattern of adverse events related to medical devices in geriatric ICU patients and determine the causal relationship between device use and reported events.

Methods: This cross-sectional observational study was conducted over seven months (November 2024–May 2025) at a tertiary care hospital in Bangalore, India. A total of 100 ICU patients aged 65 and above, using one or more medical devices, were included. Adverse events were identified through clinical records, nursing notes, and interviews. In the absence of a validated Indian tool, causality was assessed using the EU MDCG framework, which, though not locally validated, offers a structured and systematic approach. Data were analyzed using descriptive statistics and chi-square tests to explore patterns and significant associations.

Results: A total of 122 medical device-associated adverse events (MDAEs) were documented. Intravenous cannulas, particularly 20G, were most frequently involved (37.7%). Common MDAEs included swelling (30.3%), hematoma (11.5%), leakage (7.4%), and bluish discoloration (6.6%). Most events involved invasive (88.5%), sterile (91.8%), and single-use (91.8%) devices. Causality assessment classified 53.3% of events as probable and 42.6% as related. Significant associations were found with patient age (p=0.03), number of devices used (p=0.01), comorbidities (p=0.04), and education level (p=0.02).

Conclusions: Geriatric ICU patients are at high risk of MDAEs, primarily from commonly used invasive devices. This underscores the need for geriatric-focused Materiovigilance protocols, regular monitoring, and staff training to minimize device-related harm.

Keywords: Materiovigilance, geriatric intensive care, medical device safety

D2/P398

Medical Device Vigilance in Pulmonology and ICUs: A Prospective Observational Study

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Background: Medical device-related adverse events (MDAEs) pose significant risks in specialized healthcare settings like Pulmonology and Intensive Care Units (ICUs), where devices are integral to patient management. Despite their critical role, limited research has explored the factors influencing causality assessments of MDAEs in these settings. This study addresses this gap by examining demographic, clinical, and device-related factors associated with causality judgments, aiming to improve patient safety and materiovigilance practices.

Objective: To describe the demographic and clinical characteristics of participants experiencing MDAEs, profile the medical devices and adverse events involved, and assess associations between various factors (age, gender, device category, event seriousness, device use, device type) and causality assessments.

Methods: A cross-sectional study was conducted among 64 participants (mean age 63.8±17.1 years; 68.8% aged ≥60; 71.9% male; 96.9% with comorbidities) in Pulmonology and ICU departments. Inclusion criteria included patients who experienced a device-related adverse event; patients with incomplete documentation were excluded. Data were collected on device characteristics (risk category A–D, use: single/reusable; type: diagnostic/therapeutic), event seriousness, and management. Causality was classified as 'possible' or 'probable'. Descriptive statistics and Chi-square (χ^2) tests were used for initial analysis. Logistic regression was employed to evaluate the independent contributions of variables while adjusting for confounders.

Results: Catheters were the most frequently implicated devices (35.9%). Category C (moderate-to-high risk) devices accounted for 51.6% of cases. Most MDAEs involved single-use (79.7%) and therapeutic (78.1%) devices, with 87.5% being non-serious. Causality assessments were 57.8% 'possible' and 42.2% 'probable'. Significant associations were observed with device category (χ^2=24.4, p=0.001), event seriousness (p=0.045), and device use (p=0.004). No significant association was found with age (p=0.955) or gender (p=0.37).

Conclusion: Device characteristics and event severity significantly influence MDAE causality assessments, highlighting the need for targeted safety protocols and robust reporting systems in critical care settings.

Keywords: medical device vigilance, pulmonology, ICU, adverse events, causality assessment

D2/P399

Patterns of Disease Prevalence and Multimorbidity Using Real-World Data from Northern Thailand

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Introduction: Noncommunicable diseases (NCDs) are becoming the leading contributors to Thailand's health burden, driving more complex treatment needs as multimorbidity becomes increasingly common. Thus, understanding who develops which conditions when, and how diseases co-occur, is essential for healthcare planning.

Aim: To quantify the burden of disease across the life course and describe patterns of multimorbidity and comorbidity in Northern Thailand.

Methods: We conducted a observational cohort study using routinely collected, pseudo-anonymized electronic health records from all public inpatient and outpatient healthcare interactions in Lampang province, covering nearly the entirety of the provincial population. Using data from 2018–2022, we estimated overall, age-, sex-, and year-specific period prevalence for ~300 high-burden conditions, including NCDs and severe infections, based on ICD-10 phenotypes among individuals aged ≥15 years. We also identified the most frequent multimorbidity triads and quantified comorbidities relative to index conditions.

Results: We identified 731,529 individuals. Among those under 40, the most prevalent condition across the life course was dermatitis, affecting 8.79% (95% CI: 8.48–9.09) of those aged 15–19; 5.26% (5.11–5.40) of 20–29-year-olds, and 4.66% (4.54–4.80) of 30–39-year-olds. From age 40 onwards, hypertension became the most common condition, with prevalence increasing steadily from 11.82% (11.62–12.03) in 40–49-year-olds to 90.47% (90.09–90.83) in those aged 80 and above.
Overall, the most common multimorbidity triad was chronic kidney disease (CKD), hypertension and diabetes. With hypertension as the index condition, the most frequent comorbidities were diabetes (33%), chronic CKD disease (17%) and osteoarthritis (15%).
Results varied by age, sex and calendar year.

Conclusions: This study captures real-world clinical experience of individuals in a Southeast Asian setting, highlighting opportunities for drug development and discovery by identifying unmet healthcare needs and frequently co-occurring diseases that may share underlying biological mechanisms

Keywords: Thailand, disease burden, multimorbidity, electronic healthcare records.

D2/P400

Inspection Findings from Chinese Clinical Trials: Enhancing Quality Management in Real-World Studies

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Introduction: Real-world studies (RWS) face unique challenges in ensuring data quality and regulatory compliance, particularly in regions with evolving regulatory environment like China. The dedicated inspection standards remain underdeveloped compared to trials, highlighting the need for targeted quality management.

Objective: To synthesize insights from Chinese literatures on clinical trial inspections and provide actionable recommendations for improving quality management in RWS.

Methods: A systematic search of two Chinese databases (CNKI and Wanfang) from 2015 to 2025 using subject terms "inspection" and "clinical trials" identified 2,214 articles. After removing 466 duplicates and screening for titles and abstracts, 82 articles underwent independent full-text review. Ultimately, 39 articles were included for data extraction using a pre-designed table, including inspection finding types, frequencies and solutions, for content analysis.

Results: Quality issues can be categorized into three main types: participant protection (n=37,94.8%), protocol adherence (n=32,82.1%) and data quality (n=31,79.5%), with data quality as the critical quality concerns in 59.0% studies. First, participant protection issues included non-standard informed consent (n=31), incomplete adverse event reporting (n=30), insufficient ethical review (n=17), and inadequate privacy protection (n=10). Second, protocol deviations were most frequently related to non-compliance of inclusion/exclusion criteria (n=28), follow-up visits exceeded time windows (n=28), and medication adherence (n=25). Finally, data quality concerns centered on data accuracy (n=31) and completeness (n=27). To address these issues, efforts were focus on the life-cycle quality management in improving data traceability, standardizing protocol execution, establishing a regular monitor mechanism, and introducing independent quality check.

Conclusions: The findings highlight common quality issues in Chinese clinical trials, offering valuable lessons for the developing standardized quality management in RWS. Learning from the FDA and EMA well-established inspection system and policies, standardized quality management procedures, including improved data traceability, protocol adherence, and participant protection, are essential for building a high quality RWS in China and beyond.

D2/P401

Multimodal spectral and thermal assessment of packaging for photosensitive pharmaceuticals

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Introduction: Photostability is a critical factor influencing the quality, safety, and efficacy of pharmaceutical products. Active pharmaceutical ingredients (APIs) may undergo photodegradation upon exposure to ultraviolet (UV), visible, or near-infrared (NIR) radiation, potentially reducing therapeutic effect or increasing toxicity. Packaging serves as the primary barrier against radiation-induced degradation, yet its photoprotective potential is often insufficiently assessed. This study highlights the need for non-destructive, reproducible methods for evaluating the photoprotective properties of pharmaceutical packaging for light-sensitive drugs.

Aims: The aim of the study was to evaluate the shielding capacity of multilayer packaging systems used for solid pharmaceutical dosage forms containing digoxin and doxycycline. The focus was placed on identifying packaging layers that offer the most effective protection within critical optical and thermal ranges.

Methods: Commercial drug products were analyzed using hemispherical directional reflectance spectroscopy (335–2500 nm) and passive infrared thermography (7.5–13 µm). Reflectance was measured for tablets or capsules, blister components (PVC, PVDC), and outer cartons using the SOC 410 Solar reflectometer. Thermal buffering capacity was assessed using a FLIR T420s thermal camera after 180 seconds of standardized radiant exposure.

Results: Outer cartons showed the highest reflectance in the 335–540 nm range (up to 80%), while the tablet and capsule surfaces exhibited <20% reflectance. Blisters had intermediate values depending on their composition. Thermal analysis confirmed that unprotected capsules reached ~45 °C, while blister-plus-carton systems limited temperature increase to <35 °C. A strong correlation was observed between high reflectance and reduced thermal absorption.

Conclusions: The combination of hemispherical reflectance and infrared thermography provides a reliable, non-invasive framework for assessing packaging photoprotection. Multilayer systems significantly enhance shielding properties and may serve as a reference in developing improved packaging standards for photosensitive pharmaceuticals.

Keywords: hemispherical directional reflectance, infrared thermography, pharmaceutical packaging, photostability, doxycycline, digoxin

D2/P402

Establishing sex-age-specific TSH and FT4 reference intervals among adults in Hong Kong

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Introduction: Thyroid dysfunction typically manifests as nonspecific symptoms, necessitating reliance on biochemical markers, specifically thyroid-stimulating hormone (TSH) and free thyroxine (FT4), for diagnosis. Existing laboratory-specific reference intervals (RIs) often disregard sex and age variations, risking over- or underdiagnosis.

Aims: To establish dynamic, sex-age-stratified RIs for TSH and FT4 among adults in Hong Kong and evaluate their impact on thyroid dysfunction diagnosis compared to conventional RIs.

Methods: We analyzed Hong Kong's electronic medical records (EMR) from 2006 to 2019, excluding individuals with prior thyroid-related medications (N=2,111,661 TSH; N=854,781 FT4). Participants were stratified by age, from 18-29 to ≥85 years. After harmonizing TSH/FT4 measurements across institutions, we derived sex-age-specific RIs annually using the 2.5th and 97.5th percentiles, with conventional RIs (TSH: 0.27-4.2mIU/L; FT4: 12-22pmol/L) serving as comparators. Diagnostic reclassification rates and incidence trends for overt/subclinical hypo-/hyperthyroidism were compared between these RI methods.

Results: Sex-age-specific upper reference limits (URLs) for TSH generally exceeded the laboratory-established URL, ranging from 4.2 to 7.1 mIU/L. FT4 URLs in women exhibited a pronounced U-shaped age distribution, peaking in young adulthood (18-29: 21.7-24.3 pmol/L) and advanced age (≥85: 23.6-26.4 pmol/L)—a pattern less pronounced in men. Using sex-age-specific RIs reduced overt/subclinical thyroid dysfunction diagnoses by 1-4% while increasing euthyroid cases by 14.8%. Incidence rates for sex-age-specific RIs-defined overt hypothyroidism (average annual percentage change [AAPC]=1.56%) and subclinical hypothyroidism (AAPC=1.81%; both $P<0.05$) showed sustained increases from 2010 to 2019.

Conclusions: This study establishes the first long-term, large-scale population-based RIs for TSH and FT4 in Hong Kong. Adoption of these RIs may help personalize thyroid monitoring intervals and therapeutic decisions, particularly for older populations. Future randomized controlled trials are warranted to examine the consequence of implementing sex-age-specific RIs in clinical settings on thyroid function management, particularly their potential to reduce overdiagnosis and overtreatment.

Keywords: Electronic medical records; sex-age-specific reference intervals; thyroid hormones.

D2/P403

Impact of Pesticides Knowledge and Practice on Quality of Life Among Farmers

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Introduction: Globally, pesticide poisoning accounts for over 385 million unintentional cases annually, with a significant burden in low- and middle-income countries. In India, occupational hazards from pesticides remains a common challenge, leading to chronic health issues. However, limited studies have examined how farmers' knowledge, attitudes, and practices (KAP) relate to Health-Related Quality of Life (HRQoL) and laboratory parameters.

Aim: This study aimed to assess the association of pesticides on KAP and HRQoL domains, by correlating laboratory parameters and perceived health status among pesticide-exposed farmers.

Methods: An analytical, cross-sectional design was implemented to assess baseline KAP, HRQoL and laboratory parameters among 175 farmers in Karnataka, India. A validated KAP questionnaire covering various aspects of pesticides were administered, followed by the SF-36 tool to evaluate HRQoL. Statistical analysis included Spearman's correlation and regression to assess associations among age, KAP, HRQoL, and lab parameters.

Results: Of the 175 farmers, majority were male (89.1%) with a mean age of 47.66±13.33 years and an average farming experience of 25.62±13.73 years. Baseline KAP scores revealed that 6.9% of farmers reported high knowledge and 2.3% demonstrating good pesticide safety practices. Increasing age showed significant negative correlations with reduced HRQoL ($p<0.01$). Knowledge positively correlated with physical functioning ($\rho = 0.219$) and energy ($\rho = 0.215$), while practice positively correlated with energy ($\rho = 0.356$), emotional well-being and general health ($p<0.01$). Total protein, serum globulin, and AST showed significant negative correlations with HRQoL domains. Regression analysis revealed that knowledge and practice were significant predictors influencing HRQoL domains ($p < 0.05$).

Conclusion: This study highlights that higher KAP towards safe pesticide use are significantly associated with better HRQoL among farmers. Targeted educational interventions may support long-term well-being of farmers.

Keywords: Pesticide exposure, Health-related quality of life, KAP assessment

D2/P404

What makes a drug innovative: Innovation indicators and FDA expedited programs

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Introduction: FDA expedited programs were introduced to accelerate access to innovative therapies. However, there is a lack of consensus on what constitutes "innovation" in pharmaceuticals.

Aims: This study examines how innovation-related features—first-in-class status, clinical innovation, and orphan designation—influence the likelihood of receiving FDA expedited program designations.

Methods: We conducted a retrospective analysis of 129 new drugs approved by the FDA from 2020 to 2024. Innovation-related features included first-in-class status, orphan designation (from FDA sources), and clinical innovation, based on HTA value ratings from France (HAS) and Germany (IQWiG/G-BA). Outcomes were four FDA expedited programs: Fast Track (FT), Breakthrough Therapy Designation (BTD), Accelerated Approval (AA), and Priority Review (PR). We used univariate and multivariate logistic regression models for each program, and Poisson models to evaluate associations with the number of designations.

Results: Among the 129 drugs, 82 (63.6%) received PR, 47 (36.4%) FT, 46 (35.7%) BTD, and 27 (20.9%) AA. In univariate logistic regression, all three innovation-related features were significantly associated with at least one expedited program. Clinical innovation was associated with all programs except for AA, while orphan designation showed strong associations with BTD and AA. In multivariate models, clinical innovation remained significant for FT (OR=3.33, p=0.009) and BTD (OR=3.93, p=0.007), and orphan designation for BTD (OR=5.81, p<0.001) and AA (OR=4.47, p=0.006). First-in-class status was only associated with PR (OR=2.32, p=0.036). Poisson models showed that orphan designation significantly increased the number of expedited designations (OR=1.69, p<0.001), while other features had weaker or borderline effects. Results were consistent in ordinal logistic models.

Conclusions: Orphan designation showed the strongest association with expedited program use, while clinical innovation had mixed effects and first-in-class status the weakest. These findings highlight differing priorities across programs and the need for clearer alignment between regulatory incentives and meaningful innovation.

Keywords: Innovation, Expedited programs, Regulatory science

D2/P405

Treatment-Resistance Phenotypes in Administrative Healthcare Data: A Scoping Review

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Introduction: Treatment-resistance is broadly defined as the failure of a disease to respond to adequate treatment. Research into treatment-resistant disease is increasingly conducted using administrative healthcare data; phenotypes are often constructed using available data elements to identify treatment-resistant populations or outcomes.

Aims: To conduct a scoping review and identify the disease areas, definitions, data elements and validation status of treatment-resistance phenotypes used in administrative healthcare data.

Methods: We searched MEDLINE, Embase, and Web of Science from inception to July 5th, 2024 for original articles using the concepts 'treatment-resistance', 'administrative healthcare data' and 'identification'. We extracted data on the disease area; data elements and measures used to define treatment-resistance; and the source, validation status, and validation method for identified phenotypes.

Results: We identified 122 articles that identified treatment-resistance in administrative healthcare data, primarily in depression, asthma, epilepsy, cancer, schizophrenia, and hypertension. Most articles (n=121, 99%) utilised pharmacy claims as part of their definition, while almost half (n=58, 47%) used additional elements such as hospital admissions and procedural codes. Operationalisation of treatment-resistance varied substantially, particularly in the consideration of dose, duration, severity, and hospitalisations. Phenotype reuse was uncommon, with over half of articles (n=77, 65%) developing phenotypes on a 'per-study' basis, while the remainder reused (n=22, 18%) or adapted (n=21, 17%) existing phenotypes. A minority of identified articles (n=14, 12%) either used or developed a validated phenotype. Of the six unique validated phenotypes, four were validated using manual chart reviews, one using a proxy for treatment-resistance, and one through laboratory measurements.

Conclusions: Treatment-resistance phenotypes in administrative data have been identified across various diseases, mostly utilising pharmacy claims. Most phenotypes were unvalidated and developed on a 'per-study' basis. Future research should quantify the impact of phenotype variability in treatment-resistance, and address barriers to phenotype reuse and validation.

Keywords: Treatment-resistance, Computable Phenotypes, Validation

D2/P406

Global landscape and time trends of stem cell clinical trials in ClinicalTrials.gov

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Introduction: Stem cell therapy holds immense potential in the field of regenerative medicine, and its clinical development has garnered significant attention.

Aims: This study aimed to summary a comprehensive evaluation of stem cell clinical trials registered on the ClinicalTrials.gov, analyzing the landscape and time trends of stem cell clinical development.

Methods: We analyzed data from Aggregate Analysis of ClinicalTrials.gov (AACT) database, focusing on stem cell trials (interventional studies) started between 1 January 2000 through 31 December 2024. Joinpoint regression analysis was employed to assess the geographical and temporal trends in stem cell clinical development.

Results: As of December 2024, a total of 1712 stem cell clinical trials were included. Trend analysis revealed a rapid increase in the number of stem cell clinical trials between 2008 and 2012, followed by a slowdown around 2018. Notably, in 2018, the number of trials using allogeneic stem cells surpassed those using autologous stem cells, marking a key inflection point in the shift between the two types of trials. The United States (476/1712, 27.80%) and China (385/1712, 22.49%) emerged as the leading countries in conducting these trials. The primary tissue sources were bone marrow (604/1712, 35.28%), umbilical cord (302/1712, 17.64%), and adipose tissue (277/1712, 16.18%). Injection was the most common route of administration (1059/1712, 61.86%). Most trials (927/1712, 54.15%) did not specify the dosage. The common ranges were 1-10*10^6 cells/kg (286/1712, 16.71%) and 10-100*10^6 cells/kg (191/1712, 11.16%).

Conclusion: This study outlines the development of stem cell clinical trials over the past two decades, showing early growth followed by a slowdown after 2018. A shift from autologous to allogeneic cell sources was observed, with most trials conducted in high-income regions and at early phases.

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Systematic review of comparative clinical studies of generic and originator drugs

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Objective: Systematically reviewing the published literature on clinical studies comparing generic drugs with original drugs, to analyze the research status, reported outcomes, and study designs.

Methods: Using evidence-based systematic review methods, formulating search keywords and strategies. Literature on clinical comparative studies of generic and original drugs from the establishment of databases up to November 2024 was retrieved from CNKI, Wanfang, PubMed, and Cochrane databases. Articles were selected based on inclusion and exclusion criteria. Information from four aspects: general details of the literature, drug information, study characteristics, and study outcomes (34 items) were extracted. The quality of RCT was assessed using the Cochrane-recommended RoB 2.0 tool, quasi-experimental study using JBI tool, cohort and case-control study using the NOS scale, and case series report using JBI criteria.

Results: A total of 451 articles (242 Chinese, 209 English) met the inclusion criteria, including 469 studies. Chinese studies included 140 RCTs, 6 non-randomized controlled trials, and 106 observational studies, with sample size ranging from 24 to 223,307. English studies included 60 RCTs, 19 non-randomized controlled trials, and 137 observational studies, with sample size from 7 to 577,314. The proportion of studies with statistically significant differences in effectiveness and safety indicators was higher in English studies. 10 Chinese studies show differences in effectiveness. , while 15 show differences in safety. 35 English studies show differences in effectiveness, while 23 show differences in safety. Quality assessment revealed moderate-to-high bias risks in RCTs, particularly in randomization and allocation concealment. Non-randomized and observational studies were rated as low-to-moderate risk.

Conclusion: Most of the studies showed no significant difference in efficacy and safety between generic drugs and original drugs. The current clinical comparison studies of generic drugs and original drugs are generally in low quality and small sample size. High-quality studies are still needed to further validate the efficacy and safety of generic drugs.

D2/P410

Respiratory risks associated with P-CAB versus PPI among COPD patients

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Introduction: Gastroesophageal reflux disease (GERD) frequently co-occurs in patients with chronic obstructive pulmonary disease (COPD), contributing to worsened respiratory symptoms. Despite their widespread use, proton pump inhibitors (PPIs) have been linked to uncertain respiratory risks. Potassium-competitive acid blockers (P-CABs), introduced in Korea in 2018 as a newer class of acid suppressants, offer an alternative, but their safety in COPD remains unclear.

Aims: To compare the risks of pneumonia and moderate-to-severe COPD exacerbations between P-CAB and PPI use in COPD patients.

Methods: We applied a target trial emulation to compare the risks of pneumonia and COPD exacerbation between P-CAB and PPI users. We identified patients aged 40 years or older with COPD and comorbid GERD who newly initiated P-CAB or PPI therapy between 2019 and 2022. Follow-up continued from treatment initiation until outcome occurrence, treatment discontinuation, drug switching, death, or study end. Study outcomes included pneumonia and moderate-to-severe COPD exacerbation. Propensity score matching (1:3) was used to balance baseline characteristics, and hazard ratios (HRs) with 95% confidence intervals (CIs) were estimated using Cox proportional hazards models.

Results: After matching, 4,671 P-CAB users and 14,013 PPI users were included. The P-CAB group showed a trend toward lower risks of pneumonia (aHR, 0.76; 95% CI, 0.54–1.07) and severe exacerbation (aHR, 0.60; 95% CI, 0.32–1.14), although neither was significant. These trends remained largely consistent across subgroups. Among patients with a Charlson Comorbidity Index ≤ 1, P-CAB use was significantly associated with a reduced risk of severe exacerbation (aHR, 0.31; 95% CI, 0.11–0.88).

Conclusions: P-CABs demonstrated a favorable pattern of reduced risks for pneumonia and severe exacerbation compared to PPIs. These findings may indicate potential respiratory benefits for COPD patients with GERD, particularly those with fewer comorbidities.

Keywords: Potassium-competitive acid blockers (P-CABs), Chronic obstructive pulmonary disease (COPD), Target Trial Emulation (TTE)

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