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Introduction

In a field as complex and demanding as health care, preparing for the future is hard, especially when — as the COVID-19 pandemic demonstrated — all it takes is a new virus to upend priorities and add new pressure to already stressed health systems.

Preparing health systems to manage the challenges and opportunities that lie ahead is essential to the continued quality of patient care and the sustainability of health care. It requires learning from this pandemic and preparing for the next one. It also means tackling existing system pressures — from the arrival of complex and disruptive scientific and technological innovation to profound social and health inequities to growing demands on finite resources.

Health technology assessment plays a vital role in preparing health systems for an uncertain future. By identifying and assessing the most promising advances in fields like broadening the evidence base to reduce uncertainty, complex technologies, artificial intelligence and incorporating environmental, equity, HTA will enable decision-makers to harness the full value of technology across its full life cycle to achieve transformative change.

The 2023 CADTH Symposium provided an opportunity to hear from national and international HTA experts, decision-makers, innovators, and patients, about the new developments, approaches, and initiatives that are shaping future-ready health systems.

Plenary Abstracts

PL1. Shaping Future-Ready Health Systems: Pan-Canadian Collaboration

Moderator: Heather Logan, CADTH

Panellists: Michael Green, Canada Health Infoway; Suzanne McGurn, CADTH; David O'Toole, Canadian Institute for Health Information; Jennifer Zelmer, Healthcare Excellence Canada

The COVID-19 pandemic made the need for collaboration very clear. New relationships were forged, existing relationships renewed, and collaboration increased during the pandemic. The pan-Canadian health organizations (pCHOs) are a case in point. Established to improve health and health care in the country, the pCHOs are working differently together as they strive to support health systems of the future by addressing a wide range of pressing issues, including data, digital health, quality care, pharmaceuticals, and innovation to name but a few. In this session, the senior leaders of pan-Canadian health organizations will discuss the individual and collaborative efforts they are undertaking to support sustainable, world-class health care today and in the future.

PL2. RWE Guidance: What Is It? Why Now? What's Next?

Panellists: Nicole Mittmann, CADTH; Farah Husein, CADTH; Laurie Lambert, CADTH; Andrew Raven, Health Canada; Catherine Njue, Health Canada; Mina Tadrous, University of Toronto

CADTH and Health Canada are the co-chairs of the Real-World Evidence (RWE) Steering Committee, together with national and international expert collaborators from government, patient organizations, industry, academia, and data holders who form the RWE Guidance Working Group (WG). The RWE Guidance WG have developed a pan-Canadian RWE Guidance document that will lay the foundation for the use of real-world evidence in regulatory approval and Health Technology Assessment (HTA) appraisal.

The objective was to develop Canadian-specific guidance on principles to guide the reporting of RWE, with the intention of consistency and alignment with regulatory and HTA standards in Canada and internationally. The principles highlight the importance of transparency in reporting to help ensure the credibility of the evidence.

This session will outline the robust multistep process to develop the RWE Guidance, overview key elements of the guidance document, and will provide an opportunity to hear from and have an open discussion with the Canadian regulator and HTA bodies.

PL3. Big Ideas for Future-Proofing Health Systems

Moderator: Suzanne McGurn, CADTH

Panellists: Eric Bélair, Health Canada; Muhammad Mamdani, Unity Health Toronto; Mitch Moneo, British Columbia Ministry of Health; Brigitte Nolet, Roche Canada; Marney Paradis, T1D Support Network

An expert panel was asked to consider the following question, "Giving particular thought to the use of technology and the role of health technology assessment, what is the best idea you have for building resilience into health systems in Canada to ensure uninterrupted care even in the face of unforeseen challenges?" Their top ideas will be presented. Symposium attendees will provide immediate input by voting for the ideas they think are truly "big ideas for future-proofing health systems" and will contribute to a discussion about how to move the big ideas forward.

Breakfast Session Abstracts

BS1. Guidelines and Processes for the Economic Evaluation of Vaccination Programs in Canada

Presenting Authors: Man Wah Yeung, Public Health Agency of Canada; Beate Sander, University Health Network; Ellen Rafferty, Institute of Health Economics and University of Alberta; Stirling Bryan, School of Population and Public Health, University of British Columbia

Co-Authors: Ashleigh Tuite, Public Health Agency of Canada; Lisa Prosser, University of Michigan; Sachoko Ozawa, University of North Carolina at Chapel Hill; Mark Jit, London School of Hygiene and Tropical Medicine; Austin Nam, Public Health Agency of Canada; Werner Brouwer, Erasmus University Rotterdam; Matthew Tunis, Public Health Agency of Canada; Nina Lathia; Althea House, Public Health Agency of Canada; Monika Naus, British Columbia Centre for Disease Control; Murray Krahn, University Health Network; Karen Lee, CADTH

The National Advisory Committee on Immunization (NACI) at the Public Health Agency of Canada (PHAC) makes recommendations on the use of human vaccines in Canada. Traditionally, NACI reviewed vaccine characteristics and burden of illness. With its recent expanded mandate, NACI now considers cost-effectiveness via economic evaluations, among other programmatic factors. This session will provide an overview of NACI's new Guidelines for the Economic Evaluation of Vaccination Programs in Canada (first edition). Unlike many other health technologies, vaccines have the potential to affect both vaccinated and unvaccinated individuals through externalities (e.g., community/herd immunity, age-shifting of disease), and spillover effects (e.g., to caregivers). The guidelines consider these population-level effects as well as non-health sector effects (e.g., productivity, consumption, education). To account for the full range of the impact of vaccination programs, a key recommendation from the Guidelines is to have the reference case analyses conducted from 2 perspectives: publicly funded health system and societal. Further, the Guidelines highlight integrating equity considerations into economic evaluations, especially in the context of vaccination. The session will also discuss NACI's process for incorporating economic evidence into federal vaccine decision-making, such as how different types of economic evidence are generated and used. The panel will include perspectives from guideline developers and public health, and will include guideline users conducting economic evaluations and end-users of economic evidence from the federal and provincial/territorial levels.

BS2. Overcoming Structural Inequity in Health Care for People with Substance Use Issues and/or Mental Illness

Presenting Authors: Uyen Ta, Mental Health Commission of Canada; Stephanie Knaak, Mental Health Commission of Canada

Structural stigma arbitrarily limits the opportunities and/or constrains the right of persons with lived and living experience of mental health problems and illnesses and/or substance use (PWLLE). While it often

occurs unknowingly, it creates inequities embedded in the fabric of our social institutions, organizations, and our shared ways of thinking and acting. In health care, structural stigma exists in the laws, policies, and models of care that deprioritize, dehumanize, and fail to treat people with mental health and/or substance use problems as equitably as those with physical health concerns. This leads to overall poorer health care access, less availability of evidence-based services, and lower quality of care for PWLLE.

In 2019, the Mental Health Commission of Canada (MHCC) set out on a multi-year initiative to examine structural stigma in health care settings and develop tools and approaches for dismantling it. The presentation will showcase the Champions and Changemakers project, where the MHCC worked with champions within the Canadian health system (health providers, leaders, and decision-makers, PWLLE, other stakeholders) who were implementing innovations to enhance the equity of care for people with mental health and/or substance use problem - including changes to service delivery, models of care, training models, as well as policy, advocacy and leadership and power-sharing structures. Through this project, we expanded knowledge of the key ingredients for structural change (features, strategies, context, mechanisms, outcomes, etc.), and co-designed an implementation guide that can be used to provide guidance to others interested in reducing structural stigma within their own organizations.

BS3. Canadian Outcomes Based Management Agreements: Promise, Progress, and Pitfalls

Presenting Authors: Kate Harback, Institute of Health Economics; Patricia Caetano, Manitoba Health and Seniors Care; Andrea Masters, Hoffmann-La Roche Limited; Glenn Monteith, Global Public Affairs

Co-Authors: John Sproule, Institute of Health Economics; Chad Mitchell, Alberta Health

Health systems around the world are continually seeking ways to provide their citizens with the best treatments to help them with their health condition and assure the public that taxpayer resources are delivering value. There is a clear trend in both Europe and in the United States towards formally establishing the option of outcome based managed access agreements to address clinical uncertainty issues and to provide improved financial/budget management for product listings. The use of outcome based managed access agreements (OBMAAs) have evolved at different rates across the world. Although there is some use in Canada, they have never been a regular transparent feature of negotiations. This session will provide an overview of work from the Institute of Health Economics Health Technology Innovation Platform on a framework and pathway for both public payers and manufacturers in Canada to more systematically pursue this option.

BS4. OMG HTA FTW IMHO: Tweetable Nuggets From HTA Leaders for People New to the Field

Moderator: Alex Haines, CADTH

Panellists: Amanda Allard, CADTH; Jeff Round, Institute of Health Economics; Chunmei Li, Ontario Health; Manik Saini, British Columbia Ministry of Health

An all-star panel of mentors with a wealth of experience in health technology assessment will share their candid insights and frank advice with junior researchers, graduate and undergraduate students, and anyone interested in pursuing a career in HTA. Using tweets containing a hashtag as the starting point, each speaker will talk about how they got started in HTA and the keys to success they've learned along the way. The session will wrap up with a free-wheeling question-and-answer session. If you're interested in working in HTA, this is a session you shouldn't miss.

BS5. Dr. Murray Krahn Memorial Scientific Panel Session

Moderator: Beate Sander, University Health Network

Panellists: William WL Wong, University of Waterloo; Andrew Mendlowitz, University Health Network; Andrea Tricco, St. Michael's Hospital, Unity Health Toronto; Yeva Sahakyan, University Health Network

In memory of the late Dr. Murray Krahn - a world renowned researcher in health technology assessment (HTA) - this session will showcase some of his innovative contributions to HTA and celebrate his life that influenced many colleagues and students.

We will open the panel session with a tribute to Dr. Krahn's legacy, highlighting his achievements to the field.

In the second part of this session, some of his mentees, students and colleagues will present highlights of studies Dr. Krahn initiated during the last chapter of his life, which are exemplary of the breadth and depth of his work, across all dimensions of HTA, from assessing clinical effectiveness, economic evaluation, and ethical, legal, and social issues. Topics include estimating the impact of direct-acting antiviral treatment on quality of life in patients with chronic hepatitis C, chronic hepatitis C modelling, estimating the health system cost and the chronic hepatitis C care cascade for indigenous population in Ontario, and a conceptual framework to incorporate ethical, legal, and social issues plus patient values into HTA.

The third part will be an "open mic" session to discuss the scientific work presented and share personal anecdotes of how Murray inspired and contributed his wisdom to HTA research.

Dr. Krahn's legacy lives on through his trainees and colleagues who champion HTA through excellence in research, dedication to training the next generations and contributing to policy and practice with the aim to improve health systems around the world.

BS6. From Vein to Vial to Vein: End-to-End Management of a National Formulary Program

Presenting Author: Sylvain Grenier, Canadian Blood Services

Canadian Blood Services operates a national formulary of about 50 brands of plasma protein and related products (PPRP) for all jurisdictions except Quebec. We also store and deliver these drugs to hospitals and clinics using a national distribution network funded as part of our blood supply responsibilities. Some of these products are made from plasma we collect.

This session will focus on:

- Modernization initiatives, including improvements to the CADTH-Canadian Blood Services interim PPRP review process — the method by which new classes of products are evaluated for potential inclusion on the formulary.
- Key aspects of our request for proposal (tendering) process for bulk purchasing of products. The pandemic required that governments bulk purchase essential supplies like vaccines. Learn about Canadian Blood Services' approach to tendering within its formulary, which seeks to balance a secure, diverse supply of therapies with highly competitive global pricing.
- Utilization optimization practices, including an award-winning initiative where clinical pharmacists are placed in hemophilia treatment centres.
- A recent agreement leveraging the private sector to collect more plasma in Canada and enable an end-to-end domestic supply chain for immunoglobulins. On-shoring medical supply chains is a pandemic lesson that Canada is striving to implement related to vaccines, essential therapies, and other necessary medical supplies.

Attendees will gain a stronger understanding of the value this unique pan-Canadian formulary brings to patients, clinicians, and health systems, including equitable access to therapies across the country at no direct cost to patients, as well as a collaborative, evolving, evidence-based approach to formulary management.

BS7. Anticipate and Transform: Shaping Future-Ready Health Systems Through Innovative Approaches

Moderator: Sudha Kutty, CADTH

Panellists: Brent Fraser, CADTH; Nicole Mittmann, CADTH; Laura Weeks, CADTH; Heather Logan, CADTH

CADTH's Evidence, Products, and Services team is poised to better shape future-ready health systems in Canada through innovative 'fit-for-purpose' approaches that will improve the agility, transparency, and impact of reviews and recommendations for drugs and other health technologies.

Two areas for new innovative approaches include new or revised procedures and the increased use of expert committees for advice or recommendations. Review procedures will anticipate the needs of health systems through a 'fit-for-purpose' approach, with examples of time-limited recommendations, proportionate reviews, and streamlined class reviews. CADTH will transform the health system through the increased use of expert committees to provide transparent and impactful advice or recommendations in response to complex health system needs (e.g., refresh of the Health Technology Expert Review Panel (HTERP) and use of implementation advice panels).

Join us for a breakfast session where you will hear from CADTH Leadership on how we are working to shape future-ready health systems through innovative approaches to procedures and use of expert committees. There will be brief presentations with Q&A with the audience.

Panel Abstracts

PA1. Post-Market Drug Evaluation Part One

Moderator: Tarry Ahuja, CADTH

Panellists: Nadine Sulatycky, CADTH, Patricia Caetano, Manitoba Ministry of Health; Melissa Kampman, Health Canada; Virginie Giroux, Merck; Kostas Trakas, Exactis Innovation

CoLab-oration: A New Standard for Excellence in Canadian Post-Market Drug Evaluation
The introduction of the Post-Market Drug Evaluation (PMDE) Program expands CADTH's supporting role within the drug review life cycle with evidence at the post-market stage. The health care needs of Canada's population continue to evolve. The requirement for appropriate access to safe, effective, and clinically relevant drugs has become an increasingly important goal for health systems. The regulatory review system also continues to be more agile, clinical development has been accelerated, and the resulting data and evidence provided are increasingly more complex. This reinforces the importance of post-market drug evaluation, filling a key gap in Canada's drug safety and effectiveness landscape. This new program will play a vital role in monitoring real-world therapeutic product use. This session will dive into the new program and how it functions and introduce you to CADTHs new evidence-generation network, called CoLab.

Embracing Innovation: a Fireside Chat on How Health System Players Ensure an Evidence-Based Approach in the Post-Market Landscape
Canada's health systems are responsible for ensuring access to safe and effective medications. This is true not only for medications entering the market, but those already on the market. Regulators approve drugs based on a series of time-controlled clinical trials involving a limited number of people. Uncertainty often exists about the long-term safety and effectiveness of drugs. And once they're in the market, drugs and therapeutic products are used by a wider range and greater number of people, many of whom have multiple medical conditions.

It is vital that we understand the long-term impact of drugs on a population by following the evidence about patients' drug use, health outcomes, and process of care. To ensure a value-based approach in the post-market landscape, all health system partners have a role to play. During this session, panellists will share the different perspectives they bring to the post-market evaluation space.

PA2. Using Labs Wisely: Learnings From One Year of a National Laboratory Stewardship Program

Moderator: Heather Logan, CADTH

Panellists: Gillian Hurwitz, Choosing Wisely Canada; Heather Logan, CADTH; Adina Weinerman, Sunnybrook Health Sciences Centre; Sebastian Landry, Montfort Hospital

Laboratory testing is the single highest volume medical activity. Low-value lab tests can lead to false positives, unnecessary follow-ups, potential patient harm and waste precious health care resources. In February 2022, Choosing Wisely Canada launched 'Using Labs Wisely', a concerted effort to curb low-value lab testing and promote lab stewardship across Canadian hospitals. To-date, more than 100 hospitals are participating in the program, which requires sites to attend monthly sessions with lab leaders from across the country, implement lab utilization quality improvement initiatives, and submit data to a centralized Using Labs Wisely data repository. Participants at Symposium will hear from a panel of experts that will share the learnings from the first year of Using Labs Wisely, including the program's impact on hospital lab utilization across Canada, how the program has partnered with CADTH, and where to go from here.

PA3. Post-Market Drug Evaluation Part Two: Moving Evidence Into Action — Asking the Policy Questions that Matter

Panellists: Michael Law, University of British Columbia; Emily Farrell, CADTH, Joan Paulin, Person with Lived Experience; Ran Goldman, University of British Columbia, and BC Children's Hospital; Scott Klarenbach, University of Alberta; Karen Fortin, Indigenous Services Canada

CADTH's Post-Market Drug Evaluation (PMDE) Program is using an innovative approach to support policy and decision-making. PMDE is applying co-production principles to help move evidence into action around the safety, effectiveness, and appropriate use of drugs. The cornerstone of CADTH's PMDE Program is CoLab — a pan-Canadian evidence generation network comprised of leading experts in applied research, drug evaluation methodologies, and data analysis. The HTA body, CoLab researchers, and decision-makers are working collaboratively, with engagement from clinicians, patients, care partners, and industry, where appropriate. This session will explore this integrated evidence-generation approach to answer decision-makers most pressing questions.

How do we ensure that the right questions are being asked? The way policy questions are framed matters. This session will walk through how to formulate policy questions that lead to evidence-informed policy decisions.

Throughout the session, we'll hear perspectives from panelists on why their involvement in the question refinement and co-production process is important.

PA4. The Role of Multi-Criteria Decision Analysis Within the Canadian Health Technology Assessment Landscape

Moderator: Stuart Peacock, BC Cancer

Panellists: Craig Mitton, University of British Columbia; Jaclyn Beca, MORSE Consulting Inc.; Doreen Ezeife, University of Calgary; Avram Denburg, The Hospital for Sick Children

Public pharmaceutical reimbursement often requires difficult and complex decisions that must be made with explicit consideration of multiple factors. Multi-criteria decision analysis (MCDA) is a tool that facilitates transparent decision-making by providing a structured approach to considering a range of relevant factors while incorporating multiple perspectives and values. MCDA typically includes both a scoring based on preselected criteria and a deliberative process to ensure decision-making reflects context. MCDA can improve the quality and consistency of health care decision-making with more explicit capture of all the relevant factors determining value. Successful application requires thoughtful development with appropriate methodology and periodic review to ensure the selected criteria and their importance accurately reflect the decision-makers' and society's values associated with the decision.

This session will explore the relevance and potential applications of MCDA methods to health technology assessment (HTA) processes and decision-making in Canada, highlighting challenges, opportunities and lessons learned. Panelists will provide applied examples of MCDA within the Canadian context. Topics include application of MCDA methods for priority setting of post-market real-world evidence generation to inform HTA reassessment, development of value assessment frameworks to assess drugs in both the adult and pediatric oncology space and the role of MCDA within the drug benefit council in British Columbia. Our pan-Canadian panel includes clinical, research, HTA and health economics perspectives. Together they have a broad range of expertise and experience in the methodology, development, and application of MCDA within HTA.

PA5. The What, Where, Who, Why and How of Data in Canada

Panellists: Anne Hayes, Health Data Research Network Canada; Charles Victor, Institute for Clinical Evaluative Sciences; Lacey Langlois, Canadian Institute for Health Information, Julie Stratton, Statistics Canada; Ted McDonald, New Brunswick Institute of Research, Data and Training

High quality data are critical to decision-making on pandemic response, pharmaceutical reviews, informing policy and improving clinical care. The importance of data is well understood – but the Canadian data

landscape is not. This multi-stakeholder, interactive panel will provide a primer for policy- and decision-makers, as well as members of the public and scientific community, on the following:

- What data currently exist in Canada to support policy and decision-making
- Where the data reside
- Who holds the data
- Why a high functioning data ecosystem is needed
- How to access the data and how it can benefit the system and public.

The panel will have representatives from pan-Canadian and provincial data holders and will introduce learning projects seeking to increase the impact of existing data assets. A series of "myth busters" will also address common misconceptions about accessing health data in Canada. Developing a common language for how we talk about data and its benefit to the public will be a key focus for the session.

COVID-19 accentuated the importance of breaking down data silos and aligning incentives for data access, collection, and use. Even with aligned incentives, challenges navigating the data landscape remain. Collaborations are necessary to address these complexities and enable access to richer data in an efficient and timely matter. Through this panel, the audience will develop an understanding of how organizations are working together to ensure the data of Canadians are being used to both understand and improve the health of our population.

PA6. Key Solutions for Concerted Action to Shape Sustainable and Resilient Health Care Systems in Canada

Moderator: Maria Judd, Healthcare Excellence Canada

Panellists: Sarah Allin, University of Toronto; Stephen Samis, Samis Health Policy Consulting Inc.; Katherine Smart, Canadian Medical Association; Fiona Miller, University of Toronto

In November 2022, the Partnership for Health System Sustainability and Resilience (PHSSR) launched its Canadian report led by Professor Sara Allin at the Institute of Health Policy, Management and Evaluation at the University of Toronto. The research analyzed Canada's health systems and drew on an analytic framework developed by the London School of Economics (LSE) and with input from an Expert Panel of Canadian health system leaders and policy-makers.

The report is divided into 7 domains, each providing an assessment of Canada's health care systems in the areas of governance, financing, workforce, medicines and technology, population health and social determinants of health, and environmental sustainability. The report provides insights into the longstanding challenges and strengths within each of these domains; and reviews the experiences during the COVID-19 pandemic to examine health systems resilience.

This panel discussion will include perspectives from researchers, clinicians and health system leaders involved in the report, calling for collaboration to translate the findings into actionable policy solutions. The areas of focus will include:

1. Primary care reform
2. Health data and outcomes-based spending
3. Health human resource planning
4. Environmental sustainability

Panelists will provide an overview of the research, establish its relevance in the context of the challenges our health systems are facing, discuss innovative models including in virtual care and health information and technology, present policy solutions that can be implemented, and reflect on the urgent need for concerted action from all stakeholders to shape health systems that are resilient in the face of crises.

PA7. Just Coverage Decisions: Incorporating Legal Analysis into the Assessment of Health Technologies

Panellists: Lorian Hardcastle, University of Calgary; Colleen Flood, University of Ottawa; Fiona Clement, University of Calgary; Manik Saini, British Columbia Ministry of Health

HTA bodies should consider the legal implications of their recommendations, such as whether a failure to fund a new technology is open to challenge under human rights law for discriminating on the grounds of disability, or whether an implantable device that collects personal health information from patients complies with relevant privacy laws. Failing to consider these issues may expose funders (e.g., governments, hospitals, insurers) to potential lawsuits and otherwise jeopardize important values such as patient privacy and gender equality. The changing nature of health care, incorporating genome sequencing, machine learning, and robotic surgery, creates a mounting imperative for HTA bodies to undertake legal analysis before making recommendations to public funders.

The CIHR-funded Canadian Law and HTA Working Group has developed an open-access Legal Guidance for HTA Bodies, to equip non-lawyers working within HTA bodies to better identify and prioritize for further analysis legal issues that may arise in assessments. Members of the Working Group will explain the types of legal issues that can confront HTA bodies and offer pragmatic ideas on how HTA bodies can identify and appropriately prioritize such issues amidst their other pressing responsibilities.

PA8. Toward a Pan-Canadian Health Evidence-Support System

Panellists: John Lavis, Global Commission on Evidence to Address Societal Challenges; Maureen Smith, Patient Partner; Marcel Saulnier, Global Commission on Evidence to Address Societal Challenges

The report of the Global Commission on Evidence to Address Societal Challenges -- released in January 2022 -- drew on its 25 commissioners' decades of experience and on lessons learned from the evidence response to COVID-19. It called for formalizing and strengthening domestic evidence-support systems (ESSs) and defined an ESS as grounded in an understanding of a provincial or national contexts and focused on contextualizing the evidence for a given decision in timely, demand-driven and equity-sensitive way. The Evidence Commission secretariat spent much of 2022 documenting what is working well that needs to be systematized and scaled up, and what gaps need to be filled, in a pan-Canadian health ESS. One panellist will describe how such a system can work and how HTA products and processes can be seen within such a system. Other panelists will describe their views on the need for and optimal features of a pan-Canadian health ESS. They will comment from the perspective of each of a federal government policy-maker, a citizen leader, and an evidence intermediary. Session participants will be engaged in a discussion about how to improve upon the ideas presented and how they could support the implementation of a pan-Canadian health ESS.

PA9. The Life Cycle of Health Technology Assessment From Inception to Implementation: the Need for Collaboration and Dialogue Across Tables to Accelerate Implementation

Moderator: Stirling Bryan, University of British Columbia

Panellists: Pardis Lakzadeh, University of British Columbia, Manik Saini, British Columbia Ministry of Health; Bernice Tsoi, CADTH; Tania Conte, University of British Columbia

HTAs is a multidisciplinary process that evaluates the properties and effects of a health technology across multiple dimensions to inform policy decisions. Traditionally, HTAs are labour- and time-intensive, requiring several years for research to impact practice. This is due to a multitude of reasons including: lack of continuous dialogue between researchers, policy-makers and health system executives and managers; limited understanding at the time of HTA on the system-level changes required for successful implementation; the need to create comprehensive de novo models vs. re-using existing models, model design considerations to produce relevant estimates for implementation. This panel will discuss recent examples of how collaboration and early dialogue can accelerate the adoption of HTA recommendations in order to transform health care systems. It will further discuss how HTA producers can advance their methods to produce system-level estimates beyond the typical cost per QALY outcomes to better support the needs of those implementing the recommendations. It will cover the full life cycle of an HTA including inception, design, deliberation and implementation. The panel will also discuss “who” needs to work together, how to establish collaborations, while managing enablers and barriers to collaborative work. By bringing together producers and “end users” of HTAs to facilitate continuous dialogue, we hope to enlighten the HTA community on the different needs and resources required across sectors involved in the HTA life cycle and re-think the HTA inception and design process to optimize HTA products to accelerate the adoption of technologies and shape “future” ready health systems.

PA10. The National Strategy for Drugs for Rare Diseases

Panellists: Lacey Langlois, Canadian Institute for Health Information, Daniel MacDonald, Health Canada; Nicole Mittmann, CADTH; Étienne Richer, Canadian Institutes of Health Research, Durhane Wong-Rieger, Canadian Organization for Rare Disorders

On March 22, 2023, the government of Canada announced the first-ever National Strategy for Drugs for Rare Diseases, supported by an investment of up to $1.5 billion to "increase access to, and affordability of, effective drugs for rare diseases to improve the health of patients across Canada, including children." In this session, representatives of organizations tasked with implementing the Strategy will discuss its purpose and major components.

PA11. Adapting to the Oncoming Avalanche of Unconventional Surrogate Outcomes Early-Stage Cancer Clinical Trials

Moderator: Bill Dempster, 3Sixty Public Affairs

Panellists: Kristian Thorlund, McMaster University; Lisa Machado, Canadian CML Network; Cal Shephard, AstraZeneca; Farah Husein, CADTH

An avalanche of early-stage cancer clinical trials is coming. Almost none of these trials use conventional measures like overall survival (OS) or progression-free survival (PFS) to establish comparative efficacy. Instead, Industry and regulatory agencies have increasingly turned to non-traditional surrogate measurements for success with relatively short-term follow-up. This creates a disconnect between regulatory and HTA evidence standards. Consequently, it may become near impossible for HTA agencies and payers to extrapolate regulatory evidence to long-term benefits for the purposes of evaluation and funding recommendations.

Collecting supplementary data on outcomes like OS or PFS would require substantial additional time and resources for RCTs or real-world data studies, thus leading to additional delays for patients to access these treatments. The uncertain pathway for review and funding could also dissuade medicine sponsors from launching their medicines.

Hundreds of early-stage cancer trials are currently being conducted or planned. Very few of these trials will be able to meet HTA agencies' evidence standards. The solution to this problem, however, is not clear as various stakeholders may not align on priorities. Industry is pushing for faster and more approvals, HTA is pushing back and rejecting a record high number of submissions. Meanwhile, novel methods and viable alternative sources of evidence are ignored. In many cases, unfortunately so is the patient perspective. Unless these challenges are resolved soon, patients may only have limited access to these novel therapeutics in the near future.

This panel will provide a detailed overview of the magnitude of the problem and contrast the priorities of various stakeholders. These include feasibility and willingness to allocate resources to gather more evidence,

address it with appropriate methodologies, and ensure that the patient's voice is heard (15 min for each presentation).

PA12. Chronic Pain in Canada — The Trajectory of Pain as a National Health Priority

Moderator: Linda Wilhelm, Canadian Arthritis Patient Alliance

Panellists: Jean-François Leroux, Health Canada; Fiona Campbell, Sick Kids/University of Toronto; Maria Hudspith, Pain BC; Desmond Williams, Pain Canada National Advisory Committee

The Canadian Pain Task Force provided its final report, An Action Plan for Pain in Canada in March 2021. This report included more than 150 recommendations to government on priority actions, so that people with pain are recognized and supported and that pain is understood, prevented, and effectively treated across Canada. Many of the Task Force recommendations highlighted the significant connections between chronic pain and some of our most significant contemporary health care challenges, such as mental health and substance use-related issues, as well as addressing health needs of marginalized populations. It also provides opportunities to contribute to shaping the future of our health care system.

Over the years, people living with pain, health care professionals, researchers, policy-makers, and non-governmental organizations have been contributing to a movement for action on pain in Canada. This movement is gaining momentum with the establishment of the Chronic Pain Policy Team within Health Canada and the creation of Pain Canada – a national initiative dedicated to enhancing coordination and mobilizing resources for people living with pain. Through these efforts, diverse perspectives are important to deliver effective policies that will help address this complex health issue. In this session, panel members will share views and experiences in the ongoing journey to address priorities and advance actions to prevent and manage chronic pain in Canada. The session will involve members from a wide range of stakeholders reflecting different perspectives, including co-chairs and a member of the Canadian Pain Task Force, a representative from the federal government, a clinician specializing in pain management, people living with pain, as well as representatives leading a national pain initiative.

PA13. Enabling Improvement in CAR T-Cell Therapies in Canada

Moderator: Peter Dyrda, CADTH

Panellists: Alan Forster, The Ottawa Hospital; Dan Zimskind, ZS; Mike Duong, Canadian Personalized Healthcare Innovation Network; Helen Chen, University of Waterloo; Mike Kennah, The Ottawa Hospital; Huong Hew, Janssen Pharmaceutical Companies of Johnson & Johnson

In March 2022, the Canadian Personalized Health Innovation Network (CPHIN) held a real-world evidence summit to determine an optimal approach to accelerate adoption of innovative treatments. While access to data describing real world evidence was deemed critically important, summit members concluded there were more significant challenges ensuring effective collaboration amongst the multiple stakeholders involved in

approving, delivering, and paying for innovative treatments. Furthermore, without addressing trust amongst these stakeholders, it will not be possible to fully resolve conflicts of interest. The summit culminated in a recommendation to use CAR-T cell therapy as an exemplar "innovative treatment" to further explore the opportunities to enhance collaboration. During a 6-month project, CPHIN and its partners used an 'action research' approach to understand opportunities to improve quality of CAR-T cell therapy in Canada and to improve collection and use of data describing CAR-T cell therapy. This initiative engaged clinicians, scientists and leaders involved in CAR-T cell therapy from across Canada. It also analyzed data submitted to the Center for International Blood and Marrow Transplant Research. During this panel discussion, the participants will describe the results of these effort and opportunities to apply this approach to other innovative treatments.

PA14. Life Cycle Health Technology Assessment for Precision Oncology

Panellists: Deirdre Weymann, BC Cancer; Samantha Pollard, BC Cancer; Emanuel Krebs, BC Cancer; Melanie McPhail, Simon Fraser University; Yvonne Bombard, St. Michael's Hospital, University of Toronto

Canadian health systems are maladapted to translate emerging precision oncology evidence into enhanced patient care. Traditional health technology deliberative frameworks support on-off recommendations used to inform jurisdiction-based decision making, with reimbursement and post-market data capture siloed across provinces. Increased evidentiary uncertainty for precision oncology innovations challenges existing evaluative processes, prohibiting timely patient access to potentially beneficial and cost-effective care.

Evaluative frameworks that consider patient engagement alongside systematic real-world data collection, standardized causal, quasi-experimental methods for real-world evidence generation, and necessary accompanying legal and regulatory frameworks are needed to generate population benefit from precision oncology. In this panel, we present a generalized life-cycle health technology assessment (HTA) framework that prioritizes patient-centred access alongside continuous evidence generation. Panelists and our audience will critically discuss the implementation of life-cycle HTA and role of real-world evidence for regulatory and reimbursement decision-making.

There will be four presentations, each lasting 10 minutes, followed by a 35-minute discussion featuring an interactive whiteboard activity. Through use of the Mural platform, this session will allow participants to integrate perspectives and critical feedback in real-time. Presentations will centre on: 1) development of a life-cycle health technology assessment framework, 2) building institutional capacity for decision-grade real-world data collection including patient preference elicitation, 3) an exemplar life-cycle evaluation of an implemented precision oncology intervention, and 4) legal and regulatory barriers and enablers to life-cycle HTA. Together, we will identify next steps for adopting life-cycle HTA for precision oncology across Canadian health systems.

PA15. Transportability of RWD Across Borders: Opportunity to Support Decision-Making in Canada?

Moderator: David Shum, Roche Canada

Panellists: Anna Steenrod, F. Hoffmann-La Roche Ltd., Seamus Kent, Flatiron Health, UK; Ashley Jaksa, AETION; Laurie Lambert, CADTH

There is an increased focus on the use of real-world data (RWD) as adjunct or complementary evidence to randomized controlled trials, especially in situations where uncertainty exists (e.g., uncontrolled trials, small populations, surrogate outcomes) as well as throughout the life cycle of the product (i.e., HTM). HTA agencies and regulators prefer local RWD data, but due to challenges that may exist in collecting sufficient data (e.g., clinical depth, data quality, sample size, data availability), local data may not be available or sufficient to answer all regulatory or HTA-relevant questions. RWD generated in other jurisdictions is one option to overcome local or jurisdictional challenges. However, there is currently a lack of guidelines and limited standardized methodologies to facilitate the use of potentially richer RWD from one jurisdiction to inform decision-making in another. Furthermore, there is little empirical evidence on the extent to which results from different jurisdictions transport, and how this varies across diseases and use cases.

This panel will discuss the challenges and opportunities related to integrating RWE in HTA and regulatory decision-making and will address the following:

- What is the role of international or intra-jurisdictional data in local HTA decision-making over the product life cycle?
- How might this vary across diseases and use cases?
- What is the current evidence on transportability of data to other countries?
- What are the methods used to complement local data with international data?
- What are some case-study examples of transporting data to other jurisdictions?

PA16. Timely Access to Novel Therapies: Can Canada's Multi-Payer System Be Inspired by International Approaches for Managing Evidence Uncertainty Related to Value While Providing Patients With Timely Access to Life Saving Therapies?

Moderator: Allison Wills, 20Sense

Panellists: Thomas Strong, The National Institute for Health and Care Excellence (NICE); Sylvie Bouchard, L'Institut national d'excellence en santé et en services sociaux (INESSS); Martine Elias, Myeloma Canada; Carole Chambers, Alberta Health Services

Timely access to novel therapies has become increasingly challenging due to the rising number of therapies with limited – but promising – evidence, coupled with long reimbursement timelines.

To manage uncertainty related to value, many countries have applied adapted HTA and listing pathways to enable patient access to life saving therapies while developing additional evidence. Such novel HTA pathways and early market access frameworks have often been utilized in publicly funded drug plans with single-payer systems. The UK's NICE and NHS have been recognized as leaders in applying a centralized approach for conducting reimbursement, pricing, and formulary listing decisions with their Cancer Drugs Fund (CDF) in oncology, as well as with the utilization of real-world evidence (RWE) development to support early market access schemes.

At present, Canada does not have formalized processes to support early access while managing evidence uncertainty, however, there has been much investigation by Canadian stakeholders to understand the effort, benefits, and outcomes of frameworks and pathways used internationally. Importantly, as Canada has a multi-payer system, it is critical to further investigate how potential approaches to support timely access could be successfully implemented.

The panel will include perspectives from international and Canadian HTA experts, Canadian patient groups and Canadian public payer jurisdictions. The panel will discuss key factors when considering approaches for managing evidence uncertainty while providing patients with timely access to novel therapies, based on findings from recent research and their experiences. Focus will be on discussing potential solutions that could be applied in the Canadian multi-payer context.

PA17. Generation of Post-Launch Evidence to Inform the Optimization of Care for Spinal Muscular Atrophy: International HTA Experiences and Perspectives

Moderator: Karen Facey, Evidence Based Health Policy Consultant

Panellists: Carlos Martín Saborido, Servicios del SNS y Farmacia; Piia Rannanheimo, Finnish Medicines Agency Fimea; Thomas Strong, The National Institute for Health and Care Excellence (NICE); Laurie Lambert, CADTH

CADTH's strategic plan emphasizes the goals of assessing health technologies across the product life cycle, working with international partners and optimizing the use of real-world evidence. To reach these goals, CADTH has been communicating with its HTA partners about the integration of RWE in decision-making about rare disease treatments.

This international panel will discuss how different HTA agencies have organized real-world data collection post HTA for 3 spinal muscular atrophy treatments. The challenges and opportunities related to planning and generating of RWE concerning uncertainties about optimal use of therapies in the context of their specific health system. Panel members will outline the process for selection of a product for additional data collection, explain how feasibility of data collection is determined and roles and responsibilities of different stakeholders. The potential value and challenges of international HTA collaboration will be highlighted.

Panel discussion will be allotted 60 minutes leaving 15 minutes for audience questions.

This is a valuable opportunity for health system stakeholders to join a discussion about the role of international HTA collaboration and RWE to inform decision-making concerning optimal use of therapies.

PA18. Grounded in Culture: Awakening the Art of Birthing and Healthy Childrearing

Panellists: Chief Christine Longjohn, Sturgeon Lake First Nation; Shirley Bighead, Sturgeon Lake Health Centre; Norma Rabbitskin, Sturgeon Lake Health Centre

Issue, focus, or project purpose: Restoring nēhiyaw (Plains Cree) birthing processes, and good childrearing teaching and caring practices, is a critical component to restoring health and well-being within our families and communities.

How the issue was addressed/ methods: On February 23, 2022, Sturgeon Lake First Nation celebrated the land's first traditional birth assisted by Aboriginal midwives for 55 years. Decades ago, babies were born under the hands of a local midwife who was grounded with cultural practices. For many years, the Nation has been working toward reawakening birthing practices using traditional knowledge systems. The first steps were hosting dialogue processes and knowledge circles, consisting of knowledge keepers and matriarchs who shared a vital piece of life history and experience of local birthing practices and all of life knowledge. Each one held a piece of the knowledge that would be used to co-create a valuable program which reflects the nēhiyaw culture within which it is grounded.

Findings: Sturgeon Lake First Nation has a rich knowledge base of birthing practices, childrearing teachings, and support for all life stages (including the last journey home). The grandmothers recalled strong family units which were identified as the backbone of the community.

Conclusion: Awakening the traditional knowledge of birthing and healthy childrearing will give future generations safety, security, and protection in a caring and nurturing environment that is grounded in the culture.

Implications: Sturgeon Lake First Nation is committed to restoring traditional birthing practices and teachings in and with the Nation. As such, a Midwifery proposal was submitted to Indigenous Services Canada and successfully funded. In addition to this, we began to collaborate with other organization such as: the Saskatchewan Ministry of Health, Saskatchewan Health Authority, National Aboriginal Council of Midwives (NACM), and academic institutions to support the return to Indigenous birthing.

PA19. Roles and Responsibilities of Real-World Evidence and Health System Stakeholders for the Treatment of Rare Disease in Children: Challenges and Brainstorming for the Future

Moderator: Nicole Mittmann, CADTH

Panellists: Sandra Sirrs, Vancouver General Hospital, Vancouver Coastal Health; Paul Gibson, Pediatric Oncology Group of Ontario; Lynne Nakashima, BC Cancer Agency; Melissa Hunt, Health Canada

As part of a learning project on pediatric low-grade glioma, CADTH hosted a multistakeholder meeting to learn about potential measurable indicators and outcomes that different stakeholders deemed important for their decision-making needs. Through this process, several challenges and unmet needs that extended beyond the objective for the pediatric low-grade glioma project were raised.

One of these challenges was that clinicians often provide "off-label" treatments for their pediatric patients; these treatments are considered standard of care but do not have specific regulatory or HTA approval for use in children. Both public and private payors must manage requests to provide coverage for these medications. Decisions are often made on a case-by-case basis and this process is associated with burden on patients, their families, and other stakeholders. The panel will discuss these challenges from various stakeholders' perspectives and panelists will discuss potential opportunities to address them, including the integration of real-world evidence to support decision-making.

This panel discussion will allot 60 minutes for moderator and panelist discussion, leaving 15 minutes for audience questions.

This is a valuable opportunity for a variety of health system stakeholders to join the discussion on challenges associated with care of pediatric patients with rare disease and the use of real-world evidence to support decision-making.

Oral Presentation Abstracts

OP1A. Virtual Care: the Impact of the COVID-19 Pandemic on Physicians, Patients, and Mental Health Services in Canada

Presenting Author: Emma Marshall-Catlin, Canadian Institute for Health Information

To reduce the spread of COVID-19 in Canada, patients receiving physician services experienced a significant shift to virtual appointments by telephone, videoconference and online messaging as many physician visits moved from in-person to virtual delivery. Simultaneously, as public health measures reduced social contacts and interrupted normal life, the mental health of individuals who experience anxiety, depression and psychological distress was negatively impacted. While physician mental health services increased overall,

access to virtual services was not equal across the country and the population. Due to the unanticipated, widespread adoption of virtual care, there are essential gaps in understanding the impact on patients. The Canadian Institute for Health Information has published 3 analyses to investigate the impact of virtual care on physician providers, on patients receiving care, and on mental health service utilization. These analyses use patient-level physician billing data from 5 different provinces (Ontario, Manitoba, Saskatchewan, Alberta, and British Columbia) between April 2019 and March 2021. The reports provide important information on who was able to receive care, where the care was available, and the scale of this impact. Reporting is broken down by demographics, and jurisdiction. Beyond the pandemic, virtual care remains a significant mode of delivery and has important implications on the future of patient care and the relationships between patients and providers.

OP1B. Recommendations to Improve Rapid Evidence Synthesis to Support Decision-Making During the COVID-19 Pandemic: a Qualitative Descriptive Study of the Perspectives of Producers and Decision-Makers in Quebec

Presenting Author: Quan Nha Hong, Université de Montréal

Co-Authors: Esther McSween-Cadieux, Université de Sherbrooke; Julie Lane, Université de Sherbrooke; Andrée-Anne Houle, Université de Sherbrooke; François Lauzier-Jobin, Université de Sherbrooke; Éliane Saint-Pierre Mousset, Université de Sherbrooke; Ollivier Prigent, Université de Sherbrooke; Saliha Ziam, Université TÉLUQ; Christian Dagenais, Université de Montréal; Christine Maltais, CISSS Laval; Pierre Dagenais, Université de Sherbrooke; Alain Lesage, Université de Montréal; Poder Thomas, University of Montreal

Background: The COVID-19 pandemic required that evidence be made available more quickly than usual to meet the needs of decision-makers in health and social services. This study aimed to document 1) the experiences of Quebec organizations in producing rapid evidence syntheses during the pandemic, 2) decision-makers' perceptions of the usefulness of these syntheses, and 3) methodological adaptations of evidence syntheses produced by these organizations. Methods: A qualitative descriptive study was conducted in 2021. Data collection included focus groups (n=9 groups; 64 persons from 8 organizations), individual interviews with decision-makers (n=12), and document analysis of evidence synthesis reports on COVID-19 from 03/2020 to 04/2021 (n=128). Results: Several organizational, methodological, professional, and personal challenges and adaptations implemented by the teams to produce urgent evidence syntheses were identified. When made available at the right time, rapid evidence syntheses were described by decision-makers as a tool useful to inform decision-making or to support positions. Several factors influencing their usefulness and use according to the decision-makers were mentioned. The document analysis also highlights certain methodological trends in the synthesis approaches. A total of 25 recommendations to improve the knowledge synthesis process within and between organizations are suggested. Conclusions: This study highlighted several important issues to produce knowledge syntheses in an emergency context, as well as their role and usefulness in the decision-making process during the pandemic. The recommendations will need to be refined and prioritized in a subsequent research project.

OP1C. Post–COVID-19 Condition Treatment and Management Rapid Living Scoping Review with Patient Consultation

Presenting Author: Gino De Angelis, CADTH

Co-Authors: Yi-Sheng Chao, CADTH; Thyna Vu, CADTH; Sarah McGill, CADTH; Michelle Gates, CADTH; Angie Hamson; CADTH

In 2022, Statistics Canada estimated more than 32% Canadian adults had lab-confirmed COVID-19 infection and 14.8% experienced symptoms 3 months after their initial infection. CADTH previously conducted a scoping review of post–COVID-19 condition, where authors screened 3,535 references and included 892. To keep pace with the evolving evidence base, CADTH initiated a living scoping review with patient consultation to understand current evidence on the treatment and management of post–COVID-19 condition and better assess additional research requirements to support health care decision-making needs in Canada. Studies that included people of all ages with post–COVID-19 condition, and pharmacological, non-pharmacological interventions and care models in all settings were eligible. Researchers screened 1,131 references from the searched databases and included 113 references. Notable evidence gaps included treatments for children and adolescents, and for those without symptoms during initial infection, and large trials. Most identified guidelines, including all Canadian guidelines, provided limited guidance specific to patients with symptoms at least 3 months after initial infection. The findings also suggested a mismatch between commonly reported symptoms and the indications often studied in the literature. We consulted patients to better understand their perspectives, priorities and lived experiences with post–COVID-19 condition treatment and their views and comments were incorporated into the scoping review. With plans to update the findings every 3 months using an online dashboard, CADTH will continue monitoring the evidence gaps and assess the opportunities for health technology assessments that are fundamental to policy-making, while also helping to reduce redundancy and research waste.

OP1D. Adjusting Criteria for COVID-19 Therapies with Emerging Evidence

Presenting Author: Jeremy Slobodan, Alberta Health Services

The Alberta Health Services COVID-19 Therapeutics Working Group is responsible for establishing and refining the access criteria for COVID-19 treatments based on the current evidence and availability of supply. Since the last half of 2022, supply issues were less of a concern. When discussing potential amendments to eligibility criteria, the Working Group considered many sources of emerging evidence to help ensure the criteria best met the needs of Albertans. This presentation will focus on the impact that different types of evidence had on adjusting criteria and provide recommendations as to how real-world evidence can be used to best inform decision-making.

OP1E. Rapid Evidence Response to COVID-19 in Saskatchewan: Lessons Learned for a Learning Health System

Presenting Author: Andreea Thiessen, University of Saskatchewan

Co-Authors: Gary Groot, University of Saskatchewan; Susan Baer, Saskatchewan Health Authority; Bruce Reeder, University of Saskatchewan; Michelle Dalidowicz, Saskatchewan Health Authority

The COVID-19 pandemic highlighted a significant gap in the knowledge to practice cycle in the health care system. In Saskatchewan, the COVID Evidence Support Team (CEST), composed of clinical experts, academic researchers, clinical librarians and health system policy makers was created to fill this gap and to provide rapid evidence support to the Emergency Operations Committee and later, the Public Health Incident Command Center. Between March 2020 and June 2022, the CEST completed 128 rapid reviews, including 2 'evergreen' reviews updated at regular intervals and 13 with one or more updates. The reviews were intended to translate rapidly emerging scientific evidence into easily actionable summaries. The reviews covered a wide range, from general topics such as the efficacy of public masking and the safety and efficacy of emerging vaccines, to specific questions for policy or decision making such as OR settle times and the use of back/neck coverings during AGMP procedures. To measure the impact of this initiative, a formative evaluation using qualitative interviews with key informants was conducted. Findings showed that the initiative improved speed and access to reliable information, supported and influenced decision-making and public health strategies, leveraged partnerships, increased confidence and reassurance, and challenged misinformation. Improved coordination and awareness were identified as important themes for the sustainable integration of rapid evidence initiatives into health systems. The CEST initiative demonstrated the need and utility of a Learning Health System approach to health care decision making, while the addition of an evaluation component provided additional insight and recommendations for improvement.

OP2A. Integrating Equity Considerations in HTA: a Pilot Approach Using Peer Support for Youth Mental Health

Presenting Authors: Andrea Smith, CADTH; Francesca Brundisini, CADTH

Co-Authors: Julie Boucher, CADTH; Shannon Hill, CADTH

CADTH's 2022-25 Strategic Plan highlights the importance of incorporating equity considerations within our work. We piloted an approach aimed at incorporating equity considerations in a Health Technology Assessment (HTA) on peer support programs for youth mental health. This tailored HTA included engagement with youth advisors with lived experience of peer support, a systematic review of the clinical effectiveness and safety, and a scan of evaluation methods for peer support programs. We selected the Equity Checklist for HTA (ECHTA), a published and applied tool, using its prompts to iteratively guide our approach. In this presentation, we describe how we incorporated equity at each phase of the HTA, from scoping through to dissemination. We explain how we considered the prompts provided by the ECHTA in the

development and conduct of each component of the HTA. We describe the central role of youth engagement within peer support development, and how we focused on incorporating the diverse perspectives of youth with lived experience from key populations throughout the project to inform the HTA approach, findings, and discussion. Equity considerations were imbedded in our key findings, with the intention that equity-contextualized findings would increase the value and relevance for decision-makers involved in peer support programming. The purpose of this presentation is to share our experiences of incorporating equity into an HTA, reflecting on the challenges and strengths of our pilot approach.

OP2B. Oppression Framework Informed Equity Cost-Effectiveness Analysis of Diabetic Retinopathy Screening

Presenting Author: Aleksandra Stanimirovic, THETA Collaborative

Co-Authors: Troy Francis, Program for Health System & Technology Evaluation; Sonia Meerai, Program for Health System & Technology Evaluation; James M. Bowen, Program for Health System & Technology Evaluation; Valeria Rac, Program for Health System & Technology Evaluation

Background: Diabetic retinopathy remains primary vision complication of diabetes and leading cause of blindness among adults, with up to 30% prevalence among low-income population. Tele-retina is cost-effective screening alternative to vision loss prevention, yet there is adverse association between screening and income. Intersectionality theory notes barriers to achieving health equity result from intersection of personal social characteristics (i.e., race and income). Experiences at intersections are influenced by interpersonal and structural systems of oppression (i.e., racism). Cost-effectiveness analysis should consider social inferences of technologies on patient health and health care system. Objective: Studies found that Tele-retina is the dominant strategy to standard of care screening for at risk populations. No study has assessed economic equity impact of DR screening using theoretical foundation. To address these shortcomings, we propose oppression framework informed equity CEA of DR screening program.

Method: Deductive theoretical drive sequential multimethod approach, consisting of 1) modified-DELPHi 2) case study of oppression framework informed equity CEA. Through Delphi (Panel (N = 35 to 50) - Patient Partners, Field experts, Decision-makers) we will select the social constructs to, alongside intersectionality theory, guide modification of equity informed CEA to understand impact of social constructs on economic outcomes. Social constructs will be integrated into validated Tele-retina CEA model.

Impact: This is first study to: 1) mainstream how health equity framework and social constructs are utilized in economic assessment, 2) improve Tele-retina screening programs by using health equity lens, and 3) scale and adopt “de-novo” integration of social constructs in economic models for evaluation of other programs.

OP2C. Striving for Accessible Health Care: Developing Evidence and Policy Recommendations Rooted in the Experiences of the Disability Community

Presenting Authors: Laurie Proulx, Canadian Arthritis Patient Alliance; Lesley Tarasoff, University of Toronto; Kate Welsh, University of Toronto

The accessibility of perinatal health care services for people with disabilities is an important topic that has received little attention, despite increasing pregnancy rates and elevated risks of pregnancy complications among people with disabilities. Aligned with CADTH's strategic plan that emphasizes equity and patient experience perspectives in the creation of evidence, this presentation will highlight the need to include the perspectives and experiences of people with disabilities in research. We will draw on our experiences working on a large Ontario-based study on the pregnancy-related health of people with physical, sensory, intellectual and/or developmental disabilities. This study used both health records data and interviews with people with disabilities who had recently given birth and service providers. Our team used an integrated knowledge translation approach, including hiring peer researchers with disabilities to conduct interviews, support study recruitment, analyze findings, and develop policy briefs for health and social service providers. An advisory committee was established that included representation from many parts of the disability community, such as Deaf and hard of hearing individuals, people with blindness and vision loss, spinal cord injuries, autism, and fetal alcohol spectrum disorder. We will describe the inclusive approach to research, from the co-production of evidence to the dissemination of findings to various stakeholders, and how this approach has shaped ongoing research about the reproductive health experiences of women and transgender people with disabilities during the COVID-19 pandemic. The presentation will highlight the equity-focused, multi-stakeholder collaboration.

OP3A. Planning for Sustainable and Secure Supply Chains: the Case of Iodinated Contrast Media

Presenting Author: Andra Morrison, CADTH

Background: With recent disruptions in supply chains, and in the context of global shortages of iodinated contrast media, CADTH's Canadian Medical Imaging Inventory program investigated measures to help plan for sustainability and secure medical imaging equipment supplies. Iodinated contrast media is used mostly in CT imaging and was used as an example to highlight ways in which procurers can help to mitigate supply chain disruptions.

Objective: Our objective was to identify practices that can be used by procurement specialists to help optimize the clinical supply chain, build health system resilience, and mitigate vulnerabilities that could compromise quality supplies and ultimately patient outcomes. Methods Literature was searched via PubMed and grey literature sources to identify relevant practices aimed at mitigating supply chain shortages in medical devices used in the delivery of patient care.

Results: Just-in-time inventory management, preferred-vendor contracting, and decentralized supply chain management are widely adopted procurement strategies. Procurement processes may benefit from considering strategies focused on stockpiling critical medical supplies, diversifying vendor suppliers, and centralizing supply chains to provide data on utilization and inventories across jurisdictions. Creating more transparency around the supply chain process and where manufacturers source materials may help procurement specialists to better understand risk.

Conclusions: It is important that health systems are equipped to handle challenges that come with disruptions to critical medical supplies. With further supply chain disruptions anticipated, strategies to modernize procurement practices may support resiliency and better patient outcomes.

OP3B. PDCI's Biopharmaceutical Ecosystem Index: Where Does Canada Rank on its Attractiveness for New Medicine Launch?

Presenting Author: Courtney Abunassar, PDCI Market Access

Background: Recent literature shows Canada receiving fewer or delayed new medicine launches in recent years versus comparator countries.

Objective: The objective of PDCI's Biopharmaceutical Ecosystem Index is to rank 14 countries on their relative attractiveness for new medicines launch.

Methods: Recognizing that global pharmaceutical manufacturers' decisions on whether and when to launch a new medicine in a country are complex and multifactorial, Index authors convened an independent Editorial Advisory Board, composed of biopharmaceutical experts and experts on pharmaceutical policy and patient access issues to identify and weight indicators and measurements that commonly influence a global biopharmaceutical decisions-maker's perspective of a country's launch attractiveness. Following an extensive literature review on each measurement, authors scored each country on 8 indicators under 3 technical areas: Development and Commercialization Infrastructure, Regulatory Landscape and Access Environment. Authors then weighted the scores on each indicator to produce a composite attractiveness score for each country.

Results: Canada ranks 10th out of 14 countries on its attractiveness for new medicine launch, putting it ahead of Italy, Norway, Belgium, and Spain which ranked 11th and 14th, respectively. Canada trailed the other countries in the analysis which were (in order of overall attractiveness ranking, from first to ninth): the United States, Germany, United Kingdom, Japan, France, Australia, Sweden, Switzerland and Netherlands.

Conclusion: This study was conducted to better understand the potential underlying reasons for fewer/delayed Canadian launches of new medicines in recent years. The goal is to help Canadian policy-makers and biopharmaceutical leaders engage in constructive dialogue toward creating the best health system for Canadian patients in the future. The presenter will include perspectives from policy-makers, industry, and patient groups.

OP3C. The Feasibility and Clinical Value of Hospital Capacity Command Centres to Manage Patient Flow and Bed Capacity: a Scoping Review

Presenting Author: Eva Suarthana, Health Technology Assessment Unit of the McGill University Health Centre

Co-Author: Nisha Almeida, Health Technology Assessment Unit of the McGill University Health Centre

Hospital overcrowding, a longstanding challenge for our health care system, has recently reached a breaking point in hospitals nationwide. A leading cause of overcrowding is patients in alternate levels of care (ALC). Recently, hospital capacity command centres (CCC) have been proposed as a more efficient way to manage patient flow and bed capacity. CCCs co-locate interdisciplinary workgroups with access to real-time data, which may also be used for predictive analytics. We conducted a scoping review to evaluate the feasibility and clinical value of establishing a capacity command centre. We identified 12 hospital CCCs in the US and 2 in Canada. Bed management was the key element. Some reported a decline in ED boarding time, while others reported improvement in other indicators such as length of stay, transfer volume and time, ambulance and ED diversion, and organizational performance. However, all studies were limited by their pre-post design, and lack of standardized indicators to evaluate performance. Experiential data gathered from 4 CCCs in Canada and the US indicate that CCCs impact the health care system by improving connectedness; on health care professionals by improving communication and workflow; on hospital administrators by increasing efficiency and accountability; and on patients by expediting care delivery. In conclusion, CCCs are a fairly new development and high-quality evidence is not available to evaluate their clinical impact. Experiential evidence suggests they have the ability to improve hospital efficiency in the short-term. In-depth understanding of the local context and culture and strong commitment from all stakeholders are essential for long-term success.

OP4A. Development of a Multi-Criteria Decision Analysis (MCDA) Rating Tool to Prioritize Real-World Evidence Questions Arising from Cancer Drug Funding Decisions

Presenting Author: Pam Takhar, Ontario Health

Co-Authors: Francois Dionne, Prioritize Software; CanREValue Core Team, CanREValue Collaboration; Planning and Drug Selection Working Group, CanREValue Collaboration

The Canadian Real-world Evidence for Value of Cancer Drugs (CanREValue) collaboration is a pan-Canadian initiative aimed at developing a framework for the generation and use of real-world evidence (RWE) to support cancer drug funding decisions. As part of this work, CanREValue developed a MCDA rating tool to help decision-makers evaluate uncertainties and prioritize potential RWE projects stemming from initial drug funding decisions.

The rating tool was developed following a 3-step process: 1) selection of criteria assessing importance and feasibility of an RWE question, 2) development of rating scales and weights for each criterion, and

3) validation testing of the rating tool. Each step was carried out in collaboration with a group of multi-disciplinary stakeholders from across Canada.

An initial MCDA rating tool composed of 7 criteria, divided into 2 groups was developed. Group one criteria assess the importance of an RWE question by examining the: 1) therapy's perceived clinical benefit, 2) magnitude of uncertainty identified, and 3) relevance of the uncertainty to decision-makers. Group 2 criteria assess the feasibility of conducting an RWE analysis including: 1) feasibility of identifying a comparator, 2) ability to identify cases, 3) availability of comprehensive data, and 4) availability of necessary expertise and methodology.

The successful development of the MCDA rating tool led to a 1-year validation exercise in collaboration with the Provincial Advisory Group of pCODR at CADTH. This exercise will evaluate the usability of the tool and provide insights on how the tool could be formally incorporated into Canadian cancer drug evaluation and funding processes.

OP4B. A Systematic Approach to the Creation of Real-World Evidence Development Plan for Novel Therapies

Presenting Author: Jeff Round, Institute of Health Economics

Co-Authors: Joana Gomes da Costa, Institute of Health Economics; Christopher McCabe, Queen's University Belfast

Regulators across the globe are working toward the integration of Real-World Evidence (RWE) within regulatory and reimbursement decision-making processes. Working through the Health Technology Innovation Platform (HTIP), we have developed a comprehensive manual to provide guidance on the creation of evidence generation plans for promising new therapies. HTIP is a collaboration between the Institute of Health Economic, industry partners and public sector bodies including Health Canada and CADTH to advance tools for the development and assessment of new therapies. Our manual provides an anchoring framework, with detailed steps and guidance, for the development of a prospective, integrated RWE development program that will produce RWE of sufficient rigour and validity to meet the needs of the different decision-makers along the technology life cycle. Through the manual we provide a structured approach to the identification of evidence gaps relating to a therapy using systematic review and evidence map generation approaches. These can then be assessed against the stated needs of regulators as well as compared with public information about prior decisions on related products. Second, we outline methods for using early economic evaluation and value of information analysis to identify the value associated with reducing uncertainty in the evidence base. Results of these analyses can then be used to support clinical and RWE study designs through identification of efficient research designs that specify priority areas of evidence generation. Use of the manual will support the development of robust RWE that meets the needs of decision-makers across the product life cycle.

OP4C. What Can RWE Learn from Qualitative Inquiry in the Search for Trustworthiness?

Presenting Author: Tara Schuller, Institute of Health Economics

The field of qualitative inquiry has long wrangled with the problem of being low on the evidence hierarchy, and how this impedes the trustworthiness of qualitative evidence for use in decision-making. Real-world evidence (RWE) is being critiqued for a similar reason, where, due to evidence being at rungs of the evidence hierarchy below randomized controlled trials, the trustworthiness of the findings is being interrogated before it is used in health technology assessment and reimbursement decision-making. This session will present some of the ways that the field of qualitative inquiry has addressed this challenge through developing techniques to bolster the rigour, reliability, and representativeness of findings. Thick description, methodological coherence, sampling strategies, prolonged engagement, negative case analysis, debriefing, member checking, triangulation, are some of the techniques the qualitative field has developed to overcome bias and strengthen the validity of findings. This session will present selected approaches taken in the field of qualitative inquiry that might inspire new ways of thinking about RWE for use in decision-making.

OP5A. Health Technology and Assessments and Artificial Intelligence — The Future Is Here

Presenting Authors: Selva Bayat, British Columbia Ministry of Health; Manik Saini, British Columbia Ministry of Health

Co-Authors: Fiona Clement, University of Calgary; Nkiruka Eze, University of Calgary

Health Technology Assessments (HTAs), especially for medical devices, are requiring rapid expansion and specialization due to technological advancements, and leading the charge is the expeditious field of Artificial Intelligence (AI). Incorporation of AI in medical technologies are creating exciting opportunities for major advancements in the field of medicine and public health care – by offering the possibility of an enticing combination of increased efficiency, clinical accuracy, and a robust and long-term solution to decreasing the ever-growing workload of our health care providers in an even more ever-expanding health care system.

However, the incorporation of AI in medical technologies has another side to the coin; substantial considerations for continued clinical accuracy and machine learning, bioethical concerns such a detection of biases and information storage and sharing, and of course, shifts in care pathways and operational logistics of service delivery – all of which become more acute given the accelerated timeline of AI introduction in health care.

HTA organizations stand on the precipice of this evolving field. HTAs must embrace innovation and advancements to bring forth emerging technologies that have potential to enhance health care services; however, they are also uniquely positioned in their duty to clearly underline implementation considerations that may inadvertently bring harm or reduce the quality of care. Given this, BC's Health Technology

Assessment Office has recently initiated an HTA on a medical device incorporating AI, and as such, is working to operationalize the various pieces of guidance that exist for the assessment of AI technologies.

OP5B. Model for ASsessing the Value of AI (MAS-AI)

Presenting Authors: Iben Fasterholdt, Odense University Hospital; Valeria Rac, Program for Health System & Technology Evaluation

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Objectives: Artificial intelligence (AI) is seen as a major disrupting force in the future health care system. However, the assessment of the value of AI technologies is still unclear. Therefore, a multidisciplinary group of experts and patients developed a Model for ASsessing the value of AI (MAS-AI) in medical imaging. Medical imaging is chosen due to the maturity of AI in this area, ensuring a robust evidence-based model.

Methods: MAS-AI was developed in 3 phases. First, a literature review of existing guides, evaluations, and assessments of the value of AI in the field of medical imaging. Next, we interviewed leading researchers in AI in Denmark. The third phase consisted of 2 workshops where decision-makers, patient organizations, and researchers discussed crucial topics for evaluating AI. The multidisciplinary team revised the model between workshops according to comments.

Results: The MAS-AI guideline consists of 2 steps covering 9 domains and 5 process factors supporting the assessment. Step 1 contains a description of patients, how the AI model was developed, and initial ethical and legal considerations. In step 2, a multidisciplinary assessment of outcomes of the AI application is done for the 5 remaining domains: safety, clinical aspects, economics, organizational aspects, and patient aspects.

Conclusions: We have developed an health technology assessment-based framework to support the introduction of AI technologies into health care in medical imaging. It is essential to ensure informed and valid decisions regarding the adoption of AI with a structured process and tool. MAS-AI can help support decision-making and provide greater transparency for all parties.

OP5C. Health Technology Assessment and Learning Health Systems: What Is the Role of HTA Units?

Presenting Author: Nisha Almeida, Health Technology Assessment Unit of the McGill University Health Centre

There is growing interest in establishing learning health systems (LHS) within our health centres, connecting evidence, practice, and measurement. Central to a LHS is access to high-quality and reliable data that would enable the smooth transition between these elements. Hospitals are exploring various facets underlying a LHS, such as digital transformation and appropriateness in health care, but there is still a lack of clarity on these concepts and how to apply them. We explored the role of health technology assessment (HTA) units in bridging the gaps between the elements of a LHS, particularly in going from evidence to practice. HTA units play an important role in evidence-based decision-making for the adoption of new technologies, but their role in evaluating existing practice (also known as health technology management) is less established. Using our experience in evaluating a low-value practice at our hospital, we defined barriers and facilitators to HTA's role in moving from evidence to practice. In exploring the reasons for non-beneficial treatment at end-of-life in cancer patients, we found that the expertise within HTA units lends itself well to defining the scientific problem, designing evidence-based solutions, planning pilot studies, and measuring impact. A major challenge is access to complete and reliable data to understand current practice and track the impact of new measures. Most importantly, a culture that promotes data-driven decision-making across all hospital stakeholders is imperative to counter resistance to change. In conclusion, the mission of health technology assessment is intricately linked with that of a learning health system, but 2 elements are essential for success: availability of a digital infrastructure, and a culture that promotes evidence-based decision-making.

OP5D. The State-of-the-Art of Artificial Intelligence Applied in Health Technology Assessment Processes: a Scoping Review

Presenting Author: Denis Satoshi Komoda, Department of Collective Health of the University of Campinas

Co-Authors: Marilia Cardoso, Hospital das Clínicas da Faculdade de Medicina de Botucatu; Rosana Evangelista, Library of the Faculty of Medical Sciences of the University of Campinas; Carlos Roberto Silveira Correa, Faculty of Medicine of the University of Campinas

Introduction: In the last few years AI has been increasingly applied in HTA processes. The hope is finding models which could aid decision-makers and researchers to speed up HTA. Objective: The objective of this scoping review is to present the state-of-the-art AI applied in HTA processes, advantages and limitations of current automation or semi-automation models in HTA processes.

Methods: A search strategy containing core expressions AI and HTA and equivalent terms was run in 9 specialized databases in February 2022. Inclusion criteria were publications dealing with AI models applied

in HTA. No filters were applied. Data on publication, models' technical aspects, HTA phase and performance measures were extracted. Analyses include descriptive metrics on publications, AI models' technicalities, HTA phase, performance, as well as qualitative descriptions regarding current applicability and trust in models.

Results: As preliminary and partial results, 86 publications out of 4,053 were selected. Sixty-two focused on measuring performance, 18 commentaries and other critical appraisals, 3 model descriptions, 2 systematic review (SR) protocols, one SR. Regarding HTA process, 2 publications approached HTA in general, 69 dealt with specific phases of SR, 14 with SR in general, one with horizon scanning. No articles dealing with HTA decision-making process were found.

Conclusion: Although recent developments in AI applied to HTA shows increasing possibilities of human-machine symbiosis, mainly in SR phases, many areas need further development, such as horizon scanning and policy-making processes. Although potential gains in productivity are expected, discussions on standards are utmost necessary.

OP6A. A Vision for Quality Mental Health Care for All

Presenting Authors: Jonathan Mitchell, HealthCareCAN; Emily Follwell, HealthCareCAN

Co-Authors: Samuel Breau, Mental Health Commission of Canada; Kam Tello, Mental Health Commission of Canada

COVID-19 has intensified the pressures on many people. Before the pandemic, about 2% of people in Canada reported moderately severe or severe symptoms of depression. Since, that number has skyrocketed to 14%. Even before COVID-19, health care workers experienced stress, depression, anxiety, burnout, and risk of suicide. A recent review revealed that 1 in 4 health care workers reported depression and anxiety, and 1 in 3 experienced mood and sleep disturbances since COVID-19. Anyone with a need should have access to quality mental health care no matter where they live or what circumstances they are in. So how can we improve the quality of care that is delivered?

Join us for a presentation by the Quality Mental Health Care Network (QMHCN) co-chairs on a new vision for quality mental health care, based on the Quality Mental Health Care Framework (Framework). The vision for quality mental health care builds on the expertise and was developed through structured interviews with people with lived and living experience, health care administrators, policy-makers, practitioners and decision-makers in each province and territory across Canada. The Framework was developed by the QMHCN, the Mental Health Commission of Canada (MHCC), and HealthCareCAN, a partnership that brings together mental health sector leaders from across Canada to improve access to quality mental health care. Health care leaders and organizations can use this tool to advance an equitable approach to providing mental health care for all. Resources and implementation supports have been developed and will be shared as part of this presentation.

OP6B. Analytic Infrastructure for Future-Ready Mental Health Systems: An Evaluation Platform for Major Depression

Presenting Author: Stirling Bryan, School of Population and Public Health, University of British Columbia

Co-authors: Shahzad Ghanbarian, University of British Columbia; Gavin Wong, University of British Columbia; Louisa Edwards, University of British Columbia; Mary Bunka, University of British Columbia; Sonya Cressman, University of British Columbia; Tania Conte, University of British Columbia; Morgan Price, University of British Columbia; Linda Riches, Patient Partner; Ginny Landry, Patient Partner; Jehannine Austin, University of British Columbia

Major depressive disorder (MDD) is a commonly occurring, frequently recurrent condition, and a large driver of health care costs. People with MDD often receive pharmacological treatment and/or psychotherapy, but multiple treatment challenges remain. There is an acute need for more effective interventions to improve patients' remission and quality of life, and to reduce the economic burden of the condition on the health care system. With an already complex and multifaceted care pathway for depression, future evaluations of new treatment options require a flexible analytic infrastructure that encompasses the entire care pathway. We, therefore, designed and developed a microsimulation Markov model in close collaboration with patient partners and clinical experts to provide this analytic infrastructure for application in Canada. The main features we prioritized were reusability and adaptability. Beginning with a cost-effectiveness analysis of a stepped-care pathway with pharmacotherapy and psychotherapy interventions (used alone or in combination), the model was further developed for the evaluation of activity-based programs. Our current project explores the value of pharmacogenomic testing as part of depression care. We re-designed the structure into a modular approach to enhance the flexibility to incorporate constantly evolving care pathways for depression. Recognizing a large gap in most existing MDD simulation models, we expanded our model to include the individual profile of all available antidepressants in Canada. The simulation model of major depression (SiMMDep) can now explore other interventions in other jurisdictions and serves as a platform to improve the quality, efficiency, and equity of care delivery for depression in Canada.

OP6C. Screening and Treatment (Paroxetine Versus Cognitive Behavioural Therapy) of Posttraumatic Stress Disorder in Canadian Wildfire Evacuees: a Cost-Utility Analysis

Presenting Author: Syed Ahmed Hassan, University of Toronto

Co-Author: Michael Lebenbaum, University of Wisconsin – Madison

Introduction: Individuals exposed to wildfires experience a high burden of post-traumatic stress disorder (PTSD) and the cost-effectiveness of the treatment options to address PTSD from wildfires has not been studied.

Objective: To conduct a cost-utility analysis comparing screening in combination with paroxetine or cognitive behavioural therapy (CBT) versus no screening in Canadian adult wildfire evacuees.

Methods: Using a Markov model, quality adjusted life years (QALY) and costs were evaluated over a 5-year-time horizon. All costs and utilities in the model were discounted at 1.5%. Deterministic and probabilistic sensitivity analyses were performed to elucidate the uncertainty in the incremental cost-effectiveness ratio (ICER) and incremental net monetary benefit (INMB) at willingness-to-pay threshold (λ) of $50,000.

Results: No screening was dominated by Paroxetine arm (incremental cost: $-189.87, incremental effect: 0.021) while screening and CBT was cost-effective compared to no screening (incremental cost: $1945.27, incremental effect: 0.051, ICER: $36,703) but not screening and Paroxetine (incremental cost: $2,135.14, incremental effect: 0.032, ICER: $66,723). In probabilistic sensitivity analyses, Paroxetine arm is cost-effective in 77% of the iterations, while CBT 55%, relative to no screening. The total number of stages, utility of remitted PTSD and utility of PTSD had the largest impact on the INMB comparing Paroxetine to no screening arm.

Discussion: Screening with Paroxetine was found to be cost saving while providing additional QALYs in wildfire evacuees. CBT was only cost-effective relative to no screening. Screening programs targeted at wildfire evacuees should be considered in regions at high risk of wildfires.

OP7A. Innovative Payment Models — Are We Ready?

Presenting Author: Ilona Torontali, F. Hoffmann-La Roche Ltd

In the coming years, there will be an increasing number of advanced therapy medicinal products (ATMPs) developed and subsequently launched in Canada. These ATMPs, often referred to as cell and gene-based therapies, will be used in targeted therapeutic areas, such as rare disease and precision oncology. The evidence base for these products is typically associated with a higher level of uncertainty in either the clinical performance and/or the cost-effectiveness of the product. Innovative agreements could be one potential solution in providing timely access to therapies with uncertainty, while mitigating the risk to payers.

This presentation will outline the results of research conducted into the readiness of countries around the world in their ability to adopt innovative payment models. The research was conducted in 13 countries and interviews with stakeholders were used to validate the research. Innovative payment models were subtyped into 7 different categories (e.g., from outcomes based agreements to pay-for-performance models), and the countries were clustered around the 'readiness' for each of the subtypes. The results of the study describe the countries that have the highest level of readiness to adopt the different innovative payment models, how Canada compares to other countries, and the conditions and best practices from each jurisdiction.

The presentation will discuss the system readiness at a global level, bring in examples in other countries, and then take a deeper dive into the Canadian system to identify potential steps needed for system readiness.

OP7B. Accelerating Access to Promising New Paediatric Medicines in Canada: Comparing International Approaches to Regulation and Reimbursement

Presenting Author: Celine Cressman, SickKids Research Institute

Co-Author: Avram Denburg, The Hospital for Sick Children

Background: Existing policies on drug regulation, HTA methods, and funding mechanisms in most health systems rarely account for the unique needs of children, resulting in significant access constraints. The relevance of innovative, precision therapeutics is rapidly expanding, as are rising costs of the same, exacerbating pre-existing challenges. Our study sought to understand the policy and regulatory challenges related to the evaluation and reimbursement of innovative therapies for children.

Methods: Using in-depth interviews with experts and comparative analysis of policy documents, we identified the policy, legislative and regulatory environments across select Canadian and international jurisdictions. Focusing on rare disease and paediatric oncology further illuminates how policy mechanisms impact access. Drawing on HTA scholarship and policy theory, a critical interpretive approach guided analysis.

Results: Health systems globally are grappling with challenges presented by precision technologies and paediatric therapies. Policies that address the unique socio-biological, economic, and ethical considerations inherent in precision child health are lacking. We describe distinct approaches to a similar set of challenges and identify how policy contexts (governance structures, processes, stakeholders, values) impact access. We highlight differences in policy priorities and attention, in the included sets of values and stakeholder voices, and in the HTA and regulatory pathways created for the needs of paediatrics and promising technologies.

Conclusions: This work illuminates a shared set of challenges ripe for collaborative efforts at policy reform. We hope to provide provincial/territorial and federal policy-makers with evidence-informed considerations for the design and implementation of policies to govern fair and sustainable access to innovative therapies for children.

OP7C. Assessment of Companion Diagnostic Tests Synchronized With the Evaluation of Drugs for Listing Purposes: An Innovative Concept Developed by the Institut National D'Excellence en Santé et en Services Sociaux (INESSS)

Presenting Author: Anne Dubé, Institut national d'excellence en santé et en services sociaux (INESSS)

Co-Author: Éric Potvin, Institut national d'excellence en santé et en services sociaux (INESSS)

Background: The rise of personalized medicine calls for the use of companion diagnostic test (CDx) inseparable from the drug. INESSS defines CDx as a test enabling the selection of patients based on

the status of a predictive marker for whom treatment is likely to bring benefit, to avoid adverse events (pharmacogenomic test) or to allow therapeutic monitoring.

Methods: In 2018, to deal with these emerging issues, INESSS developed and implemented a process to ensure that the CDx of drugs whose therapeutic value is recognized upon completion of the evaluation of drugs for listing purposes process can be available in a timely manner. To do that, INESSS documents the scientific and economics evidence considering the clinical context, result targeted, favoured technology, current laboratory service offer, and organizational requirements. Then, recommendations according to the CDx implementation are issued in line with the recognition of the drug's therapeutic value. Authorities responsible for adapting laboratory services can take the necessary steps to ensure the availability of said test upon listing of the drug.

Results: To date, more than 60 CDx have been assessed. Evaluations of new CDx associated with a listed innovative drug are now published since June 2021.

Conclusions: With this accomplishment, INESSS has become one of the first health technology assessment (HTA) agency to assess CDx leading to recommendations in a process synchronized with drug assessment for reimbursement purposes.

OP7D. Canadian Health Technology Assessment and Reimbursement Outcomes for Oncology Drugs with Regulatory Review Through Project Orbis

Presenting Author: Jaclyn Beca, MORSE Consulting Inc.

Co-Authors: Katherine Scott, MORSE Consulting Inc.; Stephanie Gosselin, MORSE Consulting Inc.; Jamie Thon, MORSE Consulting Inc.; Prab Ajrawat, MORSE Consulting Inc.; Sang Mi Lee, MORSE Consulting Inc.

Background: Project Orbis is an international collaboration led by the US FDA Oncology Center of Excellence that facilitates concurrent submission and review of oncology products among multiple international regulatory agencies. The initiative aims to give patients faster access to promising cancer treatments; however, expedited regulatory timelines may also lead to potential challenges for HTA, particularly due to limited evidence for the assessment of clinical benefit and value. We evaluated the market access impact for Project Orbis oncology products based on the first 3 years of the program.

Approach: We collected HTA and public reimbursement outcomes and timelines for Project Orbis drugs reviewed in Canada from the program's inception in 2019 to the end of 2022 (n = 30). From CADTH recommendations, we identified and categorized factors that might affect HTA or payer decision-making and value discussions, such as the type/level of evidence assessed and the disease context. We determined proportions of recommended and funded therapies, assessed trends between factors and HTA and reimbursement outcomes, and examined timelines relative to non-Project Orbis oncology drugs, using publicly available information in Canadian jurisdictions.

Findings and implications: We present the impact of Project Orbis on time to patient access in Canada with comparisons with other oncology products, along with trends in factors relevant to HTA review on HTA recommendations and public payer decision-making. These findings provide learnings on the benefits and challenges experienced when making reimbursement decisions for promising therapies that have expedited regulatory approval with high levels of uncertainties.

OP8A. Exploring Opportunities to Implement a Disease Management Approach to HTA in Canada: Findings From a Qualitative Study

Presenting Author: Marina Richardson, University of Toronto

Co-Authors: Fiona Miller, University of Toronto; Nick Daneman, Sunnybrook Health Sciences Centre; Chloe Mighton, St. Michael's Hospital; Beate Sander, University Health Network

Objective: Our objective was to explore opportunities to implement a disease management approach to health technology assessment (HTA) in Canada.

Methods: We conducted 18 semi-structured interviews between April 2022 and October 2022 to elicit informant views on the conceptualization, value, and implementation of a disease management approach to HTA in Canada. Participants were purposefully sampled from national and provincial HTA agencies and related organizations to achieve representation across the disease-pathway and decision-making pathway. Data were analyzed using thematic organizations (based on the interview guide), manual line by line coding of the data, and iterative inductive and deductive identification of key themes and subthemes. Ethics approval was received from the Health Sciences Research Ethics Board at the University of Toronto.

Results: Three key features of a disease management approach to HTA (disease-based, multi-interventional, and dynamic) emerged from informants. A disease management approach was valued as having the potential to break down system silos and support effective and efficient decision-making throughout a technology's life cycle. Potential barriers to implementation included capacity concerns (e.g., expertise, financial, comfort with uncertainty), data and analytic considerations (e.g., data availability, complexity, limited experience with non-drug assessments), system constraints (e.g., inflexible budgets, organizational mandates), and political considerations (e.g., risk aversion, change management, provincial-federal dynamics). Facilitators included clear and thoughtful communication, timeliness, relevance, strong leadership, and an approach that builds on the strengths of the system.

Conclusions: HTA has a strong foundation in Canada. A disease management approach may enhance the impact of HTA by anticipating needs, supporting dynamic decision-making, and informing system sustainability.

OP8B. An Inventory of Policy Levers for Influencing Appropriate Care

Presenting Author: Lindsey Warkentin, Institute of Health Economics

Co-Authors: Lisa Tjosvold, Institute of Health Economics; Ken Bond, Institute of Health Economics

Introduction: Health care reform through appropriate care is a current focus, and a variety of policy "levers" are available to influence appropriate care. However, there are few direct, empirical analyses of such levers. An appropriate care policy lever inventory was developed for health technology assessment (HTA) users in Alberta, Canada, to support HTA scoping and policy development.

Methods: An Excel-based inventory (with user guide) was populated with a list of policy levers, their descriptions, policy effectiveness, and implementation considerations drawn from a scoping search of the published and grey literature. Filters were developed to identify levers based on key characteristics. The inventory was iteratively refined through presentations and feedback from key user groups.

Results: The inventory contains 53 policy levers aiming to influence service provision, clinician behaviour, fiscal policies, populations or organizations, and patient behaviour. Few levers were considered high impact (>5% change to behaviour, utilization, or cost) or well-supported (>10 studies reporting effectiveness). Stakeholders found the inventory information useful, particularly for considering potential levers not frequently utilized within their respective programs.

Conclusion: A policy lever inventory can assistant health care decision-makers in developing and utilizing HTAs to improve appropriateness of care. With limited indication-specific evidence, policy-makers must utilize the broader evidence base on appropriate care policy levers to select and implement strategies that are applicable and transferable to their context. Challenges remain in identifying all relevant literature, and in updating the inventory to reflect emerging evidence.

OP8C. Health Technology Assessment at Ontario Health: Assessing the Impact of the Program

Presenting Author: Vania Costa, Ontario Health

Co-Authors: Olga Gajic-Veljanoski, Ontario Health; Elisabeth Smitko, Canadian Blood Services; Juliana Yi, Ontario Health; Yuan Zhang, Ontario Health; Chunmei Li, Ontario Health; Sarah McDowell, Ontario Health; Alexis Schaink, Ontario Health; Stacey Vandersluis, Ontario Health; Nancy Sikich, Ontario Health

HTA impact can be measured by its influence on policy decisions, delivery of care, and patients' health status. We developed a logic model for the evaluation of impact of the Ontario Health (OH)-HTA program and applied it on our impact assessment. Our OH-HTA impact logic model was based on a review of published Canadian and international HTA organizations' models and internal consultations. It describes our

program's activities and outputs, reach, stakeholder involvement, and short-, medium-, and long-term impact outcomes, with indicators addressing each outcome. We collected data on program outputs and indicators for 2017–2021. The OH-HTA program completed 8–15 HTAs annually that led to funding recommendations. In 2020, 43 rapid evidence reviews were conducted to inform COVID-19–related policy decisions. There were on average 42,268 views and 6,850 downloads of our products annually. All our funding recommendations were either accepted, endorsed or under review by the Ontario Ministry of Health (MoH). Most funding recommendations were either implemented/planned to be implemented, used in procurement, or encouraged to be followed by the MoH. Unnecessary duplication of work was avoided by using published HTAs and systematic reviews whenever possible, and by collaborating with other Pan-Canadian HTA Collaborative organizations. We estimated the clinical benefits and budget impact of the 2019 HTAs. The OH-HTA program has demonstrable value as its outputs have supported evidence-based funding decisions for health care technologies. Our logic model identified outputs, outcomes, and indicators of impact and may be useful to other HTA organizations.

OP8D. Examining Ethics in and of Health Technology Assessment in Canada

Presenting Author: Renata Axler, CADTH

Co-Authors: Deirdre DeJean, CADTH; Ana Komparic, CADTH; Elijah Herington, CADTH

Ethical considerations can augment HTA reviews and drive appraisals and policy or funding decisions, yet the value, methods and outcomes related to ethical analyses in HTA remain uncertain. Several methodologies and approaches have been proposed to forward ethical analyses in HTA and have been applied across jurisdictional settings. In addition, while ethical analyses can augment HTA reports, several ethical considerations arise in the ethics of HTA itself across the technology life cycle, including how health technologies are prioritized and pursued, and how analyses of benefits, burdens and costs are framed and ultimately used by decision-makers.

This presentation will explore both how ethical considerations are implicit in the practice of HTA in the Canadian context and explore how reports of explicit ethical considerations as part of HTA can enhance practice. Examples will be drawn from CADTH's reports of ethical considerations in the context of complex pharmaceutical reimbursement reviews (e.g., cell and gene therapies, drugs for rare diseases) to show how ethical considerations can augment the production of HTA reports, as well as inform deliberation and implications for the uptake of products and therapeutics into health systems. As current and future health systems must increasingly engage with ethical considerations related to allocation and prioritization in the context of scarce resources, equity challenges, and questions about how evidence is produced and used, the role of ethics in and of HTA is imperative in future- ready health systems.

OP9A. Introducing the Canadian Observatory on Drug Expenditure — Annual Canadian Trends in Estimated Pharmaceutical Drug Purchases and Projections for 2023

Presenting Author: Mina Tadrous, University of Toronto

Co-Authors: Pooyeh Graili, University of Toronto; Kaleen Hayes, Brown University; Heather Neville, Queen Elizabeth II Health Sciences Centre, Nova Scotia Health Authority; Joanne Houlihan, Nova Scotia Cancer Care Program, Nova Scotia Health Authority; Fiona Clement, University of Calgary; Jason Guertin, Université Laval; Michael Law, University of British Columbia; Tara Gomesm Ontario Drug Policy Research Network

Background: The Canadian Observatory on Drug Expenditure (CODE) was established to report annual updates of estimated pharmaceutical drug purchases in Canada to identify factors that may influence future spending to support decision-makers. We present the 2023 forecast and introduce our methods.

Methods: We conducted a time series analysis of annual estimated pharmaceutical drug purchases between 2001 and 2021 using IQVIA's Canadian Drugstore and Hospital Purchases Audit. We calculated the annual relative change, stratified by retail and hospital setting, and forecasted annual spending to 2023. We also assessed recent drug approvals, policies, and legislation that may influence drug spending.

Results: Total drug purchases for 2021 were approximately $35.4 billion, 8.3% higher than in 2020 (7.3% growth in the retail sector; 12.4% growth in the hospital sector). Total spending for the top 25 drugs accounted for 31.2% and 52.3% of total spending in the retail and hospital sectors, respectively. Spending has grown over the past 2 decades, with an annual average growth of 5.4% (retail sector) and 7.4% (hospital sector). In the retail sector, we forecast continued moderate levels of growth (~7% annually), with higher rates of growth (~12% annually) expected in the hospital setting.

Interpretation: We project continued growth in overall drug purchases across the entire Canadian market. New approvals of specialty and oncology drugs and generic and biosimilar formulations of the top 25 drugs are expected to influence drug purchases in 2022–2023. Annual updates will provide an independent assessment of the current pharmaceutical landscape in Canada.

OP9B. Optimizing Efficiency and Resource Allocation in Health Care Through Patient Engagement in Economic Evaluations

Presenting Author: Kednapa Thavorn, Ottawa Hospital Research Institute

Co-Authors: Emily Thompson, Ottawa Hospital Research Institute; Terry Hawrysh, Patient Partner; Justin Presseau, Ottawa Hospital Research Institute

Economic evidence is a key part of making reimbursement decisions about health technologies. Despite being an ultimate beneficiary of health technologies, patients and caregivers are traditionally underrepresented in generating economic evidence, which stands in stark contrast to the centrality of patient

involvement in clinical research and health technology assessment. We believe patients deserve a seat at the health economics table as partners in the design and conduct of economic research, and that patient input can improve the relevance and uptake of economic evidence. We sought to explore how to best enable that in Ontario by conducting a series of 6, one-hour, meetings with partners with varied lived experience of disease in Ontario, British Columbia, and Alberta. We also met with representatives from 11 Ontario SPOR SUPPORT Unit (OSSU) to clarify the interest and extent of existing support provided across centres for involving patients in economic evaluations. We identified a lack of formal infrastructure, resources, and education as barriers to patient engagement. In partnership with people with lived experience, we developed a flow diagram of the economic evaluation process as a foundational resource to enable patients and OSSU centres to situate opportunities for engagement. We also identified the steps of economic evaluation at which people with lived experience are interested in and may have capacity to get involved.

Our study highlights gaps in engaging people with lived experience in economic evaluations in Ontario and provide recommendations on how to address engagement barriers, which could better reflect patient values in health care decision-making.

OP9C. Assessing Cost-effectiveness and Value of Information Given Non-Optimal Previous Decisions

Presenting Author: Doug Coyle, University of Ottawa

Co-Authors: David Glynn, University of York; Jeremy D. Goldhaber-Fiebert, Stanford University; Ed Wilson, University of Exeter

Introduction: Economic evaluation aims to identify the best course of action by a decision-maker with respect to the level of health within the population of interest. Traditionally, it assesses which treatment choice is optimal. An alternative framework can incorporate previous reimbursement decisions and the market share of current technologies and explicitly focus on whether or not to reimburse a new technology. We demonstrate how these different approaches can lead to differences with respect to reimbursement decisions and value of information (VoI).

Methods: We developed a probabilistic Markov model for a chronic progressive anonymized condition assessing the expected long-term benefits and costs of 5 treatments (no treatment, existing treatments A, B and C, new treatment D). Cost-effectiveness and VoI was derived from the traditional framework assessing which treatment was optimal and from the alternative framework assessing whether reimbursement of the new treatment is optimal.

Results: Under the traditional framework, A is optimal and D should not be reimbursed. VoI analysis found the greatest value was in obtaining further information on the effectiveness of A and D. Under the revised framework, reimbursing D would be optimal compared to no reimbursement. Obtaining further information relating to the effectiveness of B, C and D and in the market capture rates for D would have the most value.

Conclusion: The different frameworks can lead to different conclusions regarding both cost-effectiveness and value of information. The revised framework may have greater relevance with respect to decisions explicitly considering whether to reimburse new technologies.

Poster Abstracts

PO1. Using Labs Wisely: Reduction of Low-Value Laboratory Tests — A Resource Savings Calculator

Presenting Author: Tessa Cornelissen, CADTH

Co-Authors: Christopher Vannabouathong, CADTH; Kim Le, CADTH

Choosing Wisely Canada (CWC) raises awareness on the overuse of low-value interventions in health care and encourages informed conversations between clinicians and patients regarding potential risks of unnecessary tests and treatments. Through a new program called "Using Labs Wisely", CWC identified 5 laboratory tests that are considered low-value (serum folate, urea, partial thromboplastin time, aspartate aminotransferase, and creatine kinase-MB), because they offer limited clinical value in the presence of either more sensitive or specific laboratory tests. In collaboration with CWC, CADTH developed a resource savings calculator to assist decision-makers in quantifying the direct and indirect health care resource impact associated with reductions in the use of these 5 tests over a 2-year time horizon. Default inputs were obtained from the literature, real-world data, and clinical expert consensus; all inputs in the tool were user-modifiable to allow for institution-specific analyses. Using annual lab test volumes, the calculator estimates current direct costs and analyzer time. Users may test alternate scenarios by applying hypothetical reductions in annual test volumes to estimate the total costs and time if such reductions in lab test volumes were achieved. Outcomes reported within the tool include the reduction in total costs and total analyzer time associated with each test. The calculator also included an exploratory analysis to estimate direct costs associated with reordering laboratory tests arising from abnormal results. With this tool, institutions can gain insights on the magnitude of health care resources that can be reinvested toward higher-value patient care through the reduction or elimination of these 5 laboratory tests.

PO2. Environmental Considerations in BC Health Technology Assessment and Policy

Presenting Author: Robert Bacigalup, BC Ministry of Health

Reducing environmental impacts and improving sustainability are increasingly important considerations for future planning, including in health care. Health technology assessments (HTA) consider a variety of measures, and typically focus on the clinical and cost-effectiveness of an intervention. The British Columbia HTA Committee and Secretariat continue to further incorporate other key considerations including environmental impact and sustainability as part of these evaluations. While limitations do not allow for a life

cycle assessment; we have collaborated with experts and developed a targeted tool to include alongside an HTA for the evaluation of health technologies. The tool's primary output is a custom materials, energy, and toxins (MET) matrix.

PO3. Systematic Review of Economic Evaluations of CAR-T Cell Therapies for Patients with Hematologic and Solid Malignancies

Presenting Author: Emily Rose Thompson, Ottawa Hospital Research Institute

Background: Chimeric antigen receptor (CAR) T-cell therapies have shown promise in improving survival outcomes among patients with advanced blood cancer, however, the therapies come with a significant price tag due to the complexity of its production and potential side effects. Our study summarizes evidence on the cost-effectiveness of CAR T-cell therapies for patients with hematologic or solid malignancies.

Methods: We performed a search of electronic databases and grey literature, updated in October 2022. Search strategies were developed by an experienced librarian and the research team. Eligibility criteria included systematic reviews, health technology assessments or economic evaluations comparing costs and effects of CAR T-cell therapy in cancer patients. Two reviewers independently screened studies using predefined inclusion criteria, extracted data and assessed the methodological quality of the included studies using the Phillips checklist.

Results: The searches identified 1,428 citations. Of these, we included 26 cost-utility analyses published between 2018 and 2022, of which more than half were conducted in the United States. Seven types of CAR T-cell products were evaluated: tisagenlecleucel, axicabtagene ciloleucel, idecabtagene vicleucel, ciltacabtagene autoleucel, brexucabtagene autoleucel, and lisocabtagene maraleucel. Studies suggested that the cost-effectiveness of CAR T-cell therapy varied according to patient population (pediatric vs adult), cancer type, and model assumptions, including time horizon and cure point. The lack of head-to-head clinical comparative evidence and uncertainty around CAR T-cell's costs and curative assumptions make the cost-effectiveness results questionable.

Conclusion: Cost-effectiveness of CAR T-cell therapies is highly uncertain, highlighting the need for additional comparative and long-term studies and alternative payment models to manage the uncertainty in their future costs and benefits.

PO4. Learning Health System in Clinical Genetics: The Case of Patient Recontact

Presenting Author: Guylaine D'Amours, Li Ka Shing Knowledge Institute, St. Michael's Hospital, Unity Health Toronto

Co-Authors: Emma Reble, St. Michael's Hospital; Vernie Aguda, Li Ka Shing Knowledge Institute of St. Michael's Hospital; Marc Clausen, St. Michael's Hospital; Salma Shickh, Chloe Mighton, St. Michael's Hospital; June Carroll, Sinai Health; Jordan Lerner-Ellis, Mount Sinai Hospital; Tanya Nelson, BC Children's Hospital; Julie Richer, Children's Hospital of Eastern Ontario; Kasmintan Schrader, BC Cancer Agency; Emily Seto, Institute of Health Policy, Management and Evaluation, University of Toronto; Serena Shastri-Estrada, Patient; Prof. Kevin Thorpe, Dalla Lana School of Public Health, University of Toronto; Yvonne Bombard, University of Toronto

Background: Clinical genetics needs to develop a learning health system because genetic test results can change over time, reflecting new variant-disease associations, which can impact patient management in real-time. However, continually recontacting patients with updated results can significantly impact health care resources. Digital platforms offer feasible and scalable solutions to support patient recontact but have yet to be implemented.

Objective: Describe the perspectives of genetics professionals toward patient recontact, digital platforms and factors influencing their implementation.

Methods: Qualitative study informed by the Consolidated Framework for Implementation Research (CFIR). Data were analyzed using interpretive description. Three analysts coded the data using a codebook based on the interview guide and emerging themes.

Preliminary results: We interviewed 18 clinical genetics professionals (9 genetic counselors, 5 medical geneticists, and 4 laboratory geneticists). Participants identified patient recontact as an important issue that extends beyond communicating updated results and encompasses feedback of clinical information to clinicians and laboratories to improve reclassification. They considered digital tools to be indispensable in improving the efficiency of clinical genetics services delivery, particularly with regards to access, communication, and patient engagement, but identified potential barriers to their implementation (institutional policies, competing priorities, and information technology infrastructures).

Conclusion: These findings will inform the design of an adaptable patient platform to recontact genetics patients and an implementation plan. Engaging interested groups in the design stage of a new technology can increase its fit to context and improve implementation, but also ensure it captures and manages data supporting continuous health system improvement.

PO5. Clinical Recommendations and Management Framework for Optimizing the Use of Immunoglobulins in Quebec

Presenting Author: Julie Lefebvre, INESSS

Co-Authors: Audrey Magron, INESSS; Frédéric St-Pierre, INESSS; Marie-Claude Breton, INESSS; Ann Lévesque, INESSS; Sylvie Bouchard, INESSS; Catherine Truchon, INESSS

Introduction: The steadily increasing use of nonspecific human immunoglobulins (Igs), an expensive product derived from human plasma with variable supply availability, prompted the Quebec Ministry of Health and Social Services to mandate the Institut national d'excellence en santé et en services sociaux to: 1) develop clinical recommendations to optimize their use, 2) validate the Ig shortage management framework of the emergency plan and 3) identify alternative treatments to Igs in case of shortage during the COVID-19 pandemic.

Methods: Systematic literature reviews of primary studies and clinical recommendations were conducted. The information gathered was then triangulated with the experiential knowledge of Quebec experts and clinicians and contextualized according to Quebec's background.

Results: This work led to the elaboration of recommendations for over 150 indications spanning over 6 medical specialties. These recommendations then informed the validation of the Ig shortage management framework, and the elaboration of standardized forms for prescribing Igs by the Quebec Ministry of Health and Social Services. The shortage management framework defines 4 levels to ensure a fair and equitable use according to the Igs availability. Overall, the implementation of these tools, combined with the increased awareness, contributed to reduce the use of Igs by 12,4% in 2020-2021 compared to 2019-2020.

Conclusions: The decrease in the use of Igs in 2020-2021 demonstrates how well-framed management directives based on Institut national d'excellence en santé et en services sociaux recommendations can lead to important savings for Quebec's health care system. The province-wide implementation of the standardized forms for prescribing Igs is paramount to ensure the sustainability of these gains.

PO6. Melanoma: the Financial Impact of Transformative Treatments

Presenting Author: Rohini Naipaul, Ontario Health (Cancer Care Ontario)

Co-Authors: Elena Mow, Ontario Health (Cancer Care Ontario); Rebecca Mercer, Canadian Centre for Applied Research in Cancer Control; Lyndee Yeung, Ontario Health (Cancer Care Ontario); Frances Wright, Department of Surgery, University of Toronto; Ontario Health (Cancer Care Ontario); Teresa Petrella, Odette Cancer Centre, Sunnybrook Health Sciences; Scott Gavura, Ontario Health Background: Over the past decade, patients with melanoma have experienced significant survival benefits with the introduction of novel systemic therapies. We examined the corresponding trends in costs and utilization of melanoma drugs publicly funded by Ontario's New Drug Funding Program (NDFP) and the Ontario Drug Benefit program (ODB).

Approach: NDFP primarily funds parenterally administered cancer drugs in an outpatient hospital setting where 100% of drug costs are covered. ODB is the provincial program for prescription drug coverage that funds take-home cancer drugs (e.g., oral therapies). The extent of drug costs covered depends on the beneficiary's age and income. Treatment volumes and government costs, including drug costs and pharmacy fees where applicable, were obtained from ODB and NDFP claims data. Trends were examined from 2011/12-2020/21.

Results: A total of 9 melanoma drugs were examined with 8 funded during the study period. Over 10 years, spending on publicly funded melanoma drugs increased by 4,349% ($2.2M to $96M) while the overall cancer budget grew by 237%. Treatment volumes increased by 499%.

By 2020/21, spending on melanoma drugs accounted for 6% of provincial cancer drug costs. Nivolumab accounted for 40% of melanoma spending, primarily due to the use of nivolumab/ipilimumab combination for metastatic disease and nivolumab monotherapy for adjuvant treatment.

Conclusions: Public spending on melanoma drugs has dramatically increased and outpaced growth in overall cancer costs warranting ongoing studies to assist in health care planning.

PO7. A Systematic Literature Review of Economic Evaluations on Placental Growth Factor (PlGF)-based Biomarker Tests for Diagnosis of Pre-Eclampsia

Presenting Author: Kamilla Guliyeva, Ontario Health

Co-Authors: Jennifer Guo, Ontario Health; Xuanqian Xie, Ontario Health; Kristen McMartin, Ontario Health; Corinne Holubowich, Ontario Health; Chunmei Li, Ontario Health; Nancy Sikich Ontario Health

Background: Pre-eclampsia is a potentially serious condition affecting up to 5% of pregnancies. If undetected and untreated, pre-eclampsia may result in serious complications for the pregnant person and fetus. Recent

guidelines from the Society of Obstetricians and Gynecologists of Canada (SOGC), the National Institute for Health and Care Excellence (NICE), and other health care agencies have recommended the use of placental growth factor (PlGF)-based biomarker testing as an adjunct to standard clinical assessment to help diagnose pre-eclampsia in people with suspected pre-eclampsia.

Methods: We performed a systematic literature review of the economic evidence on the cost-effectiveness of PlGF-based biomarker tests to help diagnose pre-eclampsia in people with suspected pre-eclampsia. We carried out our search between January 2015 and April 2022 in MEDLINE, Embase, Cochrane, CINAHL, and supplemented our search with additional sources.

Results: We identified 143 studies and upon screening included 13 in our review. Most studies found that PlGF-based biomarker testing resulted in cost savings, was cost-effective, or was found to be more effective and more costly than standard clinical assessment alone. These results were largely attributed to fewer unnecessary hospitalizations due to the test improving risk prediction of pre-eclampsia and therefore avoiding overtreatment.

Conclusions: Our review highlighted important factors that should be taken into consideration when determining the generalizability of cost-effectiveness results on PlGF-based biomarker testing. These include whether the test being evaluated was used to rule-out, rule-in, or both rule-out and rule-in pre-eclampsia, and whether it was used as a stand-alone or as an add-on test.

PO8. The Canadian Cancer Real-World Evidence Platform: Generating Actionable RWE to Answer Decision-Maker Questions

Presenting Author: Qi Guan, Ontario Health; Katharina Forster, Ontario Health

Co-Authors: Suriya Aktar, Ontario Health; Rebecca Mercer, Canadian Centre for Applied Research in Cancer Control; Pam Takhar, Ontario Health; Caroline Munoz, Ontario Health; Scott Gavura, Ontario Health; Jonathan C. Irish, University Health Network; Elaine Meertens, Ontario Health; Avram Denburg, Hospital for Sick Children; Winson Cheung, Oncology Outcomes; Stuart Peacock, ARCC; Prof. Kim McGrail, UBC; Mina Tadrous, Ontario Drug Policy Research Network; Kelvin Chan, Sunnybrook Health Sciences Center

The number of novel oncology pharmaceuticals is rapidly increasing, with cancer therapeutics occupying a substantial portion (25%) of public drug spending in Canada. However, there remains a knowledge gap between drug efficacy and effectiveness, as clinical trials are conducted with potentially small sample sizes, strict eligibility criteria, single-arm design, lack of relevant Canadian comparators, and short follow-up periods for study outcomes. There is thus a growing need for post-market drug evaluations (PMDE) using real-world evidence (RWE) to ensure that cancer therapies are safe, effective, and clinically relevant.

Launched in September 2022, the Canadian Cancer Real-world Evaluation (CCRE) Platform is a pan-Canadian network that supports CADTH's CoLab in PMDE. The CCRE consists of a diverse group of individuals with advanced expertise in pharmacoepidemiology, health services research, health technology assessment,

biostatistics, cancer-related health policy, and patient engagement. The team is embedded in provincial cancer agencies in Ontario, Alberta, and British Columbia, with in-house access to health administrative data. This includes population-based data on systemic treatments, radiation, and surgery, in addition to other health services utilization data. In the remaining provinces, data may be obtained through CCRE's collaborations with the Health Data Research Network Canada and the CanREValue Collaboration. Databases available to the CCRE are updated in a timely manner, with some having only a 2-month lag from real-time data collection.

Leveraging pan-Canadian data, we have developed a flexible three-stream response system to triage queries based on the complexity and resources required to generate timely oncology RWE for decision-makers in Canada

PO9. Cost-Utility of Geriatric Assessment in Older Adults With Cancer

Presenting Author: Yeva Sahakyan, University Health Network

Co-Authors: Qixuan Li, University Health Network; Shabbir Alibhai, Department of Medicine, University Health Network; Martine Puts, Lawrence S. Bloomberg Faculty of Nursing, University of Toronto; Sarah Brennenstuhl, University of Toronto; Mohammed Anwar, University of Toronto; Shant Torkom Yeretzian, Turpanjian College of Health Science, American University of Armenia; Emma Matosyan, University Health Network; Bianca Mclean, University of Toronto; Aira Wills, University of Toronto; Fay Strohschein, Jewish General Hospital; George Tomlinson, University Health Network; Lusine Abrahamyan, University of Toronto, THETA Collaborative

Objectives: Geriatric assessment is a guideline recommended approach to optimize cancer management in older adults. We conducted a cost-utility analysis alongside the 5C randomized controlled trial to compare geriatric assessment and management (GAM) with usual care in older adults with cancer.

Methods: The economic evaluation was conducted from a societal perspective, using a 12-month time horizon. The 5C study enrolled patients from 8 Canadian hospitals and randomly assigned them to receive GAM or usual care. Quality-adjusted life-years (QALYs) were measured using the EQ-5D-5L questionnaire. Health care utilization was evaluated using cost diaries and chart reviews. Multiple imputation was used to account for missing data. The 95% confidence intervals were computed using bootstrapping.

Results: The study included 350 patients of which 173 received GAM and 177 received usual care. At 12 months, the average QALYs per patient were 0.747 and 0.753 for GAM and usual care respectively (ΔQALY = -0.006, 95%CI: −0.06 to 0.05). The total average costs per patient were $48,768 and $50,991 for GAM and usual care (ΔCost = $−2,340 (95% CI: −17,537 to 9,951). The incremental net benefit was $2,021 with 59% probability of GAM being cost-effective for $50,000/QALY threshold. Supplemental analyses to explore uncertainty are in progress.

Conclusions: This is the first cost-utility analysis of GAM in cancer. Although GAM was not different from usual care in terms of its effect on QALY, it resulted in cost savings. These findings may guide further adoption of GAM in routine care for older adults with cancer in practice.

PO10. Partnering With Patients to Explore the Psychosocial and Socioeconomic Impacts of Hereditary Cancer Syndromes

Presenting Author: Jordan Sam, St. Michael's Hospital

Co-Authors: Holly Etchegary, Memorial University of Newfoundland; Marc Clausen, St. Michael's Hospital; Derrik Bishop, Memorial University of Newfoundland; Julee Pauling, St. Michael's Hospital; Claudia Pavao, BC Cancer Agency; Catriona Remocker, BC Cancer Agency; Teresa Tiano, St. Michael's Hospital; Angelina Tilley, Memorial University of Newfoundland; Carly Butkowsky, St. Michael's Hospital, University of Toronto; Sepideh Rajeziesfahani, Memorial University of Newfoundland; Ridhi Gopalakrishnan, St. Michael's Hospital; Melyssa Aronson, Zane Cohen Centre, Sinai Health System; Lesa Dawson, Memorial University of Newfoundland; Andrea Eisen, Sunnybrook Health Sciences Centre; Tracy Graham, Sunnybrook Health Sciences Centre; Jane Green, Memorial University of Newfoundland; Emma Reble, St. Michael's Hospital; Sevtap Savas, Memorial University of Newfoundland; Kasmintan Schrader, BC Cancer Agency; Yvonne Bombard, University of Toronto

Patient oriented research aims to improve patient outcomes and the quality of research by focusing on patient-identified priorities and engaging patients as partners. Methods for meaningful engagement of patient partners in genomics health research are not well described. To describe the engagement of patient partners in a Canadian grant exploring the socioeconomic impacts of hereditary cancer syndromes (HCS), six patient partners living with HCS were recruited. Regular meetings among study PIs, staff and patient partners provide consistent communication and co-development opportunities, but they are also given opportunities to review study material independently for equitable involvement. Patient partners were invited to engage across all phases of the study: grant application, study design, recruitment, data analysis, and knowledge dissemination. Offering choice in level of involvement is best practice for patient engagement because it allows flexibility around their contributions. As this study involves qualitative interviews about sensitive topics, patient partners' lived experiences have informed study materials. To date, patient partners provided feedback on the content and length of interviews, probing questions, and the language to be used. Feedback on early iterations of the interview guide revealed a bias towards negative language about the impact of HCS. Partners reminded the team that there were positive impacts as well and cautioned about the use of exclusively negative language. Patient partners also provided a training opportunity for students and study staff in mock qualitative interviews. To date, patient partners have provided important insights for the evaluation of direct and indirect impacts of hereditary cancer syndromes.

PO11. Developing an Economic Model Appraisal Checklist to Improve the Transparency of the HTA Process

Presenting Author: Doug Coyle, University of Ottawa

Co-Authors: Karen Lee, CADTH; Alex Haines, CADTH

Introduction: Existing checklists for economic evaluations do not provide the depth of guidance required to evaluate economic model validity and transparency. CADTH requires a framework that can be used to ensure consistency in assessing model validity both in terms of conceptual and technical aspects of model design.

Process: An initial draft checklist was generated from a three-stage process: a review of the grey literature, a targeted review of the published literature and consultations with health economists to determine their current process with respect to model validation. A final framework was developed after consultation with CADTH, the CADTH Health Economic Advisory Council and a roundtable of experienced economic reviewers.

Output: The model appraisal checklist covers three areas. First the validation of the conceptual model determines whether the modelling framework adopted is appropriate for the context of both the condition of interest and the specific decision problem being assessed. Secondly, the process for computer model verification relates to both assessment of model behaviour (black box testing) and scrutinization of the coding of the model (white box testing). Finally, general issues of concern relate to identifying practices in model building which reduce transparency and limit model verification.

Conclusions: CADTH has developed a model appraisal checklist which will assist producers of models (including industry) in building more robust and transparent models. Likewise, this checklist will enable users of models (such as decision-makers) to more easily and consistently validate models, improving their reliability in decision-making.

PO12. Validation of a Mixed Model for Repeated Measures Approach to Including Trials With Varying Follow-Up in Indirect Treatment Comparisons of Long-Term Outcomes

Presenting Authors: Sarah Walsh, EVERSANA Tim Disher, EVERSANA

Indirect treatment comparison (ITC) methods are required to assess the relative efficacy between treatments when no head-to-head clinical trials are available. However, trials will frequently include a combination of different follow-up lengths, making it challenging to perform long-term comparisons. The aim of this study is to validate a mixed model for repeated measures (MMRM) approach to include trials with various follow-up times in unanchored ITCs of long-term outcomes. The proposed approach uses a multivariate normal likelihood with unstructured variance covariance matrix which assumes that missing timepoints are missing at random and can be considered similar to an aggregate version of MMRM. This MMRM approach is compared to a simpler model-based network meta-analysis modelling approach with a spline smoothed trend across time and an assumed constant correlation for variance inflation. Models are conducted within a Bayesian framework using aggregate level inputs. If there are many timepoints with missing data,

applying an MMRM approach can lead to significant improvements in the precision of estimated effects. In situations where final models are combined in random effect meta-analysis, the MMRM approach allows for a more reliable estimate of between trial heterogeneity than is otherwise possible. The MMRM approach can be challenging to implement computationally and in settings where the distance between time point measurements or their correlation over time differ. Applying an MMRM approach may be valuable in situations where unanchored comparisons conducted at earlier timepoints are forced to use limited trials at later timepoints due to a lack of long-term data.

PO13. Impact of the COVID-19 Controlled Drugs and Substances Act Exemption on Pharmacist Prescribing of Opioids, Benzodiazepines, and Stimulants in Ontario: a Cross-Sectional Time-Series Analysis

Presenting Author: Shanzeh Chaudry, Leslie Dan Faculty of Pharmacy, University of Toronto

Co-Authors: Ann Chang, GSK; Daniel McCormack, ICES; Tara Gomes, Ontario Drug Policy Research Network; Anisa Sivji, Ontario College of Pharmacists; Mina Tadous, University of Toronto

Background: Due to the COVID-19 pandemic, Health Canada issued an exemption to the Controlled Drugs and Substances Act (CDSA), enabling pharmacists to act as prescribers of controlled substances to support continuity of care. Our study investigates utilization of the CDSA exemption by Ontario pharmacists.

Methods: We conducted a time-series analysis of pharmacist-prescribed opioid and benzodiazepine claims data using Ontario Narcotics Monitoring System (NMS) data between January 2019 to March 2021. We used ARIMA modelling to measure the change to the number of both classes of claims, the proportion of pharmacist-prescribed claims and opioid claims containing quantities greater than a 30-day supply.

Results: Post-exemption, the average weekly number of pharmacist-prescribed opioid, benzodiazepine, stimulant claims rose by 146% (161 to 393 claims/week), 960% (49 to 514 claims/week) and 2,150% (8 to 177 claims/week), respectively. There was a 2-week lag period between the time of announcement and the statistically significant increase in claims on April 5, 2020 ($p < 0.0001$). Pharmacist-prescribed claims for opioid quantities exceeding a 30-day supply decreased by 60%. Cumulative pharmacist-prescribed claims accounted for under 2% of the total NMS claims.

Conclusions: Ontario pharmacists utilized the CDSA exemption but were prescribing at low rates. These findings suggest an effective change to pharmacy practice that may lead to future changes to pharmacist scope to benefit patients. This may lead to further studies exploring treatment breaks during the COVID-19 pandemic and future changes to pharmacist scope to benefit patients.

PO14. Alberta Health Services Medical Device Innovation Program

Presenting Author: Katty Oishi, Alberta Health Services; Tara Klassen, Alberta Health Services

Initiated in the summer of 2022, the Provincial Advisory Council on Device Innovation (PACODI) is the new medical device innovation pathway from Alberta Health Services (AHS). This pilot project will support front-line staff and stakeholders who are dissatisfied with current medical devices and/or would like to adapt or modify a device or its use to meet real patients' needs. Although off-label use is typically associated with increased clinical and organizational risk, liability, and other negative connotations, when appropriately planned and evaluated for risk, off-label use is a form of innovation and evidence development. With a focus on safety and sustainability, PACODI is turning "off-label" use into innovative modifications and adaptations to support and improve patient care. PACODI will provide a process where all staff can receive expert feedback and be supported in their medical device innovations. The main goal is not only to support health care providers with their ideas but also to learn from them and share what is learned if deemed safe and better than the current practices. PACODI is a partnership between Quality Health Improvement (QHI), Provincial Patient Safety and the Surgery SCN's Evidence Decision Support Program (EDSP).

PO15. First-Trimester Screening Program for the Risk of Pre-Eclampsia Using a Multiple-Marker Algorithm: a Health Technology Assessment

Presenting Author: Jennifer Guo, Ontario Health

Co-Authors: Conrad Kabali, Ontario Health; Sonia Thomas, Ontario Health; Yuan Zhang, Ontario Health; Corinne Holubowich, Ontario Health; Isabelle Labeca, Ontario Health; Ishita Joshi, Chunmei Li, Ontario Health; Sarah McDowell, Ontario Health; Nancy Sikich, Ontario Health

Pre-eclampsia with delivery at <37 weeks' gestation can result in severe infant and maternal morbidity and mortality. The Fetal Medicine Foundation created "the FMF algorithm" which combines maternal factors with biophysical and biochemical markers, allowing for improved identification of people at high risk of pre-eclampsia.

We conducted a health technology assessment to evaluate the safety, effectiveness, cost-effectiveness, and budget impact of a first-trimester population-wide screening program for pre-eclampsia risk that uses the FMF algorithm ("the FMF-based screening program"). We also evaluated the accuracy of the FMF algorithm, and patient preferences and values.

We found that an FMF-based screening program likely reduces the risk of pre-eclampsia with delivery at <37 weeks' gestation compared with standard care (GRADE: Moderate) and may reduce the risks of low birth weight and low Apgar score (GRADE: Low). Additionally, the FMF algorithm can be more accurate than conventional algorithms in predicting pre-eclampsia with delivery at <37 weeks' gestation. Compared with standard care, the FMF-based screening program resulted in $3,446 per prevented case of pre-eclampsia with delivery at <37 weeks. The annual budget impact of publicly funding this screening program is estimated to be $8.50 million over the next 5 years. Patients valued the information and potential clinical benefits that the FMF-based screening program could provide in terms of preventive care.

Given that no structured program currently exists in Ontario to screen for pre-eclampsia risk, an FMF-based screening program would help to promote equitable outcomes through a structured approach to screening.

PO16. Indigenous Considerations Within Health Economic Evaluations: Where Are we? What lessons Have we Learned?

Presenting Author: Bernice Tsoi, CADTH

Co-Author: Karen Lee, CADTH

Background: Calls for reconciliation across Canada emphasize the importance that Indigenous people have full health care rights and health gaps are closed. Yet, many First Nations, Inuit and Métis People in Canada still face alarming health inequities, subpar health care access and culturally discontinuous services. This brings to question the potential role for HTA and health economics to better advance Indigenous health sovereignty. This poster will summarize the experiences and insights of Canadian health economists with experience conducting economic analyses from an Indigenous perspective.

Method: We conducted a series of unstructured interviews to explore the recent experiences of health economists who have partnered with Indigenous groups to adapt economic-based analyses. Themes from these interviews included understanding how economic analyses have been adapted to better incorporate Indigenous knowledge and priorities; necessary enablers required to support these initiatives; and outstanding methodological gaps that need to be resolved to advance the role of health economics in supporting Indigenous health and wellness.

Results: Western approaches to economic evaluations may not align with Indigenous values. Indigenous populations often define health and objectives to resource allocation decisions differently. For instance, the Western concept of health is narrower than the Indigenous holistic definition that extends beyond an individual to consider one's wellness, surroundings, and relevant health determinants. Furthermore, health interventions need to be expanded to recognize traditional Indigenous health knowledge and healing practices.

Conclusion: Conducting economic evaluations with an Indigenous perspective requires thoughtfulness and partnership with Indigenous groups. Existing methods need to be adapted when considering Indigenous perspectives.

PO17. Implications of Conditional Regulatory Approval on Public Spending of Hospital-Administered Cancer Drugs

Presenting Author: Scott Gavura, Ontario Health (Cancer Care Ontario)

Co-Authors: Rohini Naipaul, Ontario Health (Cancer Care Ontario); Rebecca Mercer, Canadian Centre for Applied Research in Cancer Control; Elena Mow, Ontario Health (Cancer Care Ontario); Kelvin Chan, Sunnybrook Health Sciences Center

Background: Health Canada's Notice of Compliance with Conditions (NOC/c) policy facilitates early access to promising new drugs before there is definitive evidence of clinical benefit. Subsequently, manufacturers need to complete confirmatory trials to be granted a NOC. Previous studies have examined the proportion of drugs that have met these conditions, and timelines to granting an NOC. For publicly funded hospital-administered cancer drugs (e.g., IV chemotherapy) in Ontario, we determined the proportion with NOC/c status and associated drug costs.

Approach: All drug-indication pairs listed as of the 2021/22 fiscal year on the New Drug Funding Program (NDFP) and High-Cost Therapy Funding Program (HCTFP) were included. We examined regulatory status at the time of listing and drug costs by regulatory status. Regulatory status was sourced from Health Canada databases and drug costs were sourced from Ontario Health's databases.

Results: In 2021/22, a total of 131 drug-indication pairs were reimbursed by NDFP/HCTFP and spending exceeded $700 million. In our preliminary analysis, 19 drug-indications had a NOC/c at time of listing. For 12 drug-indications, NOC conditions were met in an average of 4.4 years (range, 1.3 -7.3 years). While they were conditionally approved, cumulative spending was approximately $18 million. The seven drug-indications that still have a NOC/c have been listed on the formulary for an average of 3.0 years (range, 0.1-6.2 years) and over $25 million has been spent to date.

Interpretation: Given the robust pipeline of new cancer medications and budget pressures faced by public payers, confirmatory trials should be completed expeditiously.

PO18. Personalize My Treatment (PMT): a Canadian Cancer Patient Registry

Presenting Author: Maud Marques, Exactis Innovation

Co-Authors: Karen Gambaro, Exactis Innovation; Vincent Normandeau-Babin, Exactis Innovation; Rosa; Garyfallia Christodoulopoulos, Exactis Innovation; David Bouffard, Exactis Innovation; Ethan Hoang, Exactis Innovation; Suzan McNamara, Exactis Innovation; Gerald Batist, McGill Centre for Translational Research in Cancer and Segal Cancer Centre, Jewish General Hospital; Kostas Trakas, Exactis Innovation

Cancer patient registries, and associated clinical data collection, represent an emerging trend to understand the impact of disease on the population, identify contributing factors, and assess disparities in cancer incidence and outcome. In addition, longitudinal clinical data collection enhances the understanding of patterns of care. Exactis Innovation (Exactis) is a Canadian not-for-profit Business-Led National Centers of Excellence organization. Exactis has established a unique standardized digital cancer patient registry called "Personalize My Treatment" (PMT) active at 15 hospital sites across 5 Canadian provinces.

Exactis has executed agreements with the hospital sites within its network that permit on-site dedicated PMT Coordinators to enroll patients in PMT and to collect longitudinal real-world data (RWD) in a standardized secured de-identified online database. Access to digitalized pathology, images, biospecimens,

and information from patient's medical records can be collected retrospectively or prospectively for research purposes.

To date, PMT has over 8,400 participants enrolled. The main cancer cohorts enrolled are breast, colorectal, lung, prostate, melanoma, and ovarian. Information collected includes demographics, cancer type and history, events of progression/recurrence, diagnosis, tumour resection, treatment sequences, and molecular profile's results.

Exactis has established a pan-Canadian network and a cancer patient registry able to provide the capacity and a tremendous resource for RWD analysis, that reflects the full diversity of Canadian oncology patients. The Exactis' network can be leveraged to bring a higher level of certainty on the clinical benefits of new agents in a real-world population, as well as to support new indications and highlight treatment gaps.

PO19. Revisiting the COVID Impact on CADTH Submissions, pCPA Negotiations, and Time-to-Listing Processes in Canada

Presenting Author: Wei Zhe (Scott) Shi, IQVIA

Background: In the previous 2021 CADTH symposium, we explored the associated impact of the coronavirus outbreak on various market access metrics immediately following COVID-19 lockdown measures. It is valuable to examine the market access metrics two years after the initial pandemic.

Objectives: Using a data-driven approach to assess whether CADTH submissions, pCPA negotiations, and time-to-listing of CADTH reviewed files have changed in the two years after the initial pandemic measures.

Methods: This study used the IQVIA Market Access Metrics database. CADTH new drug and indication reviews were included. Pre-COVID was defined as 2015 – 2019 and post-COVID as 2020 and 2021.

Results: The average number of CADTH submissions per year increased from 58 pre-COVID to 61 in 2020 and 63 in 2021. The number of pCPA negotiations changed from 47 pre-COVID to 28 in 2020 and 62 in 2021 and pCPA negotiation duration changed from 211 days pre-COVID to 239 days in 2020 and 181 days in 2021. The number of CADTH reviewed drugs achieving provincial listing in at least one province per year changed from 35 pre-COVID to 27 in 2020 and 46 in 2021. For those listed, the time from NOC to first province listing increased from 521 days to 585 days in 2020 and 627 in 2021.

Conclusion: In 2020, the number of pCPA negotiations and provincial drug listings decreased. Both pCPA negotiation time and time-to-listing also increased. However, in 2021, several market access metrics have rebounded to above pre-COVID levels, though it remains to be seen if and when time-to-listing will normalize.

PO20. Analgesic Use Among Adults With a Trauma-Related Emergency Department Visit: a Retrospective Cross-Sectional Study

Presenting Authors: Solmaz Bohlouli, University of Alberta; Karen Martins, University of Alberta

Co-Authors: Bill Sevcik, University of Alberta; Kevin Lobay, University of Alberta; Huong Luu, University of Alberta; Khanh Vu, University of Alberta; Phuong Uyen Nguyen, University of Calgary; Dean T Eurich, University of Alberta; Lawrence Richer, University of Alberta; Scott Klarenbach, University of Alberta

Background: A better understanding of current acute pain-driven analgesic practices within the emergency department (ED) and upon discharge may identify knowledge and treatment gaps, and inform optimization of pain management strategies, as there are currently no widely accepted Canadian guidelines on pain management in the ED.

Methods: Administrative data were used to identify adults with a trauma-related ED visit in the Edmonton area in 2017/2018. Characteristics of the ED visit included time from initial contact to analgesic administration, type of analgesics dispensed during and upon discharge from the ED (within 7-days), and those who met chronic opioid use criteria in the 1-year after.

Results: 50,950 ED visits by 40,505 adults with trauma were included. Analgesics were administered in 24% of visits; non-opioids were dispensed in 77% and opioids in 49% of these visits. Time to analgesic initiation occurred a median of 133 minutes (5 minimum / 1,888 maximum) after first contact. Upon discharge, 12% received a non-opioid and 17% received an opioid analgesic; among opioid dispensations, 39% were for ≥7-days of supply, and 21% were for a daily dose ≥50-morphine milligram equivalents. 448 adults newly met chronic opioid use criteria after the visit, among whom 184 (41%) received an opioid dispensation upon discharge.

Conclusions: Findings indicate that areas for improvement may include strategies to address oligoanalgesia and reduce time to initiation of analgesics in the ED, as well as close consideration of recommendations for acute pain management upon discharge to provide ideal patient-centered, evidence-informed care.

PO21. Palivizumab for the Prevention of Severe Respiratory Syncytial Virus Infection in Infants Born 29 to 35 weeks' Gestational Age — Results of a New Canadian Cost-Effectiveness Analysis

Presenting Author: Ian Keary, Violicom Medical Limited

Co-Authors: Boscoe Paes, McMaster University; Barry Rodgers-Gray, Violicom Medical Limited; Xavier Carbonell-Estrany, Hospital Clinic; John Fullarton, Violicom Medical Limited; Prof. Jean-Eric Tarride, McMaster University

Objective: To undertake an updated economic analysis of palivizumab versus no prophylaxis in Canadian 29-35wGA infants.

Methods: Systematic reviews and expert clinical input informed the development of a new semi-Markov cost-utility model wherein prophylaxed/non-prophylaxed infants have either an RSV-associated hospitalization (RSVH), an emergency room/outpatient attended RSV infection (MARI) or were uninfected/non-medically attended. All 29-31wGA infants and those 32-35wGA infants scored at moderate-high risk by the International Risk Scoring Tool (IRST) received palivizumab. Palivizumab reduced the RSVH rate by 63.3% in 29-31wGA (baseline rate: 5.9%) and by 82.2% in moderate-high risk 32-35wGA (6.3%) infants. Mortality (0.43%) was applied only to infants admitted to the intensive care unit, with all survivors experiencing respiratory morbidity for ≤ 18 years. Palivizumab costs (50mg: CAN$752; 100mg: $1,505) were calculated from Canadian birth statistics combined with a growth algorithm (no vial sharing). Indirect costs were included, with outcomes modelled over a lifetime time horizon with 1.5% discounting.

Results: The cost per quality-adjusted life-year (QALY) for palivizumab was $28,317 versus no prophylaxis ($27,571 excluding indirect costs). The model was most sensitive to utility scores, long-term respiratory morbidity and palivizumab cost. Probabilistic analyses (10,000 iterations) resulted in incremental costs of $28,763/QALY, with a 78.6% probability of cost-effectiveness at a $50,000 willingness-to-pay threshold. The cost/QALY was $29,579 and $27,951 for 29-31wGA and 32-35wGA infants, respectively.

Conclusions: This new analysis demonstrated that palivizumab is highly cost-effective in Canadian 29-35wGA infants. For 32-35wGA infants, the IRST provides another option to capture additional at-risk infants while guiding cost-effective RSV prophylaxis in Canada.

PO22. Health Care System Costs Associated With Opioid Use and Potentially Inappropriate Opioid Use in Community-Dwelling Older Adults

Presenting Author: Carina D'Aiuto, University of Sherbrooke

Co-Authors: Carlotta Lunghi, Université du Québec à Rimouski; Line Guénette, Université Laval Djamal Berbiche, Université de Sherbrooke; Karine Bertrand, Université de Sherbrooke; Helen-Maria Vasiliadis, Université de Sherbrooke

Objective: To evaluate the costs related to health service utilization associated with opioid and potentially inappropriate opioid use in older adults and the modifying effect of sex.

Approach: Secondary analyses were performed using health survey and administrative data from a sample of 1,201 older adults consulting in primary care and covered by the public drug plan. Health system costs included inpatient and outpatient visits, physician fees, and medication costs. Unit costs were calculated using financial and activity reports, adjusted to 2022 dollars. Generalized linear models with gamma distribution were employed to study costs associated with opioid use and potentially inappropriate opioid use (defined using the 2019 Beers criteria) over three years. A phase-based approach considered the costs for each phase of opioid use.

Results: Opioid use and potentially inappropriate opioid use were associated with adjusted three-year costs of $21,358 and $26,218, respectively. Mean adjusted three-year costs were significantly higher in those with inappropriate use compared to no use (Δ$10,108, p<0.001) and opioid use (Δ$4,860, p<0.001). Health system costs were highest in the inappropriate opioid use phase ($11,738 per 365 days), mostly driven by outpatient visits and hospitalizations. Stratified results showed that men incurred higher costs than women during opioid use.

Conclusion: Potentially inappropriate opioid use is associated with higher health system costs than opioid use and no use, with men incurring the highest costs. Results can be used to improve the allocation of health resources for pain management and safer opioid use, ultimately reducing costs for the health care system.

PO23. Evaluation of Genetic Tests Within a Canadian Health Technology Assessment Program

Presenting Author: Chunmei Li, Ontario Health

Co-Authors: Sarah McDowell, Ontario Health; Xuanqian Xie, Ontario Health; Olga Gajic-Veljanoski, Ontario Health; Yuan Zhang, Ontario Health; Alexis Schaink, Ontario Health; Stacey Vandersluis, Ontario Health; Myra Wang, Ontario Health; Vania Costa, Ontario Health; Milica Jokic, Ontario Health; Corinne Holubowich, Ontario Health; Caroline Higgins, Ontario Health; Wendy Ungar, SickKids Research Institute; Nancy Sikich, Ontario Health

Background: With advancement in next-generation sequencing technologies, the use of genetic tests in clinical practice has rapidly increased. The Health Technology Assessment (HTA) program of Ontario Health along with the Ontario Genetics Advisory Committee (OGAC), a subcommittee of the Ontario Health Technology Assessment Committee (OHTAC), work together to make evidence-based funding recommendations for genetic and genomic tests to the Ministry of Health.

Objective: To share our experiences of conducting genetic HTAs at Ontario Health and highlight unique considerations relevant to the evaluation of these types of tests.

Findings: Since 2017 we have published 10 HTAs on genetic/genomic topics: 4 on single-gene tests, 2 on multi-gene tests, 3 on multi-gene tests with risk scores, and 1 on whole exome/genome sequencing. Challenges were identified in 4 areas. Topic scoping and literature search was challenged by complex and heterogeneous clinical conditions, emerging evidence, evolving/inconsistent terminologies, and comparability between different tests and platforms. Challenges in clinical evidence assessment included evaluation of clinical validity and clinical utility, estimation of diagnostic accuracy in the absence of a gold standard, and unknown/underreported disease prevalence for rare genetic conditions. Challenges in economic evaluation included complex clinical pathways, assessment of long-term impact, spillover effects beyond tested individuals, costing, and valuation of health outcomes. Genetic tests also require additional considerations for ethical and privacy issues, personal utility, and impact of secondary findings and variants of uncertain significance.

Conclusions: With a few considerations and adaptations, conducting HTA for genetic tests are feasible and can support evidence-informed funding recommendations to support decision-making.

PO24. Specialized Clinics and Health Care Professional Resources for Post–COVID-19 Condition in Canada

Presenting Author: Robyn Haas, CADTH

Co-Authors: Melissa Walter, CADTH; Sinwan Basharat, CADTH; Francesca Brundisini, CADTH

The prevalence of post–COVID-19 condition in Canada estimated to be more than 1.4 million and continues to grow. As a result, there is a need for information about the range and scope of specialty clinics for post–COVID-19 condition that may be operating across Canada as well as educational resources available to health care professionals.

CADTH researchers conducted an Environmental Scan to describe the landscape of specialized post–COVID-19 clinics operating across Canada and to describe the resources that have been developed by Canadian jurisdictions to improve education, awareness, and training of health professionals about post–COVID-19 condition.

Researchers conducted a review of grey and published literature and administered an online survey in November 2022 to 31 targeted contacts across all Canadian jurisdictions. Findings from both the literature search and the survey responses were analyzed and narratively summarized and reported.

As of December 2022, specialized clinics were established or in development in 5 Canadian jurisdictions: Alberta, British Columbia, New Brunswick, Ontario, and Quebec. The types of clinics vary as do their structural characteristics, operational characteristics, and program development and quality improvement activities. The resources developed for health professionals primarily included referral pathways, screening and assessment of symptoms, and patient management strategies. There was also a notable presence of resources intended to inform the development of clinics or models of care for post–COVID-19 condition.

This project can serve as guidance for policy- and decision-makers who are in the process of, or considering, developing specialized clinics for post–COVID-19 condition.

PO25. Identifying and Overcoming the Barriers to Virtual Electromyography Assessments: a Scoping Review

Presenting Author: Valerie Nadeau, University of Alberta

Co-Authors: Martin Ferguson-Pell, University of Alberta; Emmanuella Osuji, Liz Dennett University of Alberta

Introduction: Recently, there has been an increase in electromyography (EMG) assessments conducted virtually. Studies have been published on the barriers to conducting EMG assessments virtually and how

to overcome these. This scoping review highlights gaps based on current knowledge and practices for undertaking EMG assessments virtually.

Methods: The scoping review was conducted according to the methodology of Arksey and O'Malley. A comprehensive search using controlled vocabulary terms (electromyography and telehealth) was conducted on MEDLINE and Embase on February 7, 2022. Two independent reviewers conducted the screening of the titles and abstracts and the full-text articles. Two reviewers also extracted the data, describing the findings in a descriptive analysis.

Results: A total of 248 articles were screened during the abstract and title review, of which 64 full texts were screened for eligibility. Of these, 15 publications met the inclusion criteria. Most articles were published in 2018 or later (66.7%). The most frequently mentioned barriers to conducting a virtual EMG assessment were poor data and signal transmission (53.3%) and poor patient usability (33.3%). Solutions most frequently reported were related to patient usability (33.3%). These included interactive instructions and video chat to monitor and provide technical support to the patient.

Conclusion: The last four years have seen an increase in articles published on the use of virtual EMG to monitor or diagnose patients. Further research and development to reduce bandwidth limitations in rural communities and improve usability by non-expert clinicians and patients is required. This will then enable EMGs to be effectively transmitted virtually, thereby improving access to EMG-based assessments for patients in remote locations.

PO26. Protocol: a Study of Patients, Caregivers, and Health Care Professionals Preference in the Treatment of Relapsed or Refractory Multiple Myeloma

Presenting Author: Jessy Ranger, Myeloma Canada

Co-Authors: Martine Elias, Myeloma Canada; Josee Ivars, Bonnie Macfarlane, Janssen Inc.; Richard K Plante, Janssen Inc.; Kun Shi, Janssen Inc.; Stephanie Soltys, Janssen Inc.; Ewa Wywial, Janssen Inc.

Rationale: Patient preference studies are a source of real-world evidence (RWE) that can be valuable in supporting patient-centered health technology assessments (HTAs), particularly when comparing very different treatment options. Multiple myeloma (MM) is a chronic, incurable disease for which highly innovative treatment options are emerging. While some patient preference research regarding MM treatment options exists, it has generally been focused outside of Canada. It is important that HTA decision-makers consider the unique perspectives of MM patients, caregivers and clinicians to gain a holistic understanding of the relapsed or refractory MM (RRMM) treatment journey and inform discussions on patient needs.

Objectives: This cross-sectional study aims to capture RWE on the preferences of Canadian patients, health care professionals (HCPs), and caregivers regarding attributes for RRMM treatments and the degree of concordance between these stakeholders' preferences.

Methods: The study will comprise of two prospective phases. Phase 1 will identify RRMM treatment attributes most important to patients, caregivers and HCPs through qualitative research. Interviews will be based on protocols and discussion guides developed in collaboration with Janssen and Myeloma Canada, Canadian patients, caregivers and HCPs, and international experts on preference study design. Findings from the qualitative research will inform phase 2: a quantitative preference study, using a carefully designed discrete choice experiment to inform HTA decisions.

Impact: This study will generate important new RWE from Canadian patients, caregivers, and HCPs to strengthen evidence-based HTA decision-making about treatments for RRMM, which is especially relevant with the emergence of new treatment options.

PO27. Health Technology Assessment as a Course-Based Project: Filling Skills and Resource Gaps in Health Care Innovation

Presenting Author: Laura Pickell, Carleton University

Co-Authors: Heather MacDonald, Carleton University

Synthesizing and evaluating evidence on new health technologies for use in health care system decision-making is a resource-heavy and complex endeavour. Further, health technology assessment (HTA) requires specialized skills and knowledge that are often not addressed in relevant academic programs, leading to a skills gap in hew hires for positions in health care innovation. To address these challenges, we piloted a collaborative initiative with Bruyère Continuing Care in Ottawa, Canada, an academic health care organization that provides specialized care for seniors, in which graduate students in our Health Sciences program at Carleton University conducted HTAs to support health technology adoption in this setting. For this course project, students collected, synthesized and evaluated evidence that aligned with the quadruple aim priorities of Bruyère Continuing Care, and after several rounds of consultations and feedback from the Health Innovation team, students presented their final recommendations to stakeholders for use in their decision-making. As a result, this project facilitated evidence-based innovation in an already over-burdened facility while at the same time, students developed critical skills in grappling with often conflicting, weak or lacking evidence to make judgments about technology adoption in a real-world setting. This project also gave students an opportunity to acquire experience in working with stakeholders in the field. Given the success of this project, we plan to continue our partnership in future iterations of the course.

PO28. Ontario Diabetes Microsimulation Model

Presenting Author: Ian Sobotka, Sunnybrook Hospital

Co-Authors: Baiju Shah, Sunnybrook Research Institute; Doug Coyle, University of Ottawa; Lauren Cipriano, Ivey School of Business; Deva Thiruchelvam, ICES

Background: Diabetes affects 18% of Canadians over the age of 65, leading to many diabetes-related complications. Novel therapies purport to both improve control of diabetes and reduce the risk of

cardiovascular events. Microsimulation modelling allows for the synthesis of multiple data sources for comparative effectiveness analysis related to a variety of correlated outcomes. Existing type 2 diabetes models often use data that are decades old, are not population based, or do not fully model vascular risk.

Methods: We developed a novel microsimulation model using health state features including, sex, age, BMI, HbA1c, eGFR, blood pressure, lipids, smoking behaviours, diabetes duration, and history of major acute events. Each month, risk factors update, and simulants may experience acute events. Major acute events included are myocardial infarction, stroke, congestive heart failure, amputation, cancer, and death. Most risk factors and biomarkers update using correlated prediction equations using the U.S. National Health and Nutrition Examination Survey (NHANES) 2005-2017. The trajectories of other risk factors relied on prediction models and observational cohort analysis in the peer reviewed literature. Incidence of major acute events and acute event mortality rates relied on prediction equations derived from Ontario's ICES administrative health care datasets (2012-2017).

Results: We validated model predictions to existing models of diabetes progression and risk of acute events and to recent diabetes clinical trials.

Conclusions: We developed a microsimulation model to help address the lack of diabetes models based on Canadian data. Our model ensures the best data are available to facilitate decisions by Canadian policy-makers.

PO29. Agent-Based Model for Infection Disease

Presenting Author: Jasper Zhongyuan Zhang, The Hospital for Sick Children

Co-Authors: David M J Neimark, Sunnybrook Hospital; Beate Sander, University Health Network; Petros Pechlivanoglou, The Hospital for Sick Children

Motivation: Agent-based models (ABMs) are a type of mathematical simulation that track the individual-level trajectory of agents over time, making them useful for understanding the impact of interventions on infectious diseases. ABMs have seen increasing use in health technology assessment and can be implemented in R for efficient computation and visualization.

Methods: This study provides a step-by-step guide for developing ABMs in R for infectious disease modelling. We first introduce an algorithmic approach to developing ABMs in R based on individual-level state-transition models. These models allow for interactions between agents within assigned groups (family, school, workplace) and have been applied in the context of infectious diseases. The states' transition can be probabilistic and deterministic, and we also introduce complex feature designs such as quarantine, multiple disease variants, testing and detection, and multiple working schedules. We also discuss strategies for efficient computation, such as vectorization and parallel processing, and high-performance computers.

Conclusion: This study provides a comprehensive guide for developing ABMs in R for infectious disease modelling, including complex features and efficient programming strategies. R ABMs can simulate and

visualize disease transmission in past data and make future trend predictions. The methods presented in this study can be easily adapted for use in non-infectious disease modelling.

PO30. A Novel Approach at Enabling the Integration of Additional Data into the CDKL5 RWD Registry (NCT04486768)

Presenting Author: Leah Young, Pulse Infoframe

Co-Authors: Daniel Lavery, LouLou Foundation; Joshua Henderson, Pulse Infoframe; Alexis Zavez, Orphan Disease Center; Feminda Gwadry-Sridhar, Pulse Infoframe

CDKL5 Deficiency Disorder (CDD) is a rare developmental epileptic encephalopathy caused by CDKL5 mutations that can manifest in clinical symptoms ranging from early onset, intractable epilepsy and neurodevelopmental delay impacting cognitive, motor, speech, and visual function. Although rare, it is one of the most common forms of genetic epilepsy. With an incidence of 1 in 40-60,000 live births, no one country has sufficient patients to support a RWD registry to facilitate CDD research. The multilingual global CDKL5 Registry was launched by Pulse Infoframe in 2018 for a collaborative initiative by the LouLou Foundation (a UK non-profit) and the Orphan Disease Center (University of Pennsylvania). Data in the areas of genetics, seizures, sleep, gastrointestinal disturbances, diet responses, and treatment outcomes are collected for research and pharmaceutical development. In 2021 a novel global unique identifier (GUID, HIPAA and GDPR compliant) was integrated into the Pulse Infoframe registry platform enabling linkage to patient data collected from the CANDID observational end point study (NCT05373719), resulting in broader dataset to answer more nuanced questions around disease progressions, such as those based on geographic location and social health determinants. For drug development, linking data through a GUID impacts regulatory, pricing, and reimbursement-related decisions. This RWD has been leveraged by 7 pharmaceutical companies. This is an example of how a patient registry can provide the impetus for the development of novel end points to support future drug development and illustrates the importance of advocates, academics, biotech/pharma and technology/data experts building on real-world data to accelerate drug development opportunities.

PO31. Targeted Review of CADTH Reimbursement Reviews for Recommendations Citing Clinical Relevance Limitations

Presenting Author: Sumeet Singh, EVERSANA; Tim Disher, CRG-EVERSANA

Co-Authors: Elizabeth Halloran, EVERSANA; Michaela Spence, CRG-EVERSANA

The objective of this targeted review was to assess recently published CADTH reimbursement reviews for discussions of limiting factors related to clinical relevance, across various disease areas.

Initial and final recommendations for Common Drug Review (CDR) and pan-Canadian Oncology Drug Review (pCODR) projects posted from January 1, 2018 until December 5, 2022 were reviewed by a single reviewer. The most recent recommendation was extracted for all projects, in addition to any comments regarding the limitations of submitted evidence.

A total of 321 distinct projects were identified (145 from pCODR and 176 from CDR). Overall, 18% of these pCODR projects and 12% of these CDR projects were noted to possess key limitations regarding clinical relevance. Within these groups, negative reimbursement recommendations were more common for pCODR projects (93%) than CDR (67%), largely due to the centrality of outcomes directly implicated. For pCODR projects, reviewers often cited major issues resulting from single-arm trial designs, post hoc analyses, and limitations of submitted ITCs. For CDR projects, notable issues often pertained to a lack of defined minimal clinically important difference (MCID) for specific outcomes in the literature, or short-term clinical evidence.

These findings indicate that it is a fairly common occurrence for issues of unclear clinical relevance to be noted within negative recommendations, across CDR and pCODR projects. Potentially, additional research is needed across disease areas to more rigorously define the extent to which any limitations in defining clinically relevant benefits of novel drugs should impact overall CADTH reimbursement recommendations.

PO32. Canadian Real-World Evidence for Value of Cancer Drugs (CanREValue) Collaboration: Application of Multi-Criteria Decision Analysis to Prioritize Re-Evaluations of Cancer Drug Funding Decisions

Presenting Author: Marc Geirnaert, CancerCare Manitoba

Co-Authors: Pam Takhar, CanREValue Core Team, CanREValue; Working group members, CanREValue Collaboration

CanREValue developed a multi-criteria decision analysis (MCDA) rating tool to help decision-makers evaluate uncertainties and prioritize potential real-world evidence (RWE) projects stemming from initial drug funding decisions. The tool considers seven factors relevant to the importance and feasibility of conducting an RWE project. In collaboration with the Provincial Advisory Group (PAG) of CADTH, we conducted a 1-year validation exercise to (1) gain insight into consensus building and deliberation processes, (2) develop efficiencies in the application of the MCDA rating tool, and (3) apply the tool to various RWE proposals.

Eleven pan-Canadian experts involved with cancer drug funding decision-making were invited to form the MCDA committee. Members reviewed evidence questions and applied the MCDA rating tool prior to meetings. During the meeting, an experienced facilitator led the committee through consensus building, deliberation, and prioritization. Members provided feedback during and following meetings.

Members participated in five meetings and reviewed/prioritized nine RWE questions initially identified as high priority by PAG. Through the explicit application of the MCDA rating tool, projects were prioritized low (4), medium (3) or high (2). Although members found the tool easy to use, several modifications were suggested to improve usability and increase clarity on criterion instructions, rating descriptions, and prioritization categories. The expertise and specific knowledge of the facilitator was noted to evoke thoughtful discussion and supported the achievement of consensus among members.

Several efficiencies and refinements to the MCDA rating tool were identified and will help to facilitate the integration of the tool into existing cancer drug funding processes.

PO33. Key Factors for Consideration When Using Indirect Treatment Comparisons in Canadian Reimbursement Submissions — What Have We Learned in the Last Four Years?

Presenting Author: Nicolas Iragorri, McKesson Canada

Co-Authors: Tuhin Maity, PDCI Market Access - McKesson Canada; François-Xavier Houde, PDCI Market Access - McKesson Canada

Background: Indirect treatment comparisons (ITCs) are common in Health Technology Assessments (HTAs), as head-to-head comparative data are often not available. A CADTH review in 2018 identified multiple limitations, mainly around the heterogeneity of patient and study characteristics in sponsor's submissions that had been informed by ITC.

Objective: The objective of this study is to update and expand upon the 2018 review by CADTH to identify how ITCs have been critically appraised by CADTH in the past four years and how the feedback can be used to improve future submissions informed by ITCs.

Methods: We conducted a review of all CADTH reimbursement reviews between 2018-2022. This update included all CADTH submissions not captured by the previous review. Two independent reviewers screened all reimbursement reviews and extracted the following characteristics: (i) year of the submission; (ii) generic name; (iii) brand name; (iv) manufacturer; (v) therapeutic area; (vi) rare disease; and (vii) type of economic evaluation. Additionally, the following details regarding ITCs were captured: (i) was an ITC included for treatment effects?; (ii) type of ITC analysis (e.g., NMA, matching-adjusted); (iii) ITC-related limitations; (iii) final recommendation. These data were narratively synthesized.

Results and Significance: The results of this study will present the proportions of submissions with ITCs in the past four years for all therapeutic areas and will identify and elaborate the issues that are frequently criticized by CADTH. Limitations and key areas of improvement will be presented to help inform potential sponsors best practice guidelines for using ITCs in Canadian reimbursement submissions.

PO34. Rapid Scoping for Broad and Emerging Topics: CADTH's Experiences With Scoping Reviews to Inform Health Care Decision-Making

Presenting Author: Chantelle Lachance, CADTH; Yi-Sheng Chao, CADTH

Co-Authors: Gino De Angelis, CADTH; Joanne Kim, CADTH

A scoping review is a type of evidence syntheses that can be used to identify and map research findings and inform future research. For 2 recent projects on broad and emerging health system topics, virtual health care and post□COVID-19 condition, CADTH engaged in variations of the traditional scoping review to quickly gain an understanding of the literature. In one, we conducted rapid scoping to quickly identify the existing evidence and guidance on virtual health care for all types of health care services and in all populations.

In the other, we conducted rapid living scoping to continually map out the current evidence landscape on the treatment and management of post‐COVID-19 condition and to identify evidence gaps. We use a case study approach to illustrate how 2 rapid scoping projects balanced the needs of the end user to produce timely results while maintaining scientific integrity at each phase of the study. We also discuss how these methods can showcase evidence in a novel and interactive way, may reduce duplication of efforts, and can be used immediately to broker existing work and inform additional projects and impactful, downstream health technology assessment work. From the success of both initiatives, we expect scoping reviews will continue to inform CADTH work in broad topic areas. Based on the barriers encountered, solutions attained, and lessons learned from both scoping projects, we will provide recommendations for other researchers and health care decision-makers who plan to embark on similar types of rapid scoping work.

PO35. Use of ActionADE for Reporting and Communication of Adverse Drug Events Bringing Patients to Hospital

Presenting Author: Amber Cragg, University of British Columbia

Co-Authors: Corrine Hohl, University of British Columbia; Serena Small, University of British Columbia; Erica Lau, University of British Columbia

Background: Adverse drug events (ADEs) are a leading cause of unplanned hospital visits, 32.5% are due to repeat events. In collaboration with multiple stakeholders, we designed and implemented ActionADE, a web-based ADE reporting platform. Reports entered in ActionADE are transmitted to the provincial drug dispensation database and used to generate patient-specific flags at community pharmacies upon attempted redispensation of a culprit drug. We identified the potential impact that generating and sharing this information has on patient safety.

Methods: We conducted a multi-centre prospective observational study of ADEs reported into ActionADE in four hospitals in British Columbia between April 1, 2020 and October 31, 2022. We tabulated the characteristics of ADEs bringing patients to hospital and calculated rates of avoided redispensation when ActionADE information was shared with community pharmacies upon attempted refill of the same or same-class medication as one that previously harmed that patient.

Results: Providers reported 3,174 ADEs among 2,730 patients. Almost 30% of ADEs (906/3,174) caused hospitalization, extended hospitalization, were life threatening or resulted in death. During the study period, 592 patients had >1 report transmitted to the provincial drug database and 200 (33.8% 200/592) of these patients attempted redispensation of the culprit or a same-class drug. Redispensation was avoided in 32.0% (64/200).

Interpretation: ActionADE is the first reporting platform that communicates ADE reports via a central drug database to other providers in patient's circle of care. For every ten patients with ActionADE report information shared, one re-exposure to a culprit or same-class drug was avoided.

PO36. Leveraging Collaboration and Technology for Quality Improvement in a Future-Ready Health System

Presenting Author: Rhonda Shkrobot, Alberta Health Services; Robin Scheelar, Alberta Health Services

Implementing a province-wide electronic clinical information system (CIS) provides important opportunities for leveraging new technologies to achieve quality improvement goals, including increased formulary adherence. An electronic CIS enables greater collaboration with a broad range of stakeholders, embedding of evidence at the point of prescribing, conduct of real-time audits, and influencing prescribing to optimize drug use.

To improve formulary adherence for ondansetron oral disintegrating tablet (ODT), electronic CIS sites were audited, determining drivers of ODT prescribing. To increase front-line knowledge and confidence in assessing clinical situations for appropriate use of ondansetron ODT, we raised awareness of formulary restrictions, developing and implementing educational tools and resources, engaging Clinical Nurse Educator and CIS governance groups, collaborating with order set owners and content committees to remove the ODT formulation from electronic ordering tools, and with pharmacy site operations to remove ondansetron ODT from ward stock and automated dispensing cabinets (ADCs).

Drivers of non-adherence include historical and established practice, ready availability via order sets, and lack of awareness of bioavailability and cost differences between dosage forms. Reluctance from prescribers, nursing staff and order set owners to remove the ODT formulation from CIS order sets due to potential increased workload presented challenges, and competing organizational priorities affected the progress of this work. There is also a delayed impact at non-CIS sites.

We engaged 13 distinct stakeholder groups, successfully removing ondansetron ODT from 93 CIS order sets. So far, approximately 60 sites have been advised to remove ondansetron ODT from applicable ward stock areas and ADCs.

PO37. The PSY-SIM Model: Using Real-World Data to Inform Health Care Policy for Individuals With Chronic Psychotic Disorders

Presenting Author: Petros Pechlivanoglou, The Hospital for Sick Children

Co-Authors: Joyce Mason, Centre for Addiction and Mental Health; Paul Kurdyak, Center for Addiction and Mental Health; Tomisin Iwajomo, Centre for Addiction and Mental Health; Frances Simbulan, The Hospital for Sick Children; Linda Luu, The Hospital for Sick Children; Claire De Oliveira, Centre for Addiction and Mental health

In times of limited health care resources, it is of paramount importance to make informed decisions about resource allocation. Microsimulation models are useful tools to estimate the behavioural and economic effects of health interventions, such as smoking cessation, and help guide decision-making. However,

few microsimulations have been developed for chronic psychotic disorders, severe and disabling mental disorders associated with poor outcomes and high costs of care. Using administrative health records and survey data from Ontario, a dynamic microsimulation model – the PSY-SIM model – was developed to simulate health and cost outcomes of individuals with chronic psychotic disorders, to help guide and inform health care policy. This model was then used to examine the impact of a smoking cessation initiative – the Smoking Treatment for Ontario Patients (STOP) program – on the development of chronic conditions, life expectancy, quality of life, and lifetime health care costs. Based on model results, we estimated that individuals with chronic psychotic disorders have a lifetime risk of 63% and 49% for cardiovascular and respiratory diseases respectively, 51% for diabetes and cancer and a life expectancy of 75.4 years (6 years lower than the Ontario general population). Smoking cessation initiatives targeted at individuals with chronic psychotic disorders can reduce chronic morbidity and lead to survival and QoL gains (0.018 QALYs) with a modest increase on health care costs (CAD$430) and an incremental cost-effectiveness ratio of $23,800/QALY. These findings will be relevant for decision-makers and clinicians looking for cost-effective solutions to address smoking cessation among individuals with chronic psychotic disorders.

PO38. Factors Including Real-World Evidence That Play a Role in the Final HTA Recommendation of Oncology Drug Submissions Based on Phase II and/or Single-Arm Trial Data

Presenting Authors: Ingrid Liu, Roche Canada; Siddhi Manjrekar, Roche Canada; Kaushik Sripada, Roche Canada; Yuti Patel, Roche Canada

Objective: Perform a descriptive analysis to understand influential factors including RWE in Canadian health technology assessment (HTA) decision-making when assessing oncology submissions with phase II / single-arm trial data.

Methods: Oncology submissions to the Canadian Agency for Drugs and Technologies in Health (CADTH) that contained phase II / single-arm trial data between 2018 and 2022 were obtained and analyzed from the CADTH website. Information from the final recommendation, clinical, and economic reviewers' reports was used to determine factors that likely influenced HTA recommendations.

Results: A total of 34 submissions were identified between 2018-2022. Of these, 20 (59%) received a positive recommendation (i.e., list or list with conditions) while 14 (41%) received a negative recommendation (i.e., do not list). 85% of positive recommendations recognized a net clinical benefit despite uncertainty. Files with negative recommendations noted high uncertainty in net clinical benefit and a majority of these noted that conducting a phase 3 trial was feasible. Of the 10 submissions that used RWE, 9 used international data sources while 1 used Canadian data. 8 of these received a positive recommendation, while 2 received a negative recommendation. Mostly, RWE was used to inform comparative efficacy.

Conclusions: Positive net clinical benefit and infeasibility of conducting a Phase III clinical trial were associated with positive recommendations for phase II/single-arm trial data. Analyses using RWE were

critiqued and often noted to be interpreted with caution. It is unclear whether the inclusion of RWE was sufficient to mitigate uncertainty in HTA decision-making.

PO39. CAR T-Cell Therapy for Diffuse Large B-Cell Lymphoma in Canada: a Cost-Utility Analysis

Presenting Author: Lisa Masucci, Toronto Health Economics and Technology Assessment Collaborative

Co-Authors: Feng Tian, Univeristy of Waterloo; Kelvin Chan, Sunnybrook Health Sciences Center; William W.L. Wong, University of Waterloo

Background: Chimeric antigen receptor (CAR) T-cell therapy is a novel cell therapy for treating non-Hodgkin's lymphoma. The development of CAR T-cell therapy has transformed oncology treatment by offering a potential cure. However, due to the high cost of these therapies, and the large number of eligible patients, decision-makers are faced with difficult funding decisions. Using recent clinical trial evidence, our objective was to assess the cost-effectiveness of axicabtagene ciloleucel (axi-cel) for adults with relapsed/refractory Diffuse large B-cell lymphoma in Canada.

Methods: We developed a system-level individual-simulated discrete event simulation model to assess the costs and quality-adjusted life-years (QALYs) of axi-cel compared to salvage chemotherapy. A Canadian health care payer perspective was used and outcomes were modelled over a lifetime horizon. Costs and outcomes were discounted at 1.5% annually, with costs reported in 2021 Canadian dollars. A probabilistic analysis was used, and model parameters were varied in one-way sensitivity analyses and scenario analyses.

Results: Axi-cel led to an additional cost of $491,852 and additional effectiveness of 4.66 QALYs, with an incremental cost-effectiveness ratio of $105,548 compared to salvage chemotherapy. At a willingness-to-pay threshold of $100,000/QALY, axi-cel had a 41.6% likelihood of being cost-effective. The model results were sensitive to the time horizon, the age of the cohort, discount rate, cost of the therapy, and the utility of the progression-free health state.

Conclusions: At the current drug price, axi-cel was found not to be cost-effective, however, these results heavily depend on assumptions regarding long-term survival. Further real-world evidence is needed to reduce uncertainty.

PO40. Cost-Effectiveness of Genetic Carrier Screening Programs for Cystic Fibrosis, Fragile X Syndrome, Hemoglobinopathies Including Thalassemia, and Spinal Muscular Atrophy in Ontario

Presenting Author: Olga Gajic-Veljanoski, Ontario Health

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Background: Genetic carrier screening for cystic fibrosis, fragile X syndrome, hemoglobinopathies including thalassemia, and spinal muscular atrophy is available in Ontario based on risk status; however, there is variation in access to screening. We examined the cost-effectiveness of carrier screening programs for these conditions to improve outcomes and access to testing.

Methods: We developed probabilistic decision tree short-term models for preconception or prenatal carrier screening. We compared health outcomes and costs of four strategies (universal or risk-based screening with either single-disease panels or a hypothetical expanded [multi-disease] panel) with no screening, from the public-payer perspective. Lifetime state-transition models explored the cost-utility of carrier screening programs (QALYs and costs discounted at 1.5%).

Results: Compared with no screening, preconception or prenatal carrier screening identified more at-risk pregnancies, provided more reproductive choices, and had higher costs ($17-$660). Universal screening with single-disease panels was the preferred strategy for preconception or prenatal testing, but incremental differences in health outcomes were small (e.g., the incremental cost-effectiveness ratios [vs. no screening, preconception]: $29,106/additional at-risk pregnancy detected, and $367,731/ affected birth averted). The cost-utility analyses, accounting for program- and treatment-related costs, showed that the carrier screening programs were associated with small changes in QALYs (0.008-0.017) and cost savings (e.g., preconception programs: $635-$754 with standard, $5,275-$6,036 with novel therapies), which were the largest with universal programs.

Conclusion: Universal genetic carrier screening of the given conditions is potentially cost saving. However, there is uncertainty in the estimated costs of carrier screening programs in Ontario that warrants further study about the implementation pathway.

PO41. A National Vasculitis Patient Survey on Barriers to the Access and Use of Medications

Presenting Author: Kareena Nanda, University of Alberta

Co-Authors: Katharina Kovacs Burns, Alberta Health Services; Jon Stewart, Vasculitis Foundation Canada; Elaine Yacyshyn, University of Alberta

Background: Vasculitis is a group of rare autoimmune conditions that can result in increased rate of hospitalization due to life-threatening complications. Glucocorticosteroids, DMARDs, and newer biologics have improved the outcomes for vasculitis, however, accessibility and adherence are challenges with the use of these medications.

Objective: To explore patient perspectives on barriers to the access and use of medications for the treatment of vasculitis.

Methods: Participants were recruited from the Vasculitis Foundation Canada for an online survey. Descriptive analysis was performed.

Results: Of 76 respondents, 45% (n=34) reported barriers to accessing/using medications. Rituximab was cited as a medication of concern by 44% (n=15) of patients, with limited access due to poor insurance coverage being the most frequent concern (53%, n=8). Regarding insurance coverage, 75% (n=56) of all participants had a drug coverage plan. Sixty-eight percent of respondents (n=42) reported their drug plan excluded or limited the use of certain medications. Other challenges with the use of biologics were out-of-pocket cost, side effects, and the route of administration (i.e., infusions). Glucocorticosteroids (26%, n=9), methotrexate (21%, n=7), and azathioprine (15%, n=5), were also associated with challenges, with 100% of patients describing the adverse effects of these medications. Qualitative assessment of patient perspectives revealed a lack of counseling on side effects and low evidence on medication effectiveness as common themes.

Conclusion: Several system-level and patient-related barriers to the use of DMARDs, new biologics, and glucocorticosteroids were identified and can be used as targets for improved advocacy and counseling for patients on medication use.

PO42. Clinical Utility of Secondary Findings from Genomic Sequencing: a Systematic Review

Presenting Author: Chloe Mighton, St. Michael's Hospital

Co-Authors: Salma Shickh, St. Michael's Hospital; Vanessa Rokoszak, St. Michael's Hospital; Simran Dhaliwal, University of Western Ontario; Safa Majeed, University of Toronto; Vernie Aguda, St. Michael's Hospital; Sonya Grewal, St. Michael's Hospital; Anges Sebastian, University of Toronto; David Lightfoot, St. Michael's Hospital; Yvonne Bombard, University of Toronto

Background: Genomic sequencing is diffusing into clinical care, but secondary findings (SFs, variants unrelated to the primary indication) complicate adoption and reimbursement decisions. It is unclear whether returning SFs will lead to health benefits through early detection or prevention, or to overdiagnosis and overtreatment. Evidence synthesis is needed to understand SFs' clinical impacts and inform health technology assessment. Objective: To systematically review and synthesize evidence on the clinical utility of SFs.

Methods: A systematic review is being conducted (PROSPERO: CRD42021254662). Databases were searched in June 2021. Two reviewers screened articles. Data extraction and quality assessment are ongoing, performed by two reviewers. Preliminary, descriptive results are reported here; meta-analyses are planned.

Preliminary Results: The search identified 4,502 articles; 4,288 were excluded at title/abstract screening and 126 at full-text screening, leaving 88 included articles. Among 87 studies, SFs were identified in 0.25% to 100% of participants. This varied across types of SFs, e.g., 0.25% to 8% of participants had medically actionable findings, while 64% to 100% had results associated with drug response. A subset of patients with SFs (0% to 55%, 29 studies) had clinical features or a family history suggestive of the associated disorder. SFs led to changes in clinical management including referrals (22%-100% of participants with SFs, 3 studies), surveillance (8%-31% of participants with SFs, 5 studies), or medication changes (8%-14% of participants with SFs, 2 studies).

Preliminary Conclusions: In a subset of patients, SFs have utility for explaining a personal or family medical history, or for informing clinical management. Evidence is needed on longer-term outcomes.

PO43. Economic Costs of Medical Evacuation and Transportation of Indigenous Peoples who Travel for Obstetric Care in Canada: a Systematic Review

Presenting Author: Majd Radhaa, Western University

Co-Authors: Jennifer Leason, University of Calgary; Aisha Twalibu, Western University; Erin Davis, University of Calgary; Claire Dion Fletcher, National Aboriginal Council of Midwives, Toronto Metropolitan University; Karen Lawford, Queen's University; Liz Darling, McMaster University; Ava John-Baptiste, Western University

Background: First Nations and Inuit pregnant people living on reserves or in rural and remote areas of Canada are required to travel to urban centres once their pregnancy reaches 36 to 38 weeks gestation, then await labour and birth. Research has demonstrated the harms of this approach causing emotional, physical, and financial stress.

Methods: We conducted a systematic review of the literature to identify costs of evacuation and transportation for obstetric care. We searched PubMed, Embase, CINAHL, HealthStar ScienceDirect, PROSPERO, and Cochrane Database of Systematic Reviews up to September 12, 2022. Only studies set in Canada were included. Two reviewers independently assessed citations for inclusion. We abstracted costs

in the following Canadian Agency for Drugs and Technologies in Health guideline categories: costs to the publicly funded health care payer, government payer, patients and informal caregivers, and productivity costs. All costs were converted to 2022 Canadian dollars using the Consumer Price Index.

Results: 891 unique citations were assessed during level 1 screening and 49 studies assessed during level 2 screening. Of the 4 studies included thus far, 3 provided estimates of costs to the government payer. Travel cost estimates ranged from $90 to $17,000, with medical evacuation in Northern communities being especially costly. Only 1 of 4 studies estimated costs to patients and informal caregivers, with partner's travel expenses reaching $2,300. No studies provided estimates of productivity costs.

Conclusion: Despite the tremendous burden of obstetric evacuation on First Nations and Inuit, the costs to patients and caregivers are poorly understood.

PO44. Collaborative Implementation of eMental Health and Addictions Services in Nova Scotia

Presenting Authors: Danielle Impey, Mental Health Commission of Canada; Melanie Caulfield, Nova Scotia Health

Stepping Together for Digital Mental Health and Addictions Services is the result of a 2-year quality improvement partnership with NSH's Mental Health and Addictions Program (MHAP), Stepped Care Solutions (SCS) and Mental Health Commission of Canada (MHCC), and other key collaborators including community partners and lived expertise, to bring recovery-oriented, eMental (eMH) Health and Addictions services into the provincial stepped care model of service delivery. The main goals of this collaborative project were to deliver new eMH services within a stepped care continuum, build awareness through engagement and communication, and to strengthen connections with partners. The project achieved these goals, and the approach and highlights will be shared within the session. Through strong interdisciplinary planning approaches, cross sector collaboration, knowledge exchange and strategic partnerships, the project achieved significant system transformation and greater scale than ever in access to MH&A supports to Nova Scotians along a stepped care continuum.

PO45. Reconnecting with GENIE: Evaluating the Impact of a Telecommunications Platform on Social Isolation Experienced by Older Adults Living in Long-Term Care in New Brunswick

Presenting Authors: Ashley Crawford, The Centre for Innovation and Research in Aging; Megan Plant, The Centre for Innovation and Research in Aging

Co-Authors: Justine Henry, The Centre for Innovation and Research in Aging; Odette Gould, Mount Allison University; Marc Kanik, Ambient Activities

Social isolation and loneliness experienced by older adults living in long-term care facilities (LTCF) are not new, and unfortunately, the COVID-19 pandemic has only worsened these problems. The compounding effect of New Brunswick's aging population and the devastating repercussions of the COVID-19 pandemic result in an urgent need for a technological platform allowing older adults to connect with their loved ones. This study aimed to implement and evaluate a telecommunications platform (GENIE) specifically designed for older adults in a subset of urban and rural LTCF in New Brunswick. This easy-to-use platform allows older adults to receive and respond to voice and text messages, as well as photos, videos and other digital materials sent by family and friends.

Using a longitudinal mixed-methods design, we assessed the impact of GENIE on social isolation, loneliness, mood, health and sense of belonging. We recruited 38 older adults and their families as GENIE users, with older adults at matched LTCF serving as experimental controls. Data were collected over a 6-month period, with surveys and interviews conducted with older adult GENIE users, their families, and long-term care center staff in order to determine impact and acceptability of the intervention. Preliminary quantitative and qualitative findings are presented using pre- and mid-intervention data.

This study is set to finish in May 2023, with the final results of this project aimed to provide a framework for using GENIE in different environments (such as hospitals, community centers and in the community) both during emergencies and as a regular practice.

PO46. Renal Mass Ablation: Cost-Effectiveness Analysis to Compare Biopsy in Advance of Ablation Versus Simultaneous Biopsy and Ablation

Presenting Author: Alexandru Florea, Schulich School of Medicine and Dentistry

Co-Authors: Greg Zaric, Ivey School of Business; Ziru Kang, Western University; Derek Cool, London Health Sciences Centre

Purpose: Small renal masses (SRM, ≤ 4 cm) are increasingly being treated with percutaneous ablation. While most SRMs are malignant, up to 20% are benign based on large nephrectomy databases. Pathology methods have become more effective at distinguishing benign and malignant disease. There is a need for cost-effectiveness analysis on whether a diagnostic biopsy should be used to inform the need for percutaneous ablation or be performed concurrently with the ablation to guide follow-up management.

Methods: A decision-analytic model was developed with the base case being a cohort of 65-year-old male patients with SRMs. Health care cost and utility values were determined from public databases, published literature, or local hospital estimates converted to 2022 Canadian dollars. The primary outcome was the incremental cost-effectiveness ratio (ICER), at a willingness-to-pay threshold of $100,000 per quality-adjusted life-years (QALYs) gained. Sensitivity analysis was done over the range of sensitivity (0.78 to 1, base case 0.95) and specificity (0.75 to 1, base case 0.95) values of core needle biopsy in the literature.

Results: In the base case, biopsy first resulted in an incremental saving of $1,750 and a gain of 0.01 QALY relative to concurrent biopsy and ablation. Biopsy first is no longer cost-saving at a biopsy sensitivity below

0.84 (ICER $49,952/QALY for a sensitivity of 0.78, becoming dominant above a sensitivity of 0.91). Biopsy first is the dominant strategy throughout the range of specificity values.

Conclusion: This analysis suggests that for SRMs, diagnostic biopsy prior to percutaneous ablation is cost-saving. These results are sensitive to biopsy sensitivity.

PO47. Early Health Technology Assessment Frameworks: a Rapid Review and Roadmap to Guide Applications

Presenting Author: Nicola Kopac, University of British Columbia

Co-Authors: Nick Dragojlovic, University of British Columbia; Elisabet Rodriguez, University of British Columbia; Llorian, University of British Columbia; Louloua Ashikhusein Waliji, University of British Columbia; Kristina Michaux, University of British Columbia; Fernanda Nagase, University of British Columbia; Prof. Larry Lynd, University of British Columbia

Background: Early health technology assessment (eHTA) can be used to inform the value proposition and go/no-go decisions for medical products throughout the development life cycle. Health economic modelling, literature scanning, and stakeholder preference studies are some of the common research methods employed in eHTA. However, consolidated guidance on when and how to conduct this complex, iterative, and multidisciplinary process is lacking.

Methods: We undertook a rapid literature review to identify literature published before February 2022 that described eHTA frameworks for use in the pre-clinical and early clinical (phase I) stages of medical product development.

Results: We selected 131 publications for full-text review from 965 articles identified. In total, 53 articles describing 46 discrete frameworks were included. Frameworks were classified into three categories based on their scope: 1) criteria frameworks, which provide an overview of eHTA; 2) process frameworks, which offer stepwise guidance for conducting eHTA, including preferred methods; and 3) methods frameworks, which provide detailed descriptions of specific eHTA methods. Despite the heterogeneity across eHTA frameworks, they consistently featured concepts like unmet medical need, mapping out care and reimbursement pathways, and assessing clinical differentiation from the standard of care. Notably, we found that “target assessment” frameworks published by leading biopharmaceutical companies have not been captured by previous reviews of eHTA, despite significant overlap.

Conclusions: Barriers to the broader adoption of eHTA remain, including inconsistent terminology, limited accessibility to knowledge users, poor distinctions about early life cycle stages and technology types, and the lack of a standard eHTA definition and accompanying framework.

PO48. Pipeline Trends Shaping the Future of Drug Development

Presenting Author: Allison Carey, Patented Medicine Prices Review Board

Background: The past few years have disrupted drug development. The pharmaceutical and health care industry pivoted toward COVID-19 treatments and vaccines to kick-start halted economies, which delayed other clinical trials. Transformative technology and drug innovation have widely become the focus of development. This analysis explores key trends shaping the future of drug development.

Approach: This analysis examines new medicines in phase I, phase II, phase III, and pre-registration with clinical trials in Canada, the US, and Europe. GlobalData is the primary data source for this study, in addition to online databases from Health Canada, the US FDA, and the EMA. International markets examined include the US and geographic Europe (excluding Russia and Turkey).

Results: As of November 2022, the pipeline contained nearly 11,000 new medicines, compared to just under 8,500 the year before. Oncology continues to dominate the pipeline, representing roughly one-third (35%) of medicines in all phases. Infectious disease treatments hold the second largest share at 14%, due to the increased focus on COVID-19 treatments and vaccines. One-third (33%) of medicines in Phase III and pre-registration have an early orphan designation approved through the FDA or the EMA, which is consistent with the increasing prevalence of orphan-designated medicines entering the pharmaceutical market. As of November 2022, Health Canada was reviewing 80 new drug submissions, down slightly from almost 90 last year.

Conclusion: Recent trends in drug development include increased number of biosimilars in late-stage development, gene therapies expanding to conditions with larger populations, and new oncology innovation that has the potential to introduce competition for current top-sellers.

PO49. Clinical Outcomes and Health System Costs Associated with Leukemia and Lymphoma in Ontario: a Population-Based Observational Study

Presenting Author: Anubhav Agarwal, Ottawa Hospital Research Institute

Background: Approximately, 19,150 Canadians are projected to have been diagnosed with leukemia or lymphoma (L/L) in 2022. Advances in the treatments of cancer have led to a marked increase in L/L survival rates. Recently, immunotherapy-based treatments are being aggressively proposed for certain types of L/L, albeit at a very high cost to the health system. Is it wise to publicly fund such expensive therapies, or should the health system's limited resources be spent elsewhere? Answering this question requires an understanding of currently offered treatments for L/L, and their associated clinical outcomes and health system costs.

Objectives: 1) Describe the patterns of care and clinical outcomes of L/L; 2) Estimate the overall health system costs associated with L/L care from a health care payer's perspective; 3) Estimate attributable all-cause mortality and net health system costs of L/L care.

Methods: The study will utilize Ontario health and administrative databases and comprises patients who were diagnosed with L/L as primary cancer between January 1, 2005, and December 31, 2020. The matched

sample of controls will be randomly selected from the Registered Persons Database. Propensity score methods will be used to estimate the net costs and net survival.

Expected results: The results of this study would inform health care providers in predicting and communicating the likely trajectory of care for L/L patients, aid decision-makers in planning resources for cancer care facilities based on current L/L cases and present a more complete picture to researchers attempting to mitigate the health and cost burdens of L/L in Canada.

PO50. What Drives CADTH's Conclusions on Cost-Effectiveness: a Qualitative Assessment of CADTH Drug Reimbursement Reviews

Presenting Author: Reuben Douma, CADTH

Co-Authors: Ramon Brown, CADTH; Alex Haines, CADTH

Introduction: Health economics at CADTH contributes to the sustainability of Canada's health care system by providing objective, independent advice on the cost-effective allocation of limited health care resources. CADTH appraises sponsor-submitted economic evaluations and, where necessary, performs reanalyses in line with best methodological practices and clinical expert advice to provide a robust assessment of cost-effectiveness of new health care drugs and technologies. We sought to qualitatively analyze changes made to sponsor-submitted economic evaluations to derive CADTH base case results.

Methods: We reviewed all cost-utility analysis (CUA) submissions sent to CADTH's Drug Reimbursement Review since October 2020 for oncology and non-oncology products that received a final recommendation by December 2022. The incremental cost-effectiveness ratios (ICERs) were extracted from sponsor and CADTH reanalyses and compared across products that received positive recommendations from the expert committees. Common limitations across sponsor submissions were identified and explored further.

Results: A total of 38 oncology and 50 non-oncology CUAs were completed within the study time period. Key themes that emerged from the review that drove discrepancies between the sponsor results and CADTH reanalysis results included uncertainty around comparative clinical efficacy, time-to-event and survival extrapolations, assumptions regarding long-term efficacy of treatment, and choice of utility values.

Conclusions: This work increases the transparency into what influences CADTH's reanalysis of economic evaluations and, therefore, conclusions on cost-effectiveness. This will enable relevant stakeholders to prioritize the most prominent issues affecting cost-effectiveness in decision-making.

PO51. Traduction française de la version 2022 des directives pour la communication du CHEERS (Consolidated Health Economic Evaluation Reporting Standards)

Presenting Author: Jason Guertin, Université Laval

Co-Authors: Élodie Bénard, Centre de recherche du CHU de Québec-Université Laval; Marie-Claude Aubin, Roche; Vakaramoko Diaby, Otsuka Pharmaceutical Companies; Alice Dragomir, Montreal University; Eric Latimer, McGill University; Prof. Jean-Eric Tarride, McMaster University; Don Husereau, University of Ottawa

Introduction : Les directives pour la communication du CHEERS (Consolidated Health Economic Evaluation Reporting Standards) représentent les directives officielles dans le domaine de l'évaluation économique en santé. Révisées en 2022 dans leur version originale anglaise, aucune traduction française n'est actuellement disponible. L'objectif de ce projet était ainsi de produire cette version.

Méthodes : Un groupe de sept professionnels bilingues et possédant une expertise en évaluation économique et pharmacoéconomie a été formé afin de participer au processus de traduction. Une approche ascendante et descendante a été utilisée, à laquelle s'ajoutait une étape d'évaluation de la comparabilité du langage et de la similarité de l'interprétation entre la version originale anglaise et la version française de chacun des items. Une ébauche préliminaire de la traduction a été produite par consensus puis soumise pour commentaires à un panel d'experts anonyme, pour ensuite réaliser la version finale.

Résultats : Respectant les étapes indiquées de l'approche retenue, les 28 items compris dans la version 2022 du CHEERS ont été traduits et ont été approuvés de manière consensuelle par les experts ayant participé au processus. L'évaluation qualitative subséquente des traductions par le panel d'experts externe a amené certaines modifications à quatre items, à la suite d'une validation par nos sept experts.

Conclusion : Nous fournissons une traduction française des 28 items compris dans la version 2022 des directives pour la communication CHEERS. Cette traduction aidera à améliorer la transparence des évaluations économiques en santé entreprises au sein de la francophonie.

PO52. Perceptions of Professionals, Relatives, and Users about Children and Adolescents' Mental Health Crisis Intervention: a Qualitative Systematic Review

Presenting Authors: Nathalia Nakano Telles, University of Sao Paulo; Marilia Mastrocolla de Almeida Cardoso, Sao Paulo State University

Co-Authors: Prof. Márcia Aparecida Ferreira de Oliveira, University of Sao Paulo; Prof. Heloísa Garcia Claro Fernandes, State University of Campinas; Nathalia dos Santos Cruz, University of Sao Paulo

Mental health care specifically for children and adolescents is considerably recent in human History. Considering that mental illness in childhood and adolescence impacts adulthood, considering that

many mental health issues start in these life phases and that the mental health crisis intervention has a fundamental role in better prognostics, this presentation aims to present the preview results of a systematic review that intends to review, synthesizes and categorizes the perception of involved subjects in mental health crisis intervention for children and adolescents – mental health professionals, relatives, and users – in hospitals and mental health community services. The systematic review will follow the JBI methodology. Data collection was done in seven databases and grey literature research was made as well. The studies were selected according to inclusion and exclusion criteria. Studies in Portuguese, English, and Spanish were accepted and there was no time delimitation. PRISMA method was used. Critical Appraisal Skills Program Qualitative Research Checklist is being applied to assess the included studies.

PO53. Spasticity Treatment Patterns in Long-Term Care Using Ontario Real-World Evidence

Presenting Author: Cathy Vo, AbbVie

Co-Authors: Sandrine Aderian, AbbVie

Background: Focal spasticity affects up to 1 in 3 residents in long-term care (LTC), with potentially disabling consequences. Data are limited on access to care for patients requiring botulinum toxin (BoNT) treatment in LTC.

Methods: This retrospective, observational, real-world study was conducted using the Ontario Drug Benefit claims database. Patients with ≥1 medical claim for BoNT for focal spasticity treatment were selected, and those residing in LTC were further identified. Data were analyzed for the utilization (2000–2019), treatment rate, and time-to-treatment with BoNT in LTC residents (2015–2019).

Results: Over a 10-year period, the number of patients receiving BoNT for spasticity increased 7-fold and the proportion of patients residing in LTC versus community increased from 43% (2010) to 52% (2019). Of the LTC residents eligible for BoNT treatment, 33% received BoNT in 2015 compared with 63% in 2019. Injections/patient/year increased from 1.9 (2010) to 3.1 (2017). Following LTC admission, median time to first injection was 2.9 years.

Conclusion: In this study, approximately 40% of eligible LTC residents in Ontario were not receiving BoNT treatment, and of those who were, median time to first injection was 2.9 years. Future policy considerations should prioritize uniform access to spasticity standards of care for LTC residents.

PO54. When Can an Unanchored Analysis be More Credible Than an Anchored One?

Presenting Author: Sumeet Singh, EVERSANA

Co-Authors: Tim Disher, EVERSANA; Paul Spin, EVERSANA; Ashley Bonner, EVERSANA

Background: Methodological guidance for ITCs of RCTs typically recommend anchored analysis over unanchored analyses, since the latter relies on the assumption of all prognostic variables being balanced or

adjusted. We sought to explore scenarios where unanchored analyses may be more credible than anchored counterparts

Results: Unanchored comparisons (either adjusted or unadjusted) may be more credible than anchored alternatives in three broad scenarios: Chains of evidence are long or travel through studies with variable populations; Events in the shared comparator are rare leading to unstable effect estimates and inappropriately inflated uncertainty intervals; and highly effective comparators have biological/empirical rationale to be stable across patient populations while placebo/control is highly variable. In these situations in mature disease areas where most prognostic variables are known/reported, adjusted (and sometimes unadjusted) unanchored ITCs may be expected to make weaker assumptions than their anchored counterparts.

Conclusions: Despite generally unanimous focus on anchored comparisons are methodologically preferrable, unanchored comparisons may actually make fewer or weaker assumptions in special cases. It is likely inappropriate to maintain a strict hierarchy of ITC methods.

PO55. Projecting the Future Prevalence of Childhood Cancer in Ontario Using Microsimulation Modeling

Presenting Author: Alexandra Moskalewicz, The Hospital for Sick Children

Co-Authors: Sumit Gupta, The Hospital for Sick Children; Paul Nathan, The Hospital for Sick Children; Petros Pechlivanoglou, The Hospital for Sick Children

Background: Health technology assessments (HTA) and economic evaluations often require information about the incident/prevalent population of interest for model conceptualization and budget impact purposes. Though the prevalence of childhood cancer has been steadily increasing in Ontario, no prevalence projections exist to anticipate future health system demands. To support future HTA assessments, and long-range provincial system planning for acute cancer care and long-term follow-up services, we constructed a population-based, open-cohort microsimulation model to project the incidence and limited-duration prevalence of childhood cancer in Ontario, by cancer type, until 2040.

Methods: We used novel methods to derive microsimulation model inputs, including generalized additive modeling of cancer incidence rates, multi-state parametric survival modeling, and population forecasting. Data sources included health administrative databases, provincial population estimates, and external literature. The model population was updated annually from 1970-2040 accounting for births, deaths, net migration, and incident cases of childhood cancer. One hundred Monte Carlo simulations were run to vary model inputs and generate median health outcomes with 95% credible intervals (CI).

Results: Annual incidence counts are projected to increase by 34% between 2020-2040. In 2040, 24,442 (95% CI: 22,101-25,782) prevalent individuals are projected to be residing in Ontario who were diagnosed in 1970 or later, 87% of whom will be 5-year survivors.

Conclusions: Future directions include hosting the model in an R Shiny application for stakeholder use, incorporating phase-based costs to examine the health system-level economic burden of childhood cancer, and expanding the model to estimate comorbidities and quality of life among the prevalent population.

PO56. Late Mortality Among 5-Year Survivors of Childhood Cancer: a Systematic Review

Presenting Author: Alexandra Moskalewicz, The Hospital for Sick Children

Co-Authors: Benjamin Martinez, University of Toronto; Petros Pechlivanoglou, The Hospital for Sick Children; Sumit Gupta, The Hospital for Sick Children; Paul Nathan, The Hospital for Sick Children

Background: In health economic models that utilize life tables to model mortality, estimates of relative mortality can inform risk of death when long-term disease-specific survival data are not available. Estimates of late mortality (≥ 5 years from diagnosis) have been described in cohorts of childhood cancer survivors but have not been synthesized.

Methods: A systematic review was conducted to assess literature addressing estimates of late mortality (all-cause and cause-specific) among 5-year survivors of childhood cancer. Multiple databases were searched from inception to November 2022 for relevant cohort studies. Outcomes of interest included standardized mortality ratios (SMR), absolute excess risks, and the cumulative incidence of mortality. Risk of bias was assessed using the Newcastle-Ottawa Scale. Between-study heterogeneity precluded meta-analyses.

Results: Twenty-one studies were included. Compared to the general population, cohorts of 5-year childhood cancer survivors had an overall 7.5 (95% confidence interval (CI) 5.4-10.1) to 17.2-fold (95% CI 14.3-20.6) increased risk of all-cause mortality. As time from diagnosis increased, SMRs for all-cause mortality declined but remained consistently elevated. Despite variation in how deaths were categorized, deaths related to the primary cancer and to second malignant cancers were the leading and second leading causes of death, respectively, across most studies.

Conclusion: Five-year survivors of childhood cancer have a statistically significantly increased risk of mortality that remains elevated throughout survivorship. There is a lack of Canadian data on late mortality risk in this population. Pooling individual participant data from these studies could facilitate meta-analysis and further comparison across international cohorts.

PO57. Assessing the Impact of the Slow-Release Oral Morphine Drug Shortages in Ontario: a Population-Based Time Series Analysis

Presenting Author: Shaleesa Ledlie, University of Toronto

Co-Authors: Mina Tadrous, Ontario Drug Policy Research Network; Daniel McCormack, ICES; Tonya Campbell, Ontario Drug Policy Research Network; Pamela Leece, Public Health Ontario; Robert Kleinman, CAMH; Gillian Kolla, Canadian Institute for Substance Use Research; Jes Besharah, Ashley Smoke, Ontario Drug Policy Research Network; Beth Sproule, CAMH; Tara Gomes, Ontario Drug Policy Research Network

Slow-release oral morphine (SROM) is used to manage pain, and increasingly as opioid agonist treatment (OAT). Between 2017 and 2021, several drug shortages occurred for a formulation of SROM (i.e., Kadian©) due to manufacturing issues and increased demand. The purpose of this study was to evaluate the impact of the shortages on treatment discontinuation.

We conducted a retrospective population-based time series analysis of people treated with SROM between January 1, 2014, and December 31, 2021, in Ontario. We used interventional autoregressive integrated moving average (ARIMA) models to evaluate the impact of the SROM drug shortages on treatment discontinuation. All analyses were stratified by indication (OAT vs. to manage pain).

Among 22,479 SROM users identified over the study period (mean age: 56.38 years; 51.93% female), monthly treatment discontinuation ranged from 9.21% to 24.96%. A significant ramp increase in treatment discontinuation was observed following the shortage reported in November 2019 (+0.29%/month, p<.001), with pulse increases in March 2020 (+2.00%, p<.001), July 2021 (+3.53%, p<.001) and August 2021 (+4.98%, p<.001). At the end of the study period a sustained increase in treatment discontinuation was observed among OAT users (21.38%), which was higher compared to those using SROM to manage pain (11.17%).

We found that the brand-specific SROM drug shortages had a significant impact on treatment discontinuation, especially among OAT recipients. These findings have important implications for identifying gaps in access to treatment for opioid use disorder. Improved strategies are needed to ensure continuity of care and mitigate harmful patient impacts of drug shortages.

PO58. Developing a Canadian Managed Entry Approach for New Innovation: What Can Canada Learn From Europe?

Presenting Authors: Viktoria Roman, Innovative Medicines Canada; Joe Farago, Innovative Medicines Canada; Neil Grubert, Global Market Access Consultant

Introduction: Many new therapies coming to the market are not well served by the traditional drug reimbursement approaches currently employed by Canada's public plans. Given that many of these interventions address significant unmet clinical needs, European regulatory authorities have been using novel

managed entry (MEA) and innovative access (IAA) agreements to accelerate approval times and improve availability to patients.

Methods: An environmental scan was conducted detailing international trends in innovative agreements that have similar systems to Canada in terms of HTA market or health care system. The study explores how RWE data are operationalized in other countries and provides examples of reimbursement agreement types throughout the product life cycle.

Results: The numerous types of MEAs and IAAs are categorized into three main approaches serving different objectives: 1) financially based schemes, 2) outcomes-based schemes, and 3) coverage with evidence development. Along these major categories, the study shows key trends in innovative access agreement approaches in European countries (England, Italy, Spain, Germany, France, Netherlands, and Sweden). The study also provides examples on population health management in a common chronic disease and in oncology, delinked payment deals to incentivize the development of new reserve antibiotics, and hybrid outcomes-based agreements and coverage with evidence-developed deals.

Conclusion: There is a need for public payers and manufacturers to work collaboratively to build the infrastructure to develop a pan-Canadian risk sharing approach to innovative agreements. Ultimately, this will benefit patients with improved timely access to treatments and improve fiscal sustainability and predictability for payers.

PO59. Stakeholder Engagement in Health Technology Assessment of Complex Interventions: Using a Value-Based Health Care Approach Toward Diabetic Foot Care and Limb Preservation in Canada

Presenting Author: Prof. James M. Bowen, University Health Network

Co-Authors: Prof. Sonia Meerai, Program for Health System & Technology Evaluation; Suja Mathew, Program for Health System & Technology Evaluation; Aleksandra Stanimirovic, University Health Network/University of Toronto; Trop Francis, Program for Health System & Technology Evaluation; Isabella Moroz, Conference Board of Canada; Nicola Waters, University of British Columbia; Valeria Rac, Toronto General Hospital Research Institute

Background: Conducting an early health technology assessment (HTA) of a complex intervention requires stakeholder engagement to ensure that the evaluation is aligned with patients, providers, and health system needs. The development of complex interventions, such as care pathways, requires a systems approach to health care improvement. One such approach is value-based health care (VBHC), a patient-centric care model guided by six core principles. Here we describe the early stakeholder engagement related to diabetic foot care and limb preservation pathways in Ontario using a VBHC approach.

Methods: This mixed-methods study is being conducted with two stakeholder groups: 1) Patient Partners from diverse communities; 2) health care providers, hospital leadership, and policy-makers of diabetes foot and wound care pathways. Aligned with VBHC principles, Patient Partner Focus Groups have discussed

values and priorities for care needs, experience with foot and wound care pathways, benefits and challenges associated with care received, and out-of-pocket expenses and impact on treatment. The Clinical Site Forum, following a clinical site questionnaire, will discuss wound assessment parameters (pathway categories), documentation methods for diabetes foot care (i.e., clinical notes, electronic health record (EHR) data entry, and digital wound capture tools and applications, billing and reimbursement (e.g., ICD codes; dressing costs; human resources, etc.), evaluation of outcome measures.

Discussion: Value-based health care is a leading approach to improving the organization of health care to transform health outcomes and insight into the development of a care pathway from the patients, practitioners, organizations, and stakeholders' perspectives is essential.

Short Course Abstracts

SC1. Precision Oncology Implementation: What's Next for Health Technology Assessment?

Presenting Authors: Dean Regier, BC Cancer - University of British Columbia; Tania Bubela, Simon Fraser University; Samantha Pollard, BC Cancer Research Institute; Deirdre Weymann, BC Cancer Research Institute; Melanie McPhail, University of British Columbia

What You Will Learn: Participants will: (1) Become familiar with precision oncology evidence generation; (2) Understand the use of patient preferences as evidence; (3) Get a practical grounding on the methods of real-world evidence (RWE); and (4) Gain understanding of the regulatory issues surrounding RWE.

Background: Health care systems' increasing use of 'omics data to select treatments independent of cancer type represents a paradigm shift known as precision oncology. In Canada, reimbursed access to precision oncology is highly variable because quality evidence is lacking. Generating evidence for precision oncology presents challenges, however. Evidence generation is hindered by a minority of patients having known driver or actionable mutations; a paucity of randomized controlled trials available for causal inference; and persistent concerns about the quality of real-world evidence and appropriate integration of patient preference information for deliberations. Convened by the Canadian Network for Learning Healthcare Systems and Cost-effective 'Omics Innovation, this interactive workshop will use precision oncology case studies of implemented multi-gene panels for prognostication and selection of reimbursed and non-reimbursed therapies to facilitate discussions on real-world evidence that causally determines patient value, effectiveness, and cost-effectiveness. Workshop structure: This hands-on 3-hour workshop will inform participants on fundamental methods for generating real-world and patient preference evidence. Chaired by Drs. Regier and Bubela, there will be 3 interactive sessions drawing on individual patient data to debate: (1) causal inference using real-world and clinical trial data; (2) patient preference information for regulatory and reimbursement deliberation; and (3) policy and practice enablers and impediments for real-world evidence. Each workshop component will last 45 minutes, combining didactic presentation with facilitated discussion

and debate. Target audience: This workshop is intended for researchers, HTA practitioners, industry representatives, and policy-makers interested in furthering the science of patient preference information and real-world evidence for beneficial and cost-effective health care.

SC2. Introduction to Budget Impact Analysis

Presenting Author: Doug Coyle, uOttawa School of Epidemiology and Public Health; Tessa Cornelissen, CADTH; Reuben Douma, CADTH; Bernice Tsoi, CADTH; Karen Lee, CADTH

What You Will Learn: Participants will learn both the rationale for the development of CADTH's BIA template and how to use the template to estimate budgetary impacts of introducing new drugs to Canadian public drug plan formularies.

This introductory course will provide participants with a comprehensive overview to the basics of BIA and hands-on experience conducting BIAs using a standardized template developed by CADTH for BIA producers.

The CADTH BIA template aligns with CADTH's submission requirements for drug reimbursement reviews and was developed with the intent of streamlining the development and critical appraisal of BIAs submitted to CADTH. While some aspects of BIAs are unique to the given clinical condition and characteristics of the health care technology, the steps to estimate the budget impact of a new policy scenario remain consistent. Many parameters (e.g., population size, coverage rates, mark-ups, and dispensing fees) and calculations (e.g., estimation of the target population size, estimation of annual budget impact) can be standardized. The Excel-based template provides a platform for users to enter the parameters required for a BIA to calculate an estimated budget impact result. This interactive workshop will demonstrate the use of the BIA template to attendees.

The first half of the session will consist of a brief introduction to BIAs and their role in supporting public decision-making, followed by a walkthrough of the CADTH template to demonstrate its functionality. In the second half of this workshop, participants will have hands-on opportunity to use the template by either working through an example case provided by CADTH or one of their own. By the end of the session, users will gain an introductory understanding of BIAs and of how to use the CADTH BIA template.

SC3. An Introduction to Health Technology Assessment

Presenting Author: Don Husereau, University of Ottawa

What You Will Learn: Participants will leave with an understanding of HTA, where it fits in the Canadian health care system, how it relates to other programs in the drug and medical devices spaces, opportunities to engage in HTA processes, and future trends.

Attendees will gain a better understanding of what HTA and health technology management (HTM) are, become more familiar with key concepts and terminology, and learn the role of common analytic and

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

SC4. Using RWE for Research-Oriented Market Access for High-Cost Therapies

Presenting Authors: Prof. Jeff Round, Institute of Health Economics; Erin Kirwin, Institute of Health Economics; Sasha van Katwyk, Institute of Health Economics

What You Will Learn: Participants will be able to explain the key concepts of ROMA, including the role of uncertainty in decision-making for high-cost therapies, how to value uncertainty in decision-making and how ROMA can support decision-makers.

Health technology assessment (HTA) uses evidence appraisal and synthesis with economic evaluation to inform adoption decisions. Standard HTA processes sometimes struggle to: (i) support decisions which involve significant uncertainty, and (ii) encourage continued generation of and adaptation to new evidence. We have developed the Research-Oriented Market Access (ROMA) framework, addressing these challenges by providing additional tools to decision-makers and improving outcomes for all stakeholders. Under ROMA, HTA processes align to life cycle management. ROMA introduces changes in HTA methods to minimize analytic time while optimizing decision certainty. Where decision uncertainty exists, we recommend risk-based pricing and research-oriented managed access. Contractual procurement agreements define the terms of reassessment and provide additional decision options to HTA agencies. ROMA extends value-of-information methods to inform agreements, leveraging routine, administrative data as well as registries to reduce uncertainty. In this workshop we describe the ROMA framework and how it can address key challenges of health system sustainability, continuously evolving evidence, and uncertainty. We will show how ROMA is built around on-market evidence generation and risk-based pricing strategies. Where decision uncertainty exists, we will illustrate how risk-based pricing and research-oriented managed access can improve the value proposition for payers. ROMA enables the adoption of high-value high-risk innovations while improving health system sustainability through risk-sharing and reducing uncertainty. Responsiveness to evolving evidence is improved through contractually embedded decision rules to simplify reassessment.

ROMA allows conditional adoption to obtain additional information, with confidence that the net value of that adoption decision is positive.

SC5. Would You Recommend This Drug for Reimbursement? Role of Expert Committees

Presenting Authors: Sarah Berglas, CADTH; Ian Cromwell, CADTH; Sayako Yokoyama, CADTH Renata Axler, CADTH

What You Will Learn: Taking the role of an expert committee member, participants will learn how trial data, economic model outcomes, patient and clinician perspectives, and ethical considerations are integrated in committee deliberations to make a drug reimbursement recommendation.

The workshop will begin with a simplified, but realistic, case study of a drug assessment presented by CADTH staff involved in preparing similar evidence for CADTH expert committees. Strengths of the data and uncertainties will be highlighted and explained. Working in small groups, participants will work through a framework to integrate the evidence and deliberate whether the fictional drug should be recommended for reimbursement. CADTH staff will be on hand to answer questions and further explain or explore data uncertainties in the small groups. Each small group will present their reimbursement recommendation and explain their reasons for the recommendation. The session will conclude with an exploration of what further information would have allowed for a clearer, or different, recommendation.

SC6. Introduction to the GRADE Approach

Presenting Authors: Carlos Cuello, CADTH; Michelle Gates, CADTH; Allison Gates, CADTH

What You Will Learn: Participants will: assimilate the principles of the GRADE approach: definitions, purpose, advantages, and limitations; learn to estimate the certainty of evidence using GRADE criteria in evidence syntheses of health technologies' and gain an understanding of going from evidence to decisions.

GRADE (Grading of Recommendations Assessment, Development, and Evaluation) is a transparent and sensible approach that provides specific criteria to rate the certainty of a body of evidence. Evidence syntheses (systematic reviews) evaluating the effectiveness of health technologies (drugs, devices, etc.) can present certainty in the effect estimates obtained from the review and synthesis process. To achieve this, GRADE provides several criteria that can increase or decrease this certainty evaluated for each question and outcome. Furthermore, GRADE can help decision-makers by providing different domains to consider when a body of evidence is used in the face of a decision, considering the net balance between desirable and undesirable effects, values from patients, costs, as well as feasibility and implementation issues. The goal of this workshop is to provide the basics of the GRADE approach, aimed at anyone with an interest in the best use of evidence syntheses on drugs and medical devices for decisions. Participants will learn the importance and how to use GRADE criteria to rate the certainty of a body of evidence and how to communicate the findings by building evidence profiles and summary of findings tables in dynamic lectures and with worked examples.