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ABSTRACT BOOKLET

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1

Impact of supply chain disruptions and drug shortages on drug utilization: a scoping review

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Purpose: Drug shortages are a growing challenge in health systems across the world. A better understanding of the impacts of shortages on patient drug access and use will guide policies aimed at mitigating shortages. This scoping review aims to summarize observational literature assessing the impact of drug shortages on drug utilization trends.

Methods: We searched Ovid MEDLINE and Ovid EMBASE for studies published between 1946 to September 17, 2024. An extensive grey literature search was conducted through targeted website searches, grey literature databases and the Google search engine. Observational studies examining the impacts of drug supply disruptions on drug use were included. Study screening and extraction were conducted by two independent reviewers.

Results: We identified 55 published articles and 5 grey literature reports. Most studies were conducted in North America (n = 42, 70%). Population level data was most used (n = 34, 57%), and most studies used drug prescription data to assess changes in use (n = 30, 55%). Most studies reported changes in drug use as a percent change and the magnitude in decreases ranged from 1-99%. Many different data sources, methods and measures were used to study the impact of drug shortages on drug utilization, and a broad range of decreases in drug utilization following the shortages were reported.

Conclusions: It is important to synthesize findings across studies to understand how different drugs and settings are affected by shortages. The findings here can inform future studies on drug shortages and assist in developing frameworks and policy decisions regarding drug supply challenges.

2

Cost analysis of hospitalized pediatric patients undergoing conventional genetic testing in a Canadian hospital

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Background: Conventional genetic tests (CGT) are currently employed in Canada for the investigation of critically ill children with suspected rare genetic disorders (RGD). Though generally viewed as costly, their true cost remains unknown. We aimed to estimate the cost of all assessments and tests associated with CGT as well as the total hospital costs.

Methods: We identified a retrospective cohort of patients who were investigated with CGT at CHU Ste-Justine between January 2021 and November 2022 and examined their healthcare expenditures. The analysis considered a single hospitalization for each patient and adopted the hospital's perspective. The total hospitalization cost was assessed using an in-hospital cost database, which included direct costs (e.g., lab tests and in-hospital drugs), and indirect costs (e.g., food and cleaning services). We provide mean costs with 95% confidence intervals obtained with non-parametric bootstrap analyses.

Results: Data from a total of 223 children were analyzed. Mean age was 3.0 years and 119 (53.4 %) were male. The average length of hospital stay was 42 days. Nine patients (4.0%) included in our cohort did not survive their hospitalization; average survival time for this subset of patients was 156 days. The mean hospitalization cost per patient in the CGT cohort was $170,337 (95% CI. 128,231 - 219,277). The cost for newborns (0-30 days) $219,498 (95% CI. 144,061 - 312,395) was higher than for other age categories (p = 0.037). The cost of those who had more than one CGT was over twice as much as those who had only a single CGT (n = 161) ($292,305 (95% CI. 171,658 - 441,870) compared to $123,368 (95% CI. 92,319 - 159,544), p-value = 0.014). Based on sensitivity analyses, these estimates remained robust to assumptions and parameter uncertain

Conclusions: Cost incurred by the CGT cohort were substantially greater than what has previously been reported as hospitalization costs for the general pediatric population. Subgroup analyses revealed that newborns investigated with CGT were the most expensive among all pediatric cases. Our results can serve as a basis for comparison to assess the cost impacts of new diagnostic genomic technologies.

3 – Evaluated Oral Presentation

Fluoroquinolones and the associated risk of panic attacks: A systematic review and active-comparator restricted disproportionality analysis

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Background: Fluoroquinolones (FQs) are broad-spectrum antibiotics commonly prescribed for respiratory and urinary tract infections. While FQs have been associated with various neuropsychiatric effects, their specific link to panic attacks remains unclear. To date, no study has systematically examined this association using both published literature and pharmacovigilance databases. It is hypothesized that FQs may be associated with an increased risk of panic attacks.

Objectives: To systematically review the literature on FQ-related panic attacks and assess whether FQs are associated with a higher risk of reported panic attacks compared to other antibiotics using the FDA Adverse Event Reporting System (FAERS).

Methods: A systematic search of MEDLINE and Embase (1946–November 11, 2024) was conducted to identify studies on panic attacks associated with FQs. A disproportionality analysis using FAERS data (2004Q1–2023Q4) compared the frequency of panic attack reports for FQs (ciprofloxacin, levofloxacin, moxifloxacin) to non-FQ antibiotics (azithromycin, trimethoprim-sulfamethoxazole). Reporting odds ratios (RORs) were calculated, adjusting for urinary and respiratory tract infections, age, and sex (aRORs). Bayesian Confidence Propagation Neural Networks were used to calculate Information Components (IC025). The study outcome, "panic attacks," was identified using Medical Dictionary for Regulatory Activities (MedDRA) terms to detect safety signals.

Discussion: The findings suggest that FQs may be associated with an increased risk of panic attacks, warranting further validation through large pharmacoepidemiologic studies. If confirmed, physicians should exercise caution when prescribing FQs, particularly in patients at risk for anxiety-related disorders.

4 – Evaluated Poster Presentation

Representativeness of Vulnerable Populations in Randomized Controlled Trials Evaluating the Efficacy and Safety of SGLT-2 Inhibitors: A Systematic Review and Meta-analysis

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Background: RCTs have demonstrated the efficacy of SGLT-2 inhibitors in managing type 2 diabetes and heart failure. However, concerns remain regarding the underrepresentation of vulnerable populations—children, older adults, women, racial and ethnic minorities, and patients with chronic kidney or liver disease—potentially limiting the generalizability. This study aimed to assess the pooled prevalence of these populations in SGLT-2 inhibitor RCTs and identify factors influencing their inclusion.

Methods: We searched Central, Medline, and Embase for relevant studies published up to January 8, 2025. Eligible studies were phase 3 or 4 RCTs with ≥300 participants that reported data on at least one vulnerable population. We calculated pooled prevalence estimates with 95% confidence intervals using a random-effect model and explored heterogeneity using meta-regression.

Results: Among 91 included RCTs, the pooled prevalence was 42.1% for females (95% CI: 40.2–44.1%), 42.3% for older adults (95% CI: 36.4–48.2%; 28 RCTs), and 33.7% for patients with CKD (95% CI: 20.9–47.9%; 37 RCTs). Racial and ethnic representation included 4.8% Black (95% CI: 4.2–5.4%; 72 RCTs), 17.2% Asian (95% CI: 13.5–21.3%; 75 RCTs), 1.7% Indigenous (95% CI 0.7% to 3.1%, 19 RCTs), and 20.0% Hispanic or Latino (95% CI 13.4% to 27.6%, 16 RCTs) participants. Data on liver disease and participants under 18 were insufficient. The study population and number of trial centers may significantly influence their inclusion.

Conclusions: Vulnerable populations remain underrepresented in SGLT-2 inhibitor RCTs. Targeted strategies are needed to enhance inclusion and improve the external validity of trial findings.

5

Mapping Levothyroxine related Adverse Events: A Disproportionality Analysis of FAERS Individual Case Safety Reports

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Background: Levothyroxine is commonly prescribed for hypothyroidism and thyroid cancer, yet concerns about its safety particularly at higher doses persist. Despite widespread use, real-world evidence on adverse effects remains limited. This study aims to evaluate levothyroxine's safety profile using individual case safety reports from the FDA Adverse Event Reporting System (FAERS) through active disproportionality analysis (ADA). The primary objective is to identify and characterize adverse events (AEs), with secondary objectives including detection of dose-specific safety signals and analysis of age- and gender-related patterns.

Methods: Disproportionality analysis was performed using Reporting Odds Ratio (ROR), Proportional Reporting Ratio (PRR), Bayesian Confidence Propagation Neural Network, and Multi-Item Gamma Poisson Shrinker. AEs were considered signals if they met all four criteria (IC025 > 0, lower bound of ROR and PRR > 1, EBGM05 > 2). Dose-dependent signals were assessed using ROR, PRR, and IC025. AEs were coded using MedDRA-v27.1 preferred terms.

Results: Analysis of 45,877 FAERS reports identified 201,473 levothyroxine-related AEs and 291 safety signals compared with other drugs. Among these, 22 signals were labeled (e.g., irritability [ROR: 13.49] and palpitations [ROR: 13.29], while 269 were unexpected (e.g., polyglandular autoimmune syndrome type II [ROR: 118.76], social avoidant behavior [ROR: 48.49]). Comparing high (≥100 µg) and low-dose (<100 µg) levothyroxine, 21 signals were identified, including acute kidney injury (ROR: 4.69) and increased blood triglycerides (ROR: 3.67).

Conclusions: This study highlights levothyroxine's known and unexpected AEs, with evidence of dose-related risks. Further research is needed to validate these findings and explore underlying mechanisms.

6

Trimethoprim-Sulfamethoxazole (TMP-SMX) and Risk of Hemophagocytic Lymphohistiocytosis (HLH): A Literature Review and Disproportionality Analysis Using Individual Safety Case Reports from FAERS

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Background: Trimethoprim-sulfamethoxazole (TMP-SMX) has been linked to hematologic adverse events, but its association with hemophagocytic lymphohistiocytosis (HLH) remains unclear. The objective is to review the literature on TMP-SMX and HLH and assess its risk using the FDA Adverse Event Reporting System (FAERS).

Methods: A Medline/Embase search (up to March 1, 2025) identified studies on TMP-SMX and HLH. The Naranjo scale assessed causality in case reports. FAERS data (2004Q1–2023Q4) were analyzed, comparing HLH reports for TMP-SMX versus amoxicillin/clavulanic acid and azithromycin. Disproportionality analyses used Reporting Odds Ratios (ROR), Proportional Reporting Ratios (PRR), and Information Components (IC025), with logistic regression adjusting for confounders. The study follows READUSPV guidelines.

Results: Five case reports (median age: 34 years, 80% male) described TMP-SMX-associated HLH, with symptom onset 2–12 days post-initiation. The Naranjo scale suggested a possible to probable association. In FAERS, HLH was reported in 0.09% of TMP-SMX cases, compared to 0.03% for amoxicillin/clavulanic acid and 0.01% for azithromycin. TMP-SMX-associated HLH was more common in males (75.7%) and in patients ≤18 years (69.2%). Disproportionality analysis showed that HLH reports were significantly higher for TMP-SMX compared to amoxicillin/clavulanic acid (ROR: 3.08; 95% CI 1.67–5.68) and compared to azithromycin (ROR: 13.89; 95% CI 5.88–32.82). These findings remained consistent across frequentist and Bayesian methods and adjusted analyses.

Conclusion: TMP-SMX may be linked to an increased risk of HLH. Clinicians should remain vigilant for this rare but serious adverse event. Further pharmacoepidemiologic studies are needed to ensure safe use.

7 – Abstract Withdrawn

8

Real-world trends in prenatal antirheumatic drug utilization in Ontario, Canada: a cross-sectional time series analysis

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Background: Pregnant individuals living with rheumatic diseases, including rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), psoriatic arthritis (PsA), and ankylosing spondylitis (AS), are at a higher risk for adverse pregnancy outcomes due to significantly increased systemic inflammation. Therefore, many continue disease-modifying antirheumatic drug (DMARD) therapy to control maternal disease activity.

Objectives: To describe real-world trends in prenatal DMARD use among pregnant individuals with rheumatic conditions by leveraging routinely collected population-based healthcare administrative claims data.

Methods: We conducted a repeated cross-sectional time-series analysis using claims data at ICES in Ontario, Canada and reported annual utilization patterns of conventional synthetic and biological DMARDs among pregnant individuals with RA, SLE, PsA, or AS who delivered a live born or stillborn singleton infant between April 1, 2006, and March 31, 2021. We also characterized the beneficiary population for calendar years 2007, 2011, 2015, and 2019, covering demographic information, healthcare utilization, and DMARD utilization.

Results: The study cohort included a total of 6,732 pregnant individuals with rheumatic conditions. Over our study period, prenatal DMARD use among ODB beneficiaries significantly increased 6% from 53.6 beneficiaries per 100 eligible population in fiscal year 2006 to 56.9 beneficiaries per 100 eligible population in fiscal year 2020 ($p = .04$). While conventional synthetic DMARD use remained relatively stable, the rate of biological DMARD use increased 292% from 7.1 beneficiaries per 100 eligible population in fiscal year 2006 to 27.8 beneficiaries per 100 eligible population in fiscal year 2020 ($p = .01$). Across our annual cohorts from 2007, 2011, 2015, and 2019, DMARD use overall increased from 22.9% in 2007 to 26.0% in 2019 ($p < .001$). The proportion of DMARD users receiving only one drug increased from 18.8% in 2007 to 20.0% in 2019, while the proportion of those receiving two or more drugs also increased from 4.2% in 2007 to 6.0% in 2019 ($p < .001$). Further, the proportion of conventional synthetic DMARD users increased from 14.6% in 2007 to 14.7% in 2019 ($p = .001$), while the proportion of biological DMARD users increased from 8.3% in 2007 to 12.7% in 2019 ($p < .001$). Lastly, the proportion of individuals continuously using biological DMARDs throughout pregnancy increased from 13.8% in 2007 to 21.8% in 2019

(p = .04).

Conclusion: DMARD use during pregnancy has risen, with biological DMARDs increasingly being used in frequency and duration to control maternal disease activity throughout pregnancy. Future studies should consider how prenatal DMARD use trends correlate with pregnancy outcomes in this patient population.

9 – Evaluated Poster Presentation

Risk of severe maternal morbidity and severe neonatal morbidity in individuals with rheumatic diseases using antirheumatic therapies during pregnancy: a population-based cohort study

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Background: Many pregnant individuals living with rheumatic diseases such as rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), psoriatic arthritis (PsA), and ankylosing spondylitis (AS) continue disease-modifying antirheumatic drug (DMARD) therapy despite lacking pregnancy safety data.

Objectives: To assess the risk of severe maternal morbidity (SMM) and severe neonatal morbidity (SNM) in individuals with rheumatic diseases using DMARDs during pregnancy.

Methods: Leveraging routinely collected population-based healthcare administrative claims data at ICES in Ontario, Canada, we included pregnant individuals with RA, SLE, PsA, and/or AS who delivered a live born or stillborn singleton infant between April 1, 2006, and March 31, 2021. Only the first pregnancy after rheumatic disease diagnosis for each individual was included. DMARD exposure was defined as having at least one DMARD dispensation reimbursed from estimated conception to delivery. To adjust for confounders such as maternal age, rheumatic conditions and comorbidities, healthcare utilization, and concomitant medication use, propensity scores were calculated to estimate the probability of DMARD exposure. Overlap weights derived from propensity scores were used in logistic regressions to estimate the odds ratios (ORs) of SMM and SNM in the DMARD-exposed cohort versus unexposed comparators.

Results: There were 836 pregnant individuals with rheumatic conditions, with 304 being exposed to DMARDs. In unadjusted analyses, DMARD exposure was associated with SMM (OR: 1.79, 95% CI: 1.10–2.92) but not associated with SNM (OR: 0.96, 95% CI: 0.61–1.49). After adjusting for confounders, DMARD exposure was not associated with SMM (OR: 1.57, 95% CI: 0.57-4.32) or SNM (OR: 1.00, 95% CI: 0.42-2.43). Further stratifying exposure by DMARD type, biological DMARD exposure (including combination therapy with conventional synthetic DMARDs) was not associated with SMM (OR: 0.89, 95% CI: 0.30-2.70) or SNM (OR: 0.63, 95% CI: 0.24-1.63). Similarly, conventional synthetic DMARD exposure only was not associated with SMM (OR: 1.38, 95% CI: 0.47-4.02) or SNM (OR: 1.09, 95% CI: 0.44-2.72). Sensitivity analyses using stabilized inverse probability of treatment weighting and a longer exposure window from six months prior to conception to delivery did not result in significant changes in point estimates and CIs.

Conclusion: These population-based data suggest that using DMARDs, including biological agents, before and during pregnancy is not associated with an increased risk of SMM or SNM. Further studies to better understand the long-term maternal and fetal outcomes associated with prenatal DMARD use will aid in developing real-world evidence-based clinical guidelines for safe prescribing during pregnancy.

10

Healthcare transition of newcomer international students in Canada and the role of pharmacists in bridging care and medication gaps: a qualitative study

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Backgrounds: Canada is recognized as one of the healthiest countries; however, health status and access to care remain unequal. Newcomers including international students, face difficulties when transitioning to the Canadian healthcare system. These include unfamiliarity with services, cultural differences, language barriers, and problems accessing medications, which can compromise their health. As accessible healthcare providers, pharmacists are well-positioned to support students by improving system navigation, medication safety, and continuity of care. This study explored international students' healthcare experiences and pharmacist-led strategies to support their transition.

Methods: We conducted a qualitative exploratory descriptive study using interviews with newcomer international students (n=23). Participants were recruited through purposeful sampling. Guided by Transition Theory, data were analyzed using conventional content analysis.

Results: Four overarching concepts were identified, each reflecting related themes: 1) Navigating the Unknown: captured participants' early impressions and challenges; 2) Building Bridges: described participants' efforts to understand new realities and address care gaps; 3) Pharmacist as a Guide: highlighted pharmacists' contribution to improving medication literacy and providing accessible care; and 4) Overcoming Barriers, Building Resilience, and Improving Access: included participants' recommendations to improve healthcare navigation and access. These concepts were integrated into a conceptual model reflecting students' healthcare transition and the pharmacist's role in supporting them.

Conclusion: Newcomer international students faced complex challenges transitioning to the Canadian healthcare system. Pharmacists can address medication-related challenges and broader healthcare gaps. Pharmacist-led virtual education and medication management services can help achieve better integration and outcomes, contributing to a more equitable and responsive healthcare landscape.

11

Assessing Quality of Life Among Canadian Multiple Myeloma Patients and Caregivers

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Background: Multiple myeloma (MM) imposes a substantial burden, affecting patients' quality of life (QoL) and that of caregivers, who often lack psychological support. Real-world data on QoL remains limited despite recent therapeutic advances that have altered the disease course.

Methods: A cross-sectional, observational study was conducted across Canadian provinces in MM patients and caregivers of MM patients to assess their QoL. Participants were identified through Myeloma Canada's database and data were collected using the PROxy Network web-based platform. All data were self-reported by patients or caregivers and included demographic and disease-related characteristics. Patients completed the EORTC QLQ-C30, EORTC QLQ-MY20, EQ-5D-5L, and ESAS-R. Caregivers completed the CarGOQoL.

Results: A total of 305 patients (49.8% female; mean age: 65.6 years) and 104 caregivers (74.0% female; mean age: 61.6 years) participated in the study between October 2024 and February 2025. 27.2% of patients and 32.7% of caregivers reported that the patient had experienced a relapse of MM. Patients reported a mean Global Health/QoL score of 65.68 on the EORTC QLQ-C30. On the EORTC QLQ-MY20, the mean disease symptoms and side effects of treatment scores were 23.22 and 22.36, respectively. The mean total distress score on the ESAS-R was 18.33, and the mean EQ-5D-5L utility value was 0.80. Caregivers reported a mean CarGOQoL index score of 62.14.

Conclusion: Advances in MM treatment have extended survival and changed side effect profiles, which may contribute to a moderately impaired QoL in patients. These changes may also impact caregivers, potentially altering the burden of care.

12 – Evaluated Poster Presentation

Auditory System Adverse Events with Sacubitril/Valsartan: An Active-Comparator Disproportionality Analysis of the FAERS Database

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Background: Sacubitril/Valsartan (Sacu-Val), the first angiotensin receptor neprilysin inhibitor, was approved in 2015 for heart failure with reduced ejection fraction. Concerns have since emerged about potential ototoxicity, but supporting evidence remains limited. This study aimed to evaluate the association between Sacu-Val and reports of hearing impairment and vestibular disorders, compared to Lisinopril and Losartan, using data from the FDA Adverse Event Reporting System (FAERS).

Methods: We conducted an active comparator-restricted disproportionality analysis of FAERS reports from 2015Q3 to 2023Q3. The analysis was restricted to primary suspect cases and utilized MedDRA v27.1 preferred terms. Adjusted reporting odds ratios (RORs) were calculated controlling for age, sex, and indication. Bayesian signal detection metrics, including Information Component (IC) and Empirical Bayes Geometric Mean (EBGM), were also computed.

Results: Out of 55,101 individual safety reports, Sacu-Val accounted for 51.0%, Lisinopril 33.5%, and Losartan 15.6%. Hearing impairment was reported more frequently with Sacu-Val (1.47%) than with Lisinopril (0.53%) or Losartan (0.93%). Adjusted RORs for hearing impairment were 2.35 (95% CI: 1.80–3.06) vs. Lisinopril and 1.97 (95% CI: 1.46–2.66) vs. Losartan. Hypoacusis accounted for 71.91% of hearing reports and showed significantly elevated RORs and EBGM with Sacu-Val. Vestibular disorders were also more frequent with Sacu-Val (1.47%), with adjusted RORs of 2.58 vs. Lisinopril and 1.78 vs. Losartan.

Conclusions: Sacu-Val is associated with higher reporting rates of hearing impairment and vestibular disorders compared to Lisinopril and Losartan. Further pharmacoepidemiologic studies are needed to validate these findings.

13

Pressures behind the rising costs in Canadian private drug plans pre- and post-COVID-19 pandemic: 2018-2023

Zhang Y

National Prescription Drug Utilization Information System (NPDUIS) Research Initiative, Patented Medicine Prices Review Board (PMPRB)

Background: Private drug plans play an important role in the Canadian healthcare system, with costs being a major concern for plan sponsors. This study explores the key cost pressures facing private plans, differentiating between short-term effects and those with longer-lasting impacts, and highlighting the impact of the COVID-19 pandemic.

Methods: Using data from the IQVIA Private Pay Direct Drug Plan Database, an expanded Laspeyres cost driver model isolates the key factors contributing to the growth in drug expenditures: demographic, volume, price, substitution (generic and biosimilar), and drug-mix (i.e., shifts in utilization). The study focuses on 2023, with retrospective trends from 2018.

Results: Prescription drug expenditures for private plans rose by 12.9% in 2023, returning to the pre-pandemic trend, with a compound annual growth rate of 7.1% between 2018 and 2023. Increased use of higher-cost medicines—the drug mix effect—was the primary driver, pushing costs up by 5%–9% annually. Medicines costing over $10,000 and $25,000 annually represented one-third and one-sixth, respectively, of total drug costs. Cost-mitigating effects, including generic and biosimilar substitutions and price reductions, did not fully offset the increasing drug-mix effect. The pandemic reshaped drug plan claims, initially causing a downward demographic effect due to fewer reimbursed beneficiaries in 2020, followed by a rebound surpassing pre-pandemic level after 2021.

Conclusions: Greater adoption of high-cost drugs is a significant driver of expenditure growth in Canadian private drug plans. These insights will help benefit plan advisors and sponsors benchmark their individual claims experience to the rest of the market.

14

Canada’s evolving market for biosimilar and what it means for payers

Zhang Y

National Prescription Drug Utilization Information System (NPDUIS) Research Initiative, Patented Medicine Prices Review Board (PMPRB)

Background: Potential savings from biosimilar are a topic of international interest with particular relevance for Canada. Given the high price and high use of biologics, greater biosimilar adoption offers a significant cost saving opportunity for Canadian payers. Biosimilar switching is expected to accelerate cost reductions, helping to offset the pressure from new higher-cost medicines. This analysis aims to identify opportunities in the Canadian biosimilar market in comparison with international practices.

Methods: Using data from various sources, including the IQVIA MIDAS® Database, Canadian Drugstore and Hospital Purchases Audit, US Food and Drug Administration, Europe Medicines Agency, and Health Canada, this presentation compares the evolving Canadian market for biosimilar with international counterparts. It focuses on biosimilar market dynamics in Canada from 2019 to 2023, assessing the impact of biosimilar switching to date and the potential for further cost savings.

Results: Biologics sales in Canada exceeded CAD$15 billion in 2023, representing more than one third of pharmaceutical spending. By the end of 2023, Health Canada had approved biosimilar for 18 distinct biologic medicines, lagging Europe (22) but ahead of the United States (15). Canada achieved biosimilar uptake similar to or above that of the OECD median for most high-selling biologics. Realized savings grew from 23% in 2020 to 62% in 2023. With uptake continuing to accelerate, further cost savings are anticipated through ongoing and expanded switching initiatives.

Conclusion: This presentation offers insights into Canada’s efforts to promote biosimilar use and unlock unrealized savings, contributing to a better understanding of cost-saving initiatives and healthcare system sustainability.

15

Efficacy and safety of mixed MAOB inhibitors in treatment of adults with Parkinson's disease: A systematic review and meta-analysis

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Background: Safinamide and zonisamide, novel mixed monoamine oxidase-B (MAO-B) inhibitors, have beneficial effects in motor fluctuations as add-on therapy in Parkinson's disease (PD). This meta-analysis aimed to examine the efficacy, safety, QoL and CF of safinamide and zonisamide in adults with PD compared to placebo.

Methods: We searched MEDLINE, EMBASE, Cochrane Central, Scopus, PsycINFO, and trials registries up to December 2022, identifying 11 RCTs with 4,284 PD individuals. Primary outcomes were change from baseline in Unified Parkinson's Disease Rating Scale section III(UPDRS-III) and serious adverse events. Secondary outcomes included change from baseline in OFF-time, Parkinson's Disease Questionnaire 39(PDQ-39), and Mini-mental state Examination (MMSE). Random effect models were used to calculate the pooled mean differences (MD) and risk ratios (RR) with 95% confidence intervals (CI).

Results: UPDRS Part III scores were significantly lower with mixed MAO-B inhibitors than with placebo (MD -2.21, 95%CI -2.21 to -1.43; I2 65%). Subgroup analysis showed a significant improvement in UPDRS-III in both safinamide (MD -2.06, 95%CI -3.16 to -0.96; I2=72%) and zonisamide (MD -2.43, 95%CI -3.66 to -1.20; I2= 61%). Similarly, subgroup analysis by doses showed an improvement in UPDRS-III. MAO-B inhibitors significantly decreased OFF-time compared with placebo (MD -0.94, 95%CI -1.39 to -0.48; I2=16%). No significant differences in MMSE and PDQ-39 scores were observed and examined doses were well tolerated.

Conclusion: Evidence suggests that mixed MAO-B Inhibitors as adjunct therapy are effective for motor symptoms and well-tolerated among adults with PD. However, there was no evidence of additional benefit in non-motor symptoms nor improvement of CF and QOL.

16

Antiseizure medications use and the risk of Parkinson's disease: a 15-year population-based study

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Background: Recent studies linked epilepsy to an increased risk of Parkinson's disease (PD), but there is limited evidence regarding the role of antiseizure medications (ASMs). This population-based cohort study investigated the association between ASM use and PD incidence in adults.

Methods: Using Manitoba administrative health databases, we included individuals aged >25 years from April 2008 to March 2022. We included all ASMs and divided individuals into quartiles based on number of prescriptions, with the first quartile having the fewest and the fourth quartile with the most prescriptions. We defined PD diagnosis as individuals with either 1 hospitalization diagnosis code or 2 physician claims within 1 year using ICD codes. We used Cox proportional hazard models with propensity score matching to calculate the hazard ratios (HRs) and 95% CI. Sensitivity analysis was performed by excluding those diagnosed with PD within 1 year of being prescribed any ASM.

Results: Among almost 500,000 individuals, individuals exposed to ASMs had higher incidence of PD compared with those not exposed, with rates increasing from 0.91% (n=4,559) to 1.10% (n=745). Excluding gabapentin, PD incidence significantly increased with any ASM use (HR=2.46,95%CI2.26-2.68). Individuals in the fourth quartile who filled more than 44 prescriptions had higher odds of developing PD (HR=3.85,95%CI3.36-4.41) compared with individuals in quartile 1(HR=1.14,95%CI0.94-1.38). PD Incidence was significantly associated with the use of polytherapy (HR=2.99,95%CI 2.32-3.86).

Conclusion: Over the 15-year study period, our findings show an association between ASMs and PD incidence. The use of any ASM, polytherapy, and a higher number of prescriptions were associated with an increased risk of PD. Future research is warranted to understand the underlying mechanisms.

17

Prenatal care and pregnancy outcomes before and during the COVID-19 pandemic: An interrupted time series study

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Background: The COVID-19 pandemic had a profound impact on healthcare service, but there is limited population-based evidence on the impact on prenatal care and pregnancy outcomes. Our aim was to investigate the impact of the pandemic on prenatal care visits, mode of delivery, breast feeding initiation (BFI) and Neonatal ICU (NICU) admissions.

Methods: Using Manitoba, administrative health databases, we conducted a retrospective population-based study of pregnancies occurring before (April2008-February2020) or during (March2020-March2022) the pandemic; for the latter period, they were defined as partially (March-November 2020) or fully (December2020-March2022) exposed. We estimated monthly rates of insufficient care (<5 visits), C-sections, BFI, and NICU. Interrupted time series analyses using season-adjusted generalized linear models were conducted to test immediate and lagged pandemic effects.

Results: Pandemic was associated with an abrupt 36% relative increase in insufficient care ($p<0.001$), followed by a non-significant decline ($\beta=-0.007$, $p=0.125$) during the pandemic. An abrupt rise in C-sections by 11.7% ($p<0.001$), and NICU by 17.3% ($p=0.77$) were observed followed by non-significant declines (C-section $\beta=-0.001$, $p=0.9$; NICU $\beta=-0.001$, $p=0.8$). The pandemic was associated with a decrease in BFI ($p=0.002$) followed by an increase ($\beta=-0.002$, $p=0.007$). There were no significant differences in insufficient care, C-section, BFI, and NICU among the partially exposed pregnancies. Among fully exposed pregnancies, there was a significant increase in BFI ($p=0.017$) and NICU admissions ($p=0.044$) during pandemic.

Conclusion: Our findings suggest that the COVID-19 pandemic was associated with increased rates of insufficient prenatal care and C-sections. Over the 2-year pandemic period, we observed increased NICU admissions and BFI, particularly amongst pregnancies in which the full term occurred during the pandemic.

18

Sociodemographic Determinants and Inequities in Prenatal Healthcare in the Canadian province of Manitoba: A Population-Based Cohort Study (2010-2022)

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Background: Access to prenatal care (PNC) services is essential for the health and safety of mothers and their infants, as it helps reduce complications and adverse pregnancy outcomes. Exploring the clinical and demographic factors affecting the adequacy of PNC services is important for equitable access. This study aimed to investigate the rates and determinants of inadequate PNC among all women giving birth in Manitoba, Canada.

Methods: We conducted a retrospective cohort study using province-wide mother-infant-linked administrative health databases from January 2010 to March 2022. We identified inadequate PNC using the Revised Graduated Prenatal Care Utilization Index. Annual rates were estimated, and trends were analyzed using linear regression. Multivariable multinomial logistic regression models were used to identify determinants of inadequate PNC (e.g., sociodemographic, comorbid health conditions); adjusted odds ratios (aOR) and 95% confidence intervals (CI) were estimated.

Results: Among 192,274 pregnancies, 10.4% (n=19,926) received inadequate PNC, 33.9% (n=65,143) adequate, 47.2% (n=90,732) intermediate PNC, and 7.9% (n=15,275) intensive PNC. The estimated rate of inadequate PNC increased from 10.5% in 2010 to 11.52% in 2022(p=0.036). Pregnant women living in rural (aOR=2.30, 95%CI: 2.06-2.57) or northern rural areas (aOR=2.3, 95% CI: 2.04-2.61) were more likely to receive inadequate PNC, as were women with lower income (aOR=1.97, 95%CI: 1.89-2.04). Older maternal age and comorbid conditions such as diabetes, maternal psychological distress, and hypertension were also associated with lower odds of inadequate PNC. Women with a parity of 2 or more were significantly more likely to experience inadequate PNC (aOR 4.31, 95%CI: 4.14-4.48).

Conclusions: This study highlights significant inequities in prenatal care access in Manitoba, with socioeconomic status and area of residence representing key determinants. Addressing these disparities presents an opportunity for implementing targeted interventions to improve prenatal care and outcomes. Further research is needed to identify additional factors contributing to this inequity and assess the association between inadequate care and adverse pregnancy outcomes.

19

Navigating the Market Landscape for Rare Disease Drugs in Canada

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Patented Medicine Prices Review Board

Background: The emergence of a growing number of high-cost drugs for rare diseases (EDRDs) presents new treatment possibilities while raising concerns around affordability and access. This study analyzes EDRDs launched in Canada over the past two decades, using quantitative data to assess their economic impact and inform future policy development.

Methods: Drawing on IQVIA MIDAS data and treatment cost information from Canada's Drug Agency, we examined 159 EDRDs approved in Canada between 2005 and 2024. The analysis explores launch trends, treatment costs, and market growth from 2010 to 2024, comparing oncology and non-oncology EDRDs. It also compares 2024 Canadian list prices with those in PMPRB 11 countries: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the UK.

Results: Our preliminary result shows that EDRD approvals in Canada tripled in the past decade compared to the previous one. EDRDs accounted for roughly 30% of patented pharmaceutical sales in 2024, up from less than 1% in 2004. Most of these drugs cost over $200,000 annually, with over 60% exceeding this threshold—especially non-oncology drugs. In 2023, Canadian ex-factory list prices for EDRDs ranked the third highest among the PMPRB11 countries, behind only Spain and Italy.

Conclusions: The study highlights the economic reality of the growing number and cost of EDRDs in Canada. The rise in approvals and expanding market presence underscore the need for effective policies that support individuals with rare diseases while maintaining the sustainability of the health care system.

20

Concomitant use of medical cannabis and Drugs Associated with Risks of Interaction: A longitudinal cohort study

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Background: Cannabinoids interact with multiple drugs with some interactions having significant clinical effects. The worldwide increasing use of cannabis for medical care potentially exposes patients, particularly older patients, to adverse drug reactions.

Objectives: This study aimed to evaluate among the elderly 1) the trends in the concomitant use of cannabis and drugs associated with a risk of significant clinical interaction with cannabinoids (DARSCIC) including those with a narrow therapeutic index (DNTI) such as warfarin, and 2) the risk of warfarin-related bleeding and drug-related intoxication.

Methods: For objective 1, we conducted an interrupted time series study among12599 seniors who received an authorized cannabis prescription in Ontario from 2014-2019, and 48651 controls. Using clinical and medico-administrative data, dispensations of DARSCIC were assessed pre-post cannabis prescription. For objective 2, longitudinal cohorts' studies were conducted in patients concomitantly exposed to cannabis and warfarin (bleeding) or to DNTI (intoxication) versus controls exposed to warfarin or DNTI only.

Results: For objective 1, the trends of DARSCIC/DNTI dispensations were similar in the year before and after cannabis prescription. For objective 2, among 378 patients exposed to cannabis and warfarin, the risk of bleeding was 1.19, 95%CI (0.71-1.98), compared to 1646 controls. The risk of drug-related intoxication was 3.24, 95%CI (1.70-6.15) among 3917 patients exposed to cannabis and DNTI compared to 12213 controls.

Conclusions: The results suggest that the prescription of cannabis does not account for DARSCIC/DNTI. This possible lack of DARSCIC knowledge among cannabis prescribers may expose patients to high risk of intoxication and potentially bleeding.

21

Derivation of a clinical decision rule for emergency department triage of adults with acute infectious diarrhea

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Introduction: Acute infectious diarrhea is often a self-limiting condition. If emergency department (ED) patients at low risk of complications could be identified at triage, they could be redirected to walk-in clinics or sent home. This study aimed to develop a triage risk-stratification score to identify patients who need to see an emergency physician and those who do not.

Methods: A multicenter prospective cohort study was conducted between February 2022 and March 2023 in 4 academic hospitals in Quebec and Montreal (Canada). A convenience sample of adults with at least one episode of 3 loose stools within 24 hours and a Canadian Triage and Acuity Scale score between 3 (urgent) and 5 (non-urgent) was recruited. Data were obtained from the participants at the index visit or the 7-day follow-up phone call. Research assistants were unaware of patient outcomes. The primary outcome was a composite measure of 7-day hospital admission and the need for intravenous (IV) rehydration. Multivariate logistic regression was used to identify the predictors, and bootstrapping was performed to internally validate the final model. The model performance was assessed using the area under the curve (AUC) of the receiver operating characteristic curve. Spiegelhalter's test was used to evaluate the calibration of the model.

Results: Of the 327 participants included, 68.2% were women, with a mean age of 44 years old and 72.5% had a Charlson Comorbidity Index of 0. Forty-two percent of patients were either hospitalized, received IV rehydration, or both. The final model includes the following 9 predictors: arrival by ambulance; heart rate <60 or >100; vomiting; symptom duration of <7 days; regular cannabis use; presence of a caregiver in the ED; coronary heart disease; cancer; rheumatic disease. The final model has an original AUC (95%CI) of 0.75 (0.69-0.80) and of 0.74 (0.72-0.75) after bootstrapping internal validation. The p-value of the Spiegelhalter's test is 0.88. Once the model is converted into a 16-point score based on the weight of each predictor, scores between 0- 4, 5-7, and 8 or higher are associated with a 24.2%, 58.2%, and 88.9% risk of the primary outcome, respectively.

Conclusion: We have derived a score with good discrimination and calibration properties to identify ED patients with acute infectious diarrhea who may not need to see the emergency physician. A validation prospective cohort study is now needed to further validate and refine the score in a larger population.

22

Improving Time to Patient: Insights from the Canadian Cancer Treatment Hackathons

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Background: Canada's drug reimbursement process is complex, involving multiple levels and jurisdictions, resulting in an average wait of 598 days for patients to access new medicines in 2024. Consequently, Canada ranks 19th out of 20 OECD countries for timely access, posing a serious challenge for cancer patients needing new and effective treatments.

Methods: To explore ways to improve access, Colorectal Cancer Canada held The Canadian Cancer Treatment Hackathons from November 2022 to March 2025, engaging over 180 thought leaders from Canada and internationally.

Results: The first Hackathon in 2022 focused on novel ideas within existing systems and identified actionable, time-saving opportunities at each step of the HTA process. The second examined critical success factors from five leading HTA agencies in England/Wales, France, Germany, Italy, and Australia. The third enabled participants to design a new drug review and reimbursement process, identifying five key themes to improve time for patients. The fourth highlighted high-priority ideas to expedite access through international collaboration agreements. The fifth identified actionable changes among key stakeholder groups, including patients, industry, and clinicians. The sixth explored improvements at the negotiation level, including earlier integration of patient and caregiver values. The seventh refined tools for collecting and using patient experience data (PED). The eighth examined outcomes-based agreements (OBAs) to improve access, identifying key success factors for implementation.

Conclusions: These collaborative efforts demonstrate a strong commitment to improving patient outcomes by advancing Canada’s drug review and reimbursement through strategic partnerships, patient engagement, and adopting international best practices to accelerate access to new cancer treatments.

23

Evaluating Healthcare Resource Utilization and Costs of Individuals Diagnosed with Cancer Exposed versus Unexposed to the Edmonton Symptom Assessment System (ESAS)

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Objective: The objective was to evaluate the economic impact on the provincial healthcare system, for cancer patients exposed to a patient-reported outcome measure like the Edmonton Symptom Assessment System (ESAS) to those not exposed.

Methods: This was a retrospective matched cohort study of adults diagnosed with their first-ever invasive cancer between April 1, 2010, and March 31, 2022. Patients were categorized as exposed if they completed the ESAS any time after diagnosis, and unexposed if no ESAS. The date of the ESAS assessment was the index date for the exposed, and an equivalent date for the unexposed. Healthcare resource utilization (HCRU) and total mean healthcare costs (2023 CAD$) per patient year (PPY) were determined.

Results: 139,285 propensity score matched pairs were analyzed. Exposed and unexposed cases were balanced regarding age, gender, cancer diagnosis, and comorbidities. For HCRU, 1.8±6.2 was the mean number of hospitalizations for the ESAS group versus 3.8±14.8 the unexposed group, 71.8±111.8 versus 89.4±177.6 for physician visits, 7.6±16.4 versus 4.4±15.1 for cancer clinic visits, and 62.3±107.8 versus 61.2±114.7 for oral medication prescriptions of the exposed and unexposed groups, respectively. The total mean cost PPY was $59,230 ± $104,328 versus $76,447 ± $183,127 for the exposed and unexposed groups ($p<0.0001$). Cost drivers included hospitalizations and physician visits (higher for unexposed) as well as cancer clinic visits and oral medications (higher for ESAS).

Conclusions: ESAS exposure was associated with lower HCRU and overall lower healthcare costs among cancer patients in the provincial system. This trend could reflect ESAS screening resulting in more outpatient care compared to costlier inpatient care for the unexposed group.

24 – Evaluated Oral Presentation

Measuring the impact of the substitution of innovator biologics with biosimilars on uptake and costs among Ontario public drug benefit recipients

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Background: In Ontario, biologics have historically represented a small proportion of public drug claims but a large proportion of spending. Biosimilars, lower-cost alternatives to biologics, offer a potential solution to the rising spending on biologics. From March 2023 to January 2024, the Ontario Ministry of Health required public drug program beneficiaries to transition from eight innovator biologics to biosimilars. Clinicians were reimbursed for supporting patients who transitioned.

Objective: To evaluate the impact of this biosimilar switch policy on uptake and costs among public drug program beneficiaries.

Methods: We conducted a repeated cross-sectional study using administrative data from April 1, 2019, to June 30, 2024. We examined biosimilar market share, public drug program spending, and clinician support fees. We used interrupted time series analyses to evaluate the policy's impact, and forecasting to estimate cost savings had the policy not been implemented.

Results: In March 2023, biosimilars accounted for 21.7% of prescription claims for biologics included in the switch policy. Drug cost savings were $65.2 million between April 2023 to June 2024, with most savings attributed to non-insulin biosimilars. We estimated savings of $46.6 million in Year 1 (April 2023 to March 2024) and $95.9 million in Year 2 (April 2024 to March 2025). Clinician support fees totaled $3.4 million across the study period.

Conclusions: Ontario's biosimilar policy achieved high biosimilar uptake and substantial cost savings. Future research should examine the impact of this policy on clinical outcomes to assess its broader implications for patient care and long-term sustainability.

25

Comparative assessment of trends in the economic evaluation of therapies for early-stage cancers in Canada: Analysis by tumor site

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Introduction: Cancer remains the leading cause of mortality in Canada, imposing a significant burden on patients and healthcare systems. In a context of accelerated therapeutic development, health technology assessment (HTA) agencies are faced with clinical evidence based on surrogate endpoints, the validity of which as predictors of clinical outcomes remains uncertain.

Objective: This project aims to compare the assessment of surrogate endpoints by the two Canadian HTA agencies for early-stage cancers, stratifying the analysis by tumor site.

Methods: Thirty-two reimbursement reports published from July 2015 to March 2025 were extracted from IQVIA's HTA Accelerator database. The collected data pertains to the favorability of clinicians and HTA agency reviewers towards surrogate endpoints, the recognition of a survival benefit, and the final recommendation issued. A comparative analysis was conducted between disease-free survival and the co-primary endpoint of event-free survival and pathological complete response, as well as between early-stage breast cancer and lung cancer.

Results: Overall, in both investigated tumor sites, clinicians express a favorable opinion towards these endpoints, in contrast to the HTA agency reviewers, which expressed reservations, although a survival benefit is generally acknowledged. Most recommendations are positive (81%), but the negative ones (19%), occurring only in early-stage breast cancer, are mainly due to uncertainty regarding the magnitude of the clinical benefit.

Conclusions: These results suggest an overall acceptability towards surrogate endpoints in early-stage cancers. Furthermore, the gradual evolution of Canadian guidelines suggests a potential reinterpretation of surrogate endpoints in light of new scientific evidence.

26

Enhancing access to CAR T in the Canadian healthcare system

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Background: Chimeric Antigen Receptor T-cell (CAR T) therapy represents a paradigm shift in personalized medicine, offering unprecedented hope for individuals battling rare, complex, and potentially lethal conditions. Ensuring equitable access to this innovation requires strategic planning and collaboration to address the nuances of delivering this relatively complex therapy within Canada's decentralized healthcare system.

Methods: Shift Health facilitated a series of interviews and discussions with an Expert Panel to develop recommendations for the next 2–5 years.

Results: The Panel proposed 5 key recommendations to improve access to CAR T: 1) Increase the capacity to deliver CAR T in Canada through targeted investments, optimizing resource utilization, expanding scope of existing cancer centres and enhancing industry support to upskill HHR. 2) Expand support for patients and caregivers by addressing travel costs and other treatment expenses through strategic funding, enhanced inter-provincial agreements and stronger industry collaboration. 3) Improve physician and patient awareness of CAR T through increased education by leveraging professional networks and developing educational programs to improve awareness. 4) Enhance CAR T data collection by increasing support for the national CTTC registry and educating people receiving cancer treatment about data security and utility to encourage consent. 5) Optimize the cost-efficiency of CAR T for patients and payers by adopting innovative contracting models and exploring the potential benefits of "made-in-Canada" CAR T.

Conclusions: Through strategic investments and coordinated efforts, Canada can maximize the transformative potential of CAR T, ensuring all eligible cancer patients have equitable access to this life-saving therapy.

27

Lithium, Divalproex and Risk of Chronic Kidney Disease: Target Trial Emulation Using Administrative Health Data

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Background: Previous observational studies have suggested an association between lithium use and chronic kidney disease (CKD), but these findings may be affected by pharmacoepidemiologic biases. This study aimed to evaluate the risk of CKD in patients using lithium and/or divalproex, using advanced analytic methods to minimize bias.

Methods: We used provincial administrative health data from Alberta, Canada, to identify individuals with at least one ICD-9 or ICD-10 code for bipolar disorder (BD) and prescriptions for lithium and/or divalproex between January 1, 2008, and December 31, 2020. We applied a target trial emulation framework to simulate a comparison of CKD risk among individuals without mood stabilizers, lithium, divalproex, or both using survival models-weight adjusted for baseline and time-varying covariates and exposures.

Results: A total of 12,708 patients with BD contributed 280,307 person-half-year. Compared to groups of no mood stabilizer, lithium (Hazard Ratio (HR) ranges from 1.08 to 1.26) or divalproex (HR range from 0.47 to 0.51) were not at increased CKD risk. However, when compared to divalproex, both lithium (HR ranged from 2.30 to 2.61) and no mood stabilizers (HR ranged from 1.96 to 2.08) were at increased risk of CKD.

Conclusions: Mood stabilizer treatment was not associated with increased CKD risk overall; however, lithium and no mood stabilizer groups showed higher risk compared to divalproex, possibly reflecting underlying patient differences.

28

Two Decades of ADHD Diagnosis Trends in British Columbia: A Population-Based Study

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Background: To help anticipate future health system needs, this study aimed to evaluate age- and sex-specific shifts in the incidence and prevalence of ADHD diagnoses in British Columbia (BC), Canada.

Method: Using population-based administrative data from 2003 to 2023 in BC, we included residents in four age groups: preschool (3–5), elementary (6–12), high school (13–17), and young adult (18–29). Yearly prevalence and incidence of ADHD diagnoses were calculated. Interrupted time series analyses assessed changes in incident diagnoses following DSM-5 updates in 2013 and the COVID-19 pandemic in 2020.

Results: Among 3,655,001 BC residents, ADHD period prevalence was highest among elementary- (2003 to 2023: 4.0% to 9.5%) and high-school boys (3.5% to 8.9%), while prevalence in high-school girls (1.0% to 6.6%) and young women (0.3% to 5.7%) surpassed that in elementary-school girls (1.2% to 4.4%).

Among 2,743,914 ADHD-naïve residents, 110,874 men and 74,264 women were newly diagnosed. Incidence rose across all age and sex groups, peaking in elementary-school boys (2013 to 2023: 128.0 to 346.2 per 10,000). DSM-5 accelerated ADHD diagnoses in elementary- and high-school boys and girls (additional incidence ranging from 3.5 to 9.8 per 10,000 annually). Post-COVID, ADHD diagnoses surged in 2021 by 107.3 (95% CI: 95.8-118.7) per 10,000 high-school girls and 123.1 (95% CI: 115.9-130.2) for young women, shifting peak incidence from elementary school to older age groups for girls.

Conclusions: This study revealed accelerating increases in prevalence and incidence of ADHD diagnoses, particularly among teenage girls and young women post-COVID.

29 – Evaluated Poster Presentation

ADHD Pharmacotherapy Patterns in Canada: Trends and Summer Break Effects in a

Population-Based Study

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Background: With increasing recognition of ADHD across the lifespan, less is known about how pharmacologic treatment patterns evolve across developmental stages. Amid concerns about overprescribing driven by academic pressures rather than clinical need, it is important to monitor how ADHD medication use aligns with the academic calendar. This study aimed to (1) describe temporal trends in ADHD medication use, and (2) evaluate the impact of summer school breaks on prescribing patterns.

Methods: Using linked administrative health data from British Columbia (2014–2023), we analyzed individuals with ADHD diagnoses or filled prescriptions by four age groups: preschoolers (ages 3–5), elementary school–aged children (6–12), high school–aged adolescents (13–17), and young adults (18–29). Trends in dispensation over time and during July–August were analyzed using generalized estimating equations. No clinically meaningful differences were observed in temporal or seasonal prescribing patterns by sex.

Findings: Among 192,383 individuals included, 113,139 (58.8%) were male; 153,009 (79.5%) filled ≥1 ADHD prescription, totaling 3.3 million dispensations. Compared to a decade ago, use of extended-release stimulants declined in preschoolers diagnosed with ADHD (RR [95% CI]: 0.66 [0.58–0.76]) but increased among young adults (RR [95% CI]: 1.40 [1.38–1.42]). Stimulant use declined during summer breaks in high-school (RR [95% CI]: 0.92 [0.91–0.92]) and elementary-school students (RR [95% CI]: 0.94 [0.94–0.94]).

Conclusion: We observed inconsistent ADHD medication use among younger populations, including declining stimulant use in preschoolers and periodic drug holidays in school-aged children, raising concerns about prescribing influenced by non-clinical factors.

30

Evaluating feasibility of expanding an Inherited Retinal Dystrophy (IRD) Patient Registry for longitudinal data collection

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Background: Fighting Blindness Canada's IRD Patient Registry was established in 2004 and collects baseline genetic and clinical data from Canadians diagnosed with an IRD. This Registry has supported patient recruitment for clinical trials and research; however, a lack of longitudinal data limits its ability for evidence generation. We aimed to assess the feasibility of expanding the IRD Registry to collect longitudinal data by evaluating the Registry platform setup including data collection and data elements, stakeholder perspectives of expansion including the patient, and resourcing and logistical needs.

Methods: An evaluation of the existing Registry was conducted and combined with a literature review of registries (IRD and rare disease registries (RDRs)) and IRD clinical trials to identify opportunities for expansion. We also conducted 13 stakeholder interviews with five patients, four site leads/staff, one FBC staff, and three RDR representatives.

Results: This evaluation identified current challenges faced by the IRD registry and provided recommendations to meet these challenges. Patients interviewed were open to providing more clinical information to help advance research. From site lead interviews, we identified challenges unique to each site and the need to standardize operational processes. The main barrier to Registry expansion was limited resources, making it difficult for sites to sustain enrollment and data collection.

Conclusion: RDRs require substantial resourcing to operate and require dedicated effort from all stakeholders involved for long-term sustainability. Increased funding and standardized processes can help RDRs collect patient data for real-world evidence generation that can inform health care decision-making and improve patient outcomes.

31

Understanding the use of single-arm trials in health technology assessments (HTAs) for CDA-AMC review of oncology drugs

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Background: It is unclear how single-arm trials are viewed by HTA bodies in Canada. The objective was to assess the proportion of single-arm trials in HTA submissions completed over the past 3 years and to determine the association between study design and recommendation outcomes.

Methods: All CDA-AMC reviews in oncology, defined as “oncology pharmaceutical” and “oncology cell and gene therapies” with recommendations between January 1, 2022, and December 31, 2024, were analyzed. Clinical evidence from CDA-AMC’s recommendation report were reviewed to identify study design and recommendation outcomes. Conditional recommendations were considered positive.

Results: A total of 93 recommendations were published by CDA-AMC, with 41 in 2022, 22 in 2023, and 30 in 2024. Majority (69.9%) of the HTA reviews used Phase III trial data as evidence whereas 27.0% of reviews used single-arm trials as evidence. The proportion of reviews using single-arm trials have decreased from 31.7% in 2022 to 13.3% of recommendations given in 2024. Overall, 76.0% of reviews with single-arm trials received a positive recommendation. Notably, 53.8% received a positive recommendation in 2022 whereas all recommendations in 2023 and 2024 were positive. All submissions through oncology cell and gene therapies with single-arm trials received a positive recommendation.

Conclusion: Over time, fewer single-arm trials submissions were being reviewed, but those that were reviewed received more favourable recommendations. This may suggest better understanding of when single-arm trials, with supplemental ITCs, are sufficient for HTA and when comparator trials may be required. However, further research is required to better understand these trends.

32

Risk of herpes zoster in adults with immune-mediated inflammatory diseases and associated costs in Ontario

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Background: Studies suggest higher herpes zoster (HZ) risk among individuals with immune-mediated inflammatory diseases (IMIDs), such as rheumatoid arthritis (RA), systemic lupus erythematosus (SLE) and inflammatory bowel disease (IBD). We quantified HZ risk in the IMID population in Ontario and healthcare costs among those with HZ.

Methods: This retrospective cohort study using administrative claims from ICES captured incident HZ diagnoses (cases) among Ontarians ≥18-years between 01/04/2011 and 31/03/2022. An all-history lookback to 01/04/2002 identified diagnosed IMIDs by specified diagnostic codes. Conditional logistic regression quantified the association (adjusted odds ratio [aOR]) between IMID and HZ (reference group: no IMID). Associated costs from 7 days before to 365 days after first HZ visit were compared to individuals without HZ (controls).

Results: Among 617,352 HZ cases, 368,914 had IMIDs/other chronic conditions. The most prevalent IMIDs were RA (39,368; 6.38%) and SLE (29,032; 4.70%). IMIDs were associated with increased HZ risk (aOR [95% confidence interval] of ≥1 IMID: 1.31 [1.30–1.32]). HZ risk associated with specific IMIDs were: IBD 1.46 (1.42–1.50), multiple sclerosis 1.19 (1.16–1.23), psoriatic arthritis 1.16 (1.14–1.18), RA 1.24 (1.23–1.26), and SLE 1.25 (1.24–1.27). Cases incurred an additional mean direct healthcare cost of $1,475.55 (95% CI: $1,403.28–$1,511.83) than controls; this difference between cases and controls was greater among patients with IMIDs/other chronic conditions ($1,640.03 [95% CI: 1,555.04–1,725.03]).

Conclusion: Compared with controls, HZ risk was higher in the IMID population. Preventive strategies such as HZ vaccination could be considered to reduce HZ occurrence and associated costs.

33

Respiratory syncytial virus (RSV) hospitalization, discharge patterns, and associated costs among adults aged ≥50 years in Ontario, Canada

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Background: Respiratory syncytial virus (RSV) can cause lower respiratory tract disease, causing substantial morbidity/mortality. Older adults and individuals with chronic conditions face increased risks of RSV-related complications and/or exacerbation of underlying disease, generally effecting considerable healthcare burden globally. As Canada-specific data are limited, we characterized the burden of RSV-hospitalized cases (RSV-H) versus matched controls of influenza-hospitalized cases (Flu-H) or the general population (GenPop) in Ontario.

Methods: RSV-H≥50-years-old (Sep/2010–Aug/2023) were identified retrospectively using healthcare data from Institute for Clinical Evaluative Sciences. RSV-H seasonal incidence, baseline demographics and comorbidities, healthcare resource utilization (HCRU), and direct healthcare costs (2022/CAD) were evaluated.

Results: 6,705 RSV-H were identified; mean annual seasonal incidence was 9.42/100,000 population. 5,298 eligible RSV-H matched with Flu-H or GenPop controls with comparable baseline characteristics. All-cause-mortality (1-year-post-index) was greater for RSV-H than Flu-H (29.7% versus 25.5%; p<0.001) and GenPop (29.5% versus 9.3%; p<0.001). All-cause-re-admissions 30/60/90-days-post-index were numerically higher for RSV-H (11.8%/17.7%/22.4%) than Flu-H (11.6%/17.5%/21.6%); RSV-H re-admissions were highest from exacerbation of underlying cardiovascular disease (4.6%/7.6%/9.8%), pneumonia (3.3%/4.9%/6.2%), and chronic obstructive pulmonary disease (1.7%/3.1%/3.9%). HCRU (1-year-post-index) was greater for RSV-H than GenPop, but generally equivalent to or higher than Flu-H. Total direct healthcare costs (1-year-post-index) were greater for RSV-H than Flu-H ($62,051 versus $58,019; p<0.001) and GenPop ($61,272 versus $24,391; p<0.001).

Conclusions: Findings demonstrate considerable healthcare burden from RSV in Ontario comparable to or greater than influenza, and greater than healthy individuals. Public health measures (e.g., vaccination) can mitigate short and long-term impacts of RSV in older adults, particularly those with comorbidities.

34

Predicting burn mortality: score accuracies in a Canadian cohort

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Background: In-hospital mortality remains a key indicator of care quality for burn injuries. The original Baux Score (1961), based on age and total body surface area burned (%TBSA), predicted mortality, with scores over 75 indicating high risk. The Revised Baux Score (2010) added inhalation injury as a third factor, with scores over 165 suggesting likely death. However, whether these thresholds remain valid in clinical practice warrants re-evaluation.

Objective: Test current common scoring systems for predicting death before discharge in adult patients with acute burns in our multi-center cohort.

Methods: A retrospective cohort study of burn patients in the province of Quebec was conducted using health administrative databases. We included all patients aged ≥ 14 years who were admitted for a burn injury between April 1, 2006, and March 30, 2021. Patients without %TBSA were excluded. Descriptive analyses of patient and injury characteristics were examined based on survival status at discharge. We examined current scoring systems for predictive burn mortality and assessed each system's discrimination and calibration.

Results: Preliminary results indicate that among the 6630 eligible patients, 285 died (4%) during their initial hospitalization. Most patients were male (69%), with an average age of 49 years and an average TBSA of 10%. Survivors had an average Baux Score of 57 and Revised Baux Score of 58, compared to 99 and 102, respectively, for those who died.

Conclusions: Although the Baux Score appears to predict mortality accurately, Revised Baux Score thresholds for high-risk patients may require adjustment to better reflect current outcomes.

35

An evaluation of the use of the Incremental Cost-Effectiveness Ratio (ICER) Threshold in Canadian Cost-Effectiveness Analyses Studies

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Background: Incremental Cost-Effectiveness Ratio (ICER) thresholds are important for determining the funding of cancer and other treatments. They represent the maximum amount a government is willing to pay for health benefits. While previous research has examined trends in ICER thresholds over time in the US, only Canada's Drug Agency submissions have been examined in Canada. Therefore, among Canadian published studies, we examined trends over time in ICER thresholds variation across disease categories.

Methods: We included Canadian articles published from 1983 to 2024 in the Tufts Cost-Effectiveness Registry, which complies data from systematic reviews. The dependent variable was the ICER threshold, measured in dollars per quality adjusted life year (QALY). We conducted descriptive analyses to examine trends in ICER thresholds over time and compared cancer versus non-cancer diagnosis. We will also include results from a multinomial logistic regression and other explanatory variables (pharmaceutical versus other interventions, societal versus health care perspectives).

Results: Approximately 70% of studies from 1983 to 2010 and 75% from 2020 to 2024 used an ICER threshold of $50,000 per QALY. There was no increase in use of ICER thresholds of $100,000 or more per QALY. Studies focused on cancer were more likely to use $100,000 per QALY threshold (cancer: 53.6%, non-cancer: 21.6%).

Discussion: Unlike the US, most Canadian studies have consistently used an ICER threshold of $50,000 per QALY, with minimal change over time despite decades of inflation. This suggests that many recommendations may have required a significant price reduction to fund cancer and other treatments.

36

Use of patient support program data for real-world evidence generation: opportunities and pitfalls illustrated in a case study assessing trastuzumab deruxtecan among patients with breast cancer

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Background: In Canada, patient support programs (PSPs) help patients access specialty medications prior to reimbursement. PSPs are also a rich source of real-world evidence (RWE) as data can be collected across the patient journey. Here, we discuss opportunities and pitfalls associated with using Canadian PSP data for RWE, illustrated in a case study assessing trastuzumab deruxtecan (T-DXd) in breast cancer.

Methods: A hybrid longitudinal cohort study was conducted among patients with HER2-positive and HER2-low metastatic breast cancer receiving treatment with T-DXd. Mainly, this study leveraged secondary data from the PSP, which included clinical/demographic characteristics and treatment information (e.g., duration, modification). These data were supplemented with primary data collected via an optional patient questionnaire (e.g., follow-up on therapies). Key outcomes included early discontinuation rates, dose modifications, time to treatment discontinuation, and reasons for treatment discontinuation.

Results: This study showed that it was feasible to generate robust RWE using PSP data. We employed several strategies to ensure the quality and rigor of RWE, including study registration (NCT06386263), strict data governance/quality processes, third-party verification of analyses, a robust study design to meet RWE reporting guidelines, and an optional patient questionnaire for additional baseline data collection. Additionally, this study leveraged unique strengths of PSPRWE, including national representation of patients across Canada and the earliest opportunity to assess T-DXd in the real-world. A few challenges, common to PSP RWE, were identified. First, due to reliance on secondary data from the PSP, all potential prognostic/confounding variables were not captured. Second, there were methodological/data rigor challenges (e.g., limited follow-up time, perceived bias with industry-funded PSP). These challenges were mitigated using strategies highlighted above.

Conclusion: RWE using PSP data offers unique opportunities to enhance decision making and improve patient outcomes. However, RWE leveraging the PSP should be planned early, ensure transparency/methodological rigor, and outline all known limitations.

37

Real-World Persistence and Adherence to Cabotegravir/Rilpivirine Long-Acting Injectable Among Canadians with HIV-1 Enrolled in a Patient Support Program

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Background: Patient Support Programs (PSPs) are designed to help healthcare providers and patients navigate the challenges of accessing and initiating specialty medications, which may impact treatment adherence. In 2020, ViiV Healthcare ULC launched a Cabotegravir+Rilpivirine Long-Acting injectable (CAB+RPV LA) Supports Program for virologically stable and suppressed people with HIV-1 (PWH) initiating CAB+RPV LA. This study evaluated real-world persistence and adherence to CAB+RPV LA among PWH in the PSP.

Methods: This retrospective study identified PWH (≥18 years-of-age) enrolled in the CAB+RPV LA PSP who started CAB+RPV LA between 18/10/2022 and 30/05/2024. PWH were followed from first injection (index date) up to 12-months. PWH were censored if they opted out of the PSP program (not due to treatment discontinuation), died, or reached the end of the study period. Outcomes included persistence (proportion persistent on medication at 6- and 12-month follow-up) and adherence (proportion of days covered [PDC] at 12-month follow-up).

Results: We identified 628 eligible PWH who initiated CAB+RPV LA in the PSP (mean age: 46.4 years [SD 12.3], 75.3% male, 55.3% reside in Ontario, 87.7% on prior single-tablet ART). Of the eligible PWH, 603 had 6-month follow-up data and 431 had 12-month follow-up data. At 6-months, 99% (597/603) were persistent on medication (min-max: 30-180 days). At 12-months, 96.8% (417/431) were persistent (min-max: 30-365 days) and 94.9% (409/431) had adherence rates ≥90% (PDC).

Conclusion: Among PWH enrolled in the CAB+RPV LA Supports Program, persistence and adherence to CAB+RPV LA were high, suggesting the PSP may contribute to treatment success.

38

A Pharmacoepidemiologic Study of Antibiotics Prescription Patterns in a Tertiary Care Hospital

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Background: Optimal and rational drug prescribing - particularly antibiotics - is necessary to improve patients' health and avoid antibiotic resistance. Several reports observed inadequate prescribing practices in tertiary care hospitals from developing countries.

Objectives: This study aimed to assess antibiotics prescribing practices in a tertiary care hospital in Iran.

Methods: A retrospective study was conducted, using data from Zeinabiyeh Hospital, Shiraz, Iran with an average of 500 admissions per day. Prescription data were collected from inpatients' records of 23 wards and clinics from March 2019 to March 2020.

Results: We included 13,909 patients with an average hospitalization time of 3.12±5.491 days. Information on 371,056 prescribed medications was included and analyzed. There were 9871 (70.2%) orders with at least one antibiotic agent. The average number of antibiotics in the hospital was 5.55 and in neonatal wards it was 13.66 per patient. The most common prescribed antibiotics were ampicillin 1gr vial (18.6%), cefazolin 1gr vial (14.0%), followed by amikacin sulfate 100 mg vial (11.2%) and cephalexin 500 mg capsule (10.5%) (total of 54843 antibiotics prescriptions). Fifty% of all vials of ampicillin sodium were prescribed in the neonatal ward, which had the most antibiotics prescribed (24.3%). Also, in entire eight wards of neonates and NICU and phototherapy, the most common antibiotic was ampicillin (35.7%), even the most common prescribed drug among all the drugs (7.2%).

Conclusion: This study showed that although the neonatal ward has 15.7% of total prescriptions, it has the highest portion of total antimicrobial agents prescribed in the hospital (24.3%). newborns are often prescribed extended antibiotics therapy for suspected neonatal infectious with short and long-term effects. Careful use of antibiotics in neonates is crucial to prevent adverse events and resistance among this vulnerable population.

39

Potential Drug-Drug Interactions in Pediatric Patients with Cancer: A Hospital-Based Prospective Study

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Background: The combination of chemotherapeutic, anti-microbial, and supportive care medications that pediatric oncology patients receive place them at higher risk for drug-drug interactions (DDI). Monitoring and detecting potential DDI in the pediatric oncology population is crucial to reducing complications from adverse events.

Objectives: The primary objective of this study was to examine the prevalence of potential DDIs, both total and clinically relevant, in hospitalized pediatric patients at the oncology unit. The secondary objectives were to describe the most common DDIs in these children and to investigate the risk factors associated with the presence or absence of clinically relevant DDIs.

Methods: A prospective observational study was conducted, with data collected during each patient course of admission at the Amir oncology Hospital affiliated to Shiraz University of Medicine from November 2019 to June 2020. We compared two commonly used drug interaction databases: LEXI INTERACT™, and Drugs.com™. The study did not focus on the clinical consequences of drug interactions, but rather on their potential for occurrence. All patients younger than 18 years-old and taking treatments with two or more drugs at the hospital were included.

Results: Eighty patients were included in this study, 59% were male while 41% were female. The most common malignancy type detected was leukemia, particularly acute lymphocytic leukemia, which accounted for 31% of cases. Most of the potential drug-drug interactions (PDDI's) were between anti-neoplastic drugs (54%), where 90% of them were moderate, 4.5% major, and 4.5% minor. We observed 33% of PDDI were between non-anti-neoplastic drugs, while 50% were type C, 21.5% type B, 14.2% type A, and 14.2% type D, according to Lexi interact analyzer. DDIs between anti-neoplastic- and non-anti-neoplastic drugs accounted for 14.2% of all DDIs, where 66.6% were type C and 33.3% type D. The most common interaction among anti-neoplastic drugs was detected between Methotrexate-Vincristine (MTX-VCR), which may cause liver complications with moderate severity. MTX was the most common drug involved in DDIs, followed by VCR (both with moderate severity).

Conclusion: The study shows a high prevalence of DDIs in pediatric cancer patients in a hospital setting. Physicians and clinical pharmacists should collaborate to develop a routine computer-based screening method to identify and prevent the DDIs risk in hospital settings of developing countries.

40

Prenatal Exposure to Antiseizure Medications and ADHD Risk in Children

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Background: Antiseizure medications (ASMs) are frequently prescribed during pregnancy, but their potential effects on neurodevelopmental outcomes in children, such as attention-deficit/hyperactivity disorder (ADHD), remain uncertain.

Objective: To assess the association between prenatal ASM exposure during the second and/or third trimester and the risk of ADHD in offspring.

Methods: A population-based cohort study was conducted using data from the Manitoba Research Data Repository (1998-2019). Pregnancies were classified by epilepsy diagnosis and ASM exposure. High-Dimensional Propensity Score (HDPS) analysis accounted for maternal factors, including age, asthma, chronic pain, psychiatric disorders, area of residence, socioeconomic status, multiple births, diabetes, hypertension, and the 300 most frequent covariates. While HDPS adjustment accounted for diagnostic codes, severity assessment remains limited in administrative data. Inverse Probability of Treatment Weighting (IPTW) with Cox proportional hazards regression was applied to assess ADHD risk. Children were followed from birth until ADHD diagnosis, age 18, death, or study end.

Results: The study included 251,109 pregnancies, of which 3,271 involved ASM exposure during pregnancy. ADHD incidence was 15.1% among children exposed to ASMs with maternal epilepsy, 18.6% in those exposed without maternal epilepsy, and 11.2% in the unexposed group without epilepsy. HDPS IPTW-adjusted models showed an increased risk of ADHD across the overall exposed cohort (HR = 1.99, 95% CI: 1.96-2.02), particularly among pregnancies without epilepsy (HR = 2.38, 95% CI: 2.34-2.42). No significant association was observed in pregnancies with epilepsy (HR = 1.00, 95% CI: 0.96-1.05).

Conclusion: Prenatal exposure to ASMs was associated with a higher risk of ADHD in children, particularly in pregnancies without maternal epilepsy. These findings suggest a potential association and underscore the need for further research and careful consideration of ASM use during pregnancy, especially for non-epilepsy-related indications.

41

Health system evidence from British Columbia on the survival impact and cost-effectiveness of tumour-agnostic precision oncology

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Background: Precision oncology uses next generation sequencing (NGS) to identify therapeutic targets independent of cancer type. Globally and across Canada, health system adoption of precision oncology is uneven due to uncertain real-world clinical and economic impacts. We determined the cost-effectiveness of a tumour-agnostic NGS panel compared to single-gene testing for advanced cancers.

Methods: We used real-world individual-level data for patients with advanced cancers in

British Columbia to emulate a randomized trial. We 1:1 matched NGS patients with controls using genetic algorithm-based matching, a machine learning approach that finds optimal matches based on a generalized weighted Mahalanobis distance metric. Following matching, we estimated survival differences using Weibull regression survival analysis. We calculated mean life years gained (LYG), incremental costs, incremental net monetary benefit (public healthcare payer perspective; 2021CAD) using inverse probability of censoring weighted linear regression and nonparametric bootstrapping.

Results: We matched 1,102 patients receiving NGS to 1,102 controls, achieving balance on all covariates and successfully emulating a randomized trial. We found a statistically significant reduced hazard of death (HR: 0.86, 95%CI: 0.78, 0.96]. Incremental LYG were 0.14 (95%CI: 0.05, 0.23), almost 2 months of additional survival. Incremental health system costs were $4,473 (95%CI: $-1,255, $10,364). Net-benefit was $3,171 (95%CI: -$2,090, $9,305) at $50,000/LYG, with an 87% probability that BC's tumour-agnostic NGS panel was cost-effective.

Conclusion: Tumour-agnostic NGS for advanced cancers is likely cost-effective for health systems at an NGS price of $1,200 per patient. RWE from learning healthcare systems are key to supporting policy for reimbursement of precision oncology interventions.

42

Use of Cancer Therapies for Advanced Non–Small Cell Lung Cancer with an Oncogenic Driver Mutation

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Background: Lung cancer is the most frequently diagnosed cancer in Canada and the primary cause of cancer-related deaths. Immune checkpoint inhibitors (ICIs) are used following targeted gene therapies and chemotherapy to treat non-small cell lung cancer (NSCLC), however their effectiveness remains uncertain. We aimed to understand treatment patterns for patients starting targeted therapy for NSCLC and assessed the feasibility of a subsequent study examining the effectiveness of ICI after targeted therapy.

Methods: We examined population-based data from Ontario, Alberta, and British Columbia from the Canadian Cancer Real-world Evaluation (CCRE) platform, and additional data from patients captured in the Personalize My Treatment registry treated in Quebec, New Brunswick, and Nova Scotia to conduct this retrospective cohort study. We tracked up to 4 treatment exposures to determine NSCLC treatment sequence.

Results: We identified 4,222 patients who received targeted therapy as first-line treatment for NSCLC. Patients were in their mid-sixties when starting targeted therapy and the majority were female. We found that 62% and 58% of patients respectively had targeted therapy in the second and third exposures. ICI were used in 4% of patients while 25% received single agent chemotherapy for their third treatment. In the fourth exposure 14% received ICIs vs 30% single-agent Chemotherapy.

Conclusion: For patients who receive subsequent treatments after first-line targeted therapy, the most common options are different targeted therapies and platinum doublet chemotherapy. The number of patients who received ICIs for their third exposure was too small to conduct a comparative effectiveness study of ICIs against other therapies.

43

Re-treatment with Immune Checkpoint Inhibitors: Utilization Analysis

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Background: Immune checkpoint inhibitors (ICIs) block inhibitory pathways to enhance immune responses against tumours. Pembrolizumab has improved overall survival and disease control in advanced melanoma, non-small cell lung cancer (NSCLC), and classical Hodgkin lymphoma (cHL). Cemiplimab has shown disease control in cutaneous squamous cell carcinoma (CSCC). Both treatments are publicly funded in Canada with fixed durations for initial treatment and re-treatment. The aim of this study was to assess the utilization of such therapies in the initial and re-treatment settings to aid policymakers in their decision-making for the funding of a second re-treatment.

Methods: We conducted a retrospective, population-based cohort study analyzing pembrolizumab use in advanced melanoma, NSCLC, and cHL, and cemiplimab use in CSCC across Ontario, Alberta, and British Columbia (2016–2022). We evaluated utilization of these drugs across initial treatment and re-treatment periods, and characterized drug utilization over time, treatment duration, and re-treatment patterns, stratified by ICI agent and

treatment indication.

Results: We identified 9,845 patients receiving pembrolizumab and 409 patients treated with cemiplimab. Most patients did not complete initial treatment, and re-treatment was rare, e.g. 27 months from start, 6 – 13% of NSCLC patients in Ontario, Alberta and British Columbia finish it. The average duration of initial pembrolizumab treatment was ranged from 10.8 – 20.0 months for NSCLC, melanoma and cHL. For cemiplimab, it was 15.0 months.

Conclusion: Few patients undergo re-treatment with pembrolizumab or cemiplimab, and fewer still complete it. These findings suggest that a limited number of individuals would be eligible for a second re-treatment.

44

Real-world experience with therapeutics for ATTR in the Canadian population

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Background: Transthyretin amyloidosis (ATTR) is a systemic disorder marked by organ deposition of misfolded transthyretin aggregates. In ATTR, significant morbidity, manifesting as cardiomyopathy (ATTR-CM), can result from cardiac TTR amyloid deposition. Recent pharmacotherapies have transformed ATTR-CM management by specifically targeting the disease's pathophysiology. However, more real-world evidence is needed regarding utilization experience with these treatments for clinical practice. This study describes the real-world experience of Canadian patients on the currently approved ATTR-CM stabilizers Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis).

Methods: This retrospective observational cohort study leveraged IQVIA's Private Drug Plan and Ontario Drug Benefit claims databases from April 2019 to September 2024 to investigate polypharmacy, treatment history, adherence, and persistence of patients initiated (indexed) on Vyndaqel or Vyndamax who were active in the study period. Adherence and persistence with the medications were assessed over a 12-month period post-index. Polypharmacy and treatment history were assessed over a 6-month period pre-index. Descriptive statistics were reported.

Results: The analysis included 351 patients. Over half of patients using Vyndaqel (55.2%) and Vyndamax (61.6%) had medication claims across ≥7 Anatomical Therapeutic Chemical

level 2 classes in the lead-up to index; diuretics were the most common treatment used, followed by beta-blockers and mineralocorticoid receptor antagonists. 81.5% of patients were adherent to Vyndaqel and 86.0% adherent to Vyndamax. Vyndamax showed a 12-month persistence rate of 79.5%, with Vyndaqel at 66.5%.

Conclusion: High polypharmacy rates suggest that ATTR-CM patients have a large medication burden. Despite this, adherence to ATTR-CM medications remained strong, though persistence on drug could be improved.

45

Biosimilar market entry and jurisdictional variability in public reimbursement: ustekinumab as a case example

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Background: Stelara (ustekinumab) is an originator biologic approved for multiple indications including plaque psoriasis, psoriatic arthritis, Crohn's disease (CD), and ulcerative colitis (UC). Despite positive reimbursement recommendations from Canada's Drug Agency (CDA) and Institut national d'excellence en santé et services sociaux (INESSS) for certain indications, pan-Canadian Pharmaceutical Alliance (pCPA) negotiations have not always resulted in product listing agreements for Stelara across jurisdictions. The recent market entry of several ustekinumab biosimilars presents an opportunity to reassess public reimbursement approaches to biosimilars with multiple indications across Canada.

Methods: A descriptive policy analysis was conducted using publicly available data on CDA and INESSS recommendations, pCPA negotiations, and provincial formulary listings before and after biosimilar market entry. Reimbursement trends for Stelara and its available biosimilars were compared across multiple indications and provinces.

Results: Jurisdictional biosimilar transition or "switch" policies have accelerated the uptake of ustekinumab biosimilars, although Saskatchewan and the Yukon have yet to list any biosimilars for ustekinumab (as of June 2025). Despite receiving a recommendation from CDA to not list Stelara at the submitted price for psoriatic arthritis and limited success in pCPA negotiations for Stelara reimbursement in CD and UC, many provinces have expanded access for ustekinumab to include these indications that were previously not publicly reimbursed for the originator biologic.

Conclusion: Biosimilar entry may mitigate access barriers even when health technology assessments or pricing negotiations were unsuccessful for the originator biologic.

46

Canadian generic market trends and international comparison, 2018-2024

O'Shea B

Patented Medicine Prices Review Board

Background: In Canada, over 75% of the annual volume of prescription drugs sold are generic medicines, representing an important cost control option for payers. The purpose of this study is to analyze utilization and spending in Canadian and international generic markets over a six-year period.

Methods: The primary source for this study is the IQVIA MIDAS® database, containing sales, unit quantity, and list prices of prescription generics in Canada and internationally. Population and exchange rates are from the OECD. Analysis of generic sales, utilization, and per capita spending is conducted from 2018 to 2024. Sales-weighted price levels in Canada and comparator countries are calculated for a basket of oral solid generic medicines with at least $1 million CAD in annual sales and a year on the Canadian market.

Results: Inflation-adjusted generic sales in Canada increased 20.4% from 2018 to 2024. Generic utilization rose steadily over the same interval, from 76.1% of total units sold to 80.5%. The US was the only comparator country with higher per-capita generic spending than Canada. Meanwhile, the generic share of sales in Canada fell from 24.2% in 2018 to 23.0% in 2024. The sales-weighted price index for the select oral solids was 1.1% lower at the end of 2024 than in 2018.

Conclusion: Even as usage has increased, the price index for select Canadian oral solids has been steady over the study period. This research provides an overview of generic markets in Canada and other countries, showing a common trend of increasing utilization.

47

Exploring the Differences in Workload and Treatment Patterns in Academic vs Community Care Settings

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Real World Solutions, IQVIA

Background: Canadian cancer care is often organized by academic and community treatment settings with varying levels of outreach and coordination. Gaining insights into the oncology treatment landscape using real-world data can help understand differences in healthcare delivery.

Methods: This analysis used the 2024 IQVIA Oncology Practice Insights (OPI) and syndicated Oncology Patient Outcomes (OPO) datasets obtained from oncology physicians across Canada to compare real-world patient workloads and treatment patterns of patients with late-stage HR+/HER2-negative breast cancer between academic and community treatment settings.

Results: The overall cancer patient workload of community-based physicians were larger when compared to academic-based physicians (OPI: 27%; OPO: 30%, relative proportion). Among breast cancer patients, academic-based physicians had a higher proportion of late-stage breast cancer patients (OPI: 41%; OPO: 53%) than community-based physicians (OPI: 31%; OPO: 50%), and a higher proportion of patients on third or later lines of therapy (OPI: 22%; OPO: 33%) compared to community-based physicians (OPI: 15%; OPO: 16%). Using OPO data, patients with late-stage HR+/HER2-negative breast cancer treated in academic settings tended to be older (average age 63 vs 58 years) and were less likely (90% vs 95%) to be prescribed CDK4/6 inhibitors in the first-line setting.

Conclusion: This real-world data analysis suggests that differences exist in healthcare delivery between academic-based and community-based settings in Canada. Academic-based physicians may be referred more patients with advanced disease and have more treatment options available such as clinical trials and novel therapies. Future exploration into provincial differences and association between specific network models and healthcare outcomes may improve healthcare delivery.

48

Benchmarking CDA-AMC submissions, pCPA negotiations, and time-to-listing processes in Canada for priority review drugs

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Real World Solutions, IQVIA

Background: Health Canada's Priority Review (PR) designation is a process to expedite the review of promising new drugs for Canadians. We aim to use a data-driven approach to assess if overall time-to-listing and market access outcomes are different for drugs with and without a PR designation.

Methods: This study used the IQVIA Market Access Metrics database with data up to March 2025. All non-oncology CDA-AMC new drug and indication reviews with Notice of Compliance (NOC) post-2010 were included. PR status was referenced from the Health Canada NOC database. Regulatory review time was calculated from the 1st of the review-initiated month to date of NOC.

Results: The number of non-oncology CDA-AMC reviews was 96 and 383 for PR and non-PR, respectively. The median regulatory review time was 196 days for PR and 318 days for non-PR. The CDA-AMC review process yielded more positive or conditional recommendations for PR (87%) compared to non-PR (76%) with similar review times (median of 203 days vs. 211 days for PR and non-PR, respectively). The pCPA negotiation process yielded more successful negotiations (79% vs. 64%) and longer negotiations (median of 217 days vs. 160 days) for PR. Time from Health Canada submission to 1st province listing was shorter for PR (median of 727 days vs. 939 days).

Conclusion: Drugs with PR status have considerably quicker review times by Health Canada and approached the review target of 180 days. The accelerated timeline translated to reaching 1st province listing roughly 7 months earlier, which facilitated quicker access for drugs with PR designation.

49 – Evaluated Oral Presentation

No Cause for Concern: Early eGFR Decline Following SGLT2 Inhibitor Use in People with HIV Mirrors Trends of the General Population

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Background: Sodium-glucose cotransporter 2 inhibitors (SGLT2i) are nephroprotective but are associated with early eGFR decline, also termed "eGFR dip." Despite elevated risk of kidney disease, this phenomenon is understudied among people with HIV (PWH).

Methods: In a 1:1 propensity score-matched cohort study using data from 9 Centers for AIDS Research Network of Integrated Clinical Systems (CNICS) sites, we compared new SGLT2i users with new users of other antihyperglycemic classes. We estimated time to ≥10% and ≥30% declines in eGFR within 6 months of treatment initiation using Cox proportional hazards models and analyzed eGFR change using linear mixed models. Additionally, longer-term eGFR trends over 24 months were visualized using locally weighted scatterplot smoothing (LOWESS) curves.

Results: Among 1554 eligible PWH, we obtained 295 matched pairs. At 6 months, SGLT2i users had a higher incidence of ≥10% (58.2% vs. 37.4%; aHR 1.79, 95% CI: 1.40–2.28) and ≥30% (17.3% vs. 9.8%; aHR 1.69, 95% CI: 1.05–2.73) eGFR declines compared to users of other antihyperglycemic classes. Mean eGFR change at 6 months was −2.62 mL/min/1.73m² for SGLT2i versus 0.05 mL/min/1.73m² for other classes. Long-term eGFR trends revealed an expected initial decline following SGLT2i initiation, followed by stabilization and a slower subsequent decline compared to other classes.

Conclusion: Acute eGFR dips were more common in PWH initiating SGLT2i, but declines were modest, transient, and consistent with patterns seen in the general population. Further research is needed to assess long-term renal effects of SGLT2i in PWH.

50

List price assessment of expensive drugs for rare diseases to determine factors that influence pCPA negotiations

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Background: Drugs for rare diseases (DRDs) have historically faced reimbursement challenges in Canada due to high data uncertainty and costs. This assessment aims to identify factors and trends from CDA reimbursement recommendations for expensive DRDs, including recommended price reductions that influence pCPA negotiation timelines and success rates.

Methods: CDA reimbursement recommendations between 2019 and 2025 were reviewed to identify non-oncology DRDs using the Orphanet database, given the lack of orphan drug designations in Canada. DRDs were categorized by annual cost per patient as ultra-high-cost (≥$1million/patient/year), very high-cost ($500,000 to <$1million/patient/year), and high-cost ($100,000 to <$500,000/patient/year).

Results: A majority (94.9%) of DRDs ≥$100k/patient/year received a CDA recommendation to reimburse with clinical criteria and/or conditions, with 83.1% under consideration for pCPA negotiation, under active negotiation, or concluded with a Letter of Intent (LOI).

Similar proportions of CDA reimbursement recommendation types were observed across ultra-high-cost, very high-cost, and high-cost DRDs. Very high-cost DRDs more often concluded without pCPA agreements or did not have negotiations pursued, while high-cost DRDs more frequently concluded with an LOI. Among ultra-high-cost DRDs, six gene therapies requiring single doses with curative intent were identified, with recommended price reductions ranging from 39 to 99%.

Further analyses of adult and pediatric indications and CDA recommended price reductions revealed factors influencing pCPA negotiation success. Although not statistically significant, higher price reductions were associated with longer pCPA negotiation timelines.

Conclusion: This assessment shows promising findings for future costly DRDs to achieve pCPA agreements, despite CDA recommendations involving clinical criteria and/or conditions for reimbursement, and significant price reductions.

51

A framework for the routine reporting of real-world utilization and outcomes for cancer therapy in British Columbia

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Background: With the rising cost of therapeutics and uncertainty in evidence at the time of initial reimbursement, health care organizations must fill the evidence gap to better understand the value of newly funded therapies. To meet this need, we developed a framework for the routine reporting of real-world utilization and outcomes for systemic therapies at BC Cancer.

Methods: We reviewed previous research reports to identify common features and outcomes. We worked with senior leaders in the Provincial Systemic Therapy Program to understand their needs, and to iteratively review the proposed framework.

Results: The framework is organized around three dimensions of study designs: (1) Perspective: population level or individual level; (2) Type of analysis: descriptive or comparative; and (3) Scope: within organization or health system level.

To adequately characterize real-world utilization and outcomes, minimum reporting will be done at both the population and individual level, using descriptive analysis, with data from within BC Cancer. For some interventions, where adverse events or health resource use are of particular concern, the scope will be broadened to include health system data. Where feasible within data, time, and resource constraints, comparative analysis will also be done to estimate comparative effectiveness, cost, and safety.

Conclusion: The framework presents a straightforward set of minimum outcomes that can be generated for any therapeutics of interest at BC Cancer. This framework will be applied to high-priority drug programs at BC Cancer this year and will serve as tool to facilitate the generation of timely and policy-relevant evidence for the organization.

52

Patient-Level Resource Utilization for Acute Pediatric Trauma Care in a Regionalized Canadian Trauma System: A Multicenter Retrospective Cohort Study

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Background: Trauma system effectiveness relies on optimal resource allocation aligned with specific patient needs. With finite resources, understanding acute trauma care resource utilization is critical to enhance care quality, optimize resource distribution, and improve health service planning. We aim to estimate patient-level resource utilization for acute pediatric trauma care and assess its association with trauma center type (pediatric; adult Level I/II; adult Level III/IV).

Methods: We conducted a multicenter retrospective cohort study including children <16 years admitted to the 59 trauma centers of the province of Québec (2016–2020). Data were extracted from the Québec Trauma Registry and hospital financial reports. Resource utilization was estimated using an activity-based costing method. The association between cost and trauma center type was modeled using a multilevel linear model. A generalized propensity score was used to adjust for observable differences among patients treated in different trauma center types. Subgroup analyses were performed based on age, injury type, and severity.

Results: Among 9,302 children admitted, 39.6% were treated in Level I pediatric centers, 14.9% in adult Level I/II centers, and 45.5% in Level III/IV centers. Preliminary results indicated a median cost per admission of $10,844-CAD (IQR:7,208–15,691). After adjusting for propensity scores, median costs were $11,598-CAD (IQR:7,214–16,581) in pediatric centers, $10,875-CAD (IQR:6,238–15,922) in adult Level I/II centers, and $9,548-CAD (IQR: 5,578–14,933) in Level III/IV centers.

Conclusion: Preliminary findings suggest that injured children require significant healthcare resources during their management in trauma centers and that these resources vary by type of trauma center.

53

Comparative Effectiveness of GLP-1 Receptor Agonists, SGLT2 Inhibitors, DPP-4 Inhibitors, and Sulfonylureas on Weight Change in People with HIV: A Real-World Longitudinal Cohort Study

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Background: Obesity is becoming increasingly prevalent among people with HIV (PWH). Data on the effects of GLP-1 receptor agonists (GLP-1RA) and SGLT2 inhibitors on weight are limited in PWH.

Methods: We conducted a new-user, active-comparator cohort study using data from 9 U.S. sites in the Centers for AIDS Research Network of Integrated Clinical Systems (CNICS). PWH initiating GLP-1RA, SGLT2 inhibitors, DPP-4 inhibitors, or sulfonylureas between 2013 and 2023 were included. Percent weight change at 1 year was assessed using adjusted linear mixed models. Subgroup analyses stratified by diabetes status and baseline BMI were performed for GLP-1RA and SGLT2 inhibitors.

Results: Among 1,572 PWH, 619 initiated GLP-1RA, 290 SGLT2 inhibitors, 199 DPP-4 inhibitors, and 464 sulfonylureas. Weight change at 1 year was –4.44% (95% CI: –5.51 to –3.36) for GLP-1RA users, –1.00% (95% CI: –2.25 to 0.24) for SGLT2 inhibitors, minimal for DPP-4 inhibitors and sulfonylureas (reference group). Both GLP-1RA and SGLT2 inhibitors showed significant weight loss compared to sulfonylureas ($p < 0.05$), while DPP-4 inhibitors did not differ significantly. Among GLP-1RA users, weight loss was greater in those without diabetes versus with diabetes (−6.68% vs. −3.13%; p-interaction=0.002), and in BMI ≥35 versus BMI <30 (−5.61% vs. −1.93%; p-interaction=0.002). For SGLT2 inhibitors, significant weight loss occurred only in PWH with diabetes (−1.85%; 95% CI: –3.20 to –0.50).

Conclusion: GLP-1RAs resulted in the greatest weight loss, especially in PWH without diabetes and with higher BMI. SGLT2 inhibitors showed modest benefits mainly in those with diabetes. Both may offer effective options for obesity management in PWH.

54

Trends of Utilization of Antiretroviral Drugs among Pregnant People in Manitoba, Canada

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Introduction: Manitoba's HIV rate is about three times the national average, with half of new

cases in 2023 being among women, many of whom are of childbearing age. Antiretroviral therapy (ART) during pregnancy is critical for managing maternal HIV and preventing perinatal transmission. However, there is limited local evidence on ART prescribing trends in this population. This study aimed to examine ART utilization patterns among pregnant people over time in Manitoba, Canada.

Methods: We conducted a population-based study using administrative health data from the Manitoba Centre for Health Policy, analyzing pregnancies between January 2007 and March 2022. ART use during pregnancy was identified using Anatomical Therapeutic Chemical (ATC) codes. We calculated yearly prevalence of any ART use and by regimen class, including nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), integrase strand transfer inhibitors (INSTIs), and fixed-dose combinations. ART regimens will further be classified according to HIV treatment guidelines (Preferred/Alternative vs. Non-Recommended) and stratified by trimester.

Results: Preliminary findings from 238,516 pregnancies (mean age 28.1 years) show stable ART use from 2007–2021 (0.5 to 1.5 per 1,000 pregnancies), rising to 2.9 per 1,000 in 2022. Fixed-dose combinations were most common, and INSTI use increased over time, reflecting guideline-aligned prescribing.

Conclusion: ART utilization among pregnant people in Manitoba remained low but stable over the 15-year period, with a recent increase in 2022.

55

Antiretroviral therapy utilization trends in Manitoba, Canada (2007-2022): A population-based cohort study

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Background: Antiretroviral therapy (ART) has evolved substantially over the past two decades, but data on uptake of newer agents remain limited. Manitoba has the second highest HIV prevalence in Canada, highlighting the need to understand local ART trends. This study examined ART use patterns in Manitoba.

Methods: We conducted a population-based study using the provincial health databases including all individuals in Manitoba from January 2007 to March 2022. ART use was assessed quarterly overall and by class: protease inhibitors (PI), integrase strand transfer inhibitors (INSTI), nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), and non-nucleoside reverse transcriptase inhibitors (NNRTIs). We also evaluated use of first-line regimens: 2 NRTIs plus either INSTI, PI, or NNRTI. Trends were analyzed using linear regression models.

Results: Among 5,749 ART users (mean age 27.9 years; 49.5% male; 58.9% from lower-income groups). Overall ART use increased more than threefold, from 0.04% in Q1-2007 to 0.14% in Q1-2022 ($p< 0.001$). Males and lower-income individuals had higher ART use. We observed a 79-fold increase in INSTI-based regimens, rising from 0.0008% in 2007 to 0.07% in 2022 ($p< 0.001$). In contrast, use of NNRTI-based regimens peaked at 0.013% in 2014 then steadily declined to 0.005% by 2021/2022 ($p=0.002$); PI-based regimens increased by 4% in 2014 before declining to 0.014% in 2021/2022 ($p=0.03$).

Conclusions: ART use in Manitoba has grown significantly over 15 years, driven by increased uptake of INSTI-based regimens and declines in older combinations. These trends align with HIV treatment guidelines recommending INSTI-based regimens as preferred first-line therapy.

56

AI for Precision Oncology Evidence Generation in British Columbia

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Background: Globally, precision oncology access is variable and often limited to research settings. Improved patient access requires healthcare systems to rapidly integrate research data with other real-world health and equity information to generate evidence that supports decision-making. This is an application of learning healthcare. Persistent siloing of real-world patient data within electronic health records (EHRs), institutions, and healthcare systems

impedes learning healthcare.

Methods: We present case study research de-siloing patient data and deploying AI for precision oncology evidence in British Columbia, Canada. Our first case study validates natural language processing (NLP) and large language models (LLMs) for automating real-world data extraction from EHRs for adult patients enrolled in a precision oncology program. Our second demonstrates how desiloed health system and 'omics data and AI can support evaluations of emerging targeted therapies, focusing on entrectinib, a TRK-inhibitor evaluated in single-arm phase I/II trials.

Results: For our first case study, we obtained 113,024 EHR documents, consisting of 194 distinct document types, for 211 patients meeting eligibility criteria. An LLM engine automated extraction of 24 clinical features of interest, with accuracy ≥85% per feature. Our second case study fused single-arm entrectinib trial data with cross-jurisdictional real-world data from British Columbia and the United States (Flatiron Health), identifying 210 eligible patients with a rare biomarker. Target trial emulations using genetic algorithm matching and clone-censor weighting enabled estimation of comparative survival outcomes.

Conclusion: AI-augmented data and evidence produced can facilitate learning healthcare, informing life-cycle decision-making and patient access to precision oncology.

57

Sex-based differences in penicillin allergy labels and associated comorbidities in a Canadian ambulatory care hospital: a cross-sectional study

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Background: Although penicillin allergy labels (PALs) affect approximately 10% of the population, our understanding of sex-based differences in PAL prevalence and patient level characteristics remain under-explored. Therefore, we sought to examine sex-based differences and risk factors associated with PAL.

Methods: We conducted a cross-sectional study of 29,645 adults in an ambulatory care hospital (2015–2024). Chi-squared and Fisher's Exact tests compared PAL/no PAL groups

and sex. Multinomial logistic regression assessed allergy label frequency. Multivariable logistic regression estimated associations with sex, allergy severity, number of allergies, and PAL, adjusting for comorbidities, where applicable. Firth's method addressed separation.

Results: Mean age was 67.5 years, 59.7% female, and 24.4% had >1 allergy label. There were 2,777 (9.4%) people with a PAL of which 71.9% were low risk. Females had higher odds of PAL than males (12.7% vs. 6.6%; crude odds ratio (OR) 2.17, 95% CI 2.14-2.19). High-risk PALs (25.9% vs 16.8%), medication-related allergies (30% vs. 16%) and presence of >1 allergy were significantly more common in females. After adjusting for atopic conditions, autoimmune conditions, and obesity, female sex was associated with a higher prevalence of PAL (adjusted OR 3.46, 95% CI 1.41-11.5). In the multivariable model, obesity, type 1 diabetes, rheumatoid arthritis, lupus, multiple sclerosis, and Sjögren syndrome were associated with increased odds of PAL (ORs ranging from 1.52 to 3.72, all p-values<0.05).

Conclusion: PALs were more prevalent and more often reported as high-risk in females. Sex-based differences between various comorbidities and PAL presence highlights the need for exploring sex sensitive allergy assessment in healthcare.

58

Literature Review of Safety Outcomes for First line (1L) Treatments in Chronic Lymphocytic Leukemia (CLL) in Canada

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Objective: This study aimed to investigate and summarize published safety profiles of current 1L CLL treatments relevant to the Canadian setting.

Methods: A literature review was conducted on 05/05/2025 following Cochrane and PRISMA guidelines targeting clinical trials and real-world evidence (RWE) studies reporting safety outcomes of 1L CLL treatments available in Canada (Bruton's tyrosine kinase inhibitors [BTKi; acalabrutinib, ibrutinib, zanubrutinib], acalabrutinib+venetoclax [AV], ibrutinib+venetoclax [IV], and venetoclax+obinutuzumab [VO]). Eligible studies were identified through Embase and supplemented by European Public Assessment Reports. Data extraction focused on treatment-emergent adverse events (TEAEs), treatment-related adverse events (TRAEs), adverse event (AE)-related discontinuations and dose reductions,

AEs of special interest (AESIs), and mortality. Descriptive analyses summarizing relative safety across regimens were reported.

Results: Of 2,094 publications identified, 10 were included for evidence synthesis. Pivotal clinical trials demonstrated that AV may provide a favorable safety profile relating to TEAEs, treatment discontinuation, and dose reductions relative to other 1L CLL regimens. For instance, AV demonstrated numerically lower rates of grade ≥3 TEAEs (53.6%) compared to IV (64.7%, 75.5%) and VO (78.8%, 80.3%), with each rate reported from a distinct trial. AV was also found to exhibit lower within-trial rates of AESIs like cardiac toxicities, hypertension, infection, second primary malignancies, infusion-related reaction, and tumor lysis syndrome compared to one or more other regimens. RWE on 1L CLL treatment, especially for combination therapies, was limited.

Conclusion: Current literature suggests AV may have a favorable safety profile relative to other 1L CLL treatments; additional research will be beneficial to further investigate differences.

59

Medication Safety Alerts in Electronic Medical Records: A Characterization of Inaccurate Alerts

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Background: Medication safety alerts are ubiquitous in electronic medical records (EMRs) and pharmacy software, derived from limited single sources. They are very commonly overridden and contribute to suboptimal prescribing, alert fatigue, and provider burnout.

Methods: We extracted data from the Epic-Dovetale Clarity database at St Joseph's Healthcare Hamilton for medication safety alerts posted from December 2017 to December 2023, including provider type, alert type, rating of alert, changes made, medications

involved, and comments. We focused on alerts overridden as ‘inaccurate warning’ as a potential indicator of alerts that could be removed. Anonymized comments were analyzed for themes on reasoning for alerts rated inaccurate using ChatGPT-o3.

Results: 3,176,577 interruptive medication safety alerts were displayed to providers in 6 years with 3,074,655 (96.8%) overridden. Of these, 130,725 (4.3%) were overridden as inaccurate warning, most commonly involving hydromorphone (10.7%), ondansetron (6.1%), and haloperidol (4.9%). The most common alerts rated inaccurate were ondansetron and QT prolongation (5.3%) and prescribing opioids with a codeine allergy listed (3.7%). The source of the ‘inaccurate alert’ rating was most frequently done by physicians (56.2%), followed by pharmacists (24.5%) and nurses (16.3%). Volunteered comments were left for 1,566 (1.2%) of the inaccurate alerts, mostly debating dosing or duplication of therapy alerts, but did not provide enough information to remove or fix them.

Conclusion: Medication alert override is universal in the Epic EMR indicating alert information is very suboptimal. Alerts rated as inaccurate provide limited direction as to which alerts should be revamped or removed.

60

Evaluation of the impact of societal perspectives on CDA-AMC reviews in AML

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Background: Acute myeloid leukemia (AML) is a heterogenous blood cancer, with significant impact on patient and caregiver lives. Specific mutations, like FLT3-ITD, are associated with higher risk of relapse and shorter overall survival, further impacting patient QoL and caregiver burden. Most CDA-AMC reviews in AML estimate the long-term cost-effectiveness of treatments from the healthcare system payer’s perspective rather than the patient or societal perspective.

Methods: Evaluations of cost variances between payer and societal perspective were obtained from CDA-AMC Reimbursement Recommendation Reports for AML (n=2). Impact to patient and caregivers were extracted from quantitative inputs in Patient Input submissions (n=3, including oral azacitidine [completed review], ivosidenib [complete review], quizartinib [active review]), acknowledging that these may not necessarily inform the basis for health economics model inputs.

Results: Differences in ICER between payer and societal perspective were obtained, and a relative increase in ICER of 0.48% (azacitidine, CDA-AMCreanalysis) to 12.3% (ivosidenib, sponsor-submitted) were noted. While the inputs of the health economics model are not

publicly available, societal perspective typically includes additional costs associated with productivity loss, both from the patient and caregiver perspective. In the Patient Input submissions, 64% of patients indicated that they require caregiver support, and 33-65% indicated AML has had a negative impact on their mental health.

Conclusion: Current practices with a focus on the health system perspective may underestimate the overall burden and long-term cost-effectiveness of treatments. While current societal perspective methodology poses a challenge for stakeholders, it also highlights the potential for a more equitable approach to decision-making.

61

How do meta-analyses account for treatment switching? A systematic review of evidence synthesis practices in oncology

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Background: The 2019 ICH E9(R1) adopted the estimands framework to operationalize research questions clearly and consistently. This framework includes specifying post-randomization events that may affect the interpretation of clinical trial outcomes (i.e., intercurrent events; ICEs) and strategies to handle these events. Compared to trials, there is limited discussion of estimands in trial-based meta-analysis.

Methods: We conducted a comprehensive review of the Cochrane Library for pairwise meta-analyses of immuno-, targeted, hormone, and other novel oncology therapies that assessed progression-free survival (PFS) and overall survival (OS). To allow time for addendum adoption, dates were restricted to 2021 and onwards. Information on treatment switching and analytic strategies were extracted from each meta-analysis and the trials they included.

Results: Out of 1,180 oncology reviews published in the Cochrane Library since 2021, eight

pairwise meta-analyses and 68 RCTs met inclusion criteria. Most RCTs were Phase 3 (68%; n = 46) and/or open label (76%; n = 52). While the majority of trials explicitly allowed treatment switching (59%; n = 40), more than one third (n = 26, 38%) did not report on treatment switching. Censoring mechanisms were not available for all trials. Among trials that allowed treatment switching, censoring for treatment switching varied in analyses of PFS but not OS. Meta-analyses did not adjust for different censoring mechanisms when pooling estimates of PFS.

Conclusion: It is unclear how to interpret the results of meta-analyses that pool PFS estimated using differing censoring mechanisms. Revised trial reporting guidelines are needed to ensure meta-analyses can yield meaningful results.

62

Application of Observational Research Methods to Real-World Studies for Rare Disease Treatments: A Scoping Review

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Background: With over 7,000 globally recognized rare diseases affecting fewer than 200,000 individuals each, generating robust evidence through randomized controlled trials (RCTs) is often infeasible. Observational studies offer a real-world evidence (RWE) alternative, though challenges around randomization and bias remain. This scoping review identifies observational research methods used between 2018 and 2023 to evaluate rare disease treatments and their role in assessing effectiveness and safety.

Methods: We searched Ovid MEDLINE and EMBASE for relevant studies, complemented by manual screening of references. Eligible studies included observational research assessing the effectiveness or safety of rare disease treatments. Screening and data extraction were conducted independently by two reviewers.

Results: Eighty-three studies met inclusion criteria. Nearly half (n = 41, 49%) were conducted in Asia, with the remainder from Europe (28%) and North America (12%). Rare oncology conditions were most frequently studied (n = 41). Single-arm designs (n = 41) often used historical or trial-based external controls and self-controlled methods. Comparative studies (n = 42) frequently employed propensity score matching and Cox models to address confounding and small sample sizes. Multicenter collaborations, registry linkages, and

extended retrospective timeframes helped mitigate sample size limitations, though issues like missing data and selection bias remained.

Conclusion: Observational studies are essential for rare disease research, offering feasible alternatives where RCTs fall short. Greater standardization of methodologies is needed to improve the reliability and policy relevance of RWE in this space.

63

Predicting and characterizing high-cost healthcare users in Québec: a population-based analysis using linked administrative health and survey data

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Background: A small proportion of patients, referred to as high-cost users (HCU), accounts for a disproportionate share of healthcare expenditures. Most studies examining these individuals rely strictly on administrative or on hospital data, with limited data on their characteristics. This study aims to predict and characterize HCU in Québec using linked longitudinal administrative health data with data from the Canadian Community Health Surveys.

Methods: HCU were defined as the 5% of patients with the highest annual healthcare costs in 2012. Cost trajectories were observed over a ten-year period (2007–2016). The Andersen behavioral model was used to structure explanatory variables. Statistical tests were conducted to compare the profiles of HCU and non-HCU. A random forest model was then used to identify predictors of HCU status in 2012.

Results: Cost analysis showed that HCU had significantly higher healthcare expenditures prior to 2012 and that the expenditure decline in the following years. Cost differences between HUs and non-HUs were statistically significant each year, with substantially greater variability among HUs. The analysis revealed that HCU are disproportionately older, socioeconomically disadvantaged, burdened with multiple chronic conditions, and demonstrate high healthcare needs. Random forest models identified key predictors of HCU

status, including multimorbidity, poor self-rated health, low income, and high medication use.

Conclusion: The study shows that high-cost utilization is not solely explained by clinical needs, but also by social and behavioral factors. Early identification of individuals at risk is essential to implement targeted interventions aimed at improving care coordination and reducing avoidable healthcare expenditures.

64

Assessment of stroke awareness among community pharmacists in Lebanon: A Cross-Sectional study

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Background: Stroke is a global health issue. Community pharmacists, as one of the most accessible healthcare providers, play a key role in its early identification. However, their preparedness regarding stroke management remains unclear, particularly in developing countries.

Objective: This study assessed community pharmacists' knowledge and practices regarding stroke in Lebanon.

Methods: A cross-sectional study was conducted among community pharmacists in Lebanon, using a validated and structured questionnaire. The questionnaire covered demographics, professional practice, stroke-related knowledge, risk factors, signs and symptoms, complications, and counseling. Scores were computed for knowledge and practice, and their association with sociodemographic and pharmacists' characteristics analyzed using Mann-Whitney and Kruskal-Wallis tests. Linear regression models examined the association between age stratified pharmacist-patient interaction with the pharmacists' overall stroke management scores.

Results: The study included 260 pharmacists (median age 32 years). Pharmacists showed competent knowledge regarding stroke (median score 15/18). Knowledge of stroke risk factors (median score 9/9), signs and symptoms (7/7), and complications (9/9) was

consistently high. Interaction with stroke patients aged ≥80 years was associated with higher score in knowledge, risk factors, complications, and practice compared to interactions with younger patients (p = 0.008, 0.020, 0.011, and 0.004, respectively). However, gaps were observed in blood pressure monitoring (60.8% correct), direct oral anticoagulants role (28.5%), and LDL targets post-stroke (45.0%).

Conclusion: Community pharmacists in Lebanon have satisfactory baseline knowledge of stroke management. However, critical gaps persist in guideline-specific areas.

65

Trajectories of high-cost healthcare users in Québec: a latent class and multinomial regression analysis using linked administrative and survey data.

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Background: High-cost users (HCU) are often treated as a homogeneous group, despite considerable heterogeneity in their care trajectories. This study aims to classify patterns of healthcare utilization, identify associated patient profiles, and determine the factors associated with being in each trajectory classes.

Methods: This study used data from the TorSaDe cohord and included all respondents to the Canadian Community Health Surveys (CCHS) from 2007 to 2016 who were classified at least once in the top 5% of annual healthcare users. Trajectories of HCU status were modeled using latent class analysis (LCA). The optimal number of classes was determined based on AIC and BIC statistical criteria. A multinomial logistic regression model was then estimated to examine the factors associated with membership in the different trajectory classes.

Results: The LCA identified six distinct care trajectory classes, including one class predominantly composed of persistent HCU those classified as such in at least five out of ten years. The multinomial logistic regression revealed that persistent users were more likely to exhibit severe comorbidities and poor mental health, whereas transient users were characterized by more acute and episodic healthcare needs.

Conclusions: The integration of survey and clinical data allows for a better understanding of care trajectories. The trajectories of HCU are heterogeneous and require targeted interventions based on profiles.

66

Real-world treatment patterns, outcomes and burden of illness of autologous stem-cell transplant ineligible patients with Mantle Cell Lymphoma in Ontario, Canada

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Introduction: Mantle cell lymphoma (MCL) is an aggressive form of non-Hodgkin lymphoma. First-line (1L) treatments are differentiated by patient fitness, with autologous stem cell transplant (ASCT) reserved for younger, 'fit' patients. There is limited population-based data on treatment patterns, outcomes and healthcare resource utilization (HCRU) of ASCT-ineligible patients, in 1L and relapsed/refractory (R/R) settings, to quantify burden of illness.

Methods: This retrospective study utilized health administrative data from Ontario, Canada. All patients (65+ years) diagnosed with MCL in the Ontario Cancer Registry between January 1, 2013, and December 31, 2021, who were ASCT-ineligible were included, with follow-up to December 31, 2022.

Results: 754 MCL patients were identified; 71.1 % male, and median age at diagnosis was 76 years. Among 1L-treated patients (N=540), 414 (77 %) received bendamustine+rituximab (BR), 54 (10%) received rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP), and 72 (13%) received other treatments. For 2L-treated (N=149), 109 (73.1%) patients received Ibrutinib. 39.3% and 68.5% of patients died following 1L and 2L treatment, respectively. Median overall survival (95% CI) was 3.51 (3.66-4.79) years from 1L treatment initiation. HCRU in the first year of treatment was similar for any 1L regimen, however, physician visits on average were higher amongst R-CHOP patients (48.4) compared to BR (34.9), while in 2L, Ibrutinib patients had fewer visits (26.4) than other 2L therapies (50.3).

Conclusion: These results characterize burden of illness of MCL patients in Ontario, Canada. Poor real-world outcomes support the need for additional 1L and R/R therapies for management of an ASCT-ineligible population.

67

Effect of Cannabis on Renal Function in Patients Using Cannabis for Medical Purposes: A Longitudinal Cohort Study

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Background: This study evaluates the association between the medical use of cannabis and the risk of acute kidney diseases in patients who have received a prescription for cannabis, compared to a non-user population. This study will provide essential data on the risks of medical cannabis use for kidney health, thereby helping to better inform healthcare professionals in their clinical decisions and patients.

Methods: This is a retrospective longitudinal cohort study conducted on adults without a history of kidney diseases, followed using data from the Institute for Clinical Evaluative Sciences. Exposure is defined by the prescription of cannabis, while the outcome is the onset of acute kidney diseases. Propensity scores and Cox regressions were employed to examine the association between medical cannabis and the outcome.

Results: The cohort consists of 48,948 exposed individuals and 166,140 non-exposed individuals after exclusions. The incidence rate is 5.96 per 1000 person-years among the exposed and 5.50 per 1000 person-years among the non-exposed. Additionally, the risk is higher in the first few months and tends towards null over time: before 6 months, the HR is 1.4 with a confidence interval of 1.15 to 1.71, and after, the HR is 1.01 with a confidence interval of 0.9 to 1.12. The same trend is observed among people aged ≥ 66.

Conclusion: The results suggest a higher risk of acute kidney failure in the first few months following the prescription of cannabis. This risk could be attributable to the complexity of cannabis use at the beginning of treatment.

68 – Evaluated Oral Presentation

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

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Background: Younger children in a classroom are more likely to be diagnosed with and treated for ADHD, suggesting a relative-age effect. Prior studies used narrow age ranges and predated DSM-5. This study investigates whether relative age continues to influence ADHD diagnosis and treatment in the post DSM-5, and whether such an association differs across age groups and between sexes.

Methods: We included BC children aged 3-17 at any point between Jan 1, 2014, to Dec 31, 2024. We estimated period prevalence of ADHD diagnosis and treatment by birth month and calculated the absolute and relative risk of diagnosis and treatment for children born in December vs. January, stratified by age group: preschool (3-5), elementary school (6-12), and high school (13-17).

Results: 1,345,917 children were included in the cohort. Elementary and high school boys born in December were more likely to receive ADHD diagnosis (relative risk [RR] 1.26, 95% confidence interval [CI] 1.21, 1.31, RR 1.27, 95% CI 1.21, 1.33, respectively). Meanwhile, when comparing girls born in December vs. January, the relative-age effect was stronger in elementary school (RR 1.36 95% CI 1.27, 1.45), but became weaker in high school (RR 1.18, 95% CI 1.11, 1.25). This effect was not present among preschool-aged children. Similar relative-age effects were observed for the use of ADHD pharmacological treatment.

Conclusions: Relative-age effect in ADHD diagnosis and treatment persisted into high school – rising among boys and declining among girls. These findings challenge existing assumptions and highlights sex-specific patterns. Future ADHD assessment and research should consider a child's relative age.

69

Risk prediction for lung cancer screening: a systematic review

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Background: Lung cancer (LC) is the leading cause of cancer mortality, often diagnosed at advanced stages. Screening reduces mortality in high-risk individuals, but its efficiency can improve with pre- and post-screening risk stratification. With recent LC screening guideline updates in Europe and the US, numerous novel risk prediction models have emerged since the last systematic review of such models. We reviewed risk-based models for selecting candidates for CT screening, and post-CT stratification.

Methods: We systematically reviewed Embase and MEDLINE (2020–2024), identifying studies proposing new LC risk models for screening selection or nodule classification. Data extraction included study design, population, model type, risk horizon, and internal/external validation metrics.

Results: Of 1987 records, 68 were included: 41 models were for screening selection (19 without biomarkers, 22 with), and 27 for nodule classification. Regression-based models predominated, though machine learning and deep learning approaches were increasingly common. Discrimination ranged from moderate (AUC≈0.70) to excellent (>0.90), with biomarker and imaging-enhanced models often outperforming traditional ones. Model calibration was inconsistently reported, and fewer than half underwent external validation.

Conclusion: 78 models had been identified prior to 2020; we found 68 models since. This reflects growing interest in personalized LC screening. While many demonstrate strong discrimination, inconsistent calibration and limited external validation hinder clinical adoption. Future efforts should prioritize improving existing models rather than developing new ones, transparent evaluation, cost-effectiveness analysis, and real-world implementation.

70

Efficacy and safety of biosimilar therapy for the treatment of inflammatory bowel disease in Northwestern Ontario

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Background: Biosimilars are highly similar versions of originator biologics. They offer a promising opportunity to improve the health and quality of life for individuals with autoimmune disorders requiring treatment, primarily due to their reduced cost. However, there is a national and worldwide limitation of available and updated data assessing the comparative effectiveness and safety of biologic drugs, including biosimilars. The CAN-AIM (Canadian Network for Advanced Interdisciplinary Methods for Comparative Effectiveness Research) team launched a nationwide study to fill this knowledge gap. This study focuses on data collected from one site in Northern Ontario.

Objective: The primary objective of this study is to describe baseline characteristics and 12-month outcomes (change of therapy and adverse events) of participants living in Northern Ontario.

Methods: Enrolment began in December 2022. Eligible participants were individuals aged 18 and older with a clinical diagnosis of inflammatory bowel disease (Crohn's disease, ulcerative colitis), starting either a biosimilar or an originator biologic. Prospective data were collected through interval chart reviews and distributed surveys. This analysis reports on 12-month post-enrollment data for 14 participants.

Results: Among the participants, 50% were male and 50% were female, the majority were over the age of 65 (42.9%) and identified as Caucasian (78.6%), 71.5% had Crohn's disease and 28.6% had ulcerative colitis. At the time of enrollment, three participants were on biologics. All participants were on biosimilar therapy for three months. One experienced a change in their initial biosimilar therapy due to arthralgias and myalgias. No activation of disease, further side effects, adverse events, or serious adverse events were observed.

Conclusions: This study highlights the safety of biosimilars used for the treatment of inflammatory bowel diseases. The results suggest biosimilars may provide a more affordable alternative to legacy drugs. Future research should consider assessing long-term health outcomes for patients on biosimilar therapy in the underserved region of Northern Ontario.

71

Number Needed to Harm (NNH) in metastatic castration-sensitive prostate cancer (mCSPC) – darolutamide (D), apalutamide (A) and enzalutamide (E) clinical trials

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Background: Androgen receptor pathway inhibitors (ARPIs) in combination with androgen

deprivation therapy (ADT) have demonstrated benefit in mCSPC but offer different adverse event (AE) profiles. NNH measures the number of patients needed to be treated before a harmful outcome occurs with the intervention, versus placebo. Higher NNH reflects lower incremental likelihood of harm. A NNH analysis to contextualize differences in AE risks between ARPIs can inform treatment choices.

Methods: AEs of interest (all grade and grade≥3) reported in the primary analysis of ARANOTE (D), TITAN (A), and ARCHES (E) clinical trials were analyzed through NNH, calculated as the inverse of absolute risk increase. The population impact of these AEs was examined by applying the NNH results to an estimated 2,928 Canadian mCSPC patients.

Results: D showed a trend of higher NNH than A and/or E for most all-grade and ≥3 AEs suggesting a lower risk of incremental harm for hot flash, fatigue, rash, falls, cognitive impairment and dizziness. NNH for all-grade anemia and constipation were lower for D. Rash had the lowest NNH among all-grade and grade ≥3 AEs. In 2,928 mCSPC patients, treatment with D could lead to 656 and 387 fewer additional all-grade AEs than A and E, respectively.

Conclusions: This analysis shows the favorable safety profile of D versus A or E. D is associated with a lower risk of incremental harm for AEs such as rash, falls, hot flash, fatigue, and dizziness, which affect patient quality of life and health system burden.

72

Comparing perceived and unmet mental health needs among LGB and heterosexual individuals in Canada.

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Mental health disorders affect many people in Canada—about one in five each year. Lesbian, gay and bisexual (LGB) individuals face higher rates of depression, anxiety and

suicidal thoughts because of stigma, discrimination and fewer welcoming, supportive services. Two measures help us see these challenges clearly: perceived needs (when someone feels they need mental health care) and unmet needs (when they cannot access that care). Yet we lack national data on these measures for LGB Canadians over time.

This study compares perceived and unmet mental health needs for LGB and heterosexual Canadians using two national surveys: the 2012 Canadian Community Health Survey–Mental Health and the 2022 Mental Health and Access to Care Survey. Our sample includes people aged 15 and older in all ten provinces. We calculated the percentage of each group reporting perceived or unmet needs, then used adjusted logistic regression to estimate odds ratios (OR) with 95% confidence intervals (CI), controlling for age, sex and income.
In 2012, LGB respondents were 2.30 times more likely to report perceived needs (95% CI 1.60–3.30) and 1.52 times more likely to report unmet needs (95% CI 1.10–2.30) than heterosexuals. In 2022, the odds of perceived needs for LGB people rose to 2.61 (95% CI 1.97–3.47), while unmet needs decreased slightly but not significantly.

Despite policy efforts since 2012, LGB Canadians still face higher mental health needs than heterosexuals, and the gap has not improved meaningfully over the past decade.

73

Uptake of oncology-related biosimilars: a global analysis of usage data

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Background: Biologics have greatly improved cancer management but are costly. Biosimilars cost less and do not have clinically meaningful differences compared to reference products. However, they are not identical, leading to hesitation among clinicians and patients to use them.

Objective: To measure the uptake of oncology-related biosimilars versus reference products in Canada and countries with similar regulatory frameworks.

Methods: We conducted a cross-sectional sales analysis from 13 countries between October 2022 and September 2023 for five oncology-related biologics with biosimilars: bevacizumab, filgrastim, pegfilgrastim, rituximab, and trastuzumab. We used IQVIA MIDAS® data on country-level quarterly sales volume and value.

Results: Among the 13 countries, Canada ranked seventh in the proportion of oncology-related biosimilar uptake by units sold (89% versus median 86%). Canadian biosimilar uptake was 99% for pegfilgrastim (versus 83%), 92% for filgrastim (versus 95%), 89% for trastuzumab (versus 70%), 86% for bevacizumab (versus 86%), and 75% for rituximab (versus 93%). Canada spent USD $488 million on these biologics during the study period. European countries including Norway, Italy, and Sweden had the highest uptake, while New Zealand, Japan, and Belgium had the lowest. Across countries, biosimilar filgrastim had the highest uptake (95% of units) and trastuzumab the lowest (70%).

Conclusions: Oncology-related biosimilar uptake in Canada was average among included countries. Increasing biosimilar uptake may reduce spending, and savings can be reinvested into cancer care. Future research on time trends can help assess barriers and enablers of biosimilar uptake across countries.

Author Index:

Anderson H	51
Ante Z	23
Askin N	15
Baer PA	32
Bai N	42,43
Ballios B	30
Bamford L	49
Ban JK	32,33,37
Barakat M	65
Barbera L	23
Baskaran BS	4,5
Bassett K	28
Beauchemin C	11
Beaudoin CC	34
Berard A	40
Bérété ZC	20,67
Berger H	8,9
Bergeron MG	21
Bernatsky S	70
Berthelot S	21,52
Bluteau A	21
Boissinot M	21
Booth G	55
Bourgoin T	60
Bredeson C	26
Bulloch A	27
Burkholder G	49
Burry L	1
Cachay E	49
Campbell T	24
Carlin S	47
Carney G	29,28,68
Chai J	73
Chalabianloo N	7,6,12
Chan KKW	42,43,62,73
Chang SL	34
Chaudhry S	1,73
Chen B	37
Cheung WY	42,43
Chouinard NH	34

Choy K	69
Christopoulos K	49
Colasurdo G	11
Collet J	58
Commanday A	49
Crane HM	49,53
Cui Z	29,28,68
Dadamo F	25
Danese D	44
DeAngelis C	73
Delaney JA	18,40,53,49
Derksen S	40
Dick M	44
Djedou BY	63,65
Dolovich L	10
Dormuth C	28,29,68
Doupe MB	49
Dragan R	40
Dron L	61
Drumright LN	49
Dubois C	20
Dupont F	11
Dupuis L	62
Dutta N	58
Dyck J	20,67
Earle CC	23
Eddin LE	4
Elias M	11
Elliot M	27
Elmatary B	55
Elsayed S	57
Eltonsy S	15,16,17,18,38,39,40,49,53,54,55,65
Eurich DT	20,67
Fahey CA	49
Falk J	40
Farrer Rogers C	42
Fazeli M	58
Feng C	72
Fleury I	26
Forster K	42,43

Frost S	35
Fuller K	1
Gambaro K	42
Gamble JM	57
Gandhi B	59
Gaudette E	1
Gavura S	42
George S	66
Gesy K	26
Ghaddar L	62
Gilca R	21
Gnanou S	52
Golden S	32
Gomes T	24
Gregory-Evans K	30
Guan Q	42,43
Guertin JR	2,21,34,52
Guilcher SJT	8,9
Haidar H	18
Haidar L	15,49,53,54,55,65
Haines P	44
Hallit S	65
Hamilton M	66
Hanlon J	20,67
Hanna W	45
Hany N	65
Harland E	70
Hawkins M	26
Heath S	49
Heffernan M	44
Ho C	42,51
Ho M	1,24,73
Holbrook AM	59
Hosseini H	65
Houle G	44
Houle SKD	57
Hussain S	8,9
Iacono A	24
Jafari A	4,12
Johnson K	69

Kadish S	33
Kalayjian R	49
Karim N	62
Kasireddy E	58
Kim C	58
Kim K	51
Kirby M	69
Kitahata MM	49
Koenekoop R	30
Kosgoda S	36
Kouame JM	2
Kowalec K	17,18,40
Krebs E	41,51,56
Kyle RP	49
Laberge AM	2,63,65
Lachaine J	11
Laforty C	37
Lam S	69
Lane J	72
Lapierre M	48
Larche M	32
Larue S	2,34
Latifovic L	37
Lau R	6
Lavu A	15,38,39,40
Lebenbaum M	35
Ledlie S	24
Lee N	33
Légaré A	11
Leong C	40,49
Leung C	69
Li A	29,28,68
Liang TY	50
Lin Y	62
Ling J	48
Liu N	23
Lix L	17,18
Loeb M	33
Longtin Y	21
Loukov D	33

Lukusa L	70
Machado A	45
Mahendira D	8,9
Majer E	24
Maleab D	65
Mallet MC	21
Mansour S	65
Marques M	42
Mathew Stephen M	42,43
Maximos M	57
Maxwell CJ	57
May JR	58
Mayer KH	49
McCarthy LM	8,9,10
McCracken A	10
Metcalfe RK	61
Mhishi SB	32,37
Michaud JL	2
Millson B	48
Mittmann N	23
Mksyartinian P	22
Moe G	44
Moniz L	30
Moore L	52
Moore RD	49
Moura CS	70
Muanda FT	4,5,6,12
Nam A	36
Nance RM	53,49
Napravnik S	49
Navani V	42
Neish CS	32,33
Neville A	70
Ng G	32,33
Ng M	40
Ng R	30,37
Noor N	59
O'Shea B	46
Ogunbameru A	37
Omidifar N	38

Omrani MA	3,4,6
O'Rourke B	26
Oskuie P	38
Padilla Paternina M	54
Park JJH	61
Pataky RE	42,43,51
Patel YP	50,62
Patenaude J	11
Patten S	27
Peacock S	42,43
Pettit AC	49
Peymani P	15,18,38,39,40,54,55
Pinto AD	10
Pompeo A	32
Pourrahmat M	58
Preyra R	6
Prica A	66
Prior H	16
Privolnev Y	60
Punjani T	59
Qadeer RA	36
Qian C	30
Rabbani R	15
Rachedi K	42
Raguram K	3
Rahman T	19
Regan J	32
Regier DA	41,51,56
Rezaeianzadeh R	69
Rizzardo S	19
Robitaille J	30
Ronksley P	27
Ruderman SA	49,53
Ruth C	40
Saag MS	49
Sadatsafavi M	69
Sadeghi H	4
Sadeghi S	6
Saidi Y	21
Santhireswaran A	1

Sayani A	36
Schneider T	59
Sebgo AA	20,67
Seung SJ	23,66
Shafey M	26
Shafiq S	27
Sharma A	30,31,37,60
Shearer D	24
Shi S	31,47,48,60
Shokar S	36
Simonyan D	21
Singbo MNU	21
Singh S	24
Sit C	26
Sketris I	7
Smith B	69
SMKZ Prince	72
Srinivasan S	71
Stein BD	22
Stewart S	7
Strub S	42
Tadrous M	1,8,9,17,18,24,42,43,62,73
Tamim H	7
Tan Q	17,18,55
Tehrani A	48
Tharmarajah S	8,9
Thibault S	66
Thomas D	33
Thompson W	28,29,68
Tong M	30,31
Trejo MEP	37
Trenaman SC	7
Trottier S	21
Tsobo Muanda F	3
Upton A	71
Vachon ML	21
Varin-Tremblay C	2,21
Vieira M	35
Von Maltzahn M	7
Vuong V	58

Wang JL	72
Weymann D	41,51,56
Whitney BM	53,49
Willig AL	49
Wong A	23,66
Woods RR	51
Wynne W	24
Xu I	34
Yan Y	61
Yanchar N	52
Yang J	19,24
Yip AM	7
Yip YY	71
Zarsanj N	39
Zarychanski R	15
Zekavat OR	39
Zezos P	70
Zhang Y	13,14
Zongo A	20,67

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