

Supplement

Proceedings of Canada's Drug Agency Symposium 2024

From Disruption to Opportunity: Embracing Change in Health Care
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Introduction

We are in a period of extreme disruption to health care in Canada and globally. The convergence of the COVID-19 pandemic, the rise of artificial intelligence, changing demographics, patient and public expectations, and other factors are having a profound effect on the delivery and sustainability of health care.

At the same time, this disruption is creating opportunities for Canada's Drug Agency and other organizations and health care systems to innovate, adapt, and transform to meet the evolving needs of patients and decision-makers. We've seen increased adaptability throughout health care, accelerated innovation and research, improved collaboration and information sharing, and greater awareness of health disparities.

Canada's Drug Agency Symposium 2024 delved into the strategies, technologies, and best practices that can help health technology assessment bodies and health care decision-makers navigate disruption and unlock new opportunities, including appropriate use of health technology.

Plenary Abstracts

PL1. Introducing Canada's Drug Agency

Moderator: Beth Kidd, Health Coalition of Alberta

Panellists: Guillaume Couillard, Patented Medicine Prices Review Board; Patrick Dicerni, Ontario Ministry of Health and Long-Term Care; Bettina Hamelin, Innovative Medicines Canada; Daniel MacDonald, Health Canada; Suzanne McGurn, Canada's Drug Agency; Dominic Tan, pan-Canadian Pharmaceutical Alliance

The Government of Canada announced that Canada's Drug Agency would build on and expand the mandate and functions of CADTH. Join us for a dynamic plenary focused on 1 of the new drug agency's core missions: system coordination and alignment. An esteemed panel will delve into the pivotal role of Canada's Drug Agency within the nation's pharmaceutical landscape, exploring shared priorities and collaboration opportunities to boost system efficiency. Discover how all system contributors will navigate disruption, embrace change, and innovate to meet the evolving needs of patients and decision-makers in Canada.

PL2. From Disruption to Opportunity: How AI is Changing Health Care and HTA

Moderator: Muhammad Mamdani, Unity Health Toronto and University of Toronto

Panellists: Nick Crabb, National Institute for Health and Care Excellence (NICE); Irena Guzina, French National Authority for Health (HAS); Pascale Lehoux, Institut national d'excellence en santé et en services sociaux (INESSS); Nicole Mittmann, Canada's Drug Agency; Dan Ollendorf, Institute for Clinical and Economic Review (ICER)

From drug development to diagnostic imaging to robotic surgery, artificial intelligence (AI) is having a profound effect on health care. AI is also changing how health technology assessment (HTA) organizations do their work and challenging them to consider different elements when assessing technologies that utilize AI. An international panel of senior HTA leaders will share their insights and experiences on how AI is being incorporated into HTA processes and how HTA can effectively address AI to create opportunities for improved patient outcomes and cost-effective health care delivery. They'll discuss why disruptive innovation is needed, the potential risks and benefits of AI, and what jurisdictions around the world are doing to adapt to these new challenges. Attendees will gain valuable insights into the role of HTA in embracing change and driving innovation in health care. They will leave with a deeper understanding of how HTA can help health care systems adapt to disruptions, seize opportunities, and ultimately improve patient outcomes and the sustainability of health care delivery.

Early Morning Session Abstracts

EM1. Operationalizing Outcomes-Based Agreements in Canada

Presenting author: Kate Harback, Institute of Health Economics

The Institute of Health Economics is launching an Outcomes-Based Agreement (OBA) Playbook to accelerate operationalization of OBAs in Canada. In 2023, the Institute of Health Economics convened a series of multistakeholder workshops with representatives from provincial and federal health technology assessment bodies, payers, patient associations, academia, and industry. Outputs from these engagements, including criteria for successful OBA pilots, form the foundation for the OBA Playbook. During this session, we will present our method for framing, building, and implementing an OBA Playbook. We will also hear perspectives from a panel of stakeholders about how this practical and action-oriented approach to supporting value-based decision-making can help move innovative agreements forward in Canada.

EM2. The Growing Problem of Drug Shortages: Understanding Their Impact on Research, Patients, and Health Care Systems

Presenter, panel moderator, author: Mina Tadrous, University of Toronto

Presenter: Stephanie Di Trapani, Health Canada

Presenting coauthor: Saad Ahmed, University of Toronto

Background: Drug shortages are a serious and growing concern around the world. One in 4 Canadians have been impacted by a drug shortage in the past 2 years. Managing drug supply issues is a daily issue for health care systems. Drug shortages are not limited to certain types of drugs, but are cross-cutting across indications, formulations, companies, and generic status. Drug supply is complex and is impacted by both supply and demand in several ways. These supply chains can be impacted by a variety of factors such as

commercial interests, geopolitical issues, natural disasters, and pandemics. This session will serve as a primer to the problem and its causes and ongoing initiatives to curb this growing important issue.

Description: The session will be divided in 3 parts (10 minutes each) assigned to each of the speakers. Dr. Saad Ahmed will introduce the problem and highlight some examples of drug shortages and their clinical impact. Dr. Mina Tadrous will introduce the underlying causes and reasoning for drug shortage through the lens of a supply and demand framework. He will share ongoing work to develop predictive models and to develop a national at-risk medicine list. Next, Stephanie Di Trapani, Director of the Drug Shortages Division in Health Canada (Canadian regulator) will provide an overview of potential policies and potential solutions that can be applied to help reduce the impact of drug shortages and lessons learned from the COVID-19 pandemic. The session will conclude with a 15-minute Q&A from panel members.

EM3. Health Economics

EM3-1. Severity Weighting of QALYs in Economic Evaluation: Why, How, and Where Next?

Presenting author: Shehzad Ali, Western University

Coauthors: Karen Lee and Alex Haines, Canada's Drug Agency

In the standard economic evaluation framework, health gains and losses are weighted equally across individuals, disease types, and severity, and decisions are made to maximize the sum total of population health (measured in quality-adjusted life-years [QALYs]) given available resources. This approach is agnostic to the pretreatment level of quality of life (i.e., disease severity) and assumes that a QALY is a QALY.

In the health technology assessment literature, a moral case is sometimes made for prioritizing treatments for severe conditions by valuing their health gains higher than those of treatments for less severe conditions. While there is notable heterogeneity in the evidence on severity weighting, several studies support the use of a severity premium. However, there is limited Canadian evidence informed by public preference studies.

We will discuss the current approaches used in the UK, the Netherlands, and Norway, based on the shortfall approach and a decision modifier, and their limitations. We will also discuss the implications of severity weighting for health technology assessment decision-making. Finally, we will discuss the groundwork needed to better understand societal values on distributional trade-offs between severe and nonsevere conditions, stakeholder considerations in relation to decision modifiers, and the opportunity cost of interventions that might be displaced by severity weights.

EM3-2. Using a 1-Day Living Kidney Donor Evaluation Process to Boost Kidney Transplant Rates: An Early Economic Evaluation

Presenting author: Andrew Scarffe, Ottawa Hospital Research Institute (OHRI)

Coauthors: Ann Bugeja, OHRI; Anubhav Agarwal, University of Ottawa; Edward Clark, OHRI; Kevin Burns, OHRI; Jessica McDougall, The Ottawa Hospital; Ariana Noel, The Ottawa Hospital; Manish Sood, OHRI; Gregory Knoll, OHRI; Kednapa Thavorn, OHRI; Heather Badenoch, The Ottawa Hospital

Introduction: Living donor kidney transplant is the optimal treatment to improve the quality and length of life for patients with kidney failure. Yet, the need exceeds demand. The evaluation period for a donor candidate in Canada is long, averaging 10 months. Early evidence has shown that evaluating potential kidney donors in 1 day can significantly increase the number of living donor kidney transplants. However, it remains unknown whether this expedited process offers good value for money compared to the current standard of care.

Methods: We developed a probabilistic Markov model to simulate the lifetime costs and quality-adjusted life-years (QALYs) for patients with kidney failure undergoing a 1-day evaluation process versus usual care. Data on the effectiveness and costs of the expedited program were sourced from a pilot study at The Ottawa Hospital, while transition probabilities and utility data were derived from published literature. A series of sensitivity analyses will be conducted.

Results: From the health care system and societal perspectives, our deterministic results demonstrate the cost-effectiveness of a 1-day donor evaluation process. We observed that the 1-day evaluation dominates the current standard of care by decreasing health system costs (Δ cost = $-\$5,798$) and improving patient QALYs (Δ QALY = 0.16). Sensitivity analysis results will soon be available.

Conclusion: We identified a positive net incremental benefit for patients receiving a living kidney donor transplant, from both the health care system and societal perspectives. As the number of patients requiring kidney transplants continues to rise, innovative solutions are required to increase living donor kidney transplant rates.

EM3-3. Equity of Financial Protection for Health in High-Income Countries: A Scoping Review of Methodologies and Values

Presenting author: Edward Xie, University of Toronto

Coauthor: Diego Proaño, University of Toronto

Financial protection (FP) is the mechanism that underlies recent expansions to prescription drug and dental care coverage in Canada. Ensuring equitable access to health care and mitigating financial hardship are critical concerns and core functions of health systems. Despite this relevance to current priorities and

substantial research in low- and middle-income countries, little is known about the equity of FP in Canada and other high-income settings.

To address this knowledge gap, our scoping review aims to characterize evidence on the distribution of FP in high-income countries as well as how the equity of FP is conceptualized and measured. Our research will be of interest to policy-makers, health services researchers, and economists, with direct relevance for citizens in Canada and other high-income countries. Preliminary results are being produced from May 2024 onwards.

Our presentation will report evidence from academic and grey literature regarding the variables and indicators used to characterize equity in FP, levels of protection or resource allocations in high-income jurisdictions, and the value judgments or frameworks informing each analysis. By focusing on literature published since 2010, we ensure relevance to contemporary policy challenges. Our findings can inform the ongoing design of new health coverage programs in Canada as well as their evaluation, including in equity-informative cost-effectiveness analyses. During this session, we anticipate a discussion with various stakeholders about how this evidence can be integrated into the work of Canada's Drug Agency and other health system actors to eliminate inequitable cost-related barriers to care.

EM4. Real-World Evidence (RWE): Empowering Patient Advocacy Groups to Co-Design Registries That Fill a Data Gap for Their Community

Presenters: Shawn Paron, Chief Operating Officer, Alzheimer Society of Ontario; Christa Studzinski, Ontario Brain Institute

Recent disruptions in the health care space have created an opportunity to evolve the ecosystem where patient advocacy groups can fill an important data gap and ensure that the needs of their community are better reflected in the health technology assessment and health care decision-making process. While clinical trials remain the primary source of evidence for regulatory decision-making, the recent release of guidance for reporting real-world evidence provides a valuable framework for patient advocacy groups to build registries as a source of real-world evidence. These registries can fill an important data gap to help understand the patient journey and how potential innovations can impact their daily lives and improve outcomes. This is especially relevant in the context of dementia, where Health Canada is currently reviewing the first disease-modifying therapy for Alzheimer disease, with a second one expected to be submitted by the end of 2024. The Alzheimer Society of Ontario and Ontario Brain Institute co-created a dementia registry to 1) increase capacity for memory testing in the community, 2) capture the patient journey (especially in suburban and rural areas), and 3) test digital cognitive assessments; and eventually could support the monitoring of cognitive function in patients receiving disease-modifying therapies. The Alzheimer Society of Ontario and the Ontario Brain Institute will share their journey for co-creating and launching the registry, provide a description of the participant demographics, and share some preliminary findings on how suburban and rural populations are accessing the health care system for dementia care.

EM5. Insight Into How CIHI's Data and Tools Can Be Leveraged to Improve the Information Available on Drugs for Rare Diseases

Presenters: Karleen Jung, Canadian Institute for Health Information (CIHI); Tracy Fisher, CIHI; Lacey Langlois, CIHI

Information gaps relating to drugs for rare diseases and fragmentation of data across multiple systems presents a challenge for decision-makers and patients in Canada. This has intensified over the last few years due to disruptions in health care systems by the pandemic and AI. As a leader in health care data and information, the Canadian Institute for Health Information (CIHI) is navigating through these disruptions and is using them as opportunities for improved collaboration with partners and stakeholders. CIHI is creating innovative tools for information sharing and strategically assessing bringing different kinds of data together to meet the evolving needs of stakeholders in the pharmaceutical space.

One example is how CIHI is supporting the National Strategy for Drugs for Rare Diseases using our existing pan-Canadian health data, leveraging and linking it to produce actionable information and real-world evidence. This includes understanding what evidence can be derived from our data, its limitations, and highlighting new data sources for rare disease-specific analyses. In addition, CIHI is also assessing the feasibility of linking rare disease registry data to our current health administrative data to investigate the challenges, risks, and value add of registry data for real-world evidence about rare disease populations and treatment outcomes.

The creation of the new and innovative Pharmaceutical Data Tool is a key resource in this work as it brings together the pharmaceutical data collected from jurisdictions making it more accessible, searchable, and comparable. It contains key contextual information on coverage of publicly funded drugs, including those for rare diseases. This presentation will provide insight into how CIHI's data and tools are being linked to existing and new data sources to enhance patient care and create an environment for more effective use of data and analytics for decision-making.

EM6. Tackling Environmental Impacts in Health Care Systems and in Health Technology Assessment Agencies Toward 2030: Where Do We Stand With 6 Years Left?

Presenting author: Corélie Kostovic, Institut national d'excellence en santé et en services sociaux

Climate change is now unequivocally linked to adverse impacts on human health. Health care systems have emerged as contributors to the problem, responsible for approximately 5.2% of global carbon emissions. As global awareness increases, change is taking place within health care systems around the world to reduce their environmental footprint. As we approach 2030, critical questions arise: What does the current landscape look like? What is the magnitude of change left for the next 6 years?

In late 2022, the Institut national d'excellence en santé et en services sociaux (INESSS) launched a scientific monitoring initiative focused on environmental impacts in health and social care services. Through a review of PubMed records, the Health careLCA database, and websites of health technology assessment (HTA) organizations and of environmental health associations, INESSS explored HTA methodologies, environmental impacts in health care systems; global initiatives; or a change in practice at an intervention, a specialty, or a hospital scale.

Findings reveal that several countries have committed to provide low-carbon health services and reach net zero health care systems between 2035 and 2050. In these systems, HTA agencies are reassessing their methodologies to holistically incorporate environmental considerations. Concurrently, medical communities and researchers are scrutinizing interventions based on their environmental impact or looking for alternatives with a lower environmental footprint.

By comprehending the measures being proposed in health care systems and discerning interventions with greater impact, HTA agencies can reflect on their role in the global effort to diminish the environmental footprint of health care systems. These evolving methodologies in HTA also prompt a redefinition of what value creation means in health care systems.

EM7. What's New in US HTA? A Snapshot of ICER's Value Assessment Framework Update

Presenters: Daniel Ollendorf and Marina Richardson, Institute for Clinical and Economic Review

The Institute for Clinical and Economic Review (ICER) in the US announced key updates to its value assessment framework (VAF) in 2023. ICER's VAF sets the foundation for assessing the value of health interventions and offers a resource for local and global health technology assessment efforts. Key updates include advances in how considerations for health equity and disease severity are factored into assessments and incorporating methods to ensure that a modified societal perspective analysis is undertaken for every assessment.

ICER presenters will feature key updates and discuss relevant case studies 1 year into the update cycle. ICER now calculates absolute and proportional quality-adjusted life-year shortfalls for every assessment. What does that look like? Is the approach enough to capture considerations for disease severity in committee deliberations? ICER is committed to conducting a modified societal perspective for every assessment. How is that possible if there is no data available to support the analysis? What is ICER's alternative to the highly contested quality-adjusted life-year? These and other updates will be explored during the session.

The audience will come away with a clear understanding of the key features and updates to ICER's VAF. The discussion will emphasize methods that address ICER's response to the evolving policy and practice landscape and will allow participants to reflect on how these methods may be useful in their own jurisdiction

and what the implications may be. This session will be a key anchor for continued global health technology assessment collaboration.

EM8. Using a 1-Day Living Kidney Donor Evaluation Process to Boost Kidney Transplant Rates: An Early Economic Evaluation

Presenting author: Andrew Scarffe, Ottawa Hospital Research Institute (OHRI)

Coauthors: Ann Bugeja, OHRI; Anubhav Agarwal, University of Ottawa; Edward Clark, OHRI; Kevin Burns, OHRI; Jessica McDougall, The Ottawa Hospital; Ariana Noel, The Ottawa Hospital; Manish Sood, OHRI; Gregory Knoll, OHRI; Kednapa Thavorn, OHRI; Heather Badenoch, The Ottawa Hospital

Introduction: Living donor kidney transplant is the optimal treatment to improve the quality and length of life for patients with kidney failure. Yet, the need exceeds demand. The evaluation period for a donor candidate in Canada is long, averaging 10 months. Early evidence has shown that evaluating potential kidney donors in 1 day can significantly increase the number of living donor kidney transplants. However, it remains unknown whether this expedited process offers good value for money compared to the current standard of care.

Methods: We developed a probabilistic Markov model to simulate the lifetime costs and quality-adjusted life-years (QALYs) for patients with kidney failure undergoing a 1-day evaluation process versus usual care. Data on the effectiveness and costs of the expedited program were sourced from a pilot study at The Ottawa Hospital, while transition probabilities and utility data were derived from published literature. A series of sensitivity analyses will be conducted.

Results: From the health care system and societal perspectives, our deterministic results demonstrate the cost-effectiveness of a 1-day donor evaluation process. We observed that the 1-day evaluation dominates the current standard of care by decreasing health system costs (Δ cost = $-\$5,798$) and improving patient QALYs (Δ QALY = 0.16). Sensitivity analysis results will soon be available.

Conclusion: We identified a positive net incremental benefit for patients receiving a living kidney donor transplant, from both the health care system and societal perspectives. As the number of patients requiring kidney transplants continues to rise, innovative solutions are required to increase living donor kidney transplant rates.

Panel Abstracts

PA1. Innovation in the Pharmaceutical Ecosystem

Panel moderator: Sudha Kutty, Canada's Drug Agency

Panellists: Peter Dyrda, Canada's Drug Agency; Karen Reynolds, Health Canada; Gail Attara, GI Society; Dominic Tan, pan-Canadian Pharmaceutical Alliance

With the Symposium theme as “from disruption to opportunity,” the pharmaceutical ecosystem is consistently embracing change to respond to these challenges. Some of these changes are in response to what other players within the system are doing within Canada and globally. This session will showcase how various members of the pharmaceutical ecosystem are responding to change and will include perspectives from patients and from the regulatory environment as well as the payer perspective.

PA2. Cultivating INDequity Through Indigenous-Led Pathways to E-Health Using an Innovative P3 Model to Partnership

Panel moderator: Vanessa Ambtman-Smith, Western University

Presenters: Mehmood Alibhai, Boehringer Ingelheim Canada Ltd., Laurie L. Buffalo, Samson Cree Nation; Rebecca Elizabeth Morton, Boehringer Ingelheim Canada Ltd.

The COVID-19 pandemic has catapulted a rise in digital health and shed light on opportunities to enhance remote care, triggering more innovative applications that will enhance quality of life and access to care for people with chronic disease. However, the application of innovative technology requires innovative partnerships, especially within Indigenous communities where there is a history of inequitable access to health care. As demonstrated through 1 project in western Canada, unique P3 partnerships have facilitated success in bridging the gap through the use of sensory insoles for diabetic patients in 1 First Nation. Through this holistic approach to health and healthy lifestyles, we are looking to create respectful relationships to advance Indigenous-led health innovations to address the reconciliation gap. This panel will focus on the following objectives: to share information and evidence related to the implementation of an Indigenous-led P3 model; to demonstrate the value of investment in Indigenous community-based, e-health interventions on bridging the equity gap; to highlight results and impact from 1 First Nation using sensory insoles to reduce complications from diabetic foot ulcers; to present results at 3 levels (systems, philanthropic, and community); to share results of a systems change and innovation in diabetic patient care through industry partnerships and Indigenous communities. The panel will comprise 3 representatives — an independent Indigenous health scholar; a senior leader from the philanthropic partnership underscoring the P3 model; and an Indigenous leader from a First Nation community in western Canada. By featuring these 3 perspectives, the panel seeks to share promising practices and lessons learned through the first 5 years' experience with an Indigenous-led P3 model.

PA3. Developing a Real-World Readiness Framework for Patient Support Programs: A Collaborative Approach

Panel moderator: Rob Chalmers, ZS

Presenters and coauthors: Bryan Asher, Shoppers Drug Mart; Sarah Power, Takeda Canada Inc.; Barry Stein, Colorectal Cancer Canada; Rishma Abdulhusein, Roche Canada; Farah Husein, Canada's Drug Agency; Melina Tsagaris, Canadian Personalized Healthcare Innovation Network

This collaborative effort, led by the Canadian Personalized Healthcare Innovation Network, represents a new pathway to elevate Patient Support Programs (PSPs) into a robust source of decision-grade real-world evidence, thus providing additional options and data considerations for decision-makers in the face of disruptive forces. PSPs play a pivotal role in facilitating access to specialty medications for many people living in Canada, integrating financial support, education, and navigation assistance within complex health systems. Recognizing the potential for PSPs to contribute more meaningfully to the evolving health care landscape, this project aims to develop a practical real-world readiness framework.

The development of this framework is made possible through integrating the diverse perspectives of multiple key stakeholders, including Canada's Drug Agency, bio-pharma, academia, hospitals, PSP management vendors, and patient organizations. The project unfolds through 3 key milestones: 1) meticulous identification and definition of use cases for PSP data, 2) leveraging advanced data analysis to establish a unified set of PSP data elements and uphold quality standards for real-world evidence, and 3) innovatively proposing solutions to bridge existing gaps in PSP data collection practices. During this presentation, we will spotlight the evolving progress of the framework, actively inviting valuable contributions from the health care community to refine and elevate its practical application.

PA4. Breaking Barriers: Tackling Challenges in Mental Health Drug Health Technology Assessments

Moderator: Matthew Dick, IQVIA Solutions Canada Inc.

Presenters: Don Husereau, University of Ottawa; Susan Farrell, Canadian Mental Health Association Ottawa Chapter; Pierre Blier, University of Ottawa; Kobina Quansah, Johnson & Johnson; Nancy Zorzi, Mood Disorders Society of Canada

Accurately assessing the value of drugs designed to treat mental health conditions is complex and challenging. Despite the growing awareness of Canada's mental health crisis, mental health drugs have a health technology assessment success rate 33% lower than that of nonmental health drugs. To address this gap, Canada's Drug Agency conducted the Mental Health Listening Tour at the end of 2023 where key themes to improve access were identified by stakeholders.

This proposed panel aims to delve into the unique challenges faced when performing health technology assessments for mental health drugs with a focus on the themes identified by the listening tour. Panel members will include a patient advocate who will describe the patient perspective and impact of mental illness on Canadians, their families, and caregivers. A psychiatrist with extensive clinical research experience will speak to the unique clinical challenges posed by mental illnesses, the current unmet need, and the challenges with clinical trial design for mental health drugs. An expert in health economics and health technology assessments will speak to the challenges that arise when evaluating drugs for mental health conditions. And a member of the pharmaceutical industry will discuss the challenges associated with the collection and use of real-world data for mental health conditions and the implications on mental health drug development.

PA5. Delivering Precision Oncology as Standard of Care — How Genomic Testing Is Driving Better Patient Outcomes and Increased Access to Clinical Trials for Cancer Patients

Presenters: Michael Carter and Tanya Gillan, Nova Scotia Health; Ravi Ramjeesingh, Dalhousie University

Coauthor: Noel Guscott, Nova Scotia Health

Personalized or precision medicine is an emerging approach that uses information about a person's genomic structure and their environment to diagnose, treat, and even prevent diseases like cancer. Precision oncology creates an individualized treatment plan for a patient's cancer based on the unique genomic fingerprint of the patient's cancer. Precision medicine aims to improve survival and quality of life by allowing clinicians to provide treatments that best work for the individual patient. Being able to tailor therapies relies on biomarkers and objectively measured biological traits of individuals of different types (i.e., genetic, substances in the blood, and so forth).

Nova Scotia Health and the Isaak Walton Killam Health Centre have delivered high-quality genomic testing for some time and for various cancer indications. In 2022, the Queen Elizabeth II Health Sciences Centre Foundation helped expand genomic testing capacity at Nova Scotia Health by funding a new genomic sequencer, which has become part of clinical practice. Each site provides a suite of integrated molecular and cytogenetic testing for the Maritimes. A high level of collaboration between these health systems helps ensure maximum possible access to public genomic testing for patients.

This panel will discuss the patient and clinician impacts of delivering precision oncology as standard of care, such as access to innovative treatments and improved treatment plans. This panel will also discuss plans to expand the province's capacity for precision oncology, and how genomic testing also contributes to increased and earlier access to clinical trials for cancer patients who may benefit most from treatment.

PA6. Enhancing Rare Disease Registries for Health Technology Assessment: Current Initiatives and Preliminary Findings

Moderator: Trish Caetano, Canada's Drug Agency

Panellists: Claudia Sikorski, Viktoria Roman, and Sinwan Basharat, Canada's Drug Agency; Alfonso Iorio, McMaster University

Rare disease registries are invaluable sources of real-world data, offering the potential to significantly enhance regulatory and health technology frameworks. However, a comprehensive inventory of these registries, alongside a set of standards for their appropriateness in health technology assessment (HTA), has been lacking.

In this session, participants will gain insights into ongoing initiatives and preliminary results in the realm of rare disease registries. We will cover 3 key areas:

1. Inventory of Rare Disease Registries in Canada

We conducted a thorough review of published and grey literature, engaging the Canadian rare disease community to compile an inventory of registries that collect data on specific rare diseases from at least 1 Canadian province or territory. Our findings identified approximately 130 registries, with meta-data compiled to better understand their content and patient representation. This comprehensive inventory will be presented, providing a valuable resource for stakeholders.

2. Establishing Registry Standards

Co-led by the Centre for Health Economics and Policy Analysis (CHEPA) at McMaster University, in collaboration with rare disease registries (RDRs) and other stakeholders, this project developed standards and processes to enhance the quality of data in RDRs across Canada. This presentation will outline the development process for the Standards for RDRs in Canada, highlighting key elements of the final document. This session will be particularly relevant for registry data holders, researchers, and professionals in regulatory and HTA bodies involved in reviewing and appraising evidence from RDRs.

3. Funding Registry Improvements

We funded approximately 20 RDRs to undertake specific data infrastructure and/or data quality improvement initiatives. This session will showcase best practices observed, common data infrastructure issues, and future funding opportunities. Additionally, we will present basic assessments of registries' readiness and ability to contribute to health technology assessments, regulatory decision-making, and identify gaps and opportunities for quality improvements.

This work establishes a crucial foundation for future initiatives at Canada's Drug Agency to assess the capability and suitability of registries for generating decision-grade real-world evidence. Join us to explore how these efforts can transform RDRs into robust tools for health technology assessment and beyond.

PA7. A Researcher–Policy-Maker Partnership to Design, Implement, and Evaluate Canada’s First Universal Contraception Subsidy: Impact of British Columbia’s Contraception Subsidy

Moderator and coauthor: Bonnie Henry, British Columbia Ministry of Health

Panellists and coauthors: Laura Schummers, University of British Columbia (UBC); Wendy V. Norman, UBC; I Fan Kuo, British Columbia Ministry of Health; Martin Odendaal, British Columbia Ministry of Health; Michael Law, UBC

Coauthor: Lucy Cheng, UBC

Purpose/educational objective: Attendees will understand the process of developing and implementing this novel health policy and will describe impacts of British Columbia’s contraception subsidy on contraception use and payer type for dispensed contraception.

Abstract: In April 2023, British Columbia became the first province to provide free contraceptives under the full payment pharmacare plan. This policy was developed through a longstanding partnership between researchers, policy and system leaders, and health care professionals, informed by research examining health system costs.

Moderated by Dr. Bonnie Henry, this panel includes 4 presentations:

1. Dr. Norman will describe the researcher–policy-maker collaboration that yielded this first-in-Canada policy, including a sexual health survey and cost-effectiveness simulation study estimating short- and long-term health system costs.
2. Dr. Kuo will describe the implementation for the contraception subsidy policy in tandem with pharmacist contraception prescribing, development of the internal Ministry of Health program, and evaluation through researcher–policy-maker partnerships.
3. Dr. Schummers and Mr. Odendaal will present results of a quasi-experimental controlled interrupted time series evaluation of this policy. British Columbia’s contraception subsidy led to an additional 1,195 (95% CI, 1,091 to 1,334) contraception users and 849 (95% CI, 809 to 897) additional long-acting reversible contraception users. Compared with synthetic controls, the subsidy increased contraception dispensations by 2,417 (95% CI, 909 to 4,447) and long-acting reversible contraception dispensations by 1,159 (95% CI, 570 to 1,581) per month. British Columbia’s subsidy decreased the fraction of contraception dispensations with out-of-pocket prescription payments by 27% (95% CI, 31% to 24%).
4. Dr. Law will discuss implications of this policy for evolving national pharmacare policy and provincial budgets.

Impact: British Columbia’s contraception subsidy is a landmark Canadian policy. Jurisdictions across Canada are looking to British Columbia to understand how a contraception subsidy through national pharmacare will affect their population and health system. This panel provides a first look at these data.

PA8. Disruptive Partnership: Charting the Future of pan-Canadian Data and Analytics

Moderator: Elena Lungu, Canada's Drug Agency

Panellists: Connie Côté, Health Charities Coalition of Canada; Brent Diverty, Canadian Institute for Health Information; Kimberlyn McGrail, Health Data Research Network Canada; Brad Millson, IQVIA Solutions Canada Inc.

“Disruptive partnership” suggests a collaboration that challenges traditional approaches or norms in a particular field or industry. It implies a dynamic and innovative alliance between entities that are willing to shake up the status quo and introduce new ideas, technologies, or strategies to bring about significant change or transformation. In the context of drug data and analytics for policy decisions, a disruptive partnership might involve organizations, institutions, or companies working together to challenge existing methodologies, introduce novel technologies, or pioneer unconventional approaches to improve the effectiveness or efficiency of drug policy data for better patient and health system outcomes.

PA9. Accelerating Access: Leveraging Target Zero to Expedite Time to Access for New Therapies

Moderator: Katherine Scott, MORSE Consulting Inc.

Panellists: Lana Duan, MORSE Consulting Inc.; Beth Kidd, Health Coalition of Alberta; Imran Ali, Bristol Myers Squibb Canada; Sudha Kutty, Canada's Drug Agency; Angie Wong, pan-Canadian Pharmaceutical Alliance

The panel aims to highlight actionable strategies aimed at accelerating access to innovative therapies in Canada, aligning with the objectives of Target Zero, a new initiative aimed at eliminating delays between Health Canada's drug approval and the Canada's Drug Agency reimbursement recommendation. The initiative supports a broader collective goal with stakeholders across the pharmaceutical sector to balance necessary evidence review and implementation processes with efficiencies to enable timely access to new treatments.

Drawing upon expert insights and data analysis, the panel will explore the impact of Canada's complex reimbursement landscape on drug access timelines, identifying key barriers in the process from Notice of Compliance to listing. Noting that only about half of reviews are submitted ahead of regulatory approval, we will present an analysis of timelines and impacts of various factors on time-to-listing for the panel to discuss. The analysis will also discuss emerging trends in time-to-listing and negotiation timelines, including increased 0-day negotiations at the pan-Canadian Pharmaceutical Alliance (pCPA). Further, the panel will share the health technology assessment, payer, industry, and patient perspectives on the implications, enablers, and barriers of early health technology assessment submission, opportunities to conduct market access processes in parallel, and other related efforts to expedite access.

This discussion promises to provide valuable insights for stakeholders across the health care sector by highlighting the cooperative effects of Target Zero strategies and evolving negotiation dynamics. Ultimately, the panel seeks to inspire collaborative efforts and strategic interventions that propel Canada toward a future with timely access to transformative therapies.

PA10. Incorporating the Child's Perspective in Health Technology Assessment in Canada

Moderator: Feng Xie, McMaster University

Presenters: Jesse Elliot, Canada's Drug Agency; Brittany Humphries, McMaster University; Wendy Ungar, The Hospital for Sick Children Research Institute

There is growing interest in measuring and valuing health-related quality of life in children and adolescents in recent years. The objective of this panel is to explore this issue from a Canadian perspective. It will include stakeholders involved in the development (Dr. Brittany Humphries, McMaster University) and application of these child health instruments in economic evaluations (Dr. Wendy Ungar, The Hospital for Sick Children) and in health technology assessment and reimbursement recommendations (Dr. Jesse Elliott, Canada's Drug Agency) in Canada.

Dr. Feng Xie will moderate the panel. He will provide the audience with a 15-minute overview of the unique methodological and normative challenges in measuring and valuing child health. Each speaker will then have 15 minutes to present their perspective.

Dr. Brittany Humphries will start by presenting the quantitative and qualitative findings from a methodological research program that is under way to inform the design of an EQ-5D-Y valuation study in Canada.

Dr. Wendy Ungar will then discuss the impact of new research on child health valuation in health economic evaluations.

Dr. Jesse Elliot will end by discussing how recent developments in the measurement and valuation of child health affect health technology assessment and can inform reimbursement recommendations.

PA11. Rethinking How We Do HTA — Toward a Broader Health System Approach

Presenting authors: Leslie Anne Campbell, Dalhousie University; Craig Mitton, University of British Columbia; Laura Weeks, Canada's Drug Agency

Health technology assessment (HTA) responds to the needs of decision-makers by using multidisciplinary methods to determine the value of health technologies in support of equitable, efficient, and high-quality health systems. Typically, HTAs focus on single health technologies. However, there is increasing recognition that technologies are not used in isolation, and care is delivered within pathways and health systems that

have unique goals, challenges, and budgets. Perhaps relatedly, decision-makers are increasingly asking questions that move beyond single health technologies toward broader health system issues in which health technologies are used (e.g., virtual care, primary care, long-term care, mental health care). This context provides an opportunity to consider how HTA methods and processes may be adapted to respond to these broader health systems issues.

Panellists from diverse perspectives will discuss opportunities, challenges, and early experiences with “health system assessment.” We will first set the stage by describing current health system priorities and challenges that present opportunities and needs for assessment of broad health system issues. A health services and policy researcher will then describe key learnings from a recent study to support the uptake of HTA in Canada, including suggestions for a way forward. The chair of an HTA deliberative committee will describe what a shift to health systems assessment means for deliberative committees and what is needed to support the shift. Next, an HTA producer will present early experiences with health system assessment, including how HTA methods were adapted and what impact is being observed. Finally, an HTA user will describe why a shift to health system assessment is needed and perspectives on the opportunities and challenges with this approach.

PA12. Advancing Patient Engagement and Impact in Canada’s Drug Agency Deliberative Process: A Multistakeholder Collaboration

Panel moderator: William Dempster, 3Sixty Public Affairs

Presenters and panellists: Gail Attara, GI Society; Bonnie Macfarlane, Jassen Inc.; Nicole Mittmann, Canada’s Drug Agency; Jessy Ranger, Myeloma Canada; Nancy Zorzi, Mood Disorders Society of Canada

Deliberative frameworks are used in health technology assessment (HTA) to discuss the complexities surrounding the value of new technologies and to provide recommendations to payers regarding public reimbursement.

In 2023, a multistakeholder committee comprised of patient organizations and industry representatives was formed to discuss opportunities for advancing patient engagement and impact in the Canada’s Drug Agency deliberative process.

The committee identified and prioritized actionable areas for improvement, ultimately developing several proposals to discuss with Canada’s Drug Agency. These proposals were purposefully aligned with Canadian and international guiding principles in HTA, with the goal of strengthening the patient voice within the decision-making process for new medicines in Canada. The prioritized initiatives focused on 3 themes:

1. Improved representation of the lived patient experience in expert committee deliberations.
2. Transparent use of clinician(s) with relevant experience as the clinician expert(s) weighing in on the deliberations.

3. Consideration of the totality of patient group input and clarity regarding how this input is valued and integrated into the expert committee's recommendation.

Canada's Drug Agency met with the steering committee to contextualize and collaboratively discuss the proposals.

This panel will share best practices regarding the approach to this collaboration with the broader HTA community and will help inform further refinement of proposals that aim to improve patient engagement and impact in the Canada's Drug Agency deliberative process.

PA13. Closing the Gap or Widening the Divide: Do We Need a Framework for Truly Embedding Equity in Health Technology Assessment?

Panel moderator: Jonathan Pearson-Stuttard, Lane Clark & Peacock LLP

Panellists: Stephen Duffield, National Institute for Health and Care Excellence; Susan Griffin, University of York; Chris Lübker, Novo Nordisk; Marina Richardson, Institute for Clinical and Economic Review

There are several challenges to incorporating equity into health technology assessment (HTA) including multiple domains of equity with different relevance across diseases, which may have hampered systematic consideration of the problem.

This issue panel aims to debate whether or not an equity-specific framework, including 1 that considers adjacent evidence concerns like real-world evidence (RWE) is a valuable next step to improve the consideration of equity in HTA.

Chris Lübker, Novo Nordisk, will provide insights from the pharmaceutical industry highlighting efforts to further equity across the medicine life cycle and why understanding how HTA agencies value equity will guide decisions on pipeline, clinical trial design, evidence to generate, and market access strategy.

Prof. Susan Griffin, University of York, will discuss efforts needed to foster wider formal, quantitative treatment of equity issues and the adoption of distributional cost-effectiveness analysis in the HTA community.

Next, Marina Richardson, will discuss the Institute for Clinical and Economic Review's 2023 update to its value assessment framework and supporting white paper on advancing HTA methods that support health equity. Marina will discuss the institute's rationale for selecting certain methods, highlight recent experience applying the methods, and discuss opportunities for HTA to provide more definitive direction to the field.

The final speaker, Steve Duffield, from the National Institute for Health and Care Excellence (NICE), will shed light on the learnings from developing NICE's RWE framework, which targets a continually developing area where some form of flexible but not prescriptive guidance was needed. Steve will highlight how RWE could support advances in equity alongside challenges across different diseases and domains of equity.

PA14. Improving Patient Safety and Outcomes: A Vision for a pan-Canadian Coordinated Approach to Appropriate Use

Panel moderator: Sudha Kutty, Canada's Drug Agency

Panellists: Stephen Samis, Co-Chair, Canada's Drug Agency Appropriate Use Advisory Committee; Connie Newman, Lived Experience Partner, Canada's Drug Agency Appropriate Use Advisory Committee; Jim Silvius, Co-Chair, Canada's Drug Agency Appropriate Use Advisory Committee

Across the country, prescribing and use of medications has continued to increase. It is well known that suboptimal prescribing can have significant negative health, safety, social, and financial impacts. Many appropriate use programs and initiatives are working to tackle this issue at various levels. However, there has been limited coordination or collaboration across these groups.

Recognizing the current landscape, appropriate use has been identified as a key function for Canada's Drug Agency. Canada's Drug Agency will look to support and enable a coordinated pan-Canadian approach to appropriate use and prescribing. This will require working closely with jurisdictions and partners to bolster regional and local capacity, reduce duplication, and maximize resources.

This panel discussion will bring together key voices with diverse perspectives on this issue to unpack the current state and explore a vision for the future of appropriate use of medications in Canada, what needs to be done to get there, and how this can be achieved.

PA15. An Innovative and Learning Health System Fuelled by Digital and Technological Transformation — Recent Successes from the Nova Scotia Health Cancer Care Program

Presenting authors: Amanda Caissie, Helmut Hollenhorst, and Gail Tomblin Murphy, Nova Scotia Health

A learning health system is “a health system in which internal data and experience are systematically integrated with external evidence, and that knowledge is put into practice. As a result, patients get higher quality, safer, more efficient care, and health delivery organizations become better places to work.”

The Nova Scotia Health Cancer Care Program (NSHCCP) has focused on improving access to and analysis of health records data and electronic patient-reported outcomes (ePROs) as forms of internal data and experience, while aligning with key clinician champions and other system partners like the Nova Scotia Health Innovation Hub to collect, leverage, and apply a combination of internal learning and external evidence to inform strategic transformations that are improving patient care.

This panel discussion will reflect on recent successes and the future direction of the NSHCCP in the operationalization of a patient-focused learning health system. The proposed panel discussion will focus on 3

areas that address the themes of conditions for data collection, considering patient and clinician experiences, and operationalizing knowledge to inform innovation system transformations in the following areas:

1. The acquisition and implementation of a transformational oncology information system and patient-reported outcome application
2. The implementation of artificial intelligence (AI)-driven medical technologies, such as adaptive radiotherapy systems, to deliver higher quality, faster, and personalized patient care
3. Leveraging new systems and technologies to create AI-ready data standards and analytics that will lead to improved patient outcomes and value-based models of care, such as analyzing impact of innovative drugs accessed through special access programs or time limited reimbursement mechanisms for cancer patients.

Participants will leave with better understanding of how successful digital transformation improves patient care and systems.

PA16. From Disruption to Opportunity: What Can HTA Learn from Taylor Swift

Panel moderator: Nancy Sikich, Ontario Health

Panellists: Laura Weeks, Canada's Drug Agency; Wendy Ungar, Technology Assessment at SickKids (TASK), Hospital for Sick Children Research Institute; Kali Barrett, Toronto Health Economics and Technology Assessment (THETA) Collaborative; Maggie Keresteci, Canadian Association for Health Services and Policy Research (CAHSPR); Paul Bradley, MedTech Consulting; Jovan Matic, Government of Ontario

Coauthors: Sarah McDowell, Ontario Health; Chunmei Li, Ontario Health; Olga Gajic-Veljanoski, Ontario Health

Health technology assessment (HTA) is a critical tool for evaluating the clinical effectiveness and safety, cost-effectiveness, budget impact, and patient preferences and values related to health technologies. The HTA Program at Ontario Health regularly examines the value of disruptive nondrug health technologies, services, or programs of care that can potentially transform health care delivery, improve access to care, and enhance patient outcomes. These innovations may include technologies such as genomic testing, novel diagnostic algorithms, artificial intelligence (AI), portable devices, minimally invasive surgeries, and internet-delivered services. However, there is often limited evidence on such innovations when they enter the market and as a result, it may be challenging to apply traditional HTA methods and processes to disruptive innovations.

This panel session will discuss what constitutes a disruptive innovation in health care and how it differs from other types of innovation. Through examples of potentially disruptive innovation topics that Ontario Health has evaluated, the panel will explore the impact of disruptive innovations on all phases of the HTA process, from topic identification to implementation. The panel will present various perspectives from HTA collaborators and discuss what disruptions and opportunities innovations can bring to their unique areas. Learning from the Ontario experience, the panel will discuss a way forward and reflect on what changes

could be made to existing HTA methods and processes to help facilitate the assessment and adoption of disruptive innovations in Canada. By embracing rather than avoiding disruption, HTA collaborators can harness opportunities for the health care system.

PA17. Doing More Together: Aging With Dignity and in Place — Working Together Across PCHOs and Canada

Moderator: Maria Judd, Healthcare Excellence Canada

Panellists: Tanya MacDonald, Healthcare Excellence Canada; Gino De Angelis, Canada's Drug Agency; Alesha Gaudet, Department of Social Development, Government of New Brunswick

Purpose: Share integrated guidance to support the common health system priority of aging in place that builds off the core strengths of 2 pan-Canadian health organization (PCHO) partners.

Participants will learn about:

1. Integrated practice and policy guidance and promising practice supports created by Canada's Drug Agency and Healthcare Excellence Canada (HEC) to support the shared health priority of aging with dignity and in place across Canada
2. How Canada's Drug Agency and HEC are working together to support aging in place
3. The invitation to reach out on priorities for a coordinated response in the future.

Abstract: Supporting people to age in place, with dignity, is a shared priority across jurisdictions in Canada, exemplified by bilateral funding agreements and supporting action plans across federal, provincial, and territorial (FPT) partners. To support FPT partners, different PCHOs typically contribute their strengths and expertise to unique strategies to advance different aspects of shared health priorities. With acknowledgement of complementary strengths, HEC and Canada's Drug Agency, 2 of the PCHOs, have entered into a new and informal collaboration to promote the knowledge to action cycle in a partnered way, focused on the shared priority of aging in place.

In this panel, we will describe the unique work being led by both HEC and Canada's Drug Agency to support aging in place, as well as the collaborative strategies being implemented that build off the Canada's Drug Agency core strength in evidence synthesis and appraisal and HEC's core strength in supporting implementation with a focus on knowledge to action. Canada's Drug Agency will describe their process to develop pan-Canadian guidance to support evidence-informed and equitable aging-in-place initiatives, HEC will describe their process to identify and support organizations to implement promising practices that enable older adults to age in place. Both will highlight collaborations across organizations to support knowledge to action in a coordinated way (e.g., shared evidence syntheses, collaborative review phases, jointly hosted decision-maker round table event). HEC and Canada's Drug Agency leadership will reflect on the collaboration and demonstrate that the PCHOs have been able to do more together, and a health ministry partner will describe their experiences engaging in this collaboration to support implementation

of the promising practice of nursing homes without walls, and their perspective on the opportunities such collaboration can bring to health systems in Canada.

Oral Presentation Abstracts

OP1A. The Growing Importance of Companion Diagnostics on Cancer Therapeutics and Funding

Presenting author: Scott Gavura, Ontario Health, Cancer Care Ontario

Coauthors: Jennifer Hart, Rohini Naipaul, and Aaron Pollett; Ontario Health, Cancer Care Ontario

Cancer care increasingly relies on the use of therapies that target specific genes or proteins to slow tumour growth or kill cancer cells. To ensure a patient would benefit from a targeted therapy, a companion diagnostic (e.g., a biomarker test on the tumour which predicts response to therapy) may be required.

Given the high costs of targeted therapies, patients rely on publicly funded companion diagnostic and public drug programs for coverage. In Ontario, take-home cancer drugs are covered by the Ontario Drug Benefit Program/Exceptional Access Program. High-cost hospital-administered cancer drugs, primarily IV drugs, are covered by Ontario Health programs. The funding model for companion diagnostics has changed over time. To understand the impact of companion diagnostics on cancer drug access, we examined the costs and use of companion diagnostics over 10 years.

We compared the proportion of publicly funded drug indications requiring a companion diagnostic in the 2013 to 2014 fiscal year to the 2022 to 2023 fiscal year. Ontario Drug Benefit Program, Exceptional Access Program, and IV cancer drug formulary lists and claims data were used to identify cancer drugs, indications, and requirements for companion diagnostics. Data extracted included the drug, indication, required companion diagnostic, and drug costs. Costs and volume data for companion diagnostics were compared for the same time period and sourced from Ontario Health administrative data.

Our analysis found a substantial increase in the number of publicly funded high-cost cancer medications requiring a companion diagnostic for access. The costs and use of publicly funded companion diagnostics also significantly increased, and Ontario Health instituted a new comprehensive cancer testing model at diagnosis to support patient management including timely access to treatment.

OP1B. PROgress Tracker Breast Cancer Registry: Diverse Real-World Evidence to Inform HTA via a Patient-Reported Outcomes Longitudinal Study of Canadian Breast Cancer Survivors

Presenters: Kimberly Carson and Shaniah Leduc, Breast Cancer Canada

Coauthors: Michelle Dean and Amanda Gibson, University of Calgary; Doris Howell, Princess Margaret Cancer Research Institute; Omar Khan, Alberta Health Services

There are significant gaps in understanding lived breast cancer experience across diverse patient populations in Canada as these data are rarely collected in the traditional clinical or trial-based research setting. With the greatest disability-adjusted life-years lost of all cancers, comprehensive patient-reported outcomes (PROs) would provide evidence of lived breast cancer experience across short-, mid-, and long-term periods to inform health policy-makers on broader considerations for health care needs that could evolve policy, clinical standards, and requirements for health technology assessment.

PROgress Tracker represents the first national patient-reported outcome measures breast cancer registry study in Canada with a goal to collect PROs across 10 years of lived experience representing all stages (stage 0 to IV) from 50,000 breast cancer patients (enrolment goal over 10 years). Aligned with the Canada's Drug Agency strategic plan that emphasizes equity and patient lived experience in the creation of evidence, this presentation will highlight 1) a longitudinal extensive PROs study design with national ethics approval in collaboration with an academic program, 2) a unique, inclusive implementation model outside of a medical clinic spearheaded by a patient advocacy research organization, and 3) planned analysis for evidence of gaps in current knowledge during, and after oncology care across diverse populations and Canadian jurisdictions.

PROgress Tracker aims to provide comprehensive evidence not captured in traditional clinical or research settings. With the longest collection of these crucial data points in a research study, health policy, cancer systems, and health technology assessment can enact patient-centred change with evidence-informed dimension to improve overall health outcomes in cancer care.

OP1C. Patient Values Project: Understanding Patient Preferences for Cancer Treatments to Inform a Framework for Incorporating Patient Values Into Health Technology Assessment

Presenting author: Barry Stein, Colorectal Cancer Canada

Coauthors: Deborah A. Marshall, University of Calgary; Karen V. MacDonald, University of Calgary

Background: Approaches for incorporating patient preferences into health technology assessment (HTA) processes for drug reimbursement recommendations remain relatively unexplored despite growing emphasis on patient-reported outcomes and patient engagement. The Patient Values Project will inform potential

approaches to reflect patient preferences using quantitative data in Canada's cancer drug HTA decision-making process.

Methods: In phase 1, we developed bilingual surveys informed by focus groups, literature review, and feedback from clinicians, patients, and experts. The surveys included demographic and disease history questions, general and cancer specific quality of life tools, 2 discrete choice experiments (DCE), and a best-worst scaling (BWS) experiment. After pretesting and pilot testing, surveys were administered across Canada to metastatic colorectal cancer patients, caregivers, and adults from the general population.

Results: We observed differences in preferences between patients (n = 114), caregivers (n = 57), and the general population (n = 441) in both DCEs. DCE1 results reflect trade-offs between quality of life and survival with patients having stronger preferences for survival than quality of life compared to the general population having stronger preferences for quality of life. DCE2 results reflect trade-offs between treatment regimens, side effects, and survival, with caregivers having stronger preferences for avoiding certain side effects compared to patients or the general population. BWS results reflect a ranking of tolerability of treatment side effects with the 3 most and least tolerable side effects ranked similarly across patients, caregivers, and the general population.

Conclusions: In the next phases, we will explore how quantitative patient preference information could be translated into values that could be incorporated as an explicit element of HTA.

OP1D. Timeliness of Health Technology Assessments and Price Negotiations for Oncology Drugs in Canada

Presenting author: Nigel Rawson, Macdonald-Laurier Institute

Purpose: To evaluate whether time targets for Canada's Drug Agency reimbursement reviews and pan-Canadian Pharmaceutical Alliance (pCPA) price negotiations are achieved for oncology drugs.

Methods: Recommendations and dates of submission and publication for oncology medicines issued between January 2014 and December 2023 were recorded. The dates any pCPA negotiation began and when it was completed (successfully or not), or when a decision was made not to pursue negotiation, were extracted to March 31, 2024. The duration of each Canada's Drug Agency review and pCPA negotiation was calculated, together with time between recommendation and start of negotiation or decision not to negotiate. Percentages of reimbursement reviews, times taken to decide to negotiate, and negotiations within relevant targets were calculated.

Results: Canada's Drug Agency achieved its 270-days target in 88.25% to 100% of reviews in 2015 to 2019 but only in 65.9% to 73.1% of reviews in the past 3 years of the decade. The Canada's Drug Agency "typical timeline" of 180 days was achieved in less than 40% of reviews in 2015 and not attained in any review in 2021, 2022, or 2023. The pCPA's target of 60 days for deciding whether to negotiate was achieved for all recommendations issued in 2014 but dropped below 40% for the past 7 years of the decade; its target of 130

days for negotiations was achieved for more than 85% of the recommendations in 2014, decreased to 14.3% in 2016, and increased to 61.5% in 2023.

Conclusion: The Canada's Drug Agency "typical timeline" and the pCPA's targets were not met sufficiently to be meaningful. Their processes take too long for cancer drugs.

OP2A. Navigating Growth: Ontario's CAR T-Cell Therapy Program

Presenting author: Cassandra McKay, Ontario Health, Cancer Care Ontario

Coauthors: (Dr.) Tom Kouroukis, Ontario Health (Cancer Care Ontario)/Hamilton Health Sciences Foundation; Lauren Chun, Ontario Health (Cancer Care Ontario); Scott Gavura, Ontario Health (Cancer Care Ontario); Colleen Fox, Ontario Health (Cancer Care Ontario); Dr. Christopher Bredeson, Ontario Health (Cancer Care Ontario)/The Ottawa Hospital

In 2019, Ontario Health (Cancer Care Ontario) implemented the Ontario Chimeric Antigen Receptor T-cell (CAR T) Therapy Program. This program provides oversight for the delivery of CAR T, including funding the delivery of care, product reimbursement, and monitoring access and quality of care for adult and pediatric patients. Since the launch of the program, 4 Ontario sites have treated patients with publicly funded CAR T products. The delivery of CAR T requires highly trained health human resources capable of managing cellular collection and processing, infusion and complications associated with therapy, as well as bed capacity to care for the patient. As of January 2024, the program funds 3 CAR T products for 4 indications. With the cost of currently available commercial CAR T products ranging from \$450,000 to \$533,000 per 1-time patient treatment, growth in this therapy's utilization has come with significant budget implications. In the initial year of the program (2019 to 2020), 11 Ontario patients received treatment at Ontario sites with a total program cost of \$5.6M including care costs but excluding confidential rebates. In 2022 to 2023, 108 Ontario patients received treatment with a total program cost of \$56.8M. Based on new CAR T products and indications in the pipeline, it is anticipated that volumes could grow to 394 treatments, with an estimated total cost of \$229M by 2025 to 2026. With increasing use of CAR T, it is recognized that the total cost and resources for delivering this therapy will continue to grow. Financially sustainable solutions and increased system capacity are needed.

OP2B. Developing a Drug Shortages Predictive Model Using Real-World Canadian Drug Utilization

Presenting author: Araniy Santhireswaran, University of Toronto

Coauthors: Lisa Burry, University of Toronto; Katherine Callaway Kim, University of Pittsburgh; Shanzeh Chaudhry, University of Toronto; Étienne Gaudette, University of Toronto; Martin Ho, University of Toronto; Katie Suda, University of Pittsburgh; Mina Tadrous, University of Toronto

Introduction: 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.

Objective: 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 Multinational Integrated Data Analysis (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 1,589 drugs, 998 (63%) unique drugs were exposed to 1,959 supply chain events. Meaningful supply decreases ($\geq 33\%$) were observed in 11% of cases, compared to 7% of controls. Drugs with sales less than \$100,000, anti-infectives (Anatomic Therapeutic Chemical [ATC] class J) and drugs with unit prices greater than \$100 had higher odds of experiencing meaningful supply decreases (OR: 4.03, 3.16, 2.79, respectively).

Conclusions: Our findings highlight factors strongly associated with supply issue-related decreases in the drug supply and indicate that only 1 in 10 supply chain events led to meaningful decreases. These can be used to build a predictive model to score the 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 delivering health care.

OP2C. Improving Equity Assessment in Drug Policy Decisions

Presenter: Jolanta Piszczek, University of British Columbia

Improving equity is often cited to be an important factor in decision-making. Drug policy processes, such as those used by the British Columbia's Drug Benefit Council in reimbursement decisions, often incorporate an equity assessment as part of multicriteria decision analysis (MCDA) tools. Despite definitions of equity and considerations that impact its scoring on an MCDA, equity remains a challenging component of decision-making. Reasons for this include lack of direct evidence of a drug's impact on equity from currently available literature, lack of inclusion of equity-deserving groups in randomized controlled trials, intrinsic barriers to self-advocacy from equity-deserving groups in input reports, and the heterogeneity in the way available data are interpreted by decision-makers.

In 2023, the British Columbia's Drug Benefit Council initiated a process to improve the equity assessment component of its MCDA that is used to guide funding decisions. The process was initiated by 1 member

(the presenter of this session) and the council's ethicist. A literature review evaluating presently used equity assessments was undertaken, as well as a search of guidelines, recommendations, and grey literature on the topic. A model for a comprehensive equity assessment was developed and quality improvement methods were used to optimize the model. The equity assessment contained 4 components: 1) an evaluation of whether inequity is present and due to a risk factor for being underserved; 2) a determination whether the drug demonstrates efficacy in improving outcomes in the population experiencing inequity; 3) a determination whether the drug improves safety/minimizes risks in the population experiencing equity, and 4) whether the drug improves access. The model mirrors a commonly used process used in clinical decision-making by pharmacists called the "Pharmaceutical Thought Process."

This presentation describes the components of this equity assessment and shares the impact of its implementation.

OP2D. Therapeutic Value of Drugs for Orphan Diseases

Presenter: Joel Lexchin, York University

Background: Health Canada recognizes drugs designated as orphans by the US FDA and the European Medicines Agency. This study examines the additional therapeutic value from these drugs compared to drugs already on the market.

Methods: A list was compiled of new drugs approved by Health Canada from September 1, 2012, to March 31, 2022. Additional therapeutic benefit — major, moderate, little to none — was based on rankings from the Patented Medicine Prices Review Board, the French drug bulletin Prescrire International and the German health technology assessment agency the Institute for Quality and Efficiency in Health Care (IQWiG). Therapeutic value of orphan drugs was compared to that of non-orphan drugs for oncology indications and all other indications using nonparametric tests with a P value of < 0.05 considered significant.

Results: 296 drugs were analyzed: 88 (29.7%) were for oncology indications (67 orphan and 21 non-orphan) and 208 (70.3%) for all other indications (73 orphan and 135 non-orphan).

Orphan drugs for oncology indications: The distribution of therapeutic benefits was almost identical between the orphan and non-orphan drugs ($P = 0.9656$, chi-square test) with only 13 of 60 (21.7%) orphan drugs and 4 of 20 (20.0%) non-orphan drugs having a major therapeutic gain.

Orphan drugs for other indications: There was no difference in the distribution of therapeutic benefits between orphan and non-orphan drugs ($P = 0.0821$, chi-square test), and 22.2% of orphan drugs had major therapeutic benefits compared to 9.7% of non-orphan drugs.

Conclusions: Orphan drugs are no more likely to offer a significant therapeutic advantage for oncology and other indications compared to non-orphan drugs.

OP3A. Homecare Innovations: At the Intersection of Technology and Humanity

Presenting coauthors: Corélia Kostovic and Marie-Hélène Raymond, Institut national d'excellence en santé et en services sociaux

In recent years, there has been a growing emphasis on home care services in Quebec. To evaluate the landscape and consider avenues for modernizing the sector, the Ministry of Health and Social Services entrusted the Institut national d'excellence en santé et en services sociaux (INESSS) with a global horizon scanning initiative.

Tasked with identifying innovations in health and social services for those experiencing loss of autonomy at home, INESSS delved into the scientific and grey literature published since 2021, including reports from health technology assessment agencies, US FDA-targeted approvals, government bodies supporting innovation, and the industry.

A total of 1,094 innovations from 30 countries were selected and categorized based on objectives and primary targets — patients and caregivers, staff, or service organization.

Emerging trends highlight the diversity of innovations. A global shift toward digital health is observed with telemonitoring, telerehabilitation, and teleconsultation innovations potentially useful for staff. Another trend involves innovations facilitating or strengthening daily activities, self-management, and health promotion for patients and caregivers.

Technological advancements in connected devices also tend to predominate through the development of sensors, mobile apps, artificial intelligence (AI) algorithms, and robots. Nontechnological innovations are also emerging in communities and in care delivery, expanding the roles of professionals and citizens and furthering the development of hospital-at-home programs.

These overall trends indicate changes in how care is designed and delivered to meet the needs of patients and caregivers in their home. While promising avenues are increasing, questions must be raised when implementing such innovations, including considerations for digital literacy of users or the reduction of direct human interaction.

OP3B. A National Standard for Cyber Resiliency in Health Care

Presenters: Siri Chunduri and Jonathan I. Mitchell, HealthCareCAN

Coauthor: Darryl Kingston, Digital Governance Council

Virtual health, telemedicine, wearable devices, and electronic health records are some examples of how digital transformation is reshaping our health care system. The digital transformation of health care has presented challenges with respect to cyber threats for patients, clinicians, technology developers, policy-makers, and decision-makers.

Entitled “Cybersecurity: Cyber Resiliency in Healthcare,” the new national standard of Canada presents a clear framework that will enhance cybersecurity capabilities and better protect Canada’s health care organizations from cybercrime and defend critical infrastructure. With support from Public Safety Canada’s Cyber Security Cooperation Program, HealthCareCAN and the Digital Governance Council began in 2022 by co-hosting focus groups in English and French with nearly 120 health technology leaders on their concerns around cyber security. The standard was developed with the guidance from the workshops and the expertise of a technical committee and an expert drafting team of cybersecurity experts from health care organizations, government, and the private sector. The committees oversaw multiple reviews of the draft standard with engagement from more than 1,300 cybersecurity experts, health leaders, and stakeholders, and 158 unique comments that were addressed before the final draft was completed.

From health care organizations and research institutes to medical clinics and virtual care providers, the standard is designed to help organizations manage the risks associated with the use of health information and information technology. Key areas of focus for the standard are prevention strategies, education, technology controls, cyber incident response planning and protocols, contingency planning, monitoring, and measurement.

Health care leaders will benefit from this practical guidance and the templates included in the national standard to enhance cyber resiliency across Canadian health care organizations.

OP3C. Clinical Practice in a Digital Health Environment: New Best Practice Guideline

Presenting author: Lauren Bailey, Registered Nurses’ Association of Ontario (RNAO)

Coauthors: Christine Buchanan and Amy Burt, RNAO; Maureen Charlebois, Bayshore HealthCare; Doris Grinspun and Lyndsay Howitt, RNAO; Jennifer Yoon, Humber River Health

This best practice guideline (BPG) includes evidence-based recommendations for health providers, organizations, and health systems to foster health providers’ ability to maintain, advance, and strengthen professional practice in the context of a digital health environment. The scope of the guideline was in part determined by the *Nursing and Compassionate Care in the Age of Artificial Intelligence* report and was inclusive to many types of digital health technologies including stand-alone software applications as well as integrated hardware and software systems that can utilize platforms such as computers, smartphones, tablets, and/or wearables. The expert panel identified priority recommendation areas for the BPG, which focused on: practical professional development education focused on digital health technologies; education about relational care and interpersonal communication skills for practising in virtual and digital health environments; peer champion models to facilitate use of digital health technology; and leveraging predictive analytics to inform clinical decision-making. Recommendations were developed following Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology. The BPG also includes good practice statements focused on initial and ongoing assessment of digital health technologies used in care; education to persons and families related to digital health technologies; health provider

involvement in the procurement, adaptation, adoption and implementation of digital health technologies; protected time for education for health providers related to digital health technologies; policies related to privacy, security and confidentiality; and embedding digital health competencies into entry-to-practice exams. The BPG also contains process and outcome indicators that align with the recommendations.

OP3D. Partnering Together for Integrated Person- and Family-Centric Care Across the Mental Wellness Care Continuum: Stepped Care 2.0 in the Northwest Territories

Presenting author: Danielle Impey, Mental Health Commission of Canada

Coauthors: Danielle Impey, Mental Health Commission of Canada; Carly Straker, Government of the Northwest Territories; AnnMarie Churchill, Stepped Care Solutions

Introduction: The Mental Health Commission of Canada and Stepped Care Solutions, partnered with the Government of the Northwest Territories to support the implementation of the Stepped Care 2.0 model in the Northwest Territories.

Objectives: This initiative sought to reduce wait times and improve access to services, including e-mental health services, that are responsive, culturally safe, person- and family-centric, and recovery-oriented.

Approach and methods: SC2.0 implementation involved collaborative partnerships and a multipronged approach using implementation science-based phases. Key elements included:

- Involvement of leadership, providers, and service users
- Project planning and management
- Training and information
- Communication, engagement, and feedback.

Evaluation was embedded into the implementation of SC2.0 to accelerate learning and improvement. It focused on: 1) reach (services offered and used), 2) impact (satisfaction and wait times), and 3) lessons learned (enablers and barriers). A mixed methods design was used to collect quantitative and qualitative information from service users, providers, and system leaders.

Results and discussion: SC2.0 helped to increase the variety and flexibility of mental wellness and substance use services for residents of the Northwest Territories — in person, by phone, and online. Wait lists and precursors to care were eliminated. Wait times for mental wellness counselling/therapy were reduced by 79%, with same day access. Service users felt that care was person- and family-centric, being satisfied or very satisfied with their involvement in decisions about their experience and the information provided to them. The Northwest Territories continues to strengthen their system of care through the lessons learned, which are valuable to jurisdictions across Canada.

OP4A. Prioritizing Community Partnerships: A Collaborative Approach to Promoting Medication Appropriateness Across Diverse British Columbia Communities

Presenting author: Leslie Gaudette, Council of Senior Citizens' Organizations of British Columbia

Coauthors: Camille L. Gagnon, Jennie Herbin, and Ninh Khuong, Canadian Medication Appropriateness and Deprescribing Network; Emily McDonald, McGill University Health Centre; James L. Silvius, Alberta Health Services

This presentation recognizes the essential role of patient and public engagement in health promotion and health technology assessment by highlighting the longstanding collaboration between the Canadian Medication Appropriateness and Deprescribing Network (CADeN) and the Council of Senior Citizens' Organizations of British Columbia (COSCO BC). Adopting an ecological approach to health systems change around medication appropriateness, CADeN has embedded partnerships with people with lived experience and community-serving organizations into its structure since its founding.

COSCO BC, a volunteer-run umbrella organization comprising 75 affiliated seniors' groups, actively collaborates with CADeN. COSCO BC's input helps shape the content and direction of CADeN's public awareness initiatives, while CADeN provides evidence-based medication safety information for COSCO BC members. Since 2016, many joint projects have been successfully realized, including the provincial summit "Seniors Empowering Communities" and the co-development and dissemination of CADeN's multilingual patient toolkit (a variety of resources addressing safe and appropriate use of medicines) to people from diverse cultures. Additionally, through a collaboration with the COSCO Seniors' Health & Wellness Institute, presentations in English, Cantonese, and Mandarin have been given to hundreds of older adults.

These initiatives reach more than 80,000 seniors to foster awareness, both locally and nationally, about medication overload and the importance of regular medication check-ups that specifically address opportunities for deprescribing. This presentation demonstrates the pivotal role of partnerships with people with lived experience and community-serving organizations in the design and implementation of large-scale health promotion programs, providing insights into the successes, challenges, and opportunities gleaned from this nearly decade-long collaboration.

OP4B. Advancing Justice-Oriented Patient Engagement in Health Technology Assessment

Presenter: Roma Dhamanaskar, McMaster University

Coauthors: Julia Abelson, McMaster University; Frank Gavin, Post-Market Drug Evaluation Advisory Committee; Lisa Schwartz, McMaster University; Meredith Vanstone, McMaster University

This paper advances justice as a central ethical justification for patient engagement in health technology assessment (HTA). Theories of justice provide key answers on “why should we engage” and “how should we engage” patients in HTA processes, both justifying and legitimating patient engagement. In particular, 3 justice theories — epistemic injustice, procedural justice, and social justice — are most relevant to advancing the practice of ethical patient engagement in HTA. Epistemic injustice focuses on harms that individuals experience in their capacity as knowers; for example, when their relevant knowledge is excluded from HTA processes due to identity prejudices or deficient knowledge sharing systems. Patients have high epistemic value for HTA through contributions such as the determination of patient-important outcomes. However, patients are vulnerable to epistemic injustices as their lived experience competes for legitimacy with clinical, research, and economic evidence. Theories of procedural justice aim to ensure that decision-making processes, especially those that are complex and value-laden, are governed by procedures, policies, and processes that are deemed fair. Procedural justice would call for responsible and accountable patient engagement to meet democratic ideals of participation and representation of those most impacted by the outcomes of HTA decisions. Social justice provides a final ethical rationale for patient engagement in HTA. Equity, diversity, and inclusion in HTA processes can ensure that decisions reflect the needs of structurally marginalized groups and those who are systemically excluded from participatory processes. Together, these justice theories offer a toolbox of rationales for more justice-oriented engagement, help articulate what such engagement looks like in practice, and offer novel theoretical solutions for practical issues faced in engagement practice.

OP4C. Public Preferences for Improving Health Equity in Canada: A Qualitative Focus Group Study

Presenting author: Christopher Cadham, University of Michigan

Coauthors: Shehzad Ali, Western University; Rafael Meza, British Columbia Cancer Research Institute; Lisa Prosser, University of Michigan

Background: Novel approaches to economic evaluation seek to value health equity through trade-offs elicited from population surveys. Qualitative research can serve as a valuable complement in conceptualizing public priorities for health equity.

Objective: To understand the attitudes and beliefs of residents of Canada toward advancing health equity. Results will aid in the design of future choice experiments to value health equity.

Methods: We conducted online focus groups with residents of Canada. Participants were recruited online using a purposive sampling technique. Conversations focused on conceptions of fairness in health care and identifying equity-relevant attributes that respondents consider relevant to fair resource allocation decisions. Transcripts and notes were assessed in an iterative manner using a constant comparative technique.

Results: A total of 29 individuals participated in the focus groups. Participant’s views of a fair system were based on equality in access, where all individuals can access quality care and be treated equally regardless of their characteristics and circumstances. Common themes included promoting universality, accessibility,

particularly in rural areas, and reduced wait times. Equitable access was often considered more important than efforts to achieve similar health outcomes. Respondents expressed conflicting views on privatization. Discussions highlighted the importance of framing questions of health equity. Respondents were unwilling to use characteristics such as race, ethnicity, or gender in determining equitable allocations. Yet, these characteristics were often cited as important to consider when identifying disparities to address.

Conclusions: Future choice experiments that value improvements to health equity must carefully consider how respondents conceptualize equity regarding the allocation of health care resources.

OP4D. Indigenizing Medication Appropriateness in Canada: Charting a Path Toward Equity and Healing

Presenting author: Cheryl A. Sadowski, University of Alberta

Coauthors: Jennie Herbin, Canadian Medication Appropriateness and Deprescribing Network; Amber Ruben, University of Alberta; Larry Leung, University of British Columbia (UBC); Jason Min, UBC; Wade Thompson, UBC; Emily McDonald, Research Institute of the McGill University Health Centre; James L. Silvius, Alberta Health Services

Purpose: This presentation outlines the methodology, findings, and lessons learned from the Canadian Medication Appropriateness and Deprescribing Network's (CADeN's) collaborative process to map out a safe approach to addressing medication appropriateness in Indigenous communities in Canada.

Intended audience: This presentation is for individuals and organizations aspiring to contribute to achieving health equity for Indigenous populations. It is relevant for health care organizations and executives, professional associations, researchers, and policy-makers.

Description: CADeN is dedicated to promoting safe and appropriate medication use through research, policy, and knowledge translation activities. In Canada, Indigenous Peoples experience higher rates of potentially inappropriate medication use and a higher medication burden. Recognizing the urgency of addressing health disparities in Indigenous communities, in 2023 CADeN established a dedicated working group to develop recommendations for how the network can contribute to improving appropriate medication use in Indigenous populations. Published in March 2024, the resultant decolonization and Indigenization action plan underscores strategies such as cultivating respectful relationships, compiling a body of Indigenous-owned testimonials, and co-developing focused resources promoting medication appropriateness. The report emphasizes the importance of humility, learning, and relationship building, and seeks to foster a culturally safe approach to partnering with Indigenous Peoples in research and actions that both reflect their priorities around medication appropriateness and give power to Indigenous ways of knowing and healing. Challenges in the process include determining focal points for outreach among the diverse Indigenous communities and balancing the need to develop a pan-Indigenous approach while still honouring unique community needs and priorities related to medication appropriateness.

OP5A. Improving the Impact of Health Technology Assessment in Canada

Presenter: Craig Mitton, University of British Columbia (UBC)

Coauthors: Selva Bayat, British Columbia Ministry of Health; Stirling Bryan, UBC; Lesley Dunfield, Institute of Health Economics; Stuart Peacock, BC Cancer; Manik Saini, Vancouver Coastal Health; Neale Smith, UBC; Olivia Tseng, UBC; Laura Weeks, Canada's Drug Agency

While production of health technology assessments (HTA) is pervasive in Canada and decision-makers widely acknowledge value in HTA evidence, the impact of HTA on decision-making varies considerably. The policy issue at the heart of this project is 1 of implementation — how HTAs can be better integrated into decision processes in the health system.

This 1-year, action-oriented research project employed a variety of methods including qualitative content analysis in reviewing HTA producer organization websites across Canada, a web-based survey of HTA producers, semistructured qualitative interviews with policy-makers and clinical leaders, and, finally, a virtual policy workshop with representation from key stakeholders across Canada.

We identified 3 fundamental issues: First, there is a potential disconnect between HTA production and HTA implementation. We need policy-makers and HTA producers aligned to define the parameters together for HTA production and the structure for implementation. Second, there is a disconnect between the levels of decision-making. Third, the nature of HTA questions important to decision-makers has been changing with a desire for input on programs rather than devices or individual services. In other words, HTA needs to be fully integrated with the broader actions of resource allocation and other processes in the health system.

Through this work we were able to put forward guidance for both HTA producers and decision-makers around what can be done to improve uptake. This work extends other research in the field of knowledge translation and provides insight in the use of evidence more broadly.

OP5B. An Actionable and Legible Toolbox for the Appraisal of Health Care Innovations Developed Through Provincial Stakeholder Collaboration

Coauthors: Mélanie Caron, Isabelle Ganache, Pascale Lehoux, Mélanie Martin, and Geneviève Plamondon, Institut national d'excellence en santé et en services sociaux

In Quebec, decisions about implementing innovations are taken both centrally for province-wide access and locally by health care institutions. There is no systematic evaluation process and various stakeholders are involved. There was a wish to increase consistency and clarity with the principles and methods used by various bodies across the innovation life cycle.

The starting point was the Institut national d'excellence en santé et en services sociaux (INESSS) multidimensional framework, which focuses on the population-level, clinical, economic, organizational, and sociocultural value of drugs, technologies, and interventions. The framework, already under evolution

drawing on Responsible Innovation in Health, evolved through collaborative work between INESSS' methodological and scientific teams, but also and foremost with diverse groups and institutions within the provincial innovation ecosystem (e.g., university-based incubators, regional hospitals).

This multistakeholder taskforce resulted in the development of an operational toolbox meant to guide the value appraisal of innovations through a life cycle approach. First aimed at stakeholders involved locally in health care institutions, the work conducted was equally beneficial to INESSS and has contributed to enhance clarity and legibility of the agency's processes and methods. The level of collaboration with stakeholders across the province was also unique and have strengthened the understandability and actionability of the toolbox developed. Some challenges were faced, and related actions will be discussed.

Both the taskforce process and its output contributed to improve consistency in the assessment of innovations across the province. They made more explicit what may sometimes be perceived as the health technology assessment "black box."

OP5C. Aligning Deliberative Frameworks at Canada's Drug Agency

Coauthors: Deirdre DeJean (presenting), Stephanie Chiu; Canada's Drug Agency

Deliberation in health technology assessment (HTA) is "the informed and critical examination of an issue and the weighing of arguments and evidence to guide a subsequent decision." The use of a deliberative framework guides consistent and transparent deliberations. In 2023, Canada's Drug Agency convened a cross-functional working group to develop an aligned deliberative framework with accompanying guiding principles for its expert committees.

The work drew from 2 main sources: a review of existing Canadian and international HTA frameworks, and observations of Canada's Drug Agency and other expert committee deliberations. Domains, definitions, and subcriteria from established frameworks were reviewed for their relevance to Canada's Drug Agency HTA processes and their relationship to the guiding principles. The draft framework and guiding principles were then revised based on feedback from Canada's Drug Agency staff, expert committee members who would use the framework, and advisory committee members who receive our recommendations and guidance.

The aligned deliberative framework includes 5 domains: Unmet Clinical Need, Clinical Value, Economic Considerations, Impacts to Health Systems, and Distinct Social and Ethical Considerations. It addresses previous inconsistencies in the use of different frameworks by the expert committees. Its comprehensiveness ensures that all relevant considerations are discussed by the committees. Finally, it improves transparency by allowing interested and affected parties to better understand how the committees reach a recommendation.

Using a test-and-learn approach, the framework will be evaluated in the Health Technology Expert Review Panel (HTERP) and the Formulary Management Expert Committee (FMEC) to ensure that it is implementable, relevant, and helpful to end-users and decision-makers.

OP6A. Use of Bayesian Hierarchical Models in Economic Evaluations

Presenting author: Petros Pechlivanoglou, PhD, The Hospital for Sick Children

Basket trials are becoming popular in cancer research. They are designed to study treatments that apply across multiple cancer types on patients who share a common biomarker. However, the heterogeneity among cancer types, limited sample sizes, a lack of comparators, and the use of surrogate end points pose challenges when considering the application of basket trial data in economic evaluations. Bayesian hierarchical models (BHMs) offer an approach to use information from basket trials to inform economic evaluations; they are well suited to account for the heterogeneity among cancer types while borrowing information across cancer types in basket trials. However, there is a need for clearer guidance about how these methods can be used in economic evaluation.

To address this gap, this presentation will provide an overview of methods used to analyze basket trial designs, (including BHM, and the EX-NEX method). In addition, the presentation will cover the current understanding of how BHM-analyzed basket trials can be used in economic evaluation and will provide a real-world illustration. We will also describe the limitations and challenges associated with these methods and practical considerations for interpreting and appraising such models.

OP6B. Humanizing Health Technology Assessment Practices: The INESSS Users' and Relatives' Panel

Presenters: Louis Lochhead and Marie-Pascale Pomey, Institut national d'excellence en santé et en services sociaux

Coauthors: Olivier Demers-Payette, Isabelle Ganache, and Marie-Claude Sirois; INESSS

Introduction: In 2019, a Users' and Relatives' Panel (URP) was set up at Institut national d'excellence en santé et en services sociaux (INESSS) for the social services and mental health directorate. This advisory panel mobilizes the experiential knowledge of people affected by various social conditions and supports scientific professionals to better integrate the expertise of users in their work.

Objectives: The objective of the study is to assess, from diverse stakeholders' perspectives, the added value of this innovation.

Methodology: A qualitative descriptive evaluation study was conducted between March 2021 and February 2022. A total of 19 interviews were realized: 6 with URP members and 13 with staff representatives, and all documents produced by the panel were collected and analyzed. Following a preliminary round of data analysis, a debriefing meeting was conducted with a sample of participants to validate the results.

Results: During the period studied, 12 projects were presented to the panel. The URP enabled health professionals to consider dimensions they had not identified, to better integrate the experiential data collected from users into their work, and to develop recommendations that made more sense to users.

Panel members and INESSS professionals learned to work together, shifting the working methods from consultation to collaboration and even co-construction. The panel helped also to humanize the scientific process by bringing to agency professionals the impact of their work on the people concerned.

Conclusion: This research shows the added value of this innovation to better integrate experiential knowledge to humanize decision-making and give meaning to the work done by agency professionals.

OP6C. Understanding and Measuring Health Outcomes in Children With Rare Genetic Conditions

Presenting author: Jeff Round, Institute of Health Economics

Coauthors: Alison Howie and Beth Potter, University of Ottawa; Maureen Smith, patient representative; Kednapa Thavorn, Ottawa Hospital Research Institute

INFORM RARE is a Canadian research network that is codesigned by patients and families, health care providers, policy-makers, and researchers to improve care for children with rare genetic diseases. A core focus of the network has been developing an understanding of how to capture the impacts of disease and treatment on patients and their families/caregivers for use in clinical research and economic evaluations. This is highly salient in the context of children with rare genetic disorders who often have very high care needs that place significant demands on their caregivers. Our work addresses these challenges in several ways and in this session, we report on 3 linked activities.

The first is how we are working with patients, caregivers, and physicians to define a core outcome set for mucopolysaccharidoses to establish which outcomes have meaning to patients/caregivers while also being suitable for use in evaluation of treatments. Second is work on the indirect socioeconomic impact of inherited neuromuscular disease. The third strand is a novel model for the integration of patient and caregiver quality of life within economic evaluations, accounting for the interdependence between outcomes for patients and caregivers. Here we bring these 3 strands together to illustrate the importance of taking a comprehensive approach to measuring and valuing the broad scope of outcomes associated with the care and treatment of children with rare genetic diseases.

OP7A. Model-Based Estimates of the Cost of Obstetric Evacuation for Fly-In First Nation Communities in Ontario

Presenting author: Majd Radhaa, Western University

Coauthors: Ava John-Baptiste, Western University; Jennifer Leason, University of Calgary; Negin Rouhi, University of Calgary

Introduction: First Nations and Inuit Health Branch guidelines require First Nations and Inuit birthing persons residing on reserve or in rural and remote areas in Canada to travel to urban centres at 36 to 38 weeks gestation age, where they then await labour and birth. Given the perinatal health disparities

between Indigenous and non-Indigenous people in Canada, research is needed to inform health policy to improve First Nations, Métis, and Inuit maternal-child health. This research is part of an Indigenous-led, interdisciplinary, mixed methods research project that examines the economic costs of obstetric evacuation experienced by First Nations communities in Ontario, Canada.

Objective: The objective of the model-based estimates was to estimate the cost of obstetric evacuation for the 33 First Nations communities with no year-round road access (fly-in communities). The research will contribute to understanding the cost comparisons of obstetric evacuation with Indigenous desire-based birthing options available for birthing in-community and closer to home.

Methods: Due to the complexity and context related to obstetric evacuation, multiple pathways were needed to understand the various scenarios, as such, a decision tree was developed. The journey and its associated travel distances were mapped using a Geographic Information System spatial analysis. Sensitivity analyses were conducted.

Results: Total costs ranged from CA\$21,719.56 to CA\$41,879.64. Lost productivity represented the largest cost category. The average costs of travel for fly-in First Nations communities in Ontario was CA\$6,564.11.

Conclusions: Future research should develop population-based estimates of obstetric evacuation costs and conduct economic evaluations of culturally safe obstetric services, such as Indigenous midwifery.

OP7B. Identifying High-Cost Users in Ontario: Implications of Follow-Up Time and Censoring for Measuring High-Cost Users Using Administrative Data

Presenter: Kali Barrett, University of Toronto

Coauthors: Victoria Chechulina, Western University; Hannah Chung, Institute for Clinical and Evaluative Sciences; Peter Dodek, St. Paul's Hospital; Laura Rosella, University of Toronto; Damon Scales, Sunnybrook Research Institute; Fatima Sheikh, McMaster University; Kednapa Thavorn, Ottawa Hospital Research Institute

A small number of individuals in a population account for the majority of health care spending. Previous literature has defined these “high-cost users” (HCUs) as individuals in the top 5% of spending. Individuals may be misclassified as an HCU depending on how their observation time is used. Using Ontario health administrative databases, we developed a methodology to identify HCUs that accounts for right-censoring (when an individual is no longer followed before an event) and reduces misclassification.

We calculated monthly health care costs for all individuals in Ontario between 2014 and 2022. For each month, we identified the cost thresholds that placed individuals in the top 5% of spending and the corresponding average monthly per-day thresholds.

We used these thresholds to identify HCUs after discharge in a cohort of adults hospitalized in 2016 to 2017 (n = 1,198,711). We calculated the costs for each 30-day interval after discharge to death or censoring (December 2019) and compared the 30-day costs to the HCU thresholds of the corresponding calendar

month. When there were fewer than 30 days of observation time, we used the average per-day threshold. Seventy-nine percent of hospitalized individuals (938,860) were HCUs (top 5%) for at least one 30-day interval during follow-up. Importantly, when we used the per-day thresholds for periods with fewer than 30 days of observation time, we identified an additional 45,707 individuals who were in the top 5% for that observation time.

Our proposed methodology for identifying HCUs minimizes the chance of misclassifying an HCU as a non-HCU and effectively handles right-censoring. This has important implications for health services researchers.

OP7C. Integrating Lived Experience: Developing a Theoretical and Methodological Approach to Conducting an Institutional Ethnography for Economic Evaluations

Presenting author: Chantal Valiquette, University of Toronto

Coauthors: Kathleen Armstrong, Mitchell Brown, Beverley M. Essue, and Daniel Grace, University of Toronto

Economic evaluations (EEs) provide important information for policy considerations in cost-constrained health systems. While they consider social values, there is a distinct lack of actual lived experience included in models. Institutional ethnography (IE) is a recognized method of inquiry that allows researchers to understand how individuals' everyday lived experiences can be an entry point or "standpoint" through which we can learn about social and institutional organizational structures. Integrating these methods, an IE of EE, could improve accountability in EEs by integrating lived experience.

Full literature review was conducted to evaluate broadly how IE has been utilized within the larger field of economics. Seminal texts "Institutional Ethnography: A Sociology for People" and "Methods for the Economic Evaluation of Health Care Programmes" were compared to determine how IE and EE may be integrated based on current established methodological practices. Alignments and deviations of IE practice were compared to EE decision analysis practices.

Areas for methodological alignment primarily fit in broad categories of establishing point of view (e.g., changing model perspective based on IE "standpoint"), considering system(s) scope (e.g., examining utility values), and utilization of textual materials (e.g., superimposing IE organizational system "maps" onto EE models). Along with incorporating reflexivity, these are all potential ways IE could improve EE analysis. This novel methodology can concretely begin integrating lived experience and equity into EE models aligned with current standards. As well, by analyzing EE through IE, we can comment more generally on how EE models are being used for decision-making and policy prioritization.

OP7D. 23 and (Not Just) Me: Incorporating Family Members in Economic Evaluation of Genetic Testing Technologies

Presenting author: Wendy Ungar, Technology Assessment at SickKids (TASK), The Hospital for Sick Children Research Institute

Genetic testing, including genome-wide sequencing, is rapidly diffusing into practice. The high cost, equity, and value considerations in using these technologies necessitate comprehensive health technology assessment. Cost-effectiveness analysis included in health technology assessment focuses on benefits to patients alone. However, genetics practitioners routinely consider family members, such as a child proband, parents, and siblings when examining genetic risks, interpreting results, and making management decisions. The advent of genome diagnostics is disrupting the conduct of cost-effectiveness analyses, requiring researchers to adapt new methods to assess these innovative technologies. Research using real-world evidence will be presented to demonstrate how a positive finding in a patient leads to cascade testing in family members and referrals for treatment and surveillance. Furthermore, the emerging standard of care for genome-wide sequencing that focuses on sequencing trios, consisting of the child and 2 biologic parents, will be illustrated. Incorporating the costs and health benefits of multiple family members in decision models is challenging but not impossible. The presentation will leverage burgeoning research on spillover effects to propose how health resource use and health outcomes in family members can be captured through the inclusion of parent health states, parent-child dyad health states, and household welfare function models. Measuring the costs and health consequences of genetic testing technologies in family members is integral to understanding their value to fully inform funding and adoption decisions. Guidelines for economic evaluation must go beyond mere consideration of patient effects to direct integration of costs and health benefits in family members when required.

OP8A. Level 2 Polysomnography for the Diagnosis of Sleep Disorders: An HTA

Presenting authors: Samrawit Lemma, Stacey Vandersluis, and Nancy Sikich, Ontario Health

Coauthors: Caroline Higgins, Ontario Health; Alexis Schaink, Ontario Health; Xuanqian Xie, Ontario Health; Corinne Holubowich, Ontario Health; Reshma Amin, The Hospital for Sick Children; Clodagh Ryan, University of Toronto/University Health Network; William Wong, University of Waterloo; Sarah McDowell, Ontario Health; Chunmei Li, Ontario Health; Jigna Mistry, Ontario Health; Charles de Mestral, Ontario Health/St. Michael's Hospital; Nancy Sikich, Ontario Health

Background: Polysomnography measures multiple physiologic parameters (e.g., electroencephalogram, electrooculogram, electromyogram, electrocardiogram, pulse oximetry, respiratory effort, and airflow) during sleep to evaluate for sleep disorders. Ontario publicly funds in-clinic (level-1) polysomnography. Innovative technological advancements have enabled bringing testing into people's homes (level-2 and level-3 sleep tests), which is potentially disruptive to the current diagnostic pathway.

Methods: As part of a health technology assessment, we systematically reviewed studies on level-2 polysomnography and assessed the quality of clinical evidence using Grading of Recommendations Assessment, Development, and Evaluation (GRADE). We conducted model-based cost-effectiveness and budget impact analyses for Ontario, comparing the diagnostic pathway of level-2 polysomnography versus current practice. Additionally, we interviewed people with sleep disorders to understand preferences and contextualize the value of at-home testing.

Results: Compared to level-1, level-2 polysomnography had sensitivity between 0.76 and 1.0 and specificity between 0.40 and 1.0 (GRADE: moderate to very low). We found uncertainty in cost savings with level-2 polysomnography for adults (mean: -\$27.20 per person, 95% credible interval: -\$137 to \$121). If publicly funded in Ontario, it could result in savings of \$5 million over 5 years, but the uncertainty is large (range: -\$22 million [savings] to \$43 million). People we interviewed reported negative experiences with level-1 polysomnography; most of them would prefer an at-home test, citing comfort and convenience as the main reasons.

Conclusion: At-home level-2 polysomnography has adequate diagnostic accuracy, can improve people's experience, and may lead to cost savings. The Ontario Health Technology Advisory Committee is currently reviewing this health technology assessment for a funding recommendation.

OP8B. The Canadian Medical Imaging Inventory (CMII): A Decade of Difference

Presenter: Andra Morrison, Canada's Drug Agency

Background: The Canadian Medical Imaging Inventory (CMII) collects information on the location, use, and technical characteristics of advanced imaging equipment, including the adoption of supporting tools and technologies, to help health systems mitigate challenges in meeting demand for imaging services.

Objective: We provide an analysis of trends in the use of CT and MRI in Canada over the last decade and identify past predictors of change that may help prepare for developments in medical imaging in the future.

Methods: Data from the CMII's latest survey collected for 2022 to 2023 were compared with data collected by the Canadian Institute for Health Information in 2012.

Results: CT grew in terms of overall units over the last decade (from 510 to 544) and declined in units per million people (from 14.7 to 13.6). CT exam volume experienced 29% growth. MRI experienced growth in terms of the overall number of units (from 308 to 403), and the number of units per million people (from 8.9 to 10.1). MRI exam volumes grew by 12%. Over the same time, the median wait time for CT increased by 45% and the wait time for MRI increased by 26%.

Conclusion: While there has been some growth in imaging equipment capacity, when considering wait times that exceed recommended targets in some settings, the demand for imaging is outpacing existing capacity. Health care systems are better equipped to manage surges in demand and inform future needs with information on trends in equipment use over time.

OP8C. How To Conduct Agile Reviews of Medical Devices for the Management of Diabetes

Presenting author: Julie Nieminen, Institut national d'excellence en santé et en services sociaux (INESSS)

Coauthors: Nathalie Jobin and Mélanie Caron; INESSS

Rapid technological innovation and the ongoing introduction of new devices for the prevention, diagnosis, or treatment of diseases are likely to increase over the next decade. Using the example of medical devices for the management of diabetes, this presentation will discuss the challenges involved in evaluating rapidly evolving technologies. Currently, insulin pumps sit alongside continuous glucose monitors and can be combined with different software versions, algorithms, and artificial intelligence components. New versions are launched regularly and have shortened life cycles. For example, a generation of blood glucose sensor is currently around for 3 years. The fine line between a new medical device and upgraded versions can be blurred as they can involve various levels of modifications in conception, design, software, algorithms, user interface, and more. This rapid pace of evolution toward new generations of technology has required rapid adaptation from HTA agencies. This presentation will also discuss how INESSS's evaluation practices are evolving to support responsible innovation and the creation of value for the benefit of patients, their family, the health care system, and Quebec's society.

Special Session Abstracts

SP1. Opening Doors to Meaningful Engagement

Panellists: Sudha Kutty, Nicole Mittmann, and Peter Dyrda; Canada's Drug Agency

This is an opportunity to hear from senior leaders at Canada's Drug Agency about what is new and novel at the agency. Much of the session will be devoted to engagement and dialogue with the audience. Come with your coffee and your questions.

SP2. New Initiatives in Health Economics at Canada's Drug Agency

Panellists: Karen Lee and Alex Haines; Canada's Drug Agency

This session will provide an overview of the many initiatives Canada's Drug Agency is working on in the health economics space, some of which have been recently released and others are in process. Presenters will also provide details on how to get involved and when to expect opportunities for feedback.

SP3. A New Era of Innovation and Collaboration in PMDE

Moderator: Tarry Ahuja, Canada's Drug Agency

Panellists: Nadine Sulatycky and Emily Farrell, Canada's Drug Agency; Virginie Giroux, Merck Canada Inc.

The Post-Market Drug Evaluation (PMDE) program has expanded the role of Canada's Drug Agency in the drug review life cycle. Over the past 2 years, the program has provided senior health care decision-makers with evidence at the postmarket stage to help determine if drugs used in the real-world are safe, work as intended, and are used appropriately. This session will provide an update on the work done by the PMDE program since its launch. It will also discuss the innovative approaches implemented by the PMDE program to build collaboration and increase the utility and relevance of the evidence delivered to policy-makers. Engagement is an important element of the program that is considered for each project to ensure the research is more relevant and useful to the end-user and to increase the impact of the work. PMDE aims to foster trust, confidence, and connections in their work and has heavily invested in their engagement efforts with patients, clinicians, and industry over the last year. Notably, this session will cover the principles behind their engagement initiatives and highlight the Industry Task Force, developed to understand how to engage with the pharmaceutical industry and leverage industry real-world data. As the PMDE program continues to evolve, there is much on the horizon for the innovation and collaboration the program can continue to bring to the drug review life cycle. This session will close by highlighting the future direction of the PMDE program.

SP4. Canada's Drug Agency Initiatives in Drugs for Rare Diseases

Moderator: Nicole Mittmann, Canada's Drug Agency

Panellists: Andrew Taylor, Health Canada; Trish Caetano, Matthew McDonald, and Helen Mai, Canada's Drug Agency

This session will explore the key initiatives led by Canada's Drug Agency under the National Strategy for Drugs for Rare Diseases. These initiatives aim to enhance the collection, use, and quality of evidence to inform and support decision-making in rare disease conditions. Participants will learn how Canada's Drug Agency has implemented new processes and procedures to address how reimbursement recommendations or reimbursement criteria made at a certain point in time are re-evaluated with updated evidence and to improve patient access to existing treatments in the rare disease space. Drawing on recent examples, panellists will highlight Canada's Drug Agency initiatives in the following drugs-for-rare-disease domains:

1. **Monitoring and Identifying New Health Innovations:** Canada's Drug Agency is collaborating with health system partners to monitor and identify emerging health innovations in rare disease conditions. This initiative aims to alert decision-makers and prepare health systems for the introduction of new drug treatments.

2. **Developing Pan-Canadian Guidance for Newborn Screening Programs:** Building on existing work, Canada's Drug Agency is developing pan-Canadian guidance to support newborn screening programs. This includes establishing a Newborn Screening Advisory Panel to develop a proposed common set of guiding principles for newborn screening, exploring a proposed process and the criteria for the addition or removal of conditions, and recommending conditions that newborn screening programs in Canada could begin implementing.
3. **Providing Agile and Responsive Advice through Customized Reviews:** Canada's Drug Agency is conducting tailored reviews to provide agile and responsive advice to decision-makers for rare disease conditions. An example is the recent development of nonsponsored reimbursement reviews, where previous reimbursement recommendations can be revisited when new evidence has emerged — often years after the original recommendations were published.
4. **Improving Evidence Generation and Access to Real-World Data:** To better address regulatory, health technology assessment, and payer evidence gaps, Canada's Drug Agency has undertaken activities to enhance evidence generation and access to real-world data from rare disease registries. This includes creating an inventory of rare disease registries in Canada, establishing registry standards and guidelines, and testing registries for health technology assessment readiness. The goal is to produce fit-for-purpose, decision-grade real-world evidence throughout the drug life cycle.

These initiatives highlight our commitment to supporting health systems with robust evidence and guidance to improve outcomes for rare disease conditions in Canada.

SP5. Advancing HTA Methods

Presenting authors: Farah Husein, Deirdre DeJean, Saunya Dover, Renata Axler, and Viviane Grandpierre; Canada's Drug Agency

As part of our 2022 to 2025 strategic plan and our commitment to transparency, Canada's Drug Agency has undertaken work to advance the deliberative framework, ethics, and quantitative methods for appraising clinical evidence. In this session, we will outline the work done in each of these areas, our approach to development — including alignment with international best practices — and the principles and key takeaways. We will also discuss the next steps in this process. This session will be of particular interest to those working in health technology assessment, those submitting evidence for appraisal, and those using health technology assessment outputs to inform decision-making.

Workshop Abstracts

WS1. Qualitative Thinking and Best Practices in HTA: Unlocking Opportunities for Policy Impact

Presenting author: Francesca Brundisini, Canada's Drug Agency

Presenting coauthors: Jamie Anne Bentz, Elijah Herington, and Viviane Grandpierre; Canada's Drug Agency

In health technology assessment (HTA), qualitative thinking and best practices provide vital insights into the contexts of health technologies being considered for reimbursement. These practices ensure that HTAs and recommendations remain contextually relevant, actionable, and impactful for policy and practice. As such, these practices help inform decisions that respond to disruptive changes, including new and emerging technologies, evolving demographics, and changing patients' values, needs and goals, and public expectations.

Building on a previous 2024 training session conducted with Canada's Drug Agency HTA producers, this workshop aims to share and explain how qualitative thinking and best practices in HTA support decision-makers.

The workshop will consist of 3 parts. First, we will present and discuss fundamental principles of qualitative thinking and best practices in HTA. The second part will explore the scope of qualitative thinking and best practices in HTA. By examining the scope of these practices from initiation through assessment to appraisal, we will clarify what qualitative best practices in HTA can (and cannot) do. The third part will provide an overview of the type of questions and approaches best suited to inform contextually relevant, actionable recommendations. This will include the use of demonstrative examples from HTA practice to explore how and what type of policy decisions they can inform. Each part of the workshop will feature short presentations by qualitative and health policy experts, followed by interactive small-group exercises.

WS2. Innovative Approaches to Real-World Evidence Generation: Selecting the Appropriate Study Design to Answer Your Evidence Needs

Author: Calum Neish, IQVIA Solutions Canada Inc.

Coauthor: Matthew Dick, IQVIA Solutions Canada Inc.

Approaches to generation and collection of real-world data (RWD) are evolving, driven by the expanding volume and enhanced accessibility of health data. This evolution is further supported by the emergence of novel technologies and the efforts of health technology assessment bodies to formulate guidelines on the use of RWD for decision-making purposes. Techniques such as natural language processing, machine learning, as well as traditional study designs such as chart abstraction and administrative database studies are expanding the types of questions that can be answered using real-world evidence (RWE). However, to

optimally leverage these techniques, producers of RWE must make appropriate decisions about how and when to apply them.

This workshop is designed for producers and users of RWE and aims to provide participants with an overview and understanding of several innovative approaches to the generation of RWE for decision-making. Techniques such as external comparators, pragmatic studies, patient-centric data, use of artificial intelligence and natural language processing in data extraction, and digital data collection will be explored. Each of these approaches can generate new evidence, and this workshop will focus on which questions can be answered by which methods.

Using real-life case studies, the workshop facilitators will provide guidance on how and when to apply these innovative approaches. The workshop will be facilitated by trained professionals with 10 or more years' experience in epidemiology, health care data, novel approaches to RWE generation, and innovative study designs used in health care decision-making.

WS3. An Introduction to Health Technology Assessment

Presenting author: Don Husereau, University of Ottawa

Attendees will gain a better understanding of what health technology assessment (HTA) is, become more familiar with key concepts and terminology, and learn the role of common analytic and deliberative approaches. Participants will be introduced to HTA principles and practices, including approaches to assess clinical effectiveness (benefits and harms), meta-analysis and modelling, cost-effectiveness, ethical issues, and organizational and implementation issues.

By the end of the workshop, participants will be able to describe the following:

- HTA and its connection to health care decision-making
- best practices in HTA
- best practices in assessing clinical effectiveness (benefits and harms) and cost-effectiveness
- approaches to assessing other aspects of the impact of technology and methods for integrating societal and stakeholder values
- best practices in deliberative approaches and creating and using recommendations.

Poster Abstracts

PO1. A Cross-Sectional Assessment of the Relative Timing of CDA-AMC and INESSS Sponsor-Submitted Reimbursement Reviews and pCPA Engagement

Presenting author: Sydney Whitney, EVERSANA

Coauthors: Aidan Dineen, Nathashi Jayawardena, EVERSANA

There is growing expectation from stakeholders that promising therapies will be promptly available to Canadians. The study objective was to understand the relative timing of sponsor-submitted reimbursement reviews by Canada's Drug Agency (CDA-AMC) and the Institut national d'excellence en santé et en services sociaux (INESSS), and pan-Canadian Pharmaceutical Alliance (pCPA) engagement timing. A cross-sectional analysis of 2023 CDA-AMC reviews was performed in July 2024. Of 83 records, 16 were excluded (9 non-sponsored; 7 withdrawn/suspended). A total of 62 (INESSS) and 57 (pCPA) matching records were found. Comparing CDA-AMC and INESSS, 67 (100%) versus 60 (97%) of reviews were initiated and 57 (85%) versus 51 (82%) were completed, respectively. Two months or less separated the CDA-AMC and INESSS review completion timing for 34 (79%) of the 43 overlapping reviews. Of the 57 matching pCPA records, 36 were under consideration for negotiation, 9 had signed letters of intent, and 12 were in active negotiations. A range of 0 to about 6 months elapsed between CDA-AMC and INESSS review completion and a pCPA engagement letter. These results demonstrate 5 fewer 2023 submissions to INESSS than CDA-AMC. Potential explanations include no intention to submit or delayed submission to INESSS. INESSS may initiate reviews later than CDA-AMC, but completion time points were similar based on the limited sample of currently completed reviews.

PO2. Measuring Health Inequality Aversion in Canada: An Equity-Efficiency Trade-Off Experiment

Presenting author: Nicolas Iragorri, University of Toronto

Coauthors: Shehzad Ali, Western University; Sharmistha Mishra, University of Toronto; Beate Sander, University of Toronto

Objectives: To estimate the extent to which Canadians are averse to health inequalities, a critical component for equity-informative economic evaluations but lacking in the Canadian context.

Methods: We conducted 3 experiments among representative samples of adult Canadians to elicit value judgments about reducing income-related health inequality versus improving population health. Each experiment compared 2 programs: (Experiment 1) universal and tailored vaccination; (Experiment 2) nonspecific prevention programs (universal prevention versus tailored prevention interventions); (Experiment 3) generic health care programs (program A versus program B). Tailored interventions and program B had a more equal distribution of additional life-years across income quintiles, while universal programs

and program A were more efficient. We used benefit trade-off analysis to estimate the Atkinson inequality aversion index.

Results: We recruited 3,000 adult Canadians (1,000/experiment). Preferences for the vaccination, prevention, and generic experiments were distributed as follows: minimizing health inequalities (Atkinson Index undefined): 54%, 55%, and 57%, respectively; maximizing the health of the population with the highest income (Atkinson Index < 0): 31%, 22%, and 16% respectively; willing to trade some health to reduce inequalities (Atkinson Index > 0): 13%, 19%, and 22% respectively; improving the health of the individuals with the lowest income (Atkinson Index = ∞): 0%, 1%, and 3%, respectively; and maximizing total health (Atkinson Index = 0): 2%, 3%, and 2%, respectively. The median response reflected a preference for minimizing health inequalities across the 3 experiments.

Conclusions: Our findings suggest a strong aversion to health inequality among Canadians with over half of respondents willing to minimize health inequalities regardless of the impact on efficiency.

PO3. Do Higher Prices Provide Protection Against Drug Shortages? Real-World Evidence Lessons From Canada

Authors: Étienne Gaudette,^{1,2} Shirin Rizzardo,¹ Mina Tadrous,³ and Kevin Pothier¹

¹Patented Medicine Prices Review Board, Ottawa, ON, Canada

²Institute of Health Policy, Management and Evaluation, University of Toronto, ON, Canada

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Purpose: Participants will gain an understanding of the relationship between Canadian drug shortages and the price of drugs in Canada relative to other countries.

Keywords: Drug shortages, Access to medicines, Drug prices, Statistical analysis

Primary audience: Policy-makers, Health Economists, Other: Insurers

Objectives: 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 Multinational Integrated Data Analysis (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 was found 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.

PO4. Competition in Generic Drug Markets: International Progress and Room for Improvement, 2010 to 2021

Presenter: Étienne Gaudette, Patented Medicine Prices Review Board (PMPRB)

Coauthors: Kevin R. Pothier, PMPRB; Shirin Rizzardo, PMPRB; Mina Tadrous, University of Toronto

Objectives: 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 Multinational Integrated Data Analysis (MIDAS) database and population data from the Organisation for Economic Co-operation and Development for the period from 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, a 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 or more 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 United States (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.

PO5. Decoding the Canadian Market Dynamics for Drugs Indicated in Chronic Weight Management: Budget Impact Considerations for Public and Private Payers

Presenting author: Tuhin Maity, PDCI Market Access, a division of McKesson Canada Corporation

Coauthors: Courtney Abunassar, Paul Henricks, Susan Mirabi; PDCI Market Access, a division of McKesson Canada Corporation

As evidence mounts on long-term health benefits of drugs for chronic weight management, we anticipate increasing pressure on Canadian payers to facilitate access to those treatments. However, a significant expansion in reimbursement could disrupt the market due to the large number of Canadians potentially eligible for coverage.

This research aims to estimate the proportion of Canadians potentially eligible to use drugs indicated for chronic weight management based on a body mass index criterion of 30 and above, and their relative distribution both across jurisdictions and by source of primary insurance.

Age-stratified obesity epidemiology data, information on social assistance recipients, and those eligible for non-insured health benefits were sourced from Statistics Canada. The Canadian Community Health Survey Annual Component provided the proportion of private coverage. Information on public plan designs was obtained from the Patented Medicine Prices Review Board and provincial program sources.

The analysis revealed there are approximately 9.3 million Canadians across 10 provinces aged 20 years and older potentially eligible for chronic weight management drugs. On average, 58% of this population have private coverage as their primary insurance. The proportion varies across provinces, 54% to 68%, primarily driven by population age distribution and provincial public coverage eligibility rules.

Our research highlights the significant number of Canadians potentially eligible for chronic weight management drugs. By understanding the distribution of this population across jurisdictions and by primary insurance source, policy-makers and payers can make informed reimbursement decisions about drugs for chronic weight management.

PO6. Adopting Dashboard Tools for Disseminating the Results of Health Technology Assessments: CADTH Experiences

Presenting author: Yi-Sheng Chao, Canada's Drug Agency

Coauthors: Yan Li and the Emergency Department Overcrowding Team; Canada's Drug Agency

In addition to CADTH's role of providing health care decision-makers with objective evidence to help make informed decisions about the optimal use of health technologies, we also develop tools to support our

health technology assessment (HTA) work. Tools such as online interactive dashboards that can be updated regularly allowing for the sharing of the most recent and relevant data, can highlight information trends to support policy decisions. During the COVID-19 pandemic, online dashboards provided summaries of key trends and hot spots to guide resource allocation. In 2 recent projects, we developed online dashboards to showcase study findings. In 1 project, we conducted systematic reviews on treatment and management strategies for post-COVID-19 condition and regularly updated the dashboard to include the latest findings. In the other project, we collected real-world data on emergency department (ED) utilization from various sources, including Statistics Canada, Canadian Institute for Health Information, and the Organisation for Economic Co-operation and Development. This dashboard shows the trends in ED intake, ED process, and ED outcomes by Canadian jurisdictions. While dashboards can be effective in supporting evidence reviews, there are challenges related to their development, notably when using data collected by external sources. CADTH values the importance of knowledge mobilization and continues to optimize knowledge dissemination with the use of online dashboards.

PO7. Systematic Review of Methodological Quality Assessment Instruments for Health Economic Evaluations: A Critical Evaluation and Synthesis

Presenting author: Ilke Akpinar, University of Alberta

Coauthors: Ali Unsal, Institute of Health Economics; Jeff Round, University of Alberta; Mike Paulden, University of Alberta

Background: Health economic evaluations are vital for health care resource allocation. Recent reviews reveal deficiencies in study conduct and reporting, particularly in the context of medical devices. The complexity of medical devices, including learning curve, organizational impact, and incremental innovation, poses unique challenges compared to pharmaceuticals. This review aims to identify and evaluate economic evaluation quality assessment instruments, focusing on their suitability for medical device evaluations.

Methods: A comprehensive search of databases (MEDLINE, Embase, EconLit, CINAHL, Web of Science) and grey literature was conducted. Two reviewers screened titles and abstracts. We included full-text, peer-reviewed primary studies introducing original instruments as well as new versions with distinct perspectives or developed for medical device evaluations. Only methodological quality assessment instruments were considered for data extraction. Each item was assessed for its suitability in evaluating medical device economic evaluations, relevance to Canada's Drug Agency economic evaluation guidelines, and reflection of medical device-specific features.

Results: The search identified 4,203 abstracts. Fifteen results were retrieved for full-text assessment. Five relevant tools were identified. These tools lack specificity for medical devices, particularly in addressing features like learning curve effects, organizational impact, and incremental innovation. To be more suitable, tools should include items specific to these unique characteristics.

Conclusion: Existing tools contain only general items related to the conduct of health economic evaluation studies, highlighting the need for the development of tools specifically tailored to evaluate the methodological quality of medical device economic evaluation studies.

PO8. Assessing Community-Based Diabetic Retinopathy Screening Guided by Provincial Administrative Data

Presenter: James Bowen, Toronto General Hospital Research Institute

Coauthors: Sara Bhatti, Alliance for Healthier Communities; Michael H. Brent, Donald K. Johnson Eye Institute, Toronto Western Hospital, University Health Network; Maria Consuelo Cenizal, Flemingdon Health Centre; Judy Hung, Donald K. Johnson Eye Institute, Toronto Western Hospital, University Health Network; Suja Mathew, Ted Rogers Centre for Heart Research/Peter Munk; Rebecca Meritt, South Riverdale Community Health Centre; M. Anne Phillips, South Riverdale Community Health Centre; Conrad Pow, Diabetes Action Canada; Valeria Rac; Jennifer Rayner, Alliance for Healthier Communities; Anuisa Ranjan, South Riverdale Community Health Centre; Debbie Sissmore, Diabetes Action Canada; Malcolm Sissmore, Diabetes Action Canada; Aleksandra Stanimirovic, Ted Rogers Centre for Heart Research/Peter Munk

Background: In Canada, it is estimated that 1 in 3 individuals living with diabetes has not had their eyes checked for signs of retinopathy according to treatment guidelines. Without the existence of a diabetes registry, identification is challenging at a health system level, especially for underserved systematically marginalized populations.

Methods: Using provincial health care administrative data in Ontario combined with data abstracts from Community Health Centres (CHC), individuals living with diabetes who had not had their eyes examined for signs of retinopathy within the previous 425 days were identified. The CHC data permitted the ability to identify those individuals not covered by provincial health insurance. Telephone-based outreach from the CHCs was employed to directly contact those who required Tele-Retina screening. Health care utilization patterns related to Tele-Retina screening program was examined.

Results: Telephone outreach to 4,304 individuals requiring 5,649 telephone calls across 2 centres was completed. CHCs were able to contact 1,641 (38.1%) with 438 (26.7%) consenting to have their data accessed for the study. The majority of the individuals reached (95%) were interested in the eye screening program, and 377 (90.6%) individuals booked an appointment. A total of 409 Tele-Retina appointments were booked, including re-bookings, with 217 individuals having their eyes assessed for retinopathy. Non-attendance was due to cancelling (35.2%), no show (42.8%), or re-booking (22.0%). Retinopathy was identified in approximately 29% of individuals tested.

Discussion: Community-based diabetic retinopathy screening could benefit from a provincial-level screening strategy to identify those undiagnosed individuals, especially for individuals who are systematically marginalized within our health system.

PO9. “If You Look for a Problem, You’ll Find One”: A Qualitative Study to Understand Why Parents Decline Genetic Secondary Findings for Their Child or Themselves

Presenting author: Abigail Hansen, The Hospital for Sick Children

Coauthors: Riyana Babul-Hirji, The Hospital for Sick Children; Teresa B. Coe, The Hospital for Sick Children; Katherine Fooks, The Hospital for Sick Children; Robin Hayeems, The Hospital for Sick Children; Stephanie Luca, The Hospital for Sick Children; Olivia Moran, The Hospital for Sick Children; Secondary Findings Study Team, The Hospital for Sick Children; Viji Venkataramanan, The Hospital for Sick Children

Background: Genome-wide sequencing (GWS) can identify disease-causing genetic variants and secondary findings (SF). SF are variants in genes unrelated to the indication for testing but are associated with risk for other medically actionable conditions. Debate persists internationally regarding consent and reporting practices for SF. Genome-wide Sequencing Ontario (GSO) reports SF associated with actionability in childhood for all pediatric patients, with optional reporting for those actionable in adulthood. For adult patients and parents of pediatric patients, SF disclosure is optional. To date, 10% of GSO cases have declined optional SF. This study aims to explore decisional factors and characteristics of those who decline SF.

Methods: Individuals who decline SF are invited to complete a semistructured interview focused on factors related to their decision to decline SF (e.g., psychological concerns, cultural/religious beliefs) and a demographics questionnaire. Interviews are recorded and transcribed for thematic analysis.

Results: Ten interviews have been completed with parents of pediatric patients. Preliminary data suggest that parents decline SF to maintain focus on their child’s current health condition, or to avoid anticipated negative psychosocial effects. Some parents reported that learning SF was not aligned with their general mindset toward managing their health care. Parents appreciated having the option to decline SF when GWS is offered, but many wanted the ability to receive SF in the future. The mandatory disclosure of SF actionable in childhood was met with mixed reactions.

Conclusions: The decision to decline SF is complex. This research aims to guide clinical practice and policy related to reporting SF.

PO10. Comparisons of Budget Impact Analysis Forecasting Versus Real-World Utilization Data

Presenter: Caroline Muñoz, Ontario Health

Coauthors: Jessica Arias, Scott Gavura, Sumaid Khan, and Lyndee Yeung; Ontario Health

Background: The cost of funding cancer drugs continues to rise with each year. In 2022 to 2023, Ontario Health's New Drug Funding Program (NDFP) expenditures climbed to \$846M with anticipated 2023 to 2024 expenditures reaching above \$1B. Forecasting expenditures partly relies on budget impact analyses (BIA) of pipeline drugs. We compared forecasted versus actual drug expenditures for select recently implemented NDFP drugs to inform future BIA processes and support improved budgetary planning.

Methods: We used patient-level claims data to assess utilization of 3 funded NDFP drug indications: avelumab, pembrolizumab, and daratumumab. We compared financial estimates, patient numbers, treatment uptake, treatment duration, and relevant data elements provided in manufacturer and Ontario Health BIAs against internally generated utilization data to identify possible drivers of variance between forecasted and actual expenditures.

Results: Drivers of forecasted versus actual expenditure variation included market share and treatment duration for avelumab, patient uptake for pembrolizumab, and patient uptake for daratumumab. Input from clinical experts was sought to better understand how relevant disease and treatment factors may have influenced utilization. Introduction of new drug and indication pairings earlier in treatment pathways and for the same indication as those treated with avelumab, daratumumab, and pembrolizumab were noted as drivers of unanticipated patient uptake, specifically.

Conclusions: Comparisons of forecasted versus actual drug expenditures highlight the importance of validating BIA assumptions through the local and national health technology assessment processes to support fiscal planning. Collaboration with clinicians regarding the impact of pipeline drugs on patient volumes and treatment pathways will support improved accuracy of predictions and impact on program budgets.

PO11. Understanding Equity-Efficiency Trade-Offs for Health Care Resource Allocation in Canada: A Best-Worst Scaling Exercise

Presenting author: Christopher Cadham, PhD Candidate, University of Michigan

Coauthors: Shehzad Ali, Western University; Rafael Meza, BC Cancer Research Institute; Lisa A. Prosser, University of Michigan

Background: Understanding the domains and trade-offs considered important by the public is essential for novel approaches to economic evaluation that seek to value improvements in health equity.

Objective: To rank the importance of health equity and efficiency attributes.

Methods: We developed and fielded a best-worst scaling survey online in April 2024 and May 2024 to evaluate the preferences of Canadians for allocating resources to mitigate health disparities and improve efficiency (n = 567). We included attributes related to health benefits (e.g., disease severity, individual health gains, or improved life expectancy), group-level demographics (e.g., income level, education level, age, sex, or immigration status), and system functioning (e.g., costs, wait times, or number of people treated) for a combined total of 37 attributes. Group demographic and select health-related attributes were framed

as reducing disparities in access or health outcomes (e.g., reducing differences in access across income levels or reducing differences in health outcomes across income levels). Attributes were ranked by relative importance score.

Results: The most important attributes were reducing wait times and increasing the number of individuals who could be treated, improving access and outcomes for people with severe diseases, and reducing costs for individuals. The most highly ranked equity-relevant characteristic was income level. Attributes related to improved access were almost always ranked higher than attributes related to health outcomes.

Conclusions: Our findings highlight public preferences for equity in access, particularly emphasizing system-wide improvements, while equity in outcomes was of secondary concern. Results will inform the design of a future survey to generate equity weights.

PO12. Real-World Data From Selinexor Patient Support Program Demonstrates Patient Need for Novel Combinations to Treat Multiple Myeloma in the Relapse/Refractory Setting

Presenters: Alison Vanlerberghe, Elaine Lai, Dana Packer, Diane Brown; FORUS Therapeutics Inc., Oakville, ON

Background: Multiple myeloma (MM) patients refractory to early-line lenalidomide and/or daratumumab represent the most common population of patients in the relapsed/refractory MM (RRMM) setting. RRMM treatment options are limited by prior therapy and funded access. Selinexor — a first-in-class, oral, selective inhibitor of XPO1 — was approved in combination with bortezomib and dexamethasone (SVd) for the treatment of adult patients with MM who have received at least 1 prior therapy. The FORUS Therapeutics Patient Support Program (PSP) provided access to SVd post Notice of Compliance until listing and compassionate access to selinexor for combinations with pomalidomide/dexamethasone (SPd), carfilzomib/dexamethasone (SKd), and dexamethasone (Sd). Data from the STOMP [NCT02343042] study, STORM [NCT02336815] study, and National Comprehensive Cancer Network (NCCN) guidelines supported use of the SPd, SKd, and Sd regimens.

Aim: This report provides real-world data from the PSP for selinexor and demonstrates the clinical need for its combination with other approved anti-MM drugs in RRMM.

Methods: From July 11, 2022, to October 1, 2023, RRMM patients enrolled in the selinexor PSP and consented to use of their data. All patients with confirmed start were evaluated. Patients receiving SKd, SPd, or Sd were required to be intolerant/refractory to bortezomib with no other reasonable therapeutic options, including clinical trials.

Results: Data from 185 patients were analyzed. Patient age range was 40 to 89 years, 65% were 65 years or older. Regimens were SVd (n = 91), SKd (n = 21), SPd (n = 40), and Sd (n = 33). Average starting doses for SVd, SKd, and SPd were 82 mg, 67 mg, and 57 mg once weekly and 85 mg for Sd either once or twice weekly. Overall, 38% of SVd, SKd, and SPd use was in 2L and 3L versus Sd (97% in 4L+).

Conclusions: Physician demand for the use of selinexor in various regimens highlights the need for combinations of anti-MM drugs that meet the needs of patients while minimizing health care system budget impact and implementation challenges. CADTH's pilot non-sponsored drug review may be appropriate for evaluation of future MM treatment combinations with selinexor.

PO13. Toward Transparency in the Appraisal of Clinical Evidence: One Year of GRADE at Canada's Drug Agency

Presenting author: Allison Gates, Canada's Drug Agency (CDA-AMC)

Coauthors: Amanda Allard, Matthew Bryan, Stephanie Chiu, Carlos Cuello, Michelle Gates, Farah Husein, Sayako Yokoyama; CDA-AMC

In 2023, Canada's Drug Agency (CDA-AMC) adopted the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach as a framework for assessing the certainty of evidence for drugs evaluated via the CDA-AMC Reimbursement Reviews (CRRs) program. The aims of this presentation are to inform how and why GRADE was adopted, to elaborate on the benefits to using GRADE in the CRRs, and to share the key factors that have contributed to successful implementation.

How and why: GRADE was adopted in the Systematic Review section of CRRs with the aim of providing a consistent and transparent approach to communicating about the certainty of evidence for important outcomes.

Benefits: Benefits have included refinements to outcome selection (focus on outcomes likely to contribute most meaningfully to expert committee deliberations), a formalized approach for evaluating the clinical relevance of effects (focusing on absolute between-group differences and their position relative to thresholds of clinical importance), and greater transparency in communicating conclusions (GRADE summary of findings tables and informative statements).

Key success factors: Factors contributing to the successful implementation included comprehensive internal training and technical support, proactive adaptations to work processes, external training and communication, and an openness to feedback that will optimize the presentation of certainty of evidence appraisals.

Building on the success to date, future phases of implementation may explore how GRADE can best be integrated into other report types (e.g., health technology reviews).

PO14. Using Living Evidence Reviews and Care Pathways to Aid the Development of the Economic Model

Presenting author: Gavin Wong, UBC

Coauthor: Shahzad Ghanbarian, UBC

Care pathways developed in collaboration with clinicians and patients can be a valuable tool to aid the design and development of economic models. Integrated within the care pathway are essential components of a patient's journey, such as the expectation of benefit and harm in outcomes that are important to patients and the health care system. Our current work in health technology assessment extends how care pathways have been understood and applied.

The care pathway can serve as a map to show the patient their stage of the care journey, as well as a tool for policy-makers to visualize the need and place where the new intervention fits into the status quo. These components, essential to clinicians and patients, can be built directly into an economic model. A further advantage of integrating the care pathway into the economic model is that the care pathway can utilize updated evidence from a living systematic review. Therefore, it can ensure that the most up-to-date evidence is utilized in the model.

In 2021, we developed a living care pathway for major depression in collaboration alongside clinical experts from multiple specialties and patient partners. The Canadian guideline was used to identify interventions for depression. A living evidence synthesis was utilized to provide evidence for the intervention in the care pathway. Then, an analytical infrastructure was developed as the basis for the economic model using the living care pathway as a foundation. In presenting our framework and experience with this living care pathway and analytical infrastructure, we intend to further drive best practices for health technology assessment.

PO15. Optimizing Substance Use Health Care for Problematic Alcohol Use Through a Discrete Choice Experiment

Presenting author: Alyssa Grant, Ottawa Hospital Research Institute (OHRI)

Coauthors: Mary Bartram, Mental Health Commission of Canada; Nathorn Chaiyakunapruk, University of Utah; Kim Corace, Royal Ottawa Mental Health Centre; Mackenzie Dowson, OHRI; Gordon Garner, Community Additions Peer Support Association; Brian Hutton, OHRI; Surapon Nochaiwong, Chiang Mai University; Surachat Ngorsuraches, Harrison School of Pharmacy; Amelia Palumbo, OHRI; Justin Presseau, OHRI; Kelly Suschinsky, Royal Ottawa Mental Health Centre; Kednapa Thavorn, OHRI; Chau Tran, OHRI; Melanie Willows, Royal Ottawa Mental Health Centre

Introduction: Problematic alcohol use (PAU) is a major risk factor for morbidity and mortality globally, and the COVID-19 pandemic has exacerbated the consequences and caused abrupt disruptions to its care. This study used a discrete choice experiment (DCE) survey to identify preferred characteristics of Rapid Access Addiction Medicine (RAAM) clinics for PAU as identified by individuals with PAU and assessed how the COVID-19 pandemic may influence preferences.

Methods: A scoping review, stakeholder meetings, and an eDelphi were conducted to identify and prioritize characteristics of substance use health services for PAU that are important and relevant to RAAM clinics in Ontario and determine whether and how PAU individuals' experiences differed before and during the

COVID-19 pandemic. We then developed a DCE survey to measure preferences for PAU service features in scenarios with and without COVID-19 in the community.

Results: We identified an array of barriers, including complexity of the care pathway, high cost, wait times, lack of geographically accessible treatment, appointment hours, poor cultural/demographic sensitivity, and lack of anonymity/privacy. The stakeholder meetings and eDelphi survey refined the list of attributes to include service modes available, open hours, wait time, and the availability of peer support workers and shared decision-making. The DCE survey is under way; its results will be shared at the Symposium.

Conclusion: Our review has identified key barriers to accessing substance use health services for PAU. Findings from our studies can highlight which aspects of RAAM clinics, if modified, have the greatest potential to enhance the delivery and accessibility of substance use health services.

PO16. Unearthing the Environmental Impact of Pharmaceuticals and Related Technologies: A Call for the Incorporation of Environmental Considerations in Medication and Related Technologies Approval and Funding in Canada

Presenting author: Ariane Blanc, The Children's Hospital of Eastern Ontario (CHEO) — Ottawa Children's Treatment Centre/Canadian Association of Pharmacy for the Environment (CAPHÉ)

Coauthors: Simroop Ladhar, University of British Columbia (UBC)/CAPHÉ; Robert Pammett, Northern Health/UBC/CAPHÉ; Caitlin Roy, Saskatchewan Health Authority/CAPHÉ; Shellyza Sajwani, University of Ottawa/Ottawa Hospital/CAPHÉ; Grady Smith, University of Waterloo/CAPHÉ

Background: As the health of Canadians advances through the approval and funding of novel health care technologies and pharmaceuticals, it is imperative that we also recognize their environmental impact. This project aimed to highlight the urgency and need to include environmental sustainability in the pharmaceuticals and related health care technologies approval process.

Methods: We conducted an environmental scan of the literature using the PubMed database using relevant search terms including "sustainability," "pharmaceuticals," "health care technologies" and "climate change."

Findings: The health care system is responsible for 4.6% of Canada's total annual greenhouse gas (GHG) emissions, of which, 25% to 33% are attributed to pharmaceuticals. Upstream manufacturing is a major source of pharmaceutical-related GHG emissions, which can release pollutants into the atmosphere, water systems, and soil. Plastics in the packaging of medications and related technologies can take hundreds of years to decompose. Utilization of certain pharmaceuticals and related technologies involves the release of potent GHGs, which contribute to the detrimental effects of climate change. For example, metered-dose inhalers contain hydrofluorocarbon propellants, a GHG with a global warming potential 1,300 times that of carbon dioxide. Lastly, the improper disposal of medications and health care technologies can impact sensitive ecosystems and inadvertently enter human food and water supplies.

The impact of pharmaceuticals and health care technologies on the environment is documented, profound, and requires urgent actions. All key stakeholders contributing to the pharmaceuticals and related technology life cycle are accountable for their environmental footprint and mitigating their impact. Government, regulatory, and practices standards bodies also have an important role to play.

PO17. Pharmacotherapy in Stimulant Use Disorder

Presenting author: Christopher Holiday, BC Ministry of Health

Background: In 2022, 26,000 people in British Columbia (BC) were estimated to have stimulant use disorder (StUD). StUD carries an increased risk of physical and psychiatric complications. While there is no approved treatment, psychostimulants are increasingly being prescribed in BC to support people with StUD.

Methods: BC community pharmacy data (PharmaNet), outpatient billing (MSP), ambulatory records (NACRS), and inpatient admissions (DAD) records were used (2016 to 2023). Overall, 4,876 patients with StUD were identified. Using days of supply of psychostimulant dispenses (dextroamphetamine, methylphenidate, lisdexamfetamine, and mixed amphetamine) and including 2 days after supply ended, we generated periods of prescription psychostimulant supply and non-use. Using a self-controlled linear model, we compared frequency of all-cause and substance use disorder (SUD) related DAD or NACRS visits between these periods, controlling for covariates such as calendar year and opioid agonist treatment (OAT).

Results: Supply of dextroamphetamine, methylphenidate, lisdexamfetamine, and mixed amphetamine was associated with a 13.1%, 25.7%, 32.2%, and 34.1% reduction in all-cause DAD and NACRS visits, respectively, in comparison to periods of no prescription psychostimulant supply in the same individual. Additionally, dextroamphetamine, methylphenidate, lisdexamfetamine, and mixed amphetamine were associated with a 42.2%, 42.6%, 56.1%, and 53.7% reduction in SUD-related DAD and NACRS visits. Periods of OAT use were associated with a reduction in both all-cause and SUD-related DAD and NACRS visits.

Conclusion: BC patients with StUD had lower all-cause and SUD-related DAD and NACRS visits associated with periods of prescription psychostimulant dispensation, compared to periods in which they were not dispensed these medications.

PO18. The Cost of Potentially Inappropriate Medications in Canada: A Comparative Cross-Sectional Study

Coauthors: Émilie Bortolussi-Courval, McGill University Health Centre; Camille L. Gagnon, Canadian Medication Appropriateness and Deprescribing Network (CADeN); Jean-François Huon, Nantes Université; Ninh Khuong, CADeN; Todd Lee, McGill University Health Centre; Emily McDonald, McGill University Health Centre; Steven Morgan, UBC; Tiphaine Pierson, CADeN; Chiranjeev Sanyal, Dalhousie University; James L. Silvius, Alberta Health Services; Justin Turner, Monash University

Background: The prescribing of potentially inappropriate medications (PIMs) to older adults is associated with harms and excess drug costs borne by the public health care system. The burden of costs has not been reported in over a decade.

Goal: This study aimed to determine the direct costs of PIMs in Canada and describe how these have changed since the last available published data.

Methods: Total annual expenditure on PIMs for Canadian adults aged 65 years and older was measured using the Canadian National Prescription Drug Utilization Information System. Average costs per quarterly exposure and average quarterly exposures to PIMs per 10,000 population were measured in Canadian dollars. PIMs were primarily defined based off Beers Criteria.

Results: Canadians spent more than \$1 billion on PIMs in 2021, a 33.6% reduction compared to 2013 (\$1.5 billion, inflation-adjusted). The largest annual expenditures in 2021 were on proton pump inhibitors (\$211 million), followed by gabapentinoids (\$126 million). The quarterly rate of exposure to PIMs declined by 16.4%, from 7,301 in 2013 to 6,106 exposures per 10,000 older adults in 2021. The quarterly amount spent per older adult on PIMs fell by 40%, from \$95 to \$57 per person exposed. Exposure to most categories of PIMs decreased between 2013 and 2021; however, gabapentinoids (+ 83.7%), proton pump inhibitors (+ 6.5%), and antipsychotics (+ 5.4%) all increased and remain a challenge.

Impact: While overall expenditure on PIMs has declined over the past decade, costs remain high. Directed, scalable interventions are needed to reduce exposure to select classes of harmful and costly PIMs.

PO19. Sepsis Policies, Guidelines, and Standards in Canada: Understanding the Current Policy Landscape and Patient Values

Authors: Fatima Sheikh,¹ Victoria Chechulina,² Alison Fox-Robichaud,^{3,4} Lisa Schwartz,¹ Kali Barrett⁵⁻⁷; on behalf of the Sepsis Canada Policy Working Group

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Background: Sepsis accounts for 48.9 million cases and 11 million deaths worldwide. In 2017 the World Health Assembly passed a resolution calling on member states to recognize sepsis as a priority. Canada has not yet met those goals. To address the World Health Assembly resolution, we conducted a scoping review

to identify and describe existing sepsis policies, clinical practice guidelines, and health professional training standards in Canada to inform future evidence-based policy development.

Methods: To analyze the current landscape of sepsis policies, we conducted a scoping review and environmental scan. Policies, guidelines, or training standards related to sepsis identification, management, and/or reporting, published since 2010, and available in English/French, were included. Individuals with lived sepsis experience were involved in all stages of the review.

Results: Following systematic searches in 5 databases, 1,329 sources of evidence were included in the first screening phase. Additional sources of evidence were identified by searching Canadian organizations responsible for regulating training of health care professionals and reporting health outcomes. Among the policies, guidelines, and standards included ($n = 30$), 7 focused on acute management of sepsis, 0 focused on sepsis detection only, and 6 focused on sepsis detection and acute management. We identified 17 standards for the training, assessment, and accreditation of health care professionals. Of the 66 Royal College specialties/subspecialties, only 10 included “sepsis” as a listed competency/objective of training.

Conclusions: Understanding the current policy landscape, and patient preferences and values, is important to develop evidence-based policies to support the prevention, identification, and treatment of sepsis.

PO20. Empirical Estimates of Marginal Cost per Unit of Health for Health Technology Adoption

Presenter: Charles Yan, Institute of Health Economics

Coauthors: Jemal Mohamed, BC Health Technology Assessment Office (HTAO); Jeff Round, Institute of Health Economics

Introduction: Cost-effectiveness thresholds (CETs) are used by decision-makers to assess the value of health care interventions. However, CETs are typically not supported by empirical evidence of the opportunity cost of health spending, resulting in inefficient allocation of resources. Empirical assessments of health opportunity costs as the marginal cost per unit of health gain have been proposed to support value-based policy decisions. We present an analysis of the marginal cost of health within BC, measured in quality-adjusted life-years.

Methods: We construct 10-year panel-data regressions using instrumental variables to address time-invariant confounding and potential biases caused by unobserved factors. The analysis is conducted for individual population segments defined by BC’s Health System Matrix (HSM). The HSM categorizes BC residents into 14 segments based on health status from low to high health care needs. The regressions yield expenditure and mortality elasticities.

Results: Population distribution across segments exhibits variability, ranging from 0.5% to 33% of total BC residents. Mean costs (SD) differ across segments, with the lowest in low users (\$346, SD: 433) and the highest in residential care facilities (\$71,998, SD: 39,369). Expense elasticity varies from 0.89 to 1.16,

while mortality elasticity ranges from -0.063 to -0.96 , contributing to substantial diversity in costs per QALY gained.

Conclusions: Our empirical approach facilitates estimates of marginal productivity based on disease, geographical regions, service types, and care sectors. The implications extend to provincial and national levels.

PO21. Cost-Utility Analysis of Fractional Exhaled Nitric Oxide (FeNO) Testing for the Diagnosis of Asthma

Presenting author: Hong Anh Tu, Ontario Health

Author: Jesmin Antony, Ontario Health

Coauthors: Charles De Mestral, Caroline Higgins, Ishita Joshi, Chunmei Li, Jigna Mistry, Sarah McDowell, Nancy Sikich, Sonia Thomas, Stacey Vandersluis, Xuanqian Xie; Ontario Health

Background: For patients suspected of asthma, measuring the level of nitric oxide in the lungs using fractional exhaled nitric oxide (FeNO) testing can help determine how much inflammation there is in the airways. As a result, adding FeNO testing as an additional objective test in the current diagnostic pathway may help clinicians make accurate diagnosis.

Methods: To determine the cost-effectiveness of FeNO testing, we developed a decision tree comparing 3 different testing strategies: conducting FeNO testing if the result from spirometry is negative (sequential testing strategy), conducting FeNO testing at the same time as spirometry (combined testing strategy), and standard tests (spirometry followed by bronchial provocation test if spirometry result is negative). This decision tree was connected to 4 Markov models associated with the pathways corresponding to the true-positive, false-negative, false-positive, and true-negative results. We estimated costs and quality-adjusted life-years (QALYs) associated with each strategy from an Ontario public payer perspective using a 20-year time horizon.

Results: In children with suspected asthma, either sequential or combined testing strategy was highly likely to be cost-effective compared with standard tests. In adults with suspected asthma, sequential or combined testing strategy might become cost-effective when a FeNO threshold of 50 parts per billion or more was applied. The results were sensitive to the diagnostic accuracy of FeNO testing, time to resolve a false-positive or false-negative diagnosis, and pretest probability of asthma.

Conclusion: FeNO testing was cost-effective in the diagnosis of asthma in children but not in adults.

PO22. Real-World Evidence in CDA-AMC Resubmissions: A Decade of Integration and Impact

Author: Hussein El-Khechen, PDCI Market Access

Coauthor: Melissa Burt, PDCI Market Access

Objective: Real-world evidence (RWE) increasingly impacts all stages of the biopharmaceutical product life cycle, including health technology assessment. Canada's Drug Agency (CDA-AMC) has committed to shape the pan-Canadian discussion on how best to generate, gather, and optimize the use of RWE in its 2022 to 2025 strategic plan. However, RWE has long played a role in CDA-AMC drug reviews through resubmissions, which allowed nonrandomized controlled trial (RCT) data, including RWE. The objective of this project was to evaluate RWE use in CDA-AMC resubmissions over time.

Methods: CDA-AMC resubmissions from 2013 to 2023 were identified from CDA-AMC's website. The recommendations, their reasons, and RWE utilization were examined. Additionally, a search of CDA-AMC's website was conducted to evaluate the evolution of RWE's consideration in the review process.

Results: CDA-AMC issued recommendations for 12 resubmissions in the study period. Notably, 41.67% (N = 5) were for rare diseases. Among the initial submissions, most (83.33%, 10/12) received negative recommendations, while 16.67% (2/12) received recommendations with criteria. A total of 41.67% (5/12) included RWE, primarily from registry and observational studies, to support efficacy and safety claims. One submission used RWE for oncogenicity and natural history. On resubmission, a negative recommendation was overturned in 80% (8/10) of cases and RWE played a role in 2.

Discussion: The growing inclusion of RWE in CDA-AMC resubmissions mirrors CDA-AMC's recognition of its value. As CDA-AMC continues to expand RWE's role in drug reviews, its value, especially where RCTs are impractical or when bridging evidence gaps, is anticipated to be more fully realized.

PO23. Swift or Steady: Unveiling Roll-Out Strategies for HPV Primary Testing

Presenters: Roxanne Garaszczuk, Canadian Partnership Against Cancer (CPAC); Jean Hai Ein Yong, CPAC

Coauthors: Andrew Coldman, BC Cancer Research Centre; Rochelle Garner, Statistics Canada; Claude Nadeau, Statistics Canada; Zhuolu Sun, CPAC; John Than, Statistics Canada

Background: In 2019, the Canadian Partnership Against Cancer convened jurisdictional partners to develop the Action Plan for the Elimination of Cervical Cancer in Canada. Switching to HPV primary screening is critical to eliminating cervical cancer. Concerns about an initial surge in colposcopy demand have led to exploring roll-out strategies.

Aim: Using the OncoSim-Cervix model, we aimed to compare universal and age-based roll-out strategies for switching to HPV primary screening every 5 years.

Methods: The OncoSim-Cervix model projects screening effects on colposcopies, lesions, and cancer outcomes in Canada. We simulated 1 status quo scenario (primary Pap screening every 3 years) and 3 scenarios switching to HPV primary testing every 5 years: 1) universal roll-out, 2) age-based roll-out over 3 years, and 3) age-based roll-out over 7 years. The age-based roll-out has people older than 50 years switch first, followed by people older than 40 years and then people 25 years of age and older.

Results: Switching to HPV screening every 5 years improves CIN2+ lesion detection, reduces screening tests, and lowers costs in the long run. Universal roll-out results in a peak colposcopy demand increase of 60% (2 to 3 years after the switch). Age-based transition strategies lead to a smaller peak (35% for a 3-year roll-out, 3% for a 7-year roll-out). Clinical outcomes are similar between immediate and age-based roll-out.

Conclusion: Adopting HPV screening every 5 years enhances clinical outcomes and is cost-saving in the long run. Age-based roll-out mitigates the initial surge in colposcopy demand while achieving comparable results to universal roll-out.

PO24. Treatment Landscape and Caregiver Status for Alzheimer Disease Patients in Canada by Disease Severity: Results From a Real-World Survey

Presenting author: Jennifer Glass, Eli Lilly Canada Inc.

Coauthors: Chloe Walker, Adelphi Real World; Luc Boulay, Eli Lilly Canada Inc.; Brenda Botello Estrada, Eli Lilly and Company; Sarah Cotton, Adelphi Real World; Robert Laforce Jr., Université Laval; Serge Gauthier, McGill University; Jean-Eric Tarride, McMaster University

Aim: We aimed to describe the caregiver and treatment landscapes for patients with Alzheimer disease (AD) by disease severity.

Methods: Data were drawn from the Adelphi Real World AD Disease Specific Programme from March 2023 to October 2023. Physicians reported data on caregiver involvement in the care of patients with mild cognitive impairment (MCI)/AD and on patients' current treatment profiles. Non-professional caregivers of these patients completed a voluntary survey. Patients were defined as having MCI or mild/moderate/severe dementia due to AD, according to current diagnosis and physician-reported disease severity.

Results: Fifty physicians reported data on 384 patients (mean age 77.6 ± 9.1 years, 54.2% female). The average number of caregivers per patient was 1.7 ± 1.0 (overall) and 2.1 ± 1.1 (severe disease). Professional caregivers outside nursing home staff were primarily home help, 77.8% received nonprofessional care. Partners cared for 60.5% (overall) and 58.6% (severe disease) of patients. Nonprofessional caregivers spent 87.7 ± 65.0 hours/week caring for patients with severe disease versus an average of 63.7 ± 63.8 hours/week caring for patients overall. The most troublesome symptom was forgetting recent events. Patients needed most help with preparing meals or cooking. Physicians indicated that 49.5% of patients were receiving

treatment for AD symptoms, primarily acetylcholinesterase inhibitors. Treatment was being received by 48.6% (severe) versus 61.8% (moderate) and 58.5% (mild) of AD patients.

Conclusion: The burden of care on the family of patients with AD is substantial. More caregivers and caregiver time were required for patients with severe dementia due to AD, and fewer patients with severe disease received treatment for AD.

PO25. Diagnostic Journey and Barriers to Diagnosis for Patients With Mild Cognitive Impairment or Dementia Due to Alzheimer Disease in Canada: Results From a Real-World Survey

Presenting author: Jennifer Glass, Eli Lilly Canada Inc.

Coauthors: Luc Boulay, Eli Lilly Canada Inc.; Simona Vasileva-Methodiev, Eli Lilly Canada Inc.; Chloe Walker, Adelphi Real World; Sarah Cotton, Adelphi Real World; Jean-Eric Tarride, McMaster University; Robert Laforce Jr., Université Laval; Serge Gauthier, McGill University

Aim: We aimed to describe the diagnostic journey and barriers to diagnosis for patients with mild cognitive impairment (MCI) or dementia due to Alzheimer disease (AD) in Canada.

Method: Data were collected from the Adelphi Real World AD Disease Specific Programme, a cross-sectional survey of general practitioners (GPs) and specialists, from March 2023 to October 2023. Surveys covered patient management, referral patterns, attitudes toward diagnosis, advanced testing, and future treatment landscape. Physicians saw 5 or 10 patients/week with MCI or dementia/AD.

Result: The survey was completed by 20 GPs and 30 specialists. Patient difficulty remembering people's names (65%) was the most often prompted patient complaint for further testing. Other important complaints included problems concentrating on everyday tasks (45%) and worry about forgetting things (45%). GPs referred 25% \pm 22% of patients with MCI to a specialist after seeing them 3.9 \pm 1.3 times, and 49% \pm 28% of patients with MCI or dementia/AD were not referred to a specialist.

Specialists reported the top 3 barriers to early identification of patients with MCI and patients with mild dementia due to AD were delay due to lack of awareness of the condition, lack of understanding of "normal" aging, and slow referral.

Conclusion: Many patients with MCI or dementia/AD are not referred by GPs, especially in early-stage AD. Referrals were also often delayed, with specialists citing lack of patient awareness of MCI as the main barrier to early diagnosis. Improving awareness of early AD symptoms and AD pathology, and accelerating access to specialists, are warranted.

PO26. A Canadian Best Practice Example of Patient Group-Informed Quantitative Preference Study Design Exploring Patient, Caregiver, and Health Care Professional (HCP) Perspectives

Presenting author: Jessy Ranger, Myeloma Canada

Coauthors: Bonnie Macfarlane, Janssen Inc.; Arleigh McCurdy, The Ottawa Hospital; Richard Plante, Janssen Inc.; Kun Shi, Janssen Inc.; Stephanie Soltys, Janssen Inc.

Discrete choice experiments (DCEs) are a source of quantitative evidence for health technology assessments (HTAs) that can provide important insights into stakeholder values, complementing traditional qualitative input. DCEs can be of particular value when comparing very different treatment options.

Multiple myeloma is an incurable cancer characterized by successive cycles of diminishing remission and persistent relapse. Patients require new treatment options following each relapse to control the disease. Innovative treatment options such as chimeric antigen receptor T-cell (CAR T) therapy have recently emerged for the treatment of relapsed/refractory multiple myeloma (RRMM). Their distinctive attributes (i.e., administration process, prolonged remission rate, and safety profile) translate to a different treatment experience for patients, caregivers, and clinicians.

Several published studies describe stakeholder preferences for RRMM treatment. However, studies contrasting preferences between conventional treatments and CAR T therapy are limited, and Canadian-specific data are not available. A DCE was designed with extensive input from Myeloma Canada (a national patient organization) to explore Canadian patient preferences for treatment options in RRMM, as well as caregiver and HCP perceptions of these preferences. The design and methods for this study are described, including the unique collaborative approach with Myeloma Canada to integrate the perspectives of all 3 stakeholder groups and compare and contrast their relative perspectives. Strategies were employed to incorporate attributes of 2 very different categories of treatment in a balanced manner to ensure comprehension among diverse participants while maintaining methodological rigour.

PO27. Improving Time to Patient: Insights From the Canadian Cancer Treatment Hackathons

Presenting authors: Patil Mksyartinian, Barry Stein; Colorectal Cancer Canada

Canada's drug reimbursement process is complex, particularly with diverse levels and jurisdictions, resulting in 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. To examine the potential improvement and reduction in time to patient access to new medications, Colorectal Cancer Canada held a series of roundtables entitled The Canadian Cancer Treatment Hackathons from November 2022 to November 2023 with over 100 thought leaders, including representation from key stakeholders across Canada and internationally.

The first Hackathon in 2022, focused on novel ideation within existing systems, yielded opportunities, including global solutions for simultaneous data review in regulatory processes (e.g., Project Orbis), international sharing of health technology assessment (HTA) reviews, and concurrent negotiation by the pan-Canadian Pharmaceutical Alliance (pCPA) with HTA reviews at the pan-Canadian Oncology Drug Review Expert Review Committee/Canadian Drug Expert Committee level. Building on this momentum, 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. Noteworthy initiatives included drawing inspiration from the UK's Innovative Medicines Fund, streamlining processes with pCPA before the pan-Canadian Oncology Drug Review/Common Drug Review recommendations, and negotiating earlier in the process with a committed timeline. The fifth Hackathon built on insights from past hackathons and identified action change among key stakeholder groups, including patient groups, industry leaders, and clinicians.

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

PO28. Lipoprotein (a) Levels and Major Adverse Cardiovascular Events in Alberta, Canada: A Retrospective Cohort Study

Presenting author: Khalid El Ouagari, Dina Soliman

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Background: Elevated lipoprotein (a) (Lp(a)) is a highly prevalent, independent, causal, and genetic driver of cardiovascular risk.

Methods: A retrospective cohort study of patients with Lp(a) testing and an atherosclerotic cardiovascular disease (ASCVD) event was conducted using administrative health data from Alberta, Canada. Patients were indexed on their first ASCVD event occurring between January 1, 2015, to September 30, 2022. Major adverse cardiovascular events (MACE) were examined, including nonfatal myocardial infarction or ischemic stroke, urgent coronary revascularization, and cardiovascular death. Time to first MACE analyses were performed using Kaplan-Meier (KM) and Cox regression, stratified by 2 Lp(a) thresholds: 70 mg/dL and 90 mg/dL (using the first Lp(a) test available). Models were adjusted for significant baseline characteristics, laboratory tests, medications, and comorbidities identified by univariable analysis.

Results: The study included 6,891 patients; 1,254 (18.2%) and 828 (12.0%) had Lp(a) levels > 70 mg/dL and > 90 mg/dL, respectively. The median (interquartile range) age was 61.0 (52.0 to 69.0) years and 64.1% were male. Overall, 820 patients (11.9%) experienced MACE. At 8 years (96 months) of follow-up, the KM MACE-free probability was 76.1% (95% confidence interval [CI], 73.6 to 78.6%) for \leq 70 mg/dL, 60.7% (53.4 to 68.0%) for > 70 mg/dL, 75.4% (72.9 to 77.8%) for \leq 90 mg/dL, and 57.1% (46.8 to 67.3%) for > 90 mg/dL. The adjusted hazard ratio for Lp(a) > 70 mg/dL was 1.56 (95% CI, 1.33 to 1.83) relative to \leq 70 mg/dL and 1.60 (1.33 to 1.93) for Lp(a) > 90 mg/dL relative to \leq 90 mg/dL.

Conclusions: Patients with elevated Lp(a) levels were more likely to experience MACE following their ASCVD event.

PO29. Outcomes of Simplified Economic Approaches in CDA-AMC and pCPA

Presenting author: Jessica Moreira, Graduate Student, University of Toronto Mississauga

Coauthor: Lori Yin, Hoffmann-La Roche Ltd.

Background: Canada's Drug Agency (CDA-AMC) has taken ongoing measures to streamline the process of bringing effective drugs to Canadian patients, including simplifying economic reviews. CDA-AMC revised its procedures in 2020 to accept cost-minimization analysis (CMA) under certain clinical and cost criteria, and it removed the cost criterion in 2024.

Aim(s): This analysis examined the usage of simplified economic approaches (SEA) (CMA and cost comparison) in CDA-AMC submissions, and their recommendation and pan-Canadian Pharmaceutical Alliance (pCPA) negotiation outcomes.

Methods: CDA-AMC reimbursement reviews received after October 2020 with a final recommendation were extracted for analysis. Submissions were stratified by type of economic analysis. pCPA negotiation outcomes were extracted.

Results: Of the 208 reimbursement reviews analyzed, 189 (90.87%) included cost-utility or cost-effectiveness analyses (CUA/CEA), 11 (5.29%) included CMA, and 8 (3.85%) included cost comparison. Use of SEA has not increased over time. SEA makes up a higher proportion of non-oncology (13.64%) than oncology (3.53%) submissions. Of SEA submissions, 17 of 19 (89.47%) received recommendations to reimburse with clinical criteria and/or conditions; of those 16 of 17 (94.12%) included cost parity/savings criteria. Average pCPA negotiation was 3.91 months for SEA and 4.65 months for CUA/CEA. 76.92% of SEA with completed negotiations resulted in a Letter of Intent, compared to 83.20% for CUA/CEA.

Conclusion: The majority of CDA-AMC submissions do not use SEA. Where used, almost all recommendations included cost parity/savings criteria. SEA negotiations were faster than CUA/CEA; however, fewer resulted in a Letter of Intent.

PO30. Using a Mathematical Model to Improve HIV Self-Testing Implementation in Canada: Lessons Learned From the I'm Ready Program

Presenting author: Lisa Masucci, Ottawa Hospital Research Institute

Coauthors: Hawre Jalal, The Ottawa Hospital; Min Xi, The Ottawa Hospital Research Institute; Sean Rourke, St. Michael's Hospital; Alice Zwerling, University of Ottawa; Kednapa Thavorn, Ottawa Hospital Research Institute

Background: While HIV self-testing (HIVST) presents a promising solution for early HIV detection, access remains limited in Canada. There is a critical need for effective implementation strategies to expand its reach. The "I'm Ready" program is a prime example of such an initiative, which targets high-risk populations using assisted (peer support) and unassisted testing strategies to enhance HIVST accessibility. We evaluated the cost-effectiveness of the "I'm Ready" program from the perspective of Canada's publicly funded health care system.

Methods: We developed a Markov model to predict the lifetime costs and quality-adjusted life-years (QALYs) for high-risk individuals receiving HIVST through the "I'm Ready" program compared to usual care. The model considered testing uptake, testing accuracy, diagnostic accuracy of confirmatory testing, and HIV prognosis. A series of scenario analyses were conducted on testing uptake and accuracy. Costs and outcomes were discounted 1.5% annually, with costs reported in 2023 Canadian dollars.

Results: The base-case results demonstrated that with a 45% uptake rate, 100% HIVST sensitivity and 99.5% specificity, the "I'm Ready" program was associated with a higher cost (\$549) and improved QALYs (0.22), with an incremental cost-effectiveness ratio (ICER) of \$2,495/QALY compared to usual care. If the test uptake was reduced to 25%, the ICER was \$2,500/QALY. If the sensitivity of the test was reduced to 95%, the ICER was \$2,550/QALY.

Conclusions: At the current test uptake and accuracy, the "I'm Ready" program is cost-effective. Our study demonstrates how a mathematical model can aid in determining the optimal implementation of HIVST.

PO31. Benchmarking CDA-AMC Submissions, pCPA Negotiations, and Time-to-Listing Processes in Canada for Drugs for Rare Diseases

Presenting author: Juejing Ling, IQVIA Solutions Canada

Coauthor: Scott Shi, IQVIA Solutions Canada

Background: Drugs for rare diseases (DRDs) pose a unique challenge to publicly funded health care. As the government enacts the National Strategy for Drugs for Rare Diseases, it is valuable to examine the market access metrics of DRDs to help benchmark efforts in improving access for DRDs.

Objectives: Using a data-driven approach to assess if overall time-to-listing and market access outcomes are different for DRDs and non-DRDs.

Methods: This study used the IQVIA Market Access Metrics database up to September 2023. All non-oncology Canada's Drug Agency (CDA-AMC) new drug and indication reviews with NOC post-2010 were included. DRD status was referenced from the United States FDA's Orphan Drug Product designation database.

Results: The number of non-oncology CDA-AMC reviews was 88 and 338 for DRDs and non-DRDs, respectively. The CDA-AMC review process had similar outcomes (79% versus 76% positive or conditional recommendation) and review times (average of 230 days versus 228 days) for DRDs and non-DRDs, respectively. The pCPA negotiation process yielded fewer successful negotiations (61% versus 66%) and longer negotiations (average of 249 days versus 206 days) for DRDs. Seventy percent of DRDs and non-DRDs were publicly listed in at least 1 province; however, the time from Notice of Compliance to first province listing was longer for DRDs (average of 669 days versus 490 days).

Conclusion: Despite similar CDA-AMC review outcomes and timelines, overall time-to-listing was longer for DRDs compared to non-DRDs. With increased awareness of rare diseases and support from the Government of Canada, there is optimism for improved reimbursement and timeliness of access for DRDs.

PO32. Real-World Safety of Niraparib for Maintenance Treatment of Ovarian Cancer in Canada

Presenting coauthors: Katharina Forster and Samara Strub, Ontario Health

Coauthors: Qi Guan, Suriya J. Aktar, Reka E. Pataky, Mariet Mathew Stephen, Maud Marques, Karen Gambaro, Kahina Rachedi, Katharina Forster, Samara Strub, David Stock, Louis de Léséleuc, Winson Y. Cheung, Stuart Peacock, Christie Farrer, Scott Gavura, Mina Tadrous, Robert C. Grant, and Kelvin K. W. Chan

Niraparib was recently funded in Canada for the maintenance treatment of ovarian cancer following platinum-based chemotherapy. However, the drug's safety profile in the real-world remains uncertain. As a member of the Canada's Drug Agency Post-Market Drug Evaluation CoLab network, we conducted a cohort study to describe the patient population using niraparib and the proportion that experienced adverse events between June 2019 and December 2022 in 4 Canadian provinces (Ontario, Alberta, British Columbia [BC], and Quebec). We used administrative data and electronic medical records from Ontario Health, Alberta Health Services, BC Cancer, and registry data from Exactis Innovation. We summarized baseline characteristics using descriptive statistics and reported safety outcomes using cumulative incidence. We identified 514 patients receiving niraparib. Mean age was 67 years and most were initiated on a daily dose of 100 mg/day or 200 mg/day. Grade 3/4 anemia, neutropenia, and thrombocytopenia occurred in 11% to 16% of the cohort. In Ontario, the 3-month cumulative incidence of grade 3/4 thrombocytopenia was 11.6% (95% CI, 8.3% to 15.4%), neutropenia was 7.1% (95% CI, 4.6% to 10.4%), and anemia was 11.3% (95% CI, 8.0% to 15.2%). Cumulative incidences in remaining provinces were similar. Initial daily dose and proportions of hematological adverse events were low in the real world and may be related to cautious prescribing and close monitoring by clinicians.

PO33. Broadening the Definition of Clinical Utility for Genomic Sequencing: Family and Research Implications

Presenting author: Katharine Fooks, The Hospital for Sick Children

Coauthors: Francois Bernier, University of Calgary; Kym M. Boycott, Children's Hospital of Eastern Ontario (CHEO); Taila Hartley, CHEO; Robin Hayeems, The Hospital for Sick Children; Karen V. MacDonald, University of Calgary; Deborah A. Marshall, University of Calgary; Trevor A. Seeger, University of Calgary; Salma Shickh, The Hospital for Sick Children; Viji Venkataramanan, The Hospital for Sick Children

Introduction: Genomic sequencing (GS) technologies (exome/genome sequencing) enhance diagnosis and personalize treatment in patients, surpassing standard tests in traditional clinical utility metrics used in health technology assessment frameworks. Beyond diagnosis and management-related benefits, GS results can enable patient eligibility for research studies and targeted testing and risk assessment for relatives.

We developed a multidimensional clinical utility framework that also incorporates research and familial implications, which we quantify below.

Methods: We conducted a prospective, observational cohort study of participants from 2 provinces undergoing GS. Clinical utility-related data (e.g., diagnoses, management changes, research and familial implications) were collected from medical records and clinician-reported checklists and described using descriptive statistics.

Results: Overall, 718 participants underwent GS, 68.1% (n = 526) presented with intellectual disability, and 55% were male. Mean age at enrolment was 11.4 years (standard deviation: 11.96). GS identified a genetic diagnosis in 34% (n = 246) of participants and 40.1% (n = 288) became eligible for or more research studies based on their GS result, including 292 gene function or natural disease history studies and 5 clinical trials. There were implications for relatives in 21% of cases (n = 151), including 226 referrals for genetic counselling and 79 referrals for familial mutation testing.

Conclusion: Our findings provide evidence that GS results have utility beyond diagnosis and management-related benefits by increasing access to research studies for participants and providing accurate risk assessments for relatives. These represent additional benefits of GS, which warrant discussion for inclusion in clinical utility frameworks. Current health technology assessment evaluations may underestimate the full clinical utility of GS, potentially impacting funding and access.

PO34. What Do Patients Really Think of Patient Support Programs? A Patient-Led Evaluation of PSPs by and for Patients With Rheumatic Diseases in Canada

Authors: Laurie Proulx, Dawn Richards, Annette McKinnon, Zal Press, Julie McKenna, Linda Roy, Linda Wilhelm

In July 2023, the Canadian Arthritis Patient Alliance (CAPA, www.arthritispatient.ca), an independent and volunteer-based arthritis patient organization, launched a survey to understand rheumatic disease patients' experiences with Patient Support Programs (PSPs). PSPs are intended to support patients who are prescribed biologic/biosimilar medications (e.g., nursing support on self-injection or infusion services, help navigate public and private drug plans). The survey was co-developed by CAPA members (LW, DR, AM, JM, LR) many of whom have lived experience of PSPs. The survey included questions on awareness of PSPs and experiences with PSPs from enrolment to ongoing support while taking a medication. Descriptive statistics were reported with subgroup analysis by age, geographic location, and equity group, and were reviewed by people with lived experience of health conditions (ZP, DR, AM, JM, LR, LW). The 375 survey respondents represented a range of rheumatic diseases — for example, rheumatoid arthritis, juvenile idiopathic arthritis, and systemic lupus erythematosus — and locations (all Canadian provinces and territories). Most survey respondents (> 60%) were between the ages of 18 and 40 and many accessed a variety of PSP services, such as getting information about the medication (55%); getting information about taking, storing, or accessing the medication (48%); pharmacy services (49%); navigating drug insurance programs (41%); and getting the medication paid for completely or partially by the PSP (40%). To our knowledge, this is the first patient-led evaluation of PSPs that identifies the values, needs, and gaps in care for rheumatic disease patients, which will inform developing recommendations to support patient-centred care.

PO35. Tracking Real-World Advanced Melanoma Treatment Patterns and Trends Post-Reimbursement

Presenting author: Madeline Tong, IQVIA

Coauthors: Callahan Laforty, Sergey Muratov, Madeline Tong, Scott Shi; IQVIA

Background: There are several immunotherapies and BRAF-targeted treatments that have completed the public reimbursement journey for the treatment of advanced melanoma. Recent clinical trials provide guidance on the sequencing of these therapies; however, real-world usage and adoption information is limited.

Objectives: To determine real-world treatment patterns and trends using deidentified patient-level data collected from patient charts of oncologists who treat advanced melanoma across Canada.

Methods: This cross-sectional, observational study leveraged IQVIA's Oncology Patient Outcomes data collection platform. We analyzed 4 reports generated between January 2022 and October 2023 and extracted patient demographics, mutation status, and treatment patterns.

Results: The first report captured 137 advanced melanoma patients treated between January 2022 and June 2022, and the last report captured 115 patients treated between April 2023 and October 2023. In the first report, BRAF mutation status was assessed in 91% of patients (54.0% BRAF-positive) while 100% of patients (58.3% BRAF-positive) were assessed in the last report. In the overall patient population, 61.3% and 74.8% of patients received first-line immunotherapy in the first and last report respectively. In second line,

58.8% received immunotherapy in the first report compared to 23.1% in the last report. Specific to the BRAF-positive patients, the proportion of patients who received immunotherapy in first line increased from 40.5% in the first report to 58.2% in the last report.

Conclusion: Real-world treatment patterns reflect adoption of sequencing suggested by recent melanoma clinical trials and can inform ongoing and future HTA submissions. Further evaluation of clinician behaviour will be important in understanding the real-world usage of treatments post-reimbursement.

PO36. Fear of Missing Out: Drug Availability in Canada Versus the US

Presenting author: Martin Ho¹

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Introduction: Fewer drugs are marketed in Canada compared to the US. Canadians may be wondering if they are missing out on important therapies.

Objective: To determine if Canadians lack access to drugs with major additional therapeutic value compared to existing 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 (DPD) and clinical review, we categorized the drugs into 8 mutually exclusive groups: DPD 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. "Unavailable" drugs were assigned a likelihood of having major additional therapeutic value based on first-in-class status, type of review (standard/expedited), and trial outcome (surrogate/clinical).

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 (of which 1 had 50% likelihood of having major additional therapeutic value, 2 had 18% likelihood, 4 had 9% likelihood, and 2 had 5% likelihood).

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

PO37. How to Deliberate? Reflective Workshops to Advance Deliberation Practices at INESSS Through Collective Learning

Presenting author: Monika Wagner, Institut national d'excellence et en santé et en services sociaux (INESSS)

Coauthors: Sara Béha, INESSS; Jim Boulanger, INESSS; Olivier Demers-Payette, INESSS; Isabelle Ganache, INESSS; Mireille Goetghebeur, INESSS; Mélanie Martin, INESSS; Anne Tessier, INESSS

Background: In its Statement of Principles, INESSS has embraced multidimensional deliberation as part of its processes to arrive at fair, reasonable, and value-adding recommendations. It brings together a diverse group of citizens, clinicians, health care managers, ethicists, and scientists to weigh arguments for and against the value of a health care intervention, pondering its sociocultural, populational, clinical, organizational, and economic dimensions. After introducing this approach, a need was identified to share best practices to support organizational learning and continuous improvement.

Methods: Reflective workshops, covering specific case studies, were designed to draw on the diversity of experiences of deliberative committee members as well as of scientific teams and managers. A workshop guide was developed defining the objectives, concepts, and discussion questions. Participants were asked to identify strengths, challenges and contributing factors, and propose areas for continuous improvement. Qualitative data were thematically analyzed and synthesized.

Results: Seven workshops were held across INESSS' 3 directorates. From the organizational perspective, the workshops revealed a shared appreciation of the multidimensional approach and of the material developed to support deliberation. Areas for continuous improvement include a need to: evolve evaluation practices so that all necessary information can be mobilized to inform multidimensional deliberation; develop a shared understanding of deliberation and its role in the evaluation process; clarify the roles of all parties involved; and improve or develop means to better support them (tools, processes, and training).

Conclusion: The workshops yielded rich insights that informed organizational learning. Activities to share and implement the lessons learned are ongoing.

PO38. Uncovering the Health Economic Impact of Multi-Cancer Early Detection Tests Through Dynamic Simulation: A Study Utilizing System Dynamics Modelling for Early Value Assessment

Presenting author: Mussab Fagery, The University of Melbourne

Coauthors: Maarten IJzerman, Erasmus University Rotterdam; Özge Karanfil, Koç University; Hadi Khorshidi, The University of Melbourne; Stephen Wong, The University of Melbourne; Professor Jon Emery, The University of Melbourne

Background: Cancer screening is pivotal for early disease detection and improved patient outcomes. The integration of Multi-Cancer Early Detection (MCED) tests holds promise for enhancing screening effectiveness.

Aim: This study focuses on early value assessment and explores the health-economic implications of MCED testing using dynamic simulation modelling. The objective is to pinpoint scenarios where MCED testing optimally balances benefits and costs, thereby maximizing value for patients and the broader health care system.

Methods: Utilizing a system dynamics model, we represent the standard of care (SOC) screening for prevalent cancers and incorporate potential clinical pathways introduced by MCED tests. The system dynamics model investigates 3 key scenarios: assessing MCED testing as a substitute for non-participants in SOC screening, implementing MCED for high-risk individual's ineligible for SOC screening, and employing MCED for efficient risk stratification post-SOC screening. Additionally, an integrated cost and health outcomes model assesses screening costs and anticipated health outcomes for both SOC and MCED.

Results: Simulation results showcase the impact of MCED testing in clinical practice, including benefits and costs across different patient groups. The study reports on the influence of MCED testing-induced stage shifts on health outcomes and costs.

Conclusion: This study's findings could significantly shape the cancer screening landscape, providing crucial insights for decision-makers considering the integration of MCED to complement current screening methods.

PO39. The Role of Decision Thresholds in an Individual's Medical Decision-Making

Presenting author: Andrew Scarffe, Ottawa Hospital Research Institute

Coauthors: Wojtek Michalowski, Kevin Brand; University of Ottawa

Introduction: People are often faced with decisions that have uncertain outcomes as they relate to taking preventive action with respect to their overall health and wellbeing. People frequently make different decisions (e.g., they decide to become, or not become, vaccinated). Generally, it is believed that these

differing decisions can be attributed to individual differences in subjective judgments that result in different decision thresholds. Understanding how individuals determine their decision thresholds may have the potential to reduce variation within medical decision-making by understanding the cognitive mechanisms that inform people's decisions.

Methods: We conducted a systematic scoping review to identify the various theoretical paradigms that are used to inform decision thresholds within the field of medical decision-making. We then proposed a novel theoretical paradigm (i.e., the Extended Dual Progressing Model [DPM+]) that incorporates the field of risk perception (i.e., cultural world views) into the dual processing theory for decision threshold analysis. Finally, we conduct a proof-of-concept simulation model using Monte Carlo methods to test DPM+ on a case study related to the HPV vaccine.

Conclusion: The systematic scoping review is the first review to systematically characterize the literature on decision thresholds within medical decision-making. This study also extends the dual processing model for decision threshold analysis to include the influence of an individual's risk perception as informed by their cultural world views. DPM+ integrates cultural world views and risk perception into decision threshold analysis by way of an individual's "type I system" reasoning. DPM+ offers a prescriptive explanation of how people of differing cultural world views may have different decision thresholds. Consequently, DPM+ offers a theoretical model to explain why people make different preventive medicine decisions.

PO40. From Disruption to Empowerment: Transforming Mental Illness Medication Reviews for Positive Impact

Panel moderator: Ken Porter, Mood Disorders Society of Canada

Presenter: Atul Khullar, University of Alberta

Coauthors: Aimée Tran Ba Huy, McGill University; Nancy Zorzi, Mood Disorders Society of Canada

This poster explores the unique challenges of HTA reviews for medications for mental illnesses (MIM). Anchored in a comprehensive report by a national steering committee, our research examines these challenges, utilizing a data-driven approach to define and confirm their nature. The committee, consisting of individuals with lived experience, caregivers, physicians, and patient organizations from various regions and backgrounds, ensured a holistic and inclusive approach. Conducted by an independent third-party life sciences firm, the data analysis in the report serves as a pivotal tool in both defining and validating the challenges, contributing to a more nuanced comprehension of the complexities associated with HTA reviews for MIMs; however, the reasons for the variation in the conclusions of the identified HTA reviews are unclear.

A forthcoming national round table aims to enhance this dataset by directly soliciting insights from stakeholders across the Canadian health care reimbursement system with diverse perspectives, including government, industry, patient organizations, physicians, caregivers, researchers, and more. This collaborative forum seeks to delve into the root causes behind the issues identified in the report by

focusing on increasing the voice of lived experience, and explore potential frameworks for solutions, and their implementation, to address these challenges. This effort includes valuable input from meetings with Canada's Drug Agency during the planning phase, and whom we hope will also attend and participate in the round table.

Poster reviewers will gain profound insights into the complexities surrounding HTA shared from diverse perspectives for MIMs and leave with actionable strategies regarding how to address these challenges.

NB: By the time of the Symposium, the round table will have taken place and insights will have been gathered into a whitepaper.

PO41. Cost-Effectiveness of Statins in the Primary Prevention of Cardiovascular Disease in Older Adults: A 5-Year Retrospective Cohort Study

Presenting author: Philipp Frieden, Université Laval

Coauthors: Benoît Cossette, Université de Sherbrooke; Jason Guertin, Université Laval; Caroline Sirois, Université Laval; Denis Talbot, Université Laval

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 RCTs. However, using data from RCTs in an economic evaluation may not reflect medications' true efficiency profile in a real-world setting.

Objective: The objective of the study was to assess the real-world cost-effectiveness of statins in the primary prevention of cardiovascular diseases (CVD) in older adults (> 65 years).

Methods: We conducted a retrospective cohort study to evaluate the cost-effectiveness of statin therapy over a 5-year time horizon. The patient cohort, comprised of 61,000 patients identified using Quebec claims data, was followed from April 1, 2013, to March 31, 2018. 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%.

Results: The use of statins in the primary prevention of CVD in adults older than 65 years was found to be cost-effective compared to usually accepted thresholds, with an ICER of \$8,928 per life-year gained.

Conclusions: Study results suggest that statins could be a cost-effective solution in the primary prevention of CVD in older adults. Additional analyses accounting for baseline confounding and censoring are currently being conducted and will be available shortly.

PO42. Access to CAR T-Cell Therapy: Barriers in Treating and Referring Patients in Canada

Presenting author: Tara Bourgoin, IQVIA

Presenting coauthor: Arushi Sharma, IQVIA

Coauthors: Tara Bourgoin, Purva Barot; IQVIA

Introduction: CAR T therapy faces challenges in adoption within the Canadian health care system. This report examines perceived barriers to CAR T treatment and patient referral in Canada.

Methods: Physicians with recent CAR T treatment and referral experience were recruited from IQVIA's Community of Oncologists and surveyed between April-June 2023.

Results: Among physicians referring patients for CAR T therapy consultation, 67% expressed challenges in assessing CAR T eligibility of patients and cited a need for improved guidance and tools from CAR T treatment centres. Treating physicians (63%) agree on referring physicians' need to improve knowledge of patient eligibility profiles, with 50% to 79% of treating physicians reporting that patient eligibility was not evaluated before assessment at the CAR T centre. Further, treating physicians indicated that 75% of patients arrive at their first consultation with little to no knowledge of the therapy/process.

Barriers to CAR T referral include time from referral to treatment initiation and patient health. For multiple myeloma, 17% of treating physicians reported that time to treatment decision exceeded 3 months, whereas this time was less than 3 months for other indications. Only 26% to 64% of referred patients end up receiving CAR T therapy across indications. While disease progression is the main reason for nontreatment, patient eligibility (63%) and patient choice (44%) are important factors.

Conclusion: Lack of knowledge and tools to assess patient eligibility among referring physicians increases the burden on CAR T centres and patients, highlighting opportunity for improved communication between referring physicians and treatment centres to optimize CAR T therapy accessibility.

PO43. Costs and Utilization Trends for Publicly Funded Cancer Drugs in Ontario

Presenter and author: Rohini Naipaul, Ontario Health (Cancer Care Ontario)

Coauthors: Scott Gavura, Lyndee Yeung; Ontario Health (Cancer Care Ontario)

Background: Given the high price of new cancer medications, payers are tasked with finding sustainable approaches to offering patients timely access to effective medications. In Ontario, take-home cancer drugs (THCD) are funded by a provincial age/income-based plan (Ontario Drug Benefit Program [ODB]). Ontario Health reimburses hospitals for high-cost hospital-administered drugs that are primarily IV cancer drugs (IVCD). To inform system planning, we examined current trends in costs and utilization of THCD and IVCD.

Approach: Drugs were included that had at least 1 reimbursement claim between April 1, 2013, and March 31, 2023 (THCD = 111; IVCD = 75). Numbers of utilizing recipients, government costs, including drug costs and pharmacy fees where applicable, were extracted from ODB and Ontario Health claims data. Trends in costs and use were examined between the 2013 to 2014 and 2022 to 2023 fiscal year.

Results: Over 10 years, government spending on high-cost cancer medicines grew by 239.8% (average annual growth rate = 14.7%). In this period, THCD costs accounted for 55.9% (range, 50.2% to 59.5%) of total spending, THCD recipient use grew by 51.7%, and recipient costs grew by 159%. For high-cost IVCD, government spending increased by 212.7% over 10 years. Recipient use decreased by -2.7% due to shifting lower-cost generic IVCD to other programs. By 2022 to 2023, 10 immunotherapies accounted for 76.4% of IVCD costs.

Interpretation: Overall spending on cancer medicines is growing at a significant rate, increasing budget pressures for public payers. Growth of THCD and associated recipient costs continues to increase the need for efficient coverage solutions for Ontario patients.

PO44. Cost-Utility of Respiratory Syncytial Virus Vaccination Strategies for Older Canadian Adults

Presenting author: Ashleigh Tuite, Public Health Agency of Canada

Coauthors: Alison Simmons, Public Health Agency of Canada; Monica Rudd, Public Health Agency of Canada; Alexandra Cernat, Public Health Agency of Canada; Gebremedhin Gebretekle, Public Health Agency of Canada; Man Wah Yeung, Public Health Agency of Canada; April Killikelly, Public Health Agency of Canada; Winnie Siu, Public Health Agency of Canada; Sarah Buchan, Public Health Ontario; Nichols Brousseau, INSPQ; Matthew Tunis, Public Health Agency of Canada

Respiratory syncytial virus (RSV) vaccines have the potential to reduce disease burden and costs in Canadians, but the cost-effectiveness of vaccination programs for older adults is unknown. We evaluated the cost-effectiveness of different adult age cutoffs for RSV vaccination programs, with or without a focus on people with higher disease risk due to chronic medical conditions (CMCs). Using a static individual-based model of medically attended RSV disease, we followed a multi-age population of 100,000 people aged 50 years and older over a 3-year period, with vaccine characteristics based on the 2 RSV vaccines authorized in Canada as of March 2024 (Arexvy and Abrysvo). We calculated sequential incremental cost-effectiveness ratios in 2023 Canadian dollars per quality-adjusted life-year (QALY) using the health system and societal perspectives and a 1.5% discount rate. All vaccination strategies averted medically attended RSV disease, but strategies focused on adults with CMCs were more likely to be cost-effective than universal age-based strategies. Vaccinating adults aged 70 years and older with 1 or more CMC was the optimal strategy for a cost-effectiveness threshold of \$50,000 per QALY. Although results were sensitive to assumptions about vaccine price, strategies focusing on adults with CMCs remained optimal compared to age-based strategies even when vaccine prices were lower than assumed in the base-case analysis. These findings were robust

to a range of alternate assumptions. Our analysis shows that RSV vaccination programs in some groups of older Canadians at increased risk of RSV disease are likely cost-effective at commonly used thresholds.

PO45. Cost-Effectiveness of Geriatric Assessment and Management in Older Adults with Cancer: Model-Based Economic Evaluation

Presenting authors: Selai Akseer, Shant Torkom Yeretjian; IHPME, University of Toronto

Coauthors: Lusine Abrahamyan, IHPME, University of Toronto; Shabbir Alibhai, University Health Network; Martine Puts, University of Toronto; Yeva Sahakyan, Toronto General Hospital, University Health Network

Introduction: Geriatric assessment (GA) is a guideline-recommended strategy for optimizing cancer management among older adults. In a recent cost-utility analysis of the Canadian 5C randomized controlled trial (RCT), GA appeared cost-effective only in selective patients. With 5C as reference, we extend the analysis to other RCTs with different GA models, including GAIN, GAP70, and INTEGERATE.

Objectives: Assess the cost-effectiveness of GA plus usual care (UC) versus UC alone in older adults with cancer under a range of plausible scenarios from 3 international RCTs using a decision model.

Methods: We performed deterministic analyses using the health care payer perspective and applied a 6-month time horizon. We incorporated Canadian costs and utility data from 5C and used effectiveness data from the 3 trials. We reported health care costs per quality-adjusted life-year (QALY) and the incremental net monetary benefit (INMB) using a \$50,000 per QALY threshold.

Results: Across trials, the average QALY per patient ranged from 0.276 to 0.377 for GA and from 0.250 to 0.381 for UC, and the average total costs from \$25,052 to \$31,191 for GA and from \$23,984 to \$30,749 for UC. Chemotherapy expenses accounted for 46% to 66% of total costs across trials. The GAP70 and INTEGERATE trials had positive INMBs of \$2,635 and \$2,886, respectively. The GAIN trial had a negative INMB value of -\$268. In 5C, the total costs were \$31,191 and \$30,749 for GA and UC, respectively, with 0.377 and 0.381 QALYs, respectively, and INMB of -\$642.

Conclusion: GA's cost-effectiveness varied across scenarios, primarily driven by chemotherapy cost. Further research should identify GA and management components impacting chemotherapy-related costs to optimize cost-effectiveness.

PO46. Changes in Diclectin Utilization Trends in Ontario Following Media Attention: A Time Series Analysis

Presenting author: Shanzeh Chaudhry, University of Toronto

Coauthors: Cherry Chu, Women's College Hospital; Nav Persaud, St. Michael's Hospital; Mina Tadrous, University of Toronto; Shenthuraan Tharmarajah, University of Toronto; Setayesh Yazdani, University of Toronto

Background: Diclectin is an antiemetic authorized in Canada to treat nausea and vomiting of pregnancy (NVP), also known as morning sickness. In January 2018, there was extensive media attention following the Toronto Star reporting on Diclectin's lack of efficacy as detailed in previously unpublished clinical trial data.

Objective: To understand the impact of media coverage on the utilization of Diclectin in Canada.

Method: A time series analysis of monthly dispensation data for Diclectin across Canada from April 2016 to March 2022 was conducted using the IQVIA CompuScript database. Trends in the estimated total volume of Diclectin dispensations by retail pharmacists in Ontario and across Canada were analyzed. Birth data obtained from Statistics Canada were used to adjust for pregnancy rates. The impact of media coverage in January 2018 on Diclectin use was assessed with interventional autoregressive integrated moving average modelling.

Result: Diclectin prescribing decreased by 1.16% ($P = 0.015$) overall in Ontario, while they did not change significantly ($P = 0.0642$) across the rest of Canada. Out of 619,720 total Diclectin prescriptions, 391,722 (63.21%) were written by family physicians in Ontario, and there was a decline of 2.41% ($P = 0.01$) in Diclectin utilization among this group. There was no substantial change in prescribing by obstetrician-gynecologists in Ontario.

Conclusion: Despite garnering nationwide media attention questioning its efficacy, utilization trends of Diclectin were modestly affected and only in Ontario. This aligns with the media coverage surrounding Diclectin being primarily concentrated within Ontario, reluctance to prescribe medications not approved for NVP, and variations in patient demographics across prescribers.

PO47. CDA-AMC “Do Not Reimburse” Oncology Recommendations From 2019 to 2024: Trends and Submission Characteristics

Presenting author: Sumeet Singh, EVERSANA

Background and Methods: A positive recommendation from Canada's Drug Agency (CDA-AMC) is required for public reimbursement of novel oncology therapies in Canada (except for Quebec). CDA-AMC oncology recommendations issued from January 2019 onwards (including draft recommendations) were reviewed to assess trends in the issuance of “Do Not Reimburse” recommendations (DNRR) and the characteristics of submissions receiving DNRR.

Results: Twenty-seven of 158 (17%) recommendations from January 2019 to January 2024 were DNRR: 1 was at the draft stage, 26 were final recommendations, and 26 of 27 (96%) had undergone a Request for Reconsideration. One DNRR subsequently received a positive recommendation upon resubmission. Unmet need was acknowledged by the pan-Canadian Oncology Drug Review Expert Review Committee in 22 of 27 (82%) DNRRs. The reasons for a DNRR were uncertainty regarding the presence/magnitude of clinical benefit in 22 of 27 recommendations (82%) and uncertainty regarding the clinical meaningfulness of observed benefits in 4 of 27 recommendations (15%). Fourteen of 27 (52%) DNRRs were supported by single-arm data, 4 of 27 (15%) by comparative phase II data, and 4 of 27 (15%) by post hoc subgroup

analyses of phase III data. Additional characteristics of DNRRs will be presented, such as cancer types, and specific evidentiary limitations identified by CDA-AMC.

Conclusion: Approximately 1 in 6 CDA-AMC oncology recommendations have been DNRR in the past 5 years. Challenges in interpreting the clinical findings of single-arm trials, phase II trials, and post hoc subgroup analyses accounted for a large proportion of DNRRs. These findings have important implications for the future reimbursement of novel oncology therapies given the increasing trend toward approvals based on trial designs that do not provide the level of certainty of phase III trials.

PO48. Characterizing Files Reviewed Through the CDA-AMC Complex Review Process: 2020 to 2023

Presenting author: Sydney Jopling, EVERSANA

Coauthors: Christine Malmberg, Kamalpreet Mann, Raveen Muzaffar; EVERSANA

The objective was to characterize uptake of the Canada's Drug Agency (CDA-AMC) Complex Review Process (introduced in November 2021) and the types of drugs being reviewed through this mechanism. The CDA-AMC Reimbursement Review Reports database was used to identify all reviews with final recommendations dated 2020 to 2023 and Schedule E fees (Complex Reviews). The following data were extracted: CDA-AMC's criteria for Complex Review, type of drug (oncology/non-oncology), indication, clinical trial and pharmacoeconomic information, and recommendation type. Data were extracted by a single reviewer and validated by a second reviewer. Characteristics of the reviews were qualitatively analyzed.

There were 17 reviews (10 oncology, 7 non-oncology) of 15 unique drugs. Fourteen were for drugs for rare diseases. There were 8 cell therapies, 2 gene therapies, 1 radiopharmaceutical, and 1 RNA interference therapeutic. The majority were first-in-class and reviewed under priority mechanisms at Health Canada. It appears that no drugs were reviewed through the Complex Review Process solely based on undefined place in therapy. Three of the drugs were reviewed with phase I or II data. All but 1 drug received a reimburse with clinical criteria and/or conditions recommendation. For chronic therapies, the annual cost per patient ranged from \$120,000 to \$1.7M. For 1-time-use therapies, the cost ranged from \$450,000 to \$2.9M per patient.

In conclusion, all reviews aligned with eligibility criteria as stated in the CDA-AMC procedures. Furthermore, all reviews met at least 1 of the following criteria: cell or gene therapy, first-in-class, or reviewed through 1 of Health Canada's expedited review pathways.

PO49. A Cross-Sectional Assessment of the Relative Timing of CDA-AMC and INESSS Sponsor-Submitted Reimbursement Reviews and pCPA Engagement

Presenter and coauthor: Sydney Whitney, Eversana Life Science Services

Coauthor: Aidan Dineen, Eversana Life Science Services

There is growing expectation from stakeholders that promising therapies will be promptly available to Canadians. The study objective was to understand the relative timing of sponsor-submitted reimbursement reviews by Canada's Drug Agency (CDA-AMC) and the Institut national d'excellence en santé et en services sociaux (INESSS), and pan-Canadian Pharmaceutical Alliance (pCPA) engagement timing. A cross-sectional analysis of 2023 CDA-AMC reviews was performed in January 2024. Of 83 records, 16 were excluded (9 non-sponsored; 3 withdrawn/suspended; 4 reassessments/resubmissions). A total of 58 (INESSS) and 16 (pCPA) matching records were found. Comparing CDA-AMC and INESSS, 67 (100%) versus 47 (81%) reviews were initiated and 20 (30%) versus 15 (32%) were completed, respectively. Two months or less separated the CDA-AMC and INESSS review completion timing for all 13 overlapping reviews. Of the 16 matching pCPA records, 12 were under consideration for negotiation, 2 had signed letters of intent, and 2 were in active negotiations. A range of 0 to about 4 months elapsed between CDA-AMC and INESSS review completion and a pCPA engagement letter. These results demonstrate 9 fewer 2023 submissions to INESSS than CDA-AMC. Potential explanations include no intention to submit or delayed submission to INESSS. INESSS may initiate reviews later than CDA-AMC, but completion time points were similar based on the limited sample of currently completed reviews. An updated analysis is planned before the Symposium, when more complete data are anticipated to be available (i.e., more completed reviews and pCPA engagement). This updated analysis should provide further insights that may be useful to identify target areas for improvement of timely patient access to therapies.

PO50. Cost Drivers During the COVID-19 Pandemic: The Key Pressures for Canada's Public and Private Drug Plans in 2019 to 2022

Presenting author: Yvonne Zhang, PMPRB

Canadian public and private plans account for more than three-quarters of prescribed drug spending in Canada. This study explores the key cost pressures for public and private drug plans, differentiating between short-term effects and those with longer-lasting impacts, and highlights the impact of the COVID-19 pandemic since March 2020.

Using data from the National Prescription Drug Utilization Information System (NPDUIS) Database at the Canadian Institute for Health Information (CIHI) and the IQVIA Private Pay Direct Drug Plan Database, a sophisticated cost driver model isolates the key factors driving drug expenditure growth: demographic, volume, price, substitution (generic and biosimilar), and drug mix. The study covers the period from 2019 to 2022 and accounts for age and gender.

Increased use of higher cost medicines is the primary driver of drug cost growth, pushing costs up by 5% to 8% annually. Medicines costing more than \$10,000 and \$25,000 annually represent 1 in 3 and 1 in 5, respectively, of total drug costs in both public and private drug plans. Even pronounced savings from generic and biosimilar substitution —boosted by biosimilar switching initiatives, combined with minor price reductions — did not sufficiently mitigate 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 prepandemic levels in 2021 and 2022. The volume effect, partly tied to pandemic-related temporary prescription size limits, exerted a minor inverse force.

A greater understanding of the forces driving expenditures in Canadian drug plans will inform policy discussions on system sustainability and help anticipate and respond to evolving cost pressures.

PO51. Understanding the Relationship Between Clinical End Points and Price Reduction Requests Using CDA-AMC's Oncology Reimbursement Recommendations

Presenting author: Zahra Akbar, Innovative Medicines Canada

Objective: To assess whether a relationship exists between the use of oncology relevant end points and price reduction statements issued in Canada's Drug Agency (CDA-AMC) oncology recommendations.

Methods: Oncology products with CDA-AMC final recommendations issued between January 1, 2023, and December 31, 2023, were categorized on the efficacy outcomes of the pivotal trials. Data were analyzed on trial characteristics alongside price reduction statements issued in each recommendation. The relationship between benefit (i.e., clinical end points) and price statements was examined using descriptive qualitative analysis.

Results: Twenty-six oncology recommendations were issued by CDA-AMC. Price reduction statements were provided in all but 6 recommendations where a lack of cost-effectiveness analysis or limitations within the economic evidence was noted for the absence of a price recommendation. Price negotiations were recommended even when the product was net cost-saving. One review for a pediatric population noted that price reductions were not required. Twenty-one recommendations noted price reduction statements (range: 3% to 93%) to meet a willingness-to-pay threshold of \$50,000/QALY, with the majority more than 50%. In 31% of reviews, overall survival (OS) was the primary end point, 65% reported OS as a secondary end point, and in 1 review in acute lymphoblastic leukemia, OS was not collected. A relationship between choice of clinical end point (e.g., OS, PFS) and price reduction statements was not found.

Conclusion: Oncology relevant end points do not appear to drive HTA recommendations in 1 direction or the other with respect to price reduction recommendations. The choice of clinical end points should continue to be tailored and specific to the disease state under review.

PO52. Opioid Use Disorder Treatment in Correctional Settings: Insights from a Pan-Canadian Survey on Buprenorphine-Based Formulations

Presenting author: Louis de Léséleuc, Canada's Drug Agency

Coauthor: Sirjana Pant, Canada's Drug Agency

As the first Canada's Drug Agency Environmental Scan examining health care practices within correctional settings, this work focuses on the treatment of opioid use disorder (OUD). With a considerable population in correctional settings facing unique health risks and needs due to OUD, this initiative addresses a significant gap in the literature on the use of buprenorphine-based formulations in this population.

Drawing on responses from 29 individuals representing correctional facilities across Canada, including federal and provincial programs, the survey-based scan provides invaluable insights into real-world experiences with the buprenorphine-based opioid agonist therapy (OAT), which have broadened to 3 different formulations in recent years.

While all facilities offer the depot injection, the availability of transmucosal tablet and film formulations vary across jurisdictions. Eligibility criteria for treatment with an OAT often include OUD diagnosis and positive urine tests, and treatment protocols underscore a comprehensive approach. Some jurisdictions allow faster transition from tablets or films to depot injections, as compared to the recommended transition period. Administration and monitoring procedures ensure adherence and mitigate diversion risks. Transitioning to the community poses complexities, with varying approaches to postrelease OAT provision and continuity of care. Challenges persist with the depot injection's limited acceptance despite its advantages related to reduced diversion risks and lower administrative workload. Despite expectations, the transmucosal film formulation did not achieve the anticipated reduction in diversion.

The scan shares best practices and implementation considerations, emphasizing patient-centred care and highlighting ongoing challenges like diversion and administrative burden and the need to support patients transitioning back to the community.

PO53. Reception of RWE: A Deep Dive Into Recent Trends in CDA-AMC Reimbursement Reviews

Presenting author: Nikola Cubelic, Hoffmann-La Roche Limited

Coauthors: Rishma Abdulhusein, Hoffmann-La Roche Limited; Daniela Belovich, Hoffmann-La Roche Limited; David Shum, Hoffmann-La Roche Limited

Objectives: Canada's Drug Agency (CDA-AMC) is responsible for providing public reimbursement recommendations for drugs entering the Canadian market. The agency has had a recent focus on real-world evidence (RWE), with publications and working groups providing guidance on RWE use. This research aims to explore trends among RWE usage and appraisal in reimbursement reviews.

Methods: All CDA-AMC reimbursement reviews with recommendations issued from 2022 to 2023 were gathered. Reviews were assessed for inclusion of RWE in clinical and/or economic evidence sections. Each consideration of RWE was categorized (effectiveness/safety/economic). Data analysis examined positive recommendation rates, review duration, and comments from CDA-AMC regarding critical appraisal of RWE.

Results: 149 reimbursement reviews were assessed. Thirty-one of 149 (21%) included RWE. RWE categorization was mostly effectiveness (24/31 [77%]). A positive recommendation was issued in 123 of 149

(83%) reviews, and in reviews with RWE, 23 of 31 (74%) recommendations were positive ($P = 0.1683$). It took an average of 266 days for reviews containing RWE to receive a recommendation, compared to 254 days for reviews without RWE.

Conclusions: This research suggests RWE is examined in approximately 1 in 5 reimbursement reviews, with effectiveness data being most common. Reviews with RWE had a lower positive recommendation rate and slower average review time, although it is uncertain how RWE contributed. Research limitations include the 2-year scope and the reliance on report summaries for data. As RWE use supporting drug reimbursement submissions grows, uncertainty remains regarding its role in decision-making, suggesting further guidance and research on RWE in reimbursement reviews is needed.

PO54. Jurisdictional Funding Approaches for Cell and Gene Therapies: An Environmental Scan

Presenting authors: Scott Gavura, Ontario Health (Cancer Care Ontario); Carol Muñoz, Ontario Health

Coauthor: Jessica Arias, Ontario Health

Background: The number of cell and gene therapies (CGTs) being introduced is rapidly increasing. CGTs provide potentially life-changing benefits to patients living with rare, often deadly diseases, albeit at exceptionally high prices. There is limited knowledge on jurisdictional funding policies for CGTs. We conducted an environmental scan to understand how CGTs are funded in Canadian and international jurisdictions.

Methods: A comprehensive search was conducted utilizing PubMed, Ovid Embase, and various health-related websites, including the UK NHS, NICE, Canada's Drug Agency, and Centers for Medicare and Medicaid Service from 2013 to 2023. The search was limited to articles in English. Search terms included gene therapy, cell therapy, funding, pricing, reimbursement, cost, and policy. Eligible publications reported CGT funding policies and covered CGT-associated costs. Data extracted included article information, jurisdiction, and funding policy characteristics.

Results: We identified the application of risk-sharing agreements including payment instalments, funding caps, value-based agreements, and coverage with evidence development as mechanisms to manage high costs and uncertainties in CGT data. Costs were covered by public funding programs and administered through jurisdictional health agencies, or through government-funded or private insurance programs. Covered costs included price of therapy, cost of administration, and supportive care costs. Details of funding policies were limited due to confidentiality agreements.

Conclusions: A variety of CGT funding approaches are used across national and international jurisdictions. Differences included the use of financial agreements, reimbursement models, and costs covered through public funding. Our findings can inform CGT funding policy implementation across Canadian jurisdictions as new products enter health systems and impact health care spending.

PO55. A Portrait of Generalized Myasthenia Gravis in Canada: Interim Analysis of the Adelphi MG II Disease Specific Program

Presenting author: Kobina Quansah, Johnson & Johnson Innovative Medicine

Coauthors: Gregor Gibson, Adelphi Real World; Oliver Blanchard, Montreal Neurological Institute; Alberto E. Batista, Johnson & Johnson Innovative Medicine; Aysegul Erman, Johnson & Johnson Innovative Medicine; Joe Conyers, Adelphi Real World; Shiva Lauretta Birija, Adelphi Real World; Ciara Ringland, Adelphi Real World; Niall Hatchell, Adelphi Real World; Zaeem Siddiqi, University of Alberta

Generalized myasthenia gravis (gMG) is a rare, chronic, autoimmune disease characterized by muscle weakness and fatigue. Several novel treatment options have recently received Canadian regulatory approval, with more expected. Jurisdictions have been prioritizing monitoring of gMG drugs on the horizon. This study aims to describe the natural history, disease burden, and treatment utilization for seropositive gMG in Canada.

Interim data from the Adelphi MG II Disease Specific Programme™, a gMG patient-level, cross-sectional database collected through survey between February 2024 and May 2024 were analyzed. Neurologists provided data on sociodemographics, symptomatology, and treatments.

Seven neurologists provided data for 21 gMG patients Myasthenia Gravis Foundation of America (MGFA) class 2 to 4 receiving treatment. Mean (standard deviation; SD) age of the cohort was 58.5 (15.3) years (62% male, 76% white/Caucasian) and 86% were anti-acetylcholine receptor-positive. Mean (SD) time since diagnosis was 3.3 (2.9) years and 86% had more than 1 comorbid condition, most frequently dyslipidemia (43%). Insurance coverage was primarily public (76%). Most frequently reported symptoms were eyelid ptosis (90%) diplopia, dyspnea, and difficulty chewing (all 76%). During their disease course, 33% of patients had experienced more than 1 myasthenic crisis with an additional 28% experiencing more than 1 exacerbation. Patients used 1.7 (0.9) lines of treatment. Most frequently prescribed were acetylcholinesterase inhibitors (90%), corticosteroids (67%), nonsteroidal immunosuppressants (52%), IV immunoglobulin (38%), plasmapheresis (14%), and biologics (10%).

Despite the availability of some publicly covered treatment options, gMG patients continue to experience symptomatic burden and crises/exacerbations. These findings highlight an unmet need for new, safe, and effective therapeutics that are publicly covered to manage gMG-related clinical manifestations.

PO56. Real-World Health Outcomes of Patients Treated With CAR T-Cell Therapy in Ontario

Presenting author: Pierre Villeneuve, University of Ottawa

Coauthors: Lee Mozessohn, Sunnybrook Research Institute; Suriya Aktar, Ontario Health; Tom Kouroukis, McMaster University; Chris Bredeson, The Ottawa Hospital; Anca Prica, UHN Research; Danielle Rodin, University of Toronto; Christine Chen, UHN; Matthew Cheung, Sunnybrook Research Institute; David Hodgson, UHN; William Wai Lun Wong, University of Waterloo; Lisa Masucci, UHN; Rebecca E. Mercer, Canadian Centre for Applied Research in Cancer Control (ARCC); Bo Green, Ontario Health; Cassandra McKay, Ontario Health; Scott Gavura, Ontario Health; Kelvin KW Chan, Sunnybrook Research Institute

Background: Chimeric Antigen Receptor T-cell (CAR T-cell) therapy can revolutionize the management of patients with relapse/refractory diffuse large B-cell lymphoma. Single-arm, phase II studies demonstrate dramatic outcomes in response and survival but with significant toxicities at exceptionally high costs. We conducted a retrospective population-based cohort study to evaluate the real-world comparative safety and effectiveness of patients treated with funded CAR T-cell therapy in Ontario.

Methods: Cases received CAR T-cell therapy at the Princess Margaret Cancer Centre, Juravinski Cancer Centre, or The Ottawa Hospital with publicly funded CAR T- cells between January 2019 and June 2023. Historical controls with the same eligibility were treated with the standard of care between January 2013 and December 2018, before the funding of CAR T-cell. Balance of baseline characteristics (age, sex, income, Charlson score, rurality, treatment site, lymphoma subtypes) between exposure groups was achieved (standardized differences < 0.10) using propensity score-based inverse probability of treatment weighting.

Results: The cohort included 306 cases and 106 controls. The median age was 61 years, and 61.7% were male. The median follow-up time was 8.4 months (IQR, 4.1 to 23.0). The median overall survival was 14.0 months and 4.2 months for CAR T-cell treated patients and historical controls respectively (hazard ratio 0.39; 95% CI, 0.33 to 0.46; $P < 0.0001$).

Conclusion: The results from this first Canadian population-based study demonstrated the comparative effectiveness of CAR T-cell treatment for patients with relapse/refractory diffuse large B-cell lymphoma in routine clinical care.

PO57. Recent Trends in Oncology Submissions to CDA-AMC Supported by Single-Arm Trials

Presenting author: Yixie Zhang, EVERSANA

Coauthor: Sumeet Singh, EVERSANA

Background and objective: Many novel oncology therapies are approved based on single-arm studies (SAS) due to practical or ethical barriers in conducting randomized controlled trials, posing potential challenges to health technology assessment bodies in interpreting clinical benefits. We reviewed oncology SAS submissions to Canada's Drug Agency (CDA-AMC) from January 2021 onwards to assess trends and CDA-AMC's appraisals of these files.

Results: Twenty-one of 75 (28%) oncology submissions with a recommendation were based on SAS. Five of 21 (24%) SAS files received a negative recommendation, versus 5 of 54 (9%) files supported by controlled trials ($P = 0.096$, chi-square test). In all SAS files, CDA-AMC highlighted uncertainty regarding the treatment effect due to the single-arm design. CDA-AMC commented on the appropriateness of the single-arm design for only 6 of 21 files (28%). Twenty of 21 SAS files (95%) included indirect treatment comparisons (ITCs). The most commonly used methods were propensity score weighting (38%), matching-adjusted indirect comparisons (36%), and naive comparisons (16%). CDA-AMC considered the findings to be "uncertain"/"highly uncertain" in all adjusted ITCs. The most commonly cited ITC limitations were heterogeneity in patient characteristics (98%), study design (60%), and eligibility criteria (36%). Other issues included covariate selection (80%) and effective sample size (62%).

Conclusion: A substantial minority of recent oncology submissions to CDA-AMC were supported by SAS. CDA-AMC deemed that SAS files had a high degree of uncertainty regarding treatment benefit, and the likelihood of a negative recommendation tended to be higher than for files supported by controlled trials. In future, guidance regarding the situations in which SAS may be considered acceptable, and optimal analysis and reporting methods to mitigate uncertainty, may be helpful.

PO58. Active Surveillance for Safety and Effectiveness of Health Products Used for COVID-19: A Scoping Review

First author: Said Yousef Abdelrazeq, University of Ottawa, School of Epidemiology and Public Health.

Coauthors: Zemin Bai, Cardiovascular Research Method Centre, University of Ottawa Heart Institute; Shannon Kelly, Cardiovascular Research Method Centre, University of Ottawa Heart Institute; Becky Skidmore, private work; George Wells, Cardiovascular Research Method Centre, University of Ottawa Heart Institute

Urgent response to the COVID-19 pandemic necessitated rapid implementation or repurposing of many treatment strategies. Using a scoping review methodology, we sought to identify active surveillance (AS) tools, methods, and approaches used to support the collection of postmarket safety and effectiveness outcomes in patients taking non-vaccine therapeutic health products for COVID-19.

In a Peer Reviewed (PRESSed) strategy, we searched (MEDLINE, Embase, CENTRAL, Cochrane Database, WoS Core collection), global regulatory agency websites and registries, and implemented alerts until August 20, 2022. We broadly considered any definition of AS.

A total of 9,183 records were screened, which resulted in 15 included records describing 13 AS systems (ASSs) used for the safety and effectiveness of health products (mainly drugs) for COVID-19. Two systems considered effectiveness and safety, 6 safety, 2 effectiveness, and 3 were used to describe the treatment data. Of these, 11 were repurposed ASSs used for prepandemic health product surveillance. Except for 1, all ASSs were initiated during the early pandemic (2020). Early pandemic systems largely reported safety outcomes, and reporting effectiveness outcomes was limited. ASSs identified data through various sources, including databases, electronic medical records, and adverse drug reaction reports. Various digital tools were designed for efficient data collection, secure data transport, and near-real-time access.

The disruption caused by the pandemic resulted in a rapid response, development, and repurposing of ASSs to address the evolving challenges. These initiatives may be an opportunity to enhance health care practices and utilize technology for AS. This review emphasizes the health care system's adaptability, innovation, and resilience in the face of challenges, potentially resulting in improved monitoring and understanding of the safety and effectiveness of treatments.

PO59. Cost-Effectiveness of Specialized Trauma Care: A Systematic Review

Presenting author: Soualio Gnanou, Université Laval

Coauthor: Jason Robert Guertin, Université Laval

Background: Several meta-analyses have shown evidence of the effectiveness of specialized trauma care for improving patient outcomes, but their cost-effectiveness is unknown.

Objective: 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, EconLit 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 non-trauma centres (NTCs), with ICER ranging from 655 to 46,175 2022 international dollars per QALY. Among cost-consequence studies, 2 found STCs more costly and less effective than NTCs while 1 study showed the opposite. All cost analysis studies indicated higher costs in STCs. For subgroup analysis, 1 study suggested that STCs are more cost-effective in patients younger than 55 years with more severe injuries than their counterparts. Two high-quality reports found STCs more effective and more costly.

Conclusion: We identified 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.

PO60. Cost-Effectiveness of Timely Surgery and Timely Inpatient Rehabilitation for the Management of Hip Fracture

Presenter: Zheng Jing (Jimmy) Hu, MSc, McMaster University

Coauthors: Lehana Thabane, McMaster University; Judith Versloot, Trillium Health Partners; Walter Wodchis, University of Toronto; Feng Xie, McMaster University

Introduction: Hip fractures impose a major burden of disease on the elderly population. We sought to determine whether providing timely surgery within 24 hours of emergency department admission, timely admission to inpatient rehabilitation following acute care discharge, both, or receiving surgery beyond 24 hours and the absence of or delayed admission to inpatient rehabilitation, would be cost-effective management strategies for patients who have experienced hip fractures.

Methods: Using a Markov cohort model, quality-adjusted life-years (QALYs) and costs were evaluated over a 5-year time horizon, discounted at 3.5%. State-transition probabilities and costs were obtained from regression models fitted using linked administrative datasets from the Institute for Clinical Evaluative Sciences. EQ-5D utility values were obtained from an international prospective observational study. We performed base-case and probabilistic sensitivity analysis using 5,000 simulations to estimate the cost-effectiveness of each strategy at willingness-of-pay ranging from \$0 to \$300,000.

Results: The incremental-cost-effectiveness-ratio of timely rehabilitation, timely surgery alone, and both, compared to neither were \$124,162, -\$39,225 and \$83,713 per QALY, respectively. Five-year base-case costs ranged from \$130,747 to \$156,848 and QALYs from 2.13 to 2.37. A willingness-to-pay threshold above \$68,000 per QALY was required to achieve a positive net health benefit for all strategies. Timely surgery alone had the highest probability of being cost-effective up to \$128,000 per QALY, and the combination of timely surgery and inpatient rehabilitation had the highest probability of being cost-effective after \$130,000 per QALY.

Conclusion: Achieving timely access to surgery can improve patients' quality of life and reduce health system costs. Providing both timely surgery and inpatient rehabilitation yields greater QALYs but incurs a larger health systems cost. Further stakeholder engagement can facilitate an informed decision on resource allocation regarding rehabilitation.

PO61. What Barriers and Facilitators Do Health Care Providers Perceive in the Successful Implementation of Organizational Change Related to Electronic Medical Records?

Presenting author: Tareq Khalaf, PhD candidate, York University

Objectives: This research aims to explore the barriers and facilitators perceived by health care providers during the implementation of organizational change related to electronic medical records (EMRs).

Specifically, it seeks to identify key obstacles, examine factors that aid or impede successful EMR adoption, and understand the impact of change on providers' workflows and patient care delivery.

Methods: This study is based on literature review and implementation science theories to investigate barriers and facilitators in the implementation of EMRs. The literature review synthesizes existing research on EMR implementation challenges and effective strategies. Implementation science theories provide a framework for understanding factors influencing successful change adoption. The proposal suggests data collection that involves surveys and interviews with health care providers to triangulate findings. Analysis utilizes thematic coding to identify patterns and themes.

Results: The findings underscore the multifaceted nature of health care professionals' perceptions toward EMR systems, highlighting both positive attitudes and challenges associated with their implementation. Further analysis of the proposed data collection (through survey and interviews) will be added to this section.

Discussion: The literature review uncovered diverse perspectives on EMR implementation, its barriers, and its facilitators in health care organizations according to the COM-B approach. Despite extensive research, challenges persist across different contexts. Moreover, involving stakeholders like patients, providers, and payers enhances knowledge transfer for practical application.

PO62. Evaluating Wait Time Management Strategies for Canadian Physiotherapy Services: A Scoping Review

Presenting author: Rafael Miranda, University of Toronto

Coauthor: Amy Wenzel, University of Alberta

Background: Wait times for publicly funded physiotherapy (PT) services in Canada are high, which may force people to pay for care or face deteriorating quality of life. Wait time management strategies (WTMS) present an opportunity to change that, but much of the current research focuses on the distinctly different context of emergency rooms or surgery departments. Our objective was to map WTMS for PT in Canada.

Methods: This review was conducted using Arksey and O'Malley's 2005 framework. Six databases were searched for articles that evaluated WTMS for Canadian PT services, and a grey literature search was conducted.

Results: The 11 studies meeting inclusion criteria were conducted across Canada and most often involved changing PT service delivery. The most frequent outcomes were structural/organizational, wait times, and feedback from professionals. Research is limited, and studies did not always report enough information for health care stakeholders to examine clinical applicability. No results from the grey literature search met the criteria, suggesting that WTMS for PT are not an area of focus for PT associations or governments in Canada.

Conclusion: Further evaluation of WTMS in the context of PT is necessary and should improve reporting of context, population, and outcome measurement to support evidence-based practice. Few studies specifically

focused on strategies for patients with chronic conditions despite this population having the longest wait time. We suggest that stakeholder groups in health care should consider WTMS for PT to be a higher priority and encourage further research as the first step toward informed policy decisions.

PO63. From Disruption to Empowerment: Transforming Mental Illness Medication Reviews for Positive Impact

Panel moderator: Ken Porter, Mood Disorders Society of Canada

Presenter: Atul Khullar, University of Alberta

Coauthors: Aimée Tran Ba Huy, McGill University; Nancy Zorzi, Mood Disorders Society of Canada

This poster explores the unique challenges of health technology assessment (HTA) reviews for medications for mental illnesses (MIM). Anchored in a comprehensive report by a national steering committee, our research examines these challenges, utilizing a data-driven approach to define and confirm their nature. The committee, consisting of individuals with lived experience, caregivers, physicians, and patient organizations from various regions and backgrounds, ensured a holistic and inclusive approach. Conducted by an independent third-party life sciences firm, the data analysis in the report serves as a pivotal tool in both defining and validating the challenges, contributing to a more nuanced comprehension of the complexities associated with HTA reviews for MIMs; however, the reasons for the variation in the conclusions of the identified HTA reviews are unclear.

A forthcoming national round table aims to enhance this dataset by directly soliciting insights from stakeholders across the Canadian health care reimbursement system with diverse perspectives, including government, industry, patient organizations, physicians, caregivers, researchers, and more. This collaborative forum seeks to delve into the root causes behind the issues identified in the report, focusing on increasing the voice of lived experience, and explore potential frameworks for solutions and their implementation, to address these challenges. This effort includes valuable input from meetings with CADTH during the planning phase, and whom we hope will also attend and participate in the round table.

Poster reviewers will gain profound insights into the complexities surrounding HTA shared from diverse perspectives for MIMs and leave with actionable strategies regarding how to address these challenges.

NB: By the time of the Symposium, the round table will have taken place and insights will have been gathered into a whitepaper.



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