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OPEN TO INNOVATION:

Ontario Pathway Workshop

June 18, 2019
Toronto Ontario

Shortening the distance between discovery and transformative patient care

Open to Innovation: Ontario Pathway Workshop

Draft Discussion Paper

Shortening the distance between discovery and transformative patient care

A note on the purpose of this document

This document is a summary of stakeholder feedback, literature reviews and other findings and discussions that have emerged from consultations conducted by OICR and CCO over the past year regarding the challenge of implementing innovation into cancer care in Ontario. As this work is ongoing, this is a 'living document'.

This document is being shared with Ontario Pathway Workshop attendees as background reading to facilitate the in-person workshop discussion that will be held on June 18, 2019 in Toronto. Our expectation is that the content will change and improve following those discussions; there may be content you disagree with or think is missing, and we welcome and expect that feedback.

Following the workshop, we plan for this document to form the basis of a white paper which will be widely shared with stakeholders in the cancer community and include recommendations for addressing the problem statement, timelines and accountabilities.

June 14, 2019 Version

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Innovative technologies and processes are not easily adopted into cancer care in Ontario.

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Shorten the distance between discovery and transformative patient care.

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"Our government is committed to creating and protecting jobs by sending the message to business investors everywhere...(that) Ontario is open for business."

- *Ontario Premier Doug Ford (August 30, 2018 roundtable discussion with the representatives of Canada's five largest banks)*

"Our government will continue to ensure necessary funding for world-class health care in Ontario, but this issue must be about more than money. It will also be about embracing change and innovation, deploying technology more effectively, and committing to new models of collaboration and patient care."

- *Ontario Premier Doug Ford (January 7, 2019 letter to Ontario public servants)*

"As new technologies and best practices emerge, it is important that Ontario use its research expertise to deliver these advancements to the people as quickly and efficiently as possible."

- *Hon. Merrilee Fullerton, Ontario's Minister of Training, Colleges and Universities (June 4, 2019 press release regarding new project funding through OICR-CCO Health Services Research Network)*

"We heard from other US cutting-edge molecular diagnostics companies that expanding into Canada 'is just not worth the hassle given the obstacles'."

- *Chief Medical Officer from a US health-care technology company (January 15, 2019 email)*

"Innovative thinking can very often improve quality of care for patients while also saving money and reducing capacity pressures in hospitals."

- *Michael Sherar, CCO President & CEO (January 17, 2019 blog)*

"This is an exciting development for cancer research and innovation in Ontario, and I congratulate FACIT, OICR and Triphase Accelerator on their important collaboration". "It's partnerships like these that keep Ontario open for business and are invaluable as we work toward developing a long-term transformational health care strategy guided by innovation, integration and the better use of technology."

- *Minister Christine Elliott, Deputy Premier and Minister of Health and Long-Term Care*

"A better healthcare system starts with adoption new technologies to create better outcomes. Engage healthcare providers and government representatives looking to improve policy and infrastructure to improve lives and health care."

- *First Premier Council's Report (January 31, 2019)*

"The world economic map is being drawn around innovation and Canada is at an inflection point."

- *MaRS CEO, Yung Wu (January 22, 2019)*

"New technologies can improve patient care and make the health system more efficient – but only if they reach the hands of medical professionals."

- *MaRS EXCITE (January 22, 2019)*

4   Definition of Innovation

Innovation can be defined in many ways and is part of a continuum between research and quality improvement. Put simply, health innovation refers to new and improved ways of doing things, based on evidence.

For the purposes of this workshop and discussion document we are focusing our problem-solving on innovations related to the delivery of precision medicine in oncology. Precision or personalized approaches to healthcare are a tremendous area of focus for oncology research and represent a significant health system adoption challenge for patient care.

The following are examples of precision medicine tools that would be in scope for discussion:

- Molecular genetic testing and multi-omic characterizations;
- Companion diagnostics;
- Predictive and prognostic biomarker tests;
- Algorithms associated with precision medicine tools.

Importantly, however, the framework we design should be applicable to other innovative technologies that could improve cancer care.

5   OICR-CCO Partnership

The Ontario Institute for Cancer Research (OICR) is a collaborative research institute accelerating the development of new cancer research discoveries for patients around the world while maximizing the economic and health benefit of this research for the people of Ontario. OICR partners with Cancer Care Ontario (CCO), Ontario's cancer agency for the delivery of cancer care in the province. CCO has a mandate to rapidly transform evidence and knowledge into practice. Partnership between these two provincial organizations is critical to ensuring research discoveries are adopted by the Ontario cancer care system.

Although the activities of CCO are expected to be integrated into the new Ontario Health Agency, the critical role of this new agency as a receptor for research discoveries and evidence to improve cancer services in the province will hopefully remain unchanged.

6   Approach and Expected Outcomes

OICR and CCO leadership have conducted extensive consultations over the past year with stakeholders from academic, clinical, patient, industry, government, hospital and health system perspectives to develop a shared vision for what is needed in Ontario to improve the adoption of innovation in the Ontario cancer system. This has resulted in the development of a draft framework for the prioritization, evaluation and implementation of innovations. The need to learn from success stories in Ontario and from other jurisdictions with similar health systems and populations has been emphasized.

Through an invited workshop of diverse stakeholders the framework will be challenged, tested and modified. The workshop will also provide the opportunity to identify and explore both barriers and enabling factors that underlie implementation of the framework. The workshop itself represents the beginning of effecting change; much more and broader activity, engagement and leadership will be required for success. As an outcome of the workshop we hope to guage traction for this change initiative and begin to identify next steps, timelines and accountabilities.

7   Key Learnings from Consultations

- Patients and physicians want/need access to innovative technologies earlier;
- There is currently no obvious single path to adopting an innovation in cancer care from the perspective of inventors/academics
- Engaging patients is critical;
- 'Innovation' has many interpretations and needs defining;
- Innovative cancer technologies and processes are typically excluded from the mandates of existing evaluation organizations and their frameworks because CCO is viewed as having responsibility for this activity in Ontario; enthusiasm to build on what exists if possible;

- CCO has some existing models for evidence building (i.e., PET imaging);
- There is a strong dependency on the policy environment; critical to promoting/impeding implementation;
- Hospital/healthcare funding models and aligned incentives need consideration;
- Connectivity of healthcare records (privacy, consent and linkage) is critical;
- There is consistent enthusiasm for collaboration from all stakeholders; willingness to participate;
- Engage selected industry leads as important stakeholders;
- Engage universities/academic health care institutions to understand importance of training;
- Culture change is as important to success as process change.

8 Framework Principles

Stakeholder consultations highlighted that a successful model for evaluating and implementing cancer care innovations in Ontario should embrace the following seven principles.

8.1 Principle 1: Nimbleness

- Application of framework and data requirements needs to be a nimble process (time considerations);
- Framework must be adaptable to allow for frequent modification of technologies and clinical utility; genetic technologies and the information they provide are iterative (unlike drugs).

8.2 Principle 2: Bias to permissive

- More innovations should be prioritized, appraised, evaluated and implemented;
- More 'small bets' should be made provided there is a mechanism to subsequently remove innovations that don't meet needs

8.3 Principle 3: Transparency

- Need a clear entry point for new technologies regardless of where they originate;
- No privileged access; more deliberative, understandable, open approach to prioritization;
- Consider health system/clinical pull as well as research push.

8.4 Principle 4: Discontinuation/Disinvestment

- Establish and use a process for discontinuation of technology evaluations when evidence is insufficient to merit validity;
- Establish and use a process for disinvesting in technologies that do not offer the expected benefit in real-world settings.

8.5 Principle 5: Learning Health System Model

- Build framework on the principle of a learning or evidence-generating health system model;
- Ensure that there is a feedback loop between research, the health care/patient experience and the decision making system.

8.6 Principle 6: Leverage Existing Systems

- The evaluation and implementation of Cancer innovation strategies is typically excluded from existing evaluation frameworks but could build on what exists;
- Harness leadership and structure of existing organizations where it makes sense;
- Create networks of partnerships for evaluation and implementation, which includes ongoing assessment of value.

8.7 Principle 7: Broad application

- Framework should apply to new and existing technologies;
- Framework should accommodate Ontario and global innovations whether from industry or academia;
- Model should be applicable to other health care innovations beyond precision oncology tools.

9 Proposed Framework

Multi-phase Innovation Implementation Framework

Discovery

Purpose: Develop a nimble, transparent framework and data requirements to evaluate and implement innovations that benefit cancer patients

Appraisal

- Is this innovation a priority?
- Is there **clinical utility?**
- Is there system readiness?
- Is there technical validity??

Discontinue

- Is there a high level of **clinical validity?**
- What is the cost/health system impact?

Evaluation

Implementation

Discontinue

Disinvestment

- Is **clinically effective?**
- Is it cost effective?
- How do we diffuse innovation?
- How do we provide Ontario-based proficiency testing?

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9.1 Appraisal Phase

Gap:

- This Phase does not currently exist in a formalized manner.

Purpose:

- Clear entry point into the evaluation and implementation pathway;
- Determine whether innovation is worth evaluating?;
- Is this innovation a priority? Is there clinical utility? Is there system readiness?;
- Is this an innovation that can be robustly measured/applied/generated? Are there methods that can be applied that generate consistent results (technical validity)?
- What kind of evidence is required? How do we generate it if it not yet available?

Proposed Process:

- Hybrid intake: Invitation for priority solutions ("pull") AND submission of new innovations ("push");
- Develop checklist/guideline of required evidence;
- Develop checklist of technical metrics that must be met
- Establishment of a governance committee (including patients) for developing/evaluating priorities;
- Establishment of an adjudication committee for reviewing evidence.
- Need to establish what levels of evidence are appropriate for different categories of innovations (e.g., diagnostic vs predictive vs therapeutic biomarkers)

Recommended Outcome of this Phase:

- Decision (Yes/No/Uncertain);
- Yes – Continue on the Evaluation Phase;
- No – Discontinue;

- Uncertain – May require further evidence base, generation of additional evidence which could lead to opportunities to generate it in partnership.

Current funding approach for this type of work:

- Support from discoverer;
- Private-public partnership.

Current teams that perform this type of work:

- Formal process at CCO is limited to a few innovation technologies;
- Health Quality Ontario may have an intake/appraisal process;
- MaRS Excite may have an intake/appraisal process.

9.2 Evaluation

Gap:

- Evaluation organizations exist but do not generally focus on cancer innovative technologies;
- Reasonable timeframe for evaluation needs to be established.

Purpose:

- Critical evidence gateway to determine whether innovation should undergo pilot implementation with patients;
- Is there sufficient clinical validity? What is the cost/health system/value impact?
- Real-world outcomes evaluated in real time.

Proposed Process :

- Leverage/expand existing process and groups (e.g., HQO/OHTAC, MaRS EXCITE, CADTH);
- Evidence will include clinical validity, safety, system Impact, health technology assessment;
- Need to establish what levels of evidence are appropriate for different categories of innovations (e.g., diagnostic vs predictive vs therapeutic biomarkers) and different therapeutic needs (e.g., low vs high fatality cancers).

Recommended Outcome of this Phase:

- Decision (Yes/No/Uncertain);
- Yes - Continue to Implementation Phase;
- No – Discontinue;
- Uncertain – May require additional evidence base or further research/development.

Current funding approach for this type of work:

- Evaluation organizations exist and are currently funded, but could expand the scope of their activities to different technologies or methods;
- Private-public partnership.

Current teams that perform this type of work:

- CCO has evaluation process from Ontario perspective
- Canadian Agency for Drugs and Technologies in Health (CADTH)/pan Canadian Oncology Drug Review (pCODR) conducts drug evaluations;
- Health Quality Ontario (HQO) conduct device and genetic evaluations;
- MaRS EXCITE may have an evaluation process.

9.3   Implementation

Gap:

- This Phase does not currently exist in a formalized manner.

Purpose:

- Test clinical efficacy and cost-effectiveness in real-world setting to determine ongoing investment and diffusion of innovation.
- Develop an implementation plan for provincial deployment, including:
    o Service Delivery Model (e.g. centralized testing in one lab or decentralized in many labs)
    o Quality Assurance guidelines
    o Funding model

Proposed Process:

- Generate checklist of outcomes required for system adoption (need to engage clinical labs);
- Adjudication committee for reviewing evidence;
- Governance committee (including patients) for determining adoption of technologies;
- Identify centres/networks to test and evaluate each technology (pilot testing);
- Leverage existing evidence building programs and methods (e.g., CCO's PET and Evidence Building Program);
- Ongoing assessment-continual learning/improvement;
- Data linkage critical;
- Real-world outcomes evaluated in real time.
- Proficiency testing for Ontario labs

Recommendation:

- Decision (Yes/No/Uncertain)
- Yes – Adoption and diffusion of innovation while continuing to generate evidence, including establishment of funding models and ongoing RWE generation (continuing improvement);
- No – Disinvestment;
- Uncertain - May require additional evidence base or further research/development.

Current funding approach for this type of work:

- Private-public partnership
- Government
- Grant funding

Current teams that perform this type of work:

- Limited formal process at CCO;
- Limited formal process at CADTH;
- Health Quality Ontario may have an implementation process;
- MaRS EXCITE may have an implementation process.

10 Workshop Agenda

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Agenda – Open to Innovation: Ontario Pathway Workshop

June 18, 2019
8:00 a.m. – 4:00 p.m.
Vantages Venues, 150 King Street West, Toronto

Attendees:

John Bartlett, Liz Beecker, Chaim Bell, David Berman, Victor Castellino, Kelvin Chan, Viola Cheung, Marc Clausen, Ryan Demers, Avram Denburg, Kathy Deuchars, Sola Dokun, Michael Duong, Barry Elkind, Bill Evans, Ken Evans, Mena Farag, Harriet Feilotter, Paul Gibson, Monette Greenway, Bettina Hamelin, Jennifer Hart, Cynthia Ho, Arlene Howells, Ann Humphreys, David Hwang, Meredith Irwin, Mike Kadour, Rita Kandel, Karen Keith, Katherine Kelly Gatten, Zayna Khayat, Prateek Lala, Heather Logan, Andrea Mackesy, Jovan Matic, Christopher McCabe, Rebecca McClure, Robin McLeod, Siofradh McMahon, Tom Mikkelsen, Allan Miranda, Christopher Needles, Mark Oatway, David Palma, Raheem Peerani, Aaron Pollett, Ken Pritzker, Trevor Pugh, Jason Pun, Evelyn Pyper, Laszlo Radvanyi, Bonnie Reib, Dvorah Richler, Michael Sherar, Josh Silvertown, Kathleen Smith, Lindsay Smith, Lincoln Stein, Tracy Stockley, Rebecca Tamarchak, Caitlin Taylor, Sara Urowitz, John Wallenburg, Jim Whitlock, Christine Williams, Julie Wilson, Brad Wouters

Time	Agenda Item	Presenter
8:00 – 8:20 a.m.	**Breakfast**	
8:20 – 8:40 a.m.	**Introductions and Overview of the Day**	_Christine Williams Michael Sherar Laszlo Radvanyi_
8:40 – 9:40 a.m.	**Roundtable: Current Landscape of Biomarkers and Precision Medicine in Ontario** • Defining the problem from different perspectives: ○ Researcher ○ Clinician ○ Molecular geneticist/pathologist ○ Patient ○ Hospital/research leadership ○ Health and cancer care system ○ Industry • Q&A	_Jason Pun (Facilitator)_
9:40 – 10:10 a.m.	**Perspectives from Other Jurisdictions** _Lessons learned from Alberta Health Services_ • Q&A	_Christopher McCabe_
10:10 – 10:25 a.m.	**Proposed Framework for the Evaluation and Implementation of Health Innovations** • Q&A	_Christine Williams Harriet Feilotter_
10:25 – 10:40 a.m.	**Break**	
10:40 – 11:00 a.m.	**Review of pre-workshop survey results: Reviewing the framework** • Q&A	_Jason Pun (Facilitator)_

Agenda – Open to Innovation: Ontario Pathway Workshop
June 18, 2019
8:00 a.m. – 4:00 p.m.
Vantages Venues, 150 King Street West, Toronto

Time	Agenda Item	Presenter
11:00 – 11:45 a.m.	**Morning Breakout Session: Reviewing the Framework** a) Appraisal phase b) Evaluation phase c) Implementation phase	*Jason Pun (Facilitator)*
11:45 – 12:40 p.m.	**Feedback and Discussion**	*All*
12:40 – 1:10 p.m.	**Networking Lunch**	
1:10 – 1:20 p.m.	**Review of pre-workshop survey results: Barriers and Solutions** • Q&A	*Jason Pun (Facilitator)*
1:20 – 2:20 p.m.	**Afternoon Breakout Session: Barriers and Solutions** (Two 30-minute sessions) a) Funding for evidence generation b) Governance and prioritization of technologies c) Connectivity of research and clinical data including privacy considerations d) System and culture change e) Regulatory environment f) Others to be determined	*Jason Pun (Facilitator)*
2:20 – 3:15 p.m.	**Feedback and Discussion**	*All*
3:15 – 3:30 p.m.	**Break**	
3:30 – 3:50 p.m.	**Next Steps and Actions**	*All*
3:50 – 4:00 p.m.	**Closing Remarks**	*Christine Williams*

11 Workshop Questions

11.1 Morning Breakout Session: Reviewing the Draft Innovation Framework

Session Objective:
- Discuss/debate specific aspects of the proposed draft innovation framework.
- Understand areas for improvement of the draft innovation framework.

Discussion Questions:

Breakout groups to discuss/debate (participants will be pre-assigned to groups) the following questions.

- **Categories of Innovations and Evidence**
  The majority of people answering the survey indicated there should be different evidence for different categories of innovations.
    1) *What different categories of innovations should there be? Please define the categories with as much detail as possible.*
    2) *What type of evidence is needed to address the questions in each of the phases? Integrate with your answer to the categories of innovation if possible.*

- **Decision-Making**
  In the survey, the most chosen answers for 'who should be involved with decision-making' was a multi-disciplinary committee (researchers, clinicians, health economists, policy experts and laboratory experts) and patients/caregivers/community representatives.
    3) *Should a multi-disciplinary committee (including patients) be the only decision-maker as innovations move through the framework, or should other stakeholder groups be involved? How should decision-making work for the following 'gates'?*
        - *Entry into Appraisal*
        - *Pass Appraisal (or discontinue) and enter Evaluation*
        - *Pass Evaluation (or discontinue) and enter Implementation*
        - *Pass Implementation (or disinvestment) and enter adoption/diffusion*

- **Oversight and Organization(s) conducting appraisal/evaluation /implementation**
    4) *What type of organization(s) should govern/oversee the innovation framework (is there an existing organization(s) that can do this)? How should success of the framework be measured?*
    5) *What organization(s) should be involved in evaluating/generating evidence for innovations? Integrate with your answer to categories of innovation if possible.*

11.2 Afternoon Breakout Session: Barriers and Solutions

Session Objective:
- Provide solutions to critical barriers to implementing the innovation framework.

Barriers for Discussion:

Participants to choose two (2) barriers to discuss/debate that they feel they can best contribute to.

- **Define then provide potential solutions to overcoming the following barriers:**
    1. *Funding for:*
        - *Evidence generation*
        - *Oversight of the innovation framework*
    2. *Governance and prioritization of technologies (health system does not pull/direct research in areas of need).*
    3. *Connectivity of research and clinical data including privacy considerations.*

4. *System and culture change (silos and lack of alignment between industry/innovators, regulators, HTA agencies, system planners, implementors, funders/payers).*
5. *Regulatory environment.*
6. *General lack of evidence (published and real world) that is useful for decision-makers.*

Case Studies and Frameworks from Existing Innovation Groups

### 11.3   Canada - Alberta Health Services

In 2004, the Government of Alberta introduced the Alberta Health Technologies Decision Process (AHTDP), a formalized HTA process to provide evidence to decision makers on whether a new health technology should be publicly funded. In 2017, AHTDP was undated and the review process was reduced from two years to one year[1].

In the past, Alberta used the "technology push" model for topic selection. In this model, inventors approach Alberta Health for evaluation of their new health technology and evaluation was done in response to the needs of clinicians and industry without any alignment with the system priority needs. However, this method was prone to implementation problems due to inadequate client willingness to implement findings. At present, Alberta is moving toward a "demand pull model" that involves working with the health system to determine their priorities. Organizations such as AHS and the Strategic Clinical Network (SCN) work in partnership with the Alberta government to identify the topics that are likely to have the best implementation feasibility and impact and also to launch call for proposals to be reviewed by Alberta Health Evidence Reviews[2].
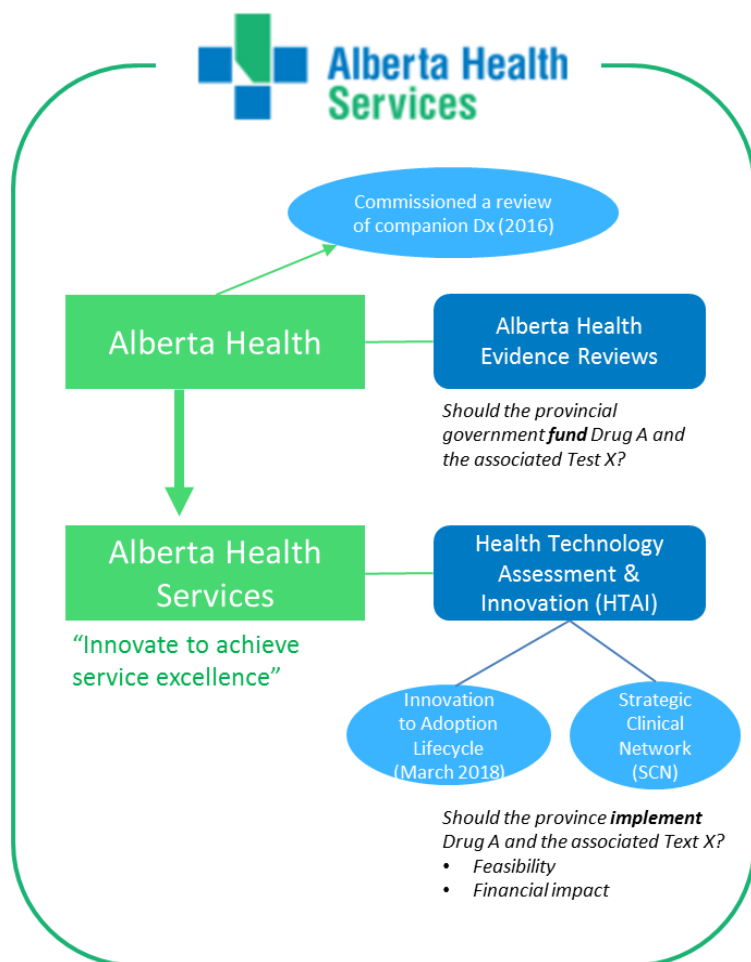
In addition to working with the Government of Alberta, SCN played a crucial role in the development of an innovation management process for AHS. SCN's Transformational Road Maps and other documents as well as the priorities identified by the Government of Alberta are used to identify areas of high priorities for AHS. The innovation management process used by AHS is known as Innovation to Adoption Lifecycle and it consists of 6-steps, namely; intake, navigation & coaching, evidence synthesis and assessment, adopt or not decision, implementation/de-implementation and monitoring and evaluation. A team oversees innovation management at AHS[2].

Managing Pushed Innovation: The Innovation to Adoption Lifecycle[2]
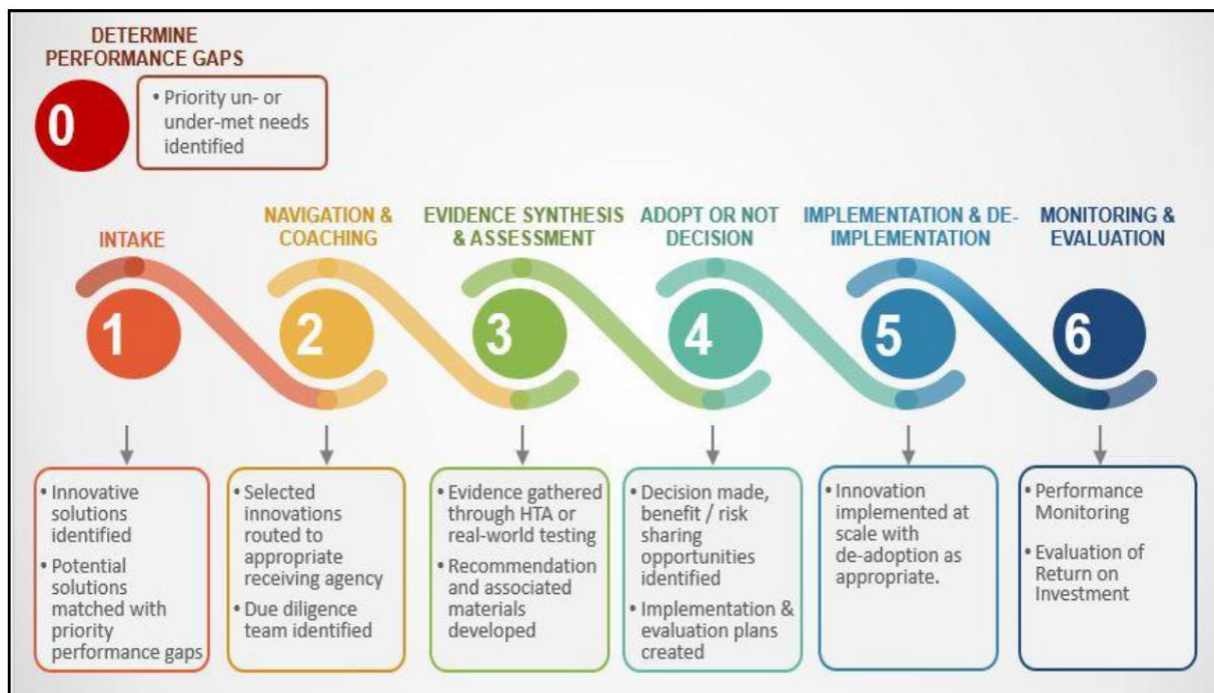
### 11.4   United Kingdom- National Health Service

National Institute for Health and Care Excellence (NICE) is an independent body of the Department of Health in the United Kingdom that produces guidelines in four areas including the use of health technologies within the National Health Service (NHS). Appraisals conducted by NICE are based on evaluations of efficacy and cost-effectiveness. It offers services to the English NHS and the Welsh NHS. The National Tariff Payment System (NTPS) is a publication by NHS England and NHS Improvement joint pricing team that provides information on prices and rules to help NHS healthcare providers and commissioners offer best value to their patients. The requirements of the NTPS are stated in the Health and Social Care Act 2012. In addition, the Act has set up NHS organizations known as the Clinical commissioning groups (CCGs) to coordinate the delivery of NHS services in England[9, 11].
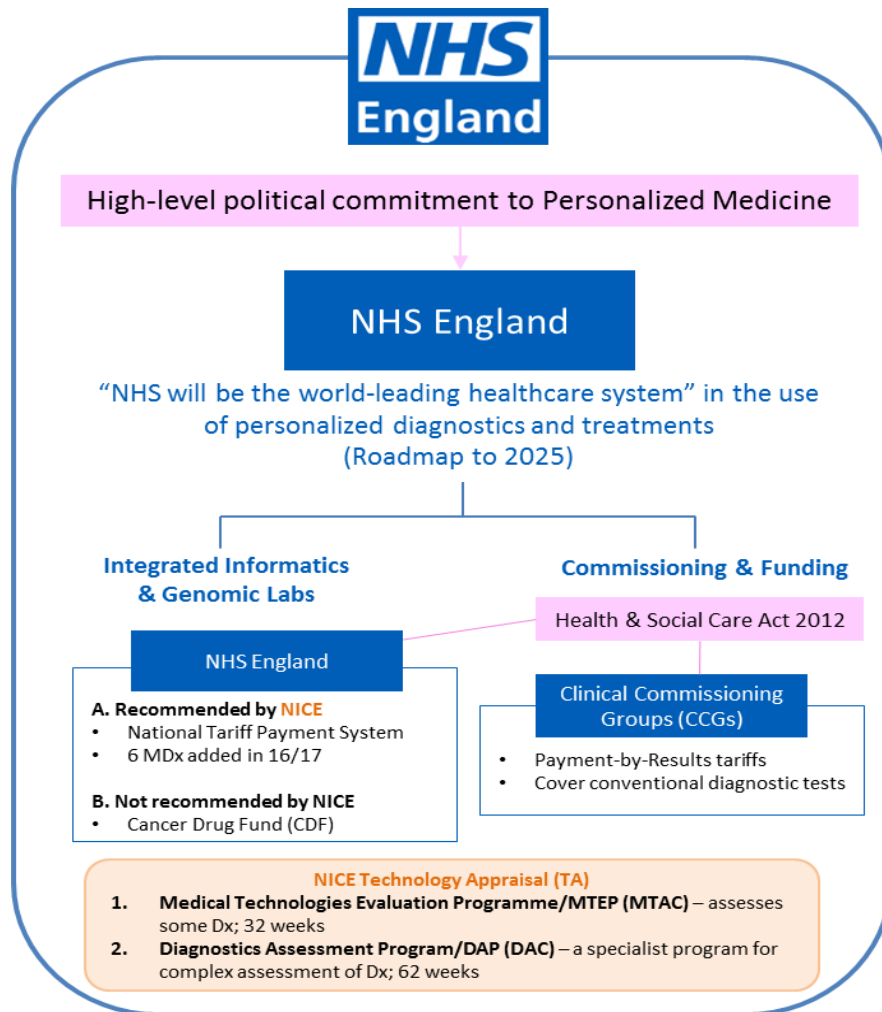
NICE has a very elaborate process for identify, selecting and routing technologies for evaluation as shown in the diagram below. Criteria for routing to the Medical Technology Evaluation Program (MTEP) include the likelihood of the new technology to save cost or be cost neutral, whether it can be evaluated as a single technology or not and if a short time is required for evaluation. The criteria for the Diagnostic Assessment Programme (DAP) are its ability to lead to an overall increase in resource costs to the health care system, if it can be evaluated as 1 of a class of similar technologies or as a single technology and if it could only be evaluated using clinical and cost utility. The evaluation processing time for MTEP and DAP are 32 weeks and 62 weeks respectively[8].

The selection and routing process
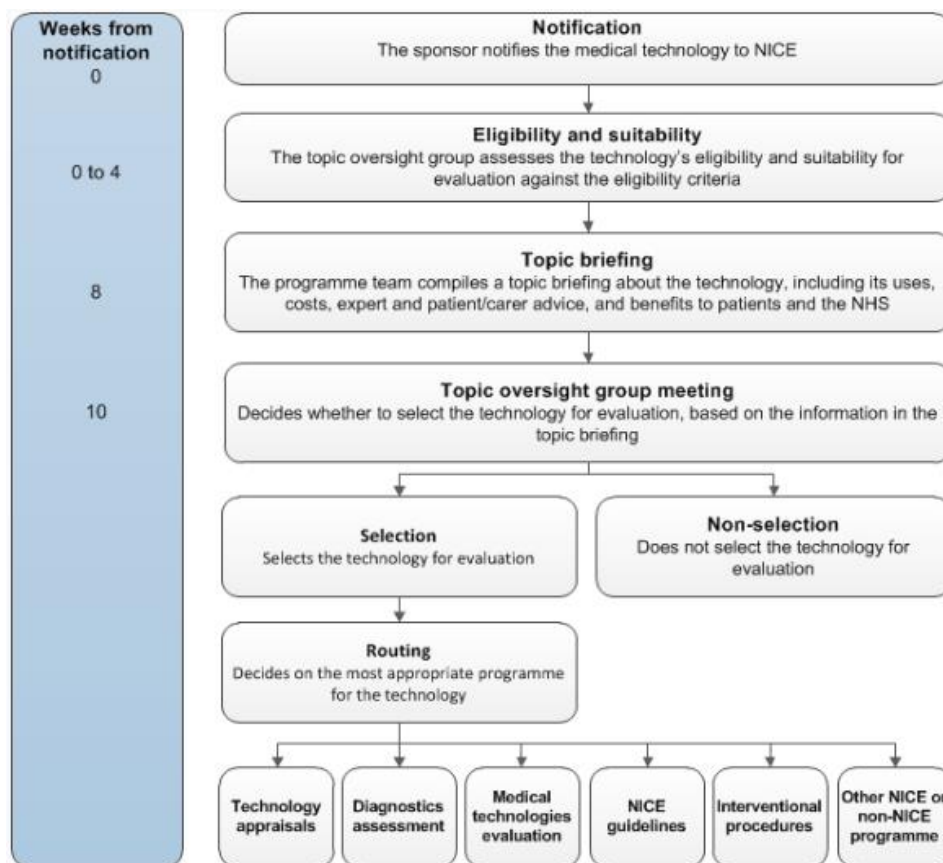
NICE assessment recommendations are prepared by independent advisory committees such the Diagnostics Advisory Committee (DAC) and Medical Technologies Advisory Committee (MTAC) for DAP and MTEP respectively. NICE adoption support team provides advice and tools to support the local implementation of its guidance[10].

11.5   United States - Kaiser Permanente

Kaiser Permanente is the largest managed care organization in the United States. It operates in eight states (Hawaii, Washington, Oregon, California, Colorado, Maryland, Virginia, Georgia) and the District of Columbia. It has 12.2 million health plan members, 39 medical centers and 690 medical facilities[3].

Kaiser Permanente (KP) has a well-established process for assessing, adopting and monitoring new innovative health technologies such as devices, equipment, diagnostics, and procedures. The process enables physicians of the Southern California Permanente Medical Group (SCPMG) to deliver the best care to their patients. Evaluation and adoption of health technologies at KP is managed by three teams of health care professionals, namely: the Medical Technology Assessment Team (MTAT) that assesses all medical technologies; the Medical Technology Deployment Strategy Team (MTDST) that develops deployment strategy and plans quality monitoring process; the Regional Product Council (RPC) that deploys all existing equipment, products, devices. These teams are supported by the Interregional New Technologies Committee, Laboratory Committees, and Pharmacy Committees.

The Joint Chairs Committee consisting of representatives from the MTAT, MTDST and RPC makes regionwide recommendations about new technology. Technologies that have programwide application are also assessed by the Interregional New Technologies Committee (INTC)[4].

11.6 Australia - Evaluations

In Australia, the Government approves health technology for public funding under different programs including the Pharmaceutical Benefits Scheme (PBS) and the Medicare Benefits Schedule (MBS). The Medical Services Advisory Committee (MSAC) and the Pharmaceutical Benefits Advisory Committee (PBAC) perform health technology assessment (HTA) processes to provide advice to the Australian Government Department of Health. Applicants seeking funding are assigned to any of these programs depending on nature of the health technology (medicine, a medical procedure, diagnostic test or a medical device). There is a dedicated HTA Team that guides applicants with codependent (e.g., a drug/test combination) or hybrid technologies on the best assessment pathways and expert advisory committee (e.g. MSAC, PBAC or others) to undertake this type of specialized assessment[5].

Australian Government HTA processes for market entry and for reimbursement processes
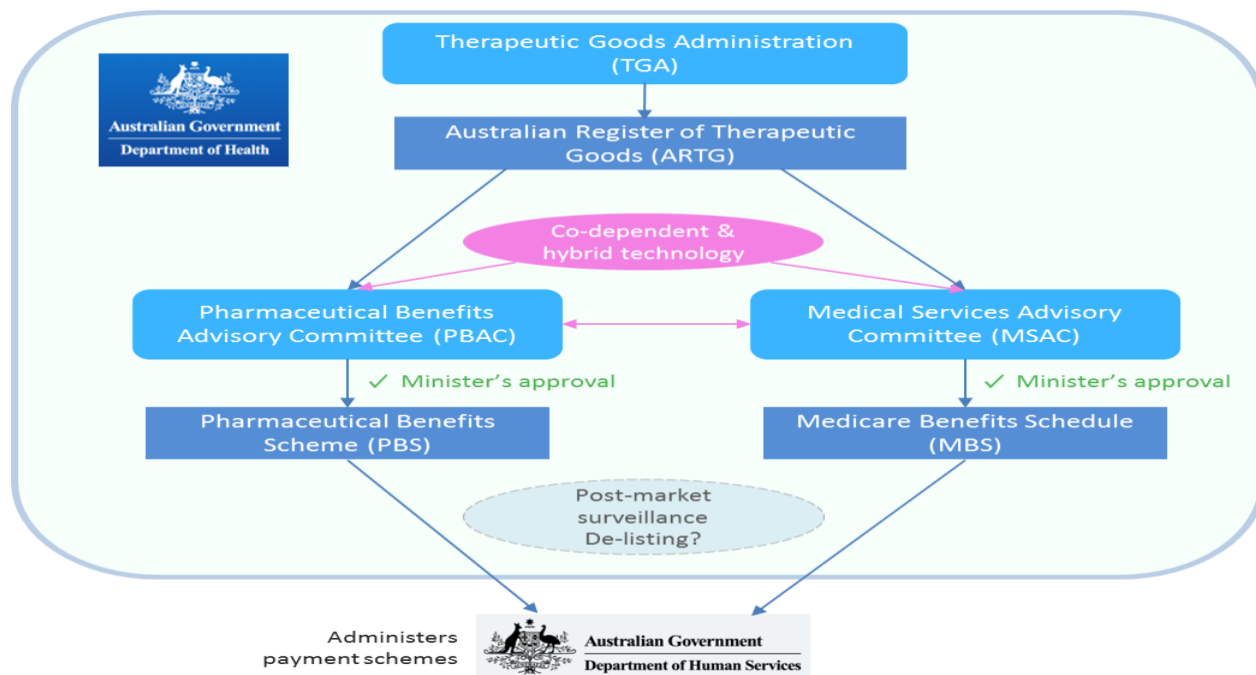
The Medical Services Advisory Committee (MSAC) was established by the Australian Government Minister for Health in 1998. It evaluates safety, clinical effectiveness and cost-effectiveness of new health technologies and advices the Government on whether to publicly fund new health technologies. Technologies approved for funding are listed on the Medicare Benefits Schedule (MBS)[6].

High-level MSAC process[7]
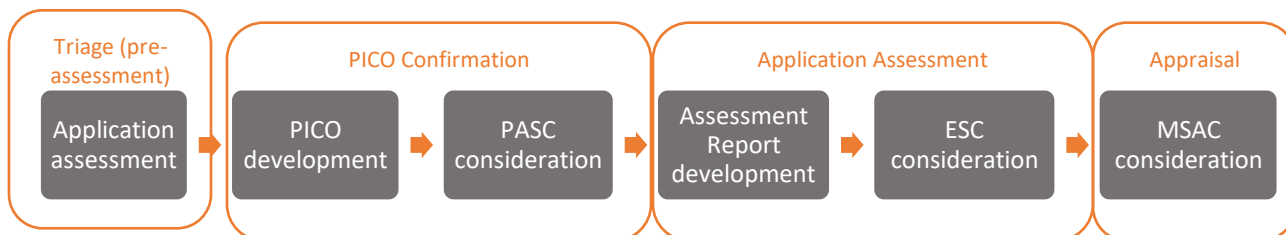
The MSAC process consist of four stages namely; Triage, Population Intervention Comparator Outcome (PICO) Confirmation, Application Assessment and Appraisal. It is supported by two sub-committees, the PICO Advisory Sub-committee (PASC) and the Evaluation Sub-committee (ESC) and Health Technology Assessment (HTA) Groups who provide a range of assessment, review and research support services to the Department. The processing time for each application varies and it depends on the time it takes to determine suitability and the MSAC pathway that the application follows. The three MSAC pathways

available are standard, comprehensive and expedited. The MSAC pathway of each application is informed by the Process Framework and the quality of the application and will depend on an application's complexity and novelty. After MSAC appraisal, the Minister will decide whether public funding should be approved based on MSAC recommendation and advice from the department. Once approved by the Minister, the department will add the approved health technology on the MBS. MSAC may give advice on MBS fees but it does not set them[6].

12 Existing Evaluation Teams in Ontario

12.1 Cancer Care Ontario Evaluation Programs

12.1.1 CCO Program in Evidence Based Care

The Program in Evidence-Based Care (PEBC) is an internationally recognized guideline development program based at McMaster University. The program produces evidence-based guidelines and resources in partnership with clinical experts in all major cancer disease sites and across all clinical programs and modalities. The guidelines help clinicians and policy makers apply the best scientific evidence in practice and policy decisions.

The purpose of the PEBC is to: i) Develop evidence-based resources to support care and policy decision-making; ii) Maintain the quality and currency of resources and iii) Disseminate and evaluate resources.

Their goals are to develop and review 25 to 30 new guidance documents annually, disseminate the guidance documents and work with clinical experts, patient and family representatives, researchers, and policy and planning experts to develop guidelines.

Examples of PEBC guidance documents include:

1. Role of Bone-Modifying Agents in Metastatic Breast Cancer: An American Society of Clinical Oncology–Cancer Care Ontario Focused Guideline Update https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/43266
2. Adjuvant Systemic Chemotherapy for Stage II and III Colon Cancer Following Complete Resection https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/231
3. The Use of Systemic Treatment in the Maintenance of Patients with Non-Small Cell Lung Cancer https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/831

12.1.2 CCO Evidence Building Program

In March 2011, the Ministry of Health and Long-Term Care (MOHLTC) announced a new Evidence Building Program (EBP) for cancer drugs. The EBP, a joint initiative between Ontario Public Drug Programs (OPDP) and Cancer Care Ontario (CCO), was designed to resolve uncertainty around clinical and cost-effectiveness data related to the expansion of cancer-drug coverage in Ontario. The EBP complements and strengthens Ontario's process for making drug-funding decisions. The objective of the EBP is to develop and collect real-world data on cancer drugs where evolving evidence demonstrates clinical benefit beyond the current reimbursement criteria. For a drug to be included in the EBP, there must be mounting evidence of its benefits, such that funding for in a fixed period will allow CCO to gather real-world data about its efficacy and cost-effectiveness. This data will be given to the Executive Officer of Ontario Public Drug Program, who will use the information to make a final funding decision. A number of EBP projects have been conducted, including:

1. Azacitidine in the 'real-world': an evaluation of 1101 higher-risk myelodysplastic syndrome/low blast count acute myeloid leukaemia patients in Ontario, Canada
2. Adjuvant Trastuzumab in Node-Negative HER2-Positive Breast Cancer Patients with Tumours Less than or Equal to 1 cm
3. Oxaliplatin with Surgery for Curative Intent for Colorectal Cancer Patients with Resectable or Potentially Resectable Extrahepatic Metastases

Each project has collected clinical outcomes, safety measures and patient information in the real world setting to support funding decision making.

12.1.3   CCO Positron Emission Tomography (PET) Access Program

The PET Scans Ontario program works with the Ministry of Health and Long-Term Care to coordinate PET scan services across the province. The program is guided by the provincial PET Steering Committee, an interdisciplinary group of experts. The committee reviews scientific evidence and makes recommendations to the ministry. This helps make sure access to PET services is supported by the best available research. Their goal is to: 1) Improve transparency, accountability and equity of PET scan services and ii) Continually review research to make sure PET scan use is based on the best available evidence.

In terms of evidence building, the Ontario PET Access Program considers, on a case-by-case basis, requests from physicians for the provision of PET scans for patients who may benefit, but who do not meet the eligibility criteria to receive PET scans under one of these other categories: insured services, the PET Registry or clinical trials. Link at https://www.petscansontario.ca/access_program/

12.2   Health Quality Ontario

Health Quality Ontario (HQO) has a legislated mandate to make evidence-based recommendations to the Minister of Health and Long-Term Care on which health care services and devices should be publicly funded.

They fulfill this mandate with the support of the Ontario Health Technology Advisory Committee, which reviews health technology assessments and then, after careful deliberation, makes their final recommendations.

The Ontario Health Technology Advisory Committee is a committee of Health Quality Ontario's Board of Directors. Sub-committees include the Ontario Genetics Advisory Committee. The Ontario Genetics Advisory Committee advises on which genetic and genomic services and devices should be publicly funded.

HQO has conducted a number of reviews in the cancer technology space. A list of projects and recommendations reviewed by HQO include.

1.   [Robotic Surgical System for Radical Prostatectomy](#)

Publication date: July 2017 Status: Final recommendation

Prostate cancer is the most common cancer in men, after nonmelanoma skin cancers. The effectiveness of robot-assisted laparoscopic prostatectomy is being investigated.

2.   [Prolaris Cell Cycle Progression Test for Localized Prostate Cancer](#)

Publication date: May 2017 Status: Final recommendation

Many men develop prostate cancer, but often it is not an immediate risk to their health. Deciding on treatment for prostate cancer can be difficult. The Prolaris cell cycle progression test aims to estimate how quickly the cancer might be progressing. This would add information to the usual ways of assessing a patient's risk from his prostate cancer.

3.   [Gene Expression Profiling Tests for Breast Cancer](#)

Project start date: August 2018 Status: In Development

For people with early-stage breast cancer, gene expression profiling tests can be used to look at the expression of different genes in cancer cells. These tests help predict cancer recurrence after initial treatment and help physicians determine if a person may benefit from additional treatment. Estimated publication date: Winter 2019

4.   [Liquid Biopsy for EGFR T790M Mutation in Patients With Non-Small Cell Lung Cancer](#)

Project start date: March 2018 Status: In Development

Lung cancer is characterized by the uncontrolled growth of abnormal cells in one or both lungs. A mutation known as T790M contributes to cancer progression in patients with non-small cell lung cancer.

Liquid biopsy is a blood test that can detect this mutation and assist clinical decision-making without requiring a more invasive tissue biopsy. Estimated publication date: Fall 2019.

5. [Prostate-Specific Antigen (PSA) Testing for Diagnosis and Monitoring of Prostate Cancer](#)

Deferment date: January 2017 Status: Review Deferred

The PSA blood test is widely used to diagnose and monitor prostate cancer, a very common but often slow-growing type of cancer as men age. In past work, Health Quality Ontario has examined the evidence for population-based PSA screening. This review would look at the evidence for testing men who have or are suspected of having prostate cancer. Deferment rationale: This topic was deemed a lower priority than others; this decision will be revisited during subsequent prioritizations.

6. [Magnetic Resonance Imaging as an Adjunct to Mammography for Breast Cancer Screening in Women at Less Than High Risk for Breast Cancer](#)

Publication date: November 2016 Status: Final recommendation

The most common form of screening for breast cancer is mammography. This review looked at the impact of magnetic resonance imaging (MRI) as an adjunct test to mammography for breast cancerscreening in women at less than high risk for breast cancer.

7. [Ultrasound as an Adjunct to Mammography for Breast Cancer Screening](#)

Publication date: July 2016 Status: Final recommendation

Screening for breast cancer is the process of looking for the disease before symptoms arise so it can be treated early. In Ontario, mammography (a low-dose x-ray) is used to screen women at average risk for breast cancer. Ultrasound is an imaging method that uses sound waves and can be used to look for breast cancer missed by mammography.

8. [Robotic-Assisted Minimally Invasive Prostatectomy](#)

Publication date: January 2014 Status: Final recommendation

Prostate cancer is the most common cancer among men. If the cancer has not spread, prostatectomy (a surgery that removes the prostate) is used for treatment. The Da Vinci system is a robotic device used to perform surgery.

9. [Vertebral Augmentation Involving Vertebroplasty or Kyphoplasty for Cancer-Related Vertebral Compression Fractures](#)

Publication date: May 2016 Status: Final recommendation

When cancer spreads to or occurs in a bone of the spine (a vertebral bone), the cancer can weaken and break this bone. Vertebroplasty and kyphoplasty are two procedures that stabilize a spinal fracture by injecting bone cement into the broken bone. With kyphoplasty, a small balloon is inserted first to restore height and create a space to inject the cement.

10. [Intrathecal Drug Delivery Systems for Cancer Pain and Noncancer Pain](#)

Publication date: January 2016 Status: Final recommendation

Some patients with chronic back pain do not feel sufficient relief with oral medications. Intrathecal drug delivery systems involve a pump connected to a small tube implanted in the spine.

11. [Prostate-Specific Antigen–Based Population Screening for Prostate Cancer](#)

Publication date: May 2015 Status: Final recommendation

The prostate-specific antigen (PSA) blood test is widely used in Canada to diagnose and monitor patients with prostate cancer. There has been debate about whether to introduce a formal program to screen all men over a certain age for prostate cancer.

12. Minimal Residual Disease Evaluation in Childhood Acute Lymphoblastic Leukemia

Publication date: March 2016 Status: Final recommendation

Leukemia is a cancer of the blood cells, and acute lymphoblastic leukemia makes up nearly 80% of childhood leukemia cases. Testing for minimal residual disease (MRD) involves the detection of tiny amounts of cancer cells in the bone marrow. Depending on whether minimal residual disease is found and at what level, treatment might be adjusted to help children have the best outcomes possible.

13. Screening Mammography for Women Aged 40 to 49 Years at Average Risk for Breast Cancer

Publication date: January 2011 Status: Final recommendation

A mammogram is an x-ray to look for signs of breast cancer. The evidence on screening women aged 40 to 49 years with average risk for breast cancer was reviewed.

14. Colon Capsule Endoscopy for the Detection of Colorectal Polyps

Publication date: July 2015 Status: Final recommendation

Many cases of colorectal cancer can be prevented through early diagnosis and the removal of polyps, or growths, which may develop into cancer. Colon capsule endoscopy is a relatively new, non-invasive test to detect colorectal polyps and help with early detection of colorectal cancer.

12.3 MaRS Excite

MaRS EXCITE supports companies whose innovative technologies could improve health outcomes, helping them navigate the complex process of gaining access to Ontario's $50-billion health system.

Working in partnership with the Ministry of Health, the main funding entity in Ontario, EXCITE helps companies generate the contextual evidence they need to access the province's market, including product value and other key stakeholder decision-making requirements.

The goal is **Faster technology adoption. Better patient outcomes. More affordable health care.**

A comprehensive service that supports health technology companies through the entire process of accessing Ontario's market. End-to-End EXCITE consists of three phases: technology appraisal, evaluation design & evidence generation, and implementation navigation.

Advantages:

- Identifies disruptive health technologies aligned to health system needs
- Co-designs a streamlined clinical trial protocol containing both regulatory and reimbursement endpoints
- Connects companies with world class methodology centres to generate contextual evidence of their technology's efficacy and value
- Identifies systemic barriers that hinder adoption and diffusion of technology
- Provides the company and Ministry of Health with a comprehensive market access plan detailing barriers, opportunities and potential implementation pathways

12.4 Canadian Agency for Drugs and Technologies in Health

Over the course of the past 10 years, the Rapid Response Service has become one of CADTH's signature programs and a trusted resource for health care decision-makers across Canada.

The program offers a range of products that help support pressing policy and practice decisions. Rapid Response reports can range from a list of relevant scientific articles to more extensive reports that include appraisals of the evidence and peer review. Approximately 70 per cent of Rapid Response reports focus on medical devices, diagnostics, and procedures.

13 Why now?

- Inflection point; common interest in solving the problem; fear of Ontario following behind
- Impetus comes from desire to improve care and also economic pressures on healthcare system with large expected increase in cancer cases in Ontario
- Large number of developed technologies; research push and clinical/care pull
- Interest from Ontario government in seeing concrete impact from innovation
- Interest from Ontario government in bending cost curves in health care
- Partnership opportunities and interest, especially for research and commercialization
- Education available
- Realization that fragmented solutions currently in place are causing inefficiencies and unequal access for patients
- Lack of standardized approach will lead to patients in different jurisdictions getting potentially different management
- Global hospital budgets cannot accommodate the growing needs in this area- this must be managed, not a reactive process
- Lack of control/process if industry continues to fund testing without governance

14 Acronyms

Acronym	Organization or Group
AHS	Alberta Health Services
AHTDP	Alberta Health Technologies Decision Process
CADTH	Canadian Agency for Drugs and Technologies in Health
CCG	Clinical commissioning group
CCO	Cancer Care Ontario
DAC	Diagnostics Advisory Committee
DAP	Diagnostic Assessment Pathway
EBP	Evidence Building Program
ESC	Evaluation Sub-committee
HQO	Health Quality Ontario
HTA	Health technology assessment
HTAI	The Health Technology Assessment & Innovation
INTC	Interregional New Technologies Committee
KP	Kaiser Permanente
MBS	Medicare Benefits Schedule
MOHLTC	Ministry of Health and Long-Term Care
MSAC	Medical Services Advisory Committee
MTAC	Medical Technologies Advisory Committee
MTAT	Medical Technology Assessment Team
MTDST	Medical Technology Deployment Strategy Team
MTEP	Medical Technology Evaluation Program
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NTPS	National Tariff Payment System
OGAC	Ontario Genomics Assessment Committee
OHA	Ontario Health Agency
OHT	Ontario Health Teams
OHTAC	Ontario Health Technology Assessment Committee
OICR	Ontario Institute for Cancer Reserach
OPDP	Ontario Public Drug Programs
PASC	PICO Advisory Sub-committee PASC
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PEBC	Program in Evidence Based Care
PET	Positron Emission Tomography
PICO	Population Intervention Comparator Outcome
RPC	Regional Product Council
SCN	Strategic Clinical Network
SCPMG	Southern California Permanente Medical Group

APPENDIX I

15 Literature Review and Environmental Scan

The following are selected references with excerpts from articles relevant to the topics to be discussed at the workshop.

Subject: Evaluation of innovative precision oncology/medicine and other technologies

CANADIAN

Articles

Leonard KJ. Critical success factors relating to healthcare's adoption of new technology: a guide to increasing the likelihood of successful implementation. Electronic Healthcare. 2004 Mar;2(4):72-81 [Freely available]

https://www.longwoods.com/content/16194//critical-success-factors-relating-to-healthcare-s-adoption-of-new-technology-a-guide-to-increasing

Over the last decade, significant attention has been paid in both academic and professional literature to the healthcare information technology conundrum, which can easily be summarized in the following question: Why have we not seen more successful implementation of information technology in healthcare? While many theories and suggestions have been proposed, there can be no argument that none have been truly effective in explaining or helping to resolve this widespread problem. As a result, the healthcare field is becoming experienced in building not-so-effective systems. The obvious question facing healthcare is: How do we get out of this cycle of poor systems begetting more poor systems? The recommendation presented herein is that we analyze the process of adopting new technology in other sectors, across different organizations and industries. There are a number of ways of illustrating experiences - through case studies, research papers or conference presentations. Here, we apply storytelling, where the stories are short vignettes that encapsulate a problem, a decision process, the solution selected and the results. We present a number of stories from within healthcare and elsewhere that illustrate the struggle and lessons learned in many different areas of innovation and new technology. We define the relevant critical success factors and provide a guideline for further adoption of innovation. Whether the information technology creates new functionality or replaces an existing system, the critical fact is that the outcomes resulting from the adoption must be measured - compared to previous statistics or results to illustrate the improvement (or not) provided by the new technology - and ultimately, this change in outcomes must be communicated to stakeholders. While all this may seem obvious and perhaps even trivial, one of the fatal flaws in information systems design is that new technology (regardless of its composition) requires an interface with human beings. If the stakeholders do not have their expectations properly established through effective communication, resistance to change and other factors will often derail an otherwise effective new technology adoption.

Woiceshyn J, Blades K, Pendharkar SR. Integrated versus fragmented implementation of complex innovations in acute health care. Health Care Manage Rev. 2017 Jan/Mar;42(1):76-86. [Open Access] Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5131693/

Abstract BACKGROUND: Increased demand and escalating costs necessitate innovation in health care. The challenge is to implement complex innovations-those that require coordinated use across the adopting organization to have the intended benefits. PURPOSE: We wanted to understand why and how two of five similar hospitals associated with the same health care authority made more progress with implementing a complex inpatient discharge innovation whereas the other three experienced more difficulties in doing so.

METHODOLOGY: We conducted a qualitative comparative case study of the implementation process at five comparable urban hospitals adopting the same inpatient discharge innovation mandated by their health care authority. We analyzed documents and conducted 39 interviews of the health care authority and hospital executives and frontline managers across the five sites over a 1-year period while the implementation was ongoing. FINDINGS: In two and a half years, two of the participating hospitals had made significant progress with implementing the innovation and had begun to realize benefits; they exemplified an integrated implementation mode. Three sites had made minimal progress, following a

fragmented implementation mode. In the former mode, a semiautonomous health care organization developed a clear overall purpose and chose one umbrella initiative to implement it. The integrative initiative subsumed the rest and guided resource allocation and the practices of hospital executives, frontline managers, and staff who had bought into it. In contrast, in the fragmented implementation mode, the health care authority had several overlapping, competing innovations that overwhelmed the sites and impeded their implementation. PRACTICE IMPLICATIONS:

Implementing a complex innovation across hospital sites required (a) early prioritization of one initiative as integrative, (b) the commitment of additional (traded off or new) human resources, (c) deliberate upfront planning and continual support for and evaluation of implementation, and (d) allowance for local customization within the general principles of standardization.

Grey literature

Institute of Health Economics. Addressing gaps and challenges with the integration of precision health technologies into the Canadian health system: Summary report of an IHE/CAPT Precision Health Workshop. Edmonton (AB): Institute of Health Economics; 2017. Can find link to report at https://www.ihe.ca/events/past/conferences/ihecapt/about-phw;.

OTHER (non-Canadian)

Articles

Misra SC, Bisui S. Modelling vital success factors in adopting personalized medicine system in healthcare technology and management. Engineering Science and Technology, an International Journal. 2018 Jun 1;21(3):532-45. [Freely available]

https://www.sciencedirect.com/science/article/pii/S2215098616309995/pdfft?md5=e7bf59acff74851305447cfc0e169221&pid=1-s2.0-S2215098616309995-main.pdf

Abstract: Biomedical engineering has grown as a vast field of research that includes many areas of engineering and technology also. Personalized Medicine is an emerging approach in today's medicare system. It bears a very strong potential to consolidate modern e-health systems fundamentally. Scientists have already discovered some of the personalized drugs that can shift the whole medicare system into a new dimension. However, bringing the change in the whole medicare system is not an easy task. There are several factors that can affect the successful adoption of Personalized Medicine systems in the healthcare management sector. This paper aims at identifying the critical factors with the help of an empirical study. A questionnaire was distributed amongst some clinicians, clinical researchers, practitioners in pharmaceutical industries, regulatory board members, and a larger section of patients. The response data collected thereby were analyzed by using appropriate statistical methods. Based on the statistical analysis, an attempt is made to prepare a list of critical success factors in the adoption of personalized medicine in healthcare management. The study indicates that eight of the thirteen hypothesized factors have statistical relationship with "Success". The important success factors detected are: data management, team work and composition, privacy and confidentiality, mind-set, return on investment, sufficient time, R&D and alignment. To the best of our knowledge, this is the first academic paper in which an attempt has been made to model the vital critical factors for the successful implementation of Personalized Medicine in healthcare management. The study bears the promise of important applications in healthcare engineering and technology.

Subject: Guidelines for implementing innovation

CANADIAN

Articles

Krahn M, Miller F, Bayoumi A, Brooker A-S. Development Of The Ontario Decision Framework: A Values Based Framework For Health Technology Assessment. International Journal of Technology Assessment in Health Care. 2018;34(3): 290-299. Abstract Available from: https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/development-of-the-ontario-decision-framework-a-values-based-framework-for-health-technology-assessment/4B4E0FF520FDED96F830C24BED31635A

Objectives: In 2007, the Ontario Health Technology Advisory Committee (OHTAC) developed a decision framework to guide decision making around nondrug health technologies. In 2012, OHTAC commissioned a revision of this framework to enhance its usability and deepen its conceptual and theoretical foundations. Methods: The committee overseeing this work used several methods: (a) a priori consensus on guiding principles, (b) a scoping review of decision attributes and processes used globally in health technology assessment (HTA), (c) presentations by methods experts and members of review committees, and (d) committee deliberations over a period of 3 years.

Results: The committee adopted a multi-criteria decision-making approach, but rejected the formal use of multi-criteria decision analysis. Three broad categories of attributes were identified: (I) context criteria attributes included factors such as stakeholders, adoption pressures from neighboring jurisdictions, and potential conflicts of interest; (II) primary appraisal criteria attributes included (i) benefits and harms, (ii) economics, and (iii) patient-centered care; (III) feasibility criteria attributes included budget impact and organizational feasibility.

Conclusion: The revised Ontario Decision Framework is similar in some respects to frameworks used in HTA worldwide. Its distinctive characteristics are that: it is based on an explicit set of social values; HTA paradigms (evidence based medicine, economics, and bioethics/social science) are used to aggregate decision attributes; and that it is rooted in a theoretical framework of optimal decision making, rather than one related to broad social goals, such as health or welfare maximization.

OTHER (non-Canadian)

Articles

Schneeweiss S, Shrank WH, Ruhl M, Maclure M. Decision-Making Aligned With Rapid-Cycle Evaluation In Health Care. International Journal of Technology Assessment in Health Care. 2015;31(4): 214-222. Abstract Available from: https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/decisionmaking-aligned-with-rapidcycle-evaluation-in-health-care/543E08FFF109798BCD2DF38D41E8827C

Background: Availability of real-time electronic healthcare data provides new opportunities for rapid-cycle evaluation (RCE) of health technologies, including healthcare delivery and payment programs. We aim to align decision-making processes with stages of RCE to optimize the usefulness and impact of rapid results. Rational decisions about program adoption depend on program effect size in relation to externalities, including implementation cost, sustainability, and likelihood of broad adoption. Methods: Drawing on case studies and experience from drug safety monitoring, we examine how decision makers have used scientific evidence on complex interventions in the past. We clarify how RCE alters the nature of policy decisions; develop the RAPID framework for synchronizing decision-maker activities with stages of RCE; and provide guidelines on evidence thresholds for incremental decision-making. Results: In contrast to traditional evaluations, RCE provides early evidence on effectiveness and facilitates a stepped approach to decision making in expectation of future regularly updated evidence. RCE allows for identification of trends in adjusted effect size. It supports adapting a program in midstream in response to interim findings, or adapting the evaluation strategy to identify true improvements earlier. The 5-step RAPID approach that utilizes the cumulating evidence of program effectiveness over time could increase policy-makers' confidence in expediting decisions. Conclusions: RCE enables a step-wise approach to HTA decision-making, based on gradually emerging evidence, reducing delays in decision-making processes after traditional one-time evaluations.

Nadauld LD, Ford JM, Pritchard D, Brown T. Strategies For Clinical Implementation: Precision Oncology At Three Distinct Institutions. Health Affairs. 2018;37(5). Abstract Available from: https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1575

ABSTRACT: Despite rapid advances in molecular diagnostics and targeted therapeutics, the adoption of precision medicine into clinical oncology workflows has been slow. Questions about clinical utility, inconsistent reimbursement for molecular diagnostics, and limited access to targeted therapies are some of the major hurdles that have hampered clinical adoption. Despite these challenges, providers have invested in precision medicine programs in an ongoing search for innovative care models to deliver improved patient outcomes and achieve economic gains. We describe the precision oncology medicine programs implemented by an integrated delivery system, a community care center, and an academic

medical center, to demonstrate the approaches and challenges associated with clinical implementation efforts designed to advance this treatment paradigm. Payer policies that include coverage for broad genomic testing panels would support the broader application of precision medicine, deepen research benefits, and bring targeted therapies to more patients with advanced cancer.

Subject: Funding for groups reviewing new health technology, precision medicine/oncology

CANADIAN

Grey literature

Townsend M. Learning from Kaiser Permanente: Integrated systems and healthcare improvement in Canada. Ottawa. Canadian Foundation for Healthcare Improvement. 2014. Report available from:

https://www.cfhi-fcass.ca/sf-docs/default-source/reports/learning-from-kaiser-permanente-townsend-e.pdf?sfvrsn=2

This report draws on a growing body of literature on integrated care, and compares two distinctive approaches to health system provision in North America: a non-profit insurance and managed care system (i.e., Kaiser Permanente), and two provincial tax-financed, single insurer, systems in Canada (i.e., Ontario's Ministry of Health and Long-Term Care and Saskatchewan's Ministry of Health). In offering such a comparison, this report does not suggest any one system has a monopoly on good ideas. The reality is that comparing Kaiser Permanente to other healthcare systems is complex, and subject to bias and error, as several differences are readily apparent between the populations served and the funding made available. Despite these differences, Kaiser Permanente has invested heavily in an integrated clinical system, and can provide many lessons to Canadian jurisdictions looking to strengthen healthcare leadership, financing, information and innovation.

Alberta Innovates – Health Solutions. Accelerating the Impact of Health Research and Innovation: Business Plan 2016-2019. Edmonton: Alberta Innovates – Health Solutions; [2016]. Available from:

https://albertainnovates.ca/wp-content/uploads/2016/12/AIHS-2016-2019-Business-Plan.pdf

The three year Business Plan (the Plan) builds on the vision of a provincial partnership of government departments and agencies, and key partner organizations, including Alberta Innovates – Health Solutions (AIHS), to better integrate health research and health care and to accelerate the impact of research and innovation in achieving economic, social and health benefits for Albertans. This broad partnership aims to strengthen a thriving research and innovation community that has a clear role in producing new knowledge that will lead to better ways of delivering care, improving patient experiences and outcomes, and reducing costs.

OTHER (non-Canadian)

Articles

Ginsburg GS, Phillips KA. Precision Medicine: From Science To Value. Health Aff (Millwood). 2018 May;37(5):694-701. doi: 10.1377/hlthaff.2017.1624. Available from

https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.1624

Abstract

Precision medicine is making an impact on patients, health care delivery systems, and research participants in ways that were only imagined fifteen years ago when the human genome was first sequenced. Discovery of disease-causing and drug-response genetic variants has accelerated, while adoption into clinical medicine has lagged. We define precision medicine and the stakeholder community required to enable its integration into research and health care. We explore the intersection of data science, analytics, and precision medicine in the formation of health systems that carry out research in the context of clinical care and that optimize the tools and information used to deliver improved patient outcomes. We provide examples of real-world impact and conclude with a policy and economic agenda necessary for the adoption of this new paradigm of health care both in the United States and globally.

Subject: Governance of HTA innovation implementation

CANADIAN

Articles

MacNeil M, Koch M, Kuspinar A, Juzwishin D, Lehoux P, Stolee P. Enabling health technology innovation in Canada: Barriers and facilitators in policy and regulatory processes. Health Policy. 2019 Feb;123(2):203-214. doi: 10.1016/j.healthpol.2018.09.018. Epub 2018 Oct 12. *(Open Access)* Available from: https://www.sciencedirect.com/science/article/pii/S0168851018305396

Abstract OBJECTIVES: Health care innovation and technologies can improve patient outcomes, but policies and regulations established to protect the public interest may become barriers to improvement of health care delivery. We conducted a scoping review to identify policy and regulatory barriers to, and facilitators of, successful innovation and adoption of health technologies (excluding pharmaceutical and information technologies) in Canada.

METHODS: The review followed Arksey and O'Malley's methodology to assess the breadth and depth of literature on this topic and drew upon published and grey literature from 2000-2016. Four reviewers independently screened citations for inclusion. RESULTS: Sixty- seven full- text documents were extracted to collect facilitators and barriers to health technology innovation and adoption. The extraction table was themed using content analysis, and reanalyzed, resulting in facilitators and barriers under six broad themes: development, assessment, implementation, Canadian policy context, partnerships and resources. CONCLUSION: This scoping review identified current barriers and highlights numerous facilitators to create a responsive regulatory and policy environment that encourages and supports effective co-creation of innovations to optimize patient and economic outcomes while emphasizing the importance of sustainability of health technologies.

Lehoux P, Roncarolo F, Silva HP, Boivin A, Denis JL, Hébert R. What Health System Challenges Should Responsible Innovation in Health Address? Insights From an International Scoping Review. Int J Health Policy Manag. 2018 Nov 28;8(2):63-75. doi: 10.15171/ijhpm.2018.110. *(Open Access)* Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6462209/

Abstract. BACKGROUND: While responsible innovation in health (RIH) suggests that health innovations could be purposefully designed to better support health systems, little is known about the system-level challenges that it should address. The goal of this paper is thus to document what is known about health systems' demand for innovations. METHODS: We searched 8 databases to perform a scoping review of the scientific literature on health system challenges published between January 2000 and April 2016. The challenges reported in the articles were classified using the dynamic health system framework. The countries where the studies had been conducted were grouped using the human development index (HDI). Frequency distributions and qualitative content analysis were performed. RESULTS: Up to 1391 challenges were extracted from 254 articles examining health systems in 99 countries. Across countries, the most frequently reported challenges pertained to: service delivery (25%), human resources (23%), and leadership and governance (21%). Our analyses indicate that innovations tend to increase challenges associated to human resources by affecting the nature and scope of their tasks, skills and responsibilities, to exacerbate service delivery issues when they are meant to be used by highly skilled providers and call for accountable governance of their dissemination, use and reimbursement. In countries with a low and medium HDI, problems arising with infrastructure, logistics and equipment were described in connection with challenges affecting procurement, supply and distribution systems. In countries with a medium and high HDI, challenges included a growing demand for drugs and new technology and the management of rising costs. Across all HDI groups, the need for flexible information technologies (IT) solutions to reach rural areas was underscored.

CONCLUSION: Highlighting challenges that are common across countries, this study suggests that RIH should aim to reduce the cost of innovation production processes and attend not only to the requirements of the immediate clinical context of use, but also to the vulnerabilities of the broader system wherein innovations are deployed. Policy-makers should translate system-level demand signals into innovation development opportunities since it is imperative to foster innovations that contribute to the success and sustainability of health systems.

Grey Literature

Granados A, Low E, Meyer F, Mujoomdar M, Bettle M. HTA, From Reacting to Innovation to Proactively Involved in Technology Development. Lessons Learnt and Ways Forward. Report of HTAi 2018 Panel Session. Health Technology Assessment International – Canada. 2018. Available from: https://htai.org/wp-content/uploads/2018/10/180910-HTAi-2018-Panel-Report-HTA-Involved-in-Technology-Development.pdf

OTHER (non-Canadian)

Articles

Nicol D, Bubela T, Chalmers D, Charbonneau J, Critchley C, Dickinson J, Fleming J, Hewitt AW, Kaye J, Liddicoat J. Precision medicine: drowning in a regulatory soup? Journal of Law and the Biosciences. 2016 Aug; 3(2) 281–303, https://doi.org/10.1093/jlb/lsw018 *(Open Access)* Available from: https://academic.oup.com/jlb/article/3/2/281/1751241

INTRODUCTION: As US President Barack Obama noted in his 2015 State of the Union address, precision medicine promises to deliver 'the right treatments, at the right time, every time to the right person' which 'gives us one of the greatest opportunities for new medical breakthroughs that we have ever seen'. These comments were a prelude to a $215 million funding commitment by the President to his Precision Medicine Initiative, the aim of which is to 'pioneer a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select which treatments will work best for which patients'. The objectives include an undertaking to modernize the current regulatory landscape.

16 References

Alberta

1. Maximizing the Impact of Health Technology Assessment: The Alberta Framework
2. Health Economics in AHS, HTAI-newsletter 2018

Kaiser Permanente

1. https://en.wikipedia.org/wiki/Kaiser_Permanente
2. Joanne Schottinger and Richard Odell. Kaiser Permanente Southern California Regional Technology Management Process: Evidence-Based Medicine Operationalized. The Permanente Journal/ Spring 2006/ Volume 10 No. 1

Australia

1. http://www.health.gov.au/internet/hta/publishing.nsf/Content/commonwealth-1
2. http://www.msac.gov.au/
3. MSAC Process Framework: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/FFDFEFDA8B25248FCA25801000123AD3/$File/Final%20Process%20Framework.pdf

NHS

1. https://www.nice.org.uk/guidance
2. NHS 2019/20 National Tariff Payment System: https://www.nice.org.uk/process/pmg34/chapter/identifying-selecting-and-routing-technologies-for-evaluation
3. http://www.legislation.gov.uk/ukpga/2012/7/section/116/enacted

Ontario