Canadian Journal of Health Technologies

Canada's Drug Agency
L'Agence des médicaments du Canada

December 2024 Volume 4 Issue 12

Drugs Health Technologies **Health Systems**

Supplement

2024 Abstracts of the Canadian Association for Population Therapeutics

Reimagining Our Canadian Potential: Working Together Through Partnerships and Collaboration

Toronto, Ontario

October 21 to 22, 2024

Withdrawn Abstracts: 22, 23, 26, 27, 29, 30, 34, 39, 42-46

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Poster Presentations

Note that presenters' names are underlined.

1. Updated breast cancer costs for women by disease stage and phases of care using population-based databases

Mittmann N,[1] Seung SJ,[2] Ante Z,[3] Liu N,[3] Yong J,[4] Yusuf A,[2] Chiarelli AM,[5] Earle CC[3]

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Background: This study assessed the health care system costs and resource utilization of women with breast cancer in Ontario, Canada. The goal was to update costs by stage, age, and phase of care from a health care system perspective.

Methods: A retrospective analysis was conducted using linked population-based administrative data. The study included women diagnosed with breast cancer between 2017 and 2021, with follow-up data until 2022. Cases were matched with controls in a 1:5 ratio, using birth year, local health integrative networks, income quintile, and resource utilization band at baseline. Incremental costs were estimated using linear regression.

Results: Among the 37,133 cases matched with 185,665 controls, the average age was 62 years. Cases incurred an additional cost of $27,485 per year compared to controls. Costs rose with disease severity, ranging from $15,588 for stage I to $137,319 for stage IV. The highest incremental costs occurred during the first 12 months after diagnosis (initial: $43,408), followed by the last 12 months before death (terminal: $25,940) and then interim years (continuous: $9,533 per year). Additionally, the incremental cost of breast cancer was higher when diagnosed before age 70 compared with age 70+ ($28,415 and $25,254, respectively).

Conclusions: The findings align with previous studies on breast cancer costs to the health care system. Additionally, variations in costs and resource utilization based on disease severity, care phase, and age were emphasized, highlighting higher costs for metastatic breast cancer cases, women < 70 years of age, and the initial 12 months following diagnosis.

2. Comparing perceived and unmet mental health needs in individuals with different sexual orientations

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Background: In Canada, not everyone can easily get the mental health help they need, and this problem can be even bigger for people with different sexual orientations. The objective of this study is to, among individuals with different sexual orientations, estimate and compare the proportions of perceived and unmet mental health needs and identify barriers to mental health services among those who did not use mental health services.

Methods: This is a cross-sectional study using the data from the Mental Health and Access to Care Survey. The study will include individuals aged 15 and older. Data collection was conducted through computer-assisted telephone interviews from March 17 to July 31, 2022. Participants who self-identify as nonheterosexual will be categorized as LGB (Lesbian, Gay, and Bisexual), while those who identify as heterosexual will be categorized as non-LGB. Descriptive analysis will be conducted to estimate the proportions of perceived and unmet mental health needs. Bivariate and multivariate analyses will be used to compare perceived and unmet mental health needs between LGB and non-LGB (heterosexual), controlling for potential confounders. The groups will also be compared with regard to their barriers to mental health services. The Promoting Action on Research Implementation in Health Services framework will be used to develop the knowledge translation plan.

Results: We'll provide more details on results when we present our poster. Preliminary results showed that there are significant differences in mental health needs among people with different sexual orientations. Many did not seek help because of problems like feeling judged (stigma), waiting too long for services, and not having services that meet their needs.

Conclusions: This study aims to shed light on the mental health challenges faced by people with various sexual orientations and the reasons why many don't seek or receive help. The findings will inform changes that make mental health services more available and welcoming for everyone. This study has the potential to exert a significant influence globally, particularly in regions where data on sexual orientation are not routinely collected, thus rendering them invisible.

3. Fear of missing out: Drug availability in Canada versus the US

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Background: Per-capita drug spending in the US is double that in Canada. One commonly debated point is whether this allows increased access to valuable therapies. Our objective was to determine if Canadians lack access to drugs with major additional therapeutic value compared to available drugs.

Methods: We used IQVIA Multinational Integrated Data Analysis (MIDAS) data to determine drugs purchased in the US but not in Canada from 2017 to 2021. Using Health Canada's Drug Product Database and clinical review, we categorized the drugs into 8 mutually exclusive groups: Drug Product Database listing status ("cancelled post-market" or "dormant, approved, or "cancelled pre-market"), other drug alternatives available ("formulation unavailable," "existing drug class," or "therapeutically similar"), "pre-approval," "atypical access available," or "unavailable" in Canada. Therapeutic value assessments of "unavailable" drugs were obtained from Prescrire International, Haute Autorité de Santé, and the Institute for Quality and Efficiency in Health Care.

Results: Our analysis included 399 drugs: 120 (30%) were "cancelled post-market"; 38 (10%) were "dormant, approved, or cancelled pre-market"; 49 (12%) were "formulation unavailable"; 130 (33%) were "existing drug class"; 35 (9%) were "therapeutically similar"; 3 (1%) were "pre-approval"; 15 (4%) were "atypical access available"; and 9 (2%) were "unavailable" in Canada. Six of the 9 "unavailable" drugs had been evaluated by 1 or more organizations and were rated as offering minor to no therapeutic value.

Conclusions: There was similar access to important drug therapies in Canada and the US. Further work is needed to better understand the therapeutic impact of the drugs unavailable in Canada.

4. Impact of systemic delays for patient access to oncology drugs on clinical, economic, and quality of life outcomes in Canada: A call to action

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Background: Canada has 1 of the most complex and rigorous drug approval and public reimbursement processes and is unfortunately 1 of the countries with the longest delays in drug access. To assess the overall impact of delayed access to cancer therapy, a targeted literature review was performed to identify studies associated with the clinical, economic, and quality of life impacts of delayed access to oncology drugs. Using MEDLINE/PubMed databases and snowballing, 56 unique records met the eligibility criteria. Results revealed that clinical outcomes were the most impacted by delayed access to oncology drugs (e.g., mortality, overall survival, and progression-free survival). Four articles retrieved by the targeted literature review specifically illustrated that a substantial number of life-years could potentially be saved by increasing systemic efficiency regarding the development, approval, and reimbursement processes of new drugs for advanced malignancies. It is imperative that initiatives are put in place to improve the performance and speed of Canadian drug regulatory and health technology assessment processes, especially for new cancer therapeutics. The proposed solutions in this paper include better coordination between health technology assessment agencies and Canadian payers to harmonize coverage decisions, international collaborations, information sharing, and national standards for timeliness in oncology drug access.

5. Developing a drug shortages predictive model using real-world Canadian drug utilization (student oral presentation)

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Background: Drug shortages are an ongoing health care challenge, but approaches to quantifying shortage risk are lacking. Research has focused on factors associated with shortage reports, but manufacturer-level reporting does not reflect population-level drug use. It is essential to determine the impact of shortage events on drug use trends and identify predictors associated with decreases in use to ascertain shortage risk and inform future policy prioritization. Our objective is to develop a predictive model to anticipate shortage risk using characteristics associated with meaningful supply decreases following shortage events.

Methods: We conducted a matched cross-sectional study analyzing monthly trends in drug purchasing using IQVIA MIDAS data from 2017 to 2021. Incidence density sampling was used to match each drug with a supply chain event (cases) to 10 drugs without an event (controls). Shortage reports were obtained from Drug Shortages Canada. A logistic regression model with random effects was used to compare odds of a meaningful supply decrease (33%) within 2 quarters following reports for cases and controls.

Results: Of 1,591 drugs, 972 (61%) unique drugs were exposed to 1,919 supply chain events. Meaningful supply decreases (≥ 33%) were observed in 11% of cases, compared to 7% of controls. Drugs with sales less than $100,000, anti-infectives (ATC class J), and drugs with unit prices greater than $100 had higher odds of experiencing meaningful supply decreases (OR = 4.17, 3.21, 3.12, respectively).

Conclusions: Our findings highlight factors strongly associated with supply issue-related decreases in drug supply and indicate only 1 in 10 supply chain events led to meaningful decreases. These can be used to build a predictive model to score shortage risk of Canadian drugs and develop a national at-risk medicines list accounting for supply chain and clinical risk. Our work will guide policies for managing drug shortages, improving patient outcomes and health care delivery.

6. Modelling the cost-effectiveness and budget impact of uterine botulinum toxin injections versus conventional treatment in severe dysmenorrhea: A French perspective

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Background: Dysmenorrhea is all pelvic pain preceding or accompanying menstruation. From 16% to 29% of women have a very severe form and 10% to 30% lose 1 to 2 working days per month. This represents an annual loss of 600 million work hours, or approximately $2 billion per year in the US. Faced with persistent pelvic pain, an innovative treatment — botulinum toxin (BoNT) — is used in the Women's Health Research Center (WHRC). The objective of this study is to assess the efficiency and budgetary impact of BoNT versus conventional treatment (CT) (hormonal treatments + analgesics), using a Markov model.

Methods: A Markov model was developed to estimate, from the perspective of French Health Insurance, the efficiency and budgetary impact of BoNT versus CT. The main health states in the model were based on Visual Analogue Scale scores and expert opinion. All model parameters were derived from a cohort of patients treated for 12 months at WHRC for severe dysmenorrhea in 2022. Direct health care costs and indirect costs were considered in the cost-utility analysis and budget impact analysis. The main evaluation

criteria were the incremental cost-utility ratio for the cost-utility analysis and the net impact for the budget impact analysis. Deterministic and probabilistic sensitivity analyses were performed to assess the robustness of our results.

Results: Over the 1-year time horizon (main analysis), the costs and quality-adjusted life-years (QALYs) of BoNT versus CT were €1,895.65 versus €3,055.20 and 2.03 QALYs versus 1.23 QALYs, respectively. Consequently, the incremental cost-utility ratio equalled –€1,651.5/QALY, which demonstrates that, although the initial costs of BoNT are higher than those of CT, the reduced follow-up costs associated with the long-term efficacy of BT make it the most effective and economically dominant option at 1, 5, and 10 years. Sensitivity analyses show that 100% of Monte Carlo iterations are below the willingness-to-pay threshold of €30,000/QALY, making BoNT an efficient strategy that could be adopted and reimbursed.

Conclusion: In the absence of a reference treatment for the management of severe dysmenorrhea, BoNT offers an improvement in quality of life as well as a reduction in follow-up costs. It is therefore the most cost-effective strategy over 10 years.

7. Cost-effectiveness of specialized trauma care: A systematic review

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Background: Several meta-analyses have shown evidence of the effectiveness of specialized trauma care in improving patient outcomes, but their cost-effectiveness is unknown. We aimed to systematically review evidence on economic evaluations of hospitals specialized in advanced trauma care.

Methods: We searched PubMed, Embase, Cochrane Library, Web of Science, and grey literature with Boolean operators and keywords on "trauma center," "injury," "cost-effectiveness," and "cost-analysis" until January 2024. Two reviewers independently assessed eligibility and extracted relevant data. Reporting quality was assessed using the CHEERS 2022 checklist. Per Cochrane recommendation, findings were synthesized qualitatively. We planned subgroup analyses by age, injury severity, and reporting quality.

Results: We identified 4 full economic evaluations, 3 cost-consequence studies, and 3 cost analyses, mostly based on retrospective cohorts conducted in the US. Reporting quality was rated high for 4 studies. In all full economic evaluations, specialized trauma centres (STCs) were more costly and more effective than nontrauma centres, with an incremental cost-effectiveness ratio ranging from 655 to 46,175 2022 international dollars per QALY gained. Among cost-consequence studies, 2 found STCs more costly and less effective than nontrauma centres while 1 study showed the opposite. All cost-analysis studies indicated

higher costs in STCs. For subgroup analysis, 1 study suggested that STC is more cost-effective in patients < 55 years with more severe injuries than their counterparts. Two high-quality reports found STCs more effective and more costly.

Conclusion: We identified a few full economic evaluations but all suggested that STCs are cost-effective according to the widely used willingness-to-pay ratio of $50,000 per QALY gained.

8. Canadian patient support program enrolment form standardization

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Background: Patient support programs (PSPs) help patients navigate the clinical and logistical challenges of treatment with specialized medicines. There are an estimated 400 PSPs in Canada and each PSP has a unique enrolment form (EF). EFs are not standardized, despite collecting similar information. This study aims to identify areas to help improve the usability of EFs by assessing the current state of Canadian PSP EFs across 3 therapeutic areas (TA): multiple sclerosis, oncology, and rheumatology.

Methods: For each TA, a formal source was used to identify all existing drugs with a PSP, resulting in 167 drugs. Corresponding EFs were obtained from manufacturers or accessed online; 107 EFs were retained for analysis. Percent sample sizes were calculated for each TA; 89% (multiple sclerosis), 87% (oncology), and 100% (rheumatology). Sections and fields of the EFs were listed in Excel, by TA. Key stakeholders were interviewed to confirm section and field information. Comparison analyses identified similarities and differences within and across TAs.

Results: More than 90% of EFs contain 6 primary sections: Patient Information, Patient Consent, Physician Information, Physician Authorization, Prescription, and Legal and Privacy Information. Field sections, section names, order of sections, and form layout are highly inconsistent. Patient Information is the only consistent section.

Conclusion: The inconsistencies across EFs indicate a high complexity for health care stakeholders who use EFs. PSP EF guidelines are needed to improve standardization across forms, which would increase usability and efficiency. This could also potentially enhance the quality of data collected by PSPs.

9. A systematic review and meta-analysis of interventions aimed at delabelling low-risk penicillin allergies with consideration for sex and gender (student oral presentation)

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Background: About 10% of people report a penicillin allergy with some studies reporting a higher prevalence in females; yet more than 90% of these can have the documented allergy removed. This research summarizes the effectiveness and safety of penicillin allergy delabelling interventions in low-risk individuals and sex and gender differences in reporting and outcomes.

Methods: A literature search was performed to identify studies reporting on delabelling penicillin allergy via direct delabel or oral challenge in adults. Screening, data abstraction, and quality assessment were conducted by 2 independent reviewers. Random effects meta-analyses were conducted, with predefined subgroup meta-analyses when I^2 was > 75%.

Results: Of 2,330 studies screened, 28 were included. Participant sex was reported in 24 studies of which 5 reported sex-disaggregated outcomes. None reported on participant gender. Oral challenge testing showed no difference in delabelling outcome from penicillin skin testing in 2 RCTs (OR = 2.84; 95% CI, 0.86 to 9.43; I^2 = 0%). High heterogeneity among quasi-experimental studies necessitated subgroup analyses by health provider. Direct delabelling (based on reported reaction without testing) by nurses resulted in 29% delabelling (95% CI, 0.15 to 0.47; I^2 = 63%), whereas by allergist/immunologist 6% were delabelled (95% CI, 0.00 to 0.99; I^2 = 20%). Oral challenge by allergist/immunologist and pharmacists resulted in 59% (95% CI: 0.06 to 0.97; I^2 = 10%) and 90% delabelling (95% CI, 0.86 to 0.97; I^2 = 37%), respectively.

Conclusion: Direct delabelling resulted in removal of penicillin allergy labels in approximately one-fifth of participants. Oral challenge resulted in delabelling in the majority of those with low-risk allergies. Sex and gender data on predictors and outcomes are lacking, highlighting opportunities for future research.

10. Drug utilization trends among patients with bipolar disorder in Alberta between 2008 and 2021

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Methods: This study used provincial administrative health data from Alberta, Canada. Individuals with at least 1 specific ICD-9 or ICD-10 code for bipolar disorder (BD) were identified from 3 databases — provider claims (from April 1, 1994, to March 31, 2021), hospital Discharge Abstract Database (from April 1, 2002, to March 31, 2021), and the Ambulatory Care Classification System file (from April 1, 2002, to March 31, 2021). Within these individuals, we identified prevalent, new, and combination use of 10 medications, including aripiprazole, asenapine, carbamazepine, divalproex, lamotrigine, lithium, lurasidone, olanzapine, quetiapine, and risperidone through prescription information from the Pharmaceutical Information Network database (from January 1, 2008, to March 31, 2021).

Results: Between April 1, 1994, and March 31, 2021, 136,628 individuals had at least 1 code of BD with 9,466,407 prescriptions dispensed between January 1, 2008, and March 31, 2021. Among all BD medications, quetiapine had the highest number of both prevalent users and new users in both total and age and sex subgroups throughout the study period. New users of all medications appeared to decline, especially from 2019 to 2021. Aripiprazole prevalent and new users increased, especially in males aged 18 to 24 years. Lamotrigine prevalent users increased in the total population, particularly in females. Conversely, prevalent and new users declined for lithium, divalproex, and carbamazepine. Most individuals relied on a single medication for BD treatment. The most common combination therapy for prevalent users was divalproex with a second-generation antipsychotic. However, prevalent users for the lamotrigine-SGA combination steadily increased, reaching parity with the divalproex–second-generation antipsychotic combination by 2021.

Conclusions: Overall, a dynamic landscape of medication use in BD treatment was evident. Along with quetiapine, newer medications like aripiprazole and lamotrigine are gaining traction, while the use of some older BD medications is declining. The current guidelines offer a wide range of first-line treatment options, potentially influencing medication selection based on side-effect profiles, individual compliance, and coexisting conditions.

11. Creating best practices in clinician and patient group policy consultations and collaboration with payers and HTA bodies: Lessons from the MS community

Glennie J,[1] Burton JM,[2] Eisner M,[3] Freedman MS,[4] Kelndorfer J,[5] Morrow SA,[2] Rotstein DL,[6] Smyth P,[7] Yeh EA[8]

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Background: Public payer access to multiple sclerosis (MS) medications varies markedly across provinces. The Conference Board of Canada cites this inequity as a key factor undermining optimal outcomes for persons with MS. To address these challenges, MS Canada and the Canadian Network of MS Clinics (CNMSC) developed an innovative, policy-focused, drug-agnostic approach to engagement with decision-makers. Direct dialogue between patient and clinician groups and provincial payers and/or health technology assessment agencies creates opportunities for constructive engagement and collaboration on practical solutions to drug access challenges. Our approach involves highlighting practical, evidence-based policy solutions to decision-makers and supporting them through the change process.

Research has identified opportunities for public drug programs to simplify MS medication access, balancing appropriate drug use with timely reimbursement while minimizing administrative burden. In 2023, CNMSC and MS Canada's collaboration with Alberta Health resulted in extending renewal periods for MS medications. Similar work in Ontario has benefited patients, clinicians, and the provincial drug program. Working at a national level to improve pan-Canadian alignment will help simplify access for persons with MS, clinicians, and government drug plans, thereby avoiding potentially life-changing delays and/or gaps in treatment.

This poster will outline the background for the CNMSC medication access initiative and share key data articulating the inequities in MS medication access across Canada. Cornerstone policy engagement activities from this initiative will also be highlighted, with particular emphasis on accomplishments and the impact that patient groups, clinicians, and policy-makers can have when they collaborate to improve medication access.

12. Exploring the prevalence of post-traumatic stress disorder and post-traumatic stress symptoms in parents within 12 months of child burn injury: A systematic review

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Background: The experience of sustaining burn injuries can be an incredibly distressing event. The psychological impact of such traumatic events on burn survivors, both adult and children, is an area of increasing interest. Yet, the psychological distress in parents of children with burns is poorly quantified in the literature. Our systematic review aimed to investigate the prevalence of post-traumatic stress symptoms (PTSS) and post-traumatic stress disorder (PTSD) among parents within 12 months of their child's burn injury.

Methods: A literature search was conducted in PubMed, Embase, Web of Science, PsycINFO and CINAHL on January 6, 2023, for quantitative studies reporting the prevalence of PTSD and/or PTSS in parents within 12 months following their child's burn injury. Risk of bias was assessed using the Mixed Methods Appraisal Tool version 2018. A narrative synthesis of prevalence was presented.

Results: We identified 15 articles that met our inclusion criteria. The prevalence of PTSS within 12 months following the burn injury ranged from 6% to 49%. Prevalence estimates of PTSD within the 12 months following a burn injury were limited, ranging from 4.4% to 22%.

Conclusions: Our findings highlight the significant impact of burn injuries on parental mental health, with a considerable proportion of parents experiencing PTSS within 12 months following their child's burn injury. Prevalence estimates for PTSD were limited and warrant further investigation. Our review also underscores the need for standardization of PTSS/PTSD terminology. Timely and targeted psychological support is needed for parents in the aftermath of their child's burn injury.

13. Use of health care administrative claims data in observational studies of antirheumatic drug effects on pregnancy outcomes: A scoping review

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Background: The safety of antirheumatic drugs in pregnancy and their impact on maternal and neonatal outcomes are understudied. Despite pregnant individuals being excluded from clinical trials, their continued use of medications raises the importance of addressing knowledge gaps regarding safety and impact on outcomes. We conducted a scoping review to describe how antirheumatic drugs and associated adverse pregnancy outcomes have been investigated in observational studies using claims data.

Methods: We searched MEDLINE, Embase, CINAHL and grey literature to identify observational studies using claims data to investigate the antirheumatic drug effects on pregnancy outcomes in individuals with rheumatic diseases. Search terms combined 4 main concepts: rheumatic diseases, drug therapy, pregnancy, and claims data.

Results: Of 3,737 articles identified, 30 eligible articles were included. The effects of conventional synthetic disease-modifying antirheumatic drugs (n = 29, 96.7%) and tumour necrosis factor inhibitor biological agents (n = 20, 66.7%) were well-reported. Preterm birth (n = 19, 63.3%), Caesarean delivery (n = 12, 40.0%), congenital anomalies (n = 12, 40.0%), stillbirth (n = 12, 40.0%), preeclampsia (n = 11, 36.7%), and small-for-gestational age (n = 11, 36.7%) were the most reported adverse pregnancy outcomes. Of 12 studies reporting congenital anomalies, 10 (83.3%) specified International Classification of Diseases codes and 4 (33.3%) specified validated definitions for identification in claims data, the most of any reported adverse pregnancy outcome.

Conclusions: We found considerable ambiguity and heterogeneity in adverse pregnancy outcome definitions in claims data. There is a need for greater transparency and consistency in outcome reporting in observational studies using claims data.

14. Optimizing surgical antibiotic prophylaxis in patients with a penicillin allergy label: A narrative review with sex and gender considerations

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Background: Cefazolin serves as the preferred antibiotic for prophylaxis of surgical site infections, but the presence of penicillin allergy labels (PALs) increases use of second-line agents. This review aims to synthesize the impact of risk-stratification interventions on antibiotic prophylaxis in patients with PALs and evaluate sex or gender-related outcomes.

Methods: A search was conducted in PubMed and Ovid Embase for articles published between January 2019 and September 2023, using the terms surgical antibiotic prophylaxis AND penicillin allergy. Relevant references were also examined. The title and abstract screening were done in COVIDENCE by a single reviewer, followed by full-text review by 2 reviewers. Included studies focused on risk-stratification strategies affecting antibiotic prescribing for surgical patients with PALs, excluding penicillin delabelling efforts.

Results: Eleven studies met inclusion criteria. Various surgical settings implemented risk-stratification interventions. Two studies involved obstetrical patients. Six studies provided sex-specific descriptive date, with an average female prevalence of 68.5% among those with PALs. Interdisciplinary teams commonly developed risk-stratification tools, often including clinician education. Optimal antibiotic prophylaxis prescribing consistently improved with an average increase of 26% across the studies post intervention. One study reported ongoing appropriate prescribing 2 years after implementation. Allergic reactions were rare, with 3 cases of anaphylaxis or IgE-mediated reactions, which all resolved with treatment. No studies reported sex or gender-specific outcomes.

Conclusion: Incorporating risk-stratification tools into perioperative practices enhances the use of optimal antibiotic prophylaxis in patients with PALs with minimal safety issues. Outcomes specific to sex or gender are lacking, highlighting a need for future research.

15. The comparative effectiveness of ambulatory care warfarin management models: A systematic review and meta-analysis

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Background: Growing evidence suggests that nonphysician providers (NPPs) can effectively manage warfarin therapy. This systematic review and meta-analysis aimed to evaluate the efficacy and safety of warfarin management by various health care practitioners compared to usual medical care (UMC) in ambulatory patients.

Methods: We conducted a systematic search of PubMed (MEDLINE), Ovid Embase, Ovid International Pharmaceutical Abstracts, Scopus, CINAHL (EBSCO), and the Cochrane Central Register of Controlled Trials (CENTRAL) from inception to January 2024. Studies were included if they were randomized controlled trials or quasi-experimental designs comparing warfarin management across professions in ambulatory patients. Two independent reviewers performed title and abstract screening, full-text review, extraction, and risk-of-bias assessment. Results were pooled using a random-effects model and inverse variance weighting.

Results: Of 19,122 citations identified, 7 met the inclusion criteria. NPPs included pharmacists, nurse practitioners, and multidisciplinary teams. Meta-analysis showed no significant difference in time spent in therapeutic range (mean difference = 2.06%; 95% confidence interval [CI], -1.22 to 5.35; I^2 = 0%) for NPPs versus UMC. There were also no differences in thrombosis (relative risk [RR] = 1.19; 95% CI, 0.39 to 3.68; I^2 = 0%), hemorrhage (RR = 0.98; 95% CI, 0.43 to 2.22; I^2 = 0%), or death (RR = 0.95; 95% CI, 0.34 to 2.59; I^2 = 0%). NPP management significantly increased patient satisfaction (standardized mean difference = 0.50; 95% CI, 0.10 to 0.90; I^2 = 78%).

Conclusion: Warfarin management by NPPs was associated with increased patient satisfaction, and comparable efficacy and safety to UMC. These findings support NPPs' role in anticoagulation management, potentially enhancing health care delivery.

16. CADTH's implementation of GRADE in reimbursement reviews: A narrative review

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Background: In April 2023, CADTH adopted the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach for evaluating the level of certainty for evidence in clinical review reports. CADTH's rationale was not to change how evidence is assessed, but to improve the transparency and structure regarding how assessments are communicated. We aimed to evaluate how GRADE is being

used by CADTH to identify patterns and generate recommendations to prepare for future reimbursement submissions.

Methods: We reviewed a sample of 6 non-oncology CADTH reimbursement reviews that included GRADE and described the certainty of evidence assessments, common reasons for upgrading or downgrading of outcomes according to the GRADE domains, and final recommendations issued.

Results: CADTH considered the 5 GRADE domains of uncertainty when assessing the clinical evidence — risk of bias, imprecision, inconsistency, indirectedness, and publication bias. Evidence was commonly rated down due to imprecision, followed by indirectedness and risk of bias. Areas for subjectivity included thresholds for appreciable benefits and harms, if they were not predefined. In all cases, CADTH issued positive recommendations to reimburse with conditions, despite the observed wide variation in the certainty of clinical evidence from very low, low, moderate, to high.

Conclusion: While GRADE aims to provide structured frameworks for rating the quality of evidence, assessments are subjective and can be based on value-and-preference judgments by reviewers. It is unclear from this review to what extent GRADE rating has weighed in the decision-making process or in CADTH's final recommendation. This remains to be analyzed in future work.

17. Cost of patients with stage I-III, nonsquamous, non–small cell lung cancer receiving surgery as primary treatment

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Background: With numerous Health Canada approvals of novel therapies such as epidermal growth factor receptor tyrosine kinase inhibitors (EGFR-TKIs) and immunotherapies, we sought to establish the real-world economic burden of managing early-stage (I to III), resectable non–small cell lung cancer (NSCLC).

Methods: This was a retrospective, longitudinal study conducted using real-world, population-level data with patients diagnosed with NSCLC in Ontario, Canada, between April 1, 2010, and March 31, 2019. Resection of stage I to III NSCLC within 180 days of diagnosis and receipt of EGFR-TKI therapy in the metastatic setting were used as indicators for early-stage NSCLC and EGFR mutation, respectively. Costs (2023 CA$) for 3 patient cohorts (overall, nonmetastatic, EGFR-TKI metastatic) were calculated using an individual person-level costing methodology with healthy matched controls for the overall cohort.

Results: Overall, 8,255 early-stage NSCLC patients were identified with mean age of 68.0 ± 9.1 years; 53.5% female; and 59.1%, 25.7%, and 15.1% stage I to III distribution, respectively. All patients underwent surgical resection at rates of 56%, 54%, and 14% for stage I to III, respectively. From resection to end of follow-up, the total mean cost per patient year for NSCLC cases was $21,383 versus $4,829 for controls. Inpatient hospitalizations, cancer clinic visits, and specialist visits generated the largest cost differences. The

total mean cost per patient year for nonmetastatic cases (N = 7,155) of $10,684 was considerably lower than the $27,689 for the EGFR-TKI metastatic cases N = 275).

Discussion: Using real-world, population-level data from the largest Canadian province, current costs associated with treating resected early-stage NSCLC patients will provide critical information for health care resource allocation.

18. Realization of biosimilar savings in Canada: Case study of ranibizumab

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Background: Given the significant cost of biologics, there is global awareness that supportive biosimilar policies are necessary to optimize drug spending. In Canada, drug plans have taken the approach of implementing biosimilar switch policies. This analysis examines the effectiveness of Canadian biosimilar switch policies in the context of the entry of biosimilar ranibizumab.

Methods: Drug plan spending in Canada was analyzed beginning at commercial availability of a ranibizumab biosimilar, up to the latest month of data. Total possible savings were calculated by multiplying units sold by the difference in list price between the originator and biosimilar. Possible savings were compared against savings achieved. Trends in savings were analyzed over time and across jurisdictions.

Results: From the period spanning March 2023 to April 2024, drug plans could have saved approximately $86 million by switching to a ranibizumab biosimilar. Achieved savings were approximately $6 million, or 7% of available savings. The proportion of savings achieved was highest in New Brunswick (23%) and Quebec (21%). Achievable savings decreased during the analysis period, from $7.4 million in the first month, to $4.4 million in the last month of observation, reflecting a decline in the market share of ranibizumab among competing intravitreal molecules.

Conclusions: This analysis showed 35% of possible savings occurred before any public formulary access, and achievable savings declined monthly, suggesting significant incentive to accelerate biosimilar listings and to promptly apply biosimilar switch policy. Future biosimilar entries within the analyzed therapeutic area will provide a greater magnitude of saving opportunities, and without improvements, a greater magnitude of missed savings.

19. Access to drugs for rare diseases (DRDs) in Canada: Health Canada approvals and public coverage

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Background: Drugs for Rare Diseases (DRDs) are critical given the estimated 1 in 12 Canadians with a rare disease. Patients with pediatric, oncology, or ultra-rare diseases may encounter challenges in accessing these medications. We aim to quantify the number of DRDs approved in Canada and their public coverage status.

Methods: DRDs with European Medicines Agency or Federal Drug Administration orphan drug designation and Health Canada approval for the same indication from January 1, 2000, to April 1, 2024 were included. DRDs were categorized as oncology, pediatric, or ultra-rare (prevalence < 1 in 50,000). Public coverage for DRD indication submitted to Canada's Drug Agency before January 1, 2023, was assessed using IQVIA's Market Access Metrics. DRD public coverage was compared to non-DRDs.

Results: Among the 353 DRD molecules approved, 150 (42.5%) have pediatric, 141 (39.9%) have oncology, and 107 (30.3%) have ultra-rare indications. Annual DRD approvals more than doubled from 2000 to 2012 (median: 9.0 per year) to 2013 to 2024 (median: 20.5 per year). Among the 184 DRD molecules submitted to Canada's Drug Agency, 149 (81.0%), 127 (69.0%), and 65 (35.3%) have coverage in > 1, > 5, and all provinces, respectively. Rates of public coverage in all provinces varied across categorizations, with 20.9%, 31.4%, and 47.4% of pediatric, ultra-rare, and oncology DRDs, respectively. Reimbursement rates are similar between DRDs and non-DRDs (coverage in > 1: 81.7%; > 5: 63.3%; all provinces: 37.1%).

Conclusions: Less than half of DRDs have coverage in all provinces, with coverage disparities across categories. Efforts to increase public coverage for DRDs are critical to ensure patient access.

20. Cost-effectiveness of statins in the primary prevention of cardiovascular disease in older adults: A 5-year retrospective cohort study

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Background: Few studies have investigated the cost-effectiveness of statins in older adults in a real-world primary prevention setting. The existing ones have based their statin effectiveness data on subgroup analyses from randomized controlled trials. However, using data from randomized controlled trials in an economic evaluation may not reflect medications' true efficiency profile in a real-world setting. The objective of the study was to assess the real-world cost-effectiveness of statins in the primary prevention of cardiovascular diseases (CVDs) in older adults (> 65 years old).

Methods: We conducted a retrospective cohort study to evaluate the cost-effectiveness of statin therapy over a 4-year time horizon. The patient cohort, comprised of 39,800 patients identified using Quebec claims data, was followed from April 1, 2013, to March 31, 2018. We will exclude individuals with any statin

prescription in the year before the index date and those with any CVD history between April 1, 2008, and March 31, 2013, to include only new users of statins for primary prevention. Patients were considered exposed to statins if they persisted in the treatment for at least 3 months and not exposed if they failed to persist. The incremental cost-effectiveness ratio between the 2 groups was measured in 2018 Canadian dollars per life-years gained from a health system perspective, applying a discount rate of 1.5%. We will be using the inverse probability weighted estimator to control administrative censoring. We will thus reweigh each complete case so that each complete case represents not only itself but also a number of incomplete or censored cases. We will also be using inverse probability weighted to control baseline confounding.

Results: The use of statins in the primary prevention of CVD in adults aged > 65 years old was found to be cost-effective compared to usually accepted thresholds, with an incremental cost-effectiveness ratio of $2,949 per life-year gained. More precisely, adjusted mean costs for exposed patients were $11,774 compared to $11,917 for non-exposed patients, with adjusted average life-years per patient being 3.39 and 3.44 for exposed and non-exposed patients, respectively.

Conclusions: Study results suggest that, in patients > 65 years old, statins could be a cost-effective solution in the primary prevention of CVD in older adults.

21. Economic evaluation of hospital costs for advanced practice physiotherapy models of care for upper extremity musculoskeletal disorders in Denmark: A registry-based cohort study

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Background: The increasing prevalence of musculoskeletal (MSK) disorders is placing significant pressure on health care systems. Advanced practice physiotherapy (APP) models of care, which provide greater autonomy and responsibility to physiotherapists, have emerged as promising solutions to increase health care access while providing cost-effective care for MSK disorders. A formal health economic evaluation of these models has yet to be undertaken in Denmark. The objective is to perform an economic evaluation of

APP care versus standard care models for managing upper extremity MSK disorders in 4 Danish orthopedic clinics using the hospital centre perspective.

Methods: This is a retrospective registry-based observational study comparing hospital costs per patient with upper extremity MSK disorders consulting in APP or standard models of care. Data related to sociodemographic, diagnoses, and hospital costs within a 2-year period after the initial consultation were extracted. Total hospital costs, as well as hospital costs specific to MSK and shoulder disorders, were extracted. Costs were adjusted for inflation and converted to 2022 Euros. Propensity score weighting was used to adjust for confounders.

Results: A total of 13,520 patients were included. The between-group difference in total hospital costs (MD = 95.3; 95% CI, −295.3 to 486) and MSK-specific hospital costs (MD = −62; 95% CI, −130.8 to 6.7) were not statistically significant. Shoulder-specific hospital costs (MD = −68.8; 95% CI, −131.4 to −6.3) were lower with APP care.

Conclusion: APP care results in similar total and MSK-specific hospital costs but lower shoulder-specific hospital costs when compared to standard care for adults with new upper extremity MSK disorders.

24. How much does it cost for the health care system to manage a person presenting with a musculoskeletal disorder to the emergency department? (student oral presentation)

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Background: Musculoskeletal disorders (MSKDs) are an important cause of costs to patients and society. Up to 25% of all emergency department (ED) visits are for MSKDs, but little data on their financial impact are available. We aimed to measure costs of care processes administered to patients presenting with a minor MSKD in a Canadian academic ED.

Methods: Cost study based on data collected during a randomized clinical trial (NCT04009369, interventions compared: physician alone, physician + physiotherapist). We recruited people (aged 18 to 80 years) who presented to the ED for a minor MSKD (n = 78). Costs incurred were estimated using Time-Driven Activity-Based Costing, in which time invested with a patient determines care costs. Care processes' costs were calculated by 1) multiplying the duration of each process by the cost per minute of each necessary resource, and 2) adding up costs for resources used.

Results: Resource costs varied considerably (2019 CA$, minimum–maximum, $/minute; human resources: 0.62 to 6.92, equipment: 0.02 to 1.06, consumables: 0.01 to 0.22, overheads: 0.03 to 0.21). The median cost of the physician's assessment was $47.09 for ambulatory patients (duration, 6.8 minutes) and $59.84 for

stretcher patients (8.6 minutes). The physiotherapist's assessment cost $80.01 for ambulatory patients (60.0 minutes) and $120.01 for stretcher patients (90.0 minutes). The minimum cost for managing 1 ambulatory patient was $62.46, and $249.92 for stretcher patients.

Conclusions: Estimating costs of care processes is an essential step toward a better understanding of the overall costs associated with managing people presenting with MSKDs in EDs. Results of this study will contribute to improving the value of care provided in the ED.

25. Improving time to patient: Insights from the Canadian cancer treatment hackathons

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Background: Canada's drug reimbursement process is complex, particularly with diverse levels and jurisdictions, resulting on an average of 732 days for patients to access new medicines. This poses a challenge for cancer patients needing timely access to new and effective treatments.

Methods: To examine potential improvements in patient access to new medications, Colorectal Cancer Canada held roundtables entitled The Canadian Cancer Treatment Hackathons from November 2022 to March 2024 with more than 100 thought leaders, including key stakeholders from Canada and internationally.

Results: The first Hackathon in 2022, focused on novel ideation within existing systems, yielded opportunities, including global solutions for simultaneous data review in regulatory processes, international sharing of health technology assessment (HTA) reviews, and concurrent negotiation by the pan-Canadian Pharmaceutical Alliance with HTA reviews at the pan-Canadian Oncology Drug Review Expert Review Committee/Canadian Drug Expert Committee level. The second Hackathon explored critical success factors and guiding principles from 5 leading international HTA/regulatory agencies — England/Wales, France, Germany, Italy, and Australia. The third Hackathon allowed participants to ideate a new drug review and reimbursement process, and 5 key themes were identified to improve time to patient, laying the foundation for more timely access to new and effective medications. In the fourth Hackathon, high-priority ideas aimed at expediting public access to new and effective drugs emerged based on international collaboration agreements. The fifth Hackathon, built on insights from past hackathons and identified action change among key stakeholder groups, including patient groups, industry leaders, and clinicians.

Conclusions: These collaborative efforts demonstrated a commitment to enhancing patient outcomes through refined processes, global insights, and strategic collaborations in the Canadian system.

28. The potentially inappropriate use of psychotropic medications in home care residents

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Background: Demand for home care services is high due to a growing preference of individuals with medically complex conditions to age in their own home rather than in long-term care. Home care recipients can experience neuropsychiatric and mental health issues for which psychotropic medications are prescribed. These medications can have significant negative consequences if not used appropriately and monitored, and can result in falls, hospitalization, or death. Deprescribing initiatives have largely focused on the long-term care population, but evaluation and development of strategies for home care recipients is limited. We sought to determine the prevalence of psychotropic medication use among home care recipients and how these rates compare to long-term care residents and the general older adult population.

Methods: We analyzed data from the Resident Assessment Instrument-HC (RAI-HC). We included home care recipients in Ontario, Canada, enrolled between April 1, 2011, and August 31, 2018, receiving services for > 6 months (n = 850,803).

Results: In the week before RAI-HC assessment, 48% of home care recipients had taken at least 1 psychotropic medication while 17.9% had taken 2 or more. The most common psychotropic medications taken were hypnotics (24.4%), followed by antidepressants (22.8%), anxiolytics (14.8%), and antipsychotics (9.6%). Twenty-one percent of the population had dementia, 14.7% had a psychiatric disorder, and 18.9% had depression.

Conclusions: The prevalence of potentially inappropriate psychotropic medication use in home care recipients is high. A deeper exploration of the appropriateness of these prescription patterns is needed to determine whether prescriber and health system–level interventions are necessary to optimize medication use.

31. Improving medication prescribing–related outcomes for vulnerable elderly in transitions on high-risk medications (IMPROVE-IT HRM): A pilot randomized trial protocol

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Background: We assess whether an expert clinical pharmacology/toxicology specialist–led medication management intervention is feasible and can decrease drug therapy problems among hospitalized seniors taking multiple medications in the transitions of care.

Methods: The design is a pragmatic pilot randomized trial with 1:1 patient-level concealed randomization, blinded outcome assessment, and data analysis. Participants were community-dwelling adults 65 years and older taking 5 or more chronic medications including at least 1 high-risk medication. The clinical pharmacology/toxicology physician in-hospital consult identified priority medication targets, patient preferences, ensured clear discharge medication reconciliation and circle-of-care communication, and saw the patient at least twice after hospital discharge by virtual visits. Primary outcomes were feasibility and drug therapy problems improved; secondary outcomes examined care coordination, quality of life, health care utilization, and costs. Follow-up was to 3 months post discharge.

Results: Recruitment took 12 months with 1,765 screened, 311 eligible (50.5% female), 215 approached (58.4% female), and 60 enrolled (66.7% female, mean age 76.7 (SD 8.2), at an estimated mean cost of $972 per patient. The mean number of baseline medications was 15.1 (SD 4.2). APEQ results showed that 58 (96.8%) patients had at least 1 inappropriate medication issue, most commonly dosing. Mean overall medication-related quality of life score was 6.4 (SD 9.6, possible range 1 to 36, higher scores worse), and most impacted domains were self-efficacy and vitality. Full end-study results are pending.

Conclusions: Although the intervention allows scarce specialty expertise to be offered widely by virtual care, patient willingness to undertake a medication improvement intervention may limit feasibility for a full randomized trial.

32. Leveraging real-world data (RWD) to improve COPD management and patient outcomes across Canada

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Background: Real-world data (RWD) can provide location-relevant and timely population-based insights to identify regions with the greatest disease burden. As chronic obstructive pulmonary disease (COPD) is associated with significant mortality and high health system costs, our aim was to utilize RWD to characterize intraprovincial geographic variability in COPD burden across Canada to facilitate targeted interventions to improve COPD patient care.

Methods: Routinely collected retrospective provincial health administrative data were obtained from Alberta (2015 to 2022), New Brunswick (2015 to 2018), Ontario (2015 to 2022), and Quebec (2015 to 2019). COPD was identified using ICD codes and validated case definitions for population-based claims data in Canadians ≥ 35 years old. Outcomes included COPD prevalence, incidence, mortality, and health care resource use for the province and province-specific health units. Age- and sex-standardized rates were calculated based on provincial population census statistics.

Results: COPD prevalence increased during the study periods in all provinces. Age- and sex-standardized hospitalization rates demonstrated large intraprovincial variability between health units. The COPD-specific hospitalization rates per 1,000 person-years (range between provincial health units) were 36.8 (7.9 to 182.5) in Alberta, 46.1 (26.3 to 73.6) in Ontario, and 26.4 (6.1 to 83.3) in New Brunswick. Similar regional variability was observed for cardiovascular-related hospitalizations and all-cause mortality among the COPD populations. Variation in interprovincial COPD outcomes may be due to differences in provincial data sources, methodology, and study periods.

Conclusions: Using Canadian RWD, we identified health units with the greatest COPD burden in Alberta, New Brunswick, Ontario, and Quebec. These findings can be used for root cause analysis and targeted interventions to improve patient outcomes, health equity, and health system performance.

33. Preparing hospital electronic medical record data for pharmacoepidemiologic research: Initial data validation (student oral presentation)

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Background: Electronic medical records (EMR) are essential for pharmacoepidemiologic research; however, information on the data quality of current hospital EMRs in Canada is scarce. Our objective was to test the data validity in the Epic-Dovetale (EpicD) EMR to prepare for an analysis of "known" QT-prolonging medications (QTPMeds) and major adverse cardiac events (MACE).

Methods: An Entity Relationship Diagram (ERD) had to be developed to understand the key tables and relationships in EpicD. Computational data validation (comparing EpicD data extractions to Slicer Dicer and CIHI DAD data) plus manual data validation (comparing EpicD to manual chart review) were applied with iterative adjustments. Plain agreement and diagnostic accuracy (sensitivity [Sn], specificity [Sp], positive predictive value, negative predictive value) were used to estimate data validity.

Results: Five key data themes were investigated, including Demographics: eligible patients, age, sex, gender, postal code, and admission (> 99% agreement); Exposures: administration of QTPMeds (235 charts abstracted, Sn 97%, Sp 100%); Outcomes: MACE — a composite of ventricular arrhythmias, syncope, and death (438 charts abstracted from CIHI DAD data, Sn 99%, Sp 81%); Confounders: lab and electrocardiogram results (100% agreement), and telemetry monitoring, comorbidities, and drug interactions (improvements ongoing); Timestamping: medication administration (56 charts abstracted, 100% agreement), and admission and outcome times (improvements ongoing).

Conclusions: New data resources require iterative development of accurate ERDs to be able to support highly accurate data extraction. At this initial stage, EpicD data shows a high degree of agreement and diagnostic accuracy for most fields, but MACE requires use of CIHI DAD data.

35. Biomarker testing patterns and turnaround times in Canadian advanced non–small cell lung cancer

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Background: Timely biomarker testing contributes to tailored treatment selection, improved outcomes, and reduced adverse events. However, access to biomarker testing and reporting varies across Canada. The purpose of this study was to describe testing rates, turnaround time, and timing of biomarker testing in locally advanced and metastatic non–small cell lung cancer (mNSCLC) across Canada.

Methods: A repeated cross-sectional study was conducted between October 2022 and March 2024 using IQVIA's Oncology Patient Outcomes platform. We extracted physician and patient demographic and biomarker data from 134 oncologists practising in academic and community settings across Canada who reported on 1,199 patient charts.

Results: Physicians saw an average of 90 NSCLC patients in the past 9 months, had 15 median years in practice, and most (81%) had access to next-generation sequencing within their practice. Most patients (67%) were 60+ years old and 59% were male. Testing for standard of care biomarkers, EGFR, ALK, ROS-1, BRAF, and PD-L1, was high. However, rates were lower and there was greater variability across regions and practice settings for tumour mutational burden, microsatellite instability, and circulating tumour cells. Turnaround ranged from 2 to 50 days with a median 14 days. Testing rates and turnaround time remained largely unchanged across regions over the study period; however, rates among community-based physicians increased. Most patients were tested for biomarkers at diagnosis.

Conclusions: Health system improvements to reduce turnaround times and improve accessibility to testing for emerging biomarkers would facilitate equal access to timely testing and appropriate treatment selection for all patients.

36. Do higher prices provide protection against drug shortages? Real-world evidence lessons from Canada

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Background: International supply chains could favour countries with higher prices when there are production disruptions, leading to more shortages in countries with lower prices. This research aimed to assess whether drug shortages reported by Canadian manufacturers were associated with lower drug prices in Canada than in other countries.

Methods: Using international drug sales data from IQVIA's MIDAS database and drug shortage reports from the Drug Shortages Canada website, logistic regression models were used to estimate the likelihood of oral

solid drugs being reported as in shortage in Canada between 2017 and 2022. Model specifications included drug-level and ingredient-level characteristics, year effects, and international price ratio variables to assess associations between the relative price of Canadian drugs and shortages.

Results: N = 31,956 drug-year observations and N = 14,750 shortage reports were included in the analysis. Among the N = 12,222 drug-year observations for which international price comparisons were available, N = 3,424 (28%) were reported in shortage. Price ratios were modestly associated with the likelihood of shortages (P = 0.0495), while stronger associations were noted with market size, therapeutic class, generic status, number of countries with sales, and number of manufacturers (P < 0.0001 to P = 0.004). In a subanalysis, no significant association was found between price ratios and shortages in the patented market segments.

Conclusion: The analysis performed did not support the hypothesis of higher drug prices decreasing the probability of a drug being in shortage.

37. Competition in generic drug markets: International progress and room for improvement, 2010 to 2021

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Background: This research aimed to compare the generic drug markets of a group of countries with similar pharmaceutical environments and study how competition has evolved in recent years.

Methods: The study used oral solid drug sales data from IQVIA's MIDAS database and population data from the OECD for the period 2010 to 2021. We investigated trends in the number of companies selling generics, the distribution of medicines sold by number of available generics, and the proportion of off-patent markets dominated by a single manufacturer. We compared the generic markets of 13 high-income countries.

Results: Between 2010 and 2021, growth was observed in the number of generic companies selling 25 or more generic products in 10 of 13 countries. Although levels were generally correlated with population size, there were cases where this correlation did not hold. While the share of drugs with 2+ generic options increased in all countries except Japan and Canada, the share remained below 50% in 10 countries in 2021, meaning that more than half of products sold did not feature competition for generic products. As a result, more than 70% of off-patent products were dominated by a single company in all countries except the US (65.1%).

Conclusion: Although we found increases in the number of competing firms and drugs with multiple generics available in most countries during the study period, significant cross-country differences remained and most off-patent drugs were dominated by a single company in all countries in 2021, suggesting considerable room for improvement.

38. Promoting collaboration to transform the health system and enable the promise of cell and gene therapies

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Background: Cell and gene therapies (CGTs) represent highly personalized and innovative approaches to addressing the underlying causes of genetic and acquired disorders. CGTs are unlocking new ways to treat, prevent, and potentially cure some diseases.

CGTs such as CAR T-cell therapies have made a positive impact on treatment options available to Canadians with various hematologic malignancies. Recently marketed gene therapies are providing hope for people with inherited eye diseases and sickle cell diseases. CGTs are in development to treat a wide range of illnesses, including cancers, rare diseases, type 1 diabetes, and chronic heart failure. The novelty and promise of these emerging therapies — as well as the important outcomes delivered by those that have made it to market so far — create new opportunities for improved health outcomes for Canadians.

Timely integration of CGTs into our health systems is a key success factor in being able to leverage these innovations. The unique and highly technical nature of these products also requires a new playbook from those who assess, deliver, and receive care.

These products represent a major wave of disruptive innovation, so anticipating and understanding how they will change standards of care is a key first step. From regulation to health technology assessment, reimbursement, implementation, and education, we must ensure that a holistic yet efficient approach is taken to ensuring appropriate patient access to CGTs. There are opportunities for all sectors involved to collaborate in the development and implementation of best practices that will enable timely assessment of CGTs and delivery of care.

The poster will provide an overview of the key success factors for ensuring that health systems are prepared to integrate these new innovations into the Canadian health ecosystem. The perspectives of patients, clinicians, and policy-makers will be explored.

40. Haloperidol and QT prolongation-related major adverse cardiac events: A systematic review

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Background: Haloperidol is a commonly used antipsychotic drug that is a frequent source of medication safety alerts because of its listing as a "known risk" QT interval-prolonging medication (QTPmed), We aimed to summarize the high-quality literature on the frequency and nature of arrhythmia-related major adverse cardiac events (MACE) associated with haloperidol.

Methods: We searched MEDLINE, Embase, International Pharmaceutical Abstracts, and Cochrane Central for randomized controlled trials involving patients 18 years or older comparing haloperidol to placebo. The FDA-adapted MACE composite included death, nonfatal cardiac arrest, ventricular tachyarrhythmia including torsades de pointes, seizure, or syncope. Random-effects meta-analyses were performed with a treatment-arm continuity correction for single-zero and double-zero event studies.

Results: Eighty-three randomized controlled trials (n = 12,038, 46% female, mean or median age > 65 years in 22.9% trials) with 37 (44.6%) involving participants with psychiatric diagnoses and 48 (57.8%) including electrocardiograms. Mean follow-up duration was 50.5 days (standard deviation [SD] = 75.3). There were 1,015 events, of which 98.0% were deaths, with 17 ventricular arrhythmias and 3 seizures or syncope. There was no increased risk of MACE with exposure to haloperidol compared to placebo (risk ratio [RR]: 0.90; 95% CI, 0.77 to 1.05; I^2 = 0%). Subgroup analysis suggested fewer events with haloperidol in trials with mean ages of more than 65 years (RR: 0.87; 95% CI, 0.76 to 1.00).

Conclusion: We did not find that haloperidol was arrhythmogenic or increased mortality in these largely short-duration trials. Further research to clarify actual clinical outcomes related to QTPMeds is important to inform safe prescribing practices.

41. Building a strategic foresight framework to support system readiness for advanced therapeutic products in Canada

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Background: In 2019, Health Canada developed a new legislative framework for advanced therapeutic products (ATPs) that created a new pathway for products that are not designated as a drug or a device. Strategic foresight provides a systematic approach to uncover hidden assumptions and address overlooked disruptions, resulting in insights into the factors influencing a system and possible emerging scenarios. Looking to enhance collaboration between Canada's Drug Agency and the biotech industry, the working group used a conceptual strategic foresight framework to identify ATPs and to anticipate system readiness.

Methods: Canada's Drug Agency and BIOTECanada formed a working group that established guiding principles and a 6-step strategic foresight framework to identify ATPs that may require additional adaptation at either the health technology assessment stage or health system implementation. Based on these criteria, islet cells were selected as a case study to test the framework steps and to develop a series of recommendations.

Results: To support the framework steps, the working group proposed recommendations categorized into 4 phases: anticipation, management, implementation, and evaluation. Each phase addresses actions for consideration throughout the process, and certain steps may occur simultaneously in some instances. The recommendations identified that equity considerations should be integrated throughout the process, and that early dialogue and collaboration with stakeholders, including the "receptor" of the ATP, are essential for success.

Conclusions: The cocreated strategic foresight framework principles and recommendations provide a valuable roadmap that can be utilized when the first ATPs come through the system.

47. Literature review and physician interviews highlight unmet need in FLT3-ITD+ acute myeloid leukemia in Canada

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Background: Acute myeloid leukemia (AML) is a heterogenous blood cancer, with guidelines recommending risk stratification based on gene mutations. Mutations of the FMS-like tyrosine kinase 3 (FLT3) gene occur in approximately 30% of all AML cases, with internal tandem duplication (ITD) being the most common (approximately 25% of all AML cases). The FLT3-ITD mutation is associated with higher risk of relapse and shorter overall survival.

Methods: Population estimates and data on the incident cases of AML were obtained from Statistics Canada. A broad literature review was conducted to identify relevant treatment guidelines. Interviews with 5 practising Canadian hematologists were conducted to gain insight into the real-world treatment of FLT3-ITD positive (FLT3-ITD+) AML in Canada.

Results: The estimated incidence rate of AML in adults aged ≥ 20 years was 4.94 cases per 100,000 in 2019. It is estimated that 1,599 adults with AML and 400 with FLT3-ITD+ AML will be diagnosed in 2024. Guidelines indicate that patients fit to receive intensive chemotherapy should be treated with standard 7

+ 3 (cytarabine and daunorubicin) induction therapy and high dose cytarabine consolidation therapy in combination with midostaurin (with eligible patients receiving allogenic stem cell transplantation), followed by maintenance therapy if available. Interviewed physicians confirmed treatment practice in the real-world setting; however, they noted a lack of reimbursed maintenance therapy options and a short time to relapse (6 to 9 months).

Conclusions: Despite currently available FLT3-targeted agents, the prognosis for FLT3-ITD+ AML remains poor. Improved treatment options will be required to address the significant unmet need in this population.

48. An examination of schizophrenia and residence on cholesterol management in newly treated type 2 diabetes

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Background: Many studies have examined how either schizophrenia or rural residence may impact type 2 diabetes management. We explored the intersection of these 2 factors on cholesterol management in individuals beginning type 2 diabetes pharmacotherapy.

Methods: Administrative health data between April 2015 and March 2020 from Alberta, Canada, were used to identify new metformin users and conduct a retrospective cohort study. A validated definition of diagnostic codes was used to identify people living with schizophrenia. Rural residence was defined using provincial geographic boundaries and postal codes. Multivariate logistic regression models were used to evaluate associations with guideline-concordant cholesterol management (laboratory measurement of cholesterol and statin use) during the first year of follow-up.

Results: Of 60,222 new metformin users (mean age 55 years; 43% women), 1.4% had schizophrenia and 23% were rural residents. Cholesterol was measured in 58% of the group; schizophrenia was not associated with a difference in likelihood (aOR = 1.13; 95% CI, 0.98 to 1.32). Statins were dispensed to 50% and there was an interaction between schizophrenia and residence (P = 0.0078). When stratified by residence, statin use was more likely in people living with schizophrenia (aOR = 1.69; 95% CI, 1.17 to 2.45) among those living in a rural area. In contrast, schizophrenia was not associated with a difference in likelihood of statin use (aOR = 1.14; 95% CI, 0.96 to 1.35) among those living in an urban area.

Conclusion: The effect of schizophrenia on statin use varies according to place of residence. Further research is required to explore the impact this may have on chronic disease management.

Canada's Drug Agency
L'Agence des médicaments du Canada
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

ISSN: 2563-6596

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