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Meeting Summary
Health Technology Strategy Policy Forum Wider Table on Personalized Medicine

February 26th & 27th, 2015 Novotel Hotel, Toronto, ON

Agenda

DAY 1 – THURSDAY FEBRUARY 26th, 2015

9:00-9:45	Introductions and Overview
9:45-10:30	Discussion on Policy Issues Related to Personalized Medicine: Jurisdictions Report Back on the Pre-Event Survey
10:15-11:00	Discussion: Policy Issues Related to Personalized Medicine: Jurisdictions Report Back on the Pre-Event Survey (continued)
11:00-12:00	Sharing Experiences: Common Issues and Concerns and Lessons Learned
1:00-3:30	Exploring Common Issues: Part I
3:30-4:15	Exploring Common Issues: Part II
4:15-4:50	Report Out and Discussion
4:50-5:00	Summary and Tee-Up for Tomorrow

DAY 2 – FRIDAY FEBRUARY 27 2015

8:30-9:00	Recap and Reflection	
9:00-9:45	Companion Diagnostics: Current State… and Prospects for the Future	Prof. Devidas Menon Health Technology and Policy Unit University of Alberta
9:45-10:30	Companion Diagnostics: Issues and Management	

10:45-12:00	Potential for Collective Action: Part I
12:30-3:30	Potential for Collective Action: Part II
3:30-3:45	Summary of Highlights
3:45-4:15	Roundtable: Advice and Takeaways
4:15-4:30	Closing Remarks

1. Policy Forum

The Policy Forum is a forum for provincial and territorial decision makers that was created by the Conference of Deputy Ministers (CDM), with secretariat support provided by CADTH. The mandate of the Policy Forum is to provide F/P/T jurisdictions with opportunities to share information and collaborate on health technology policy development. The responsibilities of the Policy Forum are to:

a. Identify health technologies of common interest and issues in their management;
b. Share health technology assessment and policy analysis information;
c. Collaborate, where beneficial to members, on the implementation, appropriate use and decommissioning of health technologies;
d. Identify policy levers to manage the implementation, the appropriate use, and the decommissioning of health technologies.

Current members of the Policy Forum are representatives from each of the provincial and territorial Ministries of Health and Health Canada.

2. Event Background

The Policy Forum hosted a two-day Wider Table discussion on the topic of Personalized Medicine in Toronto on February 26th and 27th, 2015. The purpose of the Wider Table was to bring together a broad group of stakeholders representing provincial and federal health care decision makers, lab service providers, clinicians and researchers to develop constructive solutions to the policy issues raised by these potentially transformative technologies.

The Wider Table had three main objectives:

1. To develop a better understanding of the process of the identification, assessment, and regulation of PM technologies along the technology pathway;
2. To identify common policy issues and concerns;
3. Identify potential collective actions to address those concerns with intent to formulate recommendations to senior federal and provincial health care leaders on the management of personalized medicine and companion diagnostic tests.

3. Personalized Medicine

Personalized medicine (PM) is the use of detailed information about a patient's genotype or level of gene expression and a patient's clinical data in order to select a medication, therapy or preventative measure that is particularly suited to that patient at the time of administration.

The Health Canada working group on personalized medicine defined "personalized medicine`` as follows:

``*Personalized medicine refers to the tailoring of preventative, diagnostic or therapeutic interventions to the characteristics of an individual or population. It does not mean the creation of health interventions targeted directly to an individual, but rather that the scientific advancements that underpin personalized medicine provide the ability to classify individuals into subpopulations* "Subpopulations" are defined as groups that are part of a greater whole, but who possess common traits and/or biomarkers that are not necessarily shared by the rest of the population. For instance, variation in a specific gene may only be carried by a small percentage of the entire Canadian population. Individuals with this variant can be grouped together to form a unique subpopulation *based on their susceptibility to a disease or response to a specific treatment. This can allow for earlier and/or targeted interventions to improve health outcomes.*``

Health Canada's definition also specifies that PM technologies can include but are not limited to:

1) population-based screening programs
2) brand name and generic drugs presented predictive on molecular diagnostics
3) environmental, lifestyle and diet changes
4) education
5) other health products

There are a number of policy gaps around decision making processes for PM. For companion diagnostics, there are also issues around what tests need to be assessed, and how consistency can be attained in approaches across the country. As a result, the Forum felt there is an opportunity to strategically coordinate activities across jurisdictions, while many provincial processes are still in their formative stages.

4. Day 1 Highlights

This event was facilitated with roundtable discussions and a pre-event survey sent to participants. From the survey and the event discussions, jurisdictions identified several issues of common concern. While jurisdictions are at different stages in the integration of PM in their public plans, there was general consensus amongst the jurisdictions for the need for a common PM review or a common approach to this area. The following themes summarize the core of the exchanges. The themes are not shown in any order of priority.

The following themes were discussed on Day 1:

- Burning platform
- Common PM Review – Assessment Phase
- Common PM Review – Deployment Phase
- Clinical decision-making
- Regulatory issues

Summary of Topics/Themes Discussed

4.1 Burning Platform

The expression ``Burning Platform`` means bringing an issue to the attention of senior FPT decision-makers and making it salient to them.

Key Messages:

- Differences of opinion about the promises of PM but agreement that (a) there are some interventions that are already known to be effective and should be considered best practice (i.e. BRCA screening); (b) PM is generating increasing attention among providers and the public; (c) it will impact all aspects of healthcare system with significant implications for costs and patient care; (d) there is merit in collaborative/coordinated/collective actions across Canadian jurisdictions to do better manage PM
- We have strong examples of success for this kind of effort to draw on here and elsewhere around the world (UK, CDR, pCODR)

Content Points:

- Definition (HC definition focuses on genetics but could be all "omics"); concentrate on where there is good work underway; broader definition of PM is not "in scope" (high yield longer term is not in scope at this time)
- What could be the impact of PM – example of "good" and "bad" experience – real world examples that speak to CMs/Ministers (i.e. 23 and me)
- Costs of (a) not taking some form of collective action on PM (including not fully realizing benefits of huge investments being made in research through Genome Canada/provincial efforts and CIHR/NAPHRO) (b) estimated costs of coordinated efforts for developing a management of PM vary across the country
- What could be done – CDR/pCODR example – key features

Next Steps:

ACTION: Policy Forum and CADTH will develop a common Briefing Note to be transmitted to the Conference of Deputy Ministers of Health. This action is the highest priority issue.

4.2 Assessment

Key Messages:

- Most jurisdictions have accreditation processes but there are variations between jurisdictions
- Considerable duplication of effort with different (a) assessment methods, (b) criteria
- Assessment of "intervention" and "companion diagnostics – CDx" are not linked
- Good for patients when answer is a collective "yes" but also good when the answer is a common "no" – rationale for not paying for something that is ineffective. What are the implications for cost-effectiveness?
- In many provinces, the drug budget is not connected to the lab budget so there is a disconnect between approvals for a drug and operational funding for the test

Content Points:

- Experience with successful processes here and elsewhere to build on (international; CDR/pCODR and others)
- Strong support for common effort – PM review like CDR, focused mostly on CDx; common national collaborative for non-drug; common/collaborative effort for non-cancer)
- Need commitment/resolve to adhere to collective decision to realize full value of effort – commitment to move to "(provisional) deployment" if agreed
- Consider "relaxing" evidence standard to admit promising emerging interventions… but need to (a) set evaluation criteria and process upon provisional approval, (b) review according to transparent process, (c) take action to de-list or ramp up as needed

Next Steps:

ACTION: Policy Forum will further discuss these issues. A supplementary Briefing Note could be part of a CDM common briefing note, as a first step.

4.3 Deployment

Key Messages:

- Trusted mechanism – single evidence base, implications identified, standardized recommendations to decision makers
- Value and affordability metrics needed
- Regular review and evaluation of past recommendations are critical and de-listing as indicated
- Build on good work underway in Canada and internationally

Content Points:

- Identify and explain good work underway in Canada and internationally
- Identify and explain metrics available
- Identify features of approach – "what this could look like"

Next Steps:

ACTION: Policy Forum will further discuss these issues. A supplementary Briefing Note could be part of a CDM common briefing note, as a first step.

4.4 Clinical decision-making:

Key Messages:

- "Testing with a purpose" – common pan-Canadian clinical pathway – the "right" indication, the right prescriber authority/is authorized, right education for treatment and counseling; how to "roll out" the decisions made in the Assessment and Deployment stages
- Strategic approach to training and education

Content Points:

- Explanation of the issue (proliferation of testing often generated by direct-to-consumer advertising or industry detailing; inequity of access; test may be purchased with private resources but not covered; no systematic approach to coverage within or across jurisdictions, etc.)

- Many groups need education; experts (cancer specialists, lab and medical genetics) can "teach" others – family practitioners on when/where to refer or seek consultation; special credentialing program for those who prescribe and interpret tests, do counselling
- Knowledge exchange should be "both ways" as family practitioners and primary care providers are in an ideal position to be able to monitor and inform policy-makers of what is going on in the field (public demand, emerging products/markets, etc.)

Next Steps:

ACTION: Policy Forum will further discuss these issues. A supplementary Briefing Note could be part of a CDM common briefing note, as a first step.

4.5 Regulatory issues

Key Messages:

- Several issues including: privacy, IP, data ownership but most pressing problem is lack of standardization of lab tests
- Also comments were made on how there was already some good work being done on lab quality standards
- Need pan-Canadian collaborative effort to harmonize test/accreditation processes

Content Points

- Explore possibility of Canada-wide proficiency testing – bring people together in a "bottom up" collaborative approach

5. Day 2 on Companion Diagnostic: Highlights

Day 2 followed a similar format as day 1. As on the first day, participants readily shared information and were strongly engaged in the various conversations that took place.

Participants clearly took to heart the challenges and the opportunities posed by personalized medicine in Canada's health care system, and eagerly provided their ideas to support a better approach to personalized medicine in Canada.

Professor Devidas Menon (Health Technology Policy Unit, University of Alberta), was invited to introduce the challenges and opportunities related to the companion diagnostics component of personalized medicine. Participating via telephone, Dr. Menon started by providing an overview of companion diagnostics assessment and reimbursement in the UK, Australia, Germany, France, Italy, and Spain. He then described three different reimbursement scenarios for a common national process for the assessment of companion diagnostics in Canada.

Professor Menon concluded with questions for consideration in moving forward. He also recommended that the discussions begin with a focus on a centralized review of companion diagnostics similar to the Common Drug Review process.

A question session followed Dr. Menon's presentation to identify common themes. Then a facilitated roundtable discussion was held to address the following questions:

- Given the *common challenges*, what might be done to address these?
- Of these actions, which are top priorities and why?
- Of the remaining challenges, what might be done to improve the ability of individual jurisdictions to manage these?
- Who, at what level of government/governance (provincial, federal) needs to be involved in this action and how? Who else needs to be involved and in what capacity?
- Who should lead/what should be the leadership structure for collective action in this area?
- What should be the "next steps" on this action?

Small group discussions followed on a number of different themes, including common test review, laboratory development tests, access to adoptions tools and mechanisms for knowledge translation activities, environmental scan as a comparison analysis tool, a reporting method and an accountability mechanism.

There was also a small group discussion focusing on the 1) process, 2) evidentiary and 3) legal, social and ethical aspects in the regulatory oversight of laboratory-developed tests (LDTs). It was acknowledged that some provinces are doing much more than others in terms of validation of tests, and Canadians from every province should have access to same level of quality and safety in regard of testing services.

Participants were also generally in agreement that some national requirements for clinical laboratory accreditation applicable to LDTs should exist. In terms of the scan discussion, the following themes emerged:

- Process: finance, capacity (info systems), maps/gaps/overlaps, players involved, governance, stakeholder engagement.
- Evidentiary: requirements, criteria, standards, gathering, guidelines, algorithms.
- Legal, Social, Ethical: innovation/LDTS, regulatory implications/gaps/barriers to participation, accreditation, HC/national/activities role, privacy (insurance).

There was a strong interest amongst the participants that a pan-Canadian collaboration should be developed to harmonize the assessment of diagnostic tests used in personalized medicine. Participants were also in agreement that structures similar to the Pan-Canadian Oncology Drug Review (pCODR) and the Common Drug Review (CDR) could be adapted for tests.

There was significant interest in the development of national accreditation requirements for clinical laboratories. The idea of a pan-Canadian proficiency testing program to monitor the quality of testing throughout the country also came up a number of times.

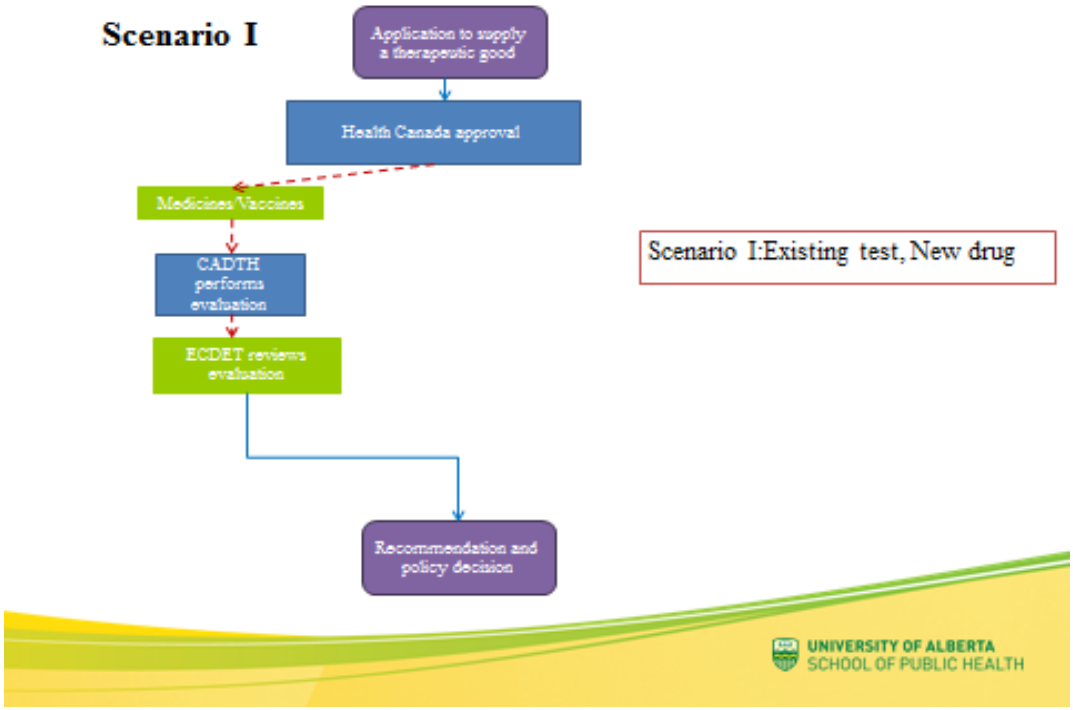
In moving forward, the following activities were discussed in support of a pan-Canadian approach to PM tests:

- Need for additional governance/mechanisms, other pan-Canadian processes and models.
- The scope: for recommendations, future engagements, best practices, which type of governance model, the feasibility and the need, the potential benefit, areas for collaboration, evaluation of the budget needed for this work (an evaluation of the resources required for a pan-Canadian approach), the risks involved.

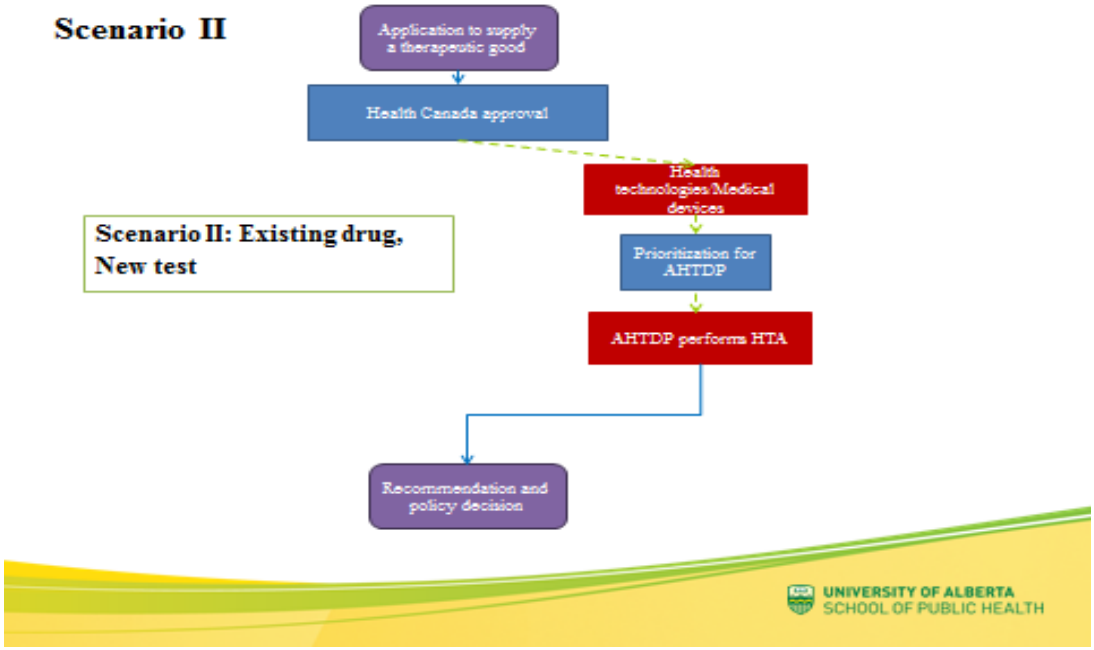
- Develop a list of stakeholders.

The two-day event was successful in bringing together stakeholders from across the country who exercise different roles in health care but share a common interest in advancing health care services to Canadians. The level of engagement amongst the participants was outstanding and much greater than expected. The discussions resulted in a general agreement that a pan-Canadian approach is needed to address PM and test issues. Participants indicated an interest in contributing to such an endeavor.

Scenario 1:



Scenario 2:



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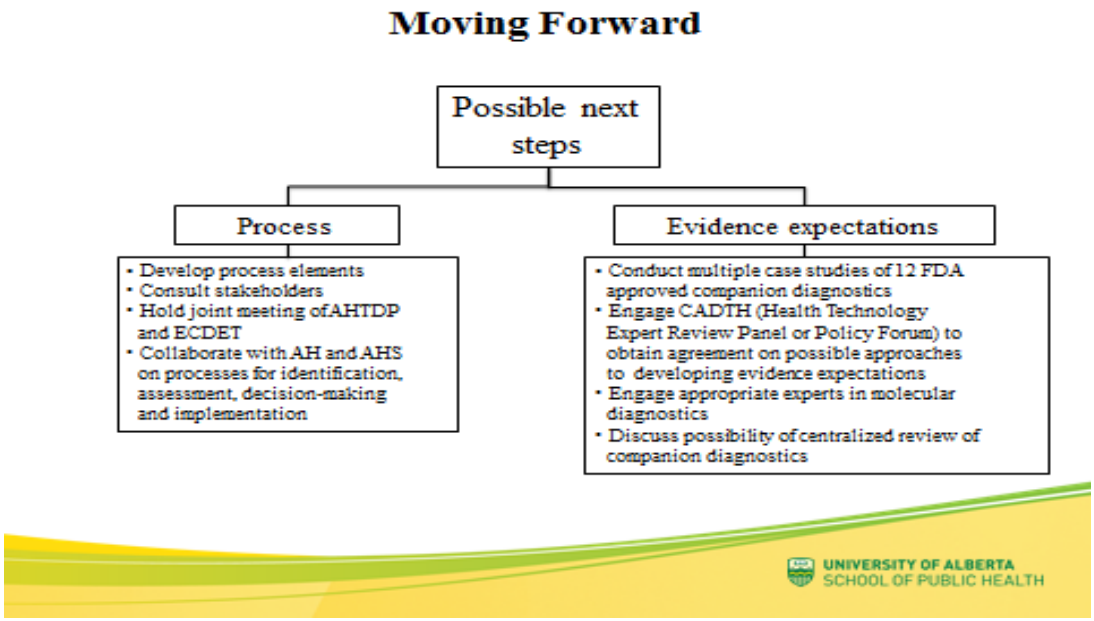

Next Steps:

ACTION: A meeting summary of the main topics discussed.

ACTION: A typology for PM and an environmental scan will be developed.

Wider Table Participants

Policy Forum Members:

Kevin Samra, Policy Forum Chair, Director, Strategic Projects Branch, HSIMT, Ministry of Health, British Columbia

Dr. Anne Tweed, Medical Consultant, Partnerships and Physician Services, Nova Scotia Department of Health and Wellness

Noortje Kunnen, Senior Policy Advisor, Policy, Legislation and Intergovernmental Relations, Department of Health, New Brunswick

Chad Blundon, Director of Policy Development and Legislative Affairs, Department of Health and Community Services, Government of Newfoundland and Labrador

Nicole Charron, Senior Policy Advisor, Office of Pharmaceuticals Management Strategies, Strategic Policy Branch, Health Canada

Dr. Ali Khan, Policy Forum Observer, Medical Consultant, Manitoba Health

Deborah Jordan, Executive Director, Acute and Emergency Services Branch, Saskatchewan Health

DPAC Members:

Dr. Patricia A. Caetano, Executive Director, Provincial Drug Programs Manitoba Health and Assistant Professor, Community Health Sciences, Faculty of Medicine, University of Manitoba

Kathy Vesterfelt, Manager Canadian Forces Drug Benefit Plan, D Med Pol, Pharm Pol & Stds

Susan Pierce, Manager, Pharmacy Policy Development Division, Non-Insured Health Benefit Program, FNIHB Health Canada

CADTH Staff:

Dr. Tammy Clifford, Vice President Strategic Initiatives & Chief Scientist

Ken Bond, Director, Strategic Initiatives

Brendalynn Ens, Director, LO & KM
Dr. Mona Sabharwal, Executive Director, pCODR

Dr. Chander Sehgal, Director CDR & Optimal Use of Drugs

Caroline Babin, Program Officer

Facilitator: Lillian Bayne, Lillian Bayne and Associates Ltd.

Guests:

Dr. Mary Argent-Katwala, Director, Diagnosis & Clinical Care, Canadian Partnership Against Cancer

Tina Babineau Sturk, Manager, Maritime Medical Genetics Service, Nova Scotia

Dr. Shantanu Banerji, CancerCare Manitoba

Dr. Mathieu Bélanger, Professor, Département de médecine de famille, Université de Sherbrooke, Québec and Director of Research, Centre de formation médicale du Nouveau-Brunswick and Epidemiologist, Bureau d'appui à la recherche du Réseau de santé Vitalité Health Network, New Brunswick

Dr. Luc Boileau, President and CEO, Institut national d'excellence en santé et en services sociaux, Québec

Bobby Chauhan, Senior Regulatory Officer, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Health Canada

Dan Coulombe, Acting Director, Hospital Services and Operations Branch, Community and Institutional Services Division, Department of Health, New Brunswick

Dr. Nicolas Crapoulet, Research scientist and platform manager, Next-generation sequencing, Atlantic Cancer Research Institute, New Brunswick

Dr. Kathy Deuchars, Director, Ontario Personalized Medicine Network & Senior Manager, Business Development & Research, Ontario Genomics Institute

Dr. Karen Dewar, Director, Genomics Programs, Genome Canada

Leota Dickey, Director of Operations, Pathology and Lab Medicine and Maritime Medical Genetics, IWK Health Centre, Nova Scotia

Dr. Ian Dubé, Consultant Clinical Analyst, Laboratory Office, Laboratory, Diagnostic & Blood Services Branch, Health Services Policy and Quality Assurance Division, British Columbia

Dr. Jennifer Fesser, Division Head, PEI Blood Transfusion Services and Laboratory Hematology, Health Prince Edward Island
Brenda Gluska, Senior Program Consultant, Health Services Branch, Ontario Ministry of Health and Long-Term Care

Dr. Paul Grundy, CPO and SrMD, CancerControl Alberta, Alberta Health Services

Dr. Anil Joy, Alberta Health Services

Dr. Aly Karsan, Medical Director, Cancer Genetics Laboratory & Centre for Clinical Genomics, Pathology & Lab Medicine and Genome Sciences Centre, British Columbia Cancer Agency and Professor, Pathology & Laboratory Medicine, University of British Columbia

Dr. Paul Lasko, Scientific Director, CIHR Institute of Genetics, Québec

Heather Logan, Executive Director, Canadian Association of Provincial Cancer Agencies

Dr. Andrés Lopez, Senior Negociations Analyst, Community and Population Health Branch, Health System Strategy and Policy Division, Ministry of Health and Long-Term Care, Ontario

Dr. Catalina López Correa, Vice President/CSO, Scientific Affairs, Génome Québec

Michele Mathae-Hunter, Director of Provincial Diagnostic Services, Cancer and Diagnostic Services Branch, Regional Policy and Programs, Manitoba Health

Dr. Fiona A. Miller, Associate Professor of Health Policy, Institute of Health Policy, Management & Evaluation, Director, Division of Health Policy & Ethics, Toronto Health Economics & Technology Assessment (THETA) Collaborative, University of Toronto

Karine Morin, Director, Ethics Innovations, Alberta Innovates-Health Solutions
Owen Parfrey, Centre for Health Informatics and Analytics, Memorial University of Newfoundland

Dennis Pegoraro, Senior Program Consultant, Provincial Program Branch, Ministry of Health and Long-Term Care, Ontario

Dr. Geoff Porter, Senior Scientific Lead, Diagnosis & Clinical Care, Canadian Partnership Against Cancer

Maricon Sanelli, Program Manager, Laboratories and Diagnostics, Negotiations Branch, Ministry of Health and Long-Term Care, Ontario

Dr. Patrice Sarrazin, Senior Scientific Evaluator, In Vitro Diagnostic Devices, Device Evaluation Division, Medical Devices Bureau, Health Canada

Mark Schroter, Senior Policy Advisor, Community and Population Health Branch, Health System Strategy and Policy Division, Ministry of Health and Long-Term Care, Ontario

Christine Seager, Drug Program Services, Ontario Ministry Health and Long-Term Care

Jim Slater, Chief Executive Officer, Diagnostic Services Manitoba

Dr. Tracy Stockley, Associate Director, Molecular Diagnostics, Department of Pathology, University Health Network and Assistant Professor, Department of Laboratory Medicine and Pathobiology, University of Toronto, Toronto General Hospital

Catherine Street, Director Newfoundland and Labrador SUPPORT, Memorial University of Newfoundland

Dr. James C. Wesenberg – Provincial Medical/ Laboratory Services Scientific Director, Alberta Health Services

Dr. Yagang Xie, Head, Division of Molecular Diagnostics and Cytogenetics, Department of Laboratory Medicine, Saint John Regional Hospital, Horizon Health Network, New Brunswick and Professor, Department of Pathology, Faculty of Medicine, Dalhousie University

By Teleconference:

Dr. Étienne Richer, Assistant Director, CIHR Institute of Genetics

Invited Guest:

Dr. Devidas Menon, Professor, School of Public Health, University of Alberta