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Abstract Book



I. Oral Presentations

Abstract 100 - 253

100

Data-driven focal windows selection in self-controlled case series: COVID-19 vaccine case study

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Introduction: In self-controlled case series (SCCS) studies, properly specifying the focal window is crucial to avoid biased estimates. This is challenging when limited clinical information is available to inform design decisions.

Aims: Using COVID-19 vaccine as a case study, we compare three data-driven methods for identifying optimal SCCS focal windows across two databases.

Methods: We studied individuals aged ≥12 years hospitalised for myocarditis, pulmonary embolism (PE), or thrombocytopenia and received 1-2 doses of BNT162b2 or ChAdOx1 vaccine using the Malaysian surveillance and administrative data and the Taiwan's National Health Insurance Research Database (NHIRD). Using the SCCS design, we scanned focal window lengths (day 1-70 post-vaccination) using three methods: (i) maximum and graphical approach (Xu 2011) using the maximum incidence rate ratio (IRR) or the decreasing "change point" within a linear relationship between IRR and the inverse of average person-time at risk, (ii) linear-quadratic spline-based method (Campos 2017) identifying knot with the minimum error on IRR-inverse window length plots, and (iii) scan-based test (Hunsberger 2015) detecting temporal event clusters by likelihood ratio statistics.

Results: For myocarditis, Xu and Campos identified a 6–8-day focal window for BNT162b2 first dose, while Hunsberger suggested a 11-20-day window across databases. All methods estimated a 4-day window for BNT162b2 dose 2 in both databases. For thrombocytopenia, signals appeared only in the NIHRD database: Hunsberger identified a 34-day window for BNT162b2, while Xu and Campos suggested an 8-9-week window for ChAdOx1. For PE, no signal was identified across all scanned windows in both databases.

Conclusion: The optimal focal windows across methods and databases are consistent when signals and clustering of events are strong post-vaccination, while weaker signals increases variability between methods. The variations between databases further suggest that results are influenced by the specific risk profiles of underlying populations.

Keywords: self-controlled case series; vaccine safety; covid-19 vaccine

101

No signal left behind: multi-modal vaccine safety surveillance

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Background: Vaccination is one of public health's greatest achievements, second only to clean water in preventing death and disease globally. While intensified scrutiny obviously accompanies new vaccines, variants, or use in new populations, sustained monitoring of established vaccines is equally critical to ensure detection of rare adverse events, identify risks in sub-populations and rapidly recognise anomalies by brand, batch, provider-group, recipient characteristics, or even spurious findings. Because safety signals may emerge from multiple pathways, effective vigilance demands diverse surveillance systems and analytic methods to ensure that no meaningful signal goes unnoticed.

Aim: Describe Victoria's routine weekly vaccine safety vigilance supporting safe immunisation program delivery.

Methods: Victoria operates an integrated, multi-modal vaccine safety surveillance system. Weekly spontaneous reports to SAEFVIC are assessed using disproportionality analyses of vaccine–adverse event pairs and reporting rates per 100,000 doses administered, stratified by sex, age group, vaccine target disease, and, where relevant, vaccine brand. Serious AEFI reports undergo line-list review for epidemiological clustering. Telephone helpline contacts and emergency department presentations are monitored using modified CUSUM methods to detect deviations from historical patterns in post-vaccination contacts and presentations within 28 days of vaccination. Monthly VaxPulse social listening monitors online personal adverse-event discussions and misinformation trends for prioritised vaccines. Signal hypotheses are evaluated for cross-method consistency, biological plausibility, known associations, and clinical significance to determine escalation, investigation, or return to routine surveillance.

Results: The framework integrates passive reporting, syndromic surveillance, healthcare utilisation data, and social listening to support timely signal detection and evaluation. Multiple complementary methods enable assessment of potential signals across diverse data sources and facilitate rapid prioritisation of issues requiring further investigation.

Conclusion: Integrated, multi-source, sex- and age-disaggregated routine vaccine safety surveillance strengthens pharmacovigilance capacity, supports timely signal detection and evaluation, and provides ongoing assurance for immunisation program safety.

Keywords: vaccine safety, pharmacovigilance, signal detection

102

Influenza vaccination and septic shock in elderly heart failure patients

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Introduction
Evidence on influenza vaccination and septic shock in elderly heart failure patients remains limited. Standard self-controlled case series (SCCS) analyses are vulnerable to informative censoring, event-dependent exposure, and depletion of pre-vaccination events reflecting healthy vaccinee bias in this high-mortality population.

Aims
To assess the association between influenza vaccination and septic shock, and how sequentially correcting these assumption violations affects the estimates.

Methods
We identified septic shock cases aged ≥65 with heart failure vaccinated against influenza between October 2022 and September 2023 using nationwide claims data. Septic shock required a first inpatient diagnosis with concurrent vasopressor use, and heart failure by any prior diagnosis and medication use in the preceding year. Five analyses were applied sequentially, beginning with a standard SCCS without a pre-exposure period, then adding a 21-day one. Modified SCCS, which requires no pre-exposure period, then sequentially addressed event-dependent exposure using Horvitz-Thompson weighting, informative censoring by extending follow-up to study end regardless of death, and depletion of pre-vaccination events by adding unvaccinated cases. Sensitivity analyses varied the pre-exposure period from 28 to 98 days in 7-day intervals.

Results
Among 4,185 septic shock cases, 1,656 were vaccinated. IRRs for days 0–14, 15–56, 57–120, and 121–180 were 0.86, 1.52, 1.55, and 1.60 (standard SCCS), 0.30, 0.61, 0.86, and 1.15 (pre-exposure period added), 0.01, 0.01, 0.04, and 0.11 (Horvitz-Thompson weighting), 1.04, 1.33, 1.34, and 1.24 (informative censoring corrected), and 0.57, 0.75, 0.89, and 0.92 (fully adjusted model). Across sensitivity analyses, IRRs declined steadily without convergence.

Conclusions
Influenza vaccination was associated with a waning protective effect against septic shock. Modified SCCS outperformed standard approaches, which failed to adequately address event-dependent exposure even with varying-length pre-exposure periods. Correction for informative censoring and healthy vaccinee bias was additionally required for unbiased estimates in this high-mortality setting.

Keywords: Influenza vaccination, septic shock, self-controlled case series

103

Integrating multi-method signal detection using Bayesian networks for enhanced vaccine safety surveillance

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Introduction: Timely responses to potential vaccine adverse event (AE) signals are essential for translating real-world data into public health decisions. Signal detection methods should be sensitive to identify emerging safety concerns while remaining specific to minimise false alerts. We present a novel augmented Naïve Bayes model (AugNB) that combines established signal detection approaches, improving performance over individual methods alone.

Aims: Developing AugNB for AE signal detection in general practice (GP) data by integrating complementary statistical methods, improving predictive performance compared with individual approaches, and validating against expert-led signal investigation outcomes.

Methods: AugNB incorporated four signal detection methods: Proportional Reporting Ratio (PRR), Bayesian Confidence Propagation Neural-Network (BCPNN), Farrington, and Maximised Sequential Probability Ratio Test (MaxSPRT). When any method identifies a potential signal, AugNB estimates the probability of a true safety problem. Performance was evaluated against each individual method and unaugmented NB using POLAR primary care data for 16 Adverse Events of Special Interest (AESIs) and four priority vaccines (influenza, COVID-19, shingles, and RSV), linked to prior investigation outcomes from January 2017 to March 2024.

Results: AugNB outperformed MaxSPRT, BCPNN, PRR, Farrington, and NB using leave-one-out cross-validation achieving 81% accuracy, 87% F1 score (harmonic mean of precision and sensitivity), and 75% AUC (measure of the model's ability to distinguish signals from non-signals) —exceeding the strongest baseline (NB: 75%, 82%, 71%). This included detection of menstrual changes (rejected by PRR) and rejection of appendicitis (detected by PRR, BCPNN and Farrington) following COVID-19 vaccination, matching expert-led investigations.

Conclusions: AugNB improved signal classification performance and may support prioritisation of vaccine safety signals for further investigation. It offers a transparent, data-driven framework synthesising multiple surveillance methods, strengthening timely vaccine safety surveillance, and supporting evidence-based public health decisions in routine pharmacoepidemiologic surveillance.

Keywords: Vaccine safety; Signal detection; Probabilistic Inference

104

A Multi-Datasource Investigation of a Consumer-Initiated Vaccine Safety Signal

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Introduction: Vaccine safety surveillance relies on multiple sources of information, including spontaneous reports, healthcare datasets, and consumer concerns. During Australia's COVID-19 vaccination program, a consumer who developed giant cell arteritis (GCA) following COVID-19 vaccination sought further investigation of a potential association, prompting a signal assessment using multiple Australian healthcare datasets.

Aim: To investigate the potential association between COVID-19 vaccination and incident GCA.

Methods: A staged signal assessment was undertaken. Stage 1 involved review of spontaneous reports of giant cell arteritis (GCA) following COVID-19 vaccination received in Victoria, including reporting rate and disproportionality analyses. Stage 2 involved investigation using Australian general practice (POLAR; ~12 million electronic health records) and linked hospital (VSHL) datasets covering January 2021 to September 2024. Incident GCA cases were identified using coded diagnoses and analysed using a self-controlled case series design. Relative incidence (RI) was estimated for a 42-day post-vaccination risk period compared with baseline periods, with sensitivity analyses using 1–7, 1–14 and 1–28-day risk windows. Analyses were stratified by vaccine platform, age group and sex.

Results: Six spontaneous reports of GCA following COVID-19 vaccination were identified. No disproportionality signal was detected (PRR 0.05, chi-squared 2.75). No increased risk of GCA was observed within 42 days of vaccination in general practice (RI 0.96, 95% CI 0.76–1.21) or linked hospital datasets (RI 0.79, 95% CI 0.68–0.91). Results were consistent across vaccine brands, age groups, and sex.

Conclusion: No evidence of an increased risk of GCA following COVID-19 vaccination was identified. Multi-datasource robust pharmacoepidemiological methods can provide evidence-based answers to support vaccine safety surveillance, address consumer concerns and maintain public trust.

Keywords: Vaccine safety; Pharmacovigilance; Consumer engagement

105

mRNA COVID-19 Vaccination and Incident Autoimmune Disease

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Introduction: Evidence on mRNA COVID-19 vaccination and incident autoimmune diseases remains limited, with the potential for residual event-dependent exposure in standard self-controlled case series (SCCS) analyses, even with pre-exposure periods incorporated.

Aims: To assess the association between mRNA COVID-19 vaccination and incident autoimmune diseases and to quantify the impact of event-dependent exposure by comparing standard and modified SCCS estimates.

Methods: Two SCCS analyses were conducted using nationwide health insurance claims data linked with a COVID-19 registry, among incident autoimmune cases aged ≥20 who received at least one mRNA COVID-19 vaccination dose between March 2021 and September 2022, without prior autoimmune diagnosis. Autoimmune cases were defined as the first diagnosis across 10 organ system categories, identified from inpatient, outpatient, or emergency settings. The standard SCCS incorporated a 14-day pre-exposure window, while the modified SCCS treated post-event exposure as missing and applied Horvitz-Thompson weighting. Both analyses estimated IRRs for day 1-21 post-dose risk windows, adjusting for SARS-CoV-2 infection and variant period.

Results: Among 295,749 incident autoimmune cases who received at least one mRNA COVID-19 vaccination, the modified SCCS estimated an overall day 1-21 IRR of 1.69 (95% CI, 1.66-1.71). Dose-stratified IRRs were 1.75 (95% CI, 1.72-1.79), 1.49 (95% CI, 1.45-1.52), and 1.80 (95% CI, 1.77-1.84) for the first, second, and third doses, respectively. In contrast, the standard SCCS yielded a lower overall IRR of 1.20 (95% CI, 1.19-1.21), with the third-dose estimate suggesting a protective effect (IRR, 0.95, 95% CI, 0.93-0.97).

Conclusions: mRNA COVID-19 vaccination was associated with increased risk of incident autoimmune disease within 21 days after each dose. The reversed third-dose estimate in standard SCCS underscores the necessity of modified SCCS that address event-dependent exposure rather than relying solely on fixed pre-exposure periods in multi-dose vaccination safety research.

Keywords: mRNA COVID-19 vaccination, incident autoimmune disease, self-controlled case series

106

Risk assessment of herpes zoster associated with DPP-4 inhibitor in T2D patients

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Introduction: Dipeptidyl peptidase-4 inhibitors (DPP-4i) are widely prescribed for type 2 diabetes mellitus, yet their safety profile regarding cellular immunity remains controversial. Theoretically, inhibiting the DPP-4 enzyme (CD26) on T lymphocytes could compromise T-cell activation, which might increase the risk of herpes zoster (HZ) recurrence. However, some laboratory safety data demonstrate conventional gliptins preserve T-cell proliferation and do not adversely impact cell-mediated immune responses.

Aim: This study aimed to evaluate the risk of HZ in patients with type 2 diabetes initiating DPP-4i compared to those initiating SGLT2i.

Methods: We used TriNetX U.S. Network (2016-2025) to conduct a retrospective cohort analysis under target trial emulation framework. Adults aged ≥ 18 years with type 2 diabetes were included. The index date was defined as the date of the first DPP-4i or SGLT2i prescription. Patients with prior exposure to either class within 1 year before the index date were excluded. This 1-year pre-index period also defined covariate assessment, with groups balanced via propensity score matching. The primary outcome was 5-year HZ incidence. The follow-up period extended from index date to HZ occurrence, death, attrition, or study end. Subgroup analyses were conducted based on age, sex, baseline corticosteroid use, and HbA1c level. Cox proportional hazards models and Kaplan-Meier curves estimated hazard ratios and 95% confidence intervals.

Results: Among 136,751 propensity score-matched pairs, DPP-4i initiation was not associated with significantly higher risk of HZ compared to SGLT2i (HR = 1.044; 95% CI, 0.980–1.113). Generally, results were consistent across most subgroups. However, there was a slightly elevated risk of HZ among female DPP-4i initiators (HR = 1.097; 95% CI, 1.007–1.194).

Conclusions: DPP-4i therapy is generally not associated with an increased risk of HZ compared to SGLT2i, while the potential risk observed in female patients warrants closer clinical monitoring.

Keywords: DPP-4inhibitors, Herpes zoster, Type 2 diabetes

107

Semaglutide/Tirzepatide-Associated Myopathy and Rhabdomyolysis: Systematic Review and FAERS Disproportionality Analysis

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Introduction: Glucagon-like peptide-1 receptor agonists (GLP-1RAs) such as semaglutide and tirzepatide are used to treat type 2 diabetes and obesity. Recent case reports have linked these medications with myopathy and rhabdomyolysis.

Aims: To systematically review case reports linking semaglutide or tirzepatide with myopathy/rhabdomyolysis and investigate associated reporting in the U.S. Food and Drug Administration Adverse Event Reporting System (FAERS).

Methods: We systematically searched PubMed and Embase for reports of semaglutide- or tirzepatide-associated myopathy/rhabdomyolysis and inferred the Naranjo score. FAERS reports from 2018-2025 were analysed to estimate reporting odds ratios (RORs) for semaglutide- and tirzepatide -associated myopathy/rhabdomyolysis using three comparator frameworks: other GLP-1RAs; active comparators (other GLP-1RAs, SGLT2 inhibitors, and DPP-4 inhibitors); and all other medications. Interaction with statin was assessed using additive and multiplicative interaction models and Ω shrinkage.

Results: The systematic review identified 13 semaglutide- or tirzepatide-associated myopathy/rhabdomyolysis case reports, 12 involving weight-loss use and six had a probable association by the Naranjo scale. In FAERS, 1,378 semaglutide-associated and 916 tirzepatide-associated myopathy reports were identified, including 103 and 41 rhabdomyolysis reports, respectively. Compared with other GLP-1RAs, semaglutide showed higher reporting odds of myopathy (ROR 1.80, 95%CI 1.67-1.95) and rhabdomyolysis (1.89, 1.41-2.52), whereas tirzepatide showed lower reporting odds. Neither medication showed higher reporting odds when compared with active comparators or all other medications. Statin co-use occurred in 449 semaglutide and 126 tirzepatide myopathy cases, and 47 and 20 rhabdomyolysis cases, respectively. Tirzepatide showed weak statin interaction signal for myopathy and rhabdomyolysis in Ω shrinkage (Ω025=0.57; 0.50) and multiplicative models (ROR 1.31, 95%CI 1.08-1.60; 2.79, 1.52-5.11). Semaglutide only showed weak interaction in Ω shrinkage analyses for myopathy and rhabdomyolysis (Ω025=1.06; 0.70).

Conclusion: Although case reports suggest myopathy and rhabdomyolysis, inconsistent signals across comparison groups were noted. Prospective studies are needed to clarify this association.

Keywords: GLP-1 receptor agonists, Disproportionality Analysis, Rhabdomyolysis

108

SGLT-2i and Risk of Self-Harm in T2DM: A Target Trial Emulation Study

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Introduction: Type 2 diabetes mellitus (T2DM) patients have twice the self-harm risk compared to the general population.The association between sodium-glucose cotransporter 2 inhibitors (SGLT-2i) and self-harm is unclear.

Aims: This study aimed to assess whether SGLT-2i use is associated with a lower risk of self-harm in T2DM patients.

Methods: Through the Shenzhen Public Health Data Platform, we constructed two cohorts (SGLT-2i versus dipeptidyl peptidase-4 inhibitors [DPP-4i], SGLT-2i versus glucagon-like peptide-1 receptor agonists [GLP-1RA]) via a target trial emulation framework with an active comparator, new-user design. Hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated using overlapping weighting Cox regression models.

Results: The SGLT-2i versus DPP-4i cohort included 85,789 SGLT-2i users and 53,810 DPP-4i users. After a median follow-up of 1.85 years (interquartile range: 0.91-2.70), 567 (0.66%) cases of self-harm occurred in the SGLT-2i group and 567 (1.05%) in the DPP-4i group. After overlapping weighting, SGLT-2i was associated with a lower risk of self-harm compared with DPP-4i (HR: 0.86, 95%CI: 0.76-0.98), and this result was consistent across various sensitivity analyses. In the SGLT-2i (n=130,330) versus GLP-1RA (n=5,126) cohort, a lower risk of self-harm (HR: 0.76, 95% CI: 0.59-0.99) was associated with SGLT-2i compared with GLP-1RA. However, in some sensitivity analyses, no statistically significant difference was observed between SGLT-2i and GLP-1RA users.

Conclusions: SGLT-2i use is associated with a lower risk of self-harm in T2DM patients. These findings provide supportive evidence for the safety of SGLT-2i and highlight their potential role in mental health management of T2DM patients.

Keywords: type 2 diabetes mellitus, self-harm, sodium-glucose cotransporter-2 inhibitors, glucagon-like peptide-1 receptor agonists, target trial emulation

109

Non-arteritic Anterior Ischemic Optic Neuropathy and GLP-1RAs in Non-Diabetic Individuals with Obesity

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Introduction: Rapid use of GLP-1RAs, including semaglutide and tirzepatide, has raised concerns regarding a potential association with non-arteritic anterior ischemic optic neuropathy (NAION). However, evidence among non-diabetic individuals with obesity remains limited.

Aims: To assess the association between NAION and GLP-1RAs in non-diabetic individuals with obesity.

Methods: The retrospective cohort study used TriNetX global network, including individuals aged ≥20 years with BMI ≥30 kg/m^2 and no prior diagnosis of DM within 3 years who initiated tirzepatide, semaglutide, or traditional anti-obesity medications (AOMs) between January 1, 2022, and March 31, 2025. We defined index date as the date of first prescription. Individuals with prior study-drug exposure, optic nerve disorders, relevant systemic diseases, or contraindications one year before the index date were excluded. The primary outcome was incident NAION. To mimic randomization, we applied 1:1 propensity score matching using baseline characteristics, including metabolic parameters, comorbidities, and co-medications. We used the Cox proportional hazards models to generate hazard ratios (HR) and 95% confidence intervals. Sensitivity analyses included HbA1c <6.0% restriction, and conjunctivitis as a negative control outcome.

Results: We identified 163,790 tirzepatide initiators, 420,543 semaglutide initiators, and 153,187 AOMs initiators. Baseline characteristics were well balanced after PS matching. Compared with AOMs, tirzepatide (HR, 2.97;1.66-5.31) and semaglutide (HR, 3.42;2.10-5.58) were associated with an increased risk of NAION. These associations were attenuated toward the null (HR, 1.36;0.62–2.96 for tirzepatide; HR, 1.76;0.91–3.41 for semaglutide) following PS matching, including age, sex, comorbidities, and HbA1c. Findings were consistent after HbA1c restriction.

Conclusions: Both tirzepatide and semaglutide were associated with an increased risk of NAION among non-diabetic individuals with obesity, though the association attenuated toward the null after PS matching. This suggested residual differences in baseline health status, such as age, sex, comorbidities, or abnormal metabolic profiles, may partially explain the observed association between GLP-1RAs and NAION.

110

HbA1c trajectories and associated factors in Thai patients with type 2 diabetes

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Introduction: Glycemic control among patients with type 2 diabetes mellitus (T2DM) is heterogeneous, and average HbA1c values may not adequately reflect long-term glycemic patterns. Identifying HbA1c trajectories and associated factors may support individualized diabetes management.

Aims: To identify distinct HbA1c trajectory patterns among Thai patients with newly diagnosed T2DM and evaluate factors associated with longitudinal HbA1c levels.

Methods: This retrospective population-based cohort study used the Thai Ministry of Public Health 43-file national health database from 2017 to 2025. Adults newly diagnosed with T2DM during 2017–2019 with at least four HbA1c measurements and five years of follow-up were included. Group-based trajectory modeling was used to identify longitudinal HbA1c patterns. A time-lagged generalized estimating equation model with robust standard errors evaluated demographic, clinical, and treatment-related factors associated with repeated HbA1c levels. Missing BMI and blood pressure values, accounting for approximately 3.8% of repeated observations in the longitudinal dataset, were handled using multiple imputation with 20 imputed datasets.

Results: Among 106,005 patients, three HbA1c trajectories were identified: stable glycemic control (80.4%), poor glycemic control with partial improvement (16.1%), and persistently very poor glycemic control (3.5%). In the time-lagged GEE analysis, female sex, younger age, smoking, high comorbidity burden, higher diastolic blood pressure, and prior insulin use were associated with higher longitudinal HbA1c levels. Greater antidiabetic medication burden at the previous visit, higher BMI, higher systolic blood pressure, and alcohol use were associated with lower HbA1c levels.

Conclusions: Distinct HbA1c trajectories were identified among Thai patients with newly diagnosed T2DM, with approximately one-fifth showing poor or persistently very poor glycemic control. Demographic, clinical, and treatment-related factors were associated with longitudinal HbA1c levels, supporting early risk stratification and individualized follow-up.

Keywords: Type 2 diabetes mellitus; HbA1c; glycemic control; trajectory analysis; Thailand

111

Incidence of type 2 diabetes mellitus in men receiving finasteride and tamsulosin

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Introduction: The risk of type 2 diabetes mellitus (T2DM) regarding finasteride and tamsulosin remains controversial.

Aims: To investigate the incidence of T2DM in finasteride and tamsulosin users among China and UK populations.

Methods: Using Exchange Xiamen PLatform Of Resident E-health Records (EXPLORER) in China and UK Biobank (UKB), this study included men aged 40-80 years diagnosed with benign prostatic hyperplasia. Hazard ratios (HRs) with 95% confidence intervals (CIs) were estimated using Cox models, incorporating propensity score-based overlap weighting and inverse probability of censoring weighting. The covariates included age, race, smoking status, alcohol consumption, physical activity, socioeconomic status, educational attainment, marital or cohabitation status, dietary habits, healthcare utilization, comorbidities, and medication use.

Results: The EXPLORER cohort comprised 34,075 patients, with 21,399 untreated, 2,122 on finasteride alone, 5,012 on tamsulosin alone, and 5,542 on combination. The UKB cohort comprised 11,905 patients, with 7,050 untreated, 492 on finasteride alone, 3,105 on tamsulosin alone, and 1,258 on combination. Both cohorts showed satisfactory group balance post-weighting (standardized mean differences [SMD]<0.1). Compared to patients receiving tamsulosin alone, those receiving finasteride alone showed a higher T2DM risk (HR = 1.36 [95% CI 1.15-1.60] in EXPLORER; 1.32 [0.96-1.82] in UKB). When compared to non-treatment, finasteride monotherapy was not associated with an elevated T2DM risk (1.00 [0.89-1.13] in EXPLORER; 1.04 [0.77-1.41] in UKB), whereas tamsulosin monotherapy and combination therapy were associated with a reduced T2DM risk (0.71 [0.64-0.80] and 0.44 [0.40-0.49] in EXPLORER; 0.67 [0.56-0.81] and 0.45 [0.34-0.59] in UKB).

Conclusions: Tamsulosin treatment, with or without finasteride, was associated with a lower risk of developing T2DM. In contrast, finasteride users showed a higher T2DM risk than tamsulosin users, particularly among the Asian population. The potential benefits of tamsulosin against T2DM require further investigation, and clinicians may consider regular assessment of T2DM risk in patients using finasteride.

112

Impact of Cardiovascular-Kidney-Metabolic Syndrome on Clinical Outcomes in Taiwan:A Retrospective Cohort Study

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Background: Cardiovascular-kidney-metabolic (CKM) syndrome has emerged as a major clinical challenge, yet longitudinal evidence characterizing stage-specific adverse outcomes in Asian populations remains scarce.

Objectives: To evaluate the associations between CKM stage and the risks of metabolic, cardiovascular, renal, hepatic, and mortality outcomes.

Methods: We conducted a retrospective cohort study using individually linked data from the Taiwan Biobank and the National Health Insurance Research Database (2009–2021). CKM stages (0–4) were defined per the American Heart Association advisory, and incident outcomes spanned three domains: metabolic progression (hypertension, chronic kidney disease [CKD], diabetes, hyperlipidemia); major clinical events (three-point major adverse cardiovascular events [3P-MACE], heart failure, renal and hepatic endpoints); and all-cause mortality. Multivariable Cox proportional hazards models estimated hazard ratios (HRs), referenced to stage 0, with adjustment for demographics, comorbidity burden, and established risk factors. In addition, Fine–Gray subdistribution hazard models addressed the competing risk of death.

Results: Among 153,591 participants, 28,191 (18.4%) were stage 0, 35,882 (23.4%) stage 1, 61,980 (40.4%) stage 2, 20,859 (13.6%) stage 3, and 6,679 (4.3%) stage 4. Mean age rose progressively from 43.1 years at stage 0 to 59.1 years at stage 4. Higher stage was consistently associated with graded increases in risk. Relative to stage 0, stage 2 conferred elevated risks of hypertension (HR 6.53, 95% CI 6.07–7.02), diabetes (HR 7.41, 6.60–8.32), and hyperlipidemia (HR 2.39, 2.29–2.54). At stage 4, risks were markedly higher for 3P-MACE (HR 4.66, 3.31–6.56), acute myocardial infarction (HR 7.56, 4.26–13.41), advanced CKD (HR 11.42, 6.85–19.03), fatty liver disease (HR 4.04, 3.45–4.73), and all-cause mortality (HR 2.07, 1.62–2.65). Competing-risk analyses yielded consistent estimates.

Conclusions: Advancing CKM stage was associated with graded increases in metabolic, cardiovascular, renal, hepatic, and mortality risks. CKM staging may therefore facilitate risk stratification and stage-targeted intervention.

113

Early SGLT2i initiation and outcomes in ADHF without sustained dual guideline-directed therapy

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Introduction:
Hospitalization for acute decompensated heart failure (ADHF) identifies a vulnerable period characterized by high risks of mortality and heart failure (HF) readmission. Although guideline-directed medical therapies improve outcomes, many real-world patients lack foundational renin–angiotensin system inhibitors (RASi) and beta-blockers. Whether early sodium-glucose cotransporter-2 inhibitor (SGLT2i) initiation improves outcomes among ADHF patients lacking sustained dual therapy remains uncertain.

Aims:
This study emulated a target trial to evaluate the clinical impact of early post-discharge SGLT2i initiation versus non-use among ADHF patients lacking prior sustained dual RASi and beta-blocker therapy.

Methods:
Using a nationwide healthcare database (2018-2021), we identified patients newly hospitalized for ADHF with ischemic, hypertensive, or cardiomyopathic etiologies. We excluded patients with acute cardiovascular events within 90 days prior, confounding cardiac conditions, end-stage renal disease, type 1 diabetes, prior SGLT2i exposure, or at least 6 months of concomitant RASi and beta-blocker use before admission. Early SGLT2i initiation was defined as prescription within 90 days post-discharge with continued exposure at the 91-day landmark. Propensity score matching was used to balance baseline demographics, medications, comorbidities, healthcare utilization and frailty index. All-cause mortality was analyzed using Cox models and HF rehospitalization using Fine-Gray models.

Results:
Among 28,797 eligible patients, 1,036 SGLT2i initiators were matched to 4,026 non-users. Over a median follow-up of 36 months, SGLT2i initiation in the per-protocol analysis was significantly associated with a lower risk of all-cause mortality (HR=0.73, 95% CI: 0.60–0.89) and a lower risk of HF rehospitalization (subdistribution HR [sHR]=0.80, 95% CI: 0.67–0.97).

Conclusions:
In hospitalized ADHF patients lacking prior sustained dual RASi and beta-blocker therapy, early post-discharge SGLT2i initiation was significantly associated with lower mortality and reduced HF rehospitalization. These real-world findings support prioritizating SGLT2i during the high-risk post-ADHF period, even in the absence of foundational dual therapy.

Keywords: SGLT2 inhibitor, Target trial emulation, Acute Heart failure

114

Treatment intensification in atherosclerotic cardiovascular disease: high-intensity statins versus ezetimibe add-on therapy

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Introduction: Many patients with atherosclerotic cardiovascular disease (ASCVD) require treatment intensification beyond moderate-intensity statin (MIS) monotherapy to achieve guideline-recommended low-density lipoprotein cholesterol (LDL-C) targets. However, real-world patterns and comparative effectiveness of alternative intensification strategies remain underdetermined.

Aims: To characterize patients undergoing treatment intensification with high-intensity statin (HIS) versus ezetimibe add-on therapy (MIS+EZE) and emulate a target trial comparing their risk of major adverse cardiovascular events (MACE).

Methods: Using a national claims database (2014-2024), we identified adults aged 18 to 80 years with ASCVD who intensified treatment with HIS or MIS+EZE after at least 4 weeks of newly initiated MIS monotherapy. The primary outcome was MACE, defined as all-cause mortality, nonfatal myocardial infarction, or nonfatal stroke. Follow-up began 30 days after intensification to mitigate protopathic bias. Inverse probability of treatment weighting (IPTW) was used to balance baseline characteristics and weighted Cox proportional hazards models estimated hazard ratios (HRs) and 95% confidence intervals (CIs).

Results: Among 166,230 patients with ASCVD who initiated MIS monotherapy, 22,727 (14.2%) subsequently underwent intensification. The mean age was 63 years, and 62.9% were male. Compared with HIS users (43.5%), MIS+EZE users (56.5%) had a longer median time to intensification (887 vs. 831 days) and a lower burden of cardiovascular, metabolic, and renal comorbidities (all $p<0.001$). After IPTW adjustment, MIS+EZE was associated with a lower risk of MACE than HIS during a median follow-up of 3.2 years (HR 0.72, 95% CI 0.65-0.79).

Conclusions: Treatment intensification was uncommon among patients with ASCVD receiving MIS monotherapy, suggesting potential clinical inertia in lipid management. Compared with switching to HIS, intensification with MIS+EZE was associated with a lower risk of MACE. Further studies incorporating LDL-C measurements are needed to assess whether differences in lipid control or residual confounding contributed to this association.

Keywords: Atherosclerotic cardiovascular disease; Major adverse cardiovascular events; Treatment intensification

115

Pharmacogenomic and Statin Response in UKB Primary Care: A Longitudinal Linear Mixed-Effects

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Background: Despite their widespread use and efficacy in cardiovascular prevention, statins show considerable inter-individual variability in LDL-C response. CPIC-justified PGx variants may explain part of this variability through pharmacokinetic and pharmacodynamic mechanisms, but longitudinal real-world evidence is limited.

Objectives: To examine associations between 14 CPIC-justified PGx variants and absolute on-statin LDL-C, statin LDL-C lowering response, and SNP × statin-type interactions in a large UK primary care longitudinal cohort.

Methods: 20,808 statin users in UK Biobank primary care were included with median age 62 years and 58% male. Three lmer model families: (a) = absolute on-statin log(LDL-C); (b) = per-visit delta LDL-C from pre-statin baseline; (c) = SNP × statin-type interaction were constructed. All adjusted for age, sex, BMI, smoking, deprivation, diabetes, hypertension, chip, PC1–10. FDR correction was done within each model.

Results: Nine SNPs predict absolute on-statin LDL-C (a): APOE rs7412 (+23.4% per allele), PCSK9 rs11591147 (+15.8%), LPA rs10455872 (−7.3%), SORT1 rs646776 (+5.6%), HMGCR rs3846662, PCSK9 rs11206510, CETP rs708272, CYP7A1 rs2073547, and SLCO1B1*5 rs4149056. These are dominantly pharmacodynamic variants influencing ambient LDL-C rather than statin response per se.
Four SNPs predict the LDL-C lowering response itself (b): APOE rs7412, LPA rs10455872, CYP3A5*3 rs776746, and CYP3A4*22 rs35599367. Notably, the two CYP variants are pharmacokinetic, and their appearance here but not in (a) is mechanistically coherent.
No interaction survived FDR in (c), though directional patterns in the focus pairs (SLCO1B1*5 × simvastatin, CYP3A4*22 × atorvastatin) are consistent with CPIC predictions. The limited rosuvastatin sample (n = 285) constrained power for that arm.

Conclusions: PGx variants: APOE, LPA, PCSK9, and SORT1 robustly predict on-statin LDL-C, and CYP3A5 and CYP3A4 predict statin LDL-C response in longitudinal primary care data. Larger statin-stratified studies are required to confirm pharmacogenomic interactions, particularly for rosuvastatin and pravastatin.

Keywords: pharmacogenomics; statins; LDL cholesterol;

116

Suboptimal LDL-C response to PCSK9 inhibitors: prevalence and risk factors

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Introduction: The prevalence of and risk factors for suboptimal low-density lipoprotein cholesterol (LDL-C) response to proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9i) remain unclear.

Aims: To determine the prevalence of and risk factors for suboptimal LDL-C response to PCSK9i.

Methods: We conducted a cohort study using electronic health records from the Hong Kong Hospital Authority. A total of 2899 patients initiating alirocumab, evolocumab, or inclisiran between 1 August 2016 and 31 December 2024 were followed through to 31 December 2025. The primary outcome was the prevalence of one-year suboptimal response, defined as <30% LDL-C reduction from baseline. Risk factors were identified using multivariable logistic regression, and population attributable fractions (PAFs) were estimated to quantify their contribution to suboptimal response.

Results: Overall, 33.4% (95% CI, 31.7–35.1) of PCSK9i users experienced suboptimal LDL-C response. Female sex (odds ratio [OR], 1.37; 95% CI, 1.12–1.67), ischemic stroke (OR, 1.53; 95% CI, 1.12–2.07), and familial hypercholesterolemia were associated with higher odds of suboptimal response. Older age (OR per year, 0.99; 95% CI, 0.98–1.00), higher baseline LDL-C (OR per mmol/L, 0.49; 95% CI, 0.45–0.53), hypertension (OR, 0.65; 95% CI, 0.50–0.84), liver disease (OR, 0.65; 95% CI, 0.46–0.91), adherent statin and ezetimibe use (OR, 0.54; 95% CI, 0.41–0.70), and adherent statin use (OR, 0.57; 95% CI, 0.43–0.74) were associated with lower odds. A significant interaction was observed between PCSK9i type and adherence trajectory. The largest PAFs were joint non-evolocumab use and partial adherence (23.96%; 95% CI, 18.64–28.82), absence of adherent statin use (21.42%; 95% CI, 13.98–28.23) and partial adherence to PCSK9i alone (16.78%; 95% CI, 14.46–19.32).

Conclusions: Suboptimal LDL-C response to PCSK9i is common in clinical practice, with poor PCSK9i adherence and the absence of statin use being the primary modifiable contributors.

Keywords: PCSK9i; Interindividual response; Medication adherence

117

Gabapentinoid use and risk of heart failure: a case-crossover and case-case-time-control study

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Introduction: Gabapentinoids are prescribed for neuropathic pain and other chronic conditions, particularly among older adults. Concerns remain regarding cardiovascular safety, including fluid retention and worsening heart failure. Evidence on the acute association between gabapentinoid use and heart failure is limited. Within-person designs can help account for time-invariant confounding.

Aims: To assess whether gabapentinoid use is associated with increased risk of heart failure. We further examined robustness across sensitivity analyses and clinically relevant subgroups.

Methods: We conducted case-crossover and case-case-time-control analyses using UK CPRD database linked to hospitalisation and mortality records. Adults aged ≥18 years with a first-ever heart failure event were included and patients with cancer were excluded. Gabapentinoid exposure during a 30-day hazard window before the event was compared with exposure during a randomly selected 30-day reference window between days -180 and -61. In the case-case-time-control analysis, current cases were matched 1:1 with future cases by sex, age, ethnicity and socioeconomic status, and conditional logistic regression estimated odds ratios adjusted for time-varying co-medications.

Results: The case-crossover analysis included 31,794 heart failure events and showed an increased odds of gabapentinoid exposure before heart failure (OR, 1.71; 95% CI, 1.60–1.82). In the case-case-time-control analysis, 18,838 current cases were matched to future cases. Gabapentinoid use remained associated with increased risk of heart failure (1.29, 1.14–1.46). Results of subgroup analyses are generally consistent with the main analysis. Estimates were also similar after alternative co-medication adjustment and remained elevated in analyses using different windows, washout periods, lag periods and future-case definitions.

Conclusions: Gabapentinoid use was associated with increased risk of heart failure across complementary within-person designs. Baseline cardiovascular vulnerability should be considered when initiating gabapentinoids, particularly in older adults and patients with hypertension.

Keywords: Gabapentinoids; heart failure; within individual study

118

Nationwide outpatient antineoplastic prescribing trends surrounding policy implementation in Japan

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Introduction: Outpatient cancer treatment can reduce burden on healthcare providers and improve patients' quality of life. In Japan, the Ministry of Health, Labour and Welfare (MHLW) increased the reimbursement incentive for outpatient antineoplastic prescribing from 6,000 JPY (37.4 USD) to 7,000 JPY (43.7 USD) in 2022.

Aims: This study analyzed nationwide trends in outpatient antineoplastic prescribing surrounding the 2022 reimbursement incentive increase in Japan.

Methods: A serial cross-sectional study was conducted using NDB Open Data, an aggregated national reimbursement claims database published by MHLW. The study period covered fiscal year (FY) 2019 to FY2023 (Apr 2019–Mar 2024). The outcome was defined as the annual outpatient prescribed units of antineoplastic agents per 100,000 population. Prefecture-level paired t-tests (n=47) comparing FY2019 and FY2023 values were performed for four categories: all oral agents, all injectable agents, and their subsets of new oral and new injectable antineoplastic agents. New antineoplastic agents were defined by MHLW as the 429 category including immunotherapeutic and molecular-targeted agents. $p < 0.05$ was considered statistically significant.

Results: For all oral antineoplastic agents, the mean (95%CI) outpatient prescribed units per 100,000 population increased from 324,815 (315,288–334,341) in FY2019 to 393,442 (382,599–404,285) in FY2023; for new oral agents, from 231,395 (224,939–237,852) to 298,940 (291,144–306,736). The mean difference was 68,627 (65,767–71,487; $p<0.001$) for all oral agents and 67,544 (64,905–70,184; $p<0.001$) for new oral agents.
For all injectable antineoplastic agents, the mean increased from 10,099 (9,619–10,579) to 12,475 (11,918–13,033); for new injectable agents, from 4,562 (4,366–4,757) to 6,324 (6,059–6,588). The mean difference was 2,376 (2,182–2,570; $p<0.001$) for all injectable agents and 1,762 (1,645–1,879; $p<0.001$) for new injectable agents.

Conclusions: Surrounding the reimbursement incentive increase in 2022, outpatient antineoplastic prescribing increased nationwide for both oral and injectable agents in Japan, particularly among new agents.

Keywords: antineoplastic agents, outpatient cancer treatment, health policy

119

Phase-IV External-Comparator Superiority Trial of Immunotherapy-Based Regimens in Metastatic Driver Mutation-Negative NSCLC

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Introduction: Immunotherapy (IO) has redefined the therapeutic landscape of metastatic non-small cell lung cancer (NSCLC), as reflected across landmark trials. Despite these advances, Chemotherapy remains the cornerstone of treatment for this tumor subtype, particularly in Low-Middle Income Countries (LMICs). The comparative clinical and economic effectiveness among these regimens remains scarce and necessitates real-world evaluation.

Aims: To compare the overall survival (OS), progression-free survival (PFS), and objective response rate (ORR) between IO-based regimens and standard chemotherapy in driver mutation-negative metastatic NSCLC. To evaluate the incremental cost-effectiveness of IO-based treatment.

Methods: This phase IV real-world external comparator study included adult patients with driver mutation-negative metastatic NSCLC and Eastern Cooperative Oncology Group performance status 0–2. Patients received either IO alone or IO combined with chemotherapy (external comparator arm) or standard chemotherapy (control arm). Patient-level external comparator data were obtained from the cBioPortal for Cancer Genomics. Inverse Probability of Treatment Weighting (IPTW) was applied to minimize treatment-selection bias, and survival outcomes were analyzed using adjusted hazard ratios (HRs).

Results: A total of 119 patients were included, with 68 receiving IO-based therapy and 51 receiving chemotherapy. Median OS was significantly longer in the IO arm compared with chemotherapy (26.0 vs 8.5 months; adjusted HR 0.28, 95% CI 0.16–0.49; $p<0.001$). Median PFS was also improved with IO (10.6 vs 5.4 months; adjusted HR 0.48, 95% CI 0.31–0.71; $p<0.001$). The ORR was higher in the IO arm than in the chemotherapy arm (42.2% vs 21.3%; $p<0.001$). The incremental cost-effectiveness ratio for IO was INR 723,615 per additional month of PFS gained.

Conclusions: Immunotherapy-based regimens demonstrated superior survival outcomes compared with standard chemotherapy in driver mutation-negative metastatic NSCLC. Despite these clinical benefits, the high economic burden associated with immunotherapy may limit its accessibility and affordability, particularly in LMIC settings.

Keywords: Non-Small Cell Lung Cancer, Immunotherapy, Cost-effectiveness Analysis

120

Association of chemotherapy dose intensity with clinical outcomes in early breast cancer

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Introduction: Chemotherapy dose modifications occur in clinical practice due to patient characteristics and disease-related factors. Relative dose intensity (RDI) quantifies delivered chemotherapy intensity relative to the planned regimen. Although reduced RDI has been linked to poorer outcomes in some malignancies, evidence in early breast cancer (EBC) remains inconsistent.

Aims: To characterize patient characteristics and evaluate the association between reduced RDI and clinical outcomes in patients with EBC.

Methods: Utilizing a single-center medical database (2010-2021), patients with EBC who completed first-line chemotherapy were enrolled and stratified into adjuvant or neoadjuvant cohorts according to treatment sequence. RDI was dichotomized using an 85% cutoff. Primary outcomes were overall survival (OS) and disease-free survival (DFS) in the adjuvant cohort, and pathological complete response (pCR) in the neoadjuvant cohort. Inverse probability of treatment weighting and landmark analysis were applied to address potential confounding and immortal time bias.

Results: Of 13,374 screened patients, 2,924 were eligible, including 443 (15.2%) with RDI <85%. Patients with RDI <85% were older, had higher comorbidity burden and poorer performance status. In the adjuvant cohort (n=2,548; 15.5% with RDI <85%), reduced RDI was not significantly associated with OS or DFS; however, a significant association with DFS emerged when the cutoff was shifted to 80% in sensitivity analysis (aHR = 1.89; 95% CI, 1.11—3.22). In the neoadjuvant cohort (n=376; 13.0% with RDI <85%), reduced RDI was not significantly associated with pCR. Subgroup analysis demonstrated obesity (BMI ≥27 kg/m^2) as a potential effect modifier (aHR = 2.19; 95% CI, 1.02–4.68).

Conclusions: Among patients with EBC completing chemotherapy, RDI <85% was not associated with inferior outcomes, while RDI <80% was linked to worse DFS, and obesity was a potential effect modifier. Larger studies are warranted for confirmation and safety outcome evaluation.

Keywords: Relative dose intensity, Early breast cancer, Clinical outcomes

121

Dual Immunotherapy Versus Pembrolizumab in Metastatic Head-Neck Cancer: An External Comparator Analysis

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Introduction: Immune Checkpoint Inhibitors (ICIs) demonstrate promising efficacy in Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma (R/M HNSCC), as reflected across the landmark CHECKMATE-651 and KEYNOTE-048 trials. However, comparative evidence between dual ICI blockade and pembrolizumab monotherapy in patients with high PDL-1 expression remains limited.

Aim: To compare the effectiveness and safety of nivolumab plus ipilimumab versus pembrolizumab monotherapy in PD-L1 CPS >20 R/M HNSCC

Methods: This was an observational, external comparator (EC) study. The patient-level data used for the EC group were accessed via the cBioPortal for Cancer Genomics. Control arm data were obtained from the KEYNOTE-048 trial and adjusted using the Matching-Adjusted Indirect Comparison (MAIC) to align baseline covariates with the EC population. Adult patients with R/M HNSCC who had an ECOG PS of 0-2 and a PD-L1 CPS score >20 were recruited. The patients received either nivolumab plus ipilimumab (EC) or pembrolizumab monotherapy. The primary endpoints were median OS, PFS, and ORR. Safety was the secondary endpoint.

Results: A total of 239 patients were recruited, 106 in the nivolumab plus ipilimumab group and 133 in the pembrolizumab group. The median OS for the nivolumab plus ipilimumab group was 16.3 months (95% CI, 11.9-20.3), compared to 14.64 months (95% CI, 12.10-17.63) for the pembrolizumab group (P=0.04). The median PFS among patients receiving nivolumab plus ipilimumab was 11.0 months (95% CI, 10.61-13.38) compared to 9.3 months (95% CI, 7.62-13.17) in the pembrolizumab group (P=0.08). The ORR was 28.8% in the nivolumab plus ipilimumab arm and 23.3% in the pembrolizumab arm. The rate of grade >3 adverse events were 31% in the nivolumab plus ipilimumab group and 45% in the pembrolizumab group.

Conclusion: Dual ICI blockade demonstrated improved survival outcomes and higher response rates compared with pembrolizumab monotherapy among higher PDL-1 expressing R/M HNSCC patients.

Keywords: Immunotherapy, HNSCC, Cost-effectiveness

122

Risk of colorectal cancer and GLP-1 RAs in type 2 diabetes

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Introduction: Although glucagon-like peptide-1 receptor agonists (GLP-1 RAs) confer pleiotropic benefits, evidence regarding their association with colorectal cancer (CRC) risk, site-specific effects, and potential mechanisms remains limited and conflicting.

Aims: To assess 5-year incident CRC risk associated with GLP-1 RAs overall and by anatomical site, and explore potential mechanisms.

Methods: We conducted a retrospective cohort study embedded in target trial emulation framework using the TriNetX global dataset. The study included adults with type 2 diabetes and eGFR ≥30 mL/min/1.73 m2 who initiated GLP-1 RAs or dipeptidyl peptidase-4 inhibitors (DPP4i) between 2016 and 2025. We used the propensity score-matching to balance baseline covariates, including demographics, comorbidities, co-medications, laboratory data, colonoscopy history, and healthcare visits. The primary outcomes were 5-year risk of any CRC, right-sided colon cancer, left-sided colon cancer, and rectal cancer. We employed Cox proportional hazard models to generate hazard ratios (HRs) and 95% confidence intervals (95% CIs).

Results: After matching, 143,236 matched pairs were included in the analysis. The mean age was 59.40 years, 47.50% were male, and baseline characteristics were balanced between groups. GLP-1 RA use was associated with significantly lower risks of overall CRC (HR, 0.81; 95% CI, 0.73 to 0.90), right-sided CRC (HR, 0.73; 95% CI, 0.60 to 0.88) and left sided CRC (HR, 0.81; 95% CI, 0.70 to 0.94) compared with DPP4i. GLP-1 RA use was also associated with a nonsignificant trend toward a lower risk of rectal cancer (HR, 0.870; 95% CI, 0.720 to 1.050). Lower BMI levels among GLP-1 RA users suggest a potential role of improved weight control in the observed reduction in CRC risk [-3.50 (-9.47%) vs 1.15 (3.64%)].

Conclusions: Our finding suggests that GLP-1 RA initiation is associated with a lower risk of CRC across anatomical sites, evidenced by improvements in weight control.

Keywords: GLP-1 RA, cancer, diabetes

123

Consumption and expenditure on lower ESMO-MCBS oncology medicines: a global drug-utilisation analysis

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Introduction: Novel oncology medicines often enter the market at high prices despite uncertain clinical benefit, raising concerns about patient management and health-system sustainability. Evidence remains limited on how much real-world consumption and expenditure is accounted for by medicines without European Society for Medical Oncology Magnitude of Clinical Benefit Scale scores (ESMO-MCBS) defined substantial clinical benefit (SCB) across countries.

Aims: We quantified early post-approval drug utilisation for novel oncology medicines and related association with clinical-benefit status.

Methods: We conducted a multinational drug-utilisation study of 53 oncology medicines approved by the FDA or EMA during 2015–2022. Clinical benefit was classified using updated ESMO-MCBS. Using IQVIA MIDAS, a commercial pharmaceutical sales database, we measured two-year post-approval consumption in standard units (SU) and expenditure across 71 countries or regions. In the US and Europe, we used two-part models to assess access, defined as any observed consumption within two years, and uptake, defined as consumption intensity among medicines with observed consumption.

Results: Overall, 37 medicines (69.8%) did not demonstrate substantial clinical benefit (SCB) by ESMO-MCBS. In the US, these medicines accounted for 483.3 SU and US$212,689.4 per 10,000 population, representing 61.0% of consumption and 73.8% of expenditure. Across 27 European countries, corresponding median values were 127.9 SU (interquartile range: 37.6–360.9) and US$11,762.6 (2,280.8–33,649.7), representing 63.0% (48.7–69.8) of consumption and 51.5% (45.2–60.2) of expenditure. Medicines without SCB were associated with lower access (odds ratio 0.59 [95% confidence interval 0.41–0.86]; p=0.006), and lower uptake (consumption ratio 0.42 [0.30–0.58]; p<0.001), corresponding to 58% lower mean uptake.

Conclusions: Across countries, many novel oncology medicines without ESMO-MCBS defined SCB accounted for substantial consumption and expenditure despite lower uptake than drugs with SCB.

Keywords: Oncology medicines, Health technology assessment, Drug utilisation

124

Geographic variation of ADHD medicine use in Australian adults, 2019-2024

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Introduction: Pharmacotherapy of attention-deficit hyperactivity disorder (ADHD) in adults has increased internationally. The global prevalence of persistent adult ADHD is estimated to be 2.6% (95% CI 1.5-4.5). While unexplained geographic variation in paediatric ADHD treatment rates has been reported in Australia, this has not been investigated in adults.

Aims: Describe ADHD medicine use among adults at the person level, stratified by geographic area.

Methods: We accessed linked Pharmaceutical Benefit Scheme (PBS) and demographic data via the Person Level Integrated Data Asset (PLIDA) using the Australian Bureau of Statistics (ABS) DataLab for all Australian residents during the years July 2019-June 2020 and July 2023-June 2024. We quantified annual prevalence of ADHD medicine dispensing by Statistical Area, Level 3 (SA3) of residence, calculating age-standardised rates for people aged 20-44 years using ABS estimated residential population counts as denominators.

Results: Among people aged 20-44 years, the overall national prevalence increased from 0.7% in 2019-20 to 2.4% in 2023-24. In 2023-24, treatment prevalence varied markedly by location, ranging from 5.8% for people aged 20-44 years in Fremantle (Western Australia) to 0.5% in Fairfield (New South Wales). Small-area mapping shows striking variation by: State, with 13 of the top 20 SA3 in Western Australia; rurality, with typically higher rates in major cities and across the eastern seaboard; and socioeconomic status (SES), with large disparities within major cities e.g. 10-fold difference between SA3s within inner and south-west Sydney.

Conclusions: Treatment rates in some areas exceeded the estimated international prevalence of ADHD in adults, suggesting either unexpected geographic variation in disease prevalence or overdiagnosis. Low rates in other areas, particularly remote regions and areas of low SES, suggest financial and health system barriers may be preventing people from accessing the care they need.

Keywords: Attention-deficit hyperactivity disorder, psychostimulants, drug utilisation, clinical variation, health equity, record linkage

125

Association Between Methylphenidate Treatment and Psychiatric Hospitalization by Psychiatric Burden in ADHD

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Introduction: Previous studies have reported that treatment is associated with favorable clinical outcomes among individuals with attention-deficit/hyperactivity disorder (ADHD), including reduced psychiatric hospitalization. However, individuals often present with varying degrees of pre-treatment psychiatric burden, and whether this influences treatment benefit remains unclear.

Aims: To evaluate the association between ADHD stimulant treatment and psychiatric hospitalization across levels of pre-treatment psychiatric burden.

Methods: Using the Korean nationwide health insurance database, individuals aged 6–64 years with a new ADHD diagnosis between January 2013 and April 2023 were identified. A target trial emulation framework was applied, defining the initiation arm as those who commenced methylphenidate within three months of diagnosis. The cloning-censoring-weighting method was used to address confounding, with treatment effects estimated using weighted pooled logistic regression. The primary outcome was psychiatric hospitalization within two years after ADHD diagnosis (time zero). Pre-treatment psychiatric burden was assessed across four domains including psychiatric comorbidities, psychotropic medication use, health care utilization, and prolonged mental health service use. Burden was classified as high if two or more domains were present, and low otherwise, with analyses stratified accordingly.

Results: A total of 436,702 individuals with ADHD were included (159,324 females [36.5%]; mean age, 17.4 years [SD, 11.7]). Of these, 302,100 (69.2%) were assigned to the initiation arm. Methylphenidate initiation was associated with a lower risk of psychiatric hospitalization (adjusted incidence rate ratio [aIRR], 0.72; 95% CI, 0.69–0.77). The association varied according to pre-treatment psychiatric burden (Pinteraction <0.01), with aIRRs of 0.73 (95% CI, 0.64–0.80) among individuals with low burden and 0.68 (95% CI, 0.64–0.73) among those with high burden.

Conclusions: Methylphenidate initiation was associated with a lower risk of psychiatric hospitalization, with treatment benefit differing by the pre-treatment psychiatric burden. Further investigation into specific burden components is warranted.

Keywords: Methylphenidate; Psychiatric Hospitalization; Treatment Effect Heterogeneity

126

Methylphenidate–Antiseizure Drug-Drug Interactions Associated with Movement Disorders: Disproportionality Analysis Considering Concomitant Medication

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Introduction: Attention-deficit/hyperactivity disorder (ADHD) is a frequent comorbidity of epilepsy, and patients with both may receive concomitant methylphenidate (MPH) and antiseizure medications (ASMs). Although both MPH and ASMs have been independently associated with movement disorders (MDs), evidence on potential drug-drug interactions affecting MD risk remains limited.

Aims: To identify MPH-ASM drug-drug interaction (DDI) signals for MDs and assess age patterns and robustness to concomitant medications.

Methods: This disproportionality study used nervous-system individual case safety reports from VigiBase (2015-2025). Reports co-reporting MPH and ASM with movement-disorder Preferred Terms under five MedDRA High Level Terms (choreiform movements, dyskinesias and movement disorders, dystonias, Parkinson's disease and parkinsonism, and tremor) were identified. For each MPH-ASM pair with at least 5 co-reported MD cases, the Omega shrinkage (Ω) measure tested whether co-reporting exceeded each drug's individual expectation (Ω0.025>0). Interaction signals were also assessed in a pediatric subgroup (<18 years). Because antipsychotics independently cause MDs and are commonly co-prescribed, a sensitivity analysis excluded antipsychotic-exposed reports.

Results: Among 5,116,183 nervous-system reports, 9,093 involved MPH-ASM co-exposure, of which 486 reported movement disorders. Thirteen MPH-ASM pairs met the ≥5-case threshold, of which five reached the signal criterion: oxcarbazepine (n=38, Ω0.025=0.555), phenobarbital (n=7, 0.359), carbamazepine (n=26, 0.294), valproate (n=109, 0.222), and lamotrigine (n=105, 0.075). In the pediatric subgroup, only the MPH-valproate signal remained (n=43, Ω0.025=1.393). In the sensitivity analysis excluding antipsychotics, all signals disappeared, suggesting that the observed signals may be attributable to antipsychotic co-medication rather than direct MPH-ASM interactions.

Conclusions: This disproportionality analysis detected movement-disorder signals for several MPH-ASM combinations, most notably MPH-valproate in pediatric reports. However, these signals were not robust to co-reported antipsychotics. These hypothesis-generating findings require confirmation in pharmacoepidemiologic studies that can account for concomitant medications.

Keywords: drug-drug interaction; attention-deficit/hyperactivity disorder; antiseizure medication

127

Benzodiazepines versus Z-drugs and adverse outcomes among adolescents and young adults

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Introduction: Benzodiazepines (BZDs) and Z-drugs are increasingly prescribed to adolescents and young adults (AYAs) in Hong Kong, despite limited guidance. Given the burden of sleep disturbance during this developmental period, comparative safety data are needed.

Aim: To compare adverse clinical outcomes after initiation of BZDs versus Z-drugs among AYAs.

Methods: Electronic health records from all public hospitals in Hong Kong were used to emulate a target trial with an active-comparator, new-user design. Individuals aged 12–25 years who initiated a BZD or Z-drug in 2009-2023 were followed from the index date until censoring (drug switch, discontinuation, epilepsy diagnosis). Outcomes were self-harm, overdose, substance use disorder (SUD), and long-term drug use, defined as continuous prescribing for ≥180 days. Individuals with a history of the outcome were excluded from the corresponding analysis. We applied inverse probability-of-censoring weights using baseline characteristics (age, sex, baseline psychiatric diagnosis) and time-varying covariates (diagnosis of depression/anxiety/psychosis and use of other psychotropics). Pooled logistic regression was used to estimate absolute risks and risk ratios (RRs) at 6 months, with 95% confidence intervals. Subgroup analysis was conducted by sex.

Results: Among 25,979 eligible AYAs, analyses included 23,940 for self-harm, 25,215 for SUD, 24,582 for overdose, and 25,819 for long-term drug use. Median follow-up was 5 and 4 months for BZD and Z-drug users. Compared with Z-drugs, BZD use was associated with higher risks of self-harm (RR 1.20, 1.02–1.49), overdose (1.52, 1.22–1.99), and long-term drug use (1.24, 1.08–1.42), but not SUD (1.04, 0.81–1.39). Similar associations were observed among females; among males, BZD use was associated only with higher long-term drug use risk (1.29, 1.05-1.59).

Conclusion: When pharmacological treatment is needed, Z-drugs may have a comparatively safer profile than BZDs in AYAs. Careful risk assessment is warranted, particularly when prescribing BZDs to females.

Keywords: Comparative safety, benzodiazepines and Z-drugs, young people

128

Sleep-related prescribing cascades following ADHD medications in Korean adults

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Introduction: Adult attention-deficit/hyperactivity disorder (ADHD) pharmacotherapy has expanded rapidly with growing recognition of ADHD beyond childhood. These medications are associated with adverse effects including insomnia that may trigger prescribing cascades. While cascades have been studied in elderly populations, evidence among the growing adult ADHD population remains limited.

Aims: To detect prescribing cascade signals following ADHD medication initiation among adults across multiple adverse effect domains using nationwide claims data.

Methods: A prescription sequence symmetry analysis was conducted using the Korean Health Insurance Review and Assessment Service database, covering approximately 98% of the national population (January 2015 to August 2024). Adult (aged 19 years and older) patients diagnosed with ADHD who initiated methylphenidate, atomoxetine, or clonidine were identified as incident users using a 365-day prescription-free washout period. New prescriptions of five marker drug groups were assessed within a 365-day symmetric interval: sedative-hypnotics, prokinetics, proton pump inhibitors, selective serotonin reuptake inhibitors, and second-generation antipsychotics, with an antibiotic (amoxicillin/clavulanate) as negative control. Adjusted sequence ratios and 95% confidence intervals were calculated using null-effect sequence ratios, with signals identified when the lower confidence limit exceeded 1.0.

Results: Among 257,276 adult incident ADHD medication users, annual use increased from 8,064 in 2015 to 54,858 in 2023. A prescribing cascade signal was detected for atomoxetine followed by sedative-hypnotics (adjusted sequence ratio 1.49; 95% confidence interval 1.41 to 1.57). No signals were detected for methylphenidate or clonidine followed by sedative-hypnotics. No signals were observed for the remaining marker drug groups with any index drug. The negative control demonstrated no sequence asymmetry, supporting analytical validity.

Conclusions: A sleep-related prescribing cascade signal was identified specifically for atomoxetine among Korean adults, while no signals were detected for methylphenidate or clonidine. As adult ADHD pharmacotherapy continues to expand, targeted monitoring for atomoxetine-related sleep disturbances and subsequent prescribing cascades is warranted.

129

Ethnic and socioeconomic differences in ADHD diagnosis and treatment in United Kingdom

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Introduction: Ethnic and socioeconomic differences in ADHD diagnosis and treatment remain poorly characterised, despite substantial increases in diagnosis and medication prescribing in England.

Aims: To describe ethnic and socio-economic patterns in recorded ADHD diagnosis, medication initiation and discontinuation in English primary care (2008-2025).

Methods: Using IQVIA Medical Research Data (IMRD), we conducted a retrospective cohort study of individuals aged 3–99 years. Separate cohorts were constructed for diagnosis, initiation and discontinuation. Diagnosis analyses excluded prior recorded ADHD diagnosis, initiation analyses excluded prior ADHD medication use. Discontinuation was assessed among incident medication initiators and confirmed following ≥180 days without subsequent medication coverage. Poisson regression, adjusted for age, sex and calendar year, estimated adjusted incidence rate ratios (aIRRs) across ethnicity and Index of Multiple Deprivation (IMD) quintiles. Age- and sex-standardised annual rates were estimated using direct standardisation. Time to discontinuation was analysed using Cox regression.

Results: The diagnosis, initiation and discontinuation cohorts included 3,832,111, 3,840,470 and 8,833 individuals, respectively. Of the 8,833 individuals in the discontinuation cohort, 7,630 contributed to the primary analysis. Adjusted diagnosis and initiation rates were lower in every ethnic group than in White British patients. The largest differences were observed in South Asian (aIRR 0.20, 95% CI 0.17–0.24), East Asian (0.26, 0.21–0.31) and Black African patients (0.29, 0.26–0.33). Medication initiation followed a similar pattern, with aIRRs of 0.16 (0.13–0.20), 0.27 (0.20–0.36) and 0.21 (0.18–0.24), respectively. Adjusted diagnosis and initiation rates were similar across IMD quintiles overall, although recent increases in initiation were greater in less deprived groups, suggesting widening socioeconomic differences. Discontinuation showed no clear socioeconomic differences, while ethnic estimates were imprecise.

Conclusions: Marked ethnic differences persisted in recorded ADHD diagnosis and medication initiation despite recent increases in rates. Further research is needed to understand the underlying drivers of these differences.

Keywords: ADHD, ethnicity, socioeconomic deprivation, primary care

130

Risk of maternal infection and adverse birth outcomes following acid-suppressive medications use

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Introduction: Acid-suppressive medications (ASMs) may increase the risk of infections, which could contribute to adverse birth outcomes. However, evidence in pregnancy remains limited, particularly regarding differences between ASM classes and duration–response relationships.

Aims: To investigate whether early-pregnancy ASM (i.e., PPIs, H2RAs, or PCAB) use is associated with maternal infection and adverse pregnancy outcomes

Methods: We conducted a population-based cohort study using the Korean healthcare database, including all pregnancies reaching ≥20 weeks' gestation (2019–2024). Exposure was defined as ASM use with days' supply overlapping early pregnancy (last menstrual period (LMP) to LMP+140 days). Outcomes were (1) maternal infections (any and serious infections; LMP+141 days until delivery) and (2) adverse birth outcomes (preterm birth and stillbirth). Adjusted relative risks (aRRs) and 95% confidence intervals (CIs) were estimated using log-binomial regression with propensity score fine-stratification weighting. We further conducted subgroup analyses by mediation classes and cumulative ASM use (<14, 14–27, ≥28 days).

Results: Of 898,409 pregnancies, 134,722 (15.0%) were exposed to ASM. ASM use was associated with an increased risk of maternal infections (any infection: aRR 1.17, 95% CI 1.16–1.19; serious infection: 1.34, 1.29–1.40), whereas no increased risk was observed for adverse birth outcomes overall (preterm birth: 0.99, 0.97–1.01; stillbirth: 1.03, 0.95–1.12). These findings were generally consistent across medication classes; notably, a higher risk of serious infection was observed among H2RA users (1.33, 1.27–1.40). However, in the duration–response analysis, ASM use of ≥28 days was associated with significantly increased risks of both preterm birth and stillbirth (1.18, 1.11–1.25 and 1.42, 1.11–1.81, respectively).

Conclusions: ASM use was associated with maternal infection risk and showed a potential duration–response relationship with adverse birth outcomes. These findings highlight the need for careful clinical consideration when prescribing ASMs during pregnancy.

Keywords: acid-suppressive medications, infection, adverse birth outcomes

131

Paternal Valproate Exposure and Neurodevelopmental Disorders in Children

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Introduction: In 2024, the EMA endorsed precautionary measures for valproate use in male patients, citing a potential increased risk of neurodevelopmental disorders (NDDs) in children born to treated fathers during spermatogenesis. However, accumulating evidence — predominantly from European populations — has found no significant association, warranting further corroboration.

Aims: To investigate whether paternal valproate exposure during spermatogenesis is associated with an increased risk of NDDs in children.

Methods: We conducted a cohort study using a nationwide mother-father-child linked dataset (Big-CHENS) of live births in South Korea (2015–2021). Exposure was defined as valproate monotherapy during spermatogenesis, the 90-day period prior to conception. The outcome was any NDD diagnosis, encompassing autism spectrum disorder, ADHD, learning disability, speech/language disorder, intellectual disability, developmental coordination disorder, and behavioral disorder. Three comparator groups were examined: valproate-unexposed fathers from the general population, valproate-unexposed fathers with epilepsy, and an active comparator group (levetiracetam/lamotrigine) with epilepsy. Propensity score-based inverse probability of treatment weighting was applied, and hazard ratios (HRs) with 95% confidence intervals (CIs) were estimated using weighted Cox regression.

Results: Among 1,835,598 father-child pairs, 10,128 children were exposed to paternal valproate, with 130 NDD events observed (crude HR 1.62, 95% CI 1.35–1.93). After restriction to fathers with epilepsy and granular adjustment of confounders including indication-related factors, no increased risk was observed for valproate-exposed (n=744) versus unexposed (n=3,442) (HR 1.02, 95% CI 0.73–1.42). Results were similarly null against the active comparator (557 vs. 559; HR 1.07, 95% CI 0.74–1.53), and consistent when allowing combination therapy.

Conclusions: Paternal valproate exposure during spermatogenesis was not associated with an increased risk of NDDs in children. The crude excess risk disappeared in both indication-restriction and active-comparator analyses, indicating confounding by indication. Consistent with the growing body of evidence, these findings may support reconsideration of current regulatory precautions.

Keywords: Valproate, Neurodevelopmental Disorders, Paternal Exposure

132

Prenatal paracetamol use and risks of ASD and ADHD among sibling-matched cohorts

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Introduction: Paracetamol is the first-line analgesic globally during pregnancy. Observational studies have reported associations between prenatal paracetamol exposure and increased risks of autism spectrum disorder (ASD) and attention-deficit/hyperactivity disorder (ADHD) in offspring, raising concern. However, these findings may be confounded by unmeasured familial factors.

Aims: To assess the association between prenatal paracetamol exposure and risks of ASD and ADHD in offspring using a sibling-matched study design to control for familial confounding.

Methods: This population-based cohort study (2001-2023, Hong Kong) used deidentified electronic health records within a triangulation framework. From 708,020 mother-child pairs (43.3% exposed), sibling-matched cohorts were constructed of children from families with discordant prenatal paracetamol exposure and sufficient follow-up (≥2 years for ASD and ≥5 years for ADHD). Exposure was identified from electronic dispensing records. Outcomes were incident diagnoses of ASD (ICD-9-CM 299) or ADHD (ICD-9-CM 314), or a prescription for ADHD-specific medication.

Results: The final cohorts comprised 124,333 children for ASD analysis (mean age 9.3 years; 50.3% male) and 97,285 for ADHD analysis (mean age 7.6 years; 50.2% male). In sibling-matched analyses, prenatal paracetamol exposure was not associated with the risk of ASD (aHR, 1.00; 95% CI, 0.91-1.11) or ADHD (aHR, 1.01; 95% CI, 0.93-1.08). Null associations were consistent across exposure timing, cumulative dose, and usage patterns. However, positive associations were observed in conventional cohort analyses, and importantly, also in negative control analyses of prepregnancy exposure for ASD (HR, 1.12; 95% CI, 1.08-1.17) and ADHD (HR, 1.24; 95% CI, 1.20-1.28).

Conclusions: This sibling-matched analysis found no evidence of an association between prenatal paracetamol exposure and the risk of ASD or ADHD in offspring. The positive signals observed in conventional studies are likely attributable to residual familial confounding.

These findings provide important reassurance regarding the safety of indicated paracetamol use during pregnancy.

Keywords: Prenatal paracetamol exposure; Autism; Sibling-matched design

133

Maternal opioid prescriptions and subsequent risk of hospital admission in offspring

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Introduction: Prenatal opioid exposure may affect child health, yet evidence on its long-term impact on hospital admissions remains limited by unmeasured confounding, small samples, and short follow-up periods.

Aims: We aimed to investigate the association between prenatal opioid exposure and the risk of hospital admission in children.

Methods: A population-based birth cohort in South Korea was established by linking mothers and children using National Health Insurance Service data (January 2009–December 2023). Propensity score (PS)-matched and sibling comparison cohorts were constructed, and dose-dependent and time-attenuation analyses were performed. All 5,249,439 individuals with eligible children born between 2010 and 2017 were included (2,236,167 mothers and 3,013,262 children), with follow-up of up to 14 years. Prenatal opioid exposure was defined as two or more maternal prescriptions within any trimester to exclude single-use prescriptions. Analyses were also stratified by opioid type. The primary outcome was adjusted incidence rate ratio (aIRR) of hospital admissions, including infections, non-infectious respiratory, gastrointestinal, oral cavity, genitourinary conditions, and injuries/external causes.

Results: Of 2,928,186 pregnancies, 2,809,515 and 118,671 infants were unexposed and exposed to prenatal opioids, respectively. Hospital admission rates in exposed children were 29% higher in the PS-matched cohort (aIRR, 1.29 [95% CI, 1.29–1.30]). The association was attenuated in the sibling comparison cohort, indicating potential shared familial influences, but remained significant (aIRR, 1.08 [95% CI, 1.07–1.09]). A dose-dependent relationship was observed (low-dose: aIRR, 1.19 [95% CI, 1.18–1.19]; high-dose: aIRR, 1.39 [95% CI, 1.39–1.40]). Significantly elevated rates were observed across all examined morbidity categories. These effects diminished with age but remained evident up to five years of age.

Conclusions: In this nationwide birth cohort study, maternal opioid prescription during pregnancy was significantly associated with increased risk of hospital admissions in the offspring across various causes of morbidities, with a dose-dependent pattern.

Keywords: maternal opioid prescriptions, prenatal opioid exposure, hospital admissions

134

Ezetimibe exposure during early pregnancy and the risk of spontaneous abortion

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Introduction: Dyslipidemia is increasingly common among women of reproductive age, yet lipid-lowering options become limited once pregnancy is recognized. Ezetimibe lowers cholesterol through intestinal absorption rather than endogenous cholesterol synthesis, suggesting a fetal risk profile that may differ from statins. However, evidence regarding ezetimibe exposure during early pregnancy remains scarce.

Aims: To evaluate the association between ezetimibe exposure during early pregnancy and spontaneous abortion (SAB) among women with dyslipidemia.

Methods: We conducted a nationwide cohort study using the Korean National Health Information database (2013–2023). Women aged 15–49 years with diagnosis of dyslipidemia and prior use of ezetimibe or statin within 180 days before the estimated last menstrual period (LMP) were included. Ezetimibe exposure was defined as a prescription overlapping the period from LMP through gestational week 6. The outcome was SAB between 7 and 20 gestational weeks. Risk ratios (RRs) were estimated using log-binomial regression weighted by propensity score overlap weights for maternal and clinical covariates and inverse probability of censoring weights for induced abortion. Given common statin co-prescribing, sensitivity analysis compared concurrent ezetimibe-statin exposure with statin exposure alone using the same window as ezetimibe exposure.

Results: Among 19,021 pregnancies with prior dyslipidemia, 2,121 (11.2%) were ezetimibe-exposed and 16,900 (88.8%) were unexposed, mean age 36.4 vs. 35.5 years. Concomitant statin use during the exposure assessment period was 98.1% in ezetimibe-exposed and 37.3% in unexposed. Ezetimibe exposure was not associated with increased SAB risk (crude RR 0.93 [95% CI 0.90–0.96], weighted RR 0.92 [95% CI 0.87–0.99]). Results were consistent in sensitivity analysis (weighted RR 0.92 [0.85–1.00]).

Conclusions: Ezetimibe exposure early in pregnancy was not associated with increased risk of SAB in women with dyslipidemia. These findings provide population-based evidence on the safety of early-pregnancy ezetimibe exposure, although further studies are needed to confirm these results.

Keywords: ezetimibe, spontaneous abortion, perinatal pharmacoepidemiology

135

Benzodiazepine exposure during early pregnancy and risk of miscarriage

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Introduction: Benzodiazepines may increase the risk of miscarriage owing to their potential effects on fetal development. Most previous studies have assessed benzodiazepines as a drug class, with limited evidence regarding their dose, half-life categories, or individual agents. In addition, benzodiazepine use patterns vary by region.

Purpose: To evaluate the association between benzodiazepine exposure during early pregnancy and the risk of miscarriage, with a focus on dose-response, half-life, and individual agents.

Methods: This nested case-control study was conducted using a large Japanese administrative database. Cases were defined as pregnancies ending in miscarriage between 2005 and 2023. Controls were randomly selected through risk-set sampling with replacement and matched in a 3:1 ratio. Conditional logistic regression, adjusted for confounders, was used to assess the associations.

Results: Overall, 44,118 cases were matched with 132,317 controls, with a mean age of 33.2 years. The prevalence of benzodiazepine exposure was 1.7% and 1.2% among cases and controls, respectively. Etizolam (0.3%) had the highest prevalence, followed by alprazolam (0.3%) and brotizolam (0.2%) in both groups. Adjusted odds ratio (OR) for benzodiazepine exposure during early pregnancy was 1.241 (95% confidence interval: 1.136–1.357). Adjusted ORs for high-dose (1.212 [1.050–1.400]) and medium-dose (1.189 [1.037–1.363]) exposure were numerically higher than that for low-dose exposure (1.111 [0.934–1.322]). Adjusted OR for long-acting benzodiazepines (1.308 [1.124–1.522]) was numerically higher than those for intermediate- (1.132 [0.999–1.284]) and short-acting (1.157 [1.030–1.300]) agents. Adjusted ORs for etizolam, alprazolam, and brotizolam were 0.929 (0.782–1.103), 0.853 (0.707–1.030), and 1.454 (1.180–1.791), respectively.

Conclusions: Benzodiazepine exposure during early pregnancy was modestly associated with an increased risk of miscarriage. Although associations tended to be stronger with higher

dose levels and longer half-life categories, estimates across subgroups lacked precision and should be interpreted with caution.

Keywords: anxiety; benzodiazepine; miscarriage

200

Impact of opioid stewardship on postoperative opioid prescribing patterns: interrupted time-series analysis

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Introduction: Opioid analgesic stewardship aims to optimise postoperative opioid prescribing and promote safer opioid use. The impact of the 2022 Australian Opioid Analgesic Stewardship in Acute Pain Clinical Care Standard on surgical opioid prescribing remains unclear. This study evaluated temporal changes in opioid prescribing patterns following stewardship implementation.

Methods: We conducted a retrospective interrupted time-series analysis of surgical patients (2016–2024). Quarterly changes in opioid recipient rates, modified-release opioid prescribing, and oral morphine equivalent (OME) per opioid recipient were assessed before, during, and after stewardship implementation. Models evaluated immediate and sustained changes, adjusted for the COVID-19 period, with subgroup analyses by surgical specialty.

Results: Opioid recipient rates were already declining before stewardship implementation (2.1% reduction per quarter; IRR 0.98, 95% CI 0.97–0.99, $p<0.001$), with no additional significant post-implementation change. Modified-release opioid prescribing demonstrated a sustained post-implementation decline of 3.3% per quarter (IRR 0.97, 95% CI 0.95–0.98, $p<0.001$). OME per opioid recipient decreased during the implementation period (−21.7 OME/quarter; 95% CI −39.1 to −4.2) with an immediate reduction following full implementation (−44.3 OME; 95% CI −81.5 to −7.1), although no further sustained decline was observed.

Conclusion: Opioid stewardship was associated with improved prescribing quality, particularly sustained reductions in modified-release opioid use, rather than universal reductions in opioid exposure. The impact of opioid stewardship varied across surgical specialties, highlighting the importance of procedure-specific evaluation to account for differences in postoperative pain severity and analgesic requirements.

201

Trends in pregabalin use and concurrent opioid and health service utilisation

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Introduction: Pregabalin is commonly used for neuropathic pain; however, its widespread use has been linked to adverse events, dependency, and misuse. Multidisciplinary health services play a crucial role in pain management and may reduce reliance on pharmacotherapy, yet recent trends in pregabalin use in the context of these services remain poorly characterised.

Aims: To investigate longitudinal trends in pregabalin use in Australia, and examine concurrent utilisation of opioids and pain-related health services among pregabalin users.

Methods: This nationwide repeated cross-sectional study (2020-2025) utilised linked Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Schedule (MBS) data. Adults aged ≥18 years with at least one annual PBS or MBS claim were included. Annual prevalence of pregabalin use was calculated. Among users, trends in opioid and health service utilisation were examined, stratified by age, sex, socioeconomic status, remoteness, and region of birth.

Results: An average of 18,880,825 Australians were included annually. Pregabalin prevalence remained stable from 2020 (n= 603,088; 3.3%) to 2025 (n= 607,611; 3.2%), with highest use observed in adults ≥81 years (8.2%). Among users, concurrent opioid use decreased from 59% in 2020 to 53% in 2025. Median annual defined daily dose (DDD) of pregabalin declined from 51 (IQR: 14-168) to 42 (IQR: 14-159). Health service utilisation remained stable, with physical allied health services most commonly used (19%). Notably, demographic groups with higher health service utilisation (females, residents of major cities, Asian-born individuals) were dispensed lower median annual DDDs of both pregabalin and oral morphine equivalents.

Conclusions: While overall pregabalin prevalence remained stable, concurrent opioid use and dosages declined. Higher engagement with allied health services was associated with lower pharmacotherapy burden, suggesting a potential role for multidisciplinary care in optimising pain management. Furthermore, complex cultural and access-related factors likely play a critical role in shaping these prescribing patterns.

Keywords: Pregabalin, Health service, Pain

202

Do comprehensive medication reviews impact concurrent gabapentin-opioid use in Medicare beneficiaries?

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Introduction: Gabapentin is increasingly used as an alternative to opioids. However, concurrent gabapentin-opioids use remains common despite FDA warnings regarding potential safety risks, highlighting the need for interventions to reduce potentially inappropriate co-prescribing.

Aims: To evaluate whether concurrent gabapentin-opioids prescribing patterns change following receipt of a comprehensive medication review (CMR) among Medicare beneficiaries enrolled in the Medication Therapy Management (MTM) program.

Methods: We conducted a retrospective cohort study of Medicare beneficiaries enrolled in the MTM program who initiated gabapentin while concurrently using opioids. Beneficiaries who received a CMR after gabapentin initiation were classified as CMR-exposed, with the CMR date defined as the index. Using exposure density sampling, beneficiaries who did not receive a CMR were matched 1:2 on days from cohort entry to index and classified as CMR-unexposed. Both groups were required to be concurrent gabapentin-opioid users at index, allowing a 7-day grace period between prescription fills. Outcomes included discontinuation of concurrent gabapentin-opioid use (defined as ≥30 days without overlap) and naloxone prescribing during the 6 month or one year follow up.

Results: Among eligible beneficiaries, 781 CMR-exposed (mean [SD] age: 76.8 [6.3]; 65.9% female) and 1,562 CMR-unexposed (77.1 [6.6]; 63.3%) concurrent gabapentin-opioid users were identified. During 6 months of follow-up, 62.9% of CMR-exposed and 58.2% of CMR-unexposed beneficiaries discontinued concurrent gabapentin-opioid use. During 12-month follow up, 72.5% of CMR-exposed and 67.0% of CMR-unexposed beneficiaries discontinued concurrent gabapentin-opioid use. Naloxone prescribing was higher in the CMR-exposed (2.6%) than the CMR-unexposed beneficiaries (0.8%).

Conclusions: Beneficiaries who received a CMR were more likely to discontinue concurrent gabapentin-opioid use and receive naloxone than those who did not. CMRs may represent an opportunity to improve medication safety among concurrent users, although further research is needed to evaluate the impact on gabapentin-opioid prescribing.

Keywords: gabapentin, opioid, comprehensive medication review

203

Segmented Trends in Pharmaceutical and Illicit Opioid Poisonings in Victorian EDs

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Introduction: In response to rising opioid-related harms, Australia has implemented several policies to reduce opioid prescribing. However, existing surveillance often aggregates opioid poisonings, limiting assessment of trends by opioid type and potential shifts between pharmaceutical and illicit opioids.

Aims: To leverage structure and unstructured data to examine and compare temporal trends in opioid poisoning presentations to emergency departments and identify and quantify significant structural changes over time.

Methods: We analysed ED presentations recorded in the Victorian Emergency Minimum Dataset (VEMD), managed by the Victorian Injury Surveillance Unit (VISU) between July 2009 and June 2024. Opioid poisoning presentations were identified and classified by opioid type using a rule-based algorithm that combined ICD-10 diagnostic codes and free-text clinical descriptions. Age-standardised presentation rates for heroin-, codeine-, oxycodone-, and other controlled opioid-related poisonings were modelled using sex-stratified generalised additive models, and first-derivative analyses were used to identify periods of statistically significant change.

Results: A total of 15,678 opioid poisoning presentations were identified, of which 7,049 (45.0%) involved illicit opioids. Heroin-related presentations among females remained stable throughout the study period. In contrast, heroin-related poisoning among males declined significantly between February and December 2020 (monthly change: -0.50 per 100,000 population; 95% CI: -0.92 to -0.24), followed by a brief increase between August and October 2021 (0.50 per 100,000 per month; 95% CI: 0.01–0.70). Codeine-related poisoning presentations declined significantly between 2016 and 2018 among both males and females, with rates remaining stable thereafter. Oxycodone-related poisonings showed a brief increase during 2012 but remained otherwise stable over the 15-year period. No trend changes were observed for controlled prescription opioids.

Conclusions: Pharmaceutical and illicit opioid poisonings showed different temporal patterns over the study period. Enhanced surveillance using both coded and free-text clinical information provides a more comprehensive understanding of opioid-related harms and can support more targeted public health responses.

204

Association between ambient temperature, hip-fracture, and sedative medication use: A case-crossover analysis

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Introduction: Cold weather and sedative use are both risk factors for hip fracture in older adults. However, potential interactions between them have not been investigated.

Aims: To investigate whether sedative medication use modifies associations between ambient temperature and hip fracture risk.

Methods: We conducted a time-stratified case-crossover study of people aged ≥50 years hospitalised for first hip fracture in Victoria, Australia, between 2013/07/01-2018/06/30. Gridded daily meteorological data from Scientific Information for Land Owners (SILO) were linked to residential postcodes to capture mean ambient temperature exposure. Conditional logistic regression was used to estimate odds ratios (ORs) and 95% confidence intervals (CIs) for temperature percentile categories (≤1st, 2nd-5th, 6th-15th, 16th-25th, >75th) referenced against the 26th-75th percentile. Effect modification by sedative use (ATC:N05B/N05C) in 60 days before hospitalisation was assessed using an interaction term. ORs were adjusted for public holidays and healthcare utilisation in preceding six days. Subgroup analyses were conducted for age, sex, and hospital frailty risk score (HFRS).

Results: We identified 28,904 people hospitalized for hip fracture, of which 4,854 (16.8%) were dispensed a sedative prior to hospitalisation, 19,779 (68.4%) were female, 18,611 (64.39%) were aged ≥80 years, and 11,191 (38.7%) had HFRS > 5. In non-sedative users, temperature exposure was not significantly associated with hip fracture (≤1st: adjusted OR 1.09[CI 0.90–1.31]; 2nd-5th: 0.95[0.86–1.04]; 6th-15th: 1.01[0.94–1.08]; 16th-25th: 1.01[0.95–1.07]; >75th: 0.96[0.91–1.01]). Among sedative users, elevated odds of hip fracture were associated with lower temperatures (≤1st: 2.09[1.33–3.30]; 2nd-5th: 1.36[1.08–1.73]), but not higher temperatures (6th-15th: 1.16[0.98–1.36]; 16th-25th:1.02[0.87–1.19]; >75th: 0.94[0.84–1.06]). Within sedative users, lower temperatures were significant for both age and sex subgroups, and only significant for the higher HFRS subgroup.

Conclusions: Lower temperatures were associated with increased hip fracture risk in sedative users with higher frailty risk, suggesting increased vulnerability to environmental conditions in this population.

Keywords: Environmental pharmacoepidemiology, hip fracture, sedative

205

Concurrent opioid or gabapentinoid use with benzodiazepines or anti-depressants: adverse outcomes

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Introduction: Use of opioids and gabapentinoids is increasing, despite high risk of medication-related harms. Concurrent use with other central nervous system depressants, including benzodiazepines and anti-depressants, further increases the risk of medication-related harms and poor outcomes, especially for the older population.

Aims: To examine the prevalence of opioid or gabapentinoid use concurrently with benzodiazepines or anti-depressants in the older population and to quantify the risk of mortality or entry to a long-term care facility(LTCF).

Methods: A retrospective cohort study was conducted using the Registry of Senior Australians National Historical Cohort of all individuals aged ≥65 years between 2017-2020 receiving home care. Concurrent use of opioids or gabapentinoids with benzodiazepines or anti-depressants were compared to opioid or gabapentinoid use alone, using an intention-to-treat design. Individuals were followed from first dispensing of single or concurrent medication episode. Adjusted Cox regression models estimated HRs(95%CI) for mortality and adjusted subdistribution hazard ratios(aSHRs) for LTCF entry using Fine-Gray models.

Results: 121,333 individuals were included (median age 82years, 66% female and median 6 chronic conditions). Prevalence of opioid use alone was 30.9%, with 20.5% using a benzodiazepine and 37.1% anti-depressant concurrently. There was a higher risk of entry to a LTCF with concurrent benzodiazepine (6% increased risk: aSHR=1.06,95%CI 1.03-1.10) or anti-depressant (17%: aSHR=1.17,95%CI 1.14-1.21) use compared to opioids alone. Prevalence of gabapentinoid use alone was 7.8% and 7.3% had concurrent benzodiazepine and 16.4% concurrent anti-depressant use. Compared to gabapentinoids alone, there was 19% and 39% higher risk of LTCF entry with concurrent benzodiazepine (aSHR=1.19,95%CI 1.08-1.31) or anti-depressant (sHR=1.39,95%CI 1.26-1.52) use.

Conclusions: Concurrent use of opioids or gabapentinoids with benzodiazepines or anti-depressants are associated with increased risks of adverse outcomes in the older population. Medication reviews and targeted deprescribing of these commonly used medications are needed to mitigate medication-related harms.

Keywords: inappropriate co-prescribing, adverse outcomes, older population

206

Delphi consensus adapting international clinical standards for tuberculosis ADR management in Indonesia

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Introduction: Adverse drug reactions (ADRs) represent a significant challenge in tuberculosis (TB) treatment, affecting adherence and outcomes. International clinical standards for ADR management exist, yet their direct implementation in high-TB-prevalence countries is hindered by differences in healthcare system capacity, infrastructure, and policy. A high TB-burden country requires contextually adapted standards to guide clinical practice effectively.

Aims: This study aimed to adapt the International Clinical Standards for Adverse Effects Management in TB Treatment to a national healthcare context through structured expert consensus. The adapted standards were evaluated for their relevance and feasibility of implementation across healthcare tiers.

Methods: A modified Delphi survey was conducted from June to September 2025. Eighty-five TB-related experts from clinical, academic, and policymaking backgrounds with at least four years of TB management experience from both hospital and community health centers were invited to participate. Eight international standards comprising 62 statements were rated across two rounds for relevance and implementation feasibility, with consensus defined as ≥70% agreement and an interquartile range of ≤1.

Results: Fifty-nine experts completed the survey. In the first round, 32 of 62 items (51.6%) reached consensus (IQR<1.00), covering counseling, core psychological and pharmacological management, ADR resumption protocols, and health worker training and reporting. Twenty-seven items (43.5%) required revision, primarily those concerning laboratory monitoring, referral coordination, and cross-level feasibility, while three items (4.8%) were excluded (IQR>1.00). After second-round revisions, 64 of 71 items (90.1%) reached consensus (IQR<1.00). The finalized framework comprises eight clinical standards mapped across community-based care and hospital settings within a tiered healthcare system.

Conclusions: International ADR management standards were successfully adapted to a national healthcare context through rigorous expert consensus. The resulting framework is contextually relevant and implementable across healthcare tiers, providing a practical foundation for strengthening pharmacovigilance and improving TB treatment outcomes nationwide.

Keywords: Adverse drug reactions, Delphi method, tuberculosis

207

Risk factors for extended carbapenem-resistant Enterobacteriaceae colonisation: case-control study on healthcare database

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Introduction: Persistent colonisation of carbapenem-resistant Enterobacteriaceae (CRE), which are resistant to most antibiotic classes and to carbapenems, may increase the risk of untreatable infections.

Aims: To identify risk factors for extended CRE colonisation.

Methods: Setting: We collected data from the Hong Kong Hospital Authority (HA) electronic health records (EHRs). Patients aged >18, tested between 01/01/2017-30/06/2023 were included. CRE laboratory tests used genotypic (polymerase chain reaction) or phenotypic (antimicrobial susceptibility test) methods.
Design/Exposure: Patients with positive CRE tests were case; negative tests were controls. Repeated CRE colonisation detected during certain duration was categorized into short-term (0-3 months), prolonged (4-6 months), and persistent (6-12 months). Risk factors included healthcare resources utilisation, co-morbidities, medication exposure in the past year.
Statistical analysis: We matched each duration of case and controls in 1:3 ratio by a propensity score of CRE infection, adjusting sex, age, and CRE onset year-month. Conditional logistic regression was used to calculate the odds ratio (OR) at 95% confidence interval (CI). We conducted backward model selection by computing Akaike information criteria.

Results: Out of 441,426 episodes from 439,394 patients who received ≥1 CRE test, 4,638 episodes (1.05%) had ≥1 CRE positive result. They were further grouped into short-term (N=3,146, 0.71%), prolonged (N=750, 0.17%), persistent (N=742, 0.17%)
History of renal disease and number of antibiotic types prescribed in the past year were associated with elevated risk of CRE extended colonisation.
[Renal: Short-term OR 2.04 (95% CI 1.42-2.95); Prolonged 3.56(1.57-8.08); Persistent 5.45(2.24-13.29);
Number of antibiotic types: Short-term OR 1.18(1.16-1.2); Prolonged 1.22(1.18-1.26); Persistent 1.32 (1.25-1.39)].

Conclusions: Patients with renal disease and those prescribed multiple antibiotics in the past year are at heightened risk for persistent CRE colonization, likely due to increased susceptibility and slower clearance of infections.

Keywords: antimicrobial resistance, Carbapenem-resistant Enterobacteriaceae, hospital surveillance, antibiotics use, test-negative design

208

Uncovering real-world drivers of hepatitis C treatment failure in Pakistan

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Introduction: Direct-acting antivirals (DAAs) have transformed the management of chronic hepatitis C virus (HCV) infection, achieving high cure rates in routine clinical practice. However, a subset of patients infected with genotype 3 HCV continue to experience treatment failure. Identifying factors associated with non-response is essential for optimizing treatment strategies and supporting disease elimination efforts.

Aims: To identify real-world predictors of treatment failure among patients with genotype 3 HCV receiving DAA-based therapy. To evaluate the impact of demographic and clinical factors on sustained virological response.

Methods: A multicenter prospective cohort study was conducted among 2000 genotype 3 HCV-infected patients treated with sofosbuvir plus daclatasvir with or without ribavirin or sofosbuvir/velpatasvir with or without ribavirin. Clinical, demographic, and laboratory data were collected from patient records. Sustained virological response at 12 weeks post-treatment was assessed. Multivariable logistic regression was used to identify independent predictors of treatment failure.

Results: Overall sustained virological response was achieved in 95.5% of patients. Response rates at 12 weeks were comparable between sofosbuvir plus daclatasvir (94.4%) and sofosbuvir/velpatasvir (94.7%). Treatment failure was more common among older patients and those with cirrhosis. Age greater than 60 years was independently associated with treatment failure (OR 4.46; 95% CI 2.35–8.46; $p<0.001$). Cirrhosis was the strongest predictor of non-response (OR 53.91; 95% CI 26.49–109.60; $p<0.001$). Cirrhotic patients receiving sofosbuvir/velpatasvir plus ribavirin achieved higher response rates than those receiving sofosbuvir plus daclatasvir plus ribavirin (88% vs 83%). Both regimens were well tolerated; skin rash and oral ulcers occurred more frequently with sofosbuvir plus daclatasvir.

Conclusions: DAA-based therapy achieved high effectiveness among genotype 3 HCV patients. Advanced age and cirrhosis were the primary predictors of treatment failure. Early diagnosis and treatment before progression to advanced liver disease may improve treatment outcomes and support HCV elimination programs.

Keywords: Hepatitis C; Drug effectiveness; Pharmacoepidemiology; Safety Outcomes

209

Pharmacovigilance signals and regional burden of antibiotic-associated Clostridioides difficile infection

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Introduction: Despite the substantial global burden of Clostridioides difficile infection (CDI) and its close relationship with antibiotic exposure, evidence remains limited.

Aims: We aimed to characterize antibiotic-associated CDI by assessing drug- and age-specific signal patterns, and geographic and temporal variations.

Methods: This study used the United States Food and Drug Administration Adverse Event Reporting System (FAERS) to evaluate antibiotic-associated CDI. Antibiotics were classified by pharmacological class, and CDI events were defined by the Medical Dictionary for Regulatory Activities. CDI event signals were identified using disproportionality analyses with the information component (IC) and reporting odds ratio (ROR), along with corresponding 95% confidence intervals (CIs). We also assess the WHO-regional burden of CDI between 1990 and 2023, using data from the Global Burden of Disease Study 2023. Burden of CDI was assessed using disability-adjusted life years (DALYs) and age-standardized DALY rates (ASDRs) per 100,000, with 95% uncertainty intervals (UIs).

Results: Among 19,346,526 FAERS reports, 2464 antibiotic-associated CDI cases were identified, 43.55% in males. Antibiotic-associated CDI showed a disproportionality signal overall (IC, 3.17 [IC0.25, 3.10]; ROR, 10.56 [95% CI, 10.11-11.02]). The strongest signals were observed for penicillin combinations and carbapenems, while clindamycin showed the greatest individual level signal (IC, 4.85 [IC0.25, 4.64]; ROR, 32.63 [95% CI, 28.76-37.02]). Signals increased with and peaked among adults aged ≥80 years. The Region of the Americas surpassed Europe around 1997 in ASDR and around 2000 in absolute DALY counts, recording the highest regional burden by 2023, with an ASDR of 10.69 (95% UI 9.49-12.20) per 100,000.

Discussion: Antibiotic-associated CDI showed drug-specific signals and peaked among adults aged ≥80 years, whereas WHO-regional estimates indicated a geographically uneven, rising global burden. Our findings underscore the need for risk-stratified antibiotic stewardship, diagnostic vigilance in older adults, and specific surveillance and strategies.

Keywords: Clostridioides difficile infection, antibiotics, DALY

210

Risk Factors For Children Staphylococcus Aureus and Antimicrobial-Resistance Carriage: A Case-Control Study

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Introduction: Staphylococcus aureus is a common commensal bacterium causing opportunistic infections particularly in immunocompromised children. Antimicrobial resistance (AMR) limits treatment options, elevating disease severity and facilitating caregiver-to-child household transmission through close interactions.

Aims: To investigate the epidemiology and risk factors associated with S.aureus carriages and corresponding AMR status in Hong Kong children, adolescents and their caregiver.

Methods: Children (aged 0-18years) and caregiver were recruited at Hong Kong Children's Hospital. Nasal swabs were collected to screen S.aureus carriage, alongside demographic and antibiotic-history questionnaire. Bacteria identification using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOFMS). AST on isolates involved 10 antibiotics based on local epidemiology and CLSI-guidelines utilizing disc diffusion. Cases included children with S.aureus carriage; controls were those without. Resistance subgroup analysis compare carriers with ≥1 antibiotic resistance against fully susceptible non-carriers. Risk factors were determined via logistic regression optimized by bidirectional stepwise Akaike Information Criterion (AIC) selection.

Results: Among 293 analyzed child-caregiver pairs (children: mean age 7.4 years, 57.8% male), 80 children (27.3%) were cases, and 213 (72.7%) non-carrier controls. Child isolates exhibited highest resistance to penicillin (63.7%); doxycycline (11.3%); azithromycin (10%) and oxacillin (5%; Methicillin-resistant Staphylococcus aureus indicator). Significant risk factors for S.aureus carriage in child was S.aureus carriage in caregiver (OR:2.06, 95%CI:1.06-3.97). In subgroup analysis, 75% of children carriers exhibited ≥1 antibiotic resistance. Caregiver ≥1 antibiotic resistance carriage was identified as significant risk factor for children ≥1 antibiotic resistance carriage (OR:9.60, 95%CI:1.03–98.30).

Conclusions: Prevalence of S.aureus and MRSA carriage were similar to previously documented providing reassuring evidence that carriage is well managed. Close contacts, such as children and caregivers, exhibited a strong association with resistance carriage. However, a high prevalence of antibiotics resistance was observed. While phenotypic risk factor associated with resistance carriage were absent, further microscopic epidemiological investigations are warranted.

Keywords: Antimicrobial resistance, Methicillin-Resistant Staphylococcus aureus, Antibiotic Stewardship

211

Serious Infection after Denosumab versus Zoledronic Acid Discontinuation in Patients with Osteoporosis

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Introduction: Denosumab is often discontinued, and its rapidly reversible biologic effects may alter the risk of infection after treatment. However, this post-discontinuation risk remains unclear.
Aims: To compare the risk of serious infections after discontinuation of denosumab compared to zoledronic acid (ZA) among patients with osteoporosis using nationwide claims data

Methods: Using the Korean National Health Insurance Service database, we conducted a retrospective cohort study. Individuals aged more than 65 years with osteoporosis were eligible, and initiators of denosumab or ZA between October 1, 2017 and December 31, 2023, and subsequently discontinued their drug were included. Patients with chronic kidney disease in the year before initiation, overlapping use of both drugs, or missing data were excluded. Denosumab discontinuers were matched 1:1 to ZA discontinuers using propensity scores derived from age, sex, insurance type, Charlson Comorbidity Index, fracture history, hospital days, and treatment duration. Treatment duration was calculated using episodes constructed using a 60-day grace period. Serious infection was defined as hospitalization with ICD 10 codes for pneumonia, urinary tract infection (UTI), tuberculosis, cellulitis/erysipelas, and infective endocarditis (IE). Patients were followed from the end of drug coverage until the serious infection, initiation of new osteoporosis medication, death, or 31 December 2024. Cox proportional hazards models in matched cohort estimated hazard ratios (HR) with 95% confidence intervals (CIs).

Results: Among 405,776 new users (340,447 denosumab; 65,329 ZA), 65,329 matched pairs were included. The denosumab discontinuation was not associated with a higher risk of serious infection compared to ZA discontinuation. The adjusted HR for pneumonia was 1.02 (CI 0.99–1.05), UTI 0.94 (CI 0.86–1.04), tuberculosis 1.03 (CI 0.99–1.06), cellulitis/erysipelas 1.03 (CI 1.00–1.06), and IE 1.03 (CI 1.00–1.06).

Conclusions: Among older adults with osteoporosis, denosumab discontinuation was not associated with higher risks of serious infection compared with ZA discontinuation.

Keywords: Denosumab. Zoledronic acid, Serious infection

212

Nationwide trends in biosimilar utilization and biologic expenditures following policy interventions

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Introduction: Biosimilars contribute to healthcare system sustainability worldwide. To promote biosimilar utilization, various policy interventions have been implemented internationally, yet evidence regarding their population-level impact remains limited. The Ministry of Health, Labour and Welfare (MHLW) introduced a 1,500 JPY (9.4 USD) incentive to promote biosimilar initiation for home care patients in April 2020, which was expanded to outpatient treatments in April 2022.

Aims: This study described nationwide trends in biosimilar utilization and biologic expenditures surrounding policy implementation in Japan.

Methods: A nationwide serial cross-sectional study was conducted using the publicly available national database (NDB) Open Data, which anonymously aggregated reimbursement claims data on an annual basis. The study period was from FY2019 (April 2019-March 2020) to FY2023 (April 2023-March 2024).

Prescribed units of biosimilars per 100,000 inhabitants were analyzed across outpatient and inpatient settings, with means (95% CI) calculated across 47 prefectures.
Additionally, this study calculated biologic expenditures based on the defined unit price by MHLW. Expenditure analyses were restricted to biologics with approved biosimilars as of FY2023 to ensure comparability across years.

Results: The means (95% CI) of biosimilar prescription units per 100,000 inhabitants were 3700 (3487–3913) in FY2019, and 5051 (4781–5320) in FY2020, 6510 (6119-6901) in FY2021, 7701 (7242-8160) in FY2022, and 9020 (8532-9507) in FY2023, representing a 146% increase from FY2019 to FY2023.

The expenditure for biosimilars and their reference biologics decreased from 3,036 million USD in FY2019 to 2,561 million USD in FY2023, representing a 16% reduction. However, the biosimilar expenditure increased from 153 million USD (5% of total expenditures) in FY2019 to 469 million USD (18% of total expenditures) in FY2023.

Conclusions: Biosimilar utilization increased substantially, accompanied by a shift in expenditure from reference biologics to biosimilars and an overall reduction in biologic expenditures.

Key words: biosimilar, pharmaceutical policy, drug expenditure

213

Impact of China's pharmacovigilance legislation on medication safety: a litigation-based evaluation

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Introduction: China established its pharmacovigilance system in 2019, placing primary responsibility for drug safety on the Marketing Authorization Holder (MAH). A pilot MAH system was launched in 10 provinces in 2016. However, the real-world impact of this legislation on medication safety has not yet been examined from a judicial perspective.

Aims: This study aims to evaluate the real-world effectiveness of China's 2019 pharmacovigilance legislation for medication safety using judicial data. It also seeks to identify weaknesses in the pharmacovigilance system.

Method: We analyzed 379 drug safety litigation cases from China Judgments Online and the Peking University Law Science Database, covering December 2014 to November 2024. Key indicators included the proportion of drug safety litigation cases, the average compensation amount, the proportion of MAH responsibility determinations, and the classification of drug-related problems (DRP). Interrupted time series and breakpoint regression were used to evaluate the 2019 policy effects, and difference-in-differences was used to analyze the 2016 MAH pilot.

Results: The median compensation was 209,933 yuan. Medical institutions accounted for 93.1% of responsible entities, while MAH accounted for only 4.5%. Post-policy, drug safety litigation (β_3=-0.0291, p=0.043) and average compensation (β_3=-25,543, p=0.018) decreased from rising trends, while MAH responsibility attribution showed no statistically significant change. The most common drug issues were insufficient monitoring (59.4%) and lack of informed consent (39.1%), with informed consent cases increasing post-policy (53.3%→63.4%, p=0.059).

Conclusions: The establishment of the pharmacovigilance system was observed to be associated with a reversal of trends in the proportion of drug safety litigation and compensation amounts, but MAH liability has not yet been reflected in judicial outcomes. Challenges remain in drug monitoring and informing obligations. Judicial case data can provide a legal perspective for evaluating the effectiveness of the pharmacovigilance system.

Keywords: Pharmacovigilance; Drug Safety Litigation; Interrupted Time Series Analysis

214

Mapping public reporting of antibiotic shortage definitions, frequency, duration across OECD countries

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Introduction: Antibiotic shortages are increasing globally and may significantly affect patient care due to their role in acute infections. As medicine supply chains become increasingly globalised, standardised reporting is important to determine whether shortages reflect country-specific issues or concurrent international supply disruptions. However, little is known about how antibiotic shortages are defined and reported across countries.

Aims: To map the public reporting of antibiotic shortages across OECD countries and describe differences in reporting definitions, frequency, and duration of reported shortages.

Methods: Publicly available medicine shortage databases from OECD countries were searched for systemic antibiotic shortages (ATC code J01) reported between 1 January and 31 December 2025. Data collected included shortage definitions, number of shortages, distinct antibiotic types affected, and shortage duration. Antibiotics were categorised according to the WHO AWaRe classification.

Results: Twenty-one OECD countries with publicly available shortage databases were included. Definitions and reporting criteria varied substantially between countries, including shortages defined as “demand exceeding supply” and those affecting patient care. Reported antibiotic shortages ranged from 4 in Israel to 133 in Canada, while the number of distinct antibiotic types affected ranged from 2 in Israel to 35 in the Czech Republic. Median shortage duration ranged from 25 days in Iceland and Colombia to 365 days in Denmark, Finland, and France. Access antibiotics were most commonly reported, followed by Watch antibiotics, while Reserve antibiotics were least commonly reported.

Conclusions: Public reporting of antibiotic shortages varies substantially across OECD countries, particularly regarding definitions and inclusion criteria. These differences likely affect the reported frequency and duration of shortages and limit meaningful international comparison. More standardised reporting frameworks are needed to support global monitoring of antibiotic shortages.

Keywords: antibiotic shortages; OECD; medicine shortages

215

Prevalence and sociodemographic predictors of medication economic stress among chronic disease outpatients

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Introduction: Catastrophic health expenditure affects millions of households in India, with medicines contributing substantially to out-of-pocket costs among patients on long term pharmacotherapy. Despite its clinical relevance, medication economic stress remains poorly quantified, and no India specific instrument had measured this construct across behavioral and decisional dimensions prior to this study. Understanding its prevalence and predictors is essential to addressing cost related nonadherence.

Aims: To quantify the prevalence and severity of medication economic stress using the newly developed Medication Economic Stress and Decision-Making Scale (MESDS) and identify sociodemographic factors independently associated with this burden among patients with chronic diseases.

Methods: A cross-sectional study was conducted among 507 adults with chronic diseases attending a single tertiary care hospital in Karnataka, India. Data were collected using validated 21-item MESDS, Modified Kuppuswamy Socioeconomic Status Scale, and a structured data collection form. MESDS severity categories were based on thresholds established during scale development. Statistical analyses were performed.

Results: The mean MESDS score was 34.33 ± 14.10 (range: 6.00–76.67). Overall, 28.8% of participants experienced low stress, 57.0% moderate stress, 13.2% high stress, and 1.0% severe stress. Median monthly medicine expenditure was INR 2,000 (IQR: 1,000–4,000). Insurance coverage was independently associated with a 10.8-point reduction in MESDS score ($\beta = -0.385$; $p < 0.001$). Family income ($\beta = -0.199$; $p < 0.001$), socioeconomic class ($\beta = -0.108$; $p = 0.032$), and household size ($\beta = 0.171$; $p = 0.012$) were additional independent predictors. The model explained 44.4% of variance in MESDS scores (Adjusted $R^2 = 0.427$).

Conclusions: More than 70% of participants experienced at least moderate medication economic stress. Insurance coverage and socio-economic factors were independently associated with MESDS scores. These findings may inform medication financing policies and support pharmacist-led economic counseling and affordability screening initiatives.

Keywords: Medication economic stress, out-of-pocket expenditure, chronic disease, socioeconomic factors.

216

Long-Term Healthcare and Societal Cost Burden of ADHD in Hong Kong

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Introduction: Attention-deficit/hyperactivity disorder (ADHD) frequently persists into adulthood, yet data on its lifespan economic burden in Hong Kong remain scarce. We estimated the treated ADHD and its long-term economic burden from the caregiver, service provider and society perspectives.

Aims: To estimate the treated ADHD and its long-term economic burden from the caregiver, service provider and society perspectives.

Methods: Using electronic health records data from the Hong Kong Hospital Authority(HA), we included individuals born on or after 1 January 1997 who received at least one approved ADHD medication in Hong Kong (methylphenidate, atomoxetine and lisdexamfetamine) between 2001 and 2025. The index date was the first ADHD medication dispensing. Annual rate ware calculated using matching resident population denominators from the Hong Kong Census and Statistics Department. Caregiver cost included total co-payments plus productivity loss. Provider costs were calculated using the HA Annual Report unit cost. Societal cost was the sum of provider costs and caregiver productivity losses. All unit costs were adjusted for inflation to 2025.

Results: A 57,680 patients' cohort were identified. Of these, 76.7% were male, the median age at first treatment was 8 years, and total follow-up was 451,187 person-years. The treated ADHD incidence rose from 1.8 per 100,000 from 2001, reaching 271 per 100,000 in 2025. Total caregivers cost was HK$1.02 billion, of which 64% was indirect cost from productivity loss. Total provider cost was HK$4.71 billion, of which more than half, about 63%, came from outpatient care. Total societal cost was HK$5.36 billion.

Conclusions: The rate of ADHD medication dispensing has risen markedly since 2001, carrying a substantial and growing societal cost. And a large part of the cost in caregiver is indirect cost, underscoring the need for family-centered support alongside service planning.

217

Trends in Publicly Subsidised and Private Access to GLP-1 Medicines in Australia

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Introduction: GLP-1 medicines offer significant cardio-renal benefits for type 2 diabetes (T2D) and obesity. Despite high consumer demand for weight loss, subsidised access in high-income countries is generally limited to people with T2D. The scale of private access, the primary pathway of access for weight loss, is largely unknown.

Aims: We aimed to quantify population-level trends in publicly subsidised and private access of GLP-1 medicines in Australia.

Method: We used national pharmaceutical sales data to quantify use of GLP-1 medicines listed for T2D in Australia, May 2020 - April 2025. We used Pharmaceutical Benefits Scheme dispensing claims to measure subsidised access; we estimated private access as the difference between sales and subsidised dispensings. We measured GLP-1 use as number of units sold/dispensed and defined daily dose (DDD)/1000 population/day.

Results: Since May 2020, total sales of GLP-1 medicines increased almost 10-fold, despite significant disruptions during shortages. Most growth was in private access, driven by semaglutide and rapid uptake of tirzepatide. In the year May 2024-April 2025, over 6 million units of GLP-1 medicines were sold, predominantly semaglutide (63.3%) and tirzepatide (30.7%). Half (47.8%) of GLP-1 medicines were accessed privately, including 26.9% of semaglutide and all tirzepatide. We estimate approximately 480,000-500,000 people accessed GLP-1 medicines each month, with 180,000-240,000 people accessing privately.

Conclusion: GLP-1 medicines use has increased dramatically, with approximately half a million Australians using GLP-1 medicines each month, almost half through private access. Our findings underscore significant demands outside of subsided access, most likely for weight loss, and highlight substantial pressures for health systems meeting this demand.

Keywords: GLP-1 medicines, diabetes, obesity, equity of access

218

Implementing standardised methods to measure post-stroke medication adherence in Australia and Canada

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Introduction: Post-stroke medication adherence can be assessed using dispensing data; however, variations in methods hinder reliable comparisons across regions.

Aims: We aimed to develop and pilot test the implementation of standardised methods to compare post-stroke adherence to direct oral anticoagulants (DOACs) between countries.

Methods: An observational study was conducted across two countries participating in the International Network for Standardised Population Insights and Real-world Evidence for STROKE (INSPIRE-STROKE). Australia and Canada, with population-based data and universal healthcare systems, provided the case example. Metadata structures were shared to harmonize variables and response options. Patients admitted with incident ischaemic stroke and atrial fibrillation (Victoria, Australia [July 2014-June 2017]; Ontario, Canada; [July 2014–March 2022]), aged 66-105 years, who survived ≥90 days post-discharge were included. The proportion of days covered (PDC) of DOACs was measured from initiation to 1-year post-discharge. Adherence was measured using standardised code from the TEN-SPIDERS pharmacoepidemiology framework. Seven simulations were undertaken adjusting for different PDC measurement parameters (e.g., in-hospital stays, pre-supply, survival, early refills and switching). Aggregated outputs were compared between countries.

Results: Among 2471 Australians (50% female; 36% aged 85+ years) and 16622 Canadians (51% female; 34% aged 85+ years), 50% and 65% were dispensed a DOAC within 90 days post-stroke, respectively. Among initiators, median 1-year DOAC PDC was 86.8% (interquartile range [IQR]: 75.9%–92.6%) in Australia vs 96.2% (IQR: 89.6%–98.6%) in Canada. Simulations adjusting for pre-supply, early refills, and switching increased median PDC by +10.3% in Australia and +3.5% in Canada. Further adjustment for in-hospital stays had negligible impacts on PDC.

Conclusions: Implementation of standardised methods across two countries revealed high levels of adherence to DOACs in patients with ischaemic stroke and atrial fibrillation. Scale-up of these methods to other countries and medications is warranted to reliably measure and compare trends in post-stroke medication adherence.

Keywords: Stroke; Medication Adherence; Standardisation

219

Bridging the Treatment Gap in Dyslipidemia: A Multilingual, Pharmacist-Led Interventional Study

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Introduction: Cardiovascular disease remains the leading cause of mortality worldwide, with dyslipidemia representing a major modifiable risk factor. While pharmacist-led interventions have demonstrated clinical benefit in high-income countries, evidence from low- and middle-income settings remains limited.

Aim: To assess the impact of a structured pharmacist-led intervention on clinical and humanistic outcomes.

Methods: Following ethical approval and trial registration (CTRI/2020/12/030065), a three-phase study was conducted at a tertiary care teaching hospital. Phase I involved cross-sectional surveys to identify barriers to optimal dyslipidemia management. Phase II comprised development, validation, and user-testing of multilingual (English, Kannada, Marathi) patient information leaflets. Phase III was an 18-month randomized controlled trial enrolling 378 patients with dyslipidemia. Participants were randomized to either a pharmacist intervention group (n=186), receiving clinical review based on NCEP ATP III guidelines, individualized counseling, and culturally adapted educational materials, or a usual care group (n=192). Monthly telephonic follow-ups and in-person assessments at 3, 6, and 12 months were conducted. The primary outcome was mean change in LDL-C. Secondary outcomes included medication adherence and HRQoL.

Results: Major barriers identified were patient forgetfulness, low educational level, and the asymptomatic nature of dyslipidemia. Repeated measures two-way ANOVA showed a significant main effect of time on LDL-C reduction ($F(2.75,1033.88)=329.80$, $p<0.001$, partial $\eta^2=0.467$) and a significant time × treatment interaction ($F(2.75,1033.88)=22.85$, $p<0.001$, partial $\eta^2=0.057$), indicating greater LDL-C reduction in the intervention group. Medication adherence significantly improved in the intervention group at 6 months (mean difference=1.01, $p=0.006$) and 12 months (mean difference=1.35, $p<0.001$). HRQoL increased by 19.44% (10.10-point improvement) in the intervention group compared with 10.21% in usual care.

Conclusion: Structured pharmacist-led interventions significantly improve lipid parameters, adherence, and HRQoL among patients with dyslipidemia in a resource-limited setting supporting the integration of clinical pharmacy services into routine cardiovascular care.

Keywords:
LDL-C; Medication adherence; Quality of life

220

Digital health competency and determinants among pharmacists in Indonesia: a national survey

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Introduction: Digital transformation in healthcare requires pharmacists to have digital health competencies; however, evidence on their competency levels and determinants in Indonesia remains limited.

Aims: To assess digital health competency among pharmacists and identify determinants of lower competency levels.

Methods: This cross-sectional national survey of pharmacists was conducted across all Indonesian provinces during November 2025–April 2026 using proportional quota sampling based on provincial distribution of registered pharmacists, distributed through the Indonesian Pharmacists Association central board. Digital health competency was assessed using the Competencies for Primary Health Care questionnaire and classified by total scores as literacy (>25–33), fluency (>33–42), or mastery (>42). Literature-based covariates, including gender, age, practice location, facility type, region, years of practice, frequency of digital health training, and education, were screened by bivariate analysis; those with p-value < 0.25 were included in ordinal logistic regression and reported as ORs with 95% CIs.

Results: A total of 802 pharmacists participated, predominantly female (77.43%), aged <30 years (48.63%), urban-based (66.33%), and holding a professional pharmacist degree (84.91%). Most had 1–5 years of experience (37.91%), practiced in community pharmacies (41.40%), attended digital health training 2–4 times (38.90%), and demonstrated fluency-level competency (44.89%). In multivariate analysis, pharmacists aged >40 years had lower competency than those aged <30 years (OR = 1.50; 95% CI: 1.02–2.22; p-value = 0.042). Professional-degree pharmacists had lower competency than postgraduate graduates (OR = 1.50; 95% CI: 1.01–2.23; p-value = 0.044). Community pharmacy practice was associated with lower competency than practice in more than one facility (OR = 1.47; 95% CI: 1.02–2.13; p-value = 0.040).

Conclusion: Indonesian pharmacists demonstrated fluency-level digital health competency. Lower competency was associated with older age, lower education, and community pharmacy practice, indicating the need for targeted training and curriculum improvement; future research should evaluate interventions for lower-competency groups.

Keywords: digital health competency, pharmacists, Indonesia

221

Capability for real world monitoring of quality of medicines use: interview study

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Background: Australia's National Medicines Policy recognises that the collection, analysis and reporting of population level medicines use data is required to improve the quality of medicines use. A range of policies, systems and capability exists across the health system to conduct and respond to such monitoring; however, significant gaps remain.

Objective: To describe the current scope, processes and policies for monitoring the quality of medicines use at population level, and identify opportunities for developing more comprehensive and integrated systems and policies.

Methods: An initial eight semi-structured qualitative interviews have been conducted with purposively recruited expert stakeholders across Australia, including researchers, policymakers and lead practitioners working in quality use of medicines; population health; primary, hospital and aged care; and digital health.
Data were analysed using a thematic analysis approach. A preliminary coding framework was developed a priori and additional codes were generated from interview data.

Results: Preliminary findings show that even in the context of a National Medicines Policy, national leadership is needed for determining and implementing priorities for monitoring medicines use. Despite available and sophisticated administrative drug utilisation data and innovations in linkage methods, ongoing assessment of quality use of medicines is not coordinated other than for subsidised medicine use. Interviewees highlighted the opportunity to broaden the focus of real-world evidence generation, as pharmacoepidemiologists tend to focus on benefits and harms of individual medicines or drug classes, with disjointed determination of priorities. Interviewees proposed significant potential in applying artificial intelligence to electronic record systems. Current policy focus on value in health care and prevention of medication misadventure are drivers for improving monitoring capability.

Conclusion: To build on current monitoring capability, Australia needs coordinated leadership and effort. The significant and evolving maturity of digital health infrastructure and escalating sophistication in the use of real-world evidence offers opportunities to consolidate monitoring capability.

222

National trends of potentially inappropriate medication use and costs among older Australians

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Introduction: Potentially inappropriate medications (PIMs) are medicines where risks may outweigh benefits in older adults. PIMs are associated with increased risk of falls, fractures, and hospitalisations. There is limited national level real-world data outlining prevalence and costs of PIM use in Australia. This is the first national Australian study to identify prevalence and costs of PIMs in older Australians.

Aims: To examine national trends in prevalence and costs of PIMs among older Australians from 2014 to 2024. Sub-analysis included breakdown by sex, age, states and payer type.

Methods: A population-based retrospective study was conducted using dispensing claims from a nationally representative 10% sample of Pharmaceutical Benefits Scheme (PBS) data from 2014 to 2024. PIMs were defined using the 2023 American Geriatrics Society Beers and STOPP version 3 criteria. PIM costs were derived from publicly available PBS data. Annual prevalence and medication costs were stratified by sex, age, state and payer category.

Results: In older adults, PIM prevalence decreased from 59% in 2014 to 52% in 2024. PIM use remained consistently higher among females and was most prevalent in adults aged 85–99 years. The most prevalent PIM classes were proton pump inhibitors (25%), opioids (13%), benzodiazepines (10%), non-selective-oral-NSAIDs (10%) and gabapentinoids (7%). In 2024, national expenditure decreased from approximately AUD 600 million in 2014 to AUD 510 million in 2024. The breakdown by payer type comprised approximately AUD 360 million in government expenditure, AUD 90 million from concession patients and AUD 60 million from general patients.

Conclusions: Although PIM prevalence and costs declined over the past decade, one in two older Australians still received a PIM in 2024. With more than half a billion dollars spent annually on PIMs, targeted deprescribing initiatives are important in improving patient outcomes and reducing healthcare expenditure.

Keywords: potentially inappropriate medications; older adults; deprescribing

223

Twelve-month adherence trajectories to SGLT2 inhibitors and GLP-1 receptor agonists in Australia

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Introduction: Prior research has shown that one in two Australians initiating SGLT2 inhibitors (SGLT2i) or GLP-1 receptor agonists (GLP-1 RA) are adherent during the first 12 months. Contemporary adherence patterns since updated 2020 T2D guidelines, which recommend earlier use of these agents remain unknown.

Aims: To characterise adherence patterns to SGLT2i and GLP-1 RA during the first 12 months in adults living with T2D in 2020.

Methods: Using a 10% sample of the Pharmaceutical Benefits Scheme (PBS), we identified adults (18–99 years) who initiated SGLT2i or GLP-1 RA following metformin in 2020. Adherence was quantified using the proportion of days covered (PDC), and longitudinal adherence trajectories were examined using group-based trajectory modelling (GBTM). Models with 2–6 trajectory groups were evaluated, with the optimal model selected. Sensitivity analyses were conducted to account for death and therapy switching.

Results: Among 26,475 SGLT2i initiators, 60% were 40-69 years and 30% were women. Among 7,303 GLP-1 RA initiators, 60% were 40-69 years and half were women. In both groups, adherence of prior diabetes medications were 20% adherent for sulfonylureas and DPP 4 inhibitors, 30% for SGLT2i, but low adherence (<2%) for GLP-1 RA, insulin and thiazolidinedione. Five adherence trajectories were identified for SGLT2: early discontinuation (7.0%; PDC=0.21), late discontinuation (5.8%; PDC=0.51), intermediate adherence (11.2%; PDC=0.5), good adherence (26.5%; PDC=0.81) and very good adherence (48.6%; PDC=0.96). Five trajectories were also observed for GLP-1 RA: early discontinuation (8.2%; PDC=0.19), late discontinuation (7.6%; PDC=0.49), low adherence (9.0%; PDC=0.38), intermediate adherence (25.7%; PDC=0.76) and good adherence (49.5%; PDC=0.95).

Conclusion: Adherence to SGLT2i and GLP-1 RA varied widely, including early or gradual discontinuation pathways. Despite this, high proportion of people with good adherence is encouraging, and suggests that updated guidelines may have contributed to sustained use.

Keywords: Type 2 diabetes; SGLT2i; GLP-1 RA; adherence; GBTM

224

Cardiovascular risk after successive COPD exacerbations: dose-response analysis, New Zealand

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Introduction: Acute COPD exacerbations (AECOPD) are associated with transient cardiovascular risk, attributed to systemic inflammatory effects. Whether cardiovascular risk escalates within the same individual across successive exacerbations has not been characterised previously in the international EXACOS-CV programme. New Zealand is the first to assess a within-person dose-response pattern, which may suggest cumulative vascular injury and carry implications for cardiovascular monitoring in recurrent disease.

Aims: To determine whether the magnitude and duration of post-AECOPD cardiovascular risk increase with each successive exacerbation. To characterise the within-person dose-response gradient across first, second, and third-or-later exacerbations.

Methods: Incident COPD cohort (56,830 patients; prevalent COPD excluded) from linked New Zealand national administrative health data (2014–2019). Separate time-dependent Cox models were fitted for each exacerbation rank (first, second, third-or-later) using the patient's own unexposed person-time as reference. The composite outcome was MACE or all-cause death, adjusted for age, sex, comorbidities, ethnicity, and deprivation quintile.

Results: Among 56,830 incident COPD patients (138,479 person-years; 21,133 composite events), the 1–7 day HR after the 1, 2 and 3+ exacerbations was 2.66 (95% CI 2.33–3.03), 3.38 (2.96–3.87), and 3.49 (2.93–4.16), respectively (all $p < 0.001$). The 8–14 day HR showed the same gradient: 1.22, 1.97, and 2.19 for ranks 1, 2, and 3+. After a first exacerbation, the elevated risk normalised by 90 days; after a second, it remained elevated to 31–90 days (HR 1.34, 95% CI 1.23–1.46). The 31–90-day HR also increased to 1.23, 1.34, and 1.39 for ranks 1, 2, and 3+, respectively. Rank 2 and 3+ patients had already survived at least one prior exacerbation; the observed gradient is therefore likely conservative.

Conclusions: Post-AECOPD cardiovascular risk increases with each successive exacerbation, in both magnitude and duration. Cumulative cardiovascular vulnerability supports a vascular injury hypothesis and suggests intensified post-exacerbation monitoring and intervention.

Keywords: Disease Exacerbation; Cardiovascular Diseases; COPD

225

Ethnic and socioeconomic disparities in COPD burden and cardiovascular outcomes, New Zealand

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Introduction: Māori and Pacific peoples in New Zealand have disproportionate rates of COPD and cardiovascular disease; acute COPD exacerbations (AECOPD) further elevate cardiovascular risk. The international EXACOS-CV programme has quantified this association across eight countries without ethnic stratification; New Zealand is the first to include health equity analysis by ethnicity and socioeconomic deprivation. Whether these inequities are independent has not been examined.

Aims: To quantify ethnic and socioeconomic disparities in AECOPD frequency and MACE/death rates. To examine whether these disparities are independent structural effects.

Methods: Population-based retrospective cohort using linked national administrative health data (2014–2019); adults with COPD identified from hospitalisation and dispensing records. Negative binomial regression estimated IRRs for AECOPD frequency and MACE/death with progressive adjustment for age, sex, comorbidities, ethnicity, and deprivation quintile. Time-dependent Cox regression examined the AECOPD→MACE/death hazard by ethnicity.

Results: Among 58,037 patients with COPD (142,168 person-years; Māori 20.4%), 21,972 experienced a composite MACE/death event. Age-sex standardised MACE/death rates were 144.6 vs 99.5 per 1,000 person-years (Māori vs European); a 20% disparity remained after comorbidity adjustment (IRR 1.20, 95% CI 1.15–1.25). Māori patients had 29% more exacerbations per year (IRR 1.29, 95% CI 1.25–1.32). The most deprived quintile had 34% higher MACE/death rates than the least deprived (IRR 1.34, 95% CI 1.27–1.41). Ethnicity and deprivation were independent structural determinants; the deprivation gradient was consistent across ethnic groups (LRT $p < 0.001$). Cox interaction showed ethnic MACE/death disparities arise from higher background cardiovascular hazard in Māori and Pacific patients ($p = 0.0014$). Pacific patients showed a divergent risk profile warranting further investigation.

Conclusions: Ethnic and socioeconomic inequities in COPD outcomes persist after full comorbidity adjustment as independent structural determinants, each requiring separate policy responses. Future work should examine mechanisms driving these disparities, including post-exacerbation cardiovascular and respiratory care.

Keywords: Healthcare Disparities, Cardiovascular Diseases, COPD

226

SGLT2 inhibitors and risk of idiopathic pulmonary fibrosis: A population-based cohort study

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Introduction: Sodium-glucose co-transporter 2 inhibitors (SGLT2i) may exert antifibrotic effects in the lung. However, the extent to which these properties confer clinically meaningful benefit on idiopathic pulmonary fibrosis (IPF) remains uncertain.

Aims: To assess the risk of IPF with the use of SGLT2i in patients with type 2 diabetes (T2D).

Methods: We conducted a population-based cohort study using a nationwide healthcare database of Korea (2002–2023). Patients with T2D who initiated SGLT2i or dipeptidyl peptidase 4 inhibitors (DPP4i) were included, and followed from the date of study drug initiation until the earliest occurrence of IPF, discontinuation or switching of the index drug class, death, or Dec 31, 2023. Hazard ratios (HRs) and rate differences (RDs) per 100,000 person-years were estimated after normalized inverse probability treatment weighting. In additional analyses, we assessed risks of all-cause and respiratory-related mortality among patients with pre-existing IPF.

Results: We identified 548,411 SGLT2i users (mean age, 55.6 years; 59.4% male) and 3,177,716 DPP4i users (mean age, 61.2 years; 58.3% male). During a median follow-up of 1.16 years, weighted incidence rates of IPF were 20.53 and 31.74 per 100,000 person-years in SGLT2i and DPP4i users, respectively. Compared with DPP4i, SGLT2i was associated with a lower risk of IPF (HR 0.62; 95% CI, 0.53 to 0.72; RD -11.10, 95% CI, -13.30 to -8.91). Among patients with pre-existing IPF, SGLT2i was also associated with lower risks of all-cause and respiratory-related mortality, with HRs of 0.72 (95% CI) and 0.50 (95% CI), respectively.

Discussion: In this nationwide cohort study, SGLT2i was associated with a lower risk of IPF compared with DPP4i in patients with T2D, and lower risks of all-cause and respiratory-related mortality in patients with pre-existing IPF. These findings suggest a potential protective effect of SGLT2I against IPF and warrant further evaluation in clinical trials.

227

Thromboembolic risk after intravenous immunoglobulin therapy: a time-aligned cohort study

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Introduction: Intravenous immunoglobulin (IVIg) therapy has been associated with thromboembolic events (TEEs), but prior studies are limited by confounding by indication and heterogeneous designs. The timing and magnitude of any short-term thromboembolic risk remain incompletely characterized.

Aims: To evaluate the short-term risk of TEEs following IVIg administration and determine whether risk is concentrated in early post-infusion periods.

Methods: We conducted a new-user comparative cohort study with a secondary self-controlled risk interval analysis using linked hospital administrative data from 2013 to 2020. Adults receiving IVIg were compared with time-aligned hospitalized patients without IVIg exposure using inverse probability weighting targeting the treated population. TEEs included venous and arterial events identified from diagnosis codes within 30 and 90 days. Self-controlled analyses compared post-exposure risk windows with a later within-person control window.

Results: The analytic cohort included 2,855 IVIg recipients and 713,727 time-aligned comparators. The weighted 30-day risk of TEE was 1.61% among IVIg recipients versus 0.41% among comparators, an absolute risk difference of 1.20%. The adjusted 90-day hazard ratio was 1.69 (95% CI, 1.35 to 2.13). Risk was higher during days 0 to 30 (HR, 1.94; 95% CI, 1.37 to 2.74) than days 31 to 90 (HR, 1.57; 95% CI, 1.16 to 2.11). In self-controlled analyses, incidence rate ratios were highest during days 0 to 2 after IVIg administration (7.16; 95% CI, 3.24 to 15.82), with lower estimates thereafter.

Conclusions: IVIg administration was associated with a higher short-term incidence and risk of TEEs, particularly shortly after exposure. Findings support careful thrombotic risk assessment and close monitoring in the early post-infusion period, although residual confounding and time-varying factors cannot be excluded.

Keywords: intravenous immunoglobulin; thromboembolism; pharmacoepidemiology

228

Trend of severe VTE in locally advanced or metastatic NSCLC in Japan

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Introduction: Venous thromboembolism (VTE) is a clinically important event associated with poor prognosis in patients with locally advanced (LA) or metastatic (m) non-small cell lung cancer (NSCLC) initiating systemic therapy in Japan. However, the incidence of severe VTE and its year-to-year trends remain poorly characterized in this population, with limited published evidence despite substantial changes in treatment patterns.

Aims: This study aims to estimate the incidence of VTE within one year after initiation of systemic therapy.

Methods: This retrospective cohort study used the Medical Data Vision (MDV) claims database from 2015 to 2024. Patients aged ≥18 years initiating systemic therapy for LA/mNSCLC were included, excluding those with lung cancer surgery within 180 days before the index date. The index date was treatment initiation, and patients were followed up to 1 year. VTE was defined as a composite of deep vein thrombosis (DVT) or pulmonary embolism (PE), with severe VTE defined by inpatient diagnosis and imaging during hospitalization.

Results: A total of 99,505 patients were included; median age 72 years and 66.5% males. Of these, 733 patients experienced severe VTE. The severe VTE incidence rate per 100 person-years was 1.40 (95% CI: 1.30-1.51), with DVT and PE incidence of 0.95 (95% CI: 0.87-1.04) and 0.45 (95% CI: 0.39-0.51), respectively. Yearly VTE incidence ranged from 1.23 (95% CI: 0.90-1.63) in 2016 to 1.77 (95% CI: 1.43-2.17) in 2021, with values of 1.44 (95% CI: 1.04-1.94) in the first year (2015) and 1.24 (95% CI: 1.00-1.53) in the final year (2024).

Conclusions: This study characterized the incidence rate and year-to-year trends of severe VTE in patients with LA/mNSCLC initiating systemic therapy. These findings can support understanding of the epidemiology and the background incidence of severe VTE in this population.

Keywords: Venous thromboembolism, non-small cell lung cancer, Real World Evidence

229

Early bleeding prediction in older patients anticoagulated for acute pulmonary embolism

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Background: Older patients with pulmonary embolism (PE) are at increased risk of bleeding, which is associated with adverse outcomes, making early risk assessment particularly important. This study evaluated the short-term performance of commonly used bleeding risk scores in patients aged ≥65 years.

Methods: An analysis was conducted in a multicentre, prospective study of patients aged ≥65 years with PE receiving anticoagulation (NCT02943343, 2016). The performance of the PE-SARD, Kuijer, RIETE, BACS, and ATRIA scores was evaluated using the time-dependent area under the curve (AUC) analysis. Calibration was assessed with calibration plots. Sensitivity, specificity, and positive predictive values were calculated. The primary outcomes were major bleeding (MB) at 7 and 14 days.

Results: Among 3,661 anticoagulated patients aged ≥65 years with acute PE, MB occurred in 18 (0.5%) and 36 (1.0%) patients at 7 and 14 days, respectively, and clinically relevant non-major bleeding (CRNMB) in 69 (1.9%) and 105 (2.9%) patients. Patients with bleeding events had higher mortality than those without bleeding. Discrimination for short-term MB was low to moderate across scores, with RIETE (AUC 0.76, 95% CI 0.65-0.87) and PE-SARD (AUC 0.74, 95% CI 0.63-0.85) showing the most consistent performance at 7 days. Overall discrimination declined at 14 days. All scores demonstrated limited ability to predict CRNMB, and no model showed a consistent net clinical benefit.

Conclusions: In older patients with PE, bleeding risk scores showed low-to-moderate discrimination for short-term bleeding, with moderate early performance observed only in selected scores. None of the scores reliably identified CRNMB, highlighting the limitations of baseline risk assessment in acute care settings.

230

Interstitial-Lung Disease risk of JAK inhibitors in Rheumatoid Arthritis using claim database

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Introduction: Evidence regarding Janus kinase inhibitors (JAKi) in developing interstitial lung disease (ILD) compared with tumor necrosis factor alpha inhibitors (TNFi) and non-tumor necrosis factor inhibitors (non-TNFi) was limited due to selection of controls and regions, including US and Europe.
Aims: To evaluate risk of developing ILD with JAKi compared with individual TNFi and non-TNFi among patients with rheumatoid arthritis (RA).

Methods: We implemented an active comparator new-user design under target trial emulation framework, using Taiwan's National Health Insurance Research Database. We included patients diagnosed with RA who received JAKi (tofacitinib, baricitinib), TNFi (etanercept, adalimumab, golimumab, or certolizumab), or non-TNFi (tocilizumab, abatacept), defining first dispensing date as index date. We excluded prevalent users, patients with other autoimmune diseases, and patients with malignancy. We defined the outcome as incident ILD events (ICD-9/10-CM codes 515–516, J84) in outpatient or inpatient settings, using an intention-to-treat approach. We applied propensity scores with standardized mortality ratio weighting (SMRW) to mimic randomization in treatment assignment. We used Cox models to estimate hazard ratios (HRs) and 95% confidence intervals (CIs), using individual TNFi or non-TNFi as reference.

Results: We included 18,536 patients (2,411 JAKi, 12,933 TNFi, and 3,192 non-TNFi). After SMRW, we observed no association between JAKi and risk of incident ILD compared with TNFi (HR: 1.11, 95% CI: 0.38–3.18), while we observed that JAKi may be associated with a lower risk of incident ILD compared with non-TNFi (HR: 0.48, 95% CI: 0.21–1.11). Results of comparison between tofacitinib and individual TNFi and non-TNFi were consistent with main findings.

Conclusions: We observed that there was a differential risk of developing ILD with JAKi when compared with TNFi and non-TNFi. Future studies are warranted to explore potential benefit behind JAKi and support clinical evidence on selection of second-line regimens in RA patients.

Keyword: JAKi, Interstitial Lung Disease, TNFi, non-TNFi.

231

Interactions between BMI and clinical characteristics in skin clearance among ustekinumab-treated psoriasis

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Introduction: Elevated body mass index (BMI) is associated with reduced response to biologic therapies in psoriasis, but whether this association varies across clinical characteristics in ustekinumab-treated patients remains unclear.

Aims: This study aimed to investigate interactions between BMI and clinical characteristics in relation to ustekinumab response in psoriasis.

Methods: We included adults with moderate-to-severe plaque psoriasis who initiated ustekinumab in the Shanghai Psoriasis Effectiveness Evaluation Cohort, a prospective multicenter observational study conducted from November 2022 to March 2024. Treatment response was assessed using time to achievement of PASI75.

Multivariable Cox proportional hazards models were applied to assess interactions between BMI and clinical characteristics including age, gender, baseline PASI, disease duration, prior biologics exposure and comorbidities. Interaction terms were tested using Wald chi-square statistics. For significant interactions, predicted hazard ratios (HRs) were illustrated how the BMI–response association varied across subgroups. A sensitivity analysis was performed using logistic regression with binary outcome defined as achievement of PASI75 at week 16. Statistical significance was defined as a two-sided p value <0.05.

Results: Among 132 patients (median age 45.8 years; 79.6% male; median BMI 24.5 kg/m^2; median baseline PASI 12.5), the median time to PASI75 response was 16.4 weeks (n=97).

Disease duration significantly modified the association between BMI and time to PASI75 (P for interaction <0.05). In patients with disease duration <15 years, higher BMI was associated with delayed achievement of PASI75 (HR=0.88, p<0.05), whereas no significant association was observed in those with disease duration ≥15 years (HR=1.06, p=0.37). Sensitivity analyses using binary PASI75 achievement at week 16 yielded consistent findings. No other variables showed significant interactions.

Conclusions: The association between elevated BMI and ustekinumab response was modified by disease duration after adjustment for covariates. These findings warrant further investigation in larger studies.

Keywords: Plaque psoriasis; Ustekinumab; Skin clearance.

232

Clinical characteristics and treatment patterns of perianal Crohn's disease in Japan

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Introduction: Biologics are central to management of perianal Crohn's disease(CD), with guidelines emphasizing early initiation to improve clinical outcomes. However, real-world utilization patterns of biologics have not been systematically characterized in relation to guideline expectations.

Aims: This study aimed to describe the clinical characteristics and treatment patterns of perianal CD in a Japanese cohort.

Methods: We conducted a retrospective real-world cohort study(2018-2024) using the Japan Medical Data Vision(MDV) database. Patients with newly diagnosed CD were classified into pre-CD perianal, post-CD perianal, and non-perianal groups based on the timing of perianal disease onset. Baseline characteristics and treatment patterns, including first treatment for perianal CD, time to biologic initiation, and treatment escalation, were described. Time-to-event analyses and incidence rate ratios(IRR) were used to compare biologic initiation patterns between groups.

Results: Among 1,823 CD patients, 27.2% had perianal disease, including 17.8% pre-CD and 9.4% post-CD perianal groups. Patients with perianal CD were more frequently male and younger(~34 years) at diagnosis and were more likely to initiate biologic therapy than those without perianal involvement(IRR=1.87, 95% confidence interval[CI]:1.62-2.15, p<0.0001), particularly among post-CD perianal group. Nevertheless, biologic therapy was infrequently incorporated into initial perianal CD management(16.3% for pre-CD and 40.9% for post-CD), and substantial delays in initiation were observed (median time to biologic initiation was 229 days [95% CI: 144-583] for pre-CD and 63 days[32-152] for post-CD). Although cumulative biologic uptake increased over follow-up, a considerable proportion of patients did not initiate biologic therapy within the first 12-24 months after perianal CD onset. Among post-CD perianal patients, treatment escalation occurred in approximately one-third of patients, indicating incomplete treatment optimization.

Conclusions: Biologics remain underutilized for perianal CD in Japan, though perianal CD is associated with earlier adoption. Substantial lagging in biologic utilization indicates potential barriers, highlighting opportunities to improve guideline-concordant care.

Keywords: Crohn's disease; Biologics; Real-world data.

233

Ten-year cost savings associated with biosimilar tumour necrosis factor inhibitors

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Introduction: Biological therapies are a major and growing driver of medicine expenditure globally, with tumour necrosis factor (TNF) inhibitors among the most widely used biologics. Biosimilars offer lower-cost alternatives; however, the aggregate cost savings associated with TNF inhibitor biosimilars in Australia have not been comprehensively quantified.

Aims: To estimate Pharmaceutical Benefits Scheme (PBS) cost savings associated with the listing of biosimilars for adalimumab, etanercept, and infliximab used in the treatment of inflammatory arthritis in Australia.

Methods: A retrospective, population-level expenditure analysis was conducted using publicly available, aggregated PBS Item Reports data between 2015 and 2025. Counterfactual scenarios were constructed to isolate the effect of biosimilar entry, while accounting for key PBS pricing mechanisms, including mandated price reductions and price disclosure cycles.

Results: Biosimilar PBS listing was associated with cumulative savings of AU$562,316,855 during the study period. Etanercept biosimilar generated the largest absolute savings of AU$341,527,057 (23.7% reduction). Adalimumab biosimilars generated savings of AU$195,291,010 (9.4% reduction) despite the highest prescription volumes, reflecting delayed biosimilar entry. Infliximab produced the smallest absolute savings of AU$25,498,788 but the greatest relative reduction in expenditure (35.4%). By indication, rheumatoid arthritis accounted for the largest share of savings (AU$306,870,817; 54.6%), followed by ankylosing spondylitis (AU$124,577,892; 22.2%), psoriatic arthritis (AU$114,299,422; 20.3%), and juvenile idiopathic arthritis (AU$16,568,724; 2.9%).

Conclusions: Biosimilar listing of TNF inhibitors was associated with substantial reductions in national medicine expenditure in Australia. The magnitude of savings varied markedly by molecule and was strongly influenced by the timing of biosimilar entry and subsequent pricing mechanisms, highlighting timely biosimilar availability as a critical and modifiable policy lever for maximising cost savings.

Keywords: Biosimilars; Biologics; Pharmacoeconomics

234

Clinical and Developmental Outcomes of Cyclosporine versus Methotrexate in Pediatric Atopic Dermatitis

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Introduction: Pediatric patients with moderate-to-severe atopic dermatitis (AD) may require systemic therapy such as cyclosporine or methotrexate. However, real-world comparative evidence on broader clinical and developmental outcomes remains limited.

Aims: This study aimed to compare clinical and developmental outcomes following cyclosporine versus methotrexate initiation among pediatric patients aged 2–18 years with AD.

Methods: We applied a target trial emulation framework using retrospective cohort data from the TriNetX US Collaborative Network. We identified new users of cyclosporine or methotrexate aged 2–18 years with AD between 2015 and 2025. Patients with juvenile arthritis, systemic lupus erythematosus, or prior azathioprine or dupilumab use were excluded. One-to-one propensity score matching was performed. Clinical outcomes comprised effectiveness-related outcomes, including systemic corticosteroid rescue, very-high-potency topical corticosteroid exposure, and skin and soft tissue infection (SSTI), as well as safety outcomes, including renal and hepatic dysfunction. Developmental outcomes comprised physical developmental outcomes and neurodevelopmental outcomes. Patients were followed for up to 3 years, and Cox proportional hazards models were used to estimate hazard ratios (HRs) and 95% confidence intervals (CIs).

Results: Among 2,373 eligible patients, 957 initiated cyclosporine and 1,416 initiated methotrexate. After matching, 836 patients were retained in each group. Compared with methotrexate, cyclosporine initiation was associated with higher risks of systemic corticosteroid rescue (HR, 1.12; 95% CI, 1.01–1.25), very-high-potency topical corticosteroid exposure (HR, 1.23; 95% CI, 1.03–1.45), and SSTI (HR, 1.22; 95% CI, 1.01–1.49). Cyclosporine showed numerically lower, but non-significant, risks of renal dysfunction (HR, 0.88; 95% CI, 0.71–1.09), hepatic dysfunction (HR, 0.70; 95% CI, 0.47–1.02), physical developmental outcomes (HR, 0.77; 95% CI, 0.54–1.10), and neurodevelopmental outcomes (HR, 0.89; 95% CI, 0.67–1.18).

Conclusions: These findings suggest that cyclosporine initiation, compared with methotrexate initiation, was associated with less favorable effectiveness outcomes, while no clear differences in safety or developmental outcomes were observed.

Keywords: atopic dermatitis, cyclosporine, methotrexate.

235

Real-World Sjögren's Syndrome Study using reginal electronic health record: Nanjing Retrospective Cohort

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Introduction: Sjögren's syndrome (SS) is a chronic systemic autoimmune disease with a marked female predominance, affecting over 4.5 million individuals in China. Despite this substantial public health burden, large-scale, region-specific real-world data on SS epidemiology and treatment patterns are lacking, particularly in Nanjing, Eastern China.

Aims: To assess the epidemiology and real-world treatment patterns of adult SS patients in Nanjing, Eastern China, from 2020 to 2025.

Methods: This retrospective cohort study analyzed electronic health records from the Nanjing Medical & Healthcare Data Factor Circulation Platform (2018–2025). Adults with ≥1 SS-specific ICD-10 code during 2020–2025 were included; those with only localized dryness, prior radiotherapy, HIV, or sarcoidosis were excluded. Pre-2020 SS diagnoses defined prevalent cases. Incidence and prevalence per 100,000 population were estimated with 95% Poisson confidence intervals. Treatment patterns were assessed, and a Sankey diagram visualized medication transitions.

Results: Of 70,405 screened patients, 57,533 were eligible, yielding 44,666 incident SS cases (93.4% primary, 6.6% secondary). Annual incidence declined from 87.7 to 75.1 per 100,000, while prevalence rose from 193.91 to 243.56 per 100,000. Patients were predominantly female (84.7%) and aged ≥50 years (65.1%). Common comorbidities included hypertension (19.7%) and central nervous system disorders (11.4%); pre-diagnosis, topical therapies were common and oral NSAIDs were used by 17.9%. At initial diagnosis, hydroxychloroquine was most prescribed (40.9%), followed by conventional synthetic DMARDs (21.8%) and corticosteroids (14.6%); biologic use was minimal (0.03%). For the longitudinal treatment analysis, approximately 33.1% (n=14774) of incident patients with adequate follow-up adherence were included.

Conclusions: This large real-world cohort reveals a declining incidence but rising prevalence of SS in Nanjing, predominantly affecting women and individuals aged ≥50. Conventional therapies, especially hydroxychloroquine, dominate initial management with negligible biologic use, highlighting an unmet need for advanced therapeutics and providing evidence to guide regional healthcare planning.

Keywords: Sjögren's syndrome; epidemiology; treatment patterns

236

Examining trends in postpartum domperidone use in Australia: a retrospective cohort study

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Introduction: Domperidone is frequently prescribed postnatally to enhance lactation, however its use for this indication remains controversial owing to mixed efficacy and safety data, with particular concerns about QT prolongation. No Australian studies have examined patterns of domperidone prescribing in the general practice setting.

Aims: To describe longitudinal trends in postpartum domperidone prescribing, and to characterise dosing practices, electrocardiogram (ECG) monitoring rates, and between-practice variation across prescribing quality indicators.

Methods: Retrospective cohort study of women aged 18–49 years with one or more general practice encounters within six months of a live birth between 2011–2021, using the large general practice research dataset MedicineInsight. Individual patient prescription records were examined with data extracted on daily dose and treatment duration. Data on ECG monitoring was extracted from encounter notes, pathology tests and billing data. We examined differences in likelihood of domperidone prescribing according to patient characteristics using generalised linear modelling. Between-practice variation was quantified using two-level logistic regression with intraclass correlation coefficients (ICC), which included adjustments for differences in patient case mix across practices.

Results: Of 188,874 eligible live births, 16,645 (8.8%) received domperidone, increasing from 5.7% in 2011 to 11.4% in 2021. Most women (84.5%) were prescribed a dose of 30 mg/day or lower, with more than half (53.1%) having a treatment duration exceeding 28 days. Documentation of ECGs was infrequent occurring in less than 2%. Substantial between-practice variation was evident across dose, treatment duration, and ECG monitoring (ICCs ranging from 14% to 33%, all p-values <0.001).

Conclusions: Despite ongoing safety concerns, domperidone prescribing postpartum appears to be substantially increasing over time, with significant variation in prescribing practices and safety monitoring rates. Targeted quality improvement interventions at the practice level appear warranted, alongside updated prescriber guidance that addresses the gap between recommended and observed clinical practice.

Keywords: domperidone; galactagogue; lactation

237

Examining variation in contraceptive prescribing in Australian general practice

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Introduction: General practice is the primary setting for contraceptive care in Australia; however, no studies have examined the extent to which contraceptive prescribing varies across individual general practices.

Aims: This study aimed to assess variations in the prescribing of long-acting reversible contraceptives.

Methods: A retrospective cohort study of >1.6 million females aged 15-49 years attending 423 general practices between 2011 and 2021 was conducted, using a national research dataset, MedicineInsight. For each calendar year, we calculated the proportion of general practices that prescribed levonorgestrel intrauterine devices (LNG-IUDs), copper IUD and implants among practices that delivered any care to females of reproductive age and stratified results by practice remoteness. Variation in contraceptive prescribing across general practices was assessed using intraclass correlation coefficients (ICCs) derived from two-level logistic regression models adjusted for differences in patient case-mix between practices.

Results: Significant increases in the proportion of practices prescribing were observed for LNG-IUDs (from 83.1% in 2011 to 93.4% in 2021), implant (87.2% to 98.1%) and Copper IUD (3.0% to 37.8%). In 2011, IUD and implant prescribing was greater among sites located in regional/remote areas, however these differences were no longer evident in 2021. Using ICC, the highest level of variation in prescribing attributable to differences between general practices was evident for copper IUD (40%; 95%CI; 30-50%), LNG-IUD (21%; 95%CI; 17-23%) and implant (7%; 95%CI; 5-8%).

Conclusions: The proportion of Australian general practices prescribing long-acting reversible contraceptives increased over time. Observed differences in contraceptive prescribing were largely explained by patient demographic characteristics rather than differences between general practices.

Keywords: Contraception; drug utilisation; Long-acting reversible contraceptive

238

Insights on perinatal psychotropic medicine use in a population-based Australian study

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Introduction: Mental illness is common perinatally, and psychotropic medicines are recommended when clinically indicated, yet fetal and infant safety concerns often prompt treatment changes during these high-risk periods.

Aims: To describe patterns of psychotropic medicine utilisation across the perinatal period.

Methods: We conducted a retrospective population-based cross-sectional study using linked administrative data from the Early Life Course platform in New South Wales, Australia, including pregnancies with conception and childbirth between July 2013 and December 2018. We calculated monthly dispensing rates, prevalence, and incidence of psychotropic medicine use (antidepressants, antipsychotics, anxiolytics/hypnotics/sedatives, and attention-deficit/hyperactivity disorder [ADHD] medicines) from 12 months pre-conception to 12 months post-birth.

Results: The cohort included 453,923 pregnancies resulting in a birth, with 749,697 psychotropic medicines dispensed to 76,547 women (11.1%) across the pre-conception, pregnancy, and post-birth periods. Antidepressants were most commonly used across all periods (pre-conception prevalence 8.8%; pregnancy 4.8%; post-birth 10.0%), followed by anxiolytics/hypnotics/sedatives (3.4%; 0.9%; 2.4%), antipsychotics (0.8%; 0.5%; 0.8%), and ADHD medicines (0.2%; 0.1%; 0.1%). Monthly exposure declined from pre-conception through pregnancy, with the largest reductions in early pregnancy across all classes, and a further decline in late gestation for antidepressants and antipsychotics, alongside a relative increase in anxiolytic/hypnotic/sedative use. Postpartum use returned to pre-conception levels for most classes; however, antidepressant use exceeded pre-conception levels and showed a transient rise in initiation in the first two months postpartum before returning to baseline.
Conclusions: Psychotropic use declined substantially in early pregnancy and before childbirth, indicating discontinuation and low initiation despite guidelines against routine cessation. Although antidepressant use rose postpartum, overall prevalence (10%) fell below estimated perinatal depression and anxiety prevalence (12–17%), suggesting undertreatment. These findings highlight the need for better education, clearer safety guidance, and ongoing surveillance.

Keywords: perinatal, pharmacoepidemiology, psychotropics

239

Psychiatric disease relapse after antipsychotic discontinuation during pregnancy: a target trial emulation

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Introduction: While the safety of antipsychotic use during pregnancy has been established in previous literature, discontinuation of antipsychotics in pregnant women remains common. Evidence regarding the risks of relapse after discontinuing antipsychotics during pregnancy remains limited.

Aims: To compare the risk of psychiatric disease relapse during pregnancy and within 90 days postpartum between those who discontinued antipsychotics within the first trimester and those who remained on treatment.

Methods: Target trial emulation using territory-wide electronic medical records in Hong Kong. Pregnant women with live births between 2001-2023 who received antipsychotics for a consecutive ≥90 days immediately before start of pregnancy were included. They were followed up from start of pregnancy (i.e. last menstrual period) till earliest of outcome occurrence, 90 days postpartum, death, or 31-Dec-2023. Primary outcome was psychiatric disease relapse, defined as psychiatric hospitalisation. Clone-censor-weight approach was used to minimize immortal time bias. Weighted pooled logistic regression adjusted for baseline covariates (age, index year, parity, socioeconomic status, psychiatric diagnoses, psychotropic medications) were used to estimate the risks of outcomes.

Results: 1,455 eligible pregnant episodes were included. 237 psychiatric hospitalisations were observed during a median (interquartile range) follow-up of 349 [195-363] days. Discontinuation of antipsychotics during first trimester was associated with increased risk of psychiatric hospitalisations compared to remaining on treatment (hazard ratio [95% CI]: 1.355 [1.023, 1.793], risk difference at 90-days postpartum [95% CI]: 7.74% [1.73, 14.46]), especially in those aged <35 years, with schizophrenia, received first-generation antipsychotics, or received ≥1 defined-daily-dose of antipsychotics.

Conclusions: Discontinuation of antipsychotics during the first trimester was associated with increased risks of psychiatric disease relapse during pregnancy and within 90 days postpartum. Considering the maternal and neonatal safety of antipsychotic use during pregnancy reported in previous literature, remaining on antipsychotic treatment may be preferred over discontinuation during pregnancy.

Keywords: Antipsychotic discontinuation, pregnancy, disease relapse

240

Cardiovascular risk of menopausal hormone therapy in type 2 diabetes in England

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Introduction: Menopausal hormone therapy (MHT) prescribing has increased substantially in the United Kingdom (UK). Although MHT increases the risk of some cardiovascular diseases (CVD) in the general population, it is not contraindicated in women with diabetes. Therefore, evaluating the cardiovascular safety of MHT in this high-risk population is important.

Aims: We aimed to compare the risk of CVD between MHT initiators and non-initiators among women aged 48-55 years with type 2 diabetes in England.

Methods: We used data from the UK Clinical Practice Research Datalink (CPRD) linked to hospital and death records from January 2004 to June 2024. Women with prior CVD outcomes, breast or ovarian cancer, primary ovarian insufficiency, or surgical menopause were excluded. Sequential monthly trials were emulated from the date women reached the minimum eligible age, with inverse probability of treatment weighting (IPTW) to emulate randomisation. Pooled logistic regression estimated one-year risk ratios (RRs) for major adverse cardiovascular events (MACE), defined as cardiovascular death, myocardial infarction (MI), or stroke.

Results: A total of 85 trials were emulated, including 9,389 and 492,236 person-trials in initiator and non-initiator group, respectively. No significant differences in MACE were observed between groups in either intention-to-treat (ITT) or per-protocol (PP) analyses (ITT: RR 1.07 [95% CI 0.71-1.42]; PP: RR 1.16 [95% CI 0.71-1.58]). Analyses by individual outcomes showed similar results, with no significant differences observed. ITT analyses by route of administration showed no significant differences (oral: RR 1.36 [95% CI 0.62-2.26]; transdermal: RR 0.55 [95% CI 0.18-1.19].

Conclusions: In this emulated target trial, we did not observe an increased risk of MACE with MHT among women with type 2 diabetes aged 48–55 years. Route-specific analyses suggested a potentially lower risk with transdermal versus oral MHT, although wide confidence intervals may indicate limited power to detect differences.

Keywords: cardiovascular, diabetes, menopausal hormone therapy

241

Prescription Patterns in Antipsychotic Use During Pregnancy: A 17-Year Population-based Study

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Introduction: The use of antipsychotic medications during pregnancy requires careful risk-benefit consideration. Thus, managing maternal psychiatric conditions is critical. However, long-term epidemiological data in Asian populations remain limited.

Aims: This study aimed to investigate the prevalence and trends of antipsychotic use among pregnant women in Taiwan from 2004 to 2020.

Methods: This population-based cohort study utilized Taiwan's National Health Insurance Research Database and the National Birth Certificate Application database. A total of 3,261,859 pregnancies between 2004 and 2020 were identified. Women with at least 1 dispensed antipsychotic prescription during pregnancy were classified and further stratified into first-generation (FGAs) and second-generation antipsychotics (SGAs). Annual prevalence in the use of antipsychotics was assessed. We also conducted sensitivity analysis by excluding antipsychotic agents that were commonly prescribed for emesis and peptic ulcer (prochlorperazine, droperidol, and sulpiride).

Results: The overall prevalence of antipsychotic use was 8.40% during pregnancy. The prevalence of FGA use decreased from 2004 (10.14%) to 2014 (6.89%), before rising slightly to 8.19% in 2020. In contrast, SGA use remained stable between 2004 (0.45%) and 2008 (0.41%), halved in 2009 (0.17%), and increased slowly to 0.25% in 2020. In the sensitivity analysis, the overall prevalence dropped remarkably to 0.11%, and the prevalence of FGA use demonstrated a nearly threefold steady decrease from 2004 (0.14%) to 2020 (0.05%), whereas the SGA use increased from 2004 (0.01%) to 2020 (0.09%).

Conclusions: The overall prevalence of antipsychotics was a U-shaped trend with the lowest point in 2014. A distinct shift pattern in generation was observed over the 17 years, highlighting the changes in clinical practice. A more sophisticated definition of the use of antipsychotic agents was needed.

Keywords: Antipsychotics, Prevalence, Pregnancy

242

National oral health screening for oral cancer prevention: sequential target trial emulation

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Introduction: South Korea operates the National Oral Health Screening Program (NOHSP) biennially. The program primarily focuses on screening for dental caries and does not sufficiently include oral mucosal examinations for oral cancer screening. Although a few studies have attempted to evaluate cancer prevention effects of the program, evidence remains limited.

Aims: We aimed to assess the effectiveness of regular NOHSP screening in reducing the incidence of oral cancer. Based on a sequential trial emulation, we sought to adequately control for baseline differences between cohorts.

Methods: From a nationwide screening-based claims database in South Korea, we identified participants aged 40-79 with no oral cancer history from 2010 to 2014. They were followed up to 14 years, until deviation from the plan, censoring, death, or oral cancer occurrence, whichever came first. Propensity scores were matched between the screened (≥3 times within five-year grace period) and non-screened groups. We estimated hazard ratios (HRs) and their 95% confidence intervals (95%CIs), considering individuals as a cluster unit, using two approaches: pooled Cox models with or without stratification by trial; and a weighted Cox model after clone-censor-weighting (CCW).

Results: The matched dataset consisted of 22,398 pairs, with no significant differences observed in baseline characteristics between the two groups (all P>0.1). The median follow-up times were 11.45 years for the screened group and 9.03 years for the non-screened group. The pooled Cox model without trial stratification yielded an HR of 0.867 (95%CI=0.552-1.360). When considering trials as strata, the HR was 0.866 (95%CI=0.552-1.359). The HR estimated using the CCW approach was 0.833 (95%CI=0.468-1.482).

Conclusions: Regular NOHSP screening was associated with a lower estimated incidence of oral cancer, although the association was not statistically significant. Further improvements are needed to enhance early detection across a broader range of oral conditions.

Keywords: Sequential target trial; Screening program; Cancer prevention

243

BRIDGE: barrier-informed Bayesian prediction of cardioprotective medication non-adherence trajectories in primary care

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Introduction: Non-adherence to lipid-lowering therapy is common and contributes to preventable cardiovascular morbidity and mortality. Standard adherence measures summarise medication coverage but not how patients disengage over time. We developed BRIDGE, a barrier-informed Bayesian model, to predict adherence trajectories and identify plausible intervention targets.

Aims: The overarching aim of BRIDGE is to provide point of care decision support to clinicians to facilitate better adherence to cardioprotective medicines and prevent future CVD events.

Methods: This nationwide, multicentre model-development and prospective external-validation study used de-identified primary-care records from IQVIA-network general practices. Incident lipid-lowering therapy initiators were identified using a 365-day pre-index washout. Adherence trajectories were derived from prescription records using group-based trajectory modelling. BRIDGE used a monotone-spline multinomial-softmax architecture over 108 routinely available features, with World Health Organization-aligned hierarchical priors informed by patient-reported barriers. The model was developed in 2014-2017 initiators and externally validated in the 2018-2020 cohort. Generalisability was assessed using temporal validation in later initiators and geographic-temporal validation excluding Queensland, Victoria, and Western Australia from training. BRIDGE was benchmarked against random forest and XGBoost.

Results: The development cohort included 50,857 adults. Four trajectories were identified: gradual decline (10.4%), early discontinuation (40.6%), rapid decline (28.8%), and persistent adherence (20.2%). In temporal validation, BRIDGE showed stronger discrimination than XGBoost and random forest (AUROC 0.723 [0.720-0.726]) and matched the best accuracy (0.550 [0.544-0.557]). In geographic-temporal validation, BRIDGE led across discrimination, accuracy, and calibration, with AUROC 0.721 (0.716-0.725), accuracy 0.558 (0.549-0.568), and Brier score 0.618 (0.606-0.629). Counterfactual analyses suggested trajectory-specific intervention priorities.

Conclusions: BRIDGE provides interpretable, behaviour-informed prediction of lipid-lowering therapy adherence trajectories from routine primary-care records, identifying different modes of preventable cardiovascular treatment failure early enough to support tailored follow-up, medication review, and shared decision making.

244

Methodological Gaps in Clone-Censor-Weight Approach for Target Trial Emulation: A Systematic Review

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Introduction: The clone-censor-weight (CCW) method is increasingly applied in target trial emulation (TTE) to mitigate immortal time bias. However, inconsistencies in its methodological implementation pose challenges for valid causal inference using real-world data.

Aims: We systematically mapped current CCW practices in TTE studies to identify key methodological gaps throughout the core steps of CCW implementation.

Methods: We searched Medline, Embase, Cochrane Library, and Web of Science for observational studies (2016–2025) utilizing CCW. Two independent reviewers extracted 38 methodological items per study. Descriptive statistics were used to summarize the frequencies of key methodological features.

Results: The final analysis included 121 eligible studies, predominantly within infectious diseases (27.3%), oncology (19.8%), and cardiovascular diseases (12.4%). Drawing on key findings from the 38 extracted methodological items, we describe core CCW implementation practices and identify several critical methodological gaps. Clones per individual ranged from 2 to 81 (median: 2); grace periods ranged from 1 to 365 days (median: 56). Only 39 studies (32.2%) conducted sensitivity analyses on the grace period length, and 72 (59.5%) provided a clinical or literature-based justification. Artificial censoring weights were primarily estimated via pooled logistic regression (43.8%), Cox regression (22.3%), or standard logistic regression (15.7%). Notably, 54 studies (44.6%) failed to account for time-varying covariates during artificial censoring step. To handle extreme weights, 56 studies (46.3%) used truncation, 14 (11.6%) used only stabilization, and 51 (42.1%) reported no method. For confidence interval estimation, 88 studies (73.3%) utilized non-parametric bootstrapping, while 27 (22.5%) failed to report corrections for cloning-induced clustering.

Conclusions: Despite the growing adoption of CCW, significant methodological gaps persist. Infrequent sensitivity analyses on grace periods, the failure to include time-varying covariates in censoring models, and underreporting of clustering corrections threaten real-world causal inference. Standardized CCW reporting guidelines are urgently needed.

Keywords: clone-censor-weight, target trial emulation, immortal time bias, methodological review

245

Operationalizing Thyroid Eye Disease Identification in Taiwan Using Patient Journey-Based EHR Approach

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Background: Per International Council for Harmonisation (ICH) M14, use of real-world data for decision-making requires clear rationale and reproducible identification of the study population. This is challenging in thyroid eye disease (TED), where diagnosis, disease activity, and severity are variably captured due to both disease complexity and differences in healthcare practice and structured documentation across health care systems.

Objectives: To operationalize TED identification in Taiwan using a patient journey-based electronic health record (EHR) approach.

Methods: Guided by a patient journey-based approach, we identified individuals with Graves' disease and ophthalmology visits in the Chang Gung Research Database (CGRD) between 2016 and 2024, reflecting expected eye-care visits among TED patients. Structured data extraction from the claims-based module of the EHR and review of free-text physician's notes in the electronic medical charts were conducted on a random sample of 500 eligible patients to identify physician-confirmed TED cases (the gold standard) and to evaluate the implications of relying on structured data alone. We developed candidate algorithms based on diagnostic codes, examination codes, or their combinations using the structure data. We estimated sensitivity, specificity, positive predictive value (PPV), and F-score, a harmonic mean between sensitivity and PPV, against the physician-confirmed TED diagnosis.

Results: Chart review confirmed 102 (20.4%) TED cases. The performance (i.e. sensitivity, specificity, PPV and F-Score) of selected candidate algorithms were: diagnosis-based algorithm (proptosis or diplopia or eyelid retraction): 56.9%, 95.0%, 74.4% and 64.4%; examination-based algorithm using Hertel examination or Hess chart test: 79.4%, 94.0%, 77.1% and 78.2%; diagnosis/exam-combined algorithm: 85.3%, 91.2%, 71.3% and 77.7%.

Conclusions: This work demonstrates a practical framework for applying ICH M14 principles to operational definitions through integration of structured and unstructured EHR data. These algorithms offer different options for TED identification and can be selected according to the specific research objective and available data sources.

246

Development and Validation of Machine-Learning Prediction Models for Risperidone Response in Dementia

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Introduction: Risperidone is widely used in people with dementia and has an approved indication for behaviours and psychological symptoms of dementia (BPSD) in some countries. However, its clinical use is challenging, as treatment effects are modest and heterogeneous, while risks remain substantial.

Aims: We aimed to develop and evaluate clinical prediction models to estimate individual response to risperidone for BPSD.

Methods: Individual participant data from four randomised trials of risperidone use in dementia were harmonised. Three trials (N=1,327) were used for model development and one (N=337) for external validation. Symptom improvement was assessed using the Behavioural Pathology in Alzheimer's Disease (BEHAVE-AD) scale. Potential risperidone-associated adverse drug events (ADEs) included major cardiovascular events, extrapyramidal symptoms, and somnolence. Outcomes included improvement in BEHAVE-AD score (overall, psychosis, aggression) and composite benefit–risk categories (low ADE risk–high therapeutic benefit and high ADE risk–low therapeutic benefit). Predictors included risperidone use, demographic factors, and clinical characteristics. Conditional inference forest, random forest, and XGBoost models were trained and evaluated in internal–external cross-validation and external validation. Individualised treatment effect (ITE) was assessed using concordance-statistic for benefit.

Results: In the external dataset, our models can predict overall BPSD (c-statistic: 0·76; 95% CI: 0·70 to 0·83) and psychosis (c-statistic: 0·81; 95% CI: 0·75 to 0·87) improvement at week 8. Models distinguished patients benefiting from risperidone for overall BPSD (c-for-benefit: 0·74; 95%CI: 0·66 to 0·82) and psychosis (c-for-benefit: 0·71; 95%CI: 0·60 to 0·80) outcomes. They can identify those with low ADE risk-high therapeutic benefit for psychosis outcomes (c-statistic: 0·76; 95% CI: 0·69 to 0·83). Performance for aggression-related outcomes was limited.

Conclusions: Clinical prediction models can predict the ITE of risperidone for overall BPSD and psychosis. This approach could support personalised treatment decisions in BPSD, although further real-world validation is required before clinical implementation.

Keywords: antipsychotics, machine learning, clinical prediction models

247

Drug Repurposing for Dengue Fever Prevention Using Tree-Based Scan Statistics

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Introduction: Dengue fever is a major public health concern in tropical and subtropical regions, including Taiwan. Severe dengue can lead to life-threatening complications and substantial mortality. Currently, no specific antiviral treatment is available, and management remains largely supportive. Identifying existing medications with potential protective effects against dengue may facilitate drug repurposing and reduce disease burden.

Aims: To systematically identify medications potentially associated with a lower risk of dengue fever using a hypothesis-generating data-mining approach.

Methods: We conducted a population-based case-control study using Taiwan's National Health Insurance Research Database (NHIRD). Individuals with incident dengue fever between 2013 and 2024 were identified as cases and matched with up to 10 controls on age, sex, calendar time, general health status, and healthcare utilization. The index date was defined as the dengue diagnosis date for cases and the corresponding matched date for controls. Tree-based scan statistics were used to compare prior medication exposures, organized according to the hierarchical Anatomical Therapeutic Chemical (ATC) classification system, within 30-, 91-, 183-, and 365-day windows before the index date. Signals were evaluated at the 4-, 5-, and 7-digit ATC levels, with p-values <0.01 considered statistical alerts.

Results: A total of 88,605 incident dengue cases and 723,671 matched controls were included. 1378 and 1513 drugs were identified before index date from cases and controls. Significant alerts identified medications with anti-inflammatory or immunomodulatory properties, including antimalarials (P01B) and aminoquinolines (P01BA), purine derivatives (C04AD), and pitavastatin (C10AA08). Additional signals included vitamin D and analogues (A11CC), cough suppressants and expectorants other than opium derivatives (R05FB), opium alkaloid-based cough suppressants (R05DA05), and zopiclone (N05CF01).

Conclusions: The study has identified existing medications associated with a lower occurrence of dengue fever, provided potential candidates for drug repurposing and generated hypotheses for future pharmacoepidemiologic and mechanistic validation studies.

Keywords: dengue fever; drug repurposing; tree-based scan statistics

248

Increased ischemic risk with P-CAB or PPI in clopidogrel-treated stroke patients

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Introduction: Clopidogrel is commonly used after ischemic stroke, and acid-suppressive agents are often prescribed to reduce gastrointestinal complications. However, the effects of P-CABs and PPIs on clopidogrel-related outcomes remain uncertain.

Aims: This study evaluated the efficacy and safety of concomitant P-CAB or PPI use in patients with ischemic stroke receiving clopidogrel.

Methods: We conducted a retrospective cohort study using nationwide claims data from 2016 to 2022. Patients with first-recorded ischemic stroke were identified using prespecified criteria and grouped as clopidogrel only, clopidogrel with P-CAB, or clopidogrel with PPI. After propensity score matching, 6-month risks of major adverse cardiovascular events, recurrent stroke, and gastrointestinal bleeding were compared.

Results: Among 65,180 patients with newly identified stroke between 2017 and 2021, 40,752 (62.5%) received clopidogrel. Of these, 6680 (16.4%) received clopidogrel alone, 578 (1.4%) received clopidogrel with P-CAB, and 8806 (21.6%) received clopidogrel with PPI. Recurrent stroke occurred in 268 (4.0%), 26 (4.5%), and 431 (4.9%) patients, respectively. In matched analyses, P-CAB use was associated with increased risks of major adverse cardiovascular events (HR, 2.40 [95% CI, 1.18–4.85]) and recurrent stroke (HR, 2.64 [95% CI, 1.27–5.47]) versus clopidogrel alone. PPI use was also associated with higher risks of major adverse cardiovascular events (HR, 1.38 [95% CI, 1.17–1.63]) and recurrent stroke (HR, 1.41 [95% CI, 1.20–1.67]). Esomeprazole showed similar associations, whereas gastrointestinal bleeding did not differ significantly among groups.

Conclusions: Concomitant use of P-CABs or PPIs with clopidogrel was associated with worse ischemic outcomes in patients with ischemic stroke. These agents should be prescribed cautiously in this population.

Keywords: Ischemic stroke, Clopidogrel, Potassium-competitive acid blockers.

249

Depression incidence following oral prophylactics and CGRP injection for migraine or headache

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Introduction: Migraine is associated with up to a six-fold increased risk of major depressive disorder, yet comparative evidence on depression risk between oral prophylactics and CGRP-targeted injections remains limited. Prospective studies have only evaluated changes in depressive symptom severity among patients with pre-existing depression instead of incident depression.

Aims: We compared depression incidence among migraine or headache patients continuing/initiating oral prophylactics versus those switching/initiating to CGRP-targeted injections.

Methods: We conducted a retrospective cohort study using the JMDC claims database up to February 2025. A prevalent new-user (PNU) design compared patients switching from oral prophylactics (propranolol, amitriptyline, valproate, lomerizine, verapamil, and dimetotiazine) to CGRP injections (erenumab, fremanezumab, and galcanezumab) versus those continuing oral prophylactics. An active-comparator new-user (ACNU) design was restricted to incident new users. All patients had migraine/headache diagnosis and no depression at baseline. Incident depression was the primary outcome. Adjusted HRs with 95% CIs were estimated from stratified Cox models with 1:4 time-conditional propensity score matching (PNU), and from IPTW Cox models (ACNU).

Results: In the PNU cohort (19,469 continued-oral, 3,783 switch-to-CGRP), switching to CGRP was not associated with a difference in incident depression versus continuing oral prophylactics (incidence rate: 7.79 vs 7.61 per 100 person-years; adjusted HR: 1.00; 95% CI: 0.87-1.16). In the ACNU cohort (137,152 oral initiators, 2,032 CGRP injection initiators), initiating CGRP was associated with a 47% lower risk of incident depression versus initiating oral prophylactics (incidence rate: 4.97 vs. 8.28 per 100 person-years; adjusted HR: 0.53; 95% CI: 0.40-0.70). Sensitivity analyses yielded consistent results.

Conclusions: Initiating CGRP injections as first-line preventive therapy was associated with a substantially lower risk of incident depression compared with initiating oral prophylactics. However, this protective association was not observed when CGRP injections were used as a later-line option after prior oral therapy.

Keywords: CGRP-targeting therapy; oral prophylactics; migraine

250

Pharmacovigilance signals and global burden trends of epilepsy: Integrated FAERS-GBD 2023 analysis

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Introduction: Epilepsy is associated with substantial economic burden and increased risks of psychiatric comorbidities, including depression. However, pharmacovigilance evidence regarding drug-associated epilepsy remains limited.

Aims: We aimed to identify the top 10 drugs associated with epilepsy-related adverse events using FAERS and to estimate the global burden of idiopathic epilepsy using GBD 2023 data.

Methods: This study utilized the United States Food and Drug Administration Adverse Event Reporting System (FAERS) to identify the top 10 drugs associated with epilepsy. Epilepsy was defined using preferred terms based on the Medical Dictionary for Regulatory Activities. Pharmacovigilance signals were identified using disproportionality analyses with the information component and reporting odds ratio (ROR), along with corresponding 95% confidence intervals (CIs). We also assess the global burden of idiopathic epilepsy between 1990 and 2023, using data from the Global Burden of Disease Study 2023. Burden of idiopathic epilepsy was assessed using disability-adjusted life years (DALYs), with 95% uncertainty intervals (UIs).

Results: Among 3,843 reported epilepsy-related adverse events, females accounted for 55.45%. Although Adalimumab was the most frequently reported drug (n=706), disproportionality signals were not significant. Imipenem/cilastatin showed the strongest signals (IC 6.24 [IC0.25, 6.11]; ROR 96.96 [95% CI, 89.13-105.49]), with disproportionality signals progressively increasing with age and peaking among individuals aged ≥70 years. Reporting trends for Natalizumab and Bupropion declined over time. In 2023, Sub-Saharan Africa had the highest age-standardized DALY rates for idiopathic epilepsy. DALY rates showed a U-shaped age distribution, peaking among children aged <5 years, and were consistently higher in males than in females.

Discussion: Several drugs showed strong pharmacovigilance signals for epilepsy, particularly imipenem/cilastatin, with disproportionately elevated risks observed among older adults. Given the substantial burden of idiopathic epilepsy across vulnerable populations and regions, enhanced neurological safety monitoring and targeted prevention strategies may be warranted.

Keywords: Pharmacovigilance, epilepsy, DALY.

251

The real-world effectiveness of anti-osteoporosis medications in reducing incident dyslipidemia risk

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Introduction: Dyslipidemia represents a major health burden and shares complex pathophysiological mechanisms with bone metabolism. Antiresorptive medications are the cornerstone of osteoporosis management, but their pleiotropic effects on lipid profiles remain controversial. The comparative impact of denosumab versus bisphosphonates on the incidence of lipid disorders is currently poorly understood.

Aims: This study aims to compare the real-world effectiveness of denosumab and bisphosphonates in reducing the risk of incident dyslipidemia. We also sought to evaluate these metabolic effects across various high-risk clinical subgroups.

Methods:We conducted a retrospective active-comparator, new-user cohort study using a large federated electronic health record network. Participants included osteoporotic patients aged 50 years and older, excluding those with baseline lipoprotein disorders to minimize confounding by indication. Incident dyslipidemia was assessed using Cox regression after a 183-day landmark period within 1:1 propensity score-matched cohorts.

Results: After matching, 62,671 patient pairs (mean age 71.2 years, 91% female) were analyzed. Denosumab initiation was associated with a significantly lower risk of incident dyslipidemia compared to bisphosphonate therapy (HR 0.92, 95% CI 0.90-0.94, $p<0.001$). This protective effect demonstrated strong robustness to unmeasured confounding (E-value 1.33). The lipid-lowering benefit was significantly amplified in patients with baseline diabetes (HR 0.786, p for interaction=0.005). Furthermore, concurrent statin utilization synergistically enhanced this metabolic protection (HR 0.826, p for interaction<0.001). Conversely, concomitant systemic steroid use completely neutralized denosumab's advantages (HR 0.987, p for interaction=0.027).

Conclusions: Denosumab therapy significantly lowers incident dyslipidemia risk in osteoporosis, especially among patients with concurrent diabetes or statin use. These findings advocate for personalizing osteoporosis treatments based on underlying cardiometabolic risks. Future prospective trials should elucidate the specific molecular mechanisms driving this benefit.

Keywords: Denosumab, Bisphosphonates, Dyslipidemia

252

Beyond suspected drugs: class-level profiling of polypharmacy ADR reports

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Introduction: Conventional pharmacovigilance focuses on the suspected drug recorded in each adverse drug reaction (ADR) report. In polypharmacy, however, a serious outcome may reflect the full set of concurrent medications rather than any single suspected agent. We asked whether class-level profiles built from all concomitant medications capture seriousness-related patterns that are attenuated when only suspected drugs are analyzed.

Objectives: To characterize medication class profiles in polypharmacy ADR reports and to test whether restricting analysis to suspected drugs underestimates the association between medication complexity and serious outcomes.

Methods: We analyzed a Korean national spontaneous ADR reporting database (2020–2024), retaining reports with five or more concomitant medications. ATC third-level classes with at least 100 reports were profiled using medication-complexity and reporting-context variables (e.g., age, sex). We applied principal component analysis, factor analysis, and Ward clustering. Sensitivity analyses compared profiles derived from all concomitant medications against those derived from suspected drugs only.

Results: Profiling identified three dimensions: medication complexity, age-related reporting, and sex-related reporting. Although seriousness was not used to build the profiles, the complexity dimension was associated post hoc with serious-event rate, hospitalization, and death. Restricting the analysis to suspected drugs substantially weakened these associations, indicating that suspected-drug-only profiles retained less of the seriousness-related structure present in the full concomitant profile. The complexity gradient persisted across age and sex strata, arguing against a simple reflection of patient demographics. Clustering separated classes into interpretable groups with distinct complexity and seriousness gradients.

Conclusion: Seriousness-related signals in polypharmacy ADR reports were expressed more strongly in the full concomitant medication class profile than in suspected drugs alone. Suspected-drug-centered surveillance may therefore overlook context-level risk that arises from the medication environment as a whole. Routinely profiling all concomitant medications could give pharmacovigilance an additional, scalable lens for flagging high-risk polypharmacy reports that current workflows leave underexamined.

253

Anticholinergic Medication-Class Patterns and Cardiovascular Risk in Older Adults: Group-Based Multi-Trajectory Analysis

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Introduction: Prior studies link high anticholinergic burden to increased cardiovascular risk in older adults, but burden scores aggregate diverse drug classes, leaving unclear whether this risk reflects cumulative burden or specific drug-class exposures. Moreover, prior studies have failed to capture the dynamic, time-varying nature of real-world anticholinergic use.

Aims: To identify multi-trajectory subtypes of anticholinergic medication-class use among older adults and evaluate their association with cardiovascular outcomes by frailty status.

Methods: Using nationwide claims database, we identified adults aged ≥65 years newly initiating Anticholinergic Cognitive Burden (ACB) Scale-listed medication in 2012. Individuals with 4-point major adverse cardiovascular events (4p-MACE) or death before or during the 3-year exposure period were excluded. Exposure across six drug categories (cardiovascular, psychotropic, antihistamine, overactive bladder, gastrointestinal, and theophylline/other) was measured quarterly and analyzed using group-based multi-trajectory modeling. Cox proportional hazards models, adjusted for age, sex, ACB score, cardiovascular risk factors, and multimorbidity frailty index (mFI), estimated hazard ratios for 4p-MACE and all-cause mortality over 9 years, with mFI-stratified subgroup analyses.

Results: Among 55,675 eligible participants (mean age 74.0± 6.4 years; 52.5% female), four subtypes were identified: transient (57.1%) and three persistent subtypes—CV-dominant (14.5%), psychotropic-dominant (16.0%), and theophylline/antihistamine-dominant (12.5%). Relative to transient users, CV-dominant and theophylline/antihistamine-dominant trajectories showed significantly higher 4p-MACE risk (aHR 1.22, 95% CI, 1.16-1.27; aHR 1.08, 95% CI, 1.03-1.13) and all-cause mortality (aHR 1.21, 95% CI, 1.16-1.26; aHR 1.15, 95% CI, 1.11-1.20). The psychotropic-dominant group showed no significant association with 4p-MACE (aHR 0.99, 95% CI, 0.94-1.04) but a significantly higher mortality risk (aHR 1.11, 95% CI, 1.07-1.16). Risks attenuated to non-significance in the severely frail stratum (CV-dominant 4p-MACE: aHR 1.00, 95% CI, 0.81-1.24).

Conclusions: Associations between anticholinergic medications and cardiovascular or mortality outcomes are drug-class specific and frailty-dependent, supporting composition-based rather than purely cumulative risk assessment.

Keywords: anticholinergic burden, multi-trajectory modeling, cardiovascular risk

II. Spotlight Poster Presentations

Abstract SP01 - SP28

SP01

Effectiveness and safety of statins in patients with type 1 diabetes mellitus

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Introduction: Individuals with type 1 diabetes mellitus (T1DM) are at increased risk of cardiovascular disease. However, specific evidence for statins in T1DM remains limited and is extrapolated from individuals with type 2 diabetes.

Aims: To evaluate the effectiveness and safety of statins in children and adults with T1DM.

Methods: We searched Medline and Embase from inception to 20 January 2026, with backwards citation searching of reference lists using Scopus. Randomized controlled trials (RCTs) with ≥1000 participants or individual participant data (IPD) meta analyses, and observational studies with ≥2 years of average follow up evaluating statin use in T1DM were eligible for inclusion. The primary outcomes were myocardial infarction, stroke, major adverse cardiovascular events (MACE), and all cause mortality. Secondary safety outcomes included myopathy, liver injury, and worsening of glucose control. Random-effects meta-analyses were performed to pool outcomes reported in at least two cohort studies.

Results: We included six studies of adults with T1DM, comprising five cohort studies (n=63,143) and one IPD meta-analysis of statin RCTs (n=1,466). Statins were associated with reductions in myocardial infarction (hazard ratio [HR] 0.75, 95% CI 0.67–0.85; 3 studies; I^2=0.0%), stroke (HR 0.83, 95% CI 0.71–0.98; 2 studies; I^2=38.4%), MACE (HR 0.80, 95% CI 0.73–0.87; 2 studies; I^2=0.0%), and all-cause mortality (HR 0.64, 95% CI 0.49–0.85; 2 studies; I^2=85.8%). In one study, statin use was associated with an increase in liver dysfunction but not myopathy. In another study, statins were associated with reduced insulin sensitivity.

Conclusions: Although the evidence of statin effectiveness and safety is largely derived from a limited number of observational studies, this evidence indicates that statins reduce cardiovascular events and mortality in adults with T1DM. Further research is needed to clarify the effectiveness and safety of statins in children and young adults.

Keywords: type 1 diabetes mellitus; statins; cardiovascular outcomes

SP02

Tyrosine kinase inhibitors and metabolic disease in chronic myeloid leukemia patients

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Introduction: Tyrosine kinase inhibitors (TKIs) are the standard first-line treatment for chronic myeloid leukemia (CML), requiring long-term administration to sustain molecular remission and prevent relapse. As survival improves, metabolic adverse effects of TKIs, particularly second-generation agents, have become a clinical concern. However, evidence remains limited by small sample sizes, short follow-up duration, and methodological constraints, limiting comparisons of agent-specific metabolic risk.

Aims: This study investigated the incidence of type 2 diabetes mellitus (T2DM), hyperlipidemia, and hypertension among patients with CML treated with imatinib, nilotinib, or dasatinib.

Methods: This prevalent new-user, active-comparator, 1:1 propensity score-matched (PSM) cohort study used the National Health Insurance Research Database and Taiwan Cancer Registry to identify adults with newly diagnosed CML (2013-2023) who initiated nilotinib or dasatinib, including switchers from imatinib, matched to imatinib users by exposure duration. Incidence rate ratios and hazard ratios (HRs) with 95% confidence intervals (CIs) were estimated using Poisson and Cox proportional hazards regression, respectively.

Results: Following PSM, the matched diabetes, hyperlipidemia, and hypertension cohorts comprised 552, 609, and 487 nilotinib users and 688, 725, and 598 dasatinib users, respectively. Compared with imatinib, nilotinib was associated with a significantly higher risk of incident hyperlipidemia (HR 3.08; 95% CI, 1.78-5.32), while its risks of T2DM and hypertension were not significantly different. Dasatinib was associated with a significantly lower risk of incident T2DM (HR 0.39; 95% CI, 0.19-0.78) and a significantly higher risk of hypertension (HR 1.82; 95% CI, 1.05-3.18), with no significant difference in hyperlipidemia risk (HR 1.43; 95% CI, 0.88-2.32).

Conclusions: Among patients with CML, nilotinib was associated with an increased risk of hyperlipidemia relative to imatinib, while dasatinib was associated with a lower risk of T2DM but a higher risk of hypertension. These findings support routine metabolic monitoring during CML treatment.

Keywords: Chronic myeloid leukemia; Tyrosine kinase inhibitors; Metabolic disease

SP03

Granuloma recurrence post-cauterisation in peritoneal dialysis: a self-controlled case series analysis

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Introduction: Timely treatment and prevention of over-granulating peritoneal dialysis (PD) exit site is warranted to mitigate risk of life-threatening complications. However, temporal patterns of granuloma recurrence post-treatment remained rarely described. Understanding of post-treatment recurrence rates over time is important to guide management strategies.

Aims: To characterise the temporal pattern of granuloma recurrence rates post-cauterisation (with silver nitrate/ diathermy) for over-granulating exit site in PD patients.

Methods: This ambispective study conducted in a tertiary hospital at Malaysia involved PD clinic patients with over-granulating exit site from Year 2021-2025 using self-controlled case series approach to eliminate residual time-invariant confounding and confounding by indication. Treatment details and clinical information were collected from the electronic medical records. Median time to recurrence and 95% confidence intervals (CIs) were estimated using Kaplan-Meier method. Incidence rate ratios (IRRs) and 95% CIs for recurrence of granuloma during each 6 weeks-interval risk period were estimated using conditional Poisson regression, with ≥30 weeks from treatment initiation as reference, using R 4.5.0.

Results: The study cohort of 358 patients consists of 339 (58.2%) episodes with silver nitrate (Avoca® Caustic Pencil 95%w/w Cutaneous Stick, Bray Healthcare, United Kingdom) and 243 (41.8%) episodes with diathermy. The median time to recurrence was 133 days (95% CI: 114-173) for diathermy and 118 days (95% CI: 108-133) for silver nitrate. A trend towards lower recurrence was observed for diathermy [1st-6th week (IRR 0.059, 95% CI: 0.026-0.133) & 7-12th week (0.586, 0.363-0.945)] that waned over time after 12 weeks (95% CIs crossed 1.0). Silver nitrate showed similar protective pattern [1st-6th week: 0.028, 0.010-0.074] with diminishing association over successive intervals after 6 weeks.

Conclusions: Lower recurrence of granuloma in PD patients was observed first 6 weeks post-treatment for silver nitrate and 12 weeks post-diathermy that waned thereafter. These findings warrant confirmation through prospective, multicentre comparative studies.

SP04

SSRI use in the first trimester of pregnancy and risk of MCMs

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Introduction: Depression during pregnancy is increasingly common, and selective serotonin reuptake inhibitors (SSRIs) are often prescribed. Prior studies addressing confounding by indication have generally reported no significant association with major congenital malformations (MCMs). However, evidence remains limited, particularly in Japanese medical situation.

Aims: We evaluated the association between first-trimester SSRI exposure and MCMs in infants. This study provides real-world evidence from a large Japanese claims database.

Methods: This retrospective cohort study used a large claims database in Japan from 2010 to 2024. Dates of pregnancy onset and delivery were estimated using validated algorithms, and overall MCMs were defined according to the International Classification of Diseases, 10th revision codes. To address confounding by indication, the analysis was restricted to pregnant women with diagnosed depression before the end of the first trimester. We compared MCM prevalence between infants born to women with and without first-trimester SSRI exposure and estimated weighted odds ratios (wORs) using propensity score–based overlap weighting.

Results: Among 185,513 women who delivered between 2010 and 2024, 5,995 had a diagnosis of depression before the end of the first trimester. Of these, 1,072 were exposed to SSRIs during the first trimester. The prevalence of overall MCMs in infants was 8.4% (370/4,429) among unexposed women and 8.1% (87/1,072) among exposed women. First-trimester SSRI exposure was not significantly associated with overall MCMs (wOR 0.969, 95% confidence interval: 0.751–1.249). Results were consistent across multiple sensitivity analyses, including restriction to women prescribed SSRIs for ≥30 days during the first trimester, change of the exposure window ±7 days, and exclusion of women with potential teratogenic conditions.

Conclusions: Exposure to SSRIs during the first trimester of pregnancy was not associated with an increased risk of overall MCMs in infants. Further evaluation of other outcomes such as neurodevelopmental disorders is warranted.

Keywords: SSRIs, pregnancy, major congenital malformations

SP05

Risk of cardiovascular events and methylphenidate/modafinil use in patients with narcolepsy

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Background: Methylphenidate (MPH) and modafinil are central-nervous-system stimulants prescribed for narcolepsy. Both agents raise sympathetic tone, yet their cardiovascular safety in patients with narcolepsy remains uncertain, and conventional cohort designs are vulnerable to between-person confounding.

Objectives: To quantify the within-person risk of incident cardiovascular events during exposure to MPH and modafinil in patients with narcolepsy, using a self-controlled case series design that eliminates time-invariant confounding.

Methods: Using Taiwan's National Health Insurance Research Database, we identified patients with narcolepsy who experienced a cardiovascular event and received MPH or modafinil. Person-time was divided into baseline (reference), pre-exposure (1–30 d), exposed (1–7, 8–14, 15–28, 29–56, >56 d) and washout (1–28 d) windows. Conditional Poisson regression estimated crude and adjusted incidence rate ratios (aIRR) with 95% confidence intervals.

Result: A total of 405 MPH users and 105 modafinil users were identified in the analysis. For MPH, risk of cardiovascular event rose sharply in the 30 days preceding initiation (aIRR 7.93, 95% CI 5.48–11.48) and in the first week of exposure (aIRR 1.73, 1.05–2.83). Risk returned to baseline thereafter. Modafinil showed a similar pattern, elevated point estimates in the pre-exposure window (aIRR 1.97, 0.47–8.19) and during early exposure (aIRR 1.35, 0.54–3.40) with limited statistical power.

Conclusions: In patients with narcolepsy, MPH was associated with a transient excess of cardiovascular events during the first week of treatment, with a striking pre-exposure spike. Clinicians should monitor cardiovascular status closely when initiating stimulants.

Keywords: narcolepsy; methylphenidate; modafinil; cardiovascular events.

SP06

Benefit and risk of statins in young adults with diabetes

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Introduction: Cardiovascular risk models relying on 10-year predictions mask the cumulative lifetime risk in young adults with diabetes mellitus. Consequently, this demographic remains systematically undertreated in primary care. This persists despite an escalating premature cardiovascular disease burden.

Aims: We aimed to evaluate the effectiveness and safety of early statin initiation for primary prevention in young adults with diabetes. Specifically, we estimated intention-to-treat and per-protocol effects of sustained therapy.

Methods: We emulated a target trial using primary care electronic health records, including 13,602 person-trials of adults aged 18–39 with diabetes and low-density lipoprotein cholesterol ≥2.6 mmol/L. Statin initiators were matched 1:4 with non-initiators via propensity scores using a sequential trial approach. Pooled logistic models with stabilized inverse probability of censoring weights estimated intention-to-treat (ITT) and per-protocol effects. Outcomes included all-cause mortality, major cardiovascular disease (CVD), myocardial infarction (MI), stroke, and heart failure.

Results: Over a median 8-year follow-up, ITT analysis showed statin initiation significantly reduced MI risk (HR 0.736, 95% CI 0.548–0.989). However, it did not significantly reduce the primary composite of major CVD or all-cause mortality (HR 0.957, 95% CI 0.829–1.105). Real-world treatment deviation was substantial, as approximately 50% of initiators discontinued therapy. In the per-protocol analysis evaluating sustained adherence, statin therapy profoundly reduced the composite risk of all-cause mortality or major CVD (HR 0.754, 95% CI 0.619–0.920, 10-year absolute risk reduction: -2.13%). Sustained therapy also reduced major CVD alone (HR 0.739, 95% CI 0.574–0.950) and MI (HR 0.647, 95% CI 0.436–0.959). Adverse hepatic or muscular events did not increase.

Conclusions: Statin initiation in young adults with diabetes is safe and beneficial when therapy is sustained. To curb premature CVD trends, primary care strategies should evolve beyond initial prescriptions. Interventions should prioritize long-term adherence to address the 50% discontinuation rate observed in routine practice.

Keywords: Statins, Diabetes mellitus, Young adults

SP07

Real-world effectiveness and safety of trastuzumab deruxtecan in non-small cell lung cancer

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Introduction: Trastuzumab deruxtecan (T-DXd) is an antibody-drug conjugate targeting HER2. The DESTINY-Lung01 trial demonstrated strong efficacy in metastatic NSCLC patients with HER2 mutation or amplification. However, real-world data regarding its effectiveness and safety in Asian populations remain limited.

Aims: This study aimed to characterize the real-world effectiveness and safety of T-DXd within a Taiwanese NSCLC cohort.

Methods: We conducted a retrospective cohort study analyzing electronic medical data from metastatic NSCLC patients who received T-DXd between April 2022 and May 2026. To isolate true T-DXd-induced ILD, only events occurring after T-DXd initiation were attributed to T-DXd, excluding patients with pre-existing ILD or ILD from prior therapies. Confirmation required CT imaging or bronchoalveolar lavage to exclude infectious etiologies. Prognostic factors including prior lines of therapy, metastatic burden, and HER2 alteration type were evaluated.

Results: A total of 52 patients were included (mean age 61.2 years; 55.8% female), with a median of 1 prior line before T-DXd initiation. Median OS was 7.7 months (95% CI: 4.3–13.7), with T-DXd-induced ILD confirmed in 13.5% of patients. Patients receiving T-DXd within 3 total lines (n=37, 71.2%) had a median OS of 10.3 months (95% CI: 7.0–21.4) versus 2.5 months (95% CI: 0.2–6.9) beyond 3 total lines (n=15, 28.8%). HER2-mutated patients (n=35, 67.3%) achieved a median OS of 10.0 months (95% CI: 6.1–19.6) compared to 2.1 months (95% CI: 0.5–6.9) in HER2-amplified patients (n=10, 19.2%). Patients without brain metastases (n=35, 67.3%) had a median OS of 10.0 months versus 7.7 months (95% CI: 2.6–13.7) in those with brain metastases (n=17, 32.7%).

Conclusions: Real-world outcomes were significantly inferior to DESTINY-Lung01, with a median OS of 7.7 versus 17.8 months. Patient selection for T-DXd therapy warrants further optimization. The ILD rate of 13.5% remained consistent with clinical trial observations.

Keywords: trastuzumab deruxtecan, non-small cell lung cancer, real-world evidence

SP08

Development of signal prioritization system for Thailand's national pharmacovigilance program

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Introduction: Pharmacovigilance signal prioritization is essential for efficient regulatory decision-making, yet Thailand lacks a standardized framework for this purpose, risking delayed or inconsistent responses to emerging drug safety signals and potentially compromising public health protection.

Aims: To develop and validate a signal prioritization system (SPS) for Thailand, adapted from the UK Medicines and Healthcare Products Regulatory Agency's (MHRA) Regulatory Pharmacovigilance Prioritization System.

Methods: The study was conducted in two phases. In Phase 1, the Thai SPS was developed through focus group discussions with key pharmacovigilance stakeholders. The developed SPS framework incorporated four weighted evaluation criteria: public health implications, regulatory obligations, strength of evidence, and public perception. Signals were classified into three priority tiers: top priority, increased priority, and standard priority. In Phase 2, the system was prospectively applied to drug–adverse event pairs identified from the Thai Vigibase, representing distinct signal categories: two confirmed signals (Andrographis paniculata–severe allergic reactions; COVID-19 vaccine [AstraZeneca]–chest pain), one monitored signal (dimenhydrinate–Stevens-Johnson syndrome/toxic epidermal necrolysis), and one refuted signal (denosumab–diabetes mellitus).

Results: The SPS demonstrated appropriate discrimination across signal categories. The AstraZeneca COVID-19 vaccine–chest pain pair was classified as top priority. Andrographis paniculata–severe allergic reactions and dimenhydrinate–Stevens-Johnson syndrome/toxic epidermal necrolysis were classified as increased priority, and denosumab–diabetes mellitus was classified as standard priority. Priority classifications aligned logically with signal confirmation status and expert opinions and were associated with defined operational response timeframes.

Conclusions: The SPS demonstrated preliminary feasibility in stratifying pharmacovigilance signals within Thailand's regulatory context, improving transparency and consistency in safety decision-making. Linking priority scores to structured risk management guidelines and defined response timeframes offers a scalable model for strengthening national pharmacovigilance systems in middle-income countries. These findings have implications for regulatory agencies seeking evidence-based frameworks for signal management prioritization.

Keywords: pharmacovigilance, signal prioritization, drug safety

SP09

Second-line antidiabetic drugs and acute pancreatitis: absolute risk and self-controlled case series

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Introduction: Despite clinical concerns regarding GLP-1 receptor agonists and pancreatitis, evidence from traditional observational studies is inconsistent

Aims: To estimate the absolute and relative within-person risk of incident acute pancreatitis across five classes of second-line antidiabetics.

Methods: Using the Japan Medical Data Center (JMDC) Payer database (January 2005-February 2025), we characterised prescription trajectories for five second-line classes (GLP-1 receptor agonists, SGLT2 inhibitors, DPP-4 inhibitors, sulfonylureas, and thiazolidinediones) and calculated the 90-day absolute risk of acute pancreatitis following each prescription episode among adults (≥18 years) with diabetes. We subsequently conducted a multidrug self-controlled case series (SCCS) among individuals experiencing a first incident acute pancreatitis episode. Person-time was categorised into 60-day pre-risk, on-treatment, and off-treatment (baseline) periods, with additional split post-initiation windows evaluated. Age- and season-adjusted conditional Poisson models estimated incidence rate ratios (IRRs) and 95% confidence intervals (CIs). Supplementary analyses assessed pancreatitis subtypes and a forearm-fracture negative control.

Results: Among 671,118 initiators, DPP-4 and SGLT2 inhibitors were the most common index classes, with 51% of patients utilising two or more classes. The 90-day absolute risk was approximately 1.0-1.5 cases per 10,000 prescription episodes across all classes. The SCCS analysis included 2,401 individuals. On-treatment IRRs were not statistically significant across all classes (GLP-1: 1.00, 0.62-1.62; DPP-4: 1.13, 0.90-1.41; SGLT2: 1.11, 0.88-1.40; sulfonylurea: 1.17, 0.80-1.73; thiazolidinediones: 0.98, 0.56-1.73), with no risk elevation observed in the split windows. Conversely, pre-risk IRRs were significantly elevated for DPP-4 (2.44, 1.96-3.03), SGLT2 (2.99, 2.42-3.68), and sulfonylureas (1.95, 1.31-2.89), but not for GLP-1 or thiazolidinediones. The lack of association with forearm fractures further confirms the robustness of our findings.

Conclusions: Absolute risk was low among initiators, and on-treatment pancreatitis risk was not observed in the SCCS. Pancreatitis risk is comparable across all five second-line anti-diabetic drugs.

Keywords: acute pancreatitis; self-controlled case series; second-line antidiabetics

SP10

Azole-induced symmetrical drug-related intertriginous and flexural exanthema: A disproportionality analysis

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Introduction: Symmetrical drug-related intertriginous and flexural exanthema (SDRIFE), also known as baboon syndrome, is a rare, benign, and self-limiting type IV hypersensitivity reaction. This is characterized by symmetrical erythema of intertriginous and flexural regions following systemic drug exposure.

Aim: This study aimed to evaluate potential safety signals associated with azole antifungals and SDRIFE using the FDA Adverse Event Reporting System (FAERS).

Methods: A retrospective pharmacovigilance study was conducted using FAERS data from the fourth quarter of 2003 to the third quarter of 2025. Data were extracted using OpenVigil 2.1, and SDRIFE cases were identified using Preferred Terms from the Medical Dictionary for Regulatory Activities (MedDRA). Disproportionality analysis was performed using the reporting odds ratio (ROR) with 95% confidence intervals (CI). Subgroup analyses based on age, sex, and individual azole agents were also conducted. A signal was considered significant when the lower limit of the 95% CI exceeded 1 and at least 5 cases were reported.

Results: A total of 72 azole-associated SDRIFE reports were identified. The overall ROR was 22.801 (95% CI: 17.827–29.162), indicating a strong association between azole antifungals and SDRIFE. Most cases occurred in adults aged 18–55 years (n=49), and females accounted for the majority of reports (n=42). Itraconazole demonstrated the strongest signal (ROR: 162.937; 95% CI: 120.530–220.264) with 46 cases, followed by clotrimazole, fluconazole, posaconazole, and voriconazole. No SDRIFE reports were identified for ketoconazole, miconazole, oteseconazole, efinaconazole, or oxiconazole.

Conclusion: This study identified a potential association between azole antifungals and SDRIFE, with itraconazole showing the strongest disproportionality signal. Further epidemiological and clinical investigations are needed to confirm these findings and explore underlying mechanisms.

Keywords: Azole antifungals; SDRIFE; pharmacovigilance.

SP11

Pharmacovigilance of Chemotherapy-Induced ADRs in Breast Cancer: A Prospective Multicenter Study

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Introduction: Chemotherapy for breast cancer is associated with a high burden of adverse drug reactions (ADRs), yet ADR reporting in Indian oncology settings remains inadequate due to limited pharmacovigilance awareness. Active surveillance is essential to identify ADR patterns and high-risk populations for timely intervention.

Objective: To evaluate drug prescription patterns, and determine the nature, frequency, severity, and predictors of ADRs in breast cancer patients receiving chemotherapy across tertiary care hospitals.

Methods: A hospital-based longitudinal cohort study was conducted (January 2023–August 2024) at three tertiary care centers in Karnataka, India: JSS Hospital and Narayana Multispecialty Hospital, Mysuru, and M.S. Ramaiah Medical College, Bengaluru. A total of 385 female patients with histologically confirmed breast cancer were enrolled. ADRs were assessed using the WHO-UMC causality scale and Naranjo algorithm and classified by severity, preventability, and predictability. Predictors were analyzed using odds ratios. Data was analyzed using JMP® 18.

Results: The predominant age group was >51 years (48.83%). Doxorubicin + cyclophosphamide was the most prescribed regimen (62.1%). A total of 2,066 ADRs were documented; fatigue (63.64%), alopecia, and gastrointestinal disturbances were most prevalent. Most ADRs were mild-to-moderate and a significant proportion was preventable. Advanced age, higher BMI, comorbidities, and advanced cancer stage were significant predictors of ADR occurrence.

Conclusion: This multicenter pharmacovigilance study demonstrates a substantial ADR burden in breast cancer chemotherapy, with fatigue as the leading adverse event. Active monitoring revealed a high proportion of preventable ADRs, underscoring the need for individualized risk assessment and strengthened pharmacovigilance reporting to PvPI in oncology practice.

Keywords: Pharmacovigilance; adverse drug reactions; breast cancer; chemotherapy; WHO-UMC; Naranjo algorithm; PvPI; ADR predictors.

SP12

Mapping Methotrexate Toxicity in Pediatric Oncology: An Integrative Pharmacovigilance-Pharmacogenomic Database Study

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Introduction: Methotrexate (MTX), an antimetabolite that inhibits dihydrofolate reductase, is a key component of therapy for pediatric leukemia and lymphoma. However, MTX-associated adverse events (AEs) may compromise treatment outcomes. Integrating pharmacovigilance and pharmacogenomic evidence may improve understanding of toxicity susceptibility and support precision medicine approaches.

Aims: To characterize MTX-associated AEs in pediatric oncology patients and integrate pharmacogenomic evidence to identify potential genetic determinants of toxicity.

Methods: MTX-related AEs reports in children aged 1–18 years with hematolymphoid malignancies were retrieved from the FDA Adverse Event Reporting System (FAERS) via OpenVigil 2.1(Q4 2004–Q3 2025). Reports with a frequency >3 were included. Signal detection was performed using reporting odds ratio (ROR), proportional reporting ratio (PRR), and chi-square (χ^2) statistics. Signals were considered significant when ROR >1, PRR ≥2, and χ^2 >4. Pharmacogenomic annotations relevant to pediatric MTX therapy were extracted from curated pharmacogenomic databases and mapped to identified toxicity signals.

Results: A total of 3,820 MTX-associated AEs were identified. Reports were more frequent in males (51.9%) and in children aged 1–10 years (59.7%). The United States (16.3%) and Canada (13.9%) contributed the highest number of reports. Among 672 unique preferred terms, 508 significant safety signals were detected. Neurological (9.9%) and gastrointestinal/mucosal (8.7%) disorders were the most frequent AE categories, while febrile neutropenia (n=839) and neurotoxicity (n=374) were the most reported AEs. Pneumonia (PRR=224.17) and increased drug level (PRR=192.15) showed the strongest disproportionality signals. Pharmacogenomic evaluation shows variants in SLCO1B1 (rs10841753), MTHFR (rs1801131), ABCB1 (rs1045642), and TYMS (rs45445694), along with genes involved in MTX transport and folate metabolism, as potential contributors to variability in toxicity risk.

Conclusions: Integration of FAERS-derived safety signals with pharmacogenomic evidence identified clinically relevant MTX toxicities and potential genetic determinants of susceptibility in pediatric leukemia and lymphoma. Findings support future risk-stratified monitoring and precision-guided MTX therapy.

Keywords: Pediatrics, Methotrexate-toxicity, Pharmacovigilance,

SP13

Alpelisib-associated diabetic ketoacidosis: FAERS analysis and systematic review

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Introduction: Alpelisib, a selective phosphatidylinositol-3-kinase (PI3K) alpha inhibitor for PIK3CA-mutated metastatic breast cancer, is frequently associated with hyperglycemia. However, diabetic ketoacidosis (DKA) remains a rare but potentially life-threatening adverse event, and real-world evidence describing its clinical characteristics and severity remains limited.

Aims: To evaluate the pharmacovigilance safety signal and clinical outcomes of alpelisib-associated DKA utilizing the FDA Adverse Event Reporting System (FAERS) and published case reports.

Methods: A pharmacovigilance study was conducted using FAERS reports through May 2026 coded with the MedDRA preferred term “diabetic ketoacidosis.” Reporting odds ratios (RORs) were calculated to assess disproportionality, and serious clinical outcomes were evaluated. PubMed and Embase were systematically searched through May 2026 for published alpelisib-associated DKA cases.

Results: A total of 139 alpelisib-associated DKA reports were identified in FAERS, demonstrating a significant disproportionality signal (ROR 22.33, 95% confidence interval [CI] 18.87-26.41). Compared with pooled PI3K/protein kinase B (AKT)/mammalian target of rapamycin (mTOR) pathway-targeted agents, alpelisib remained associated with disproportionate DKA reporting (ROR 6.76, 95% CI 5.35-8.54). Among these reported cases, 79.1% resulted in hospitalization, 16.5% were life-threatening, and 9.4% resulted in death. The systematic review identified 24 published cases (median age: 65.5 years; range: 45-84). Only 25.0% of patients had pre-existing diabetes, while 33.3% had prediabetes. Median time to DKA onset was 28 days (range 7-180 days), with 54.2% occurring within 30 days of treatment initiation. One-third of patients required intensive care unit admission. Rechallenge was attempted in 37.5% of cases, with recurrent hyperglycemia occurring in 88.9%.

Conclusions: Alpelisib is associated with a clinically significant DKA safety signal and substantial morbidity. DKA frequently develops during the first month of therapy and can strike patients without established diabetes. Early pharmacist-led glucose monitoring and patient education may facilitate prompt recognition and management.

Keywords: alpelisib; diabetic ketoacidosis; FAERS

SP14

Gabapentinoid poisoning presentations to Victorian emergency departments: a 15-year trend analysis

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Background: Existing gabapentinoid surveillance focuses on fatalities, while non-fatal harms are poorly characterised. In hospital data, this is due to a lack of substance-specific International Classification of Diseases (ICD) codes. Free-text entries in hospital records may provide a more sensitive method for detecting gabapentinoid poisonings and co-ingestions.

Objectives: To examine 15-year trends in emergency department (ED) presentations for gabapentinoid poisoning in Victoria, Australia, and to describe patient characteristics, intent, and patterns of co-ingestion.

Methods: Gabapentinoid-related poisonings were identified using a free-text search of the 'Description of Event' field, supplemented by relevant ICD-10 codes. Two reviewers verified cases to exclude non-poisoning mentions. Quarterly presentation rates per 100,000 population were calculated, and trends were assessed by age, sex, medication type, intent, and co-ingested substances, including alcohol.

Results: We identified 1,207 presentations involving gabapentinoid poisoning from 2009/10 to 2023/24 financial year. Rates increased from 0.1 per 100,000 in 2009/10 to 2.2 in 2020/21, before stabilising in the following years. Presentations were most common among adults aged 25-44 years (45.5%), and females accounted for 56% of cases. Nearly half of presentations were recorded as intentional (49.5%), particularly among females and those aged under 65 years. Co-ingestion with opioids (22.1%) or benzodiazepines (25.0%) was frequent, although 36.2% of presentations involved gabapentinoids alone. Among gabapentinoid-alone presentations, almost one-third (29.7%) were unintentional, and most presentations in adults aged ≥65 years were unintentional (59.7%).

Conclusions: This is the first Australian study to use free-text descriptions to identify non-fatal gabapentinoid poisoning in the ED setting. ED presentations involving gabapentinoid poisoning increased substantially in Victoria over the past decade, broadly paralleling prescribing trends. A substantial proportion of poisonings involved gabapentinoids alone, underscoring the need to reassess the perceived safety profile of gabapentinoids and to strengthen prescribing vigilance.

SP15

Global trends in Esketamine utilisation: An analysis of multinational sales data

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Introduction: Esketamine, an N-methyl-D-aspartate receptor antagonist, was first approved by the United States (US) Food and Drug Administration in March 2019 as a novel treatment for treatment-resistant depression, which affects approximately 30% of people with major depressive disorder. Despite its clinical importance, global patterns of esketamine adoption and utilisation remain unclear.

Aims: To describe multinational trends in esketamine adoption and utilisation from 2019 to 2024.

Methods: This cross-sectional ecological study used quarterly pharmaceutical sales data from January 2019 to December 2024 across 54 countries, obtained from the IQVIA Multinational Integrated Data Analysis System. Esketamine consumption was estimated as the absolute number of defined daily dose (DDD) sold and DDDs per 1,000,000 inhabitants per day (DDD/1,000,000/day). Trends were analysed globally and stratified by country and income level. Adoption was defined as the first quarter with recorded esketamine sales in each country.

Results: Global esketamine consumption increased substantially after approval, reaching 11.57 million DDDs in 2024. The US was the earliest adopter and showed sustained growth, accounting for 7.84 million DDD (67.7% of global consumption) in 2024; while Austria had the highest population-standardised consumption in 2024, reaching 66.04 DDD/1,000,000/day. Although global consumption increased steadily, utilisation varied markedly by income group. High-income countries adopted esketamine earliest, with use beginning in 2019, and demonstrated the steepest growth, reaching approximately 29.06 DDD/1,000,000/day in 2024. However, adoption in upper-middle- and lower-middle-income countries was delayed by approximately one to two years and remained limited, with utilisation remaining below 1 DDD/1,000,000/day throughout the study period.

Conclusions: Esketamine utilisation increased rapidly between 2019 and 2024, driven predominantly by high-income countries, particularly the US. Marked differences across countries in both the adoption timing and consumption highlight substantial disparities in access to novel treatments for treatment-resistant depression.

SP16

Socioeconomic and geographic inequities in access to Parkinson's disease treatment in NSW

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Introduction: Parkinson's disease (PD) is the second most common neurological disorder in Australia. Despite advances in device-aided therapies (DAT), population-level evidence on how socioeconomic status and geographic remoteness influence progression from oral therapy to advanced PD treatment (aPD) and DAT remains limited.

Aims: Describe socioeconomic and geographic characteristics of people receiving PD medications or DAT in New South Wales (NSW) and quantify allied health utilisation across treatment stages.

Methods: A retrospective, population-based cohort study was conducted, using the Medicines Intelligences Data Platform-a linked dataset integrating Pharmaceutical Benefits Scheme (PBS) dispensing, hospital admissions, Medicare Benefits Schedule (MBS) claims and mortality data in NSW (2013-2020). Adults initiating PD medicines (no prior PD dispensing in 365 days) were followed longitudinally to subsequent initiation of aPD and DAT, defined using validated medicine-based proxies informed by clinical guidance. Postcode of residence was mapped to SEIFA disadvantage quintiles and ASGS remoteness categories. Allied health MBS items were grouped using AIHW definitions.

Results: Among 43,810 people initiating PD therapy, 11,550 (26%) progressed to aPD treatment and 224 (0.5%) to DAT. Median follow-up from PD treatment was 3.2 years (IQR 1.5-5.4). The proportion residing in the most socioeconomically advantaged quintile increased across treatment stages (23% in PD, 26% aPD, and 36% DAT, $p < 0.001$). While 12% of NSW residents live in regional/remote areas, only 5-7% of each cohort did. Allied health utilisation was low across cohorts, averaging 2.3 MBS claims per person-year.

Conclusions: In NSW, DAT uptake was concentrated in the most socioeconomically advantaged areas, with geographic variation and under-representation of regional/remote residents. Allied health use was similar across cohorts, supporting need to better understand barriers to multidisciplinary PD care. Linked administrative data provides robust information on population-level understanding of PD treatment patterns in Australia.

Keywords: Real-world evidence; Parkinson's disease; linked administrative data

SP17

Implementing WHO-Recommended Tuberculosis Dosing in Indonesia: A Qualitative TDF Study

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Introduction: The World Health Organization (WHO) updated its recommendations on dosing for drug-susceptible tuberculosis (DS-TB) in 2022 to improve treatment effectiveness and programmatic feasibility. However, translating these recommendations into routine practice remains challenging, particularly in high TB burden settings such as Indonesia. Understanding the behavioural and contextual determinants influencing implementation is essential to support guideline uptake.

Aims: This study aimed to explore barriers and facilitators influencing the implementation of WHO-recommended dosing for DS-TB in Indonesian primary healthcare settings.

Methods: A qualitative descriptive study guided by the Theoretical Domains Framework (TDF) was conducted in Banyumas Regency, a high TB burden district in Central Java, Indonesia. Data were collected through face-to-face focus group discussions with 45 healthcare providers, including doctors, nurses, and pharmacists, from 20 primary healthcare centers in December 2025. A semi-structured interview guide based on the 14 TDF domains was used. Discussions were transcribed verbatim and analysed using thematic analysis, with findings mapped to relevant TDF domains.

Results: Determinants influencing implementation were identified across all TDF domains. Key barriers included limited awareness of updated dosing details, confusion during the transition from previous dosing practices, increased workload related to patient education, lack of incentives, and inconsistencies between formal policies and digital information systems. Facilitators included clear professional role delineation, strong peer support, supervisory guidance, optimism related to drug availability, and formal policy endorsement from health authorities. Emotional responses characterised by uncertainty, particularly in referral cases, also influenced decision-making.

Conclusions: Implementation of WHO-recommended dosing for DS-TB is influenced by interacting behavioural, social, and system-level factors. Theory-informed and multi-level implementation strategies may strengthen guideline adoption in decentralized TB service settings.

Keywords: pulmonary anti-tubercular agents, primary health care, qualitative research

SP18

Predictors of persistent benzodiazepine prescriptions in Australian primary care

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Introduction: In recent years, escalating rates of high-risk psychotropic medicines use and harms have gained international concern, with benzodiazepines being the most commonly identified single drug type in drug-induced deaths in Australia. Despite the growing burden of benzodiazepine-related harms particularly with long-term or persistent use, research examining patterns of benzodiazepine prescribing remains limited both internationally and in Australia.

Aims: The aim of this study was to examine the predictors of persistent benzodiazepine receptor agonist (i.e. benzodiazepines and z-drugs; BZRA) prescriptions in people initiating BZRAs in Australian primary care.

Methods: This retrospective cohort study included adults (≥18 years) prescribed BZRAs between January 2018 and December 2025 using data accessed through the Population Level Analysis and Reporting (POLAR) database. Persistence was defined as being prescribed BZRAs for ≥90 days, with a gap of <60 days between subsequent prescriptions.

Results: Of a total sample of 538,095 people initiating BZRAs, 19,831 (3.7%) received persistent BZRA prescriptions, with diazepam (45.2%) and temazepam (34.7%) being the most frequently prescribed types in both persistent and non-persistent cohorts. Adjusted multivariable logistic regression showed that concessional beneficiaries (2.43, 2.35-2.51), individuals with substance use disorder diagnosis (2.63, 2.44-2.82), those prescribed opioids (1.86, 1.80-1.91), antipsychotics (1.74, 1.66-1.83) and cannabinoids (1.81, 1.21-2.71) in the year prior to BZRA initiation, and those provided ≥2 types of BZRAs (2.02, 1.83-2.23) and repeat/refill prescriptions at initiation (2.74, 2.58-2.90) had significantly higher odds of persistence following BZRA initiation.

Conclusions: Further research is needed to determine whether persistent BZRA prescriptions are associated with any unintended or adverse health outcomes. The patient-level factors associated with persistence identified in this study, such as concessional status and substance use disorder diagnosis, may help to risk stratify patients and inform policy and practice aimed at promoting safe prescribing and mitigating unintentional long-term BZRA use.

Key words: Benzodiazepines, long-term prescriptions, primary care.

SP19

Closed-loop real-time allergy communication to prevent repeat drug allergy exposure

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Introduction: Repeat drug allergy exposure is a preventable medication safety event. Root cause analysis identified major gaps in allergy information transfer, particularly during out-of-hours services, resulting in delayed documentation, incomplete hospital information system (HIS) records, A closed-loop real-time allergy communication system was developed to improve multidisciplinary allergy reporting and strengthen prevention of repeat drug allergy exposure.

Aims: To evaluate the impact of a closed-loop real-time allergy communication system on allergy documentation and prevention of repeat drug allergy exposure.

Methods: A quasi-experimental before-and-after study was conducted in inpatient and outpatient settings. The pre-intervention period was April–September 2023 using routine allergy reporting processes, while the post-intervention period was April 2024–December 2025 following implementation of a closed-loop real-time allergy communication system. The intervention integrated a Line Official Account platform into multidisciplinary workflows to facilitate real-time referral of patients with previous drug allergies identified by physicians, nurses, pharmacists, and dentists. Pharmacists on duty performed immediate allergy documentation and allergy alert activation in the HIS, including during out-of-hours periods, while ADR pharmacists subsequently verified documentation completeness during routine service hours.

Results: Documented previous drug allergy reports increased from 13.2 to 31.8 per 1,000 outpatient prescriptions ($p<0.001$) and from 19.4 to 44.7 per 1,000 inpatient medication orders ($p<0.001$). Completeness of HIS allergy documentation improved from 81.6% to 99.7%. Out-of-hours reporting increased from 11.3% to 49.5% of total reports. Median time from referral to HIS documentation decreased from 15.2 hours to 18 minutes ($p<0.001$). The system identified and prevented 172 repeat prescribing events in patients with known drug allergies. No severe repeat drug allergy exposure events were identified after implementation.

Conclusions: The closed-loop real-time allergy communication system significantly improved timely HIS documentation, closed the out-of-hours reporting gap, and effectively prevented repeat drug allergy exposure through continuous multidisciplinary communication.

Keywords: drug allergy; medication safety; communication system

SP20

Trends in contraceptive prescribing in Australian general practice: A longitudinal national study

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Introduction: General practices are the primary providers of contraceptive care in Australia where patients access most of the contraceptive types under the Pharmaceutical Benefits Scheme (PBS) for subsidised rates. However, national evidence on prescribing patterns and associated factors in this setting remains limited.

Aims: To examine longitudinal trends in contraceptive prescribing in Australian general practice

Methods: A retrospective cohort study of females aged 15 to 49 years who attended a general practice between 2011 and 2021 was conducted, using the large general research dataset, MedicineInsight. We calculated annual age standardised rates of contraceptive prescriptions overall and stratified by patient demographic characteristics.

Results: Among a total of 1,660,406 females, the annual age-standardised prevalence of contraceptive prescriptions was consistently the highest among those aged 15-29 years between 2011 and 2021. Combined hormonal contraceptive (CHC) prescribing showed a declining trend, whereas levonorgestrel intrauterine devices (LNG-IUDs) use increased from 1.0% to 1.7%, with the largest increases in those aged 15-19 years (0.2% to 0.9%) and 20-29 years (0.8% to 1.8%). The prevalence of non-PBS-listed CHC prescribing was significantly higher in females without a concession card compared to their counter parts. The prevalence of prescribing of LNG-IUDs was higher in the 40-49 years old females than in younger patients and in regional areas than in major cities. Implants were more commonly prescribed for females with concession card, living in disadvantaged areas, and residing outside major cities.

Conclusion: Contraceptive prescribing among females attending general practice declined between 2011 and 2021, driven largely by reductions in combined hormonal contraceptive prescribing. In contrast, prescribing of LNG-IUDs increased substantially, particularly among younger females, suggesting a gradual shift towards long-acting reversible contraceptives. Considerable differences in contraceptive prescribing by patient demographics highlight potential inequities in contraceptive access and choice that warrant further investigation.

Keywords: Contraception; drug utilisation; primary care

SP21

Workflow-embedded automation improves hepatitis B screening and safety in b/tsDMARD users

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Introduction: Universal hepatitis B virus (HBV) screening is mandated before initiating biological or targeted synthetic disease-modifying antirheumatic drugs (b/tsDMARDs) to prevent reactivation. Despite guidelines, screening adherence often remains suboptimal in routine clinical practice due to fragmented workflows. Closing this gap is critical to ensure patient safety during potent immunosuppressive therapy.

Aims: This study evaluated the impact of a workflow-embedded clinical decision support system (CDSS) on HBV screening completion. We further assessed the association between improved screening processes and HBV-related clinical outcomes.

Methods: A retrospective, staged implementation study was conducted comparing three periods: baseline (2004–2016), education (2017–2020), and workflow-integrated (2021–2024). Participants included adults with rheumatic diseases initiating b/tsDMARD therapy identified from a tertiary center database. The CDSS automatically verified HBV serology and generated missing screening orders at the point of computerized prescription.

Results: The analytical cohort comprised 1,909 adults across the three implementation stages. The full three-marker panel screening rate increased from 47% at baseline to 75% during the education stage and 90% in the workflow-integrated stage. These process improvements were associated with a significant reduction in HBV reactivation rates from 5.2% at baseline to 1.5% in the last stage ($p<0.001$). Hepatitis flares also decreased from 1.9% to 0.2% across stages ($p<0.001$). However, antiviral prophylaxis before treatment remained consistently low (4.2%) and longitudinal virologic monitoring was infrequently performed.

Conclusions: Workflow-embedded automation achieved near-universal HBV screening and significantly reduced clinical reactivation and flares. Future systems should incorporate automated longitudinal monitoring and stronger enforcement of prophylactic guidelines to address residual risks.

SP22

Comparative effectiveness of atezolizumab plus bevacizumab versus lenvatinib in advanced hepatocellular carcinoma

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Introduction: Head-to-head comparison of atezolizumab- bevacizumab and lenvatinib in the patients with unresectable hepatocellular carcinoma (HCC) remained limited in the Asian population.

Aims: We aimed to compare atezolizumab-bevacizumab and lenvatinib among HCC patients in viral and non-viral hepatitis groups using a target trial emulation framework.

Methods: We emulated a target trial that compared two first-line drugs using a multi-institutional hospital electronic medical record database. We included HCC patients who were newly treated with atezolizumab-bevacizumab or lenvatinib between 2023 and 2024. To confirm the HCC stage, we used an on-premises LLM, the GPT-OSS 20B model, to extract unstructured imaging text reports within 3 months of the first treatment date. Clinical outcomes were progression-free survival (PFS) and overall survival (OS). We used inverse probability of treatment weighting (IPTW) as a proxy randomization method. Pure subgroup analyses were conducted stratified by viral hepatitis, non-viral hepatitis, and liver function. Cox regression model was applied to analyze the relative effect between the two groups.

Results: A total of 397 patients were included with a median age of 67.8 years and 79.1% male. 52.5% and 24.2% patients experienced HBV and HCV infection, respectively. 34.3% and 23.6% patients had extrahepatic spread and macrovascular invasion, respectively. After IPTW, atezolizumab-bevacizumab had similar clinical outcomes with lenvatinib [PFS: 1.19 (95% CI: 0.86 - 1.65); OS: 1.14 (0.81 - 1.60)] among the entire cohort and the viral hepatitis subgroup. However, lenvatinib had better PFS and OS than atezolizumab-bevacizumab among the non-viral hepatitis group [PFS: 2.11 (95% CI: 1.15 - 3.89); OS: 1.90 (1.01 - 3.57)].

Conclusion: Our study sugguested that immunotherapy and tyrosine kinase inhibitors might have different clinical benefits for different etiologies of HCC. Futher study is suggested to confirm our finding.

Key word: target trial emulation, HCC, atezolizumab-bevacizumab, lenvatinib

SP23

Real-world outcomes of sacubitril-valsartan for treatment of heart failure in Singapore

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Introduction: In January 2022, sacubitril-valsartan was included on the funding list for patients with heart failure with reduced ejection fraction (HFrEF). A local real-world study was conducted to examine how pivotal PARADIGM-HF trial evidence translates to the local context.

Aims: This study assessed real-world outcomes of sacubitril-valsartan compared to angiotensin-converting enzyme inhibitor (ACEi) or angiotensin II receptor blocker (ARB), among patients with heart failure (HF).

Methods: A retrospective cohort study was conducted using linked national health record databases to identify patients with HF who initiated sacubitril-valsartan or ACEi/ARB between 2017 and 2023. Prevalent new user design was adopted for cohort treatment assignment. Patient characteristics such as demographics, comorbidities, previous HF hospitalisation, baseline biomarker values and use of concomitant drugs were balanced using Lasso techniques. Poisson regression estimated incidence rate ratios (IRR) with 95% confidence intervals (CIs) for cardiovascular (CV) deaths, HF hospitalisation, composite outcomes, and secondary outcomes during first year follow-up.

Results: The final cohort included 3,044 patients (sacubitril-valsartan, n=1,667; ACEi/ARB, n=1,377). Patients on sacubitril-valsartan had lower but non-significant CV deaths (IRR: 0.77; 95% CI 0.58, 1.02), HF hospitalisation (IRR: 0.86; 95% CI 0.65, 1.14) and composite outcomes (IRR: 0.85; 95% CI 0.68, 1.06). However, sacubitril-valsartan was associated with significant reductions in all-cause mortality (IRR: 0.77; 95% CI 0.64, 0.93) and hospitalisations (IRR: 0.79; 95% CI 0.70, 0.90).

Conclusion: Sacubitril-valsartan was associated with reduced HF hospitalisation and CV deaths, although these primary outcomes did not reach statistical significance. The findings align with other published real-world studies where effect estimates have shown variable statistical significance. A key limitation was the absence of left ventricular ejection fraction data, which may have impacted patient selection and confounding adjustment. Despite these limitations, sacubitril-valsartan demonstrated significant reductions in all-cause hospitalisations and mortality, suggesting clinical benefit in the local population.

Keywords: Heart failure, sacubitril-valsartan, real-world outcomes

SP24

Sulfonylurea use and vascular complications in type 2 diabetes

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Introduction: Preventing vascular complications is central to type 2 diabetes (T2D) management. Sulfonylureas remain widely used glucose-lowering agents worldwide. Previous studies indicated possible cardiovascular harms from sulfonylureas, but findings are inconsistent. Evidence simultaneously assessing cardiovascular, peripheral vascular, and microvascular complications within the same population is limited.

Aims: To systematically evaluate associations between sulfonylurea use and vascular complications among T2D patients and assess potential causality using Mendelian randomization.

Methods: UK Biobank participants with T2D receiving oral antidiabetics (sulfonylurea or others) and free of targeted vascular complications were included. Medication use was self-reported. Incident complications were identified using diagnostic codes from linked self-report, hospital, primary care, and death records. Multivariable Cox proportional hazards models were used to estimate adjusted hazard ratios. Two-sample Mendelian randomization was performed to assess causal relationships.

Results: A total of 6,144 T2D patients (2,153 sulfonylurea users) aged 59.2 ± 7.1 years with mean HbA1c of 7.0% and mean diabetes duration of 6.6 years were included. After median follow-up of 12.8–13.5 years, compared with other oral antidiabetics, sulfonylurea use was associated with significantly higher risks of peripheral artery disease (HR 1.29, 1.01–1.65) and microvascular disease (HR 1.27, 1.16–1.39). Subtype analyses for microvascular disease showed increased risks for diabetic retinopathy (HR 1.33, 1.19-1.48), neuropathy (HR 1.37, 1.10-1.70), and nephropathy (HR 1.18, 1.03-1.35). No significant associations were observed for cardiovascular disease, ischemic heart disease, or stroke. Mendelian randomization suggested causal effects of sulfonylureas on diabetic retinopathy (OR 4.85, 2.59–9.08) and coronary heart disease (OR 1.91, 1.29–2.84). No causal associations were found for the other outcomes.

Conclusions: Sulfonylureas increase the risk of microvascular disease, particularly retinopathy, among T2D patients. These findings were partially supported by Mendelian randomization analyses and highlight the need for further studies to confirm.

Keywords: Sulfonylureas; Type 2 diabetes; Diabetic vascular complications

SP25

Cost-utility analysis of subdural electrode and stereo-electroencephalography monitoring for drug-resistant epilepsy patients

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Introduction: Patients with drug-resistant epilepsy are at increased risk of mortality, disability, and poor quality of life. Epilepsy surgery is an important treatment option for these patients; however, accurate localization of the epileptogenic zone is essential prior to surgery. In some patients, non-invasive investigation methods fail to precisely identify the seizure onset zone, necessitating invasive intracranial monitoring. Two principal invasive investigations, subdural electrode (SDE) and stereo-electroencephalography (SEEG) monitoring, are being considered for inclusion in Thailand's Universal Health Coverage benefit package.

Aims: To evaluate the cost–utility of SEEG and SDE in patients with drug-resistant epilepsy whose epileptogenic zone could not be identified using non-invasive pre-surgical investigations.

Methods: A cost–utility analysis was conducted using a decision tree combined with a Markov model to estimate lifetime costs and quality-adjusted life years (QALYs) associated with SEEG and SDE compared with standard anti-epileptic drug treatment. Clinical effectiveness and transition probabilities were derived from patient data obtained from the Neurological Institute of Thailand. Direct medical costs were collected from the institute's financial database, while direct non-medical costs and utility data were obtained through patient interviews. Additional model parameters were identified through a review of national and international literature. Outcomes were presented as incremental cost-effectiveness ratios. One-way and probabilistic sensitivity analyses were conducted to assess the robustness of the model parameters.

Results: Both SEEG and SDE were found to be cost-effective compared with standard anti-epileptic drug treatment, as they resulted in lower overall costs and greater QALYs. SEEG reduced treatment costs by 300,292 THB and increased QALYs by 1.297 years, while SDE reduced costs by 346,577 THB and increased QALYs by 0.247 years.

Conclusions: SEEG and SDE should be included in Thailand's health benefit package to improve access to epilepsy surgery evaluation while generating cost savings from a societal perspective.

Keywords: Drug-resistant epilepsy; stereoelectroencephalography (SEEG); cost–utility analysis

SP26

PPCVD-HEM+: GPU microsimulation and Monte Carlo tree-search optimisation for cardiovascular prevention

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Introduction: Health technology assessment (HTA) for cardiovascular disease (CVD) primary prevention relies on individual-level microsimulation, yet the nested-loop structure of probabilistic sensitivity analysis (PSA) creates a well-recognised computational bottleneck—published runtimes range from hours to days, leading to the view that PSA is "impractical for patient-level models." Existing remedies use statistical variance reduction or cloud-based horizontal scaling, but neither restructures the simulation algorithm itself; current health economic modelling software remains CPU-bound with no GPU support.

Aims: To develop a precision medicine model for health technology assessment

Methods: We developed PPCVD-HEM+, a high-performance extension of the Primary Prevention of Cardiovascular Disease Health Economics Model that re-encodes the Markov microsimulation as tensorised array operations amenable to hardware acceleration. Three advances are introduced: (1) accelerated backends—a Numba JIT engine for CPU-vectorised execution and a PyTorch engine for GPU-batched execution (MPS/CUDA)—replacing sequential loops with parallel tensor algebra; (2) a Monte Carlo Tree Search (MCTS) framework for automated treatment optimisation across 136 PBS-listed drug-dose entries; and (3) a web platform (https://ppcvdhem.com) for browser-based cost-effectiveness analysis. All engines preserve the original sum-then-split event logic. To our knowledge, this is the first application of GPU-accelerated tensor computation to health economic microsimulation.

Results: The CPU engine achieved 29.7-fold speedup with negligible outcome differences (standardised mean difference < 0.05). The GPU engine achieved 208-fold speedup, completing 1,000 PSA iterations in 53 seconds versus ~3.1 hours for STATA. Multi-arm GPU-batched PSA completed 1,000 iterations in ~90 seconds (60-fold improvement). MCTS identified early intensive combination therapy as dominant across risk profiles, with net monetary benefits of AU$19,252– 143,953 at a willingness-to-pay threshold of AU$28,000/QALY.

Conclusions: By replacing traditional microsimulation bottlenecks with tensorised GPU-batched computation, PPCVD-HEM+ achieves orders-of-magnitude speedups that enable real-time HTA workflows, automated treatment optimisation, and accessible web-based cost-effectiveness analysis.

Keywords: Health Economics

SP27

Sequence matters: trajectories,velocities, and competing mortality risks in type 2 diabetes complications

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Introduction: Type 2 diabetes mellitus (T2DM) significantly accelerates cardiovascular risk through emerging comorbidities.

Aims: This study utilizes a multi-state illness-death model to map the precise velocities, sequential trajectories, and direct mortality risks associated with the development of isolated or concurrent hypertension (HT) and dyslipidemia (DLP) following a T2DM diagnosis.

Methods: A dynamic cohort of 56,584 adult patients diagnosed with baseline T2DM between 2015 and 2017 was tracked over a strict 4-year fixed administrative horizon. Patients and clinical transitions were identified using validated ICD-10 diagnostic codes. Continuous-time state changes were dual-validated using non-parametric estimation across a 6-state matrix spanning baseline T2DM, intermediate comorbidities, compound sequential multimorbidity, and all-cause mortality.

Results: Out of baseline T2DM, 32.76% of patients remained stable without developing secondary complications over 4 years. Transitioning to an isolated comorbidity was highly prevalent, with 30.85% developing isolated HT first and 24.04% developing isolated DLP first, while 6.31% experienced simultaneous onset. Crucially, intermediate pathways exhibited highly divergent survival windows. Patients occupying the isolated HT state faced a devastating 10.79% probability of direct all-cause mortality before developing further complications. Conversely, patients occupying the isolated DLP state experienced a direct mortality probability of only 3.15%, revealing a 3.4-fold crude risk increase for the hypertension pathway. Once patients progressed to the dual-comorbidity compound state, 4-year mortality risks converged and stabilized at 10.33% for simultaneous onset and 10.03% for sequential onset.

Conclusions: Entering the isolated HT phase represents a highly volatile clinical inflection point carrying a disproportionately elevated mortality toll compared to isolated lipid progression. These findings mandate aggressive, immediate blood pressure stabilization strategies at the earliest presentation of isolated HT, long before dual multi-morbidity manifests, to mitigate the steep velocity of early mortality in T2DM patients.

Keyword: Competing risks, Type 2 diabetes mellitus, Real-world evidence

SP28

GLP1R–SLC5A2 interactions and kidney function in Mendelian randomization

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Introduction: Combination therapy with glucagon-like peptide-1 receptor agonists and sodium-glucose cotransporter-2 inhibitors is increasingly used in type 2 diabetes (T2D). However, the joint effects of these therapeutic targets on kidney function remain incompletely understood. Drug-target Mendelian randomization may help evaluate the long-term effects of genetically proxied target perturbation on renal outcomes.

Aims: To investigate the independent associations of GLP1R and SLC5A2 variants with kidney function. To assess potential interaction effects between these therapeutic targets on estimated glomerular filtration rate (eGFR).

Methods: Target-specific genetic scores for GLP1R and SLC5A2 were constructed using cis-acting
functional variants within each gene region. Multiplicative interaction terms between genetic scores were evaluated using linear regression models adjusted for age and sex. Analyses were conducted in 464,045 UK Biobank participants with available genotype and eGFR data. Associations were estimated using beta coefficients, 95% confidence intervals (CI), and p-values.

Results: Both GLP1R and SLC5A2 genetic scores were associated with lower eGFR. The association for SLC5A2 was β = −0.101 (95% CI: −0.135 to −0.067; p = 6.78 × 10^−9). The association for GLP1R was β = −0.082 (95% CI: −0.116 to −0.048; p = 2.29 × 10^−6). A significant interaction between GLP1R and SLC5A2 genetic scores was observed (β = −0.052; p = 0.0028). The association between GLP1R scores and eGFR was stronger among individuals with higher SLC5A2 genetic scores (75th percentile: β = −0.084, 95% CI: −0.118 to −0.050; p = 1.20 × 10^−6). These findings suggest potential joint effects of GLP1R and SLC5A2 pathways on kidney function.

Conclusions: Genetic variation in GLP1R and SLC5A2 was associated with kidney function. Evidence of interaction between these pathways may inform future studies evaluating combination therapies and renal outcomes in T2D.

Keywords: Mendelian randomization; GLP1R; SLC5A2; eGFR; kidney function

III. Poster Presentations

Abstract D1/P100 - D2/P273

D1/P100

Whitening cosmetic advertisements on TikTok: violations of Thailand's Cosmetics Act

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Introduction: TikTok has experienced rapid growth in Thailand, emerging as a significant platform for online commerce, including cosmetics. Skin-whitening products represent the most frequently searched cosmetic category on this platform. The proliferation of cosmetic advertisements on social media raises concerns regarding regulatory compliance, particularly with Thailand's Cosmetic Act of 2015.

Aims: This study aimed to investigate skin-whitening cosmetic advertisements on TikTok and identify factors associated with the risk of non-compliance with Thailand's Cosmetic Act of 2015.

Methods: A cross-sectional descriptive study was conducted, analyzing 214 skin-whitening cosmetic advertisements published on TikTok between January and February 2026. Two independent evaluators assessed advertisement compliance with the Cosmetic Act of 2015. Data were analyzed using descriptive statistics.

Results: Advertisement components were categorized as follows: image only (n=8, 3.74%), image and sound (n=9, 4.20%), image and text (n=167, 78.04%), and a combination of image, sound, and text (n=30, 14.02%). Non-compliant advertisements were identified in 202 cases (94.39%). Among non-compliant advertisements, text-only violations were most prevalent (n=118, 58.42%), followed by image and text combinations (n=29, 14.36%), image only (n=24, 11.88%), sound and text (n=11, 5.45%), sound only (n=13, 6.44%), image and sound (n=5, 2.48%), and all components combined (n=2, 0.99%). The most common violations included images depicting skin tone comparisons before and after product use and textual claims of permanent skin tone alteration. A statistical analysis of factors associated with non-compliance risk was not feasible due to the substantial disproportion between non-compliant (94.39%) and compliant (5.61%) advertisements.

Conclusions: Skin-whitening cosmetic advertisements on TikTok demonstrate a critically high rate of non-compliance with Thailand's Cosmetic Act of 2015. Consumers should critically evaluate product claims prior to purchasing skin-whitening cosmetics through TikTok. Regulatory authorities should strengthen enforcement mechanisms for cosmetic advertising on digital platforms.

Keywords: skin-whitening cosmetics, TikTok advertising, Cosmetic Act

D1/P101

Prevalence and clinical profile of heart failure in hospital inpatients

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Introduction: Heart failure is a common reason for cardiology admissions and Local epidemiological data are essential to identify high-burden groups and plan targeted multidisciplinary care in tertiary settings.

Aims: To estimate the prevalence of heart failure among cardiology inpatients over five years and describe their clinical profile, including age, gender, heart failure subtype, comorbidities, length of stay and in-hospital mortality.

Methods: An ambispective cohort design was used, combining a five-year retrospective review (2020-2024) with nine months of prospective follow-up. Among 5,864 cardiology admissions, 1,254 adults met screening criteria and 585 had confirmed heart failure of any stage. Data on demographics, ejection-fraction-based heart failure subtype (reduced, mildly reduced and preserved), comorbidities, social history, length of stay, number of medications and in-hospital outcomes were extracted and analysed descriptively. Prevalence was calculated overall and stratified by age and gender.

Results: Heart failure was present in 10% of cardiology admissions (585/5,864) and 46.7% of screened patients (585/1,254). Prevalence increased with age, from 30%(<45 years) to 62% (>75 years). Males comprised 72% of the cohort and had higher gender-specific prevalence (50%) than females (39%). Reduced ejection fraction was most common (53%), followed by mildly reduced (38%) and preserved (8%). Multimorbidity was frequent, with 61% of patients having at least 2 comorbidities, and most common length of stay was 4-7 days (42%). During follow-up, 83 patients (14%) died. Pharmacotherapy in these inpatients broadly followed guideline directed medical therapy, with widespread use of loop diuretics, renin-angiotensin system blockersneprilysin inhibitors, beta-blockers, mineralocorticoid receptor antagonists and sodium-glucose cotransporter-2m-glucose cotransporter-2 inhibitors.

Conclusions: Nearly half of screened cardiology inpatients and one in ten admissions were living with heart failure, with greatest burden in older adults and reduced ejection fraction. High multimorbidity and polypharmacy underscore the need for integrated multidisciplinary strategies to improve outcomes.

Keywords: Heart failure; Ambispective cohort; Multimorbidity

D1/P103

Net reclassification of P-CARDIAC for clinical stability among patients with prior CVD

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P-CARDIAC is an AI-driven tool predicting cardiovascular disease (CVD) recurrence in Hong Kong patients with established CVD. Clinicians evaluate clinical stability, but whether ESC and ACC guidelines classifications reflect this remains unclear. This study evaluates if P-CARDIAC can simultaneously assess risk and clinical stability for secondary prevention.

To compare P-CARDIAC, ESC 2025, and ACC 2019 risk classifications against clinician-assessed clinical stability.

Forty-eight cases were randomly selected by strata from a prospective cohort of patients aged 18–80 years with prior CVD attending specialist clinics across six Hong Kong Hospital Authority hospitals. Electronic health records provided data for P-CARDIAC scoring. Anonymized clinical notes were independently reviewed by fifteen cardiologists for ESC/ACC risk category and clinical stability. Category-based net reclassification improvement (NRI) with 500 bootstrap iterations compared P-CARDIAC with ACC and ESC, using clinician-judged instability as the event.

Forty cases were evaluated by at least two clinicians. Among thirty-three consensus cases, clinicians judged 12.5% of them as unstable and 87.5% as stable. Among stable patients, 82.1% and 65.2% were classified as very high and high risk under ESC and ACC, respectively, versus 17.8% high risk by P-CARDIAC. Compared to ACC, total NRI for P-CARDIAC model was 0.02 (95% CI −0.52 to 0.71), with NRI− 0.68 (95% CI 0.43 to 0.91) among stable patients and NRI+ −0.67 (95% CI −1.00 to <0.01) among unstable patients. Compared to ESC, total NRI was approximately 0.01 (95% CI −0.52 to 0.76), with a similar pattern (NRI− 0.67, 95% CI 0.43 to 0.87; NRI+ −0.67, 95% CI −1.00 to <0.01).

ESC and ACC demonstrate limited capability in differentiating clinical stability. P-CARDIAC reduces the overclassification of stable patients into high-risk categories, showing potential for clinical triage and resource allocation. However, larger sample sizes are needed due to the few unstable cases evaluated.

D1/P104

Six-Year Surveillance Reveals Escalating Antifungal Resistance in Hospitalized Patients

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Introduction: Invasive fungal infections (IFIs) are associated with significant morbidity, mortality, prolonged hospitalization, and increased healthcare costs, particularly among critically ill and immunocompromised patients. The increasing emergence of antifungal resistance among Candida and Aspergillus species has complicated treatment strategies and underscores the importance of antifungal stewardship (AFS) programs. Continuous surveillance of antifungal utilisation and susceptibility patterns is essential for optimising therapy and mitigating resistance.

Aim: Ths study evaluated antifungal utilization patterns, characterised antifungal resistance profiles, and assessed clinical outcomes among hospitalized patients receiving systemic antifungal therapy.

Methods: A retrospective stewardship and surveillance study was conducted among patients receiving systemic antifungal therapy between 2020 and 2025 in a tertiary care hospital. Data on fungal isolates, antifungal prescribing patterns, resistance profiles, and clinical outcomes were analysed.

Results: A total of 300 patients were included. The predominant isolates were Candida tropicalis (19.7%), Aspergillus fumigatus (11.7%), Candida albicans (9.7%), and Candida auris (8.7%). Empirical therapy accounted for 76.0% of prescriptions, while targeted therapy represented 20.7%. Fluconazole was the most frequently prescribed antifungal (51.7%), followed by itraconazole (17.3%) and caspofungin (15.3%). Resistance was highest to fluconazole (27.6%) and itraconazole (24.0%), whereas caspofungin demonstrated lower resistance rates (6.7%). Year-wise surveillance revealed a progressive increase in antifungal resistance from 2020 to 2025, particularly among Candida species and azole antifungals. Clinical improvement was observed in 67.0% of patients, ICU admission occurred in 64.7%, and 30-day mortality was 23.3%.

Conclusion: This six-year evaluation demonstrated increasing azole resistance, extensive empirical antifungal use, and relatively preserved echinocandin susceptibility. Strengthened antifungal stewardship, routine susceptibility-guided therapy, and continuous surveillance are essential to curb antifungal resistance and improve clinical outcomes. Broader implementation of stewardship programs may help preserve antifungal effectiveness and reduce the global burden of antifungal resistance.

Keywords: Antifungal Stewardship, Antifungal Resistance, Invasive Fungal Infections, Candida, Surveillance

D1/P105

Health service utilisation prior to drug-related deaths: a systematic review and meta-analysis

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Introduction: Drug-related deaths remain a major and preventable cause of mortality, and every interaction with health services provides an opportunity to identify risks, intervene, and potentially prevent deaths.

Aims: We aimed to systematically synthesise international evidence on the prevalence of health service utilisation preceding drug-related deaths.

Method: We performed a systematic review and meta-analysis. We systematically searched PubMed, EMBASE, and PsycINFO on 10/10/20 for peer-reviewed literature. We included observational studies that reported the prevalence of any health service utilisation for any reason in the period prior to drug-related deaths. The pre-mortem observation period must have been consistently defined for all study participants. We used the Joanna Briggs Institute Critical Appraisal Tool to identify the risk of bias for each study.

Results: We included 32 studies; half were from the USA, and half involved general population samples. Accessing primary care and emergency department (ED) services were more common than drug-related services. Primary care was the most utilised service within 1 month (68.3%), 1 year (93.0%), and 2 years (81.0%) prior to death, and ED was the most utilised service in the 3 years prior to death, at 83.2%. In a meta-analysis of general population samples, 62.1% of decedents visited an ED within 1 year of death (95% confidence interval, CI 54.8%–69.0%). The one-year pooled prevalence of primary care use was 86.9% (95% CI, 79.3%-92.0%), regardless of population type.

Conclusions: This is the first systematic review and meta-analysis examining health service use prior to drug-related deaths. The high engagement with ED and primary care services presents a critical opportunity to expand overdose prevention efforts within mainstream healthcare settings. Additionally, it underscores the value of integrated models that link general healthcare with harm reduction services to increase access and enable timely risk identification.

Keywords (3): Drug overdose; facilities and services utilisation; intervention opportunities.

D1/P106

Incidence surveillance for extended Carbapenem-Resistant Enterobacteriaceae colonisation: an Interrupted time series

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Introduction: High-risk patients admitted to public hospitals in Hong Kong were routinely screened for carbapenem-resistant Enterobacteriaceae (CRE) colonisation. Social distancing and increased antibiotic use during the COVID-19 pandemic might have affected the incidence of CRE colonisation.

Aims: To examine the trend and duration of CRE colonisation pre-, during and after the COVID-19 pandemic.

Methods: Design: Interrupted time series

Setting: We collected data from the Hong Kong Hospital Authority (HA) electronic health record, patients aged >18, between 01/01/2017–30/06/2023 were included. CRE laboratory tests were conducted using either genotypic (polymerase chain reaction) or phenotypic (antimicrobial susceptibility test) methods.

Statistical analysis: We examined the changes in CRE monthly incidence before, during, and after the COVID-19 pandemic (Feb 2020–Oct 2022) in an interrupted time series using quasi-Poisson regression model to estimate the incidence rate ratio (IRR). We also conducted additional analyses with a negative control outcome (appendicitis incidence), lagged effect of COVID-19 pandemic interventions by 2 months.

Results: We identified 441,426 episodes from 439,394 patients who received ≥1 CRE test during the study period. Of these, 4,638 episodes (1.05%) had ≥1 CRE positive result. The CRE test-positive incidence trend showed increasing with seasonality before the onset of the COVID-19 pandemic in February 2020. The start of the pandemic period was marked by an immediate level reduction in CRE incidence [IRR: 0.47 (0.24, 0.91)]. Subsequently, the incidence trend experienced a steeper rise after the pandemic phase (Oct 2022), with social distancing no longer mandated. No statistical significance resulted in any additional analyses.

Conclusions: The observed rising trend prior and after to pandemic may reflect increased surveillance in public hospitals. The reduction in non-urgent hospital admissions, social distancing measures, and border closures may have contributed to decreased surveillance of CRE and a subsequent decline in CRE incidence.

Keywords: antimicrobial resistance, Carbapenem-resistant Enterobacteriaceae, hospital surveillance, antibiotics use

D1/P107

Associations of CAD genetic risk-driven proteins with MASLD and liver-related events

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Importance: Coronary artery disease (CAD) and metabolic dysfunction-associated steatotic liver disease (MASLD) frequently coexist. However, whether CAD genetic susceptibility is associated with the development of MASLD and progression to liver-related events, and whether shared therapeutic pathways underlie these associations, remains unclear.

Objective: To investigate whether CAD genetic risk is associated with incident MASLD and liver-related events, and whether shared proteins explain this association.
Methods: Genetic epidemiologic study integrating cross-trait genetic analyses, Mendelian randomization, proteomic analyses, and a prospective cohort analysis. Publicly available genome-wide association study summary statistics and individual-level data from the UK Biobank. The study population included individuals with genetic information, comprising both the general population without prevalent liver disease at baseline and the MASLD population, as well as corresponding subsets with available proteomic data.

Results: Overall genetic correlations were observed between CAD and both MASLD and cirrhosis, along with shared genetic loci. Mendelian randomization supported causal effects of CAD on MASLD and cirrhosis. High CAD genetic risk was associated with increased risks of incident MASLD (HR = 1.15; 95% CI = 1.05–1.25), cirrhosis (HR = 1.23; 95% CI = 1.06–1.42), and liver-related mortality (HR = 1.30; 95% CI = 1.03–1.65). These associations were amplified in individuals with established MASLD, among whom high CAD genetic risk was also associated with higher hepatocellular carcinoma risk (HR = 1.86; 95% CI = 1.11–3.12). CAD-associated proteins showed good discrimination for MASLD (AUC = 0.827) and cirrhosis (AUC = 0.916). Drug-target Mendelian randomization and colocalization analyses identified MENT as a potential therapeutic target for MASLD and both MENT and CXCL9 as potential therapeutic targets for cirrhosis.

Conclusions and relevance: CAD genetic risk offers dual risk-stratification value for both CAD and liver-related outcomes, especially among individuals with MASLD. CAD-associated proteins show discrimination for liver-related events and provide potential therapeutic targets in cardio-hepatic pathways.

D1/P108

Nutritional Status and Renal Function as Determinants of Geriatric Fragility Fractures

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Introduction: Femoral fracture is a major cause of disability, care dependence, and mortality. Malnutrition, frailty, and impaired renal function may increase fracture susceptibility. The association between Geriatric Nutritional Risk Index (GNRI)-defined nutritional risk, renal function, and femoral fracture remains unclear in populations with and without chronic kidney disease.

Aims: To examine the association between GNRI-defined nutritional risk and femoral fracture. To explore whether the eGFR-fracture relationship differs by nutritional status.

Methods: We conducted a retrospective longitudinal study using administrative claims and health examination data from April 2014 to December 2024. Eligible participants had calculable GNRI and estimated glomerular filtration rate (eGFR), with no fracture recorded during a 180-day look-back period. The outcome was first femoral fracture (ICD-10 S72). GNRI <98 defined nutritional risk. Incidence rates were calculated per 1000 person-years. Fine-Gray models estimated sHRs with death as a competing risk, adjusted for age, sex, chronic kidney disease stage, and region. Restricted cubic splines evaluated capped eGFR, referenced to 60 mL/min/1.73 m2, stratified by GNRI group.

Results: Among 102,937 participants, 622 incident femoral fractures occurred. Incidence was 0.92 per 1000 person-years with GNRI >=98 and 4.36 per 1000 person-years with GNRI <98. Nutritional risk was associated with higher femoral fracture hazard after adjustment (sHR 1.49, 95% CI 1.19 to 1.86; p<0.001). In spline analyses, lower eGFR was associated with higher femoral fracture hazard versus eGFR 60 mL/min/1.73 m2. This increase appeared more pronounced among participants with GNRI <98. Confidence intervals were wide at extreme eGFR values.

Conclusions: GNRI-defined nutritional risk was independently associated with incident femoral fracture in a large population with and without chronic kidney disease. Lower eGFR was linked to higher fracture hazard, particularly among participants with nutritional risk. Renal function and GNRI may jointly improve fracture risk assessment.

Keywords: femoral fracture; GNRI; eGFR

D1/P109

BRI vs. BMI for predicting the incident diabetes and hypertension: SKDB study

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Introduction: Obesity is a key risk factor for cardiometabolic disease and is commonly assessed using body mass index (BMI). However, BMI does not capture body fat distribution and may inadequately reflect adiposity-related metabolic risk. The body roundness index (BRI)—derived from height and waist circumference—has been proposed as an alternative indicator of central adiposity.

Aim: To investigate the predictive performance of BRI relative to BMI in a long-term population-based setting.

Methods: We analyzed data from the Shizuoka Kokuho Database (SKDB), a large regional healthcare database in Japan covering more than 2.5 million individuals between 2012 and 2024. Participants aged 40–74 years who underwent routine health checkups in 2013 and were free of diabetes and hypertension at baseline were followed for up to 11 years. We evaluated associations of BRI and BMI with incident diabetes and hypertension and compared predictive performance using net reclassification index (NRI) and c-statistic.

Results: A total of 93,532 individuals (median age, 64 years; 72% female; median BMI, 21.5 kg/m^2) were included. Over a median follow-up of 6 years, 57% had a newly-recorded diagnosis of diabetes, hypertension, or both. Compared with a base model adjusted for age and sex, adding either BRI or BMI significantly improved risk stratification to a similar degree (NRI: 12.1% [95% CI: 10.9–13.2%] for BRI and 13.2% [95% CI: 12.3–14.3%] for BMI). Both indices improved model discrimination, with c-statistic increases of 1.07% (95% CI: 1.06–1.07%) for BRI and 1.30% (95% CI: 1.30–1.31%) for BMI. BMI demonstrated modestly better discrimination than BRI, with a 0.24% (95% CI: 0.23–0.24%) higher c-statistic. Findings were consistent when diabetes and hypertension were analyzed separately.

Conclusions: Although both BRI and BMI predicted incident diabetes and hypertension and improved risk prediction beyond age and sex, BRI did not outperform BMI in the study population.

D1/P110

Latent class analysis-derived multimorbidity patterns and mortality in pharmacologically-treated type-2-diabetes in Australia

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Introduction: Type 2 diabetes (T2D) guidelines emphasize individualized treatment, yet there are limited representative studies on comorbidity patterns. People with T2D have a higher and growing burden of comorbidities, including non-cardiometabolic conditions.

Aims: To identify the multimorbidity patterns of persons with pharmacologically treated T2D and assess the risk of all-cause mortality using Australian real-world data.

Methods: A cohort of adults with T2D (≥30 years; N=95,187) and receiving glucose-lowering medication(s) was identified from the Victorian Admitted Episodes Dataset linked to Pharmaceutical Benefits Scheme (07/01/2012–12/31/2014). Latent class analysis was applied separately within three age groups (30–64, 65–74, ≥75) to identify multimorbidity patterns among those with ≥2 chronic conditions, excluding T2D. Cox regression was used to assess associations between these patterns and all-cause mortality through 06/30/2018.

Results: The sample included 34,855 individuals in the 30–64-year-old (56% male), 29,667 in the 65-74-year-old (58% male), and 30,665 in the ≥75-year-old (52% male) age groups. Five multimorbidity patterns were present in both younger age groups—complex multimorbidity, osteoporosis/cancer, cardiovascular, musculoskeletal, and unspecific (i.e., no diseases overexpressed)—while the oldest age group had only three: complex multimorbidity, osteoporosis/cancer, and unspecific. Relative to the unspecific pattern (reference), the complex multimorbidity pattern was associated with the highest mortality across all age groups (30–64: adjusted hazard ratio (aHR) 5.2, 95% confidence interval (CI) 4.5–6.0; 65–74: aHR 5.2, 95%CI 4.5–6.0; ≥75: aHR 2.1, 95%CI 2.0–2.3) followed by osteoporosis/cancer (30-64: aHR 2.9, 95%CI 2.5-3.4; 65-74: aHR 3.1, 95%CI ≥75: 1.2, 95%CI 1.1-1.2) and cardiovascular (30-64: aHR 1.5, 95%CI 1.3-1.7; 65-74: 2.2, 95%CI 1.9-1.7-2.1).

Conclusions: Complex multimorbidity was associated with five-fold higher risk of death in people aged 30-74 years and two-fold higher risk of death in people aged 75 years and older. Strategies addressing complex multimorbidity in older adults with T2D are needed.

Keywords: Latent Class Analysis, multimorbidity patterns, Type 2 diabetes

D1/P111

Obesity phenotypes and cardiovascular risk in metabolic dysfunction–associated steatotic liver disease

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Introduction: Metabolic dysfunction–associated steatotic liver disease (MASLD) is an established independent risk factor for major adverse cardiovascular events. Combined body mass index (BMI) and waist circumference (WC) categories define distinct obesity phenotypes reflecting general versus central adiposity, yet their long-term cardiovascular impact in MASLD remains unclear.

Aims: This study evaluated the long-term cardiovascular risk associated with combined BMI/WC obesity phenotypes among patients with MASLD.

Methods: This nationwide retrospective cohort study linked Taiwan's Adult Preventive Health Care Service database with the National Health Insurance Research Database. Patients with MASLD, defined as a Hepatic Steatosis Index >36 plus at least one cardiometabolic risk factor, were identified between January 2013 and December 2018 and classified by overweight status(BMI ≥23 kg/m^2) and central obesity(WC ≥90 cm in men, ≥80 cm in women) into four phenotypes: non-obesity, overweight only, central obesity only, and overweight with central obesity. Primary outcomes were all-cause mortality and 5-point major adverse cardiovascular events(5pt-MACE). Multivariable Cox proportional hazards models, adjusted for demographic and clinical covariates, estimated hazard ratios(HRs) with 95% confidence intervals(CIs).

Results: Among 1,644,704 participants followed for a mean of 7.7 years, central obesity only(HR 1.15; 95% CI, 1.08–1.22) and overweight with central obesity(HR 1.22; 95% CI, 1.17–1.26) were significantly associated with increased 5pt-MACE risk, whereas overweight only was not(HR 0.99; 95% CI, 0.95–1.03). For all-cause mortality, only central obesity only showed a marginally increased risk(HR 1.06; 95% CI, 1.00–1.14), whereas overweight only were associated with significantly reduced risk(HR 0.73; 95% CI, 0.71–0.76).

Conclusions: Cardiovascular and mortality risks varied substantially across BMI/WC phenotypes in MASLD. Central obesity, alone or combined with overweight, conferred the greatest cardiovascular risk, whereas overweight only appeared inversely related to mortality. These findings underscore the clinical value of phenotype-specific cardiovascular risk stratification in MASLD management.

Keywords: metabolic dysfunction–associated steatotic liver disease, obesity phenotypes, cardiovascular risks

D1/P112

Physical Frailty, Genetic Susceptibility, and Osteoporosis Risk: A Cohort Study

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Introduction: Osteoporosis is a major public health concern characterized by a high risk of debilitating fractures. While genetic predisposition is a known risk factor, modifiable characteristics like physical frailty also play a critical role. However, their combined longitudinal impact on incident osteoporosis remains poorly understood.

Aims: This study aimed to examine the longitudinal association between the physical frailty phenotype and incident osteoporosis. It additionally explored the modifying role of genetic predisposition on this relationship.

Methods: A prospective cohort study analyzed 437,045 participants (aged 37–73 years) initially free of osteoporosis. Exposures included the five-domain Fried frailty phenotype and a categorized polygenic risk score. Hazard ratios, risk advancement periods, and measures of additive interaction were estimated.

Results: Over a median 13.62 years of follow-up, 15,481 (3.5%) incident osteoporosis cases were identified. Baseline prevalence was 43.5% for pre-frailty and 8.1% for frailty. Osteoporosis risk increased with frailty severity, showing hazard ratios of 1.40 (95% CI, 1.35–1.45) for pre-frailty and 2.80 (95% CI, 2.63–2.99) for frailty. This association was strongest in younger adults (HR=4.90; 95% CI, 3.81–6.30). Jointly, high genetic risk and frailty markedly elevated risk (HR=6.40; 95% CI, 5.71–7.18), advancing the risk period by 19.98 years. A significant additive interaction existed between frailty and genetic susceptibility (RERI=1.52 for frailty).

Conclusions: Physical frailty is strongly associated with incident osteoporosis, particularly among younger populations. Integrating both frailty and genetic predisposition assessments into clinical screening could substantially enhance targeted preventive strategies. Future research should evaluate the clinical feasibility of implementing these combined screening tools in practice.

Keywords: Osteoporosis, Physical frailty, Polygenic risk score

D1/P113

Path-specific effects of persistent pain on incident hearing difficulty through time-varying mediators

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Introduction: Persistent pain and hearing difficulty are common later-life conditions linked to reduced independence, psychosocial distress, cognitive vulnerability, and healthcare burden. Evidence suggests persistent pain is associated with hearing difficulty, but pathways remain unclear. Tracing repeatedly measured mediators may identify dynamic, modifiable pathways through which persistent pain contributes to hearing difficulty.
Aims: This study quantified path-specific indirect effects through repeatedly measured, time-varying mediators in the association between persistent pain and incident hearing difficulty.
Methods: We used 1998-2022 biennial U.S. Health and Retirement Study data. Persistent pain was moderate or severe pain in both 1998 and 2000; incident hearing difficulty was first fair or poor self-rated hearing from 2004 onward among participants with excellent to good hearing in 2002. We estimated this association using competing-risk multi-state models and applied path-specific mediation analyses with repeatedly measured mediators spanning depressive symptoms, cognition, BMI, self-rated health, ADL/IADL, physical activity, sleep disturbance, mobility and muscle limitation, social isolation/loneliness, incident morbidity, falls, and healthcare utilization.
Results: Among 12,093 participants, mean age was 63.5years (SD 9.6) and 63.2% were women. Within the persistent pain-incident hearing difficulty association, sleep disturbance showed significant indirect effects across follow-up (e.g., 0.019, 95% CI 0.014-0.025 at 12 years), with the estimated proportion mediated increasing from 41.3% at 2 years to 58.0% at 20 years. Stable indirect effects were also observed for CES-D depressive symptoms (0.017, 95% CI 0.011-0.021; 39.9%), cognition score (0.005, 95% CI 0.002-0.007; 11.7%), BMI (0.006, 95% CI 0.002-0.008; 13.4%), self-rated health (0.014, 95% CI 0.008-0.023; 35.5%), large muscle index (0.017, 95% CI 0.008-0.025; 41.3%), incident arthritis/rheumatism (0.003, 95% CI 0.002-0.004; 10.1%), and outpatient surgery (0.001, 95% CI 0.0001-0.002; 2.7%).
Conclusions: Time-varying mediators partly explained the association between persistent pain and incident hearing difficulty, highlighting modifiable pathways for preventing or delaying hearing difficulty.
Keywords: persistent pain; hearing difficulty; mediation analysis

D1/P114

Real-World Renal Outcomes of Sglt-2 Inhibitors in Diabetic Kidney Disease

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Introduction: Type 2 Diabetes Mellitus is a leading cause of chronic kidney disease, a major global health burden affecting nearly 700 million people worldwide. SGLT2 inhibitors have demonstrated favorable renal outcomes in patients with T2DM and CKD, with landmark trials such as DAPA-CKD showing reductions in albuminuria and slowing of CKD progression. However, prospective real-world evidence on the effectiveness of SGLT2 inhibitors among Indian patients with T2DM and CKD remains limited.

Aims: To evaluate the real-world effectiveness of SGLT-2 inhibitors on renal outcomes in patients with Type-2 DM and CKD.

Methods: A prospective cohort study was conducted among 81 adults with Type-2 DM and CKD receiving SGLT-2 inhibitor therapy at a tertiary care teaching hospital in Mysuru, India. Eligible patients were followed for 6 months, and renal and glycemic parameters were assessed at baseline, 3 months, and 6 months. Changes in UACR, eGFR, serum creatinine, RBS, and HbA1c over time were analyzed using repeated-measures ANOVA.

Results: Among 81 patients with T2DM and CKD, SGLT-2 inhibitor therapy resulted in a significant reduction in UACR from 417.38 ± 119.66 mg/g to 295.05 ± 104.01 mg/g over 6 months ($p < 0.001$). Renal function remained stable, with no significant changes in eGFR (47.43 ± 19.60 vs. 47.51 ± 17.64 mL/min/1.73m^2; $p = 0.993$) or serum creatinine levels (1.75 ± 0.58 vs. 1.69 ± 0.49 mg/dL; $p = 0.797$). Modest reductions were observed in HbA1c and RBS, although these changes were not statistically significant.

Conclusion: SGLT2 inhibitor therapy was associated with a significant reduction in albuminuria and preservation of renal function in patients with T2DM and CKD in a real-world clinical setting. These findings support the effectiveness of SGLT2 inhibitors in the management of diabetic kidney disease and reinforce their role in slowing renal disease progression.

Keywords: SGLT-2 inhibitors; CKD; Real-World Evidence

D1/P115

Alzheimer's and Dementia Risk: JAK Inhibitors vs Abatacept in Rheumatoid Arthritis

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Introduction: JAK inhibitors, established therapies for rheumatoid arthritis (RA), have been proposed as drug repurposing candidates for Alzheimer's and Dementia Risk (ADRD) through modulation of the JAK/STAT pathway, but real-world evidence remains limited.

Aims: To evaluate whether JAK inhibitors reduce the risk of developing ADRD in patients with rheumatoid arthritis.

Method: We conducted a retrospective cohort study under a target trial emulation framework using data from the TriNetX US Collaborative Network. Patients aged ≥ 65 years initiating either JAK inhibitors (tofacitinib, baricitinib, or upadacitinib) or abatacept were included. We applied a one-year washout period to exclude prevalent users. Patients with other autoimmune diseases sharing treatment indications were excluded. We incorporated a 6 month induction period to account for the latency window of ADRD. Thus, the index date was defined as 6 months after study drug initiation. Participants were followed until outcome occurrence, death, or study end. We used intention-to treat analysis and 1:1 propensity score matching to emulate randomization in the target trial and ensure similar probabilities of treatment assignment. ADRD were identified using ICD-10-CM codes for Alzheimer's disease (G30) and unspecified dementia (F03). We applied Cox models to estimate hazard ratios (HR) and 95% confidence interval (CI), using abatacept as reference. We conducted subgroup analyses by individual JAK inhibitor agents, sex and age.

Results: We included 16,606 patients (8,837 JAK inhibitors, 7,769 abatacept) respectively. The mean age was 71.4 years (SD 5.22) and 72.2 years (SD 5.22), with 22.46% and 22.33% male, respectively. We observed an association between a reduced risk of ADRD (HR=0.866, 95% CI: 0.683-1.098).

Conclusions: We observed that JAK inhibitors were associated with a reduced risk of developing ADRD compared with abatacept, suggesting a potential effect on prevention of developing ADRD that requires validation in future studies.

Keywords: JAK inhibitors, Alzheimer's Disease, dementia, rheumatoid arthritis.

D1/P116

Real-world effectiveness of enfortumab vedotin plus immunotherapy for urothelial cancer in Taiwan

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Introduction: The landmark EV-302 trial established enfortumab vedotin plus pembrolizumab (EV+P) as the standard first-line treatment for advanced urothelial carcinoma (aUC). However, real-world evidence regarding enfortumab vedotin plus immunotherapy (EV+IO) in Asian populations remains extremely limited.

Aims: To evaluate the real-world effectiveness and safety of EV+IO in patients with aUC.

Methods: This multicenter retrospective cohort study utilized electronic medical records in Taiwan. Patients with aUC initiating EV+IO (i.e., nivolumab and pembrolizumab) between August 2022 and May 2024 were included. The index date was defined as the first EV+IO prescription and was followed through May 2026. Primary outcomes of progression-free survival (PFS) and overall survival (OS) were analyzed using the Kaplan-Meier method, alongside the objective response rate (ORR) and disease control rate (DCR). Safety endpoints focused on treatment-related adverse events (TRAEs), specifically peripheral neuropathy and dermatologic toxicities, and subsequent dose modifications.

Results: A total of 33 Asian patients (median age 68 years; 66.7% metastatic) were analyzed. Notably, upfront dose reduction (<1.25 mg/kg) was implemented in 84.8% of patients. The median number of EV cycles administered was 5.0 (range, 1.0–30.0), with achieving ORR as the primary reason for discontinuation. The ORR reached 45.4% (21.2% complete, 24.2% partial), and the DCR was 60.6% with an additional 15.2% achieving stable disease. After a 16.0-month median follow-up, the median PFS was 14.5 months, while the median OS was not reached. (overall survival rate: 69.7%). Regarding safety, only 3.0% experienced grade 3–4 toxicities (maculopapular skin rash), which were managed with dose reduction.

Conclusions: EV+IO demonstrates comparable real-world effectiveness and a manageable safety profile in Asian patients, with clinical outcomes consistent with those of the landmark EV-302 trial. However, a longer follow-up study is warranted to confirm long-term survival benefits in routine clinical practice.

Keywords: Urothelial carcinoma, enfortumab vedotin, Taiwan

D1/P117

Treatment patterns and outcomes of neoadjuvant durvalumab plus GC in MIBC

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Introduction: Perioperative durvalumab plus gemcitabine–cisplatin has emerged as a new standard of care for Muscle-Invasive Bladder Cancer (MIBC) following the NIAGARA trial. However, real-world evidence in Asian populations remains limited.

Aims: This study evaluated the perioperative pattern in Taiwanese MIBC patients.

Methods: This retrospective observational study used a multicenter electronic medical records database. Patients with MIBC who initiated durvalumab plus gemcitabine–cisplatin, defined as the index date, between December 2024 and February 2026 were included. Patients were followed until loss to follow-up, death, or data cutoff in May 2026. Primary outcomes included treatment patterns, effectiveness, and safety. Treatment patterns were assessed by completion of neoadjuvant therapy and receipt of curative-intent surgery. Effectiveness was assessed based on tumor response at the first available radiographic or pathological evaluation following neoadjuvant treatment, while safety was assessed according to CTCAE v5.0.

Results: A total of 25 patients with a median age of 65 years were included. Most patients were male (80.0%) and had ECOG performance status 0 (88.0%). T2N0 disease accounted for 64.0% of cases, while 12.0% had regional lymph-node involvement. Among all patients, 17 (68.0%) completed four cycles of neoadjuvant GC+D, and 5 (20.0%) subsequently underwent radical cystectomy (RC). Tumor responses included 8 complete responses, 11 partial responses, and 3 stable diseases. After a median follow-up of 9.4 months, disease progression occurred in 8 patients (disease-free survival: non-reached). Grade 3 treatment-related adverse events occurred in 7 patients, with no Grade 4–5 events. Neutropenia was the most common Grade ≥2 adverse event (44.0%).

Conclusions: Real-world neoadjuvant GC+D showed encouraging effectiveness and acceptable tolerability among Taiwanese patients with MIBC. However, given the limited use of subsequent RC in routine practice, larger studies with longer follow-up are warranted.

Keywords: muscle-invasive bladder cancer; durvalumab; neoadjuvant therapy

D1/P118

Systematic Review of Chemotherapy-Induced Toxicities in Cervical Cancer Patients

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Introduction: Cervical cancer remains a leading cause of cancer-related morbidity and mortality among women worldwide, particularly in low- and middle-income countries. Although chemotherapy and concurrent chemoradiotherapy significantly improve disease control, treatment-related toxicities continue to compromise therapeutic adherence, quality of life, and clinical outcomes. Existing evidence on chemotherapy-induced adverse events in cervical cancer remains fragmented, with limited focus on standardized toxicity reporting and pharmacovigilance-based safety evaluation. Addressing these gaps is essential for optimizing supportive care and improving patient-centered treatment strategies.

Aim: To systematically evaluate the prevalence, pattern, severity, and clinical implications of chemotherapy-induced toxicities in cervical cancer patients, with emphasis on pharmacovigilance and safety outcomes.

Methods: A systematic review was performed using PubMed, Scopus, Web of Science, and Google Scholar databases for studies published between 2010 and 2025. Studies reporting chemotherapy-associated toxicities among cervical cancer patients were screened according to PRISMA guidelines. Research involving cisplatin-based therapy, combination chemotherapy, and concurrent chemoradiotherapy was included. Data regarding adverse drug reactions, toxicity grading, treatment modifications, and supportive care interventions were extracted and qualitatively synthesized.

Results: 34 studies involving over 7,500 cervical cancer patients were included. Haematological toxicities, particularly anaemia, neutropenia, and thrombocytopenia, were the most frequently reported adverse events, followed by gastrointestinal complications such as nausea, vomiting, mucositis, and diarrhoea. Cisplatin-based regimens showed increased risks of nephrotoxicity and electrolyte disturbances, while combination therapies demonstrated higher incidences of grade III/IV toxicities. Several studies emphasized that early toxicity monitoring, dose optimization, and multidisciplinary supportive care significantly reduced treatment interruption and hospitalization.

Conclusion: Chemotherapy-induced toxicities remain a critical barrier to effective cervical cancer management. This review highlights major gaps in standardized pharmacovigilance reporting and supports the integration of proactive toxicity monitoring and patient-centered safety strategies to improve therapeutic outcomes.

Keywords: Adverse drug reactions, Cervical cancer, Chemotherapy toxicity, Pharmacovigilance, Safety outcomes, Supportive care.

D1/P120

Sequential versus Concurrent Immunotherapy-Radiotherapy in Solid Tumors: Network Meta-Analysis

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Introduction: Radiotherapy (RT) combined with immune checkpoint inhibitors (ICIs) has emerged as a promising treatment strategy for patients with solid tumors. Preclinical and clinical evidence suggests that RT may enhance antitumor immune responses and improve the efficacy of ICIs. However, the optimal timing of ICI administration relative to RT remains uncertain. This uncertainty may influence both treatment effectiveness and safety outcomes.

Aims: This study aimed to compare the efficacy and safety of sequential versus concurrent ICI administration in combination with RT. A systematic review and network meta-analysis were conducted to evaluate differences in survival and toxicity outcomes between treatment strategies.

Methods: PubMed, Embase, CENTRAL, and ClinicalTrials.gov were systematically searched through February 2025. Randomized controlled trials evaluating ICIs administered either during RT (concurrent strategy) or after RT completion (sequential strategy) were eligible for inclusion. Overall survival (OS) was the primary endpoint, while progression-free survival (PFS) and grade ≥3 adverse events (AEs) were secondary endpoints. A random-effects network meta-analysis was performed.

Results: Twenty-four randomized controlled trials involving 9,480 patients were included. Compared with control treatment, sequential ICI administration significantly improved OS (HR, 0.81; 95% CI, 0.72–0.92). Sequential administration also improved PFS (HR, 0.73; 95% CI, 0.64–0.84). Concurrent administration did not demonstrate statistically significant survival benefits compared with control treatment. Direct comparison showed superior PFS with sequential administration versus concurrent administration (HR, 0.81; 95% CI, 0.67–0.97). No significant difference in grade ≥3 AEs was observed between sequential and concurrent strategies (OR, 1.02; 95% CI, 0.56–1.85).

Conclusions: Sequential administration of ICIs following RT was associated with improved survival outcomes without increasing severe toxicity. These findings suggest that treatment sequencing may be an important determinant of clinical benefit when combining RT and immunotherapy in solid tumors. Further studies are needed to identify factors that influence the optimal sequencing strategy.

Keywords: Radiotherapy; Immune checkpoint inhibitors; Network meta-analysis

D1/P121

Efficacy of iguratimod for treating rheumatoid arthritis: a systematic review and meta-analysis

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Introduction: Iguratimod is a csDMARD for treating rheumatoid arthritis, approved in China, Japan, South Korea, and India (through 2011-2019). Existing evidence primarily demonstrates superior efficacy of iguratimod plus methotrexate versus methotrexate monotherapy; systematic review evidence comparing iguratimod to other csDMARDs remains limited.

Aims: To evaluate the efficacy/effectiveness of iguratimod.

Methods: A systematic review was conducted in PubMed and China National Knowledge Infrastructure (CNKI) (through April 2026). Randomized controlled trials (RCTs) and observational studies which compared the efficacy/effectiveness of iguratimod versus another csDMARD were identified. 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: Fifteen studies were identified (8 in English, 7 in Chinese; 10 RCTs, 5 observational). Studies mostly had treatment durations of 24 weeks (9 studies) or 52 weeks (4 studies). Three studies were rated as low quality (all were RCTs), mainly due to lack of blinding and unclear dropout reporting; the other 12 studies were rated as high quality.
Nine studies evaluated monotherapies (iguratimod vs. leflunomide, salazosulfapyridine, or methotrexate); while 6 studies compared “methotrexate plus iguratimod” versus “methotrexate plus another csDMARD” (tacrolimus, salazosulfapyridine, leflunomide, or hydroxychloroquine). Iguratimod users exhibited significant improvements from baseline in 13 studies (measured by DAS28-CRP, TJC, SJC, etc.); while the remaining 2 studies did not report changes from baseline. Iguratimod demonstrated superior efficacy/effectiveness to comparators in 4 studies, and non-inferiority in the others.
Pooled meta-analysis showed significantly higher DAS28-CRP remission for iguratimod versus comparators (pooled RR: 1.39 [1.04; 1.87], 7 studies [1184 patients]); and no significant difference for ACR20 response (pooled RR: 1.06 [0.98; 1.14], 8 studies [1674 patients]).

Conclusions: This study adds to the evidence that iguratimod is effective for rheumatoid arthritis treatment.

Keywords: Iguratimod, efficacy, meta-analysis

D1/P122

Vitamin D supplementation and cardiovascular disease progression in prediabetes: a multi-state analysis

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Introduction: Vitamin D has been linked to metabolic and vascular pathways that may influence cardiometabolic health. However, evidence regarding its role in cardiovascular disease progression among people with prediabetes remains unclear.

Aims: We aimed to investigate the associations between vitamin D supplementation and transitions
across cardiometabolic disease states among individuals with prediabetes.
Methods: This prospective cohort study included UK Biobank participants with prediabetes who were free of cardiovascular disease and cancer at baseline. The exposure of interest was vitamin D supplementation. Multi-state models were used to examine six transitions from prediabetes to incident type 2 diabetes mellitus (T2DM), major adverse cardiovascular events (MACE), and death. Additional analyses separately assessed transition patterns involving heart failure, stroke, and myocardial infarction.

Results: Among 47,265 eligible participants, 7214 (15.3%) participants developed incident T2DM, 3990 (8.4%) developed MACE, and 4642 (9.8%) died during a median follow-up of 13.97 years. Vitamin D supplementation was associated with a modestly lower risk of progression from prediabetes to incident T2DM (HR = 0.93, 95% CI, 0.88 to 0.98; P = 0.012). In contrast, associations with subsequent transitions to MACE or death were closer to the null. Specific analyses for heart failure, stroke, and myocardial infarction showed patterns broadly consistent with those observed for overall MACE.

Conclusions: These findings suggest that, in prediabetes, vitamin D supplementation was more related to early metabolic progression than to later cardiovascular or mortality transitions.

Keywords: vitamin D, prediabetes, multi-state models

D1/P123

Mebeverine versus otilonium bromide for quality-of-life outcomes in irritable bowel syndrome

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Background: Irritable bowel syndrome (IBS) is a common chronic gastrointestinal disorder that significantly impairs quality of life, with a prevalence of 5.5–14.4% in Vietnam. Mebeverine and otilonium bromide (OB) are commonly used first-line antispasmodics; however, comparative evidence on their effectiveness remains limited. This study aimed to compare the efficacy and safety of mebeverine and OB, with IBS-QOL as the primary outcome.

Methods: This single-center prospective cohort study (from December 2024 to July 2025) included adult IBS patients fulfilling Rome IV criteria. Treatment allocation (mebeverine 200 mg twice daily or OB 40 mg twice daily for 4 weeks) was based on the treating physician's decision. The IBS-QOL questionnaire was interviewer-administered at baseline and at week 4. IBS-QOL total and subdomain scores were compared within and between groups. Adverse events were recorded and graded according to the Common Terminology Criteria for Adverse Events.

Results: A total of 110 patients were included in this study. Most baseline demographic and clinical characteristics, were similar between groups, although regular exercise and the use of rifaximin and trimebutine were more frequent in the mebeverine group. IBS-D was the most common subtype. IBS-QOL total scores increased from 74.3 (66.4–85.2) to 98.2 (92.6–100.0) in the mebeverine group and from 77.9 (66.0–86.80) to 97.4 (85.8–100.0) in the OB group ($p < 0.05$). Greater improvements favoring mebeverine were observed in the IBS-QOL total score, interference with activity, and health worry domains ($p = 0.034$, 0.043, and 0.029, respectively). Mild adverse events occurred in 7.7% of patients, with no significant difference between groups ($p = 0.875$). Concomitant sulpiride use was independently associated with greater improvement in IBS-QOL ($\beta = 6.72$; 95% CI 0.30–13.14; $p = 0.040$), representing a hypothesis-generating finding.

Conclusion: Both mebeverine and OB were safe and effective in improving IBS-QOL over 4 weeks, with greater benefits observed for mebeverine.

D1/P124

Real-world streptokinase outcomes in acute myocardial infarction

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Introduction: Timely reperfusion for acute myocardial infarction is often constrained in resource-limited health systems by delayed presentation, affordability barriers, and limited catheterization capacity. Streptokinase remains a low-cost thrombolytic option, but real-world evidence on its clinical value and safety in routine care is needed. Understanding outcomes in patients who receive or do not receive streptokinase can inform pragmatic reperfusion pathways.

Aims: To compare real-world clinical outcomes of patients with acute myocardial infarction treated with streptokinase versus those not treated with streptokinase. The study assessed recovery, in-hospital mortality, complications, length of stay, follow-up need, and short-term survival.

Methods: A retrospective observational study used medical records of 100 adult patients with acute myocardial infarction admitted to coronary care units from April to June 2024. Patients were classified as streptokinase-treated (n=50) or non-streptokinase (n=50). Demographic, laboratory, treatment, and outcome variables were extracted using a structured form. Comparative analyses and Kaplan–Meier survival analysis were performed using statistical software.

Results: Streptokinase-treated patients presented earlier than non-treated patients (4.44±3.90 vs 7.04±5.08 hours; p=0.005). Despite higher admission troponin (1.85±0.84 vs 0.78±1.02 ng/mL; p<0.001) and CK-MB levels (37.50±7.43 vs 17.55±15.06 U/L; p<0.001), the streptokinase group had substantially higher full recovery (74% vs 20%). In-hospital mortality was lower with streptokinase (6% vs 28%). Complications were more frequent with streptokinase (54% vs 18%; p<0.001), mainly cardiogenic shock, post-infarction angina, arrhythmias, and thrombolysis-related bleeding. Length of stay was similar between groups (8.14±1.68 vs 8.24±2.74 days; p=0.826). Survival distributions were not significantly different during short-term follow-up (log-rank p=0.136).

Conclusions: Streptokinase was associated with improved recovery and lower in-hospital mortality despite higher manageable complications. These findings support protocol-driven patient selection, timely administration, and safety monitoring when advanced reperfusion options are limited.

Keywords: Streptokinase; drug effectiveness; acute myocardial infarction.

D1/P125

Impact of Semaglutide on Diabetic Microvascular Complications: A Systematic Review and Meta-Analysis

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Introduction: Semaglutide, a glucagon-like peptide-1 receptor agonist, provides significant glycemic and weight-loss benefits in type 2 diabetes mellitus (T2DM). However, its impact on microvascular complications, particularly diabetic retinopathy, remains uncertain due to conflicting evidence.

Aims: To evaluate the association between semaglutide and microvascular complications in patients with T2DM and to assess its effects on key metabolic outcomes including HbA1c, body weight, and body mass index.

Methods: A systematic review and meta-analysis of randomized controlled trials (RCTs), registered with PROSPERO, was conducted following PRISMA 2020 guidelines. PubMed, Embase, and Scopus were searched from inception to August 2025 for English-language RCTs involving adults (≥18 years) with T2DM receiving semaglutide at any approved dose or frequency and reporting microvascular outcomes. Risk of bias was assessed using the Cochrane RoB 2 tool, and pooled risk ratios and mean differences were calculated through meta-analysis.

Results: Semaglutide did not show a significant increase in diabetic retinopathy compared with active comparators (RR 0.89, 95% CI 0.75–1.06) or placebo (RR 1.16, 95% CI 0.92–1.46), with low heterogeneity across analyses. A lower incidence of diabetic nephropathy was observed with semaglutide than placebo recipients (3.8% vs 6.1%), suggesting potential renoprotective effects. Evidence regarding diabetic neuropathy was limited and inconclusive. Semaglutide consistently improved metabolic outcomes, demonstrating HbA1c reductions of up to 2.0%, body weight reductions of up to 13.2 kg, and BMI reductions of up to 4.1 kg/m^2. Dose-dependent improvements were observed across multiple trials.

Conclusions: This meta-analysis of 25,442 participants provides robust semaglutide-specific evidence demonstrating no significant increase in microvascular risk while confirming substantial metabolic benefits in T2DM. These findings support the continued clinical use of semaglutide and help address ongoing concerns regarding its microvascular safety profile. Future long-term studies with dedicated microvascular endpoints are warranted.

Keywords: Semaglutide; Type 2 Diabetes Mellitus; Microvascular Complications.

D1/P126

Combined effects of statin adherence and PCSK9 inhibitor persistence on post-revascularization outcomes

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Introduction: Patients undergoing revascularization require intensive lipid-lowering therapy. However, the impact of lipid management patterns on outcomes remains unclear in China.

Aims: To evaluate the association of lipid management patterns with low-density lipoprotein cholesterol (LDL-C) and major adverse cardiovascular events (MACE) following revascularization.

Methods: Retrospective cohort data were obtained from the EHR system covering > 70 secondary and tertiary hospitals in Tianjin, China. Patients undergoing revascularization who newly initiated PCSK9 inhibitors (PCSK9is) in 2022 were included. A 90-day landmark design was applied. Patients were classified into four lipid management patterns based on statin adherence in the first 6 months post-revascularization and PCSK9i persistence during the landmark period (persistent: >1 prescription; non-persistent: 1 prescription): Group 1 (adherent/persistent), Group 2 (adherent/non-persistent), Group 3 (non-adherent/persistent), and Group 4 (non-adherent/non-persistent). Multivariable linear regression and Cox models were used to evaluate the associations of lipid management patterns with LDL-C and MACE, respectively. A 180-day landmark analysis served as sensitivity analysis.

Results: Among 1,560 eligible patients (mean age 63.0 years, 69.0% male), Group 1 achieved significantly lower LDL-C levels than Group 4 in the 90-day landmark analysis (adjusted β=-0.25 mmol/L, 95% CI -0.43 to -0.07; P=0.006). Among patients with discordant lipid management patterns, Group 3 had numerically lower LDL-C levels than Group 2 in the 90-day landmark analysis (adjusted β=0.16 mmol/L, 95% CI -0.02 to 0.35; P=0.084). This association became statistically significant in the 180-day landmark analysis (adjusted β=0.26 mmol/L, 95% CI 0.04 to 0.48; P=0.023). During a median follow-up of 1.7 years, MACE showed a directionally consistent pattern, with the lowest risk in Group 1.

Conclusions: Both statin adherence and persistent PCSK9is use were associated with improved lipid outcomes following revascularization. Persistent PCSK9i use may contribute substantially to LDL-C control, even among patients with poor statin adherence at baseline.

Keywords: Lipid management; PCSK9is; Real-world evidence

D1/P127

Efficacy and safety of treatments for idiopathic pulmonary fibrosis: a network meta-analysis

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Introduction: Idiopathic pulmonary fibrosis (IPF) is a progressive, chronic interstitial lung disease. Although approved antifibrotic agents (pirfenidone and nintedanib) can slow disease progression. Multiple investigational agents have entered clinical trials, a network meta-analysis (NMA) is needed to simultaneously compare their relative efficacy and safety.
Aims: To compare the efficacy and safety of antifibrotic agents and novel therapeutics for slowing disease progression in patients with IPF.
Methods: A systematic review of randomized controlled trials (RCTs) was conducted using PubMed, Scopus, and Google Scholar (inception to March 2026). Outcomes included forced vital capacity (FVC in mL and %predicted), six-minute walk test (6MWT) distance, all-cause mortality, and diarrhea. Risk of bias was assessed using RoB 2, and network consistency was evaluated using the side-splitting approach
Results: Among 44 included RCTs, four agents significantly preserved FVC (mL) versus placebo: Zinpentraxin alfa (MD 126.05; 95%CI 11.21, 240.88), Bexotegrast (MD 106.08; 95%CI 31.72, 180.45), Pirfenidone (MD 86.81; 95%CI 37.35, 136.27), and Nintedanib (MD 74.83; 95%CI 51.05, 98.60). Significant FVC %predicted improvements were observed with BMS-986020 (MD 3.41; 95%CI 0.48, 6.33), Nintedanib (MD 2.99; 95%CI 2.17, 3.80), and Pirfenidone (MD 2.51; 95%CI 1.12, 3.91). Treprostinil significantly improved 6MWT (MD 31.12; 95%CI 13.65, 48.59). For all-cause mortality, Pirfenidone showed the greatest risk reduction (RR 0.60; 95%CI 0.44, 0.80), followed by Nintedanib (RR 0.81; 95%CI 0.67, 0.97). Nintedanib carried the highest diarrhea risk (RR 3.11; 95%CI 2.91, 3.32). Most studies had low risk of bias; network consistency was confirmed for FVC mL (p=0.37) but not FVC %predicted (p=0.004), warranting cautious interpretation of those indirect comparisons.
Conclusion: Standard antifibrotic agents remain the cornerstone of IPF treatment. Based on this NMA, pirfenidone showed reduction of all-cause mortality, followed by nintedanib; both significantly preserve lung function. However, diarrhea with nintedanib, require protective management.
Keywords: Idiopathic Pulmonary Fibrosis; Antifibrotic Agents, FVC, Network Meta-Analysis

D1/P128

Determinants of diabetes medication adherence across ABC taxonomy phases: an umbrella review

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Introduction: Medication adherence is a key determinant of glycaemic control and long-term outcomes in people with diabetes. The ABC taxonomy conceptualizes adherence as three interrelated phases: initiation, implementation, and discontinuation. However, existing evidence on adherence determinants is often fragmented and does not consistently distinguish between these phases. Understanding phase-specific determinants is essential for developing targeted interventions to improve adherence.

Aims: To identify factors associated with medication adherence in diabetes and classify these determinants according to the initiation, implementation, and discontinuation phases of the ABC taxonomy.

Methods: An umbrella review was conducted using MEDLINE, EBSCO, and Scopus from database inception to May 2025. Systematic reviews examining factors associated with medication adherence among adults with type 1 or type 2 diabetes were eligible. Determinants were mapped to the ABC taxonomy and five conceptual domains. Methodological quality was assessed using the AMSTAR 2 tool.

Results: Twenty-eight systematic reviews comprising 795 primary studies were included. Most evidence focused on the implementation phase, whereas initiation and discontinuation were less frequently examined. Initiation was primarily influenced by patient-related factors, including fear of injections, health beliefs, and self-efficacy, as well as socioeconomic factors such as income, education, and social support. Implementation was associated with a broader range of determinants, including health literacy, treatment regimen complexity, adverse effects, and financial burden. In the discontinuation phase, financial constraints, insurance coverage, perceived treatment efficacy, and adverse effects were the most frequently reported determinants. The majority of included reviews were rated as moderate to high methodological quality.

Conclusions: Medication adherence in diabetes is a multifactorial and phase-dependent process characterized by distinct yet overlapping determinants across the adherence continuum. Future research should consistently apply the ABC taxonomy to generate phase-specific evidence and support the development of targeted adherence interventions.

Keywords: diabetes mellitus; medication adherence; ABC taxonomy

D1/P129

Age-specific trends and projections in insulin use in Hong Kong:2002-2030

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Introduction: Insulin prescribing has shifted with newer non-insulin agents and insulin formulations, but age-specific trends in East Asians remain understudied despite high young-onset diabetes and beta-cell deficiency in older adults.

Aims: To examine age-specific trends in insulin use in Hong Kong (2002-2023) and project to 2030.

Methods: We conducted a serial cross-sectional analysis using Hong Kong electronic-health-records (2002-2023) including 313,861 insulin users among 1,148,281 adults with diabetes. We calculated annual age- and sex-standardized proportions, estimated annual-average-percent-change (AAPC), and used exponential smoothing to project trends to 2030.

Results: The number of adults with diabetes increased from 166,559 in 2002 to 836,976 in 2023. The proportion of insulin users decreased modestly (11.9%-to-11.2%, AAPC= -0.4 [95% CI: -0.5, 0]), while absolute number increased by 4.5-fold (from 20,096 to 95,623). By age-groups, insulin use declined in the 20-44 (18.7%-to-14.5%), 45-59 (12.1%-to-9.7%), and 60-74 age-groups (11.6%-to-10.6%) in 2020-2023. Across all age-groups, human insulin use decreased substantially, while insulin analogue use increased markedly, particularly among older adults (0.3%-to-3.1%, AAPC=23.2% for 60-74 years; and 0.04%-to-3.7%, AAPC=28.1% for ≥75 years). By 2030, overall insulin use is projected to reach 11.3% or 124,793 users (95% prediction intervals [PIs]: 73,231-90,297]) in Hong Kong. Insulin use will remain highest among adults aged ≥75 years at 13.0% (95% PI:10.7-15.4%), reach 14.5%(95% PI:11.9-17.1%) in the 20-44 age-groups, remain at 10.6% (95% PI: 8.5-12.6%) in the 60-74 age-group, and decline to 8.9% (95% PI: 4.9-12.8%) among the 45-59 age-group.

Conclusions: Overall, the proportion of people treated with insulin remained stable at 11%, absolute number of users increased by 4.5-fold due to rising prevalence of diabetes. Overall insulin use declined in younger and middle-aged adults but increased in the oldest group. Projections suggest overall insulin use is expected to remain relatively stable, with the highest levels in the youngest and oldest age-groups.

D1/P130

Utilisation pattern and costs of first-line antiseizure medications in Australia

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Introduction: In January 2021, levetiracetam and lamotrigine were listed on the Pharmaceutical Benefits Scheme (PBS) for first-line treatment of epilepsy to include women of childbearing age. This provided subsidised access to these medicines in addition to other first-line treatments for epilepsy (carbamazepine, clonazepam, ethosuximide, nitrazepam, phenobarbital, phenytoin, primidone, sulthiame, valproate).

Aims: To evaluate changes in the 1) utilisation patterns; and 2) estimated government costs for first-line antiseizure medications in Australia, between pre-policy (2017-2020) and post-policy (2021-2025).

Methods: Publicly available (2017-2025) and aggregated PBS dispensing data were used. Data were obtained in monthly intervals, stratified by medication. Corresponding Estimated Resident Populations at 30th June each year were obtained from the Australian Bureau of Statistics. Dispensing rates per 10,000 person-years were estimated, with changes compared over time and pre/post policy change.

Results: Overall, 20,181,161 (levetiracetam (31%), valproate (28%), lamotrigine (20%), and carbamazepine (11%), clonazepam (4.5%), phenytoin (3.6%), ethosuximide (0.6%), primidone (0.6%), phenobarbital (0.4%), nitrazepam (0.2%), and sulthiame (0.05%)) prescriptions were dispensed (2017-2025). Dispensing rates increased over this period, with lamotrigine (123.84 to 222.83 per 10,000 population), and levetiracetam (186.11 to 316.39 per 10,000 population). The dispensing rates of valproate increased slightly (233.15 to 241.53 per 10,000 population). Comparing the dispensing rates from pre-policy to post-policy: lamotrigine dispensing significantly increased by 68%; levetiracetam by 53%; valproate by 14%; and carbamazepine by 10%. Whereas, the dispensing rate of phenytoin decreased by 13% during post-policy compared to pre-policy period. The total government cost for subsidising first-line epilepsy medicines from 2017–2025 was AU$477,680,081. Compared to pre-policy period, the average annualised cost for lamotrigine increased by 13% (AU$915479) and levetiracetam by 29% (AU$4,402,943) after the post-policy change.

Conclusion: Dispensing patterns of levetiracetam and lamotrigine increased significantly after expansion of PBS prescribing restrictions allowing subsidy of these medicines as a first-line use.

Keywords: Antiseizure medications, utilisation, cost

D1/P131

Uptake of longer prescription durations for type 2 diabetes in Australia

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Introduction: Medicines account for 30% of healthcare expenditure among people with type 2 diabetes (T2D), with the cost of prescribed medicines being a significant treatment barrier.

Aims: We evaluated the uptake of Australia's Pharmaceutical Benefits Scheme 60-day prescription policy (PBS 60DP policy) for T2D medicines introduced in March 2024. The policy allows for double of supply per dispensing, from 30- to 60-days, with potential major cost savings.

Methods: We used national dispensing records of a 10% random sample of PBS eligible people from March/2024 to February/2025 to examine the number of people dispensed at least one 60-day prescription, and the total volume of 60-day dispensings. We calculated savings with T2D medicines using co-payment fees ($31.60 for general beneficiaries and $7.70 for people with government entitlements) and the number of 60-day dispensings observed. We estimated population-level use and savings by multiplying the results by 10.

Results: 32,098 (19.4%) people were dispensed at least one 60-day prescription,with a total of 43,907 dispensings of 60-day prescriptions for general and 57,825 for concessional beneficiaries. Uptake reached 23.5% of people dispensed T2D medicines, and 21% of all dispensings by February/2025. Uptake was highest for fixed-dose combinations, particularly dipeptidyl peptidase 4 inhibitors + sodium-glucose co-transporter 2 inhibitors, 35.9%. People who were older people, with more comorbidities, and dispensed more T2D medicines had higher usage of 60-day prescriptions. Savings reached $1,387,461 for general patients and $445,252 for people with government entitlements.

Conclusions: The uptake of the 60DP policy for T2D medicines in the first year of implementation was modest. Extrapolating our results to the Australian population, we estimate 320,980 people accessed at least one 60-day prescription for T2D, equating to $18 million in savings in co-payments. Targeted education for clinicians and patients should further bolster policy uptake.

Keywords: Prescription duration, Pharmacotherapy, Pharmacoepidemiology, Health Policy, Type 2 diabetes

D1/P132

Potentially inappropriate prescribed medicines among people hospitalised with heart failure in Australia

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Introduction: People with heart failure (HF) often have a high comorbidity burden and use multiple medicines. Many medicines are known to potentially exacerbate HF or increase the risk of harm, yet there is limited information on the scope of use.

Aim: We aimed to evaluate real-world use of potentially inappropriate medicines following HF in Australia.

Method: We performed a population-level retrospective study among adults hospitalised with HF (primary or secondary diagnosis) in NSW, 2020. We identified medicines which may potentially cause harm based on a European Society of Cardiology position paper on potentially inappropriate prescribing for HF with reduced ejection fraction. We measured prevalent use in the 120 days following first hospitalisation, and in a subset of people using medicines indicated for HF with reduced ejection fraction.

Results: We identified 21,794 people hospitalised for HF; 53.3% male, mean age 77, using a mean of 8.5 medicines. Two-thirds (65.2%) of people dispended at least one medicine of interest, with 33% having two or more, and 40.7% with a medicine considered to have a major magnitude of effect. The most prevalent classes were corticosteroids (30.7%), beta-2 agonists (22.4%) and antiarrhythmics (12.2%). Prevalent use highest in people of older ages and using multiple medicines. We found similar rates in people using medicines indicated for reduced ejection fraction (64%).

Conclusion: Two-thirds of people hospitalised with HF were using medicines which could potentially exacerbate risk. While use of these medicines may be appropriate in many cases, prescribers must remain vigilant to ensure the risks and benefits of specific therapeutics for both HF and comorbidities are carefully managed.

Keywords: heart failure, potentially inappropriate prescribing, polypharmacy

D1/P133

Economic development, ADHD-related disease burden, and medication utilization in China: a correlational analysis based on provincial level data

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Introduction: Attention-deficit/hyperactivity disorder (ADHD) is a common childhood neurodevelopmental disorder, yet systematic studies integrating disease burden and medication utilization across provinces remain limited in China.

Aims: To evaluate temporal trends and regional differences of ADHD burden and drug utilization among Chinese children.

Methods: Using national and provincial GBD data (2000-2021) and ADHD drug procurement data (2015-2023), we analyzed temporal and provincial patterns through descriptive statistics. We calculated average monthly percent change in drug utilization via log-linear regression, and performed cross-correlation analyses to assess contemporaneous and lagged associations between drug utilization and ADHD prevalence.

Results: From 2000 to 2021, ADHD incidence rose from 387.38 to 461.64 per 100,000 population, while prevalence declined from 3825.65 to 3636.24 per 100,000, and DALYs rate fell from 47.10 to 44.86 per 100,000. Notable provincial heterogeneity was observed: higher rates clustered in eastern coastal provinces (e.g., Shanghai, Jiangsu), whereas larger absolute numbers were in populous provinces (e.g., Guangdong and Henan). From 2015 to 2023, drug utilization grew steadily, with an average monthly increase of 2.54% (95% CI: 2.36-2.71%). All provinces experienced rising drug utilization, though at different paces. The fastest growth occurred in Ningxia, Hainan, and Qinghai, while the highest absolute usage levels were seen in Shanghai, Beijing, and Zhejiang. No statistically significant correlation with economic level was found overall; however, regions with medium-low and medium-high economic levels grew faster than high-income regions. Nationally, no significant contemporaneous or lagged association between drug utilization and ADHD prevalence was found. Provincially, patterns varied: Fujian, Guangxi, Hebei, and Shandong showed positive contemporaneous correlations, Beijing and Liaoning showed negative correlations, and Henan, Shanghai, and Zhejiang showed lead-lag patterns.

Conclusions: ADHD burden and drug utilization show significant regional disparities. Drug utilization has expanded but aligns poorly with burden across regions, highlighting needs for targeted resource allocation.

D1/P134

Suboptimal antiretroviral treatment patterns in Australian dispensing data

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Introduction: Lifelong antiretroviral therapy (ART) requires sustained access and adherence. Modern regimens simplified treatment, but dispensing data can show periods where a complete regimen is unavailable. Cumulative proportion of days covered (PDC) can hide short gaps. Evidence on rolling adherence and prolonged gaps is limited.

Aims: To describe first observed complete ART regimens among adults from 2013 to 2023; to estimate suboptimal 90-day adherence and >90-day gaps within two years of follow-up.

Methods: We conducted a retrospective cohort study using linked national dispensing records, mortality data, and census-derived variables. Adults with complete oral ART regimens assembled within 14 days were followed for up to 730 days. Quantity dispensed and standard adult daily dosing were used to estimate days supplied; early refills were carried forward; daily complete-ART coverage required all regimen components to overlap. Outcome 1 divided follow-up into consecutive 90-day blocks, and a block was suboptimal if complete-ART PDC was <85%. Outcome 2 was a consecutive >90-day gap in complete ART coverage. Cox models adjusted for index year, age, sex, and census variables.

Results: The cohort included ~16,400 adults. Index regimens shifted from NNRTI--based regimens to INSTI + 2 NRTI. Median complete-ART PDC was 96%. Two in five patients had a suboptimal 90-day block in year 1 and more than half by two years. One in five had a >90-day gap; one in nine restarted after a >90-day gap. INSTI + 2 NRTI had similar adjusted hazards to NNRTI + 2 NRTI for either outcome. Younger age and markers of social disadvantage, especially unemployment/not in labour force, were associated with worse outcomes.

Conclusions: Despite high cumulative PDC and INSTI uptake, frequent short-term suboptimal coverage and gaps remained common. Rolling 90-day adherence and gap outcomes provide insight beyond simple regimen trends and cumulative PDC.

Keywords: antiretroviral therapy; medication adherence; suboptimal treatment

D1/P135

How do clinical guidelines support appropriate use of ketamine/esketamine for depression

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Background: Ketamine and esketamine are novel treatments for major depressive disorder (MDD). Clinical practice guidelines (CPGs) vary across jurisdictions. Clinicians and people living with MDD depend on high-quality guidance documents to inform treatment decision-making. However, no study has examined the quality of CPGs and consensus statements related to ketamine/esketamine.

Objective: The primary objective was to assess the quality of CPGs and consensus statements published from 2019-2025 related to ketamine/esketamine for MDD. The secondary objective was to categorise actionable statements in CPGs.

Methods: Searches were conducted in MEDLINE, EMBASE, PsycINFO, Scopus, Web of Science, the Cochrane Library and grey literature. The quality of CPGs and consensus statements was assessed using the Appraisal of Guidelines for REsearch & Evaluation II (AGREE II) and ACcurate COnsensus Reporting Document (ACCORD) checklist, respectively. Actionable statements within CPGs were extracted and mapped to the World Health Organization's Pharmacological Treatment of Mental Disorders in Primary Health Care framework.

Results: Seven CPGs and 12 consensus statements were included. Forty-one actionable statements (12 recommendations and 29 good practice statements) related to ketamine/esketamine were identified within CPGs (n=1 – 20 per CPG). Most actionable statements provided guidance on pre-initiation steps (n=32), particularly risk/benefit assessment. Two actionable statements in one CPG focused on the post-treatment step. For CPGs, scope and purpose had the highest mean AGREE-II score (84.1%), while applicability had the lowest (48.2%). For consensus statements, the most concordant ACCORD domain was aim and scope and the least concordant domains were related to engagement of interest holders.

Discussion: Recommendations in CPGs predominantly focused on pre-initiation steps for ketamine/esketamine treatment, with few addressing post-prescribing steps. Only one consensus statement described direct input from the public/patients. Although most CPGs and consensus statements clearly described their aims and scope, few adequately addressed the values/preferences of people living with MDD.

D1/P136

Patterns of psychotropic dispensing among people with and without intellectual disability

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Introduction: People with intellectual disability experience high rates of psychiatric and physical comorbidities and are frequently prescribed psychotropic medicines. Although some psychotropic use reflects greater health needs, there are concerns regarding potentially inappropriate prescribing and associated adverse outcomes.

Aims: This study aimed to describe psychotropic medicine dispensing among people with and without intellectual disability between 2014 and 2023.

Methods: This retrospective cohort study used linked disability and health datasets from New South Wales (NSW), Australia, and Pharmaceutical Benefits Scheme (PBS) dispensing records. Psychotropic medicines, classified using Anatomical Therapeutic Chemical (ATC) codes, were extracted from the PBS for people with intellectual disability and a comparison cohort without intellectual disability matched on age, sex, and area of residence. Outcomes included annual prevalence of psychotropic medicine dispensing by class and psychotropic polypharmacy (concurrent use of two or more psychotropic medicines).

Results: Antidepressants were the most commonly dispensed psychotropic medicines among people with intellectual disability, increasing from 16.7% in 2014 to 24.7% in 2023. In contrast, dispensing of hypnotics declined over the study period (from 2% to 1%), while the prevalence of most other psychotropic drug classes remained relatively stable. Throughout 2014-2023, psychotropic use was consistently higher among people with intellectual disability than the comparison cohort; antiepileptics and antipsychotics showed the greatest differences (prevalence ratios: 10.0 [95%CI 9.7-10.3] and 7.8 [95%CI 7.6-8.0] in 2023, respectively). Among psychotropic users, psychotropic polypharmacy was threefold higher among people with intellectual disability (25.4% vs 7.8% in 2023). Antidepressants and antipsychotics were the most common combination for people with intellectual disability (28.1% in 2023).

Conclusions: Persistently higher psychotropic dispensing and polypharmacy among people with intellectual disability over time warrant regular medicine reviews and closer monitoring of prescribing. Further research should examine clinical indications, long-term outcomes, and access to appropriate health supports.

Keywords: intellectual disability, psychotropic dispensing, polypharmacy

D1/P138

Evolving glucose-lowering drug use after metformin: A nation-wide study in Australia

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Introduction: Pharmacotherapy for type 2 diabetes(T2D) has evolved with the introduction of sodium-glucose cotransporter 2 inhibitors (SGLT2i) and glucagon-like peptide-1 receptor agonists (GLP-1 RA). However, patterns of therapy following metformin and factors influencing treatment selection in Australia remain unexamined.

Aims: To describe post-metformin glucose-lowering drug (GLD) use, examine temporal changes in therapy, and identify predictors influencing treatment selection in Australia.

Methods: Using a 10% sample of the Pharmaceutical Benefits Scheme, this population-based cohort study identified 69,857 people with T2D who initiated at least one other GLDs following metformin in 2014-2024. Treatment regimens were identified using standard covered days (SCD), allowing 2-SCD gaps. Treatment transitions before and after the Australian T2D guideline updated in 2020 were visualized using Sankey diagrams. Risk ratios (RRs) for the second GLD were estimated by age group, male sex, concessional status, and comedication use, with all covariates defined during 12 months before GLD initiation.

Results: Among 176,463 metformin users, 31,537 initiated a second GLD before 2020 and 38,320 from 2020 onward. Mean ages were 60 years, 40% were female, <50% held concessional status, and 30% used lipid-lowering, antihypertensive or antidepressant therapies. Treatment shifted from dipeptidyl peptidase-4 inhibitors (DPP-4i) and sulfonylureas (SU) toward SGLT2i and GLP-1 RA. People aged ≥ 40 were more likely to initiate DPP-4i and SU, whereas younger people were more likely to initiate GLP-1 RA and insulin. Females were more likely to initiate GLP-1 RA. From 2020, age ≥ 40, male sex, and use of heart failure medications predicted SGLT2i initiation. Sensitivity analyses using alternative SCD definitions and 60- or 90-day gap thresholds supported the main results.

Conclusion: Post-metformin GLD use in Australia has shifted toward SGLT2i and GLP-1 RA. However, suboptimal uptake of these medications persists in older adults and individuals with cardiovascular risk.

Keyword: T2D, SGLT2i, GLP-1 RA, post-metformin

D1/P139

Trends in oral anticoagulant use among US adults with chronic diseases, 2009-2020

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Introduction: Since the introduction of DOACs in the United States in 2010, evolving cardiovascular guidelines have increasingly recommended direct oral anticoagulants (DOACs) over warfarin for eligible patients. However, trends in oral anticoagulant (OAC) use among special populations with complex anticoagulation management, including atrial fibrillation (AF), cancer, chronic kidney disease (CKD), and underweight/obesity, remain insufficiently characterized.

Aim: To evaluate trends in DOAC and warfarin use among U.S. adults and subgroups.

Methods: We conducted a cross-sectional study including U.S. adults (≥18 years) from the National Health and Nutrition Examination Survey (NHANES) 2009-March 2020 cycles (n=34,189) to assess trends in OAC use. Survey-weighted analyses were performed. Among patients with AF and a CHA_2DS_2-VA score (a stroke risk stratification tool) ≥2, survey-weighted Poisson regression with robust variance identified factors associated with OAC use.

Results: DOAC use increased by more than 40-fold from 0.03% in 2009-2012 to 1.3% in 2017-March 2020, while warfarin use decreased by nearly half from 1.6% to 0.9%. Similar trends were observed across subgroups. Among adults with AF and CHA_2DS_2-VA ≥2, DOAC use nearly doubled from 27.6% in 2013-2016 to 53.4% in 2017-March 2020. OAC use was more than threefold higher in adults with cancer versus those without cancer ($p<0.001$), with DOAC use increasing from 0% to 4.2%, primarily driven by apixaban. In CKD stages 3-5, DOAC use increased from 0.2% to 7.0%, with apixaban accounting for 77.4% of OAC use in stage 4 CKD during 2017-March 2020. OAC use increased among overweight/obese adults but decreased among those with normal/low body weight. Among AF patients with CHA_2DS_2-VA ≥2, higher CHA_2DS_2-VA scores were associated with greater OAC use (PR=1.08; 95% CI=1.00-1.17).

Conclusions: From 2009 to March 2020, DOAC use increased substantially among U.S. adults (>40-fold) and across chronic disease subgroups, with apixaban emerging as the predominant DOAC.

Keywords: oral anticoagulant, DOAC, NHANES

D1/P140

A retrospective drug utilization review of restricted antibiotics in a government hospital

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Introduction Antibiotic overuse remains a global threat to antimicrobial resistance. Despite the antimicrobial stewardship (AMS) program implemented in the institution, monitoring data on restricted antibiotics consumption and their correlation with antibiotic resistance were inadequate.

Aims This study aimed to: determine trends in restricted antibiotic consumption in the medicine ward, correlate consumption with resistance and design pharmacist interventions targeting pharmacy-related service gaps.

Methods A retrospective cross-sectional study reviewed dispensing records of a Philippine hospital ward from March 2019 to February 2020. Adult inpatients dispensed with at least one dose of intravenous restricted antibiotics were purposively sampled. Excluded were patients not exposed to IV restricted antibiotics, which covered 4th generation cephalosporins, aztreonam, carbapenems, colistin, vancomycin and linezolid. Correlations between antibiotic consumption using Defined Daily Dose (DDD) per 1000 patient-days and antibiotic resistance from hospital antibiograms were analyzed using Pearson correlation. Pharmacist interventions were designed to match gaps in dispensing practices.

Results One-year consumption data of restricted antibiotics revealed increasing trends of ceftazidime consumption (42.2 to 123.9 DDDs/1000-patient days) but decreasing trends for levofloxacin (350.2 to 156.7 DDDs/1000-patient days) and piperacillin-tazobactam (581.6 to 487 DDDs/1000-patient days). A significantly moderately positive association was observed for ceftazidime consumption and A. baumannii resistance ($r = 0.61$, 95% CI 0.01 – 0.86, $p=0.05$). Levofloxacin consumption was significantly strongly positively associated with P. aeruginosa resistance ($r = 0.71$, 95% CI 0.01 – 0.94, $p=0.049$). Pharmacist interventions proposed include stability chart, reconstitution and storage information, proper dispensing of restricted antibiotics.

Conclusions Decreasing trends in consumption of restricted antibiotics except for ceftazidime could mean that the hospital's AMS program is working. However, monitoring antibiotic consumption is important in controlling resistance due to significant positive correlations found between antibiotic consumption for ceftazidime and levofloxacin and resistance against A. baumanii and P. aeruginosa, respectively.

Keywords antibiotic consumption, antibiotic resistance, restricted antibiotics

D1/P141

Antibiotic Dispensing Patterns and AWaRe Utilization in Community Pharmacies

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Introduction: Antimicrobial resistance (AMR) is a growing global health concern driven by inappropriate antibiotic use. Community pharmacies often serve as the primary point of care, yet 40-60% of improper use occurs in these outpatient settings. Such practices of misuse and overuse of antibiotics significantly contribute to resistance and are a measurable determinant of treatment failure and increased healthcare burden. Evaluating dispensing patterns is essential for strengthening antimicrobial stewardship.

Aims: The research aimed to assess antibiotic dispensing patterns, identify specific antibiotic classes dispensed, and evaluate utilization patterns within community pharmacies.

Methods: A cross-sectional study was conducted over six months in community pharmacies purposively selected from different urban regions, comprising both retail and clinic-adjacent settings, using non-randomised sampling. Data from 503 antibiotic dispensing records were collected using structured forms, supplemented by interviews with pharmacists and patients. Antibiotics were analyzed using the WHO AWaRe Classification, quantified using Defined Daily Dose (DDD) methodology and evaluated using descriptive statistics.

Results: Out of 503 antibiotics dispensed, the majority (72.56%) had valid prescriptions, while a substantial proportion (21.66%) were dispensed without prescriptions, indicating continued occurrence of non-prescription sales despite existing regulatory restrictions. Penicillins were the most commonly dispensed class (48.90%), followed by cephalosporins (19.88%). AWaRe classification identified 53.87% Access and 42.94% Watch antibiotics. No Reserve group antibiotics were observed. Systemic antibiotic DDD analysis revealed tetracyclines had the highest average value (8.05 DDDs), followed by macrolides (5.48 DDDs). Penicillins (76.51) and cephalosporins (53.92) had considerably higher usage rates and were primary contributors to overall antibiotic utilization.

Conclusions: The ongoing non-prescription dispensing of antibiotics and significant reliance on 'Watch' agents expose critical vulnerabilities in pharmacy practices. These findings necessitate strict policy enforcement and pharmacist-led stewardship interventions to optimize rational drug use and mitigate the escalating threat of antimicrobial resistance.

Keywords: Antimicrobial Stewardship, Antimicrobial Resistance, Community Pharmacy

D1/P142

Effect of drug utilization review on prescription of long-acting benzodiazepines to elderly

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Introduction: A notification issued in July 2015 in South Korea recommended caution while prescribing long-acting benzodiazepines (BZDs) to older patients.

Aims: The aim of this study was to determine changes in prescription volumes for older patients before and after drug utilization review (DUR) provision for 11 long-acting BZDs.

Methods: Prescription volumes of 11 long-acting BZDs in patients aged 65 years or older were analyzed from May 2011 to December 2019 using data from the National Health Insurance Service-Senior (2002–2019) (NHIS-2024-2-082). Monthly average numbers of prescriptions per 100,000 older people within 50-month periods before and after DUR provision were analyzed.

Results: In total, 728,593 older adults were observed during the study period, of whom 723,059 (99.2%) were prescribed drugs at least once and 360,717 (49.5%) were prescribed one of the 11 long-acting BZDs at least once. The monthly average number of prescriptions per 100,000 older individuals for the 11 long-acting BZDs combined decreased by 16.1% (from 6,394 to 5,362), whereas that for all medications increased by 20.8% (from 140,000 to 169,051) during the same period. The reduction rate was more pronounced in women (-18.2%) than in men (-12.1%). By institution type, primary care clinics showed the largest decrease (-22.4%). Regarding individual BZDs, prescriptions decreased for pinazepam by 100% (0.1 to 0), clorazepate by 99.8% (24.7 to 0.1), mexazolam by 40.1% (18.2 to 10.9), oral diazepam by 29.5% (5,185.9 to 3,658.4), and diazepam injections by 5.1% (288.7 to 274). Conversely, clonazepam and flunitrazepam prescriptions increased by 81.7% (549.3 to 998.1) and 54.8% (310 to 480), respectively..

Conclusions: DUR information was shown to reduce prescriptions for most long-acting BZDs in older patients, thereby improving potentially inappropriate medication use. However, for clonazepam and flunitrazepam, where the impact was less pronounced, further analysis of their prescriptions patterns is needed.

Keywords: drug utilization review, benzodiazepines, geriatrics

D1/P143

Impact of subsidy listing on biosimilar trastuzumab adoption in HER2+ breast cancer

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Introduction: Trastuzumab is a cornerstone targeted therapy for HER2-positive breast cancer and has historically represented a significant cost burden to the healthcare budget. Subsidy listing of trastuzumab biosimilar in September 2020 following health technology assessment, aimed to improve affordability while maintaining therapeutic equivalence.

Aims: To evaluate market adoption and baseline cohort comparability of originator versus biosimilar trastuzumab following its subsidy listing in Singapore.

Methods: This retrospective study integrated patient-level dispensing data (2020-2024) from national electronic health records with the national cancer registry for residents with HER2-positive breast cancer. Pre-subsidy records and patients with diagnosis-to-treatment gap over one year were excluded. The cohort was analysed using a modified intention-to-treat framework. Demographic parameters were compared across usage groups using Mann-Whitney U and Pearson's Chi-Square tests.

Results: The cohort comprised 419 originator-initiated and 456 biosimilar-initiated patients. Post-subsidy listing, biosimilar uptake among new initiations rose from 24.1% in the first year to 63.2%, peaking at 87.7% in Year 3 before stabilizing at 71.6% in the last year. Overall, 38.4% were originator-only users, 42.4% were biosimilar-only users, and 19.2% were switchers. Baseline clinical profiles were comparable across groups, with no significant differences in cancer stage, receptor status (ER/PR), or surgery and radiotherapy utilisation. Biosimilar-initiated patients were marginally older [median 59 (IQR 51-67) vs. 57 (IQR 49-64) years; p=0.025] with slightly longer time to initiation [median 74 (IQR 46-112) vs. 66 (IQR 35.5-112.5) days; p=0.052].

Conclusions: Trastuzumab biosimilar subsidy listing drove a substantial, sustained shift in utilisation patterns with clinical decision-making remaining aligned with baseline practices, as shown by the comparable clinical characteristics across groups. Future research examining the long-term impact of the observed baseline differences in age and time-to-treatment initiation will further strengthen the evidence base for biosimilar adoption, supporting listing policies to optimise long-term expenditure on targeted therapies.

Keywords: Trastuzumab, Biosimilars, real-world outcomes

D1/P144

Global trends in consumption and expenditure of GLP-1-based therapies, 2015–2024

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Introduction: The use of GLP-1-based therapies has expanded rapidly in the management of type 2 diabetes and obesity, yet evidence on their global distribution and the impact of price on consumption remains limited.

Aims: To investigate trends in consumption, expenditure, and price of GLP-1-based therapies stratified by income level, and to identify factors associated with consumption.

Methods: We analysed sales data for GLP-1-based therapies between 2015 and 2024 across 74 countries and regions from the IQVIA-Multinational Integrated Data Analysis System. Consumption was evaluated using defined daily dose per 1000 inhabitants per day (DDD/TID). Expenditure and price were measured in international dollars (Int$) as Int$/TID and Int$/DDD, respectively. Mixed-effects models were used to evaluate temporal trends by average annual percent change (AAPC) and to identify factors associated with consumption.

Results: Global consumption of GLP-1-based therapies increased from 0.25 to 3.49 DDD/TID between 2015 and 2024 (AAPC 42.58%). In 2024, consumption was concentrated in high-income countries (15.71 DDD/TID vs. 0.06 in lower-middle-income countries). A mismatch was observed between consumption and the burden of diabetes and obesity, with several high-burden countries recording minimal consumption. Semaglutide was the most consumed molecule in 2024 (2.23 DDD/TID), while tirzepatide showed the fastest growth following its introduction in 2022 (AAPC 417.14%). Expenditure rose from 2.45 to 52.34 Int$/TID (AAPC 41.64%). Overall price declined slightly (AAPC -0.97%); in 2024, tirzepatide (42.56 Int$/DDD) and semaglutide (13.13 Int$/DDD) were the most expensive. Consumption was negatively associated with price, but positively associated with gross national income, health expenditure, and diabetes and obesity prevalence (all $p<0.01$).

Conclusions: Global consumption and expenditure of GLP-1-based therapies increased substantially between 2015 and 2024 but remained concentrated in high-income countries. High prices continue to limit access in lower-middle-income countries despite substantial burdens of diabetes and obesity.

Key words: GLP-1-based therapies; Drug utilisation; Health equity

D1/P145

Adherence trajectories to secondary prevention after ischemic stroke and cardiovascular outcomes

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Introduction: Adherence to secondary prevention therapies after ischemic stroke (IS) or transient ischemic attack (TIA) is often suboptimal, yet the clinical implications of longitudinal adherence trajectories remain unclear.

Aims: To identify longitudinal adherence trajectories to statins and antithrombotic agents and evaluate their associations with LDL-C control and cardiovascular outcomes.

Methods: Using the Chang Gung Research Database linked to Taiwan's population claims data, we identified patients with first-ever IS/TIA between 2012 and 2018 who survived ≥1 year and initiated secondary prevention. Monthly adherence was measured using proportion of days covered and classified by group-based multi-trajectory modeling. The primary outcome was a composite of recurrent IS, systemic embolism, and myocardial infarction; secondary outcomes included individual components and all-cause mortality.

Results: Among 13,299 eligible patients (mean age 65.6 years; 60.3% male), four adherence trajectories were identified: dual high adherence (46.7%), antithrombotic-only adherence (35.1%), early dual discontinuation (12.2%), and gradual dual decline (6.0%). Distinct trajectories demonstrated markedly different LDL-C responses and cardiovascular risks. Dual high adherence achieved the greatest LDL-C reduction (−24.3%) and lowest mortality. Compared with dual high adherence, early dual discontinuation was associated with higher risks of the composite outcome (adjusted hazard ratio [aHR], 1.57 [95% CI, 1.31–1.88]), recurrent IS/systemic embolism (aHR, 1.60 [95% CI, 1.31–1.95]), myocardial infarction (aHR, 1.48 [95% CI, 1.02–2.14]), and all-cause mortality (aHR, 1.56 [95% CI, 1.36–1.79]). Poor adherence had a greater adverse impact in patients with baseline LDL-C ≥100 mg/dL, younger adults, and men.

Conclusions: Longitudinal adherence trajectories were strongly associated with LDL-C control and major cardiovascular outcomes. Sustained dual adherence conferred substantial cardiovascular protection, whereas early discontinuation markedly increased recurrent ischemic and mortality risks. These findings highlight adherence as a modifiable determinant of cardiovascular risk and support targeted adherence-improvement strategies to optimize secondary prevention after stroke.

Keywords: ischemic stroke, medication adherence, secondary prevention

D1/P146

Real-world risk of hepatitis B reactivation in patients receiving Janus kinase inhibitors

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Introduction: Janus kinase inhibitors (JAKi) have expanded the therapeutic armamentarium for autoimmune diseases but may compromise immune surveillance against viral infections. Consequently, hepatitis B virus (HBV) reactivation in patients with different serological profiles remains a critical safety concern. While guidelines classify hepatitis B surface antigen (HBsAg)-positive individuals as high risk, real-world evidence comparing specific JAKi subtypes and assessing resolved HBV cases is limited.

Aims: This study aimed to evaluate the incidence and clinical characteristics of HBV reactivation among patients with varying baseline HBV serostatus receiving JAKi therapy. A secondary objective was to assess the impact of JAK1 selectivity and baseline surface antibodies on reactivation risk.

Methods: This retrospective cohort study included adult patients with autoimmune diseases treated with JAKi for at least 90 days between January 2021 and December 2025. Patients were stratified into HBsAg-positive and HBsAg-negative/core antibody (HBcAb)-positive (resolved HBV) cohorts. Incidence rates (IR) and hazard ratios (HR) for HBV reactivation, defined by standardized viral load elevations or seroreversion, were calculated using descriptive statistics and Cox regression analyses.

Results: The analysis included 194 patients, comprising 19 HBsAg-positive and 175 HBsAg-negative/HBcAb-positive individuals. Among HBsAg-positive patients without antiviral prophylaxis, HBV reactivation occurred in 26.3% (5/19), with an IR of 96.7 per 1000 person-years. Patients receiving upadacitinib and baricitinib demonstrated adjusted HRs of 4.49 (95% CI 0.67-30.02) and 4.44 (95% CI 0.36-54.89) for reactivation, respectively, compared to tofacitinib. In the resolved HBV cohort, the overall reactivation rate was 2.9% (5/175). The risk was notably higher in the anti-HBs negative subgroup (4/44 events) compared to the remaining resolved cohort (1/131 events).

Conclusions: JAKi therapy poses a risk of HBV reactivation in HBsAg-positive patients without antiviral prophylaxis, underscoring the necessity of pre-treatment antiviral coverage. For patients with resolved HBV, preemptive monitoring is generally safe, but baseline anti-HBs negativity identifies a subgroup requiring heightened vigilance.

D1/P147

Understanding the barriers to medication adherence in patients with uncontrolled asthma

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Introduction: Poor adherence to inhaled corticosteroids (ICS) remains a major contributor to uncontrolled asthma and increased exacerbations. In Singapore, Malay patients experience a disproportionately high burden of asthma and lower adherence to controller medications. However, limited research has explored the culturally specific determinants of ICS adherence and how these can inform intervention development.

Aims: Therefore, this study aims to identify barriers and facilitators to ICS adherence among Malay adults and to co-design a culturally appropriate intervention with multiple stakeholders.

Methods: This is a multi-stakeholder qualitative study conducted in Singapore using a two-round co-design approach. In Round 1, we are currently conducting semi-structured interviews among 10 Malay patients and 10 healthcare providers. Interview guides are informed by the Socio-Ecological Model and the COM-B framework. In Round 2, patients, healthcare providers, and cultural leaders will participate in co-design workshops to translate identified barriers and facilitators into intervention components.

Results: As of 10 June, we have conducted in-depth interviews with seven healthcare providers and two patients. Our preliminary analysis identified common barriers, including limited health literacy, misconceptions regarding ICS safety and dependency, and difficulties linking controller medication use to asthma prevention. Adherence was further complicated by practical challenges such as complex inhaler techniques and cultural influences such as preference for traditional remedies, heavy family commitments in large Malay families, language barriers, and concerns about inhaler use during Ramadan. Healthcare providers also highlighted the positive and negative influences of family support in Malay culture. To improve ICS adherence, participants suggested culturally tailored educational materials, community support groups, and partnerships with religious organisations and mosque leaders to improve acceptance of ICS use.

Conclusion: Findings will directly inform the development of a stakeholder-driven educational intervention tailored to the needs of Malay patients with asthma.

Keywords: uncontrolled asthma, adherence, inhaled corticosteroids

D1/P148

Trends and Risk Factors for Severe Hypoglycemia in Human and Analogue Insulin

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Introduction: Insulin remains essential for diabetes management, yet prescribing patterns by insulin type and regimen have changed alongside newer glucose-lowering drugs. Severe hypoglycemia (SH) is a major and preventable complication, particularly among insulin-treated patients.

Aims: To examine territory-wide trends in human and analogue insulin use and SH incidence as well as identify associated risk factors.

Methods: We conducted a territory-wide serial cross-sectional analysis of Hong Kong electronic health records (2002-2023) among 277,641 insulin-treated adults with diabetes. Age- and sex-standardized proportions of insulin use and SH incidence (hospitalizations) were calculated annually. Generalized Estimating Equations (GEE) evaluated associations between human versus analogue insulin and recurrent SH hospitalizations, adjusting for demographic and clinical risk factors, medications, prior SH, and participation in the Risk-Assessment-and-Management-Programme-for-Diabetes-Mellitus (RAMP-DM).

Results: From 2002 to 2023, overall insulin use decreased slightly (11.9% to 11.2%). Human insulin predominated but declined (99.6% to 78.1%), while analogue use increased (0.2% to 3.5%), largely driven by long-acting analogues. Basal-only therapy remained most common but declined (6.4% to 4.2%), followed by premixed insulin (2.5% to 2.2%). SH incidence decreased markedly (17.0 to 5.6 events/100-person-years). SH incidences were lower among analogue than human insulin users in 2023 (5.0-vs-6.6 events/100-person-years, adjusted incidence rate ratio [IRR]=0.64 [0.62-0.67]). Compared with basal-only therapy, basal-bolus therapy had the highest SH incidence in 2023 (2.2-vs-12.5 events/100-person-years, IRR=3.51 [3.43-3.59]). Use of glucagon-like peptide-1 receptor agonists (GLP-1RA) (IRR=0.74 [0.68-0.80]), sodium-glucose cotransporter-2 (SGLT2) inhibitors (IRR=0.72 [0.69-0.75]), statins (IRR=0.78 [0.77-0.80]), and RAMP-DM enrolment (IRR=0.88 [0.86-0.91]) were associated with lower SH risk, whereas sulphonylurea and prior SH were associated with higher risk.

Conclusions: Human insulin continued to dominate insulin therapy compared with insulin analogues in people with diabetes, despite evidence of lower SH risk with insulin analogues. Greater uptake of analogue insulin and adjunctive therapies may further reduce SH risk.

Keywords: insulin; trends; risk factors

D1/P149

Demographic and Environmental Risk Factors Associated with Japanese Encephalitis Exposure in Asia

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Introduction: Japanese Encephalitis Virus remains an important mosquito-borne infection in Asia, with continuing exposure despite vaccine availability. Population exposure varies widely across countries, suggesting that demographic and environmental factors may influence transmission.

Aim: To quantitatively synthesise evidence on demographic and environmental risk factors associated with Japanese Encephalitis Virus exposure in Asian populations.

Methods: Published population-based and clinical seroprevalence studies from Asia were included. Data were extracted from studies conducted in India, Nepal, Thailand, Taiwan, Japan, and South Korea. Reported seroprevalence, age distribution, sex, rural or urban residence, occupational exposure, agricultural setting, and diagnostic methods were reviewed. The findings were combined to identify common patterns of exposure across different populations.

Results: The included studies showed wide variation in Japanese Encephalitis Virus exposure across Asia. Seroprevalence ranged from 8.9% in Japan to 98% in South Korea. Studies from India reported seroprevalence of 14.1% in Manipur and 15.9% in Kerala, while Thailand reported around 44% seropositivity among humans living near monkey habitats. Nepal-based studies showed higher exposure, with JE forming a major proportion of viral encephalitis cases and outbreaks. Older age groups generally showed higher antibody prevalence, suggesting cumulative lifetime exposure. Rural residence, agricultural activity, rice cultivation, pig rearing, and proximity to mosquito breeding environments were repeatedly associated with increased exposure. Male predominance was observed in some studies, although this pattern was not consistent across all regions.

Conclusion: Japanese Encephalitis Virus exposure in Asia is shaped by both demographic and environmental determinants. Rural living, agricultural ecology, animal reservoirs, and increasing age appear to be important contributors to exposure. These findings support risk-based vaccination planning, targeted surveillance, and integrated vector control in high-risk Asian populations.

Keywords: Japanese Encephalitis Virus, Seroprevalence, Risk Factors

D1/P150

Polypharmacy and excessive polypharmacy among older adults in Indonesian residential aged-care facilities

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Introduction: Indonesian population is aging rapidly, with adults aged 60 years and over projected to exceed 20% by 2050. Long-term care infrastructure in Indonesia remains fragmented, and medication use in residential aged care is still poorly studied . Prevalence of polypharmacy especially, for residential aged-care settings in Indonesia is absent.

Aims: To describe the prevalence of polypharmacy among residents in aged-care facilities in Indonesia and to explore how socio-demographic factors including age, sex, types of aged care, multimorbidity, functional status, frailty, cognition, fall risk, and recent hospitalisation are associated with polypharmacy.

Methods: A cross-sectional study using a convenience sample of 45 consenting residents aged ≥60 years in two aged care facilities in Indonesia with different medication-management protocols. Medicines history was obtained through structured review using a standardized identification form, excluding supplements, vitamins, and traditional preparations. Frailty, functional status, cognitive function, and fall risk were assessed using a validated instrument.

Results: Median age was 79 years ([IQR] 70–82); 71.1% were female and 88.9% had multimorbidity. Polypharmacy was observed in 33.3% of respondents (15/45; 95% [CI] 21.4–47.9%) with excessive polypharmacy (i.e., > 10 medicines) in 4.4%. A significant positive association was observed between active medicine count and chronic condition (Spearman ρ = 0.34, p = 0.02). Crude odds ratios for frailty (3.25), functional dependency (2.04), fall risk, hospitalisation, and female sex were directionally positive but non-significant. Nearly two-thirds (64.4%) reported concurrent use of at least one traditional or herbal preparation in addition to prescribed medicines.

Conclusions: Polypharmacy affected one in three residents (33.3%) of Indonesian aged-care residents. Among the factors examined — age, sex, types of aged care, multimorbidity, functional status, frailty, cognition, fall risk, and recent hospitalisation — only multimorbidity showed a statistically significant association with polypharmacy.

Keywords: polypharmacy; aged-care facilities; Indonesia

D1/P151

Impact of Post-Discharge Reviews on Potentially Inappropriate Glucose-Lowering Medication Use

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Introduction: Older adults with type 2 diabetes are at increased risk of adverse events associated with potentially inappropriate glucose-lowering medications. Post-discharge medication reviews are an Australian Government funded service to reduce medication-related harm at transitions of care.

Aims: To investigate whether provision of timely post-discharge mediation reviews impacts the use of potentially inappropriate glucose-lowering medications in older adults aged 65 and above.

Methods: Administrative datasets were used to identify older adults with pre-admission use of potentially inappropriate glucose-lowering medications discharged from private and public hospitals from July 2013 to December 2017 in Victoria, Australia. The exposure was completion of a comprehensive pharmacist-led medication review within 90 days of discharge. Individuals were required to survive at least 180 days post-discharge. Discontinuation was defined as no dispensing of the pre-admission medication 91-180 days post-discharge. Inverse probability of treatment weighted regression models compared discontinuation rates between groups.

Results: Of the total 44,510 older adults, 983 (2.2%) with pre-admission use of potentially inappropriate glucose-lowering medications received a medication review within 90 days post-discharge. In the weighted analysis, adults who received a medication review were 17% more likely to discontinue a potentially inappropriate glucose-lowering medication that those who did not receive a medication review (weighted relative risk: 1.17, 95% CI 1.14-1.20). Potentially inappropriate metformin and sulfonylureas were more likely to be discontinued in those who received a medication review (weighted relative risk: 1.18, 95% CI 1.14-1.22 and 1.17 95%CI 1.14-1.21 respectively).

Conclusions: Post-discharge medication reviews may assist in the discontinuation of potentially inappropriate glucose lowering medications, particularly metformin and sulfonylureas. However, the low uptake of medication reviews highlights the need for strategies to improve provision in this high-risk population.

D1/P152

Latent class analysis of neuropsychiatric symptoms in dementia

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Introduction: Neuropsychiatric symptoms (NPS) affect 90% of people with dementia, contributing to caregiver burden and institutionalisation. NPS co-occur in heterogeneous patterns yet are rarely characterised systematically. Identifying distinct NPS clusters may improve risk stratification and guide targeted intervention in dementia care.

Aims: To identify and characterise distinct NPS clusters, examine predictors of class membership, and assess their association with dementia progression.

Methods: Data were obtained from the National Alzheimer's Coordinating Centre database. Adults with dementia at first visit aged ≥45 from 2015, with ≥1 follow-up visit, were included (N=2,007). NPS were assessed using the Neuropsychiatric Inventory Questionnaire across 12 domains, scored ordinally as absent, mild, moderate, or severe. Dementia stage was assessed using the Clinical Dementia Rating Sum of Boxes (CDR-SB). Covariates included demographics, dementia-related factors, functional status, medication use, and comorbidities. Latent class analysis identified NPS clusters; multinomial logistic regression examined predictors of cluster membership; and linear mixed-effects models estimated CDR-SB trajectories across clusters.

Results: Three NPS clusters were identified: low-burden (50%, N=999), medium-burden (37%, N=744), and high-burden (13%, N=264) groups. The high-burden cluster featured moderate-to-severe symptoms across all domains, with the highest baseline CDR-SB and functional impairment. Frontotemporal dementia (Relative Risk Ratio [RRR]: 7.45, 95%CI: 4.23–13.1), Lewy body dementia (RRR 2.82, 95%CI: 1.31–6.08), hypertension (RRR 2.11, 95%CI: 1.23–3.64), and traumatic brain injury (RRR 1.68, 95%CI: 1.02–2.75) were associated with the high-burden cluster. White race (RRR 0.15, 95%CI: 0.07–0.31) and diuretic use (RRR 0.37, 95%CI: 0.16–0.84) were negatively associated. CDR-SB increased over time (β=1.73 points/year, $p<0.001$); however, the rate of progression did not differ across NPS clusters.

Conclusions: Three clinically distinct NPS clusters exist in dementia, differentiated by dementia subtype, comorbidities, and demographics. Future research should investigate whether NPS cluster-targeted interventions can improve outcomes and reduce caregiver burden in people with dementia.

Keywords: neuropsychiatric symptoms; dementia; latent class analysis.

D1/P153

Longitudinal trajectories of anticholinergic burden and dementia risk among older adults

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Introduction: Anticholinergic medications, widely prescribed to older adults, have been linked to dementia risk in prior studies. However, real-world anticholinergic use often involves dynamic patterns of discontinuation and resumption that most existing studies, relying on single-time-point or cumulative-dose exposure measures, have failed to capture or to account for frailty, a key effect modifier of risk in older adults, leaving their differential association with dementia risk unclear.

Aims: We aimed to identify distinct longitudinal trajectories of anticholinergic burden in older adults and to evaluate their association with incident dementia, stratified by frailty status.

Methods: Using Taiwan's National Health Insurance Research Database, we conducted a retrospective cohort study of adults aged ≥65 years newly initiating an Anticholinergic Cognitive Burden (ACB) Scale-listed medication in 2012. Group-based trajectory modeling (zero-inflated Poisson) was applied to 3-year quarterly ACB scores. Cox proportional hazards models assessed associations between trajectories and incident dementia over an 8-year follow-up, adjusted for age, sex, multimorbidity frailty index, and dementia-related comorbidities, with subgroup analyses by frailty status.

Results: Among 63,250 older adults (mean age 76.9 [SD 6.3] years; 50.5% female), 12,996 incident dementia cases occurred during follow-up. Five distinct ACB trajectories were identified: Low(40.2%), Declining(13.5%), Increasing(12.2%), Constantly moderate(26.7%), and Constantly high (7.5%) use group. Relative to the Low use group, the Constantly high group carried the highest risk (aHR 1.32, 95% CI 1.24–1.41), with smaller but significant elevations in Declining (1.08, 1.02–1.14), Increasing (1.07, 1.02–1.14), and Constantly moderate (1.07, 1.02–1.12). Risk associated with the Constantly high trajectory remained significant across robust, mild, and moderate frailty strata but not in severe frailty (HR 1.16; 95% CI, 0.79–1.69).

Conclusions: The Constantly high trajectory showed significantly elevated dementia risk in older adults, supporting targeted anticholinergic burden reduction in patients with sustained high-burden use rather than uniform intervention.

Keywords: anticholinergic burden; group-based trajectory modeling; dementia

D1/P154

Melatonin Use in Australian Residential Aged Care: Prevalence and Psychotropic Co-Prescribing

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Introduction: Melatonin is commonly prescribed for sleep disturbance in older adults and sundowning in those with dementia. However, its use in residential aged care facilities (RACFs) remains understudied.

Aims: The objective of this study was to investigate the prevalence of melatonin use and concomitant psychotropic medication use in Australian RACFs.

Methods: A cross-sectional analysis was conducted involving 13,550 residents across 162 RACFs in New South Wales and Queensland, Australia. Records of prescribed medications (melatonin, orexin receptor antagonists [ORAs, e.g., suvorexant], benzodiazepines [e.g., temazepam, oxazepam], Z-drugs [e.g., zolpidem, zopiclone], antipsychotics, antidepressants and medications for dementia) were extracted from all electronic resident medication profiles in January 2026.

Results: The point prevalence of prescribed melatonin was 10.6% (n=1,437), including 9.2% (n=1,245) regular and 1.6% (n=220) pro re nata (PRN) use. The point prevalence of benzodiazepines, Z_drugs, and ORAs was 30.0%, 0.5%, and 0.1%, respectively. Melatonin users had significantly higher concomitant use of benzodiazepines (38.4% vs. 29.0%, $P < 0.001$), antipsychotics (32.8% vs. 24.9%, $P < 0.001$), antidepressants (61.5% vs. 50.3%, $P < 0.001$), and dementia medications (13.6% vs. 9.3%, $P < 0.001$), compared to non-users. Notably, concomitant use of three or more psychotropic medications (benzodiazepines, antipsychotics, and antidepressants) was nearly twofold higher among residents using melatonin (13.1% vs. 7.6%, $P < 0.001$).

Conclusions: One in ten residents were prescribed melatonin, mostly prescribed for regular dosing. Melatonin appears to be used as an adjunct to other psychotropic medications. Further research is warranted to evaluate the appropriateness and safety of melatonin use in RACFs, particularly within the context of high psychotropic burden.

Keywords: melatonin; nursing homes; psychotropic

D1/P155

Changes in prescription cannabinoids and analgesic medications among US nursing home residents

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Introduction: Efforts to reduce opioid prescribing in nursing homes may lead to substitution with other medications, such as gabapentin, cannabinoids, and non-steroidal anti-inflammatory drugs (NSAIDs) for pain symptoms, which also pose health risks among older adults.

Aims: To describe temporal changes in opioids, gabapentinoids, non-prescription analgesics, and cannabinoids in US nursing homes.

Methods: We conducted a serial cross-sectional study using electronic health record data from over 5,000 nursing homes. Each quarter between January 2016 and December 2023, we included residents aged 18-110 years with a Minimum Dataset assessment. We used the electronic medication administration record to identify administrations for opioids, over-the-counter analgesics (e.g., NSAIDs), gabapentinoids, and cannabinoids. Relative differences between Q31 and Q1 with 99% confidence intervals (CIs) summarized medication changes over time overall and by pain and cancer diagnosis.

Results: We identified 91,326 residents in Q1 (mean age = 74 years) and 656,722 residents in Q31 (mean age = 75 years). Prescription cannabinoids increased by 25% over time (Q1=0.52%, Q31=0.65%; PR=1.25 (1.10-1.41)), and dronabinol was the most common. NSAIDs and gabapentin increased by 47% (Q1=10.7%, Q31=15.7%; PR=1.47 (1.43-1.51)), and 60% (Q1=15.9%, Q31=24.4%; PR=1.60 (1.56-1.63)), respectively. Opioid use declined from 38.6% to 23.7%, PR=0.61 (0.61-0.62). Cannabinoid prevalence increased with more severe pain symptoms (e.g., among residents in Q31, mild pain=0.59%; moderate pain=0.64%; and severe pain =0.86%), and use was highest among residents with cancer (Q31=1.52%).

Conclusions: Cannabinoid use was low, but growing over time alongside increases in NSAIDs and gabapentin and decreased opioid use. Comparative safety and effectiveness research of these medications for pain in nursing homes is needed.

Key words: Cannabinoids, nursing homes, pain, opioids

D1/P156

Association of benzodiazepines with fractures among older Japanese inpatients: a new-user study

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Introduction: Benzodiazepines (BZDs) are commonly prescribed to older inpatients in Japan. However, their association with in-hospital fractures remains insufficiently investigated in Asian populations. Few studies have included non-users or accounted for hepatic and renal function.

Aims: To examine the association between incident BZD use and in-hospital fracture risk among older Japanese inpatients aged ≥75 years using a new-user design. Subgroup analyses by hepatic and renal function and sensitivity analyses were conducted to evaluate robustness.

Methods: A retrospective cohort study used the Medical Data Vision database covering approximately 30% of acute-care hospitals in Japan from April 2012 to March 2017. Patients aged ≥75 years at first hospitalization with a 180-day washout period were included. Incident BZD users (n = 50,493) initiated BZDs during the index hospitalization without prior use in the preceding 180 days; non-users (n = 115,293) had no BZD dispensing during hospitalization. Fractures were defined as hospital-acquired ICD-10 fracture codes with fracture-related procedures after BZD initiation, and multivariable logistic regression was used to estimate associations, adjusting for age, sex, Charlson Comorbidity Index, and hepatic (GPT/ALT) and renal (eGFR) function.

Results: Among 165,786 Japanese inpatients aged ≥75 years, 200 experienced in-hospital fractures. Incident BZD users had a significantly higher fracture rate than non-users (0.16% vs. 0.10%, p = 0.003). After adjustment, incident BZD use was independently associated with a 1.5-fold increased fracture risk (OR: 1.51, 95% CI: 1.14–2.00, p = 0.005). Five sensitivity analyses demonstrated significant associations (OR range: 1.41–2.39). Subgroup analyses by hepatic (GPT/ALT) and renal (eGFR) function showed no significant interactions (p = 0.216; p = 0.578), indicating similar fracture risk regardless of organ function.

Conclusions: Incident BZD use was significantly associated with in-hospital fracture risk among older Japanese inpatients. These findings support careful evaluation of BZD prescribing in Japanese acute hospitals.
Keywords: benzodiazepines, new-user design, in-hospital fracture

D1/P157

Association rule mining of medication combinations in older adults with continuous polypharmacy

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Introduction: Polypharmacy is common in older adults and is associated with an increased risk of adverse outcomes, including hospitalisation and mortality. However, the specific medication combinations contributing to polypharmacy remain poorly characterised.

Aims: To identify common medication combinations among older adults experiencing continuous polypharmacy.

Methods: We conducted a nationwide, population-based cross-sectional study in Australia. Individuals aged ≥65 years in 2022 with continuous polypharmacy were included. Continuous polypharmacy was defined as the dispensing of ≥5 unique medications during both 1 April–30 June and 1 October–31 December. Medication exposure was obtained from the Pharmaceutical Benefits Scheme (PBS) dataset. Medication classes were classified using the Anatomical Therapeutic Chemical (ATC) system, and classes with < 3% prevalence were excluded. Association rule mining was used to identify frequent medication combinations, with support, confidence and lift as key metrics.

Results: Overall, 1,449,637 older adults with continuous polypharmacy were included. The top three most frequent drug combinations were (i) lipid modifying agents with ACE inhibitor/angiotensin II receptor blockers (support: 54.7%, lift: 1.05), (ii) drugs for acid-related disorders with lipid modifying agents (support: 36.6%, lift: 1.00); and (iii) drugs for acid-related disorders with ACE inhibitor/angiotensin II receptor blockers (support: 33.9%, lift: 0.95). Combinations with the highest lift included: (i) dipeptidyl peptidase 4 (DPP-4) inhibitors, sodium-glucose co-transporter-2 (SGLT2) inhibitors, lipid modifying agents, and metformin (support: 3.0%, lift:12.2); (ii) DPP-4 inhibitors, SGLT2 inhibitors, and metformin (support: 3.4%, lift: 10.1); and (iii) opioids (ATC N02A), other analgesics (ATC N02B) and antidepressants (support: 3.2%, lift: 4.50).

Conclusion: Identified medication combinations largely reflect common multimorbidity patterns in older adults. These patterns may also highlight opportunities for regimen simplification, including the potential role of fixed-dose combination (polypill) approaches. Future research should examine temporal trends and the influence of sociodemographic factors on these patterns.

D1/P158

Dual orexin receptor antagonists and the risk of incident dementia

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Introduction: Chronic sleep disorders and use of hypnotics, particularly benzodiazepines and z-drugs, are predisposing factors for dementia. Dual orexin receptor antagonists (DORAs) and melatonin analogues represent safer alternatives and are therefore more commonly prescribed to older patients, even for long-term use. Preclinical studies suggest that, unlike other hypnotics, DORAs may limit the development of cognitive disorders. However, because DORAs were only recently introduced (August 2014 in the US), their long-term cognitive effects remain poorly characterized.

Aims: We aimed to compare the long-term risk of incident dementia following initiation of DORAs versus ramelteon in older adults with sleep disorders using real-world data, assessing risk differences and temporal trends across varying follow-up periods.

Methods: We conducted a retrospective cohort study using electronic health records from the TriNetX Global Collaborative Network. We identified older adults (aged >60 years) with sleep disorders who initiated DORAs or ramelteon (index date), excluding those with prior records of dementia, delirium, or critical care admissions. Kaplan-Meier survival analysis and Cox proportional hazards models were used to compare survival probabilities and risk of incident dementia up to 10 years after index date. We conducted sensitivity analyses with landmark periods at 3 and 5 years after the index date, excluding the individuals who experienced the event within those time windows.

Results: Preliminary results indicate that DORA initiators exhibit a significantly lower risk of incident dementia compared to ramelteon initiators. This significant risk difference persisted in landmark analyses. There was no difference in the risk of negative control events between the two cohorts.

Conclusions: DORAs may represent a safer alternative to ramelteon for mitigating the long-term risk of incident dementia in older adults with sleep disorders. This protective effect appears to be maintained for several years post-initiation, reducing the likelihood of potential protopathic bias.

D1/P159

National Antibiotic Trends among Long-term Care Facilities by Prescribing Survey Participation, 2016-2022

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Introduction: The Aged Care National Antimicrobial Prescribing Survey (Aged Care NAPS) is a one-day voluntary point prevalence survey conducted annually in Australian long-term care facilities (LTCFs) since 2016 to monitor antimicrobial use.

Aims: To examine annual trends in systemic antibiotic use in Australian LTCFs, overall and stratified by participation in the Aged Care NAPS, 2016-2022.

Methods: This population-based retrospective cohort study analysed linked data from the Registry of Senior Australians National Historical Cohort and the Aged Care NAPS, from July 2016 to June 2022. Changes in national annual trends in systemic antibiotic use, measured in mean percentage and number of defined daily doses (DDD) dispensed per 1,000 resident-days, were analysed using linear mixed-effects models.

Results: The number of LTCFs included ranged from 2,703 to 2,714 annually, with the number of LTCFs participating in Aged Care NAPS increasing from 204 in 2016-17 to 587 in 2021-22. The crude prevalence of systemic antibiotic use decreased during the study period, from 67.8% (95%CI 67.6, 68.0) in 2016-2017 to 56.3% (95%CI 56.5, 56.9) in 2021-22 in the overall cohort. When stratified by participation in the survey, use decreased from 63.9% (95%CI 62.7, 65.1) in 2016-17 to 56.2% (95%CI 55.5, 57.0) in 2021-22 in participating LTCFs and from 66.7% (95%CI 66.3,67.0) to 55.7% (95%CI 55.3, 56.1) in non-participating LTCFs. The adjusted annual prevalence of antibiotic use decreased by 2.1% (95%CI -2.4, -1.8) in participating LTCFs and 2.3% (95%CI -2.4, -2.2) in non-participating LTCFs, with no statistically significant differences in the adjusted annual changes between participating and non-participating LTCFs (0.1%, 95%CI -0.2, 0.4). Similar trends were observed in DDD/1,000 resident-days analyses.

Conclusions: The use of systemic antibiotics decreased in Australian LTCFs during 2016-2022, but remains high regardless of participation in the survey. Concerted efforts are required to implement antimicrobial stewardship interventions in this setting.

D1/P160

Cost-related nonadherence to medications among pregnant women: Findings from the U.S. NHIS

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Introduction: Chronic diseases prevalence among U.S. pregnant women has steadily increased, driving pregnancy-related medications demand. Suboptimal adherence during pregnancy can cause severe adverse perinatal outcomes. Although cost-related nonadherence to medications (CRN) remains a major public health concern, few studies have investigated specifically among pregnant women. Identifying CRN determinants is critical for optimizing maternal-fetal health.

Aims: To compare national CRN prevalence between pregnant and non-pregnant U.S. women. Additionally, to identify risk factors among pregnant women.

Methods: 2024 U.S. NHIS data were used. Pregnancy and CRN were determined via validated self-reported questionnaires. Weighted Wald chi-square test was used to evaluate prevalence differences. Multivariable logistic regression models were used to estimate adjusted odds ratios and identify CRN determinants among pregnant women.

Results: National CRN prevalence among pregnant women was 8.2% (N = 119,068), significantly lower than 16.7% (N = 7,582,790) in non-pregnant women ($P < 0.01$). Pregnant women exhibited a lower baseline prevalence of depression (19.3 vs. 26.8%, $P < 0.05$). In the overall population, multivariable regression models showed food insecurity (aOR = 3.65, 95% CI: 2.83–4.70), depression (aOR = 2.28, 95% CI: 1.84–2.83), and cardiovascular diseases (aOR = 1.96, 95% CI: 1.13–3.37) increased CRN risks. Among pregnant women, key risk factors included medical care barriers (aOR = 6.22, 95% CI: 4.94–7.84), food insecurity (aOR = 2.11, 95% CI: 1.59–2.79), and financial hardship (aOR = 2.01, 95% CI: 1.53–2.63). Additionally, bill-related anxiety (aOR = 2.08, 95% CI: 1.60–2.71), asthma (aOR = 1.55, 95% CI: 1.18–2.04), and depression (aOR = 1.77, 95% CI: 1.39–2.24) significantly increased CRN risks.

Conclusion: Pregnant U.S. women demonstrate lower CRN than non-pregnant women, suggesting Medicaid eligibility extension may alleviate the burden on pregnant women. However, clinical monitoring should prioritize pregnant women with asthma, depression, and financial hardship to ensure equitable medication access.

Keywords: Cost-related nonadherence; pregnant women; NHIS

D1/P161

Introducing non-contrast magnetic resonance imaging surveillance for hepatocellular carcinoma in cirrhosis

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Introduction: Biannual ultrasound (US) is the standard surveillance modality for hepatocellular carcinoma (HCC) in patients with cirrhosis. However, it has limited sensitivity for early-stage detection. Although contrast-enhanced magnetic resonance imaging (MRI) provides superior sensitivity, its use is limited by high cost and contrast exposure. Non-contrast abbreviated MRI (NC-MRI) has emerged as a promising alternative surveillance strategy, but its long-term clinical outcomes have not been evaluated.

Aims: We aimed to evaluate whether NC-MRI-based strategies detect HCC at an earlier stage than US surveillance in patients with cirrhosis. We also assessed the clinical benefits of earlier detection.

Methods: A microsimulation Markov model simulated 10,000 patients with cirrhosis aged 50 years over a 30-year horizon using 6-month cycles. Model parameters were collected by literature review. Three strategies were compared: (1) biannual NC-MRI, (2) alternating NC-MRI and US at 6-month intervals, and (3) biannual US. Outcomes included stage distribution at HCC detection, receipt of curative treatment, cumulative mortality, and life-years.

Results: The proportion of HCC detected at very-early stage was 69.28%, 55.56%, and 13.89% with NC-MRI, the alternating strategy, and US surveillance, respectively. Advanced-stage detection decreased from 44.82% with US surveillance to 12.56% with the alternating strategy and 10.78% with NC-MRI. Compared with US surveillance, NC-MRI-based strategies consistently yielded larger populations in the post-curative treatment state after very-early HCC detection, with the greatest difference observed at approximately 10 years after surveillance initiation. Introducing NC-MRI increased curative treatment rates by 10.34 percentage points, and reduced cumulative mortality by 2.20 percentage points. It also increased life expectancy by 0.56 years.

Conclusions: NC-MRI-based surveillance strategies improved the effectiveness of HCC surveillance in patients with cirrhosis by detecting earlier HCC stages. These findings support incorporating NC-MRI into HCC surveillance to enhance the clinical benefits of surveillance in high-risk patients.

Keywords: hepatocellular carcinoma; non-contrast magnetic resonance imaging; surveillance.

D1/P162

Cost-Effectiveness and Clinical Outcomes of Perioperative Immunotherapy in Advanced Unresectable Head-Neck Cancer

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Introduction: Locally advanced head and neck squamous cell carcinoma (LA-HNSCC) has high recurrence rates despite standard chemoradiotherapy. Recent immunotherapy trials, including KEYNOTE-689 and NIVOPOSTOP, have shown promising outcomes with pembrolizumab and nivolumab. However, comparative real-world evidence evaluating clinical outcomes, safety, and cost-effectiveness remains limited, particularly in Low- and Middle-Income Countries (LMICs).

Aim: To compare disease-free survival (DFS), recurrence, safety, and cost-effectiveness between pembrolizumab- and nivolumab-based regimens in LA-HNSCC.

Methods: This real-world observational study included adult patients with LA-HNSCC and Eastern Cooperative Oncology Group performance status 0–1 treated between October 2018 and July 2024. Patients received cisplatin-based radiotherapy combined with either perioperative pembrolizumab 200 mg every 3 weeks or adjuvant nivolumab at 240 mg, 360 mg, or 480 mg schedules. Primary endpoints were 3-year DFS and local/distant recurrence. Secondary endpoints included grade ≥3 adverse events and incremental cost-effectiveness ratio (ICER).

Results: A total of 601 patients were included; 301 received pembrolizumab and 300 received nivolumab. Three-year DFS was 61.1% (95% CI, 52.3–66.5) with pembrolizumab and 60.2% (95% CI, 57.0–68.7) with nivolumab (p=0.08). Local or distant recurrence occurred in 19.0% and 25.5% of patients, respectively (p=0.34). Grade ≥3 adverse events were observed in 44.6% of pembrolizumab-treated patients versus 54.0% in the nivolumab group (p=0.12). Economic evaluation demonstrated limited cost-effectiveness of pembrolizumab, with an ICER of INR 48.5 lakhs for incremental improvement in 3-year DFS.

Conclusion: Pembrolizumab demonstrated comparable DFS with numerically lower severe toxicity compared with nivolumab in LA-HNSCC. However, substantial economic burden limited its cost-effectiveness in LMIC settings. Further prospective studies are needed to optimize patient selection and long-term value-based immunotherapy strategies.

Keywords: Head and Neck Squamous Cell Carcinoma, Immunotherapy, Cost-Effectiveness Analysis

D1/P163

Optimal age of Helicobacter pylori eradication for gastric cancer prevention in Korea

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Introduction: Helicobacter pylori (H. pylori) infection is the most important risk factor for gastric cancer (GC). In Korea, the National Cancer Screening Program (NCSP) recommends biennial upper endoscopy from age 40, contributing to early GC detection. However, H. pylori eradication has not been introduced into the screening program. Therefore, the added preventive benefit of integrating H. pylori eradication into the NCSP requires evaluation.

Aims: This study aimed to develop a Markov model incorporating H. pylori infection and GC natural history. Using this model, we sought to identify the optimal age for H. pylori eradication for GC prevention.

Methods: A Markov model with a one-year cycle was developed for a hypothetical cohort of 10,000 individuals aged 20 years over a 60-year horizon. Age-specific transition probabilities were estimated. Five strategies were compared: no screening; biennial endoscopy; and biennial endoscopy combined with one-time H. pylori eradication at age 20, 30, or 40. The primary outcome was cumulative incidence reduction (CIR) relative to no screening, and the GC stage distribution was also assessed.

Results: The Markov model included health states reflecting H. pylori infection status, precancerous lesion progression, and GC stage. Without screening, 490 cumulative GC cases occurred per 10,000 individuals, and regional/distant GC accounted for 55%. With biennial endoscopy screening, GC cases increased to 510 (CIR: -4.1%) but improved early-stage detection, reducing regional/distant GC to 36%. All strategies incorporating H. pylori eradication showed higher CIR (14.5%, 13.6%, and 10.5%) than biennial endoscopy alone, with earlier eradication yielding greater reduction. GC stage distribution was consistent across all eradication strategies, similar to biennial endoscopy alone.

Conclusions: Incorporating H. pylori eradication into the NCSP reduced cumulative GC incidence. Eradication at age 20 yielded the greatest reduction, supporting it as the optimal age for integration into the NCSP.

Keywords: Gastric cancer; Helicobacter pylori; Screening strategy

D1/P165

Topical Hemostatic Material Use, Major Bleeding, and Healthcare Burden in Hepatectomy

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Introduction: Perioperative major bleeding remains a clinically important complication of hepatectomy and may increase healthcare resource utilization and costs. However, contemporary real-world evidence on its healthcare burden is limited.

Aims: To describe the incidence of perioperative major bleeding and associated healthcare resource utilization and costs among patients undergoing hepatectomy in Japan.

Methods: We conducted a descriptive study using a hospital-based administrative database from Medical Data Vision (MDV) in Japan between 2020 and 2023. Adults undergoing elective open or laparoscopic hepatectomy who received topical hemostatic materials (i.e., primary hemostatics, flowable microfibrillar collagen, fibrin sealants, and sheet-type biological tissue adhesives/sealants) were included. Major bleeding was defined as a composite of intra- or postoperative allogeneic blood transfusion of ≥400 mL or diagnoses of bleeding complications. Postoperative healthcare resource utilization and costs were summarized as medians with interquartile ranges (IQRs) by bleeding status.

Results: A total of 3,948 patients were included, comprising 3,328 open and 620 laparoscopic hepatectomies. Major bleeding occurred across all topical hemostatic material utilization patterns and was generally more frequent in open (35.2%–46.1%) than laparoscopic hepatectomy (15.5%–35.4%). Comparison between patients with and without major bleeding: In open hepatectomy, median (IQR) postoperative length of stay was 15 (11–23) versus 12 (9–16) days, ICU stay 2 (1–4) versus 1 (1–2) days, and postoperative hospitalization costs 643.6 (445.0–1,138.7) versus 460.0 (358.0–653.5) thousand Japanese yen. In laparoscopic hepatectomy, the corresponding values were length of stay 10 (7–15) versus 8 (6–11) days, ICU stay 1 (1–2) versus 1 (1–1) day, and costs 574.6 (401.6–1,036.5) versus 395.5 (313.3–503.1) thousand Japanese yen.

Conclusions: Major bleeding was associated with substantially greater healthcare resource utilization and hospitalization costs following hepatectomy. These findings provide real-world evidence regarding the healthcare burden associated with perioperative major bleeding in contemporary surgical practice.

Keywords: Major bleeding; Healthcare resource utilization; Hepatectomy

D1/P166

Network meta-analysis of pharmacological treatments for hypersensitivity pneumonitis

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Introduction: Hypersensitivity pneumonitis (HP) is an interstitial lung disease (ILD) that may progress to fibrosis, resulting in declining lung function and increased mortality. Several pharmacological treatments are used, including corticosteroids, immunosuppressants, antifibrotic agents, biologics, and other active drugs; however, their comparative benefits remain uncertain.

Aims: To evaluate the efficacy and safety of pharmacological treatments for HP using evidence synthesis through systematic review and network meta-analysis (NMA).

Methods: MEDLINE, Embase and the Cochrane Library were searched from inception to 10 November 2025, without language restrictions. Experimental and cohort studies were eligible if they compared any pair of medications for HP and reported at least one outcome of interest, including changes in forced vital capacity (FVC), diffusing capacity for carbon monoxide (DLCO), all-cause mortality and adverse events. A frequentist NMA was performed to estimate relative treatment effects, expressed as mean differences (MDs) and risk ratios (RRs).

Results: Twenty-one studies were included. Overall, no treatment was significantly superior to placebo in slowing declines in percentage predicted FVC or DLCO. However, in the subgroup with at least 12 months of follow-up, corticosteroids significantly reduced the decline in percentage predicted FVC compared with placebo (MD 7.15; 95% confidence interval [CI] 0.59 to 13.71). For all-cause mortality, azathioprine plus prednisolone showed the greatest risk reduction compared with placebo (RR 0.42; 95% CI 0.24 to 0.74). Regarding safety, nintedanib significantly increased the risk of gastrointestinal adverse events compared with placebo (RR 2.61; 95% CI 1.77 to 3.83), whereas serious adverse events did not differ significantly between treatments.

Conclusions: There is no definitive evidence that any medication is superior to placebo in slowing lung function deterioration in HP. Corticosteroids may help preserve FVC over follow-up periods of at least 12 months, while azathioprine plus prednisolone may reduce mortality.

Keywords: hypersensitivity pneumonitis; Interstitial lung disease; Network meta-analysis

D1/P167

Medication economic stress drives intentional non-adherence: The MESDS development study

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Introduction: Medicine affordability critically determines chronic disease outcomes, with India's out-of-pocket expenditure accounting for 39.4% of total health spending as of 2021-22. Existing instruments assess financial toxicity or medication adherence in isolation; none captures the integrated pathway through which economic stress drives cost-related non-adherence. This represents a measurable gap in patient-reported outcome measurement for chronic disease populations.

Aims: To develop and content-validate the Medication Economic Stress and Decision-Making Scale (MESDS) as a structured PROM, and to characterize its association with non-adherence behaviors and sociodemographic determinants in adults with chronic illnesses.

Methods: A two-phase study was conducted over six months at a tertiary hospital in south India. Phase I involved systematic literature-based item generation (267 items) and expert panel content validation using Item-level and Scale-level Content Validity Indices (I-CVI, S-CVI). Phase II was a cross-sectional analytical study among 507 adults with chronic diseases using the finalized scale; analysis included Spearman rank correlation and multiple linear regression.

Results: The 21-item MESDS achieved an S-CVI/Ave for relevance of 0.94 and for clarity of 0.937. Phase II participants had a mean age of 57.8 ± 13.3 years (67.7% male; 51.1% insured). The mean MESDS Total Score was 34.33 ± 14.10; 57.0% experienced moderate and 13.2% high medication economic stress. Insurance independently predicted a 10.8-point reduction in total score (Beta = −0.385; $p < 0.001$). Family income, educational qualification, and household size were additional independent predictors, with the model explaining 44.4% of score variance (Adjusted $R^2 = 0.427$). Cost-driven non-adherence showed the strongest association with the total score (rho = 0.854; $p < 0.001$).

Conclusions: The MESDS demonstrated strong content validity and discriminative ability across sociodemographic subgroups. It effectively distinguishes cost-driven from unintentional non-adherence, positioning it as a practical screening tool for chronic disease outpatient settings.

Keywords: Medication economic stress, cost-related non-adherence, patient-reported outcome measure

D1/P168

Phase-4 Non-Inferiority Trial assessing Cost-Effectiveness of Conventional versus Super-Bioavailable Itraconazole in Dermatophytosis

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Introduction: Disseminated dermatophytosis is increasingly associated with persistence, recurrence, and variable response to therapy. Conventional itraconazole remains widely prescribed; however, concerns regarding inconsistent bioavailability have contributed to the use of super-bioavailable (SUBA) formulations. Despite growing clinical use, comparative real-world evidence evaluating their therapeutic and economic outcomes remains limited.

Aim: To compare the clinical efficacy, relapse rates, symptom reduction, and cost-effectiveness of conventional itraconazole and SUBA itraconazole in patients with disseminated dermatophytosis.

Methods: This phase 4 non-inferiority trial used real-world patient data. A 5% non-inferiority margin was pre-specified for the primary endpoint. Adults with disseminated dermatophytosis involving ≥5% body surface area received oral conventional itraconazole 200 mg once daily or SUBA itraconazole 130 mg once daily for 6 weeks, followed by 4 weeks of follow-up. The primary endpoint was clinical cure at 6 weeks. Secondary endpoints included relapse rates, reductions in Physician Global Assessment (PGA) parameters, and Incremental Cost-Effectiveness Ratio (ICER) based on direct medical costs and the percentage reduction in PGA.

Results: A total of 110 patients were enrolled, with 55 patients in each arm. At 6 weeks, clinical cure rates were 73.7% in the conventional itraconazole arm and 68.2% in the SUBA arm, i.e., a difference of 5.5 percentage points (95% CI, 8.0-19.0; p=0.61). Relapse rates were 20% in the conventional itraconazole arm and 6.6% in the SUBA arm (p=0.02). Reduction in PGA parameters after 6 weeks was 11.28% with conventional itraconazole and 13.03% with SUBA itraconazole. The ICER between groups was INR 129.71 per 1-point PGA reduction.

Conclusions: Conventional itraconazole demonstrated clinical non-inferiority to SUBA itraconazole, with slightly higher cure rates. SUBA itraconazole showed significantly lower relapse rates, greater symptom reduction, and marginal cost-effectiveness advantages.

Keywords: Disseminated dermatophytosis, Super Bioavailable Itraconazole, Cost-effectiveness analysis

D1/P169

Mixed-method evaluation of a digital health and community pharmacy-supported prediabetes management program

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Introduction: Lifestyle interventions are effective in managing prediabetes, a condition that increases the risk of developing type-2 diabetes if left unmanaged. Community pharmacies are strategically positioned to provide prediabetes management programs, and digital health tools may support their delivery. The PRIME program integrates digital health tools with community pharmacy services to promote healthier lifestyle among adults with prediabetes.

Aims: To evaluate the clinical impact of the PRIME program and understand the barriers and facilitators influencing its implementation.

Methods: PRIME was implemented across 13 community pharmacies in Selangor and Kuala Lumpur, Malaysia. Eligible participants were adults with prediabetes who were overweight or obese. A 6-month two-arm cluster randomized controlled trial was conducted, with weight loss as the primary outcome. Participants in the intervention group received in-depth pharmacist counselling, in-app prediabetes education modules, and peer support, while usual care participants received counselling based on pharmacists' usual practice. Focus group discussions and one-on-one interviews were conducted to understand experiences, perceptions of implementation, and the influence of PRIME on lifestyle behaviour change. Using convenience sampling, participants and pharmacists involved in PRIME were interviewed. Qualitative data were analysed thematically.

Results: Ninety-one participants (intervention n = 46; usual care n = 45) were recruited. Intervention group participants experienced larger weight loss, with a mean difference of 1.26 kg ($p<0.05$) between groups. Key barriers were related to the use of digital health tools (technical difficulties, lacking engaging functionalities) and resources (workload management, availability of prediabetes-specific guidelines). Participants perceived the blended approach of face-to-face pharmacist support and technology-assisted interventions useful in supporting them adopt healthier lifestyles.

Conclusions: While PRIME can effectively support healthier lifestyles among adults with prediabetes, barriers related to digital tool usability and limited resources can hinder adoption. Addressing these barriers could enhance the implementation and uptake of these programs.

Keywords: prediabetes, community pharmacy, digital health.

D1/P171

Health productivity impact of risk thresholds for primary prevention of cardiovascular disease

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Introduction
Cardiovascular disease (CVD) affects over 1.3 million Australians. Current risk assessments and guidelines derive risk over 5 years and do not consider lifetime risk, or the workplace productivity impact of CVD.

Aims
To evaluate the health productivity impact of Australian and international risk thresholds for primary prevention of CVD, to determine if earlier intervention would lead to better patient outcomes, assuming cumulative lifetime risk.

Methods
We will use a previously validated microsimulation model, the health economic model for primary prevention of cardiovascular disease (HEM-PPCVD), to project individual health outcomes and CVD-related costs of 10,000 hypothetical adults (starting age, 40-69 years). HEM-PPCVD derives cumulative lifetime risk from causal inference Mendelian randomization studies. We will simulate individuals starting at age 40 under different variations of gender, systolic blood pressure, low density lipoprotein cholesterol level, diabetes and smoking status to determine the age in which the Australian guidelines recommend treatment initiation based on 5% and 10% risk thresholds and compare outcomes to lifetime risk. The model outcomes will include incident and total events prevented, mortality, costs, and productivity adjusted life years (PALY).

Results
Australian and international guidelines and thresholds will be compared to cumulative lifetime risk to determine the PALY impact of early intervention. Formal results are subject to analysis and will be presented at a later stage to this planned analysis abstract.

Conclusion
We seek to determine if rescaling risk thresholds to include patients of low and intermediate risk can improve health productivity and reduce mortality. The goal is to determine if current Australian risk equations and thresholds exclude patients when causal lifetime risk and early intervention is not considered.

Keywords
Microsimulation, Primary prevention, Productivity-adjusted life years (PALY)

D1/P172

Disease Burden and Healthcare Utilization of Glioma in China: A Cohort Study

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Introduction: Population-based evidence on glioma burden and healthcare utilization remains scarce in China, particularly from large RWD sources that integrate claims, tumor registry, and mortality information.

Aims: To provide an exploratory description of glioma incidence, prevalence, survival, mortality, subtype distribution, and annual healthcare costs in Inner Mongolia, China.

Methods: We conducted a retrospective cohort study using 2008–2021 claims records, tumor registry data, and death registry data from Inner Mongolia. Glioma cases and subtypes were identified using diagnosis text and morphology codes. Disease burden and healthcare utilization were summarized overall and by ethnicity and subtype. Cox proportional hazards models and generalized linear models were used to explore mortality risk and annual costs.

Results: Among 21.92 million insured residents, 1,707 glioma patients [median (IQR) age, 50 (39-60) years] were identified, of whom 802 (46.98%) were male, 1,377 (80.67%) were Han, and 282 (16.52%) were Mongolian. Glioblastoma was the most common identifiable subtype, accounting for 57.84%. The 2021 point prevalence was 4.16 (95% CI: 3.89-4.44) per 100,000. The overall all-cause mortality rate was 127.44 (95% CI: 118.74–136.62) per 1,000. The 1-year and 3-year survival rates were 78.00% (95% CI: 75.91%–79.93%), 61.44% (95% CI: 58.92%–63.85%). At the patient level, the median annual total cost was $2,806.20 (839.88–8,111.61) per year. No significant Han–Mongolian differences were observed in mortality or healthcare utilization. After covariate adjustment, glioblastoma was associated with higher all-cause mortality [HR = 1.71 (95% CI: 1.36–2.13), P < 0.001] and higher patient-level annual costs [cost ratio = 2.34 (95% CI: 1.71–3.19), P < 0.001] than non-glioblastoma gliomas.

Conclusions: This large real-world cohort provides evidence on glioma burden and healthcare utilization in China. Despite potential underestimation from incomplete coverage and missing fields, the findings may inform prognostic assessment, treatment planning, and healthcare resource allocation for glioma.

Keywords: Glioma; Disease burden; Healthcare Utilization; Cohort study; Disparities

D1/P173

Hidden Costs of Breast Cancer Care in Indonesia: Direct Non-Medical Expenses

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Introduction: Breast cancer remains a major health burden in Indonesia. Although cancer care is covered under Indonesia's National Health Insurance system, patients may still face direct non-medical costs. While broader financial toxicity and out-of-pocket medical costs have been studied in Indonesia, direct non-medical costs in referral-based cancer care remain poorly quantified.

Aim: This study therefore aims to quantify direct non-medical costs and describe how they vary across patient categories in a referral hospital setting.

Methods: This cross-sectional study was conducted August and October 2024 at Dr. Sardjito Hospital, a tertiary hospital in Yogyakarta, Indonesia. Of 125 patients approached, none refused or were excluded. Adults aged ≥18 years with a breast cancer diagnosis and at least three months hospital care were recruited during outpatient visits. Direct non-medical costs were collected using an interviewer-administered three-month recall questionnaire and included transportation, meals, and accommodation for patients and families. Costs were summarised descriptively, and associations with characteristics were examined using gamma generalised linear models (GLM) with log link for costs per visit; multivariable analysis adjusted for patient characteristics. Ethical approval and informed consent were obtained.

Results: Among 125 participants, 98.4% reported direct non-medical costs over three months. Mean total cost was USD 177.54 (95% CI: 130.40-224.67), median USD 80.10 (IQR: 36.41-174.76). Transportation dominated costs, with patient and family transportation contributing 55% and 27%, respectively. Follow-up visits accounted for 61.4% of 1,988 visits. In GLM analysis, log-distance was associated with higher costs per visit in univariable (coefficient 0.606; 95% CI: 0.470-0.742) and multivariable models (coefficient 0.650; 95% CI: 0.500-0.800).

Conclusions: Participants experienced substantial non-medical costs despite medical coverage. Travel-related expenses were the main burden, suggesting referral-based cancer care may create hidden financial barriers. Findings should be interpreted considering possible recall bias and selection bias from single-site outpatient recruitment.

Keywords: Breast cancer; Direct non-medical costs; Indonesia

D2/200

Barriers And Enablers to Cardiovascular Medication Adherence: A Qualitative Evidence Synthesis

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Background: Cardiovascular disease (CVD) remains a leading contributor to the global burden of disease. While pharmacological therapy is central to its prevention and management, medication adherence is often suboptimal, limiting treatment effectiveness.

Methods: This qualitative evidence synthesis followed the Joanna Briggs Institute Manual for Evidence Synthesis. A search strategy was conducted in September 2024 and updated in January 2025, with studies published between February 2004 to June 2024, were identified across four databases (Medline, CINAHL, Embase, PsycINFO) and analysed using framework analysis guided by the World Health Organization's conceptual framework for medication adherence. A purposive maximum variation sampling approach was applied across five strata: low-income countries, underserved communities, rural populations, and primary and secondary CVD prevention settings. Sub-framework analysis was conducted to compare adherence behaviours and contextual influences across these groups.

Results: Of 145 eligible studies, 27 were sampled for synthesis. Barriers to adherence included fear of side effects, limited symptom awareness, negative beliefs about medications, and poor patient-provider communication. Enablers included trust-based relationships with healthcare providers, understanding of treatment purpose, simplified medication regimens, and strong social and family support. Participants in secondary prevention settings expressed heightened risk perception, while those in primary prevention often viewed CVD as asymptomatic and less threatening. Rural populations showed a preference for natural remedies and more fatalistic views. Low-income participants faced financial constraints and limited access to care. Structurally disadvantaged communities reported a lack of personalised care and continuity.

Conclusion: Medication adherence is shaped by a dynamic interplay of individual, clinical, and contextual factors. Strengthening patient-provider communication, addressing perceptual barriers, and tailoring strategies to population-specific needs are critical to improving adherence. Future research should prioritise diverse representation and integrate qualitative insights into medication adherence prediction tools and intervention design.

D2/201

Social trust correlates of hard drug use among U.S. adults

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Introduction: Over half of the U.S. population aged 12 and older has used illicit hard drugs at least once in their lifetime. Social trust has been linked with alcohol use, smoking, and other risk behaviors. Although social trust may also share a similar pathway with hard drug use, the relationship has not been investigated in the general adult population.

Aims: This study examined the prevalence of hard drug use among U.S. adults aged 18 years and older. We also examined the associations between hard drug use with institutional social trust and interpersonal social trust.

Method: This serial cross-sectional study analyzed nationally representative data of community-living U.S. adults from the 2012–2022 U.S. General Social Survey. Participants reported ever misusing injection drugs or crack cocaine. We adopted validated measures of institutional trust (13-item) and generalized interpersonal trust (3-item). The study conducted binary logistic regression analysis and adjusted for socio-demographic factors.

Results: In our sample (n = 6,879), 7.3% reported hard drug use, and no statistically significant time trends were observed from 2012 to 2022. In unadjusted analyses, both lower levels of institutional and interpersonal trust were associated with hard drug use (OR = 1.42 to 1.88). However, only institutional trust (medium-level OR = 1.37; low-level OR = 1.50) remained independently associated with hard drug use in adjusted analyses. Among young adults, white people were more likely to use hard drugs compared to their black counterparts; blacks were more likely to do so among older adults.

Conclusion: Our findings identified institutional trust as independently related to hard drug use among U.S. adults and corroborated the crossover effect between age and race. Interventions to strengthen social trust in key institutions may reduce the likelihood of lifetime hard drug use and consequently prevent dependence.

Keywords: Social trust; Hard drug use; Population-based

D2/202

Hospital Pharmacists' Experience, Perception, Readiness in Shifting from Rule-Based to AI-Driven CDSS

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Introduction: Artificial Intelligence (AI)-driven Clinical Decision Support Systems (CDSS) are increasingly being integrated into healthcare to improve decision making, patient safety, and workflow efficiency. Currently, research on understanding and comparing the human and organizational factors influencing the transition from rule-based to AI-driven CDSS among healthcare workers remains limited, particularly in among hospital pharmacists.

Aims: To compare the characteristics and experiences of rule-based and AI-driven CDSS among hospital pharmacists and examine their perceptions, attitudes, and readiness for AI implementation compared with physicians in two Indonesian hospitals.

Methods: A qualitative study was conducted in two private hospitals in Indonesia between April and June 2026. Semi structured interviews were conducted with pharmacists using rule-based CDSS and physicians using AI-driven CDSS. Data were analyzed using thematic analysis guided by the Socio-technical Systems framework.

Results: This study identified five major themes on informants' experience, perceptions, attitudes, and readiness on AI technology in healthcare: individual factors towards AI technology, experience with CDSS, enablers of AI implementation, barriers of AI implementation, and governance and implementation readiness, along with 11 subthemes. Pharmacists and physicians emphasized that, despite the use of AI, responsibility for clinical decision making remains with healthcare practitioners. However, hospital pharmacists expressed concerns that overreliance on AI could reduce critical thinking and contribute to perception of professional replacement by AI technologies. Notably, this concern was not reported among physicians.

Conclusions: Using a Socio-technical Systems perspective, this pilot study identified social subsistem and external factors that may facilitate or hinder the transition from rule-based to AI-driven CDSS in Indonesian hospitals among hospital pharmacists and physicians. Although AI was perceived to improve analytical support and clinical vigilance, successful implementation may depend on addressing workflow integration, organizational culture, interprofessional dynamics, and also concerns regarding AI reliance.

Keywords: Artificial Intelligence; Clinical Decision Support Systems; Socio-technical Systems

D2/203

Trends in AI-Assisted Medication: A Scoping Review Facilitated by Large Language Models

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Introduction: Artificial intelligence (AI) technologies are rapidly advancing in medication assistance, yet their specific clinical implementations remain poorly mapped. Traditional systematic reviews struggle to keep pace with this exponentially growing literature.

Aims: This scoping review aims to map current developmental trends in AI-assisted medication. Additionally, it evaluates the efficacy of Large Language Models (LLMs) in accelerating literature screening and data extraction.

Methods: We systematically searched PubMed, Embase, and Cochrane database for relevant literature. Following deduplication, we designed a three-stage LLM-based automatic workflow for study screening and extraction: two sequential rounds of screening using the DeepSeek-V4-Flash model to determine study eligibility, followed by structured data extraction from the abstracts of included studies using the DeepSeek-V4-Pro model. Screening performance was evaluated on a balanced random sample of 200 records.

Results: As of April 1, 2026, we collected 91,249 initial records, leaving 74,259 after deduplication and ultimately including 2,024 studies following LLM screening. Validation of the screening process showed 93.5% agreement between DeepSeek-V4-Flash and GPT-5.5 Pro, with a Cohen's kappa of 0.87. Cardiovascular (22.01%), endocrine (16.09%), and nutritional/metabolic diseases (11.30%) emerged as the primary targets for AI intervention. Core algorithms were predominantly rule-based and clinical decision support systems (CDSS) (17.84%), followed by closed-loop control (6.62%) and machine/deep learning (4.10%). Applications concentrated heavily on dose calculation and titration (54.84%), alongside drug selection (36.17%), and monitoring-based adjustment (32.95%). Notably, AI outperformed conventional care in 30.14% of studies, 9.63% reported comparable outcomes or no significant difference, and only 0.20% found AI inferior.

Conclusions: AI-assisted medication is advancing rapidly, particularly in cardiovascular care, yielding extensive research on optimizing critical tasks such as dose calculation and drug selection. Current evidence demonstrates the robust efficacy and immense potential of data-driven precision medicine.

Keywords: AI-assisted medication, Large Language Models, Scoping review

D2/204

Estimating Individualized Treatment Effects of Methylphenidate: A Causal Machine Learning Approach

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Introduction: Methylphenidate (MPH) is widely used to treat attention-deficit/hyperactivity disorder (ADHD), 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 analyzed nationwide claims data from adults with ADHD and depression recorded in the Health Insurance Review and Assessment Service–ADHD database (2017–2020), converted to the OMOP Common Data Model. Patients were classified into MPH-treated and untreated groups and divided into training, validation, and test datasets. Propensity scores were estimated using random forests after large-scale covariate screening, and a causal forest model with inverse-propensity weighting was used to estimate average and conditional treatment effects (ATE and CATE). External validation was performed in a cohort from A tertiary hospital by applying the median CATE cutoff to classify patients into high- and low-risk groups and evaluating prediction of bipolar transition.

Results: Among 19,896 patients, 13,417 received MPH and 1,445 developed BD. After screening, 4,153 of 4,608 baseline covariates were retained, and the model was fitted using the top 30 variables by importance. The estimated ATE was 0.035 [0.025–0.102] in the validation set and 0.034 [0.025–0.102] in the test set. Significant heterogeneity in treatment effects was observed across CATE quintiles in the test set (χ^2_4=12.40, p=0.0146). In the external cohort (n=34), median-based CATE stratification showed moderate predictive performance (accuracy 0.647, sensitivity 0.800, specificity 0.621).

Conclusions: Causal machine learning identified that MPH treatment may elevate BD risk in subgroups. The CATE-derived cutoff demonstrated external validity in real-world data, supporting the potential for individualized treatment-effect–based prescribing strategies in adults with ADHD and depression.

Keywords: Causal machine learning, treatment effect, bipolar disorder

D2/205

Generalizability of an AI-driven P-CARDIAC cardiovascular risk model in diverse subpopulations

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Background: The AI-driven P-CARDIAC model family for cardiovascular disease, comprising 1°P-CARDIAC for primary prevention and P-CARDIAC for secondary prevention, has demonstrated high accuracy. However, performance can vary across distinct sub-cohorts.

Aim: To externally validate P-CARDIAC models across diverse sociodemographic and clinical subgroups and evaluate its performance against traditional risk scores.

Methods: Utilizing a large electronic health record cohort, validation was stratified across subgroups based on sex, age (< 50, 50-64, >=75 years), and major comorbidities including diabetes, hypertension, chronic kidney disease, dementia, Atrial Fibrillation (AF), dyslipidemia, and smoking. Both basic and full 1°P-CARDIAC and P-CARDIAC models were evaluated. Discrimination was assessed using Harrell's C-index and compared against benchmark models (PCE PREDICT, Chiana-PAR, and Framingham score for 1°P-CARDIAC; TRS-2P and SMART2 for 2°P-CARDIAC). Decision curve analysis (DCA) and Net Reclassification Improvement (NRI) were conducted as additional analyses.

Results: The validation included 1,085,148 primary and 260,240 secondary prevention individuals. Both the basic models and the feature-rich full models demonstrated stable discrimination across most subpopulations. And the full model has outperformed the basic model in the subpopulation: 1°P-CARDIAC yielded a strong overall primary prevention C-index of 0.819. Despite its performance declining in complex cohorts like AF (0.645) and dementia (0.658), it consistently outperformed other risk tools across all subgroups (C-index improvement over PCE ranged from +0.022 [AF] to +0.178 [age 65–74]). Secondary prevention followed similar trends. 1°P-CARDIAC full provided a higher DCA net benefit than benchmarks overall and across key high-risk subgroups.

Conclusion: Both basic and full P-CARDIAC models demonstrate a consistent discrimination advantage over traditional risk scores across diverse subgroups in Hong Kong. However, absolute predictive performance attenuates in highly complex, older, and multimorbid clinical settings. Clinical deployment in these specific settings may require targeted calibration adjustments.

D2/206

Artificial intelligence for medication safety in older adults: a scoping review

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Introduction: Medication-related harm in older adults is difficult to identify and prevent due to multimorbidity, polypharmacy, and age-related changes. Artificial intelligence (AI) may support medication safety by detecting, predicting, and prioritising medication-related risk. However, its application across the medication-safety pathway in older adults has not been comprehensively mapped.

Aims: To examine how AI has been applied across the medication-safety pathway in older adults and identify evidence gaps relevant to clinical translation. Specific objectives were to describe AI methods, medication-safety applications, validation approaches, implementation status, and barriers to clinical translation.

Methods: We conducted a scoping review of studies published from January 2016 to 16 February 2026 in MEDLINE, Embase, and Scopus. Eligible studies included populations aged ≥60 years, or those in which older adults predominated, and investigated AI-based approaches addressing medication-related safety. Two reviewers independently screened studies, with disagreements resolved by consensus or a third reviewer.

Results: Of 4,436 records identified, 2,955 unique records were screened, 273 full texts assessed, and 46 studies included. Most studies focused on model development and validation (n=33), with electronic health records as the most common data source (n=35). Four application areas were identified: harm identification and prediction (n=22); prescribing appropriateness review (n=17); dose optimisation and monitoring (n=5); and medication review prioritisation (n=9). Machine learning, particularly gradient boosting methods, was the most common AI approach (n=31). Most studies reported internal validation only (n=28), while external validation (n=11) and real-world implementation (n=3) were limited. Outcomes focused mainly on model performance and process measures, with minimal evidence that AI reduced patient-level medication-related harm.

Conclusions: AI shows promise for improving the visibility and prioritisation of medication-related risk in older adults; however, evidence of clinical effectiveness remains limited. Future research should prioritise externally validated, workflow-integrated, and human-in-the-loop evaluations using clinically meaningful medication-safety outcomes.

Keywords: artificial intelligence; medication safety; older adults

D2/207

Digital Epidemiology of Medication Adherence in Indonesia: Infodemiology Study Using X Data

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Background: Medication adherence remains a major challenge in chronic disease management, yet conventional adherence measures may miss spontaneous patient narratives in digital spaces. This study aimed to examine Indonesian public discourse on chronic disease medication adherence on X by mapping adherence facilitators and barriers using the WHO five-dimension framework and assessing whether automated affective sentiment aligns with behaviourally meaningful adherence interpretation.

Methods: We conducted a cross-sectional infodemiology study of publicly available X posts from 1 January to 30 June 2025. Data were retrieved using seven disease-specific queries combining the Indonesian medication-taking phrase with chronic disease terms. After duplicate removal and screening, 611 tweets were analysed. IndoBERT was used to classify automated affective sentiment classification, whereas researcher-annotated behavioural sentiment captured adherence orientation of each tweet. Adherence facilitators and barriers were independently coded by two reviewers using the WHO five-dimension framework, with disagreements resolved through adjudication. BERTopic was used for topic modelling to identify semantic clusters.

Results: IndoBERT classified most tweets as negative (326/611, 53.4%), whereas researcher-annotated behavioural sentiment identified positive adherence-oriented content as the largest category (260/611, 42.6%). Agreement between automated affective and behavioural sentiment was low (κ=0.174), indicating divergence between emotional polarity and medication-taking behaviour. After adjudication, 402 tweets (65.8%) contained explicit adherence determinants: 230 facilitators (37.6%), 145 barriers (23.7%), and 27 mixed (4.4%). Patient-related factors dominated the WHO classification (335/402, 83.3%). Three emotion–behaviour divergence patterns were identified, accounting for 28.5% of the corpus. BERTopic identified clusters related to medication routines, patient-provider interaction, and side effects.

Conclusion: Indonesian public X discourse on chronic disease medication-taking revealed adherence facilitators and barriers, predominantly within patient-related domains. Automated affective sentiment did not align well with behavioural adherence interpretation, indicating that emotional polarity alone is insufficient for identifying adherence-relevant signals. Domain-informed interpretation is needed for social media-based medication adherence research and intervention planning.

D2/208

ICI prediction model reporting quality before and after TRIPOD+AI: a pilot study

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Introduction: Machine learning prediction models increasingly inform immune checkpoint inhibitor (ICI) treatment in solid tumors, yet their clinical implementation depends on complete and transparent reporting. The TRIPOD+AI guideline was published in April 2024 to harmonize reporting of such models. Whether reporting quality has improved since its release is unknown.

Aims: To compare adherence to TRIPOD+AI reporting standards between ICI prediction-model studies published before versus after the guideline. We assessed both overall and item-level reporting quality.

Methods: We systematically reviewed prediction-model studies in ICI-treated patients across PubMed, Embase, Web of Science, and Cochrane Library. Two cohorts of 27 studies each were defined by first publication date (April 2019 to March 2021, pre-guideline; April 2024 to March 2026, post-guideline). Each study was scored against the 52-item TRIPOD+AI checklist (Yes/No/NA); adherence was Yes divided by applicable items. Cohorts were compared at study level (Mann-Whitney U test) and item level (Fisher exact test with Benjamini-Hochberg correction).

Results: Mean study-level adherence was 59.7% (SD 9.1) before and 66.0% (SD 8.2) after the guideline (Mann-Whitney U $p=0.009$; Cohen's $d=0.73$). Five items reached nominal significance (Fisher $p<0.05$), led by performance evaluation including calibration (12e, 18.5% to 55.6%) and predictor-distribution comparison between development and evaluation data (20c). However, no item remained significant after Benjamini-Hochberg correction (all q approximately 0.28). The least-reported items were sample-size justification (10), protocol availability (18c), health inequalities (3c), model fairness (14), and patient and public involvement (PPI; item 19). Items 14 and 19 were reported in no study in either cohort.

Conclusions: In this pilot study, overall reporting adherence improved significantly after TRIPOD+AI, but item-level gains did not survive correction. Fairness and PPI remained entirely unaddressed even after the guideline, representing the most urgent transparency gaps. These preliminary findings justify a larger confirmatory study.

Keywords: TRIPOD+AI; ML prediction model reporting; immune checkpoint inhibitors

D2/209

Enhancing Opioid Overdose Identification in Emergency Department Data via Natural Language Processing

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Introduction: Emergency departments (EDs) are a critical point of contact for opioid overdose-related presentations. However, reliance on structured coding for surveillance can lead to underreporting or misclassification; prior work shows that only 42% of drug overdoses were coded properly, emphasising the need to leverage unstructured free-text fields.

Aims: To develop and internally validate a pipeline that applies natural language processing (NLP) and Machine Learning (ML) classifiers to identify opioid overdoses in routinely collected ED data, incorporating both structured and unstructured data.

Methods: An NLP-enhanced ML pipeline was developed and trained on a stratified sample of Victorian Emergency Minimum Dataset (VEMD) records. Medical concepts were extracted from free text using the Medical Concept Annotation Tool (MedCAT) to generate a Bag-of-Words (BOW) representation. Clinical ontologies SNOMED-CT and UMLS were tested for Named Entity Recognition (NER), with adjustments to concept-filtering parameters and model configurations. Subsequently, accounting for class imbalance, several ML models were trained and evaluated against a manually coded gold standard using standard performance metrics.

Results: The pretrained UMLS model and XGBoost classifier performed best, identifying 1010 opioid overdoses (precision = 0.86, F1-score = 0.77). It outperformed the customised SNOMED-CT model (precision = 0.16, F1 = 0.26) and the ICD-10 diagnosis codes (precision = 0.12, F1 = 0.20). The performance gap reflects the fragmented nature of ED texts; UMLS excels at capturing short, granular concepts, whereas SNOMED-CT captures specific, detailed concepts. Currently, the pipeline struggles with short, ambiguous texts, brand names and clinical abbreviations. Future work will address this by fine-tuning the model on customised concepts and contextual tagging.

Conclusions: This project demonstrates the potential of NLP-enhanced ML pipelines scaled across hospital settings to improve the accuracy, robustness, and generalisability of opioid overdose identification, ultimately providing a more reliable framework for surveillance.

Keywords: Natural Language Processing, Opioid Poisoning, Emergency Department Data

D2/210

Ai-Adhere: AI-Driven Real-Time Framework for Medication Adherence Assessment in Chronic Conditions

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Introduction: Medication non-adherence remains a major challenge in the management of chronic diseases, leading to poor clinical outcomes, increased healthcare utilization, and higher costs. Conventional adherence-monitoring approaches, such as directly observed therapy and reminder-based mobile applications, are often resource-intensive, prone to inaccuracies, and lack real-time remote monitoring capabilities.

Objective: To develop, validate, and evaluate an artificial intelligence (AI)-based mobile application (Ai-Adhere) for real-time monitoring and improvement of medication adherence among patients with chronic conditions.

Methods: A prospective interventional study was conducted over six months at JSS Hospital, Mysuru. An AI-enabled mobile application was developed to assess medication adherence through video-based recordings. The prototype was initially validated using pre-recorded videos to determine model performance. Subsequently, 180 patients with chronic diseases were enrolled and instructed to use the application for two weeks by recording medication-taking events. Adherence was monitored in real time, and usability was assessed using the System Usability Scale (SUS).

Results: The AI model demonstrated robust performance, achieving a precision of 90.7%, recall of 93.2%, F1-score of 0.918, and overall accuracy of 90.5%. The application effectively monitored medication-taking behavior in real time and helped in identifying potential reasons for non-adherence. Medication adherence improved substantially among enrolled participants, increasing from 55% at baseline to 90% following application use. Usability assessment revealed a mean SUS score of 86.5 ± 8.2, indicating excellent usability and high user acceptability.

Conclusion: Ai-Adhere demonstrated high accuracy in monitoring medication adherence and showed potential to significantly improve adherence among patients with chronic conditions. The application offers a scalable, user-friendly, and real-time digital solution for adherence monitoring and may support improved long-term disease management.

Keywords: Medication Adherence; Artificial Intelligence; Chronic Disease Management; Digital Health; Real-Time Monitoring.

D2/211

AI-Enabled inhaler technique assessment and adherence monitoring in asthma and COPD

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Introduction: Asthma and chronic obstructive pulmonary disease (COPD) are major causes of global morbidity and mortality. Inhalers remain the cornerstone of treatment; however, their effectiveness depends on correct inhalation technique and adherence. Improper inhaler use contributes to poor disease control, increased exacerbations, hospitalizations, and healthcare costs. Therefore, innovative approaches are needed to support and monitor inhaler use in routine care.

Aim: To develop and validate an artificial intelligence (AI)-enabled mobile application for real-time assessment of inhaler usage technique and evaluate its impact on inhaler adherence.

Methods: A six-month prospective interventional study was conducted among adults (>18 years) with asthma or COPD using controller inhalers. An AI-enabled mobile application was developed and validated using inhaler-use video recordings in real time. Performance was assessed using accuracy, precision, recall, and F1-score. Changes in inhaler usage technique and improved adherence following application use were evaluated, while usability and acceptability were measured using the System Usability Scale (SUS).

Results: The prototype achieved 71.1% accuracy, 83.3% precision, 47.6% recall, and an F1-score of 0.60. Following refinement, application real time performance validated on 130 recordings improved to 90.77% accuracy, 84.4% precision, 88.37% recall, and an F1-score of 0.86. AI-enabled monitoring significantly improved inhaler technique adherence, with confidence scores increasing from 38% to 82% in the Metered Dose Inhaler group, 0% to 91% in the Metered Dose Inhaler with Spacer group, and 22% to 78% in the Rotahaler group following real-time AI-guided interventions. The application demonstrated excellent usability and acceptability, with a mean SUS score of 84.06 ± 5.08.

Conclusion: The AI-enabled mobile application accurately assessed inhaler usage technique and improved adherence among patients with asthma and COPD. Its high usability and acceptability support integration into routine respiratory care.

Keywords: Artificial Intelligence; Inhaler Technique; Asthma; COPD.

D2/212

Design and validation of an intelligent medication-safety application

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Introduction: Manually checking prescriptions for potential errors is time-consuming and error-prone in busy wards. Optical character recognition (OCR) and machine learning (ML) can support healthcare professionals by digitising prescriptions and flagging medication issues in real time.

Aims: To design, implement, and validate an artificial intelligence (AI) based mobile application the Intelligent Medication Assistant (IMA) for active surveillance of medication incidents, and to measure its usability among clinicians and pharmacy staff.

Methods: The IMA was developed as a progressive web application using the MongoDB, Express.js, React.js, and Node.js (MERN) stack, integrating Google Research's DocLens OCR-based ML interface to read handwritten and printed prescriptions. De-identified data were used to train and test the model, and the app was linked to a structured incident reporting workflow in inpatient wards. Validation measured detection rate and accuracy against pharmacist-validated reference data. Usability was assessed over 10 days using the System Usability Scale (SUS) by 25 doctors, pharmacists, and pharmacy students.

Results: The app successfully digitised complex prescriptions and matched drug names via a pharmacopoeia-linked database. Of 620 medications validated, 617 were correctly detected (detection rate 99.52%), with an overall accuracy of 73.39% for medication recognition and incident identification. The mean SUS score was 82.30 ("excellent"); scores were 83.81 for doctors, 82.08 for pharmacists, and 81.14 for pharmacy students. Users reported reduced manual checking time and faster incident reporting.

Conclusions: The IMA demonstrated high detection performance and excellent usability across all user groups, supporting the feasibility of AI-enabled tools for medication safety surveillance in real-world hospital settings. Further refinement may enable scaling to other wards and institutions.

Keywords: Artificial intelligence; Mobile application; Optical character recognition; Medication safety; Usability

D2/213

Machine Learning-Derived Trauma Mortality Prediction and Risk Stratification in Asia

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Introduction: Early identification of trauma patients at high risk of death is essential for triage and resource allocation. Traditional trauma scoring systems often perform suboptimally in contemporary, multicenter settings.

Aims: To develop and evaluate predictive models for emergency department (ED) and in-hospital mortality using prehospital and triage data.

Methods: We analysed Pan-Asian Trauma Outcomes Study (PATOS) registry (2015–2022) of trauma patients retrospectively, covering 14 Asian centers. Two temporally distinct outcomes were analyzed: ED mortality and in-hospital mortality among ED survivors. Predictors included demographics, prehospital interventions, triage vital signs, neurological status, injury severity scores, injury mechanism, and comorbidities. Machine learning (ML) models (Random Forest, XGBoost, Elastic-Net logistic regression, Naive Bayes), a point-based AutoScore system, and traditional trauma scores (TRISS, MGAP, GIFT) were compared using AUROC, accuracy, sensitivity, specificity, and F1 score.

Results: Of 208,184 patients, 1.17% died in-hospital. Prehospital CPR, ED CPR, total Glasgow Coma Scale, triage vital signs, and injury severity scores were consistently top predictors. For ED mortality, Random Forest and XGBoost using all variables achieved the highest discrimination (AUC 0.992), with clinical-variable-restricted models performing similarly (AUC 0.976-0.981). AutoScore yielded AUC 0.964 with high specificity (0.998) and moderate sensitivity (0.596). Traditional scores showed lower discrimination (TRISS AUC 0.958, GIFT 0.935, MGAP 0.890). For in-hospital mortality, Random Forest achieved AUC 0.989, XGBoost 0.986, and AutoScore 0.943. Traditional scores showed similar limitations (TRISS 0.930, GIFT 0.894, MGAP 0.891) with poor specificity (<0.01). An R Shiny application was developed for real-time risk assessment using key variables.

Conclusions: Neurological status, injury severity, and physiological compromise were key drivers of early trauma mortality. Tree-based ML models offered superior predictive accuracy (AUC 0.986-0.992), while AutoScore provided a practical, interpretable bedside tool for rapid risk stratification. The systematic underperformance of Western-derived traditional scores highlighted the need for region-specific prediction tools.

Keywords: trauma; mortality prediction; machine learning

D2/214

Developing a claims-based algorithm to identify infection in multiple myeloma

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Introduction: Infection management in multiple myeloma (MM) is critical, as patients are highly immunocompromised. However, identifying infection events in claims databases is challenging due to the absence of detailed clinical information. This study developed a methodological approach using a Japanese claims database to address this limitation.

Aims: To develop a claims-based algorithm to identify and characterize incident infections among MM patients.

Methods: We used a Japanese claims database (Medical Data Vision) to identify adult MM patients who initiated elranatamab (first dose as index date). Leveraging clinical expert input, we assessed patterns of infection diagnosis codes and anti-infective prescriptions to develop rules that identify infection episodes and classify them as bacterial, viral, or fungal. Incident infections were defined by mapping each episode to an anatomical site–pathogen combination, differentiating new events from pre-existing or ongoing conditions.

Results: The algorithm comprises three domains. For episode identification, an infection diagnosis requires a concurrent anti-infective prescription to reduce inclusion of rule-out diagnoses. For severe diagnoses like sepsis (<10% of episodes), distinguishing therapeutic versus prophylactic intent required either a ≥10-day continuous single-agent course or an escalation of therapy within 10 days. We excluded likely prophylaxis events (low-dose sulfamethoxazole/trimethoprim or events within 8 days post-index if the same agent was prescribed within 14 days pre-index), removing ~17% of initial episodes (mostly low-dose S/T). For type classification, infections were categorized by anti-infective class, recognizing that broad-spectrum therapy may overestimate bacterial events. Mapping episodes by anatomical site–pathogen combination distinguished new infections from pre-existing or ongoing conditions.

Conclusion: This structured approach to claims data supports improving infection identification. By focusing on anti-infective therapy patterns over diagnosis codes and incorporating site–pathogen mapping, the algorithm may help reduce misclassification. This provides a framework for evaluating infection patterns in claims-based pharmacoepidemiologic studies.

Keywords: multiple myeloma; infection algorithm; claims database

D2/215

BRAVE Protocol: Utilising HDSS for Active Monitoring of AESI Background Rates

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Introduction: Reliable background rates for conditions classified as adverse events of special interest (AESIs) are essential for interpreting vaccine safety signals in observed-versus-expected analyses, particularly for new vaccines, such as Lassa fever. In many low- and middle-income countries, pharmacovigilance relies predominantly on hospital-based data sources, which capture severe or clinically diagnosed events, potentially biasing background rate estimates for AESIs that are transient, self-managed, or treated in primary care. Yet such events can impose a significant burden and raise community concerns about immunisation programmes. Health and Demographic Surveillance Systems (HDSS) provide established population denominators and longitudinal follow-up but are not routinely configured for active vaccine safety surveillance. The Global Vaccine Data Network's Background Rates of Adverse Events for Vaccine Evaluation in Africa (BRAVE) project addresses these gaps.

Aims: To adapt existing HDSS platforms to actively ascertain population-based AESI background rates.

Methods: A harmonised screening and follow-up module will be integrated into routine HDSS data collection in Ghana, Kenya, and the Democratic Republic of Congo. A screening question asks whether health events require medical attention or disrupt usual activities. Positive screens trigger structured, community-based follow-up to characterise symptom type, severity, timing, and care-seeking pathways. Standard operating procedures guide training, data quality assurance, ethics, governance, and incidence estimation using HDSS person-time denominators, with site-specific adjustments aligned with local care access and referral pathways.

Conclusions: Integrating active assessment of health events into HDSS enables population-based estimation of background rates beyond hospital-only surveillance, thereby supporting scalable, equity-focused strengthening of community-based vaccine safety monitoring across Africa.

Keywords: Health and Demographic Surveillance Systems, Adverse Events of Special Interest, Background Rates

D2/216

Estimands in Prevalent New User Designs: Clarifying Treatment Effects and Target Populations

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Introduction: The estimand framework provides an approach to defining treatment effects by specifying the target population, treatment conditions, endpoint, summary measure, and handling of intercurrent events. Clinically relevant estimands may arise from a single research question, with intention-to-treat, modified intention-to-treat, and as-treated analyses reflecting distinct treatment strategies and causal contrasts. Although estimand specification is increasingly recognised in pharmacoepidemiologic study design, its application in the prevalent new user design (PNUD) remains challenging.

Aims: To examine how the estimand framework in PNUD studies and provide practical guidance for selecting estimands aligned with specific research questions.

Methods: We review core components of the estimand framework and discuss considerations specific to real-world evidence studies using PNUD. Using a case study of patients initiating sodium-glucose cotransporter-2 inhibitors versus dipeptidyl peptidase-4 inhibitors and cardiovascular outcomes, we illustrate alternative estimands and approaches to handling intercurrent events, including treatment discontinuation and switching. We further consider how study design and confounding adjustment methods influence the target population represented by the estimated treatment effect.

Results: Ambiguity in PNUD studies arises not only from handling intercurrent events but also from how the target population is implicitly defined through design and analysis choices. The time-conditional propensity score approach commonly used in PNUD studies targets the average treatment effect among the treated, though this is rarely stated explicitly. We propose a framework linking common design and analytic choices in PNUD studies to corresponding estimands and outline the role of sensitivity analyses in assessing robustness of findings.

Conclusions: Explicit estimand specification should be integral to PNUDs. Clearly defining the treatment strategy and target population improves transparency, aligns analysis with the research question, and strengthens interpretation of comparative effectiveness and safety findings. The proposed framework provides practical guidance for researchers implementing PNUD and evaluating study results.

Keywords: Estimands, prevalent new user design, real-world evidence

D2/217

SGLT-2i and Risk of VTE in T2DM: A Target Trial Emulation Study

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Introduction: Real-world evidence regarding the impact of sodium glucose cotransporter-2 inhibitor (SGLT-2i) on venous thromboembolism (VTE) occurrence remains scarce.

Aims: To examine whether initiation of SGLT-2i is associated with a reduced risk of VTE in type 2 diabetes mellitus (T2DM) patients.

Methods: We conducted new-user, active-comparator target trials emulation within the Shenzhen Public Health Data Platform to contrast SGLT-2i with dipeptidyl peptidase-4 inhibitors (DPP-4i) and glucagon-like peptide-1 receptor agonists (GLP-1RA), respectively, covering the period from 1 January 2019 to 1 October 2024. Overlap-weighted Cox proportional-hazard models were employed to quantify the association between SGLT-2i and outcomes.

Results: After a median follow-up of 1.86 years, VTE occurred in 423 (0.48%) of 89,141 SGLT-2i users and 478 (0.85%) of 56,815 DPP-4i users. SGLT-2i was associated with a lower risk of VTE occurrence versus DPP-4i (HR: 0.85; 95% CI: 0.74-0.97), with a more pronounced association in patients with advanced age, diabetic complications, or receiving concomitant antihyperglycemic agents (Pfor interaction<0.05). However, the significant association was observed only for deep venous thrombosis (DVT) (HR: 0.81; 95% CI: 0.69-0.94) but not for pulmonary thromboembolism (PTE) (HR: 0.98; 95% CI: 0.75-1.28). In primary analysis and sensitivity analyses, we observed no significant differences in the risk of VTE, DVT, or PTE occurrence between SGLT-2i users and GLP-1RA users.

Conclusions: SGLT-2i was associated with a lower risk of VTE compared with DPP-4i in T2DM patients, particularly among the old and those with advanced disease, while showing comparable safety to GLP-1RA.

Keywords: type 2 diabetes mellitus, venous thromboembolism, sodium-glucose cotransporter-2 inhibitors, glucagon-like peptide-1 receptor agonists, target trial emulation.

D2/218

Psychiatric adverse events of antiepileptic drugs: disproportionality analysis and risk prediction

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Introduction: Despite growing recognition of psychiatric safety in epilepsy care, the psychiatric consequences of antiepileptic drugs (AEDs) remain incompletely characterized. Prior studies have focused on individual agents or isolated outcomes such as suicidality, without systematic evaluation across pharmacological mechanisms or risk stratification for vulnerable subgroups.

Aims: This study evaluated mechanism-specific disproportionality signals for psychiatric adverse events (AEs) associated with AEDs and developed an interpretable machine learning model to support risk stratification.

Methods: This pharmacovigilance study utilized the FDA Adverse Event Reporting System (FAERS; 2004Q1–2025Q2), with the Canada Vigilance Adverse Reaction Database (CVAR) for external validation. AEDs were classified into GABA receptor agents, GABA transaminase inhibitors, and carbonic anhydrase inhibitors. Disproportionality analysis employed the information component (IC) and reporting odds ratio (ROR). For machine learning analysis, age, sex, and concomitant medications (ATC-based) served as predictors across a balanced dataset (96,207 cases with psychiatric AEs; 95,132 without). Seven algorithms were compared using stratified five-fold cross-validation, and SHapley Additive exPlanations was applied for model interpretability.

Results: Among 55,366 psychiatric disorder reports in FAERS, GABA receptor agents demonstrated the highest disproportionality signal (ROR, 5.58; 95% CI, 5.51–5.64), with signals most prominent in older adults and females. Findings were corroborated by CVAR. LightGBM was selected as the final model, achieving an AUROC of 0.704 in the FAERS test set and 0.771 in external CVAR validation. SHAP analyses identified age as the most influential predictor, followed by sex and concomitant nervous system medications.

Conclusions: GABA receptor agents exhibited the highest disproportionality signals. Routinely available clinical variables identified patients at elevated psychiatric risk via machine learning, supporting mechanism-based safety monitoring in epilepsy care. These hypothesis-generating findings warrant confirmation in future cohort studies.

Keywords: Antiepileptic drugs; Psychiatric disorders; Pharmacovigilance.

D2/219

Estimating the average treatment effect using disease risk score weighting methods

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Introduction: In pharmacoepidemiologic studies, because treatment assignment is nonrandomized and comparisons between treatment groups are subject to confounding, causal effect estimation requires careful consideration. Balancing-score methods, including propensity score (PS) and disease risk score (DRS) methods, have been proposed for confounder adjustment. Existing DRS weighting methods primarily target the average treatment effect on the treated (ATT), reflecting that the DRS summarizes potential outcomes under control. Although the ATT is a natural target for DRS weighting when effect modification is considered, this does not preclude applying DRS weighting to average treatment effect (ATE) estimation.

Aims: We formulated DRS weighting estimators for the ATE under no effect modification. We derived asymptotic variance estimators.

Methods: We proposed three weighting strategies for ATE estimation targeting the DRS distribution in the overall population: target distribution weighting (TDW), inverse probability weighting (IPW), and stabilized inverse probability weighting (SIPW). We clarified algebraic relationships among the three weights. For each strategy, we formulated Hájek-type ATE estimators. We derived sandwich variance estimators using M-estimation.

Results: In the absence of effect modification, the proposed estimators targeted the ATE standardized to the DRS distribution in the overall population. The TDW weights were algebraically equivalent to the SIPW weights. Approximate variance estimators for the ATE estimators were obtained. In simulations, we compared the proposed DRS weighting estimators with naïve estimation and PS weighting. DRS weighting showed more favorable performance than PS weighting and naïve estimation.

Conclusions: The proposed DRS weighting estimators showed promise for ATE estimation in simulations. Although the ATE is mathematically definable under effect modification, its clinical interpretation may be challenging because is averages heterogeneous effects across subpopulation. Under no-effect-modification assumption, the proposed DRS weighting estimators with asymptotic variance estimators provided a viable alternative to ATE weighting in simulations.

Keywords: Prognostic score; Effect modification; Causal inference

D2/220

Building reproducible paediatric medication safety studies using OMOP common data model

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Introduction: Medication safety studies using healthcare data are often limited by heterogeneous structures, local terminologies, and poor reproducibility. Standardised data models such as the Observational Medical Outcomes Partnership Common Data Model (OMOP CDM) improve transparency and scalability of pharmacoepidemiologic research. Intravenous aciclovir is widely used for suspected or confirmed herpes simplex virus central nervous system infection in children, yet uncertainty remains regarding aciclovir-associated nephrotoxicity in clinical practice.

Aims: To develop an OMOP-based phenotyping framework for paediatric medication safety studies using aciclovir-associated nephrotoxicity as a use case. To demonstrate how standardised phenotyping can support reproducible medication safety research.

Methods: A retrospective observational audit study was designed using electronic medical record data transformed into OMOP CDM. Eligible patients were aged under 18 years and received intravenous aciclovir between 2016 and 2023. Standardised concept sets were developed for aciclovir exposure, herpes simplex virus central nervous system disease, acute kidney injury, nephrotoxic exposures, and relevant subgroups. Cohort construction and phenotyping were implemented using methodologies compatible with the Observational Health Data Sciences and Informatics framework. Framework performance will be assessed through cohort ascertainment, phenotype validity, data completeness, and reproducibility.

Results: Phenotype development identified three key methodological challenges: defining suspected herpes simplex virus central nervous system disease using heterogeneous clinical proxies, identifying acute kidney injury using longitudinal creatinine measurements, and distinguishing aciclovir-associated nephrotoxicity from competing causes such as sepsis, dehydration, and concomitant nephrotoxic medications. These challenges informed standardised cohort definitions, temporal exposure windows, and confounder flags. Cohort extraction identified more than 3,000 eligible aciclovir exposures, with analysis underway.

Conclusions: Standardised phenotyping within OMOP CDM is feasible for complex paediatric medication safety studies and provides a transparent approach to exposure, outcome, and confounder definition. This methodology may support reproducible medication safety research and future multicentre analyses.

Keywords: OMOP Common Data Model; medication safety; aciclovir nephrotoxicity

D2/221

Vitamin D supplementation associated with vitamin D–VDR–LL37 pathway and diabetic foot healing

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Introduction: Diabetic foot infections (DFIs) are a major cause of non-traumatic lower-limb amputations. Vitamin D regulates immunity and wound healing by binding the vitamin D receptor (VDR) and inducing the cathelicidin antimicrobial peptide (CAMP) gene to produce cathelicidin (LL-37). However, its role in DFIs is not fully understood.
Aim: To find the association of vitamin D supplementation with serum vitamin D levels, VDR and CAMP gene expression, and ulcer healing in DFI patients infected with biofilm-forming bacteria.

Method: This exploratory prospective cohort study (September 2022-March 2026) enrolled 16 DFI patients each in the study group (SG) and reference group (RG), alongside 16 healthy controls (HCs). SG participants received 60,000 IU vitamin D with standard care, while RG participants received standard care alone. Both groups were followed for 4 months. Vitamin D levels were assessed using electrochemiluminescence immunoassay, while VDR protein and LL-37 were quantified through ELISA. Biofilm formation was evaluated using the tissue culture plate method. Additionally, VDR and CAMP gene expression were analysed via mRNA quantitation. The relative gene expression was calculated using the 2^−ΔΔCt method, with GAPDH as the endogenous control.

Results: Vitamin D supplementation significantly increased serum vitamin D levels ($p<0.001$), VDR protein concentrations ($p=0.001$), and LL-37 levels ($p=0.001$) in SG participants. However, differences in VDR ($p=0.067$) and CAMP ($p=0.346$) gene expression among HCs, SG, and RG were statistically insignificant. Although ulcer healing did not significantly differ between SG and RG groups ($p=0.391$), favourable healing trends were observed in SG. Furthermore, Vitamin D-sufficient SG patients had lower biofilm-producing bacteria than deficient patients, albeit without statistical significance ($p=0.163$).

Conclusion: Vitamin D supplementation may positively influence the vitamin D–VDR–LL-37 pathway and enhance wound healing in DFI patients. More extensive studies are required to validate these preliminary molecular and clinical findings.

Keywords: Diabetic foot infection, vitamin D-VDR-LL-37 pathway, wound healing

D2/222

Real-world evidence and pharmacoepidemiologic implications of hepatitis-associated HCC and viral persistence

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Introduction: Hepatocellular carcinoma (HCC) is a major complication of chronic hepatitis B virus (HBV) and hepatitis C virus (HCV) infection and contributes to liver-related morbidity and mortality. In high viral hepatitis burden settings, real-world evidence on HCC frequency and persistent viral activity in advanced liver disease remains limited. Tissue-level viral persistence may inform surveillance and disease management.

Aims: This study aimed to estimate HCC burden among patients with advanced liver disease and evaluate persistent HBV and HCV viral protein expression in liver cancer tissues.

Methods: A ten-year retrospective real-world study was conducted using clinical data from patients with liver-related complications. HCC frequency was assessed among eligible patients. Viral persistence was evaluated by immunohistochemistry on explanted liver tissues and liver resection samples from patients with HBV- or HCV-associated HCC. HCV non-structural protein 5B and HBV X protein expression were assessed using qualitative immunohistochemistry scoring. Data were analyzed using R software.

Results: Among 1,384 patients with liver-related complications, 256 were diagnosed with HCC, representing 18.5% of the study population. Nearly one in five patients with advanced liver disease had liver cancer. HCC occurrence differed significantly by age and gender, with higher burden among male patients. Among HCV-associated HCC samples, 13 of 16 patients showed detectable low-level HCV NS5B protein expression. Three HCV-associated samples demonstrated moderate-to-high expression. Among HBV-associated HCC samples, HBV X protein expression was detected with variable staining intensity. These findings suggest persistent viral activity within hepatocytes at advanced disease stages.

Conclusions: This study demonstrates substantial hepatitis-associated HCC burden and tissue-level evidence of persistent HBV and HCV protein expression. Findings support earlier hepatitis detection, timely antiviral management, and risk-based HCC surveillance to reduce preventable liver cancer burden.

Keywords: hepatocellular carcinoma; viral persistence; real-world evidence

D2/223

Impact of valproic acid concentration on BMI z-score and pediatric hyperammonemia

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Introduction: Pediatric long-term valproic acid (VPA) therapy causes weight gain and hyperammonemia, reducing compliance. Understanding concentration impacts and independent risk factors is crucial to optimizing clinical outcomes.

Aims: This study evaluated VPA concentrations, pharmacokinetic ratios, and BMI z-score changes, while analyzing age-specific dose-response relationships in drug-induced hyperammonemia.

Methods: We conducted a retrospective longitudinal study utilizing clinical records collected between March 1, 2024, and May 31, 2026 at a tertiary hospital in Southern Taiwan. Eligible participants were pediatric patients aged 2 to 12 years receiving VPA therapy. Multiple linear regression and age-stratified analyses were performed to evaluate the impacts of trough concentration, daily dosage, serum albumin, and concurrent ketogenic diet.

Results: The 2–6 years group exhibited significantly lower concentration-to-dose ratios compared to the 6–12 years group due to enhanced hepatic clearance（2.12 ± 0.94 vs 4.18 ± 1.05, P <0.005）. Conversely, the 6–12 years group demonstrated greater susceptibility to weight gain, showing a higher mean increase in Δ BMI z-score（0.98 ± 1.02 vs 0.15 ± 0.84, P <0.03）. After adjusting for age, sex, and baseline weight, high VPA concentration（≥ 80 μg/mL）was a strong independent predictor of increased Δ body mass index z-score（P <0.001）. Concurrently, concurrent ketogenic diet significantly mitigated this weight-gain trend (β = -0.214, P=0.032）. VPA trough concentration strongly correlated with serum ammonia levels (r=0.69, P <0.0001）. Furthermore, younger patients showed significantly higher vulnerability to hyperammonemia when serum albumin dropped below (<3.5g/dL).

Conclusions: High VPA exposure independently drives age-specific pediatric obesity and hyperammonemia. While ketogenic diets protect against weight gain, intensive drug monitoring and prospective threshold validation remain vital for safety.

Keywords: Valproic acid, BMI z-score, Hyperammonemia

D2/224

Prenatal antiseizure medication exposure and risk of neuropsychiatric disorders in children

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Introduction: Evidence linking prenatal antiseizure medication (ASM) exposure to childhood neuropsychiatric disorders (NPDs) remains inconsistent, although risks associated with valproate are relatively well established.

Aims: To investigate the association between prenatal ASM exposure and the subsequent risk of NPDs in children.

Methods: This longitudinal, binational birth cohort study included mother-child pairs from nationwide claims databases in South Korea and Japan, with follow-up from 2009 to 2023. Prenatal ASM exposure was defined as maternal ASM prescriptions during pregnancy, and polytherapy was defined as exposure to two or more distinct ASMs during pregnancy. Incident NPDs in children were identified based on at least two diagnostic records in both countries, and adjusted hazard ratios (aHRs) with 95% confidence intervals (CIs) were estimated using Cox proportional hazards models in the full, PS–matched, and sibling comparison cohorts, adjusting for maternal epilepsy history, maternal neuropsychiatric history, and other prespecified covariates.

Results: In the Korean cohort of 3,013,262 mother-child pairs, prenatal ASM exposure was associated with an increased risk of childhood NPDs in the PS-matched cohort (1.10 [1.02-1.18]), whereas the association was not significant in sibling-comparison analyses (0.86 [0.71-1.04]). Comparable findings were observed in the Japanese replication cohort. Increased risks were identified for first-trimester exposure, exposure across multiple trimesters, longer cumulative exposure duration, and higher prescription frequency. Among individual ASMs, clonazepam (1.27 [1.11-1.44]) and sodium valproate (1.50 [1.17-1.92]) were associated with increased NPD risk. Subgroup analyses identified that prenatal ASM exposure significantly elevated risks for intellectual disability, ADHD, autism spectrum disorder, and severe NPDs.

Conclusions: The modest association observed in PS-matched analyses was not replicated in sibling comparisons, suggesting that shared familial or maternal factors may partly explain the association, although limited power in sibling analyses should be considered. These findings support cautious, individualized ASM prescribing during pregnancy.

Keywords: antiseizure medications, neuropsychiatric disorders, pregnancy

D2/225

Risk Factors For Antimicrobial-Resistant Escherichia Coli Carriage In Children: A Case-Control Study

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Introduction: Escherichia coli poses an escalating pediatric health threat. Globally and locally, the surging prevalence of antimicrobial resistance (AMR) severely restricts therapeutic options and heightens risks for persistent clinical illness. However, the specific behavioral and environmental determinants driving pediatric colonization remain insufficiently characterized.

Aim: To evaluate the epidemiological determinants and antimicrobial resistance status of E.coli carriage among children in Hong Kong.

Methods: This case-control study at Hong Kong Children's Hospital, recruited pediatric participants (aged 0–18years) and their caregivers. E.coli carriages was screened via child rectal/stool sample and caregiver nasal swab, alongside demographic and antibiotic-use surveys. Isolates were confirmed using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOFMS). Antimicrobial susceptibility testing (AST) was performed on 11 antibiotics based on local epidemiology and CLSI guidelines using disc-diffusion and minimum inhibitory concentration (MIC). Children with and without E.coli carriage were designated as cases and controls, respectively. Risk factors for carriage were analyzed using logistic regression, with variable selection optimized via a bidirectional stepwise Akaike Information Criterion (AIC) process.

Results: Among 328 enrolled participants (mean age: 6.82 years; 57.6% male), 69 (21.0%) carried E.coli (cases) and 259 (79.0%) served as controls. Resistance profiles were characterized by high prevalence against cefazolin (91.3%), ampicillin (81.2%) followed by tetracycline (62.3%) and co-trimoxazole (53.6%). Notably, within the colonized subjects, 95.7% presented with resistance to ≥1 antibiotic, and 82.6% exhibited multidrug-resistance (MDR). Multivariable logistic regression identified caregiver colonization (OR: 29.45, 95% CI: 1.75-1284.13) and caregiver hospital exposure (OR: 0.18, 95% CI: 0.04-0.58) as the significant predictors for children carriage.

Conclusions: Hong Kong pediatric E.coli carriage exhibits high prevalence of MDR; first-line antibiotics are predominantly compromised, whereas some last-resort therapeutics remain effective. Multivariable analysis showed that significant children-caregiver carriage associations. These determinants offer critical insights for identifying high-risk pediatric populations and tailoring interventions.

Keywords: Multidrug-resistant Escherichia coli, Pediatric colonization, Caregiver-child dyads

D2/227

Aligning People, Not Just Protocols: Integrating Cultural Awareness into Multi-Country Pharmacovigilance Collaboration

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Introduction: Pharmacovigilance relies not only on robust methods and harmonised data, but also on trust among study teams, healthcare providers, health systems, and communities. In multi-country collaborations, cultural assumptions around communication, consent, authority, illness, and death can shape vaccine safety surveillance. The 'Background Rates of Adverse events for Vaccine Evaluation' (BRAVE) project recognises cultural awareness as a technical requirement for ethical, high-quality pharmacovigilance, and as such aimed to incorporate it into routine staff training.

Aim: To conduct structured, country-led cultural awareness sessions within BRAVE, strengthening collaboration, site readiness, and data quality.

Methods: Sessions were co-developed and delivered by the Global and African Coordinating Centres alongside the data collection teams from the 5 African countries. Guided by the Purnell model for Cultural Competence, they addressed heritage, communication norms, family and consent structures, workforce dynamics, health-seeking behaviours, spirituality, and death rituals. These domains were examined in relation to local working environments and health-system realities.

Results: The sessions improved familiarity with site-specific contexts and constraints, strengthening empathy and collaboration across teams. Key issues highlighted included the role of community leaders and extended family in consent processes, the impact of religious practices and rapid burial customs on outcome ascertainment and differing professional hierarchies affecting communication and decision-making. Addressing these factors has reduced misunderstandings between teams, informed more context-sensitive engagement strategies, and improved confidence in navigating cultural complexity.

Conclusion: Cultural awareness is a critical enabler of effective pharmacovigilance. BRAVE shows that embedding structured, locally led cultural competence early strengthens trust, alignment, and scientific rigour.

Key words: Cultural competence, Pharmacovigilance, Multi-country collaboration

D2/228

Evaluating electronic health record readiness for vaccine safety surveillance in resource-limited settings

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Introduction: Timely vaccine safety surveillance relies on high-quality clinical data to estimate background rates of adverse events of special interest (AESIs) and detect safety signals. Electronic health records (EHRs) offer potential for both retrospective background rate estimation and prospective vaccine safety surveillance. However, their readiness in low-and middle-income countries (LMICs) is variable due to heterogeneous information systems, variable data quality, limited interoperability, and hybrid paper-electronic workflows.

Aims: To assess the capacity and readiness of hospital EHR systems within the BRAVE (Background Rates of Adverse Events for Vaccine Evaluation) network to support vaccine safety surveillance.

Methods: A standardised EHR readiness assessment was conducted across five BRAVE network sites in Africa. Assessment domains included governance and data security, data completeness, diagnostic coding, timeliness, record linkage, interoperability (including HL7/FHIR compatibility), and data export functionality. Site-reported information was evaluated against a predefined minimum dataset for AESI identification and background rate estimation.

Results: EHR platforms were heterogeneous, ranging from open-source to locally developed systems. Most sites captured core inpatient data sufficient for retrospective AESI identification. Six of ten hospitals reported high data completeness, timely capture, functional record linkage, and automated exports. ICD coding was commonly used to support standardisation; however, dual paper and electronic systems increased workload. Other sites were better suited to hybrid approaches combining EHR-based pre-screening or denominator estimation with manual chart review. Overall, readiness varied across domains, with strengths in data capture and governance, and limitations in interoperability and workflow integration.

Conclusion: Hospital EHR systems within the BRAVE network across multiple LMICs show variable but promising capacity to support pharmacoepidemiologic vaccine safety surveillance. A tiered, pragmatic approach leveraging both electronic data and complementary manual processes may enable retrospective AESI estimation and prospective surveillance. Strengthening interoperability and workflow integration will be critical to support sustainable scale-up.

Keywords: vaccine safety; electronic health records; pharmacovigilance

D2/229

Identifying post-HPV vaccination safety mentions using natural language processing in Indonesia

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Introduction: Indonesia has one of the largest social media user bases globally. Following the recent implementation of the national Human Papillomavirus (HPV) vaccination program, public monitoring of vaccine safety has emerged as a critical imperative. However, the utilisation of social media data to monitor activities related to vaccine safety is still limited in the country.

Aims: This study aims to identify post-HPV vaccination safety mentions from social media in Indonesia using a Natural Language Processing (NLP) approach.

Methods: This retrospective observational study extracted data from the Indonesian-language Twitter/X platform during the 2016–2025 period using the search keywords "vaccine" and "hpv". All post texts obtained from the crawling process underwent pre-processing and were then classified using a rule-based NLP model to detect and map vaccine safety mentions. The categorisation was based on the standard clinical terminology categories of the Medical Dictionary for Regulatory Activities (MedDRA), followed by a quantification of the vaccine safety mentions.

Results: Out of a total of 31,870 tweets analysed, only 1,664 (5.2%) were identified as vaccine safety mentions. The trend of HPV vaccine safety mentions was found to increase sharply after 2020. Local symptom complaints were the most frequently discussed, including injection site pain (49.4%), swelling (3.5%), and erythema (1.86%). Meanwhile, the main systemic symptoms reported included pyrexia (8.6%), fatigue (6.0%), and headache (3.6%). Uniquely, this study found a high proportion of mentions related to reproductive function complaints, which were infertility (11.7%) and menstrual irregularities (8.8%).

Conclusion: Vaccine safety mentions following HPV vaccination in Indonesia are relatively infrequent, predominantly highlighting local symptoms. However, signals concerning reproductive issues warrant further detailed verification. While social media and NLP show strong potential for active surveillance, clinical validation remains essential to confirm true signals and mitigate misinformation bias.

Keywords: HPV, social media, vaccine safety

D2/230

Real-World Treatment Patterns and Cardiovascular Outcomes Among Romosozumab Users

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Introduction: Romosozumab is an anabolic agent indicated for osteoporosis in patients at high fracture risk. Concerns regarding major adverse cardiovascular events (MACE) have prompted regulatory warnings; however, real-world evidence on treatment patterns and cardiovascular outcomes remains limited.

Aims: To evaluate treatment patterns and cardiovascular outcomes following romosozumab initiation.

Methods: We conducted a retrospective single-center cohort study of patients who received at least one dose of romosozumab between January 2022 and October 2024. Patients with a prior history of myocardial infarction or ischemic stroke were excluded. Participants were followed for up to 545 days after treatment initiation, consisting of a 12-month treatment period and a 180-day post-treatment follow-up. MACE, defined as acute myocardial infarction or ischemic stroke, was identified using diagnostic codes and confirmed through medical record review. Treatment completion, cardiovascular event rates, and time-to-event analyses including Kaplan–Meier estimates were evaluated.

Results: A total of 477 patients were included, with a mean age of 72.9 years; 95.2% were women. Hypertension (38.2%), hyperlipidemia (28.3%), and diabetes mellitus (17.8%) were common baseline comorbidities. Overall, 41.7% completed the planned 12-dose romosozumab course. During 663.8 person-years of follow-up, 7 patients experienced MACE (1.47%), corresponding to an incidence rate of 10.55 per 1,000 person-years. The median time to MACE was 164 days (IQR, 142.5–195.5 days). All cardiovascular events occurred during active treatment and before the tenth dose. Kaplan–Meier analysis showed cumulative incidences of 0.85% at 180 days and 1.49% at the end of follow-up.

Conclusions: Cardiovascular events were uncommon among romosozumab users without prior myocardial infarction or ischemic stroke, whereas fewer than half completed the planned 12-dose treatment course. These findings provide real-world evidence on both treatment utilization and cardiovascular outcomes following romosozumab initiation.

Keywords: Romosozumab; cardiovascular safety; Treatment Patterns

D2/231

Protamine and naloxone trigger tools for detecting preventable adverse drug reactions

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Introduction: Preventable adverse drug reactions (pADRs) pose a critical threat to patient safety and contribute significantly to avoidable patient harm. Conventional voluntary reporting systems consistently suffer from substantial underreporting. Implementing active surveillance methods is therefore essential to overcome these limitations and optimize medication safety.

Aims: This study evaluated the effectiveness of using protamine and naloxone as active trigger tools to detect and subsequently reduce pADRs within an inpatient setting.

Methods: A cross-sectional experimental study was conducted at Nakhon Pathom Hospital , comparing inpatient medical records before and after implementing the trigger tools and clinical interventions (Smart Labeling, Rapid Digital Reporting). Severity was classified using the NCC MERP index, and preventability was assessed via the Schumock and Thornton criteria. Statistical analyses were performed using descriptive statistics and Chi-square tests.

Results: Baseline conventional reporting yielded zero pADRs. In 2024, active trigger tools identified 10 pADRs out of 303 cases: (5 from 295 protamine; 5 from 8 naloxone). These cases (9 category E, 1 category H) were primarily driven by excessive dosing, inappropriate drug switching, and treatment delays, with enoxaparin accounting for 30%. Following targeted interventions in 2025, pADRs significantly decreased to 5 cases out of 462 cases (4 from 457 protamine; 1 from 5 naloxone), all of which were category E with zero instances of severe harm (category F or higher). Heparin became the primary causative agent (80%). Overall, the intervention achieved a statistically significant reduction in pADRs ($p = 0.038$) with a Risk Ratio of 0.47

Conclusions: Protamine and naloxone trigger tools with clinical interventions demonstrated high clinical efficacy, successfully reducing the risk of pADRs by 53%. The naloxone cohort exhibited a higher pADR rate than the protamine group, indicating an urgent need for more stringent clinical guidelines for opioid management.

Keywords: Trigger tools, Preventable adverse drug reactions, Patient safety

D2/232

Adverse Drug Reactions Associated with Mucolytic Agents: A 10-Year Retrospective Study

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Introduction: Mucolytics like N-acetylcysteine, erdosteine, and bromhexine are widely used for respiratory conditions and generally regarded as safe. However, hypersensitivity reactions occasionally occur, and the clinical spectrum of mucolytic-induced adverse drug reactions (ADRs) remains poorly characterized.

Aims: To identify and describe the clinical features of ADRs associated with various mucolytic agents.

Methods We retrospectively analyzed cases of mucolytic-induced ADRs at a Korean tertiary hospital between January 2016 and December 2025. Inclusion criteria were strictly limited to: 1) cases classified as "certain" by causality assessment; 2) "probable" cases involving a single drug; or 3) cases definitively confirmed via clinical history, skin tests, and provocation tests. Ambiguous cases lacking objective evidence were excluded.

Results: Over the 10-year study period, a total of 37 ADR cases were identified: 15 attributed to erdosteine, 19 to N-acetylcysteine, and 3 to bromhexine. ADRs due to erdosteine included fixed drug eruption (FDE, n=9), maculopapular eruption (MPE, n=4), angioedema (n=1), and urticaria (n=1). For N-acetylcysteine, 15 cases were associated with the intravenous formulation - nausea/vomiting (n=10), bronchoconstriction/dyspnea (n=3), and angioedema (n=2) - while 4 cases involved the oral formulation, presenting as dyspnea (n=1) and nausea/vomiting (n=3), yielding 19 total N-acetylcysteine-related ADRs. Bromhexine was responsible for MPE (n=2) and urticaria (n=1). Cutaneous symptoms were predominant in erdosteine (n = 15) and bromhexine (n = 3) cases, but rare in N-acetylcysteine (n = 2). All skin tests yielded negative results, indicating that controlled provocation tests are essential for definitive diagnosis unless the clinical history is indisputably clear.

Conclusions: Although relatively safe, mucolytics can induce a diverse spectrum of ADRs. Erdosteine-induced FDE was the most frequent cutaneous manifestation, and N-acetylcysteine frequently caused gastrointestinal symptoms. Healthcare professionals should be aware of these potential ADRs to ensure prompt diagnosis and prevent inadvertent re-exposure.

D2/233

Eravacycline Treatment Causes a Decrease in Fibrinogen Levels

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Introduction: Eravacycline is a tetracycline-class antibiotic. Whether hypofibrinogenemia represents a class effect remains unclear.

Aims: To investigate eravacycline's effect on coagulation, particularly fibrinogen (FIB).

Methods: Retrospective study of 98 severe infection patients receiving eravacycline. Coagulation markers were monitored before, during, and after treatment.

Results: FIB levels significantly decreased after eravacycline use ($P<0.001$). Consequently, 54 cases were classified into the hypofibrinogenemia group (FIB < 2.0 g/L), and the remaining 44 into the normal fibrinogen group.In the hypofibrinogenemia group, hypofibrinogenemia occurred on average 8.57 ± 4.31 days after eravacycline treatment. In 33 patients with post-cessation data, FIB returned to normal after treatment cessation ($P<0.001$). PT, APTT, and TT prolonged after use and shortened after cessation (PT: non-significant). Multivariate analysis identified decreased eGFR, low baseline FIB, and female gender as independent risk factors. Bleeding events occurred in 5 patients (9.26%), including 3 cases of gastrointestinal bleeding and 2 cases of bloody alveolar lavage fluid.

Conclusion: Eravacycline-related hypofibrinogenemia occurs at 8.6 days, associated with baseline FIB, eGFR, and gender. Patients with lower FIB levels may experience bleeding events. Routine monitoring of FIB and coagulation is recommended.

Keywords: eravacycline, hypofibrinogenemia, risk factors

D2/234

Assessment of Adverse Drug Reaction Preventability: Comparison of LAAT and Schumock-Thornton Scales

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Introduction: Both Schumock–Thornton (S&T) scale and Liverpool Adverse Drug Reaction Avoidability Tool (LAAT) are designed to assess the preventability of Adverse Drug Reactions (ADRs). Assessing the consistency and reliability of these two tools helps in better clinical decision making.

Aim: To assess the inter-rater reliability of LAAT and S&T scales and evaluate the agreement between the two scales in determining ADR preventability.

Methods: A retrospective observational study was conducted on 80 randomly documented ADRs selected from pharmacovigilance database. Preventability assessment was independently carried out by three trained raters using the Schumock–Thornton scale and the Liverpool ADR Avoidability Tool. Inter-rater agreement for both scales and concordance between the two scales were evaluated using Fleiss' kappa statistics with 95% confidence intervals (CI). Statistical significance was set at $p < 0.05$.

Results: A total of 80 ADRs were independently evaluated for preventability by three raters using S&T scale and LAAT. Inter-rater reliability analysis demonstrated moderate agreement among raters using the S&T scale, with a Fleiss' kappa coefficient of 0.58 (95% CI: 0.46–0.70; $p < 0.001$). The LAAT scale demonstrated slightly higher agreement, with a Fleiss' kappa coefficient of 0.64 (95% CI: 0.58–0.79; $p < 0.001$), indicating substantial agreement among raters. Agreement between S&T scale and LAAT in the classification of ADR preventability was also assessed and demonstrated moderate concordance, with a kappa coefficient of 0.54 (95% CI: 0.42–0.66; $p < 0.001$). LAAT took less time for preventability assessment. Overall, the LAAT scale showed a greater inter-rater consistency than S&T scale. However, both tools had acceptable reliability for ADR preventability assessment.

Conclusion: Both the LAAT and S&T scales demonstrated moderate to substantial reliability for ADR preventability assessment. The LAAT scale showed slightly better inter-rater agreement compared to the Schumock–Thornton scale.

D2/235

From signal detection to label change: a DME-based pharmacovigilance system in Korea

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Introduction: Signal detection using spontaneous reporting systems is a key component of post-marketing pharmacovigilance. While quantitative data-mining methods are widely used, rare but clinically important adverse events may be overlooked. Designated Medical Event (DME) terminology can support qualitative review by prioritizing serious adverse events. This study assessed whether a DME-based review system can contribute to signal detection and regulatory action.

Aims: This study aimed to describe the operation of a DME-based serious adverse event review system. It also evaluated its contribution to identifying drug–event combinations requiring further assessment and regulatory action.

Methods: Monthly serious adverse event reports in the Korea Adverse Event Reporting System (KAERS) were reviewed between January 2021 and October 2023. Signal detection used three complementary approaches: individual case review of deaths and congenital anomalies, DME-based qualitative assessment, and quantitative data-mining analyses. Drug–event combinations identified through DME review were assessed for causality and further evaluated according to the signal management algorithm. Regulatory actions, including labeling changes, were proposed to the regulatory authority when warranted.

Results: A total of 2,533 drug–DME combinations were evaluated. Among these, 781 combinations included at least one case for which a causal relationship could not be excluded. Following further evaluation, 101 combinations were selected for detailed signal assessment. Six combinations were not reflected in Korean product labeling. Safety update proposals were submitted to the regulatory authority, and four regulatory label changes were implemented: pembrolizumab-associated rhabdomyolysis, atezolizumab-associated acute kidney injury, famotidine-associated anaphylactic reaction, and lidocaine-associated anaphylactic reaction.

Conclusions: The DME-based review process complemented conventional data-mining methods by identifying clinically important but infrequently reported drug–event combinations that might otherwise have been overlooked. The system contributed directly to regulatory decision-making, including product labeling changes, demonstrating the value of DME-based monitoring as an effective component of routine pharmacovigilance activities.

Keywords: designated medical event; pharmacovigilance; signal detection

D2/236

Assessment of PCOS prevalence and mental health impact among students

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Introduction: Polycystic Ovary Syndrome (PCOS) is one of the most common endocrine disorders affecting women of reproductive age and is frequently associated with psychological distress. College students may be particularly vulnerable due to academic stress, sedentary lifestyles, and poor dietary habits. However, awareness of PCOS and its mental health implications remains limited among young women.

Aims: To determine the prevalence and predisposing factors of PCOS among female students and assess its impact on mental health. To evaluate the effectiveness of a structured educational intervention on knowledge, attitude, and practice (KAP) regarding PCOS.

Methods: A dual cross-sectional and prospective interventional study was conducted among 459 female students. Confirmed PCOS cases (n=53) and undiagnosed participants (n=406) were assessed using the Depression, Anxiety and Stress Scale-21 (DASS-21), a PCOS diagnostic questionnaire, and a validated KAP questionnaire. Participants received a 90-minute educational intervention, followed by KAP reassessment after 3–4 weeks. Data were analysed using appropriate non-parametric statistical tests.

Results: The prevalence of PCOS was 11.5%. Among diagnosed participants, obesity (32.0%), anxiety (22.6%), and hypertension (13.2%) were the most common comorbidities. Among undiagnosed participants, 54.8% reported minimal physical activity, 73.2% experienced active stressors, and 10.8% were classified as having mild PCOS risk. Clinically significant anxiety and depression were reported in 73.4% and 62.3% of diagnosed participants, respectively, compared with 46.5% and 31.7% of undiagnosed participants. Significant differences were observed between groups across all DASS-21 domains ($p<0.0001$). The intervention significantly improved knowledge and practice scores in both groups ($p<0.0001$), whereas attitude scores among diagnosed participants showed no significant change ($p=0.7593$).

Conclusions: PCOS is prevalent among female students and is associated with substantial psychological burden. Educational interventions can improve PCOS awareness and health-related practices, supporting the integration of PCOS education and mental health screening into university health programs.

Keywords: Polycystic ovary syndrome, mental health, educational intervention

D2/237

Polypharmacy and clinical predictors of mortality in an ambispective heart failure cohort

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Introduction: Guideline-directed medical therapy (GDMT) is central to heart failure (HF) management, but real-world patients often have comorbidities requiring additional drugs, leading to polypharmacy. Whether polypharmacy and drug-related problems (DRPs) are independently associated with survival remains unclear.

Aim: To describe pharmacotherapy patterns and polypharmacy in an ambispective HF cohort, and to evaluate whether polypharmacy and clinical factors were associated with mortality; DRPs were examined descriptively.

Methods: Analysis included 585 adults with HF from a single-centre ambispective cohort (five-year retrospective review plus nine months of prospective data). Polypharmacy was 5–9 medications, hyperpolypharmacy ≥10, and extensive polypharmacy ≥15. DRPs used standard criteria. Cox regression examined mortality predictors; logistic regression explored DRP predictors.

Results: Of 585 patients (72.13% male, largest age group 61–80 years), polypharmacy occurred in 413 (70.59%), hyperpolypharmacy in 94 (16.06%), extensive polypharmacy in 77 (13.16%). Most received core GDMT. During follow-up, 83 (14.14%) died. In Cox models, age, HF subtype, and length of stay significantly predicted mortality; diuretics showed a trend toward lower risk (HR 0.63, 95% CI 0.39–1.02). No drug class independently predicted mortality. In logistic regression, neither medication count nor polypharmacy category was independently associated with higher DRP risk, though comorbidity number showed a borderline effect.

Conclusions: In this real-world HF cohort, polypharmacy was highly prevalent, and pharmacotherapy broadly followed guidelines. Survival was determined primarily by age, HF subtype, and hospitalisation patterns rather than by drug classes or polypharmacy burden, indicating clinical profile drives mortality.

Keywords: Heart failure; Survival; Polypharmacy; Drug-related problems; Pharmacotherapy

D2/238

Opioid use in people living with dementia: a scoping review

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Introduction: Pain is highly prevalent in people living with dementia, yet difficult to assess. Opioid use has been increasing in this population despite limited evidence on efficacy and safety. However, evidence on opioid use patterns and outcomes remains limited and heterogeneous. Mapping this evidence is critical to inform safe opioid prescribing in this vulnerable population.

Aims: To systematically map and synthesise evidence on incidence of opioid use, incidence or prevalence of persistent opioid use (POU), predictors of POU, and associated all-cause mortality outcomes in people living with dementia.

Methods: Databases searched included MEDLINE, Embase, International Pharmaceutical Abstracts, APA PsycInfo, Scopus, PubMed and Web of Science, supplemented by hand-searching reference lists. Studies were eligible if they investigated opioid use outcomes in patients with a confirmed dementia diagnosis, with no restrictions on age, dementia type, severity, setting, or geographic location.

Results: Fifteen studies published between March 2013 and June 2025 were identified, across countries in North America, Europe and Australasia, in community and residential care settings. Incidence of opioid use ranged from 13.4% to 42.0%, while incidence or prevalence of POU ranged from 4.7% to 25.1%, with substantial heterogeneity in POU definitions. Key predictors of POU included using ≥3 psychotropic drugs (aOR=3.02; 95%CI [1.04,8.76]; p=0.041), poor physical health (aOR=2.38; 95%CI [1.27,4.35]; p=0.006) and having a partner (aOR=2.06; 95%CI [1.03,4.13]; p=0.041). Opioid use was associated with increased 180-day mortality risk (aHR=5.06; 95%CI [4.86,5.29]), particularly with strong opioids (aHR=7.23; 95%CI [6.82,7.66]). Mortality risk was highest in the first 1-14 days post-initiation (aHR=10.81; 95%CI [9.74,11.99]) and with fentanyl use (aHR=8.26; 95%CI [7.18,9.51]).

Conclusions: Opioid use is common in dementia, but variable, with emerging safety concerns regarding mortality. These findings highlight the need for caution in opioid prescribing, enhanced monitoring, and evidence-based guidelines, alongside future research targeting outcomes such as hospitalisation risk.

Keywords: opioids, dementia, pharmacoepidemiology

D2/239

Assessment of medication adherence and quality of life among cancer patients

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Introduction: Medication adherence is a key determinant of therapeutic outcomes in cancer patients, influencing disease progression and overall well being. Poor adherence may result from adverse drug reactions, psychological distress, and financial burden. Quality of life is an important patient centered outcome in oncology care. Understanding this relationship is essential to improve patient outcomes.

Aims: To assess medication adherence and quality of life among cancer patients. To identify factors influencing adherence and their impact on quality of life.

Methods: A prospective observational study was conducted over six months among 60 adult cancer patients aged 18 years and above. Medication adherence was assessed using the Medication Adherence Rating Scale and quality of life using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire EORTC QLQ-C30 version 3. Data on adverse drug reactions and adherence barriers were collected through patient interviews. Descriptive statistics and ordinal logistic regression were applied.

Results: Seventy seven percent of patients showed moderate to high adherence with a mean score of 7.66. Approximately 81.7 percent acknowledged medication benefits, while 21.7 percent discontinued when feeling better and 15 percent when feeling worse. Financial constraints and psychological distress were the major barriers identified. Alopecia, fatigue, and nausea were the most commonly reported adverse drug reactions. Most patients had moderate quality of life. Lower adherence was significantly associated with poorer quality of life ($p < 0.05$), indicating a higher likelihood of reduced quality of life among non adherent patients.

Conclusions: Medication non adherence is associated with poorer quality of life and is influenced by modifiable factors.

Keywords: Medication adherence; quality of life; cancer patients

D2/240

Impact of clinical pharmacist services on quality of life in tinea patients

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Introduction: Tinea is a common superficial fungal infection associated with discomfort, social embarrassment, and reduced quality of life. Poor adherence to antifungal therapy, misuse of topical corticosteroids, and inadequate hygiene practices contribute to recurrent infections. Clinical pharmacists may improve treatment outcomes through counselling and follow-up. However, evidence regarding their impact on dermatology-related quality of life in tinea patients remains limited.

Aims: To evaluate the impact of clinical pharmacist interventions on dermatology-related quality of life among tinea patients using the Dermatology Life Quality Index (DLQI).

Methods: A prospective interventional study was conducted for six months. A total of 210 patients were screened, of whom 151 tinea patients were enrolled. Patients received structured clinical pharmacist-led interventions, including counselling on medication adherence, lifestyle modifications, avoidance of topical steroid misuse, and regular follow-up monitoring. Dermatology-related quality of life was assessed using the validated DLQI questionnaire at baseline and during three follow-up visits at defined intervals. Statistical analysis was performed using SPSS version 29.0.

Results: Among the 151 participants, 58.3% were males, and 34.4% belonged to the 41-50 years age group. Tinea corporis was the most common clinical presentation (31.7%), followed by tinea cruris (22.4%). The mean DLQI score showed a significant reduction from 25.46 ± 3.07 at baseline to 22.10 ± 1.74 at follow-up 1, 7.35 ± 2.17 at follow-up 2, and 0.38 ± 0.55 at follow-up 3 ($\chi^2 = 442.85$, $p < 0.001$). Significant improvement in DLQI scores was observed across all sociodemographic and clinical categories. Patients also demonstrated improved medication adherence, better hygiene practices, and reduced misuse of steroid-containing topical preparations.

Conclusions: Clinical pharmacist-led interventions significantly improved dermatology-related quality of life among tinea patients. Structured counselling and regular follow-up enhanced treatment adherence and therapeutic outcomes, supporting the integration of clinical pharmacists into dermatology care.

Keywords: Tinea; Clinical pharmacist; Quality of life

D2/241

Simulation-Based Assessment Tools for Pharmacy Competency in OTC Self-Medication: Development and Validation

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Introduction: Over-the-counter (OTC) self-medication is widely practised and has important implications for Self-medication with over-the-counter (OTC) medicines is widely practiced and has important implications for patient safety and healthcare utilization. Pharmacists play a critical role in ensuring appropriate OTC use; therefore, competency development in pharmacy students is essential. Existing assessment approaches mainly focus on knowledge, with limited validated simulation-based tools to evaluate applied competencies in real-world self-medication scenarios.

Aim: To develop and validate simulation-based training and assessment instruments for evaluating pharmacy students' competency in OTC self-medication management across multiple OTC drug classes.

Methods: An instrument development and content validation study was conducted. Eight subject matter experts were purposively selected based on predefined criteria (at least 3 years' experience in pharmacy practice or education and clinical pharmacy; multi-institutional panel). The training and assessment package comprised 57 MCQs, 49 simulation-based case scenarios across nine OTC drug classes, a 54-item pharmacy student competency assessment scale (PSCAS), and an 11-item standardized patient satisfaction form. Content validity was quantified using I-CVI, S-CVI/Ave, and modified kappa (κ*). Face validation was conducted with 15 Pharm D interns.

Results: All four instruments achieved excellent content validity: MCQ bank (56 items, one duplicate was present) S-CVI/Ave = 0.946; case scenarios S-CVI/Ave range 0.961–0.996 (overall 0.983); PSCAS S-CVI/Ave = 0.986 (κ* = 0.867); SP satisfaction form S-CVI/Ave = 1.000 (κ* = 1.000). Face validation confirmed high learner acceptability (mean scores 4.61–4.69/5.00; ≥80% item-level agreement). Psychometric evaluation, including Cronbach's Alpha, is planned for the pilot phase.

Conclusion: All instruments demonstrated excellent content validity and high learner acceptability, supporting pilot implementation. This simulation-based learning framework offers a structured pharmacy competency assessment model for OTC self-medication counselling, advancing experiential learning and patient safety in pharmacy education.

Keywords: OTC self-medication, Simulation-based learning, Pharmacy competency assessment

D2/242

Medication literacy failures among ethnic minority adults in Southern India

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Introduction: Medication literacy is defined as the ability to obtain, comprehend, communicate, calculate, and process medication-related information. Inadequate medication literacy leads to medication errors, poor adherence and increased hospitalisation. Limited published data exist on medication literacy among Indian ethnic minority populations. The ethnic minorities are already at a disadvantage due to low literacy rates, geographic isolation and overreliance on informal health advice and alternative medicine.

Aims: To assess medication literacy and to understand which specific medication tasks the participants fail most often. To identify the factors that are associated with medication literacy.

Methods: Cross-sectional survey of 140 ethnic minority adults at a single healthcare facility in a rural district of Southern India (convenience sample). A 14-item adapted MedLitRxSE was scored dichotomously (range 0-14). Internal consistency was assessed with Cronbach's alpha. Pearson correlations and multivariable linear regression tested associations between sociodemographic variables and total scores.

Results: Mean score was 7.54 (SD=3.65). Cronbach's alpha was 0.845. The three worst-performing items were injection angle identification (83.6% failed), warning label interpretation (77.9% failed), and paediatric dose calculation (76.4% failed). Liquid dose measurement was answered correctly by 84.3%. Education correlated most strongly with total score ($r=0.842$, $p<0.001$) and was the only variable that remained significant after adjustment (standardised $\beta=0.806$, $p<0.001$; $R^2=0.714$). Age ($r=-0.589$) and income ($r=0.329$) were significant bivariate correlates but dropped out of the adjusted model, likely because both track closely with educational attainment in this population.

Conclusions: Participants struggled with applied tasks like calculating doses, reading warnings, and identifying injection angles. These specific failures lead to predictable medication errors. Education drove most of the variance, so different approaches, like hands-on demonstration and the teach-back method, should be implemented rather than generic counselling.

Keywords: medication literacy, ethnic minority, MedLitRxSE

D2/243

Candida auris: isolation and susceptibility in a Chinese tertiary teaching hospital

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Introduction: Candida auris(C.auris) is an emerging multidrug-resistant fungal pathogen causing nosocomial infections, posing serious challenges to clinical treatment and infection control. Systematic data on its clinical distribution, specimen sources, and drug sensitivity in large tertiary hospitals remain limited.

Aims: Analyzes C.auris cases from a Chinese provincial tertiary hospital with 4,500 beds to clarify the characteristics, informing targeted prevention and treatment strategies.

Method: All clinical C.auris isolates identified at the hospital from January 2024 to April 2026 were enrolled to analyze clinical distribution, specimen sources, and antifungal susceptibility. Screening was targeted on high-touch surfaces of equipment, bed unit, healthcare workers' hands, and specific infected patients.

Results: Between January 2024 and April 2026, 194 clinical C.auris isolates were identified from 176 patients, mainly from ICU(67.05%), Geriatrics(25.00%), Pancreatic center(6.25%), Neurosurgery wards(4.55%), etc. Urine was the most common specimen source (54.64%), followed by sputum (18.04%), bronchoalveolar lavage fluid (6.70%), etc. Another 15.47% of specimens were sterile body fluids. All isolates were resistant to fluconazole; voriconazole yielded MICs > 0.03 μg/mL, and posaconazole MICs ranged from 0.008 μg/mL to 0.5 μg/mL for all isolates. Amphotericin B resistance was observed in 41.91% of isolates, which was higher than the rate reported in previous literature. Flucytosine MICs ≥32 μg/mL were observed in 2.94% of isolates. The isolates were predominantly susceptible to echinocandins, exhibiting resistance rates of 3.68% for caspofungin and 2.94% for micafungin. Screening revealed that C.auris was restricted to patient body sites (axilla, groin, wounds), with no isolates recovered from healthcare workers' hands or environmental surfaces, suggesting that the pathogen was primarily associated with patient colonization.

Conclusions: The isolation rate of C.auris has significantly increased in hospitals, and its resistance to amphotericin B has also increased significantly. Hospitals should promptly adopt a multi-level comprehensive response strategy.

Keywords: Candida auris, Multidrug-resistant, Amphotericin B

D2/244

Prescribing Appropriateness for Type 2 Diabetes Mellitus at Military Hospital 175, Vietnam

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Introduction: Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder requiring long-term pharmacotherapy, making medication appropriateness a critical concern in outpatient management. Ensuring prescribing appropriateness is essential to optimize glycemic control while minimizing adverse outcomes.

Aims: To assess the antidiabetic medication use practices, glycemic control over the preceding three months. To evaluate prescribing appropriateness using the Medication Appropriateness Index (MAI), Screening Tool of Older Person's Prescriptions (STOPP), and Screening Tool to Alert doctors to Right Treatment (START) criteria.

Methods: A descriptive cross-sectional study was conducted among 365 outpatients diagnosed with T2DM between November 2025 and May 2026. Data on medication regimens, HbA1c levels were collected, and prescribing appropriateness were evaluated using MAI and STOPP/START.

Results: The population was predominantly male (65.48%), with a mean age of 63.39 ± 12.53 years. Combination therapy was prescribed in 86.58% of patients, most commonly a triple regimen of Metformin, Gliclazide, and DPP-4 inhibitor (17.53%). The proportion of patients achieving target HbA1c was higher in the ≥ 60 age group (66.93%) compared to those under 60 years (54.95%). However, younger patients (<60 years) showed a significantly greater reduction in HbA1c over the past three months (1.10 ± 2.27). Only 6.30% of prescriptions recorded a MAI score ≥1, with dosing errors identified in 5.48%, primarily attributable to failure to adjust Sitagliptin dosage according to renal function. STOPP/START analysis revealed one case of non-selective beta-blocker use (0.27%) and three patients with heart failure lacking SGLT2 inhibitor therapy (0.82%).

Conclusions: Prescribing practices were largely appropriate and consistent with current clinical guidelines. However, attention should be directed toward renal function-based dose adjustment; particularly for Sitagliptin, to optimize therapeutic safety and efficacy in this population.

Keywords: Type 2 diabetes mellitus, medication appropriateness, STOPP/START.

D2/245

Considerations for research with industry-affiliated patient representatives: insights from an Australian survey

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Introduction: Patient representatives, individually or as part of Consumer Advisory Groups, play a crucial role in pharmacoepidemiology and other research on medicines and devices. These representatives are frequently drawn from groups that provide support and advocacy for specific health conditions. Pharmaceutical and device company financing of such groups is widespread however and creates a conflict of interest between a group's mandate and sponsors' priorities. At stake is health advocacy policy that reflects both over- and under-representation of selected patient interests. Clear guidance on how consumer groups can best address conflicts of interest that arise from partnerships with industry is lacking.

Aims: To a) analyse interactions between patient groups and pharmaceutical and device companies, b) understand the tools and practices patient groups use to manage these interactions and c) inform the development of a 'toolkit for independence'.

Methods: From June to July 2026, we are conducting a national online survey of Australian patient groups. The survey covers three key areas of patient group activity: education, advocacy, and research. The current analysis focuses on research.

Results: Survey results will map companies' involvement in patient group research activities and participation of groups' representatives in industry-led research; groups' management strategies and their perceived impact in controlling potential influence; and perceptions of influence and pressure to align with company interests. These findings will inform a practical toolkit of resources such as policy and contract templates, and disclosure standards that groups can use to better navigate research partnerships with companies.

Conclusions: This first national survey of patient groups' management of conflicts of interest arising from industry funding and subsequent development of a practical toolkit may assist researchers who are recruiting and involving patient representatives from industry-funded patient groups, to mitigate risks of undue influence and enable full representation of patient interests.

Keywords: medicine safety, COIs, governance

D2/246

Real-World Evidence of Missed Treatment Opportunities in Non-Transplant Newly Diagnosed Multiple Myeloma

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Background: Non-Transplant patients with newly diagnosed multiple myeloma represent a highly heterogeneous population with variability in age, and treatment tolerance. Although quadruplet regimens have demonstrated improved outcomes in clinical trials among transplant-ineligible patients, whether treatment intensity in real-world practice is aligned with patient fitness—and how this impacts outcomes—remains unclear.

Methods: This retrospective real-world study included adult NDMM patients identified from National Longitudinal Cohort of Hematological Diseases database (January 2013–June 2023). A frailty proxy was constructed using age ≥65 years, renal dysfunction, moderate/severe anemia and thrombocytopenia. Patients were categorized as fit (0 factors), intermediate (1 factor), or frail (≥2 factors). First-line treatment and outcome were analyzed, including triplet vs quadruplet regimens, with subgroup analyses by frailty proxy.

Results: A total of 746 NT NDMM patients were included. Overall, 97.9% were transplant-ineligible and 2.1% were transplant deferred. Mean age was 59.5 years (SD 9.1); 46.1% had ISS stage III disease and 22.0% had high-risk cytogenetics. Frailty classification was evenly distributed (fit 33.0%, intermediate 32.2%, frail 34.8%).
Triplets predominated (81%); quadruplet use increased over time (2.5% to 19.9%) but showed limited differentiation across frailty groups (fit 27.1%, intermediate 12.6%, frail 20.1%), indicating minimal treatment stratification.
Median PFS declined significantly with increasing frailty (37.5, 34.5, and 25.1 months for fit, intermediate, and frail; $p<0.01$). Among fit patients, quadruplet regimens were associated with markedly longer PFS (69.6 vs 37.5 months), whereas only modest differences were observed in frail patients (28.9 vs 24.8 months), suggesting a differential treatment effect by fitness.

Conclusions: NT NDMM represents a highly heterogeneous population, with frailty proxy strongly associated with clinical outcomes. Notably, quadruplet regimens provided substantial PFS benefit in fit patients but remained underutilized, indicating a missed opportunity for optimization. These findings underscore significant unmet needs and support more fitness-guided, personalized treatment strategies.

D2/247

Biologics use and adverse fetal outcomes among pregnant women with asthma

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Introduction: Poorly controlled asthma during pregnancy has been reported to be associated with increased risk of adverse maternal and fetal outcomes, and guideline-concordant maintenance therapy is recommended throughout pregnancy. For moderate/severe patients with asthma, several biologics have been recently available in Japan, but real-world evidence on the association between exposure to biologics during pregnancy and adverse pregnancy outcomes remains limited.

Aims: This study aimed to describe the proportion of adverse fetal outcomes by biologics use during pregnancy among pregnant women with asthma.

Methods: This retrospective descriptive study was conducted using data from the 2010-2024 JMDC administrative claims database. Pregnancies ending in live births and linked to infants in women aged 15–49 years were identified using validated algorithms. Pregnant women who received at least one dose of biologics (omalizumab, mepolizumab, benralizumab, dupilumab, or tezeperumab) during pregnancy were identified as the exposure population. The study outcome was the proportion of adverse fetal outcomes, including major congenital malformations (MCMs), preterm birth, and caesarean section. For contextual reference, we also identified pregnant women who received at least one prescription for inhaled corticosteroid (ICS)-containing inhalation therapy during pregnancy and calculated the corresponding proportions of these outcomes.

Results: We identified 3,583 pregnant women with asthma (mean maternal age 33.7 years). Six women received a biologic during pregnancy, all during the first trimester. Among them, one infant had an MCM (16.7%), one was born preterm (16.7%), and two were delivered by caesarean section (33.3%); the corresponding proportions among women receiving ICS-containing inhalation therapy were 8.1%, 11.0%, and 26.3%, respectively.

Conclusions: We found a few adverse fetal outcomes among pregnant women with asthma exposed to any biologics in the first trimester as a real-world setting in Japan. However, further investigation with a larger sample size is warranted to explore those associations.

Keywords: Maternal asthma, Biologics, Adverse fetal outcomes

D2/248

Antidepressant use and miscarriage: a cohort study with stepwise confounding control

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Background: Several studies have reported an increased miscarriage risk with antidepressant use during pregnancy, but findings may largely be attributable to key source of biases (time-related, indication, and unmeasured confounding).

Aims: To explore whether antidepressant use during pregnancy is associated with an increased risk of miscarriage using a stepwise approach to systematically address potential biases.

Methods: This cohort study included all pregnancy episodes identified from a nationwide claims database (2016–2024). Antidepressant use was defined as ≥1 prescription between the last menstrual period (LMP)-30 days and the earliest of LMP+140 days or 1 day before pregnancy end or outcome date. The outcome was miscarriage, and outcome date was shifted 7 days earlier to account for antidepressant prescribed for prodromal symptoms. To mitigate time-related and residual biases, a potential non-user set was constructed by matching on index date (±7 days) and number of obstetric-gynecology visits with the user set. Matching variables were then added progressively to further address confounding by indication: (1) hospital level, (2) main indication, and (3) number of psychiatric visits. Relative risk (RR) and 95% confidence intervals (CI) were estimated using modified Poisson regression after 1:1 propensity score matching. Additionally, a within-individual matched analysis was conducted to account for unmeasured invariant factors.

Results: Of 2.6 million pregnancies, 16,045 were identified as antidepressant users. We observed a slightly increased risk of miscarriage with antidepressant use (RR 1.17, 95% CI 1.07 to 1.28), but this attenuated after sequential matching for indication-related factors (variable 1 only: 1.11 [1.03 to 1.20]; variable 1 and 2: 1.10 [1.01 to 1.20]; all variables: 1.09 [1.00 to 1.19]). The estimate further approached the null in within-individual analysis (1.05, 0.83 to 1.32).

Conclusions: Careful attention to biases led to the attenuation of the association between antidepressant treatment and the risk of miscarriage.

Keywords: Antidepressants; Miscarriage; Bias

D2/249

Meta-analysis of Kampo medicines containing ephedra and Congenital Malformations

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Introduction: Kampo medicines containing ephedra are widely used in Japan to treat common cold symptoms during pregnancy. However, ephedrine and pseudoephedrine, active components of ephedra, have been suspected to have teratogenic potential. Although two Japanese observational studies have evaluated the association between first-trimester exposure to ephedra-containing Kampo medicines and major congenital malformations (MCMs), the evidence has not been quantitatively synthesized.

Aims: To evaluate the association between first-trimester exposure to Kampo medicines containing ephedra and the risk of MCMs using a meta-analysis of Japanese observational studies.

Methods: We conducted a fixed-effect inverse-variance meta-analysis using adjusted odds ratios (ORs) and 95% confidence intervals (CIs) from previous studies examining association between Kampo medicines containing ephedra and MCMs. One study used the Tohoku Medical Megabank Project Birth and Three-Generation Cohort Study, and the other used a nationwide Japanese administrative claims database. In both studies, women using acetaminophen during the first trimester served as the comparator group to reduce confounding by indication related to common cold symptoms. Adjusted ORs were log-transformed, and standard errors were derived from reported CIs. Sensitivity analyses included random-effects models and pooled crude OR analyses.

Results: The meta-analysis included more than 96,000 pregnancies. In the cohort study, first-trimester exposure to Kampo medicines containing ephedra was not significantly associated with MCMs (adjusted OR 1.45, 95% CI 0.57–3.71). Similarly, the claims database study showed no significant association (overlap-weighted adjusted OR 1.077, 95% CI 0.932–1.245). The pooled fixed-effect adjusted OR was 1.08 (95% CI 0.94–1.25). Sensitivity analyses yielded similar findings.

Conclusions: This meta-analysis integrating two independent Japanese data sources did not demonstrate a statistically significant increase in MCM risk associated with first-trimester

exposure to ephedra-containing Kampo medicines. Further studies are warranted to evaluate specific malformations and long-duration exposure.

Keywords: Kampo medicine, pregnancy, congenital malformations

D2/250

Association between first-trimester bromhexine/ambroxol exposure and major congenital malformations

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Introduction: Bromhexine and its active metabolite, ambroxol, are widely used mucolytic agents in Japan, yet clinical evidence during pregnancy remains limited. Although a Japanese prospective cohort study showed no clear risk of major congenital malformations (MCMs) for ambroxol, a case-control study for bromhexine suggested a potential safety signal of specific malformations. Further evaluation of these medications in pregnancy is essential.

Aims: This study evaluated the association between first-trimester bromhexine/ambroxol exposure and MCMs in infants. We aimed to provide robust safety evidence using a large claims database.

Methods: We conducted a cohort study using a JMDC claims database from 2012 to 2023. The study population consisted of mothers diagnosed with a common cold during the first trimester and their singleton live-birth infants. MCMs were defined based on the European Surveillance of Congenital Anomalies (EUROCAT) definition, mapping to International Classification of Diseases, 10th revision codes. With propensity score–based overlap weighting and log-binomial regression, we estimated the weighted risk ratio (wRR) comparing exposed and unexposed groups.

Results: We identified 32,665 pregnant women with a common cold during the first trimester. Of these, 3,300 were exposed to bromhexine/ambroxol during the first trimester. The prevalence of overall MCMs in infants was 4.8% (157/3,300) among exposed women and 5.1% (1,483/29,365) among unexposed women. Exposure was not significantly associated with overall MCMs (wRR 0.942, 95% confidence interval: 0.802–1.106). Results for overall MCMs were consistent across multiple sensitivity analyses.

Conclusions: First-trimester exposure to bromhexine/ambroxol was not associated with an increased risk of overall MCMs in infants. While these findings did not suggest an increased risk broadly, potential organ-specific associations warrant cautious interpretation and further investigation.

Keywords: bromhexine/ambroxol, pregnancy, congenital malformations

D2/251

Perinatal pharmacoepidemiology in Japan: data sources and methodological challenges

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Introduction: Medication safety assessment during pregnancy and lactation requires consideration of maternal treatment needs and fetal, neonatal, and child outcomes. Because interventional studies in pregnant women are ethically constrained, real-world evidence plays a central role in this field. However, the landscape of perinatal pharmacoepidemiology in Japan remains undercharacterized.

Aims: We aimed to map Japanese perinatal pharmacoepidemiology and pharmacovigilance studies evaluating medication-related perinatal outcomes and identify their data sources, exposures, outcomes, and methodological challenges.

Methods: We conducted a scoping review of comparative pharmacoepidemiological studies on medication exposure and perinatal outcomes in Japan. PubMed identified 2,134 records; after excluding 416 non-human studies, 1,717 records were independently screened by two researchers. Reviews, interventional studies, case reports, non-medication exposure studies, and single-site studies were excluded. We included 52 PubMed-derived studies and 11 additional studies identified through hand-searching, yielding 63 studies.

Results: Included studies used diverse data sources, including claims databases, teratology information service records, birth cohorts, spontaneous reporting databases, registries, medical records, and questionnaires. The most common exposure category was neuropsychiatric medications, followed by obstetric medications, antibiotics, immunomodulatory medications, and Kampo medicines. First-trimester exposure was the most frequently evaluated exposure window. Outcomes included congenital anomalies, miscarriages, preterm births, low birth weight, child developmental problems, and maternal adverse events. Across studies, we observed heterogeneity in how methodological issues were assessed and reported, including estimation of pregnancy timing and exposure windows, approaches to mother-child linkage, consideration of live-birth bias, handling of confounding by indication, and the validity of pregnancy identification, exposure assessment, and outcome ascertainment.

Conclusions: Studies on perinatal medication safety in Japan have developed across multiple data sources, but methodological approaches and reporting remained heterogeneous. Strengthening exposure timing assessment, linkage methods, bias considerations, confounding control, and validation practices will improve evidence generation.

Keywords: Pregnancy and lactation; perinatal pharmacoepidemiology; medication safety

D2/252

Medication Errors in Malaysia: a retrospective analysis from the national database 2013-2023

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Introduction: Medication error (ME) can lead to harm in patients and medication safety is part of Malaysian Patient Safety Goal. The Medication Error Reporting System (MERS), a voluntary reporting system, was established for healthcare professionals in both public and private health sectors to report information on the occurrence of ME in their respective settings.

Aims: Our study aims to describe the frequency and characteristics of medication error reports, focusing on the types, outcomes, and trends.

Methods: This is a retrospective cross-sectional study using data from the MERS database from 2013 to 2023.

Results: Out of 416354 reports, over 90% were from the public health facilities. The volume of ME reports rose from a baseline of 8422 in 2013 to 65767 by 2023, indicating a consistent annual growth of 100-200% over the decade. While the proportion of the total ME reports between hospital and clinic were comparable, trend analysis showed an upward trend in the annual number of reports from the clinic between 2013 and 2023. Most MEs were reported by pharmacists (95%) and occurred in clinics (47%), followed by pharmacy (26%), and ward (15%). More than two-thirds of MEs occurred at the prescribing process, 20% during medication preparation, while 4% took place during data entry. Approximately 4% of the errors reached the patients, with incorrect medication(s) being consumed in over 50% of those cases. Most events were harmless (category A-D, 99%) and 0.8% caused harm or death. Potential causes of MEs were attributed to the work environment and staff factors.

Conclusion: The MERS database provides extensive insights into the occurrence and nature of MEs which is essential for improving service delivery and clinical practices. Enhancing multi-sector reporting and implementing proactive preventive strategies are vital for reducing medication errors and improving patient safety.

Keywords: medication error, medication error reporting system

D2/253

SGLT2 inhibitors and infection-related hospitalisations in type 2 diabetes

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Introduction: Individuals with type 2 diabetes are at increased risk of infection-related hospitalisations and death. Evidence suggests sodium-glucose cotransporter-2 (SGLT2) inhibitors may influence infection-related outcomes, although findings remain inconsistent.

Aims: To assess the association between initiation of SGLT2 inhibitors and infection-related hospitalisations among individuals with type 2 diabetes following hospital discharge.

Methods: We conducted an active comparator new-user cohort study using linked administrative healthcare data from Victoria, Australia. Adults aged ≥30 years with type 2 diabetes discharged from hospital between July 2013 and June 2018 who initiated SGLT2 inhibitors or DPP4 inhibitors were included. Individuals were followed from treatment initiation until death or 30 June 2018. Weighted incidence rate ratios (wIRRs) and 95% confidence intervals (CIs) were estimated using negative binomial regression with inverse probability of treatment weighting.

Results: The study included 15,717 new users of SGLT2 inhibitors and 27,006 new users of DPP4 inhibitors. New users of SGLT2 inhibitors had lower overall rates of infection-related hospitalisations compared with DPP4 inhibitor users (wIRR 0.74, 95% CI 0.71–0.77). Lower rates were also observed for sepsis (wIRR 0.60, 95% CI 0.54–0.66), pneumonia (wIRR 0.61, 95% CI 0.55–0.66), gastrointestinal infections (wIRR 0.77, 95% CI 0.70–0.85), urinary tract infections (wIRR 0.38, 95% CI 0.34–0.43), respiratory tract infections (wIRR 0.68, 95% CI 0.63–0.74), influenza (wIRR 0.63, 95% CI 0.48–0.83), and kidney infections (wIRR 0.49, 95% CI 0.34–0.71). Higher hospitalisation rates were observed for osteomyelitis (wIRR 1.14, 95% CI 1.02–1.27), foot infections (wIRR 1.25, 95% CI 1.19–1.31), and genital mycotic infections (wIRR 1.48, 95% CI 1.24–1.76). No statistically significant differences were observed for cellulitis-related hospitalisations (wIRR 1.04, 95% CI 0.98–1.10).

Conclusions: Initiation of SGLT2 inhibitors after hospital discharge was associated with lower overall infection-related hospitalisations among individuals with type 2 diabetes. However, associations varied according to infection type.

Keywords: SGLT2 inhibitors; infection-related hospitalisations; type 2 diabetes.

D2/254

AKI risk with single-dose aminoglycoside in emergency departments among patients with CKD

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Introduction: Nephrotoxicity has been described with prolonged aminoglycoside use, but is considered low-risk with single-dose empirical therapy. However, limited data exists in patients with chronic kidney disease (CKD).

Aims: To determine the risk of acute kidney injury (AKI) from single-dose aminoglycoside (SDA) use in emergency departments (ED) in patients with and without CKD.

Methods: A retrospective cohort study was performed in four tertiary hospitals within an Australian metropolitan network. Electronic medical records of all adult patients who presented to ED and received SDA between August 2019 and July 2024 were screened for inclusion. The primary outcome was AKI (creatinine increase by 26.5micromol/L from baseline) incidence within one week of SDA. CKD was defined as glomerular filtration rate <60mL/minute.

Results: Overall, 6636 aminoglycoside administrations were identified and 1835 screened. In total, 660 patients were included, receiving gentamicin (74.1%), tobramycin (25.6%), or amikacin (0.3%). Patients with CKD were older (81.3 vs 64.1 years old, p<0.001) and had more comorbidities. AKI incidence within one week of hospitalisation was higher in patients with vs without CKD (30.9% vs 13.4%, p<0.001). CKD was associated with higher likelihood of AKI incidence (OR 2.88 95% CI 1.76-4.71, p<0.001). Patients with CKD had more severe AKI (stage 2: 10.1% vs 2.6%, p<0.001) and a trend towards higher mortality (7.6% vs 4.4%, p=0.082) and intensive care unit admissions (12.9% vs 9.9%, p=0.222) compared to patients without CKD.

Conclusions: Patients with CKD who received SDAs were more likely to have AKI compared to patients without CKD. Clinicians should consider reserving aminoglycoside use for patients with CKD only when the benefit outweighs the risk, such as in cases of septic shock or for patients with high risk of multidrug-resistant pathogens.

Key Words: Aminoglycosides, safety, acute kidney injury

D2/255

Short-term risk of falls among initiators of controlled-release tapentadol versus oxycodone

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Introduction: Opioids are associated with increased risks of falls immediately following initiation. Clinical trials suggest sustained-release (SR) tapentadol has fewer adverse nervous system effects vs controlled-release (CR) oxycodone, but real-world safety is still unclear.

Aims: To compare risks of falls at 7, 14, and 28 days following initiation of tapentadol (SR) versus oxycodone (CR) in real-world clinical practice.

Methods: We conducted an active comparator, new user cohort study using routinely collected data from New South Wales, Australia (2014-2020). We included adults initiating tapentadol (SR) or oxycodone (CR). Our outcome was a composite measure of fall-related emergency department presentations, hospitalisations or deaths. We used propensity score matching to adjust for confounding and calculated relative risks (RR), absolute risk differences (RD), and numbers-needed-to-harm (NNH). We conducted subgroup analyses among people aged ≥65 and ≥80 years and by recent opioid exposure.

Results: We identified 103,924 tapentadol and 419,732 oxycodone initiators (103,758 matched). 74% were aged between 45-84 years; slightly more than half were female. Within 28 days of initiation, 652 (0.6%) oxycodone and 457 (0.4%) tapentadol initiators experienced a fall. Across all time points, tapentadol was associated with lower fall risks vs oxycodone (7 days: RR 0.57 [95% CI 0.48 to 0.69]; 14 days: 0.62 [0.54 to 0.71]; 28 days: 0.70 [0.62 to 0.79]). Absolute differences were small (RD range: -0.001 to -0.002; NNH range: 739 to 529). These patterns persisted regardless of recent opioid exposure or age. The greatest differences were among opioid-naive people aged ≥80 years (RD range: -0.006 to -0.01; NNH range: 173 to 97).

Conclusions: Tapentadol (SR) was associated with a lower risk of falls than oxycodone (CR) within 28 days of initiation, although absolute differences were small. This may be an important consideration for older patients where the consequences of falls are most severe.

Keywords: tapentadol, oxycodone, falls

D2/256

Risk of opioid-induced nausea and vomiting after abdominal hysterectomy: a meta-analysis

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Introduction: Opioids are commonly used for pain management after abdominal hysterectomy. Opioid-associated postoperative nausea and vomiting (O-PONV) can worsen patient experience and prolong hospital stay. Despite the well-established opioid-sparing effects of multimodal analgesic strategies, dedicated safety studies evaluating the incidence of opioid-induced nausea and vomiting according to the type of opioid therapy are scarce.

Aims: This systematic review and meta-analysis aimed to evaluate the incidence of O-PONV by analgesic strategy. The risk of O-PONV was compared between opioid monotherapy and multimodal regimens for postoperative pain management after abdominal hysterectomy.

Methods: A systematic search of PubMed, EMBASE, the Cochrane Library, and RISS was conducted in March 2026 according to PICO-based criteria. Eligible studies were randomized controlled trials (RCTs) of patients undergoing abdominal hysterectomy that compared postoperative opioid-based analgesic regimens and reported PONV within 24 hours. Risk of bias was evaluated using the Cochrane RoB 2 tool. Odds ratios and 95% confidence intervals were pooled using a random-effects model in Comprehensive Meta-Analysis software, and heterogeneity was assessed by I2 statistic.

Results: A total of 10 RCTs involving 711 patients were included, comparing morphine monotherapy with morphine-based multimodal regimens. In the overall risk of bias assessment, seven studies were rated as low risk and three as having some concerns. One study with zero events in both groups was excluded from the pooled OR calculation. Morphine monotherapy showed a significantly higher risk of nausea and vomiting (OR, 1.545; 95% CI, 1.114–2.143; p = 0.009). No statistical heterogeneity was observed among the included studies (I^2 = 0%).

Conclusions: Morphine monotherapy had a significantly higher risk of O-PONV than multimodal regimens after abdominal hysterectomy. These findings suggest that multimodal analgesia may help optimize postoperative pain management by reducing opioid-associated adverse effects.

Keywords: Abdominal hysterectomy; Opioid analgesics; Postoperative nausea and vomiting

D2/257

Correlation of Linezolid Trough Concentrations with Serum Lactate in Critically Ill Patients

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Objective: To investigate the correlation between linezolid trough concentration (Cmin) and elevated lactate levels, analyze the risk factors and provide evidence for rational clinical use of linezolid and monitoring of adverse reactions.

Methods: Clinical data of 120 critically ill patients treated with linezolid were retrospectively collected. Patients were divided into three groups based on Cmin: <2.0, 2.0-8.0, and >8.0μg/mL. The distribution and influencing factors among the three groups were compared. Patients with lactate >2.0mmol/L were assigned to the elevated lactate group, and those with lactate ≤2.0mmol/L to the non-elevated lactate group. Univariate and multivariate logistic regression analyses were performed, and a nomogram of influencing factors was constructed.

Results: In the high-concentration group (>8.0μg/mL), the comorbidity index, age, APACHE II score, SOFA score, serum creatinine, blood urea nitrogen, total bilirubin (TBIL), and direct bilirubin (DBIL) were significantly increased, while estimated glomerular filtration rate (eGFR), albumin, and hemoglobin were decreased. The incidence of hypocalcemia was 59%, and the proportions of urinary tract infections and enterococcal infections were higher ($P<0.05$). Multivariate regression analysis showed that concentration groups of 2.0-8.0μg/mL (OR=5.5, 95%CI: 1.1–28) and >8.0μg/mL (OR=7.3, 95%CI: 1.4-38), as well as AST (OR=1.0, 95%CI: 1.001-1.022), were independent risk factors, while staphylococcal infection (OR=0.38, 95%CI: 0.15-0.92) was a protective factor. The area under the curve (AUC) of the nomogram was 0.79 (95%CI: 0.71–0.87).

Conclusion: Elevated linezolid trough concentration (>8.0μg/mL) is closely associated with televated lactate levels. Monitoring of trough concentration and lactate levels, along with timely dose adjustment in high-risk patients, is recommended in clinical practice.

D2/258

Bleeding and recurrent VTE associated with DOACs versus LMWH for cancer-associated thrombosis

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Introduction: Direct oral anticoagulants (DOACs) have been progressively adopted as an alternative to low-molecular-weight heparin (LMWH) for cancer-associated thrombosis (CAT). However, evidence regarding bleeding outcomes remains inconclusive, with inconsistent definitions of major bleeding across real-world studies. Moreover, head-to-head comparisons of individual DOACs against LMWH remain sparse.

Aims: To conduct a cohort study comparing the safety and effectiveness of DOACs versus LMWH in patients with CAT using territory-wide electronic health database in Hong Kong.

Methods: New users of LMWH or DOACs following a diagnosis of CAT were identified from Jan 1, 2010 to Dec 31, 2023. Primary outcomes included major bleeding, severe major bleeding, recurrent venous thromboembolism (VTE), and all-cause mortality. Outcome risks were compared using inverse-probability-of-treatment-weighting (IPTW) Cox proportional hazards model and Fine-Gray subdistribution hazard model.

Results: Among 7,700 patients, 6,532 (84.8%) were treated with LMWH and 1,168 (15.2%) with DOACs. After IPTW adjustment, DOAC was associated with significantly lower risk of all-cause mortality at both 6 months (HR 0.56, 95% CI 0.50-0.63) and 12 months (HR 0.57, 95% CI 0.51-0.63) compared with LMWH. Risks of recurrent VTE (6-month: HR 0.89, 95% CI 0.63-1.24; 12-month: HR 0.85, 95% CI 0.62-1.16), major bleeding (6-month: HR 1.01, 95% CI 0.78-1.30; 12-month: HR: 0.92, 95% CI 0.73-1.17) and severe major bleeding (6-month: HR 1.05, 95% CI 0.77-1.43; 12-month: HR 0.93, 95% CI 0.69-1.26) were comparable between groups. In agent-specific analyses, apixaban was associated with lower risk of VTE (HR: 0.55, 95% CI 0.35-0.87) and DVT recurrence (HR: 0.57, 95% CI 0.32-1.00) compared with LMWH.

Conclusions: DOACs demonstrated a safety profile comparable to that of LMWH for both major and severe major bleeding, while conferring a significant mortality benefit. Our findings support DOACs, particularly apixaban, as a safe and effective alternative to LMWH for managing CAT.

Keywords: cancer-associated thrombosis; direct oral anticoagulants; low-molecular-weight heparin

D2/259

Incidence of septic arthritis after intra-articular injection for knee osteoarthritis

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Introduction: Intra-articular (IA) injections are widely used to manage knee osteoarthritis (KOA), but septic arthritis is a rare, serious complication with limited population-based evidence on its incidence.

Aims: To estimate septic arthritis incidence after IA injections for KOA by injection type and cumulative injection exposure.

Methods: We conducted a retrospective cohort study using a nationwide administrative healthcare claims database covering 2011–2024. Patients diagnosed with KOA at secondary or tertiary healthcare institutions who received their first IA injection between 2018 and 2023 were included. Patients with septic arthritis before the initial KOA diagnosis were excluded. The first IA injection during 2018–2023 was defined as the index date. To ensure adequate outcome ascertainment, patients were required to have at least one year of potential follow-up after the index date. Follow-up continued until septic arthritis occurrence or end of follow-up. Incidence rates (IRs) were calculated per 100,000 person-years (PY).

Results: Overall, 70,033 patients contributed 418,727 person-years of follow-up. Median follow-up duration was 2,434 days for patients with index injections in 2018, decreasing to 579 days among those with index injections in 2023 (2019: 2,038; 2020: 1,657; 2021: 1,303; 2022: 930 days). Septic arthritis occurred in 1,065 patients, corresponding to an overall IR of 254.3 per 100,000 PY. IRs were 228.8, 292.1, and 283.2 per 100,000 PY for hyaluronic acid (HA)-only, corticosteroid (CS)-only, and both HA/CS injection users, respectively. By cumulative IA injection exposure, IRs were 323.1, 350.9, 273.9, and 184.5 per 100,000 PY among patients with 1, 2–3, 4–6, and ≥7 IA injections.

Conclusions: Septic arthritis occurred at 254.3 per 100,000 PY after IA injections for KOA. Higher rates among corticosteroid-only users warrant further investigation of risk factors after injection therapy.

Keywords: Knee osteoarthritis; Intra-articular injection; Septic arthritis

D2/260

Risk of finasteride on metabolic dysfunction-associated steatotic liver disease and progression

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Background: Metabolic dysfunction-associated steatotic liver disease (MASLD) affects over 39% of the global population and drives a worldwide rise in advanced chronic liver disease (ACLD). Preclinical studies have indicated that finasteride, a first-line therapy for benign prostatic hyperplasia (BPH), may promote hepatic steatosis, hepatitis, and fibrosis. However, population-based evidence remains limited.

Aims: To investigate the association between finasteride and risks of: (1) incident MASLD among non-MASLD patients, (2) incident ACLD among non-MASLD patients, and (3) incident ACLD among MASLD patients.

Methods: Employing the clone-censor-weight (CCW) approach, this target trial emulation study analyzed data from the Exchange Xiamen PLatform Of Resident E-health Records (EXPLORER; 2010-2025) in China. Men aged 40-80 years newly diagnosed with benign prostatic hyperplasia (BPH) were included and classified by baseline MASLD status. The intervention was finasteride initiation within a 30-day grace period after BPH diagnosis. The CCW method was implemented via R package “survivalCCW”. Hazard ratios (HRs) with 95% confidence intervals (CIs) were estimated using Cox models. Multi-state Markov (MSM) models were applied to evaluate the impact of finasteride on transitions between normal liver, MASLD, and ACLD states among non-MASLD patients.

Results: 57,942 non-MASLD patients (12,173 on finasteride) and 9,851 MASLD patients (1,546 on finasteride) were included. Among non-MASLD patients, compared with non-users, finasteride use was associated with an increased risk of incident MASLD (HR = 1.18 [95% CI 1.10-1.27]) and ACLD (1.47 [1.17-1.85]). However, among MASLD patients, compared with non-users, finasteride use was not significantly associated with ACLD progression. MSM models further showed that finasteride use increased the risk of transition from normal liver to MASLD (1.14 [1.02-1.27]) and ACLD (1.70 [1.10-2.63]), but not from MASLD to ACLD.

Conclusions: Finasteride use was associated with an increased risk of MASLD and ACLD development among non-MASLD patients, but may not appear to affect ACLD progression among MASLD patients.

D2/261

Sorafenib adverse events and quality-of-life trajectories in advanced hepatocellular carcinoma

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Introduction: Sorafenib is used for advanced hepatocellular carcinoma, but treatment-related adverse events may reduce tolerability and impair health-related quality of life. Real-world evidence from resource-limited settings remains limited. Understanding early toxicity and quality-of-life changes may support better treatment monitoring and supportive care.

Aims: To assess sorafenib-related adverse events and changes in health-related quality of life during the first two months of treatment.

Methods: A prospective observational study was conducted from March to November 2024 at a tertiary-care hospital in Rawalpindi, Pakistan. Adults with advanced hepatocellular carcinoma receiving sorafenib were followed at baseline, one month, and two months. Adverse events were assessed using the Common Terminology Criteria for Adverse Events, and quality of life was evaluated using the EORTC QLQ-C30 and QLQ-HCC18 instruments. Paired changes in adverse events were analysed using Wilcoxon signed-rank tests.

Results: Of 105 enrolled patients, 101 completed the first follow-up and 81 completed two months. At month two, common adverse events were weight loss (34.6%), diarrhoea (33.3%), hand-foot skin reaction (27.2%), abdominal pain (27.2%), fatigue (25.9%), and rash/desquamation (21.0%). Weight loss increased from 14.8% at month one to 34.6% at month two (p=0.003), while nausea decreased from 54.3% to 33.3% (p=0.002). Hand-foot skin reaction increased from 13.6% to 27.2% (p=0.054). The mean QLQ-C30 index score worsened from 37.58 at baseline to 53.02 at month one, then improved to 27.47 at month two. Corresponding QLQ-HCC18 scores were 30.44, 40.15, and 28.38. Financial-difficulty scores remained elevated at month two, indicating continued treatment-related economic burden.

Conclusions: Sorafenib was associated with substantial early toxicity and temporary deterioration in quality of life. Early monitoring, nutritional support, skin-toxicity management, and financial counselling may improve treatment tolerability and continuity. Findings should be interpreted cautiously because of attrition.

Keywords: Sorafenib; pharmacovigilance; quality of life

D2/262

Protective Effects of Ocimum sanctum Against Diabetic Neuropathy and Cognitive Impairment

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Introduction: Diabetic neuropathy (DN) is a common complication of diabetes associated with oxidative stress, neuroinflammation, cognitive impairment, and neuronal degeneration. Current therapies mainly provide symptomatic relief and fail to target the underlying pathology. Ocimum sanctum (Tulsi), rich in flavonoids and phenolic compounds, possesses antioxidant and neuroprotective properties that may be beneficial in DN management.

Aims: To evaluate the protective effects of aqueous extract of Ocimum sanctum against HFD/STZ-induced diabetic neuropathy and associated cognitive deficits in mice.

Methods: LC–MS/MS characterization of Tulsi extract was performed to identify phytoconstituents. Diabetic neuropathy was induced in C57BL/6 mice using high-fat diet for 10 weeks and streptozotocin (35 mg/kg, i.p.). Tulsi extract (250 mg/kg, p.o.) was administered for the final two weeks. Behavioural assessments included Morris Water Maze, hot plate, and acetone drop tests. Biochemical analyses included blood glucose, lipid profile, antioxidant enzymes, acetylcholinesterase activity, and inflammatory cytokines. Histopathological analyses of sciatic nerve and intestine were also performed.

Results: LC–MS/MS analysis identified flavonoids and phenolic acids including luteolin, kaempferol, and dihydroferulic acid derivatives. Tulsi significantly reduced blood glucose levels (170.08±3.34 mg/dL) compared to disease control (330.1±6.71 mg/dL). Escape latency time decreased from 34.71±2.51 s to 15.58±0.84 s, while time spent in target quadrant increased from 5.91±0.44 s to 14.45±0.72 s. Tulsi elevated SOD (8.48±0.54 vs. 5.51±0.30), GSH (15.82±1.01 vs. 3.54±0.10), and CAT levels (27.83±1.00 vs. 15.02±1.39), while reducing TNF-α levels (1240.92±36.36 vs. 2346.02±61.66 pg/mL). Histopathology showed reduced neuronal degeneration and intestinal inflammation.

Conclusion: Tulsi demonstrated significant neuroprotective, antioxidant, anti-inflammatory, and hypoglycemic effects against diabetic neuropathy and cognitive impairment, suggesting its potential as a multitargeted therapeutic strategy.

Keywords: Diabetic neuropathy; Ocimum sanctum; Cognitive impairment

D2/263

Network Pharmacology and In Vitro Studies Reveal Piperine's Novel Parkinson's Disease Pathways

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Introduction: Parkinson's disease (PD) is a progressive neurodegenerative disorder marked by dopaminergic neuron loss, oxidative stress, and mitochondrial dysfunction, leading to debilitating motor & non-motor symptoms. Standard interventions provide symptomatic relief but do not arrest disease progression. Natural compounds have garnered attention as multi-target therapeutics due to their pharmacological properties and low toxicity. Piperine, alkaloid from Piper nigrum (black pepper), exhibits antioxidant, anti-inflammatory, & anti-apoptotic effects. Despite growing evidence of its therapeutic benefits, exact mechanism of Piper nigrum in PD remains unclear therefore, targeting molecular pathways might be promising therapeutic potential for disease management & progression.

Aim: This study aimed to investigate the molecular targets underlying the therapeutic effects of Piper nigrum against PD through network pharmacology, molecular docking, and in vitro studies using the SH-SY5Y cell line.

Methods: Piperine was evaluated using integrated computational & experimental approach. Its physicochemical & ADMET properties were assessed using PubChem, SwissADME, and Schrödinger QikProp. Potential 158 piperine targets and PD-associated genes were identified from SwissTargetPrediction, STITCH, GeneCards, and OMIM databases, & 142 overlapping targets were subjected to protein–protein interaction (PPI) network construction, hub gene identification, and GO/KEGG enrichment analyses. Molecular docking was performed to investigate the interaction of piperine with the potential PD targets, effects of piperine were validated in vitro using SH-SY5Y neuronal cells.

Results: Protein-protein interaction and pathway network analysis demonstrated Piperine modulation of key signalling cascades, including PI3K-Akt, MAPK, NF-κB, and p53, alongside dopamine synapse regulation & mitochondrial quality control. GO and KEGG enrichment further supported Piperine neuroprotective roles. MTT assays in SH-SY5Y dopaminergic neuron findings validated Piperine dose-dependent cytotoxicity & demonstrated its cytoprotective effects against 6-OHDA neurotoxin-induced toxicity.

Conclusion: Integration of computational predictions and in vitro validation highlights Piperine multi-target mechanisms, reinforcing its potential as an effective, mechanism-based neuroprotective agent for PD therapy.

Keywords: Parkinson's disease, piperine, network pharmacology.

D2/264

Therapeutic evaluation of traditional formulation of Caesalpinia bonducella in management of Sciatica

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Introduction: Gridhrasi in Ayurveda (Indian traditional system of medicine) a condition characterised by radiating pain from the lumbar region to the lower extremities, closely resembles Sciatica in modern medicine. Ayurveda, advocates herbal preparations to restore and maintain natural physiological balance. Seeds of Caesalpinia bonducella (SCB) are indicated for the Gridhrasi were evaluated for its use in Sciatica.
Objectives: This study aimed to conduct a therapeutic evaluation of the kwatha (decoction) prepared from SCB (KCB) in the management of Sciatica.
Methods: A small, single-centred, single-blind, exploratory comparative clinical trial was conducted. Thirty patients aged between 20-50 years were randomly assigned to two groups of 15 each. Group A received KCB p.o. alone, and Group B received KCB combined with lepa (an external paste formulation containing SCB) SLL for 21 days. Outcomes were assessed using subjective symptom scores for Ruk (pain), Stambha (stiffness) and Toda (pricking sensation) graded on four-point Likert scale, alongside objective measures comprising the Straight Leg Raising (SLR) test and Braggard's test. Within-group changes were analyzed using the Wilcoxon signed-rank test, and between-group differences were compared using the Mann–Whitney U test.
Results: In Group A (KCB alone), percentage relief was 93%, 77% and 75% for stiffness, pain and pricking sensation respectively. SLR test range improved by 71% (all $P<0.001$). In Group B mean percentage relief was 100%, stiffness, 81% for pain, and 87% for pricking sensation; SLR test range improved by 72% ($P<0.001$). Group B showed numerically better outcomes for most parameters.
Conclusion: This trial provides preliminary evidence suggesting that KCB may offer benefit in Sciatica, and that adding SLL may further enhance outcomes. These findings are exploratory and should be interpreted with caution given the limited sample size, short treatment duration, absence of a placebo control, and single-centre setting.
Key words: Caesalpinia bonducella, Sciatica, Gridhrasi, SLR test.

D2/265

Sex Matters in Vaccine Pharmacovigilance

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Introduction: Sex differences in immune response and adverse drug reactions are well described, yet vaccine safety evaluations frequently aggregate outcomes, potentially obscuring important disparities in vaccine benefit–risk profiles.

Aim: To quantify sex-specific differences in adverse event following immunisation (AEFI) reporting.

Methods: Sex-specific reporting rates per 100,000 doses administered were calculated by age group and reaction type for spontaneous AEFI reports submitted to Victoria's population-based vaccine safety surveillance system (Australia) during 2020–2025 and for HPV vaccine safety surveillance data spanning two decades (2007–2025). Sex comparisons were expressed as reporting rate ratios (RR) with 95% confidence intervals.

Results: Among 52,262 AEFI reports across all vaccines, females had higher reporting rates than males (female RR 1.80, 95%CI 1.77–1.84), with the greatest disparity in mid-adulthood and diminishing after 60 years. Reproductive-health-related events accounted for only 2.2% of adult reports. Of reactions with >10 reports, 81 demonstrated ≥3-times higher rates in females compared with 8 in males; only a subset had plausible mechanistic explanations. Adult males were less likely to self-report (10.9% vs 15.4%, $p<0.0001$) but 25% more likely to have serious AEFI recorded (20.2%, $p<0.0001$), suggesting under-ascertainment of milder male experiences.
In HPV surveillance, overall reporting rates were similar between sexes (male RR 1.13, 95%CI 0.99–1.29) including serious AEFI ($p=0.781$). Fever (RR 1.82, $p<0.001$) and syncope (1.50, $p<0.001$) were more frequently reported in males, whereas allergic rash was more common in females (RR 0.57, $p=0.003$). Male preponderance of Guillain Barré syndrome (RR 2.17, $p=0.596$) was consistent with background incidence expectations. Reporting patterns remained stable over substantial programmatic changes.

Conclusions: Vaccine safety sex differences reflect biological, behavioural, and surveillance-related factors. Failure to disaggregate by sex may misrepresent benefit–risk in specific populations. Routine sex-stratified pharmacovigilance strengthens signal interpretation and supports evidence-based vaccination policy.

Keywords: Vaccine safety, sex differences, pharmacovigilance

D2/266

Methodological approaches to long-term vaccine safety assessment in observational studies: Systematic review

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Introduction: Long-term vaccine safety studies rely predominantly on observational data and are susceptible to methodological challenges like time-varying confounding. Rigorous methodological approaches are therefore essential to ensure the validity of long-term safety evidence.

Aims: To review the study designs and analytical approaches used in observational studies to assess the long-term safety of vaccines.

Methods: A systematic search was conducted across PubMed/Medline, Web of Science, and Scopus to identify observational studies evaluating vaccine-associated adverse events with long-term follow-up published between 2015 and 2025. Data extracted from the studies included key methodological characteristics, such as follow-up duration, additional vaccination during follow-up, and approaches used to address potential time-varying confounding.

Results: A total of 468 records were identified through database searches, of which 63 studies met the eligibility criteria. COVID-19 vaccines were the most frequently studied vaccine type (n=35, 55.6%), followed by human papillomavirus (HPV) vaccines (n=5, 8%). Cardiovascular outcomes were the most frequently investigated adverse events, followed by autoimmune, neurological, and thrombotic conditions. Prospective or retrospective cohort designs comprised the largest proportion of studies (n=40, 63.5%), whereas three studies (4.8%) utilized a hybrid cohort-SCCS design and one study (1.6%) utilized an SCCS design. The follow-up duration for long-term safety evaluation ranged from a minimum of 30 days to a maximum of 34 years. To control time-varying confounding, 6 studies (9.5%) identified and statistically adjusted for dynamic covariates such as vaccination status (e.g., transitions across vaccine doses), breakthrough infections, and longitudinal medication adjustments. These factors were primarily managed using time-dependent Cox proportional hazards models (n=4, 66.7%)

Conclusions: Despite the long-term periods used in these studies, explicit consideration of time-varying confounding was identified in only 6 of 63 studies. Greater transparency regarding the handling of dynamic factors during extended follow-up is needed to strengthen the long-term safety evidence.

Keywords: vaccine; long-term safety; study design

D2/267

Assessing feasibility of Zhejiang platform for HPV vaccine effectiveness evaluation in China

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Introduction: Post-licensure vaccine effectiveness (VE) surveillance can inform immunization policy and individual decision-making. The Zhejiang Provincial Vaccine Real-World Research Platform (ZVRWP) has integrated vaccination records, electronic medical records (EMRs) and free cervical cancer screening data. However, the feasibility of using ZVRWP for VE studies has not been systematically evaluated.

Aims: To assess the feasibility of using ZVRWP to evaluate the real-world effectiveness of human papillomavirus (HPV) vaccines in China. We also aimed to inform future post-licensure VE studies using the platform.

Methods: We first evaluated accessibility, governance, and secure use processes. Then assessed the relevance of key data for effectiveness evaluation of HPV vaccines, including exposure variables from vaccination records and outcome variables (cervical intraepithelial neoplasia (CIN) 2/3, adenocarcinoma in situ (AIS) and cervical cancer) from EMRs and screening data. Data completeness and linkage performance across data sources using a unique identifier were analyzed.

Results: The ZVRWP is accessible for research use under established ethics and data security governance as a comprehensive healthcare information system. As of 2025, the platform had captured 11.5 million HPV vaccine doses among 4.2 million female recipients aged 9–45 years. In the same age group, screening data identified 3,739 cases of CIN2/3, while EMRs documented 6,326 CIN2/3 cases and 64 cases of AIS cases. Key exposure fields showed near-complete capture (100% for vaccination date and vaccine name; 99.98% for manufacturer). Cross-source linkage demonstrated substantial overlap, including individuals with records present in vaccination, EMRs, and screening data.

Conclusion: Key exposure and outcome data required for post-licensure HPV VE surveillance are obtainable with high completeness and demonstrable linkage across data sources in the ZVRWP. The platform appears fit for conducting HPV VE surveillance studies, with further work recommended to refine cohort definitions and evaluate outcome validation procedures.

Key words: feasibility assessment; human papillomavirus; vaccine effectiveness

D2/268

Do Not Pass Go (Without Reading This): Linked Data Pharmacovigilance Lessons Learned

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Background: Large linked administrative health datasets are increasingly central to population-level research and public health surveillance. Victoria's Vaccine Safety Health Link (VSHL) links near real-time records from Australian Immunisation Register with statewide hospital, emergency, notifiable disease, perinatal, birth and death datasets. Monthly linkage by the Centre for Victorian Data Linkage provides de-identified extracts for secure analysis, enabling population-wide real-world vaccine safety monitoring. Despite strengths of this comprehensive linkage, pitfalls can trip up novice & experienced analysts alike.

Aims: To share practical challenges working with large, linked health data.

Methods: Vaccine safety analyses within VSHL (with a population >8 million), defining denominator and numerator populations, linking between parents and children, and assessing exposure–outcome associations using methods such as self-controlled case series, logistic regressions and rapid cycle analyses have been performed for four years. These works have highlighted challenges that can impact linked-spine administrative data systems.

Results: Case ascertainment shifts can be subtly impacted by differences in coding completeness, update cycles and temporal alignment across sources. At population scale, even small linkage error rates may create meaningful analytic distortion, including missed links, false matches or implausible records (e.g. multiple maternal links or improbable clusters of vaccinations [>50 in one individual] on a single day). Population continuity presents another critical fault line; when deaths or migration occur outside jurisdictional capture, individuals may persist analytically (like "immortals") within the cohort, skewing denominators and risk estimates, particularly in older populations. Although near real-time linkage enables rapid surveillance, delays in source data availability (eg. complete admission record coding) and limited clinical granularity can temper immediate signal interpretation.

Conclusions: Linked administrative data brings great richness and representativeness but necessitates considerations when being operationalised. Sharing experience and expertise can lift capability in linked data use and strengthen Australia's public health intelligence.

Keywords: Linked data, Vaccines

D2/269

Safety and efficacy of medications for urinary incontinence in people with dementia

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Introduction: Urinary incontinence is up to three times more prevalent among those with cognitive impairment than those without cognitive impairment. The absence of guidance regarding the pharmacological management of urinary incontinence for people living with cognitive impairment or dementia, and evidence to guide decision making, may lead to unwanted clinical practice variation and potentially avoidable medication-related harm.
Aims: To systematically review the safety and efficacy of medications for the management of urinary incontinence in people living with dementia and/or in residential aged care.
Methods: Five bibliometric databases were searched for randomized control trials (RCTs) from inception to March 2026. Randomised controlled trials that evaluated the safety and/or efficacy of a pharmacological treatment for the management of urinary incontinence versus either a placebo, another pharmacological interventions or non-pharmacological interventions among people living with dementia or cognitive impairment or those living in residential aged care were included. Risk of bias was assessed using the Joanna Briggs Institute Critical Appraisal Tool. Efficacy, adverse events and cognitive effects were synthesized narratively.
Results: Ten RCTs with a total of 325 participants were included. Effect on UI symptoms was reported in 8 studies, with oxybutynin (n=5 studies), propiverine (n=1 study), propantheline, (n=1 study) and oral oestrogen (n=1 study) reported as having minimal or no effect on UI symptoms. The most common non-cognitive adverse event reported for oral anticholinergics was dry mouth (42/142 participants). Cognitive effects on attention, alertness and memory were mostly reported within one to two hours after dosing of oral anticholinergics. Risk of bias was common across included studies due to incomplete or unclear reporting of baseline participant characteristics, trial designs and outcome measures.
Conclusions: Medications for urinary incontinence for people with cognitive impairment or dementia should be prescribed cautiously, with consideration of possible benefits and harms.
Keywords: Dementia, Incontinence, Medicine Safety

D2/270

Comparing Decentralized Clinical Trial Regulatory Frameworks: United States vs. Australia

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Introduction: Decentralized clinical trials (DCTs) can overcome the limitations of conventional site-based trials. As DCT utilization increases, international regulatory harmonization is crucial to address barriers in multiregional clinical trials. However, cross-national differences in DCT design and conduction guidelines remain underexamined.

Aims: This study compares regulatory approaches to DCTs between the United States(US) and Australia. Also, we aim to identify how regulatory perspectives on decentralized elements differ between these two leading clinical trial nations.

Methods: This cross-sectional study analyzed DCT guidelines issued by national regulatory authorities and clinical trial organizations, including official guidance from the US Food and Drug Administration, the Cancer Institute NSW, and the Clinical Oncology Society of Australia. We evaluated terminology, general design considerations, local healthcare provider roles, and decentralized element applications. All documents were re-searched as of May 31, 2026, to ensure regulatory data validity.

Results: Regulatory terminology differs: the US defines "DCTs," whereas Australia utilizes both "DCTs" and "Tele-trials." Regarding design, US guidelines focus on investigational product safety and procedural complexity, while Australian guidelines emphasize suitability for rural populations and community barriers. Furthermore, the US restricts local healthcare providers to routine care without informed consent authority. Conversely, Australia permits satellite physicians and local providers to act as investigators and obtain informed consent. Despite structural variations in specific decentralized elements, both countries permit direct-to-patient delivery and remote consent.

Conclusions: Although US and Australian regulatory frameworks share a patient-centric objective, they exhibit distinct operational and structural approaches. These disparities may pose substantive barriers to executing multiregional clinical trials, highlighting the essential need for globally harmonized standards to facilitate international DCT activation.

Keywords: Decentralized clinical trials, Teletrial, Regulatory frameworks

D2/271

Antibiotic knowledge, attitude, and behaviour among residents of Nakhon Pathom, Thailand

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Introduction: Antimicrobial resistance (AMR) is a critical public health threat, largely driven by inappropriate antibiotic use. In Thailand, self-medication with antibiotics for upper respiratory tract infections (URIs) is prevalent, contributing to rising resistance rates. Nakhon Pathom Province consistently ranks among areas with high antibiotic use for these conditions, yet post-COVID-19 evidence on community-level knowledge, attitude, and behaviour (KAB) remains limited.

Aims: This study aimed to assess antibiotic use KAB among residents of Mueang Nakhon Pathom District and to analyse associations between these variables and relevant demographic factors.

Methods: A cross-sectional analytical study was conducted between December 2023 and January 2024. A total of 439 adults aged 18 years and older who had self-administered oral antibiotics for URIs or acute bronchitis within the preceding three months were recruited using multi-stage sampling. Data were collected via a validated self-administered questionnaire assessing demographics, antibiotic knowledge (12 items), attitude (7 items), and behaviour (8 items). Chi-square tests and Spearman's rank correlation were used for inferential analyses.

Results: Most participants demonstrated low antibiotic knowledge (61.50%), negative attitudes towards correct antibiotic use (73.12%), and low accurate antibiotic use behaviour (48.97%). Education level ($p<0.05$) and occupation ($p<0.001$) were significantly associated with behaviour. Age showed a statistically significant very weak negative correlation with behaviour ($r_s = -0.20$, $p<0.001$). Knowledge demonstrated a strong positive correlation with behaviour ($r_s = +0.63$, $p<0.001$), while attitude showed a weak positive correlation ($r_s = +0.27$, $p<0.001$). Gender, monthly income, and antibiotic acquisition channel were not significantly associated with behaviour.

Conclusions: Knowledge was the strongest predictor of correct antibiotic use behaviour in this population. Targeted public health interventions are warranted for individuals aged 40 years and older, those without formal education, the unemployed, and those obtaining antibiotics through online channels, to promote rational antibiotic use.

Keywords: Antibiotic use behaviour; antimicrobial resistance; self-medication

D2/272

Quantifying Regulatory Bottlenecks in South Korea's Clinical Trial Approval Process using AHP

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Introduction: Drug lag represents a critical challenge that limits pharmaceutical competitiveness and restricts timely patient access to innovative therapies in South Korea. This issue is intrinsically linked to delays within the investigational new drug (IND) review process, which hinders the domestic introduction of advanced treatments. There is an urgent need to identify specific systemic barriers and optimize the regulatory pathway to align with global standards.

Aims: This study aimed to identify key barriers affecting IND review efficiency by analyzing real-world industry experience. Furthermore, it sought to propose concrete strategic actions to mitigate drug lag in the domestic pharmaceutical landscape.

Methods: We employed an exploratory sequential mixed-methods design. Initially, grounded theory was utilized to identify problematic factors within the IND process through semi-structured interviews. Subsequently, the Analytic Hierarchy Process was applied to evaluate these factors, followed by a quadrant analysis of importance and urgency to pinpoint top-priority tasks.

Results: Three core categories—rationality and patient-centricity, professional review, and operational efficiency—were identified as key domains for enhancing IND efficiency. Rationality and patient-centricity emerged as the most important and urgent criterion, followed by professional review. Within rationality and patient-centricity, four sub-criteria were identified in the first quadrant (highly important and urgent): integration of patient needs, global regulatory harmonization, acceptance of scientific evidence for new modalities, and adoption of overseas standards. Two sub-criteria within professional review, specifically expert team review and standardized review guidelines, were also pinpointed as top priorities. Although operational efficiency ranked lowest, simplified translation requirements were identified as the most critical factor within this category.

Conclusions: A transition from focusing solely on procedural speed toward embracing regulatory flexibility to enhance scientific rationality and patient access is essential. These findings suggest a viable pathway for effectively mitigating drug lag in South Korea.

Keywords: Drug lag, Investigational new drug, Analytic hierarchy process

D2/273

Regulatory Outcomes and Timelines of FDA Accelerated Approvals for Non-Oncology Therapeutics

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Introduction: The FDA accelerated approval pathway enables earlier access to treatments for serious
or life-threatening diseases based on surrogate endpoints. Although widely studied in oncology, regulatory outcomes for non-oncology therapeutics remain less well characterized. This gap is important because non-oncology indications often involve diverse diseases, heterogeneous surrogate endpoints, and varying post-marketing evidence requirements.

Aims: This study evaluated regulatory outcomes and approval timelines for non-oncology therapeutics granted FDA accelerated approval from 1992 to 2024. It also compared approval trajectories by drug type, approval type, and oncology versus non-oncology classification.

Methods: A cross-sectional analysis was conducted using the FDA accelerated approval database. Non-oncology indications approved between June 19, 1992 and December 31, 2024 were included. Indications were categorized by therapeutic area, drug type, approval type, and regulatory outcome. Median approval timelines were analyzed and compared according to drug type and oncology versus non-oncology classification.

Results: Among 328 accelerated approval indications, 98 (30%) were non-oncology indications. Overall, 63 (64%) converted to full approval, 14 (14%) were withdrawn, and 21 (21%) remained not yet converted. Systemic anti-infectives were the largest category, accounting for 49 (50%) indications. Original indications converted more frequently than supplemental indications, with 55/77 (71%) versus 8/21 (38%) converted. The median time to accelerated approval was 7.9 months, and the median time from accelerated approval to full approval was 38.8 months. Non-oncology biologics required significantly longer time to accelerated approval than oncology biologics (8.6 vs 6.0 months; p=0.003).

Conclusions: These findings suggest that regulatory trajectories for non-oncology accelerated approvals may differ by product type, therapeutic area, and post-marketing evidence requirements. Continued post-marketing evaluation is needed to confirm clinical benefit and support evidence-based regulatory decision-making.

Keywords: Accelerated approval; Non-oncology therapeutics; Regulatory outcomes