Ontario Pathway Towards Innovation in Cancer Care (OPTICC)

February 5th, 2020 Version 3.0

Workshop Summary Report

Prepared by Intelligent Improvement Consultants, Inc.

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1. Executive Summary

The Ontario Institute for Cancer Research (OICR) and Cancer Care Ontario (CCO) are co-leading a provincial effort to address the difficult problem of how innovative technologies and processes can be more easily adopted into cancer care in Ontario to support health system transformation. The Ontario Pathway Towards Innovation in Cancer Care (OPTICC) Workshop was a key engagement milestone within this provincial effort to address this problem. The workshop had the following overarching objectives: 1) Review the draft Innovation Framework; 2) Identify solutions to barriers to implementation; and 3) Initiate change management across the province for this important problem. In total, there were 70 workshop participants that included stakeholders representing patients, industry (pharmaceuticals/biotechnology), policy/evidence generation, clinical labs/pathology, health and cancer care system, hospital/research management, government, research, clinicians, and academia. A pre-workshop participant survey was administered to help refine the agenda and a background document was also sent to participants in advance of the workshop.

The workshop included a roundtable panel discussion with stakeholders from different disciplines about the challenges and need for a better way to bring innovation to cancer care. Panelists described the need for research funding and a defined multi-step process of gated approval for innovations that have demonstrated the appropriate scientific evidence, as well as the need for funding to implement an innovation after it has been shown to benefit patients. Some panelists spoke about the rapid pace of innovation, and that a process to approve and implement new tests with clinical benefit must be nimble and iterative. A barrier highlighted by several panelists was the slow speed of moving an approved test through lengthy regulations, licensing and accreditation and the resulting delay in impacting patients. Others described the need for coordination among the various stakeholder groups in the province to come up with an end-to-end solution, as well as the need to engage and understand patient priorities and experience.

Results from the pre-workshop survey showed that participants generally agree with the purpose and major activities of the draft innovation framework. There was limited agreement on the length of time innovations should be held in each phase of the framework, or the level of evidence required in each phase, with participants indicating that various factors (e.g. type of innovation, clinical need, disease, level of impact) would need to be understood.

Breakout group discussions about the draft innovation framework included debate on categories of innovations and evidence, decision-making, and oversight. Workshop participants developed a few variations of categories, including by type of innovation (e.g. biomarkers, technologies, processes) or purpose of the innovation (e.g. diagnostics, predictive, prognostic), with some identifying different types of evidence required to approve different categories of innovation. For decision-making, breakout groups generally supported the concept of a multi-disciplinary committee of experts and patients being involved in approving innovations, with different ideas on how the decision-making process could work in different phases (including a process for disinvestment). There was support for an arm's length non-governmental organization, with dedicated staff, to oversee the innovation framework. It was felt that this organization should have the authority to make decisions and approve innovations for use in cancer care, with the objective of fostering innovation in the health system versus acting as a gatekeeper or barrier.

A number of barriers to implementation of the innovation framework were identified and validated through the pre-workshop survey, including: 1) Funding for evidence generation and oversight; 2) Governance and prioritization of technologies; 3) Connectivity of research and clinical data including privacy considerations; 4) System and culture change; 5) Regulatory environment; and 6) General lack of evidence that is useful for decision-makers. Workshop participants worked together to define these barriers and brainstorm potential solutions.

The workshop concluded with an open discussion on how to move this initiative forward successfully. Ideas brought forward included the development of audience-specific white paper(s), a follow-up workshop that leverages the diversity of stakeholders, direct engagement of the health system decision-makers that will approve implementation of an innovation framework, and engaging other organizations (e.g. federal) with an innovation mandate. While workshop participants had different ideas on how best to move this initiative forward, there was resolute agreement that Ontario must do better in bringing innovation to patients and families faced with the burden of cancer, and this change must occur quickly.

The immediate next steps from the workshop include: a participant survey to collect feedback on the workshop and additional thoughts on moving forward; refinement of the draft innovation framework based on workshop feedback; development of a targeted white paper describing the issue and solution; a mapping of existing organizations that perform evaluation of innovations; and a project charter describing the remaining work to implement the innovation framework.

2. Background / Introduction

The Ontario Institute for Cancer Research (OICR) and Cancer Care Ontario (CCO) are co-leading a provincial effort to address the difficult problem of how innovative technologies and processes can be more easily adopted into cancer care in Ontario to support health system transformation. The Ontario Pathway Towards Innovation in Cancer Care (OPTICC) Workshop was a key engagement milestone within this provincial effort to address this problem.

Innovation can be defined in many ways and is part of a continuum between research and quality improvement. Health innovation refers to novel, evidence-based tools, structures and interventions designed and implemented to improve healthcare delivery and outcomes. For the purposes of the OPTICC, the focus of problem-solving efforts in innovation relates to the delivery of precision medicine in oncology. Precision or personalized approaches to healthcare represent a major paradigm shift in oncology research and are a significant health system adoption challenge for patient care. The following are examples of precision medicine tools that were in scope for discussion:

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

Importantly, however, an Ontario framework that embraces this paradigm shift in precision oncology should be applicable to other innovative technologies that could improve cancer care.

OICR and CCO leadership 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 concerning what is needed in Ontario to improve the adoption of innovation in the cancer system. This has resulted in the development of a draft framework (see Appendix 1 for more details) 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.

There are a number of reasons why there is a need for an innovation framework *now*:

- Opportunity; common sense of urgency about doing things differently and being proactive; fear of Ontario falling behind;
- Pressure on the healthcare system and large expected increase in cancer cases; potential to bend the cost curves;
- Lack of standardized approach/access to technology will lead to inequality in healthcare delivery and outcomes;
- Large number of developed technologies are ready for adoption;
- Ability to put data to work; evidence-generating healthcare system;
- Ontario government interest in seeing impact from innovation; and
- Recognition of potential for tremendous patient benefit.

3. Objectives of the Ontario Pathway Towards Innovation in Cancer Care Workshop

The Workshop had the following overarching objectives:

- **Review the Innovation Framework:** The draft innovation framework was challenged, tested and modified by workshop participants.
- **Identify solutions to barriers to implementation:** The workshop provided the opportunity to identify and explore both barriers and enabling factors that underlie implementation of the framework.
- **Initiation of change management across the province:** As an outcome of the workshop, it was hoped that traction for this important change initiative would be assessed, and next steps to implement the innovation framework would be identified, along with timelines and accountabilities. The workshop represented the beginning of effecting change; much more and broader activity, engagement and leadership will be required for success.

4. Approach

Overview

The Ontario Pathway Towards Innovation in Cancer Care Workshop was planned and implemented by OICR and CCO, with support by Intelligent Improvement Consultants (I2C), a company specializing in evidence-based, oncology point-of-care delivery, quality measurement and program evaluation. Key elements of the OPTICC Workshop agenda included:

- **Introductions and Overview of the Day** included brief comments from the leadership of OICR (Dr. Laszlo Radvanyi, President and Scientific Director, and Dr. Christine Williams, Deputy Director) and CCO (Dr. Michael Sherar, President and CEO) in order to set the stage for the day;
- **Multi-stakeholder Roundtable Discussion** on the current landscape of biomarkers and precision medicine in Ontario from different perspectives including patients';
- **Perspectives from Other Jurisdictions** from Dr. Christopher McCabe (Executive Director and CEO, Institute of Health Economics) and lessons learned from Alberta Health Services;
- **Overview of the Draft Innovation Framework** from Drs. Christine Williams (OICR) and Harriet Feilotter (Queen's University);
- **Review of Pre-Workshop Survey Results** by Jason Pun (Principal Consultant, I2C); and
- **Breakout Group Sessions:**
    - **Reviewing the Draft Framework** through breakout group discussions on:
        - Categories of innovations and evidence;
        - Decision-making; and
        - Oversight and Organizations conducting evaluation.
    - **Barriers and Solutions to implementation of the framework**
        - Funding for: Evidence generation and Oversight of the innovation framework;
        - Governance and prioritization of technologies;
        - Connectivity of research and clinical data including privacy considerations;
        - System and culture change;
        - Regulatory environment; and
        - General lack of evidence that is useful for decision-makers.
- **Next Steps and Actions**

The final agenda can be found in Appendix 2.

Recruiting Participants

The OICR/COO planning team developed a list of potential participants, with an emphasis on multi-disciplinary representation from across the province. Delegates included stakeholders with the following roles:

- Patients
- Industry (pharmaceuticals/biotechnology)
- Policy/evidence generation
- Molecular Genetics/Pathology
- Health and cancer care system
- Hospital/research management
- Government
- Research
- Clinicians
- Academia

An invitation was sent to each prospective participant by email (see Appendix 3). A list of participants that registered in advance for the OPTICC can be found in Appendix 4.

Pre-Workshop Survey

An online survey was administered to workshop participants and those invited to the workshop that could not attend. The objective of the survey was to collect and analyze the initial thoughts and opinions from stakeholders on the draft Proposed Framework in order to advance discussion on the day of the workshop, and to be used in the next iteration of the framework. An invitation to complete the survey was sent by email two weeks prior to the workshop by the OICR, with reminders sent over a 10-day period. The survey email invitation and questions can be found in Appendix 5.

Breakout Group Sessions

Breakout group participants for the "reviewing the framework" session were pre-assigned in order to maximize multi-disciplinary representation and have as many different types of stakeholders in each of the nine groups. Breakout group participants were asked to introduce themselves, choose a lead and recorder, and to discuss and document their answers to the workshop questions.

Breakout group participants for the "barriers and solutions" session self-selected into one of the six barrier groups and were asked to define the barrier and brainstorm potential solutions.

Delegates from the groups in both breakout sessions reported back to all workshop participants and all participants were invited to ask questions or provide other perspectives.

5. Outcomes and Discussion

Overview of Participants

There were 70 participants that registered for the workshop. Participant representation included research organizations (universities and hospitals), clinicians, scientists, molecular geneticists/pathologists, patient groups, hospital/research leadership, health and cancer care system, policy-makers, government, and industry. The list of participants can be found in Appendix 4.

Roundtable Discussion: Defining the Problem and the Need for a Solution

The opening agenda item for the workshop was a roundtable discussion, which began with participants from different disciplines and perspectives defining the problem of bringing innovations to cancer care in order to develop a common understanding of the need for a solution. The following are brief summaries from each of the stakeholders.

Dr. John Bartlett, Program Director, Diagnostic Development, OICR

Perspective: Researcher

Dr. Bartlett discussed the following problems for researchers:

1. **Funding and process to approve funding –** Dr. Bartlett spoke about his past experiences in the UK which are analogous to his Ontario experience. He described how he had demonstrated evidence for a test that warranted the need to fund a clinical trial. A government funding agency agreed with him, but there was no process/mechanism in place at the time to fund biomarker/diagnostic based clinical trials (this has since changed in the UK).
2. **Industry Partners –** Dr. Bartlett provided an example of a breast cancer test that reached a sufficient level of evidence but could not secure the necessary funding/investment from an industry partner to disseminate the test through the health care system because of insufficient return on investment. He indicated it also would have been helpful if there was a 'pull' for this test from the health system.

3. **Technical Validation of tests** is required so that clinicians, researchers and policy-makers in the health system can understand the criteria and which patient populations should be receiving specific diagnostic tests. He provided an example of Herceptin which, after a 20-year debate, now uses different assays for HER2 positivity than previously used in the pivotal trials used for drug approval.

Dr. Brad Wouters, Executive Vice President, Science and Research, UHN

Perspective: Hospital/Research Leadership

Dr. Wouters discussed three issues that have affected UHN with regard to innovation.

1. **Lack of funding for implementation after research is complete** – Dr. Wouters described how UHN researchers would complete studies on precision medicine tests but would have nowhere to go for funding for implementation of the test. An example given was a $500 test that would help determine if a patient could successfully have a bone marrow transplant. Implementation of this test had a difficult path forward because of lack of coordination in the health system (budgets are siloed and capped, even though the benefit to patients and the health system are significant).
2. **Grey zone in diagnostic tests** – Dr. Wouters also discussed a 'grey zone' in which the current system/approach cannot keep up with the rate that new tests are developed and validated. A test could be developed, and while they are waiting for it to be approved for use and provide value to patients, there would be the need and capability to develop a new and better test. The system must be nimbler.
3. **Coordination** is required to avoid duplication and overlap of effort to implement new tests, particularly with regard to bioinformatic algorithms, data processing/storage/handling – people at multiple institutions are solving the same problems. There is an opportunity for OICR, CCO, and provincial organizations to allow for more data sharing across the province so that resources can be more effectively allocated.

Ryan Demers, Senior Manager, Diagnostics – Oncology, AstraZeneca

Perspective: Industry

Mr. Demers described how AstraZeneca has created a diagnostics function to remove the barrier of testing for their therapeutics, and how the company first launched EGFR testing in Canada. AstraZeneca funded the test, which allowed

for access to their companion therapeutic, however, they did not know when funding for the test would be approved. He indicated that industry requires more certainty as to the timeframe for approvals and reimbursement for tests. AstraZeneca would like to learn how they can be a better partner within Ontario and Canada in order to help approve diagnostics in a timelier manner.

Dr. Meredith Irwin, Senior Clinician-Scientist – Sick Kids

Perspective: Clinician

Dr. Irwin discussed the challenges in bringing pediatrics and rare disease tests to the clinic through the 'grey zone' from when there is demonstrated clinical utility through to licensing. Kids are not just small adults, so many genomic tests that are relevant for adults are not for kids. Some of the challenges she has faced include:

1. **Regulatory** – Dr. Irwin described that in order to use a test in the clinic that is not considered too risky by ethics and legal, a test must be fully licensed which often requires full accreditation. There is no distinct classification between a research test and the gold/platinum standard (eg CLIA, IQMH accredited), such as a 'special access' test. Often, while a test is moving (slowly) through the accreditation pathway, a new test that is better will be discovered, but it too will be subjected to the same grueling time frame, during which time children are dying. This is especially applicable to kids, where it is difficult to study large populations with a specific disease.
2. **Financial/Funding Risks –** Dr. Irwin described how funding for the licensing aspects and the implementation of a test (through accreditation) is a challenge to obtain. In addition, there may be less of a financial incentive from pediatric academic centres to license these pediatric tests since the market may be very small and thus, may not be ordered frequently. Also, accredited tests are required to approve a clinical trial for a new drug.

Arlene Howells

Perspective: Patient/Caregiver

Ms. Howells acknowledged the great work that those in the room have been doing for cancer patients, caregivers, and their families. She also spoke about the importance of the patient voice for changing government policy and how that has, in the past, pushed the government to participate in clinical trials and fund the Evidence Building Program at Cancer Care Ontario. Ms. Howells also explained that people who work in the cancer field need to know their customers

(the patients) and study topics that are relevant to them such as the effects of vaping and tattooing in our society.

Dr. Aaron Pollett, Provincial Head, Pathology and Laboratory Medicine, Cancer Care Ontario

Perspective: Molecular Geneticist/Pathologist

Dr. Pollett described how the system needs to change to reflect the rapid development of molecular biomarker testing. There is a disconnect between the practice in the lab and the way that oncologists are using biomarkers in practice. There is almost an oppositional approach, where oncologists are requesting biomarkers to best treat their patients, but the laboratory is not funded to provide the test and looks to avoid costly molecular biomarkers… all the while a patient is waiting to see if they are eligible to receive the drug or enter a clinical trial. He described how the province has the necessary expertise but there is an urgent need for coordination and system change. The province needs to have mechanisms in place so that the data can be shared across the healthcare system (e.g. so it is clear what tests have already been done and therefore mitigate delay, duplication and waste). Dr. Pollett also discussed the administrative burden (paper-based) to order and approve molecular biomarker testing for a patient, and how this is not sustainable as more molecular tests enter practice.

Group Discussion

Following the breakout group sessions, several questions and themes emerged and were discussed by workshop participants, including:

- Could the Ministry of Health have a fast-track process and research funding role for innovations (if the appropriate evidence, safety, health benefits, cost benefits)?
    - A workshop participant from the Ministry indicated that they are exploring options to help fund innovations in the health system.
    - The need for a fast-track process was highlighted with the example of how conducting methylation profiles of brain cancer patients can change treatment decisions, however, there is no funding for this test. There is a reluctance to use philanthropic funding (e.g. hospital/institutional foundation funds) for this test because it sets a precedent and a threshold for these tests (e.g. if they pay for 500 tests with philanthropic funds, they will never get funding for these tests in the future because funders will assume that foundations can cover these costs).
    - The current system approves a test and approves it forever, while there could be a system where a test is approved for a period of

time (e.g. three years) while evidence continues to be generated and the decision revisited. There needs to be a way to discontinue tests as well.
    - In some cases, Appraisal has already been done, and the innovations are ready for Evaluation; need to find a way to quickly evaluate, test the process/system, and bring to the public.
- There are also opportunities outside of diagnostic tests in precision medicine, including radiotherapy, drugs and surgical techniques.
- There are learnings from drugs (e.g. conditional approval of drugs) such as who to partner with, and how to get the attention of government ministers.
    - Would like a clear roadmap for innovations similar to drugs.
    - Many drug approval stories in the last number of years have included a patient push, which should be leveraged.

Perspectives from Other Jurisdictions: Learnings from Alberta Health Services

Dr. Christopher McCabe, Executive Director, Institute of Health Economics (Alberta)

Dr. Christopher McCabe from the Institute of Health Economics presented an overview of what has been done with regard to adoption of innovation in the province of Alberta. This included innovation platforms, the innovation pathway, evaluation services, and current activities and challenges.

Innovation Platforms

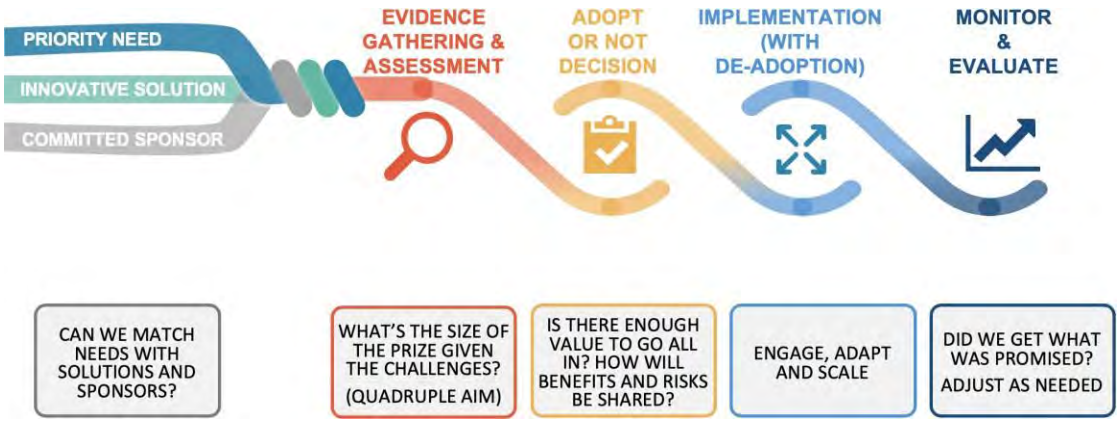
Dr. McCabe described the following innovation platforms in Alberta:

- Tec Edmonton and Innovate Calgary – university-based technology transfer and commercialization support for academic research.
- Real World Evidence Consortium – the advantage of being in Alberta is that they have a single comprehensive health system, and that the system potentially has the ability to measure the outcomes of an innovation using data within 3 months. The Consortium is a one-stop shop for working with clients on an analysis plan to understand how an innovation may be impacting the health system. It brings clinicians, analysts and subject matter experts together to serve clients and is working to complete their first seven projects, with 14 additional projects starting.
- Alberta Innovates enables the province's strategy for patient-oriented research (SPOR) by providing access to experts and knowledge in seven core areas, including: data; consultation & research services; pragmatic clinical trials; methods support & development; career development; patient engagement; and knowledge translation.
- Industry Partnerships are developed through the Health Technology Innovation Platform with the aim of creating an environment that allows companies to have clear criteria about how to move an innovation through to approval (or a conditional approval).
- Alberta Public Laboratories are a single diagnostic lab service provider for the entire province. It created a lab formulary committee and process to add new tests for the province. This includes a formal Health Technology Assessment. A current HTA nearing completion is looking at two cancer tests (an innovation and an existing, approved test) in which the assessment included the consideration of change management costs to have the health system convert to a new system. It is likely that the new test will not be approved due to the cost of change management.

- University Hospital Foundation supports the development and adoption of innovations in Alberta.

Innovation Pathways

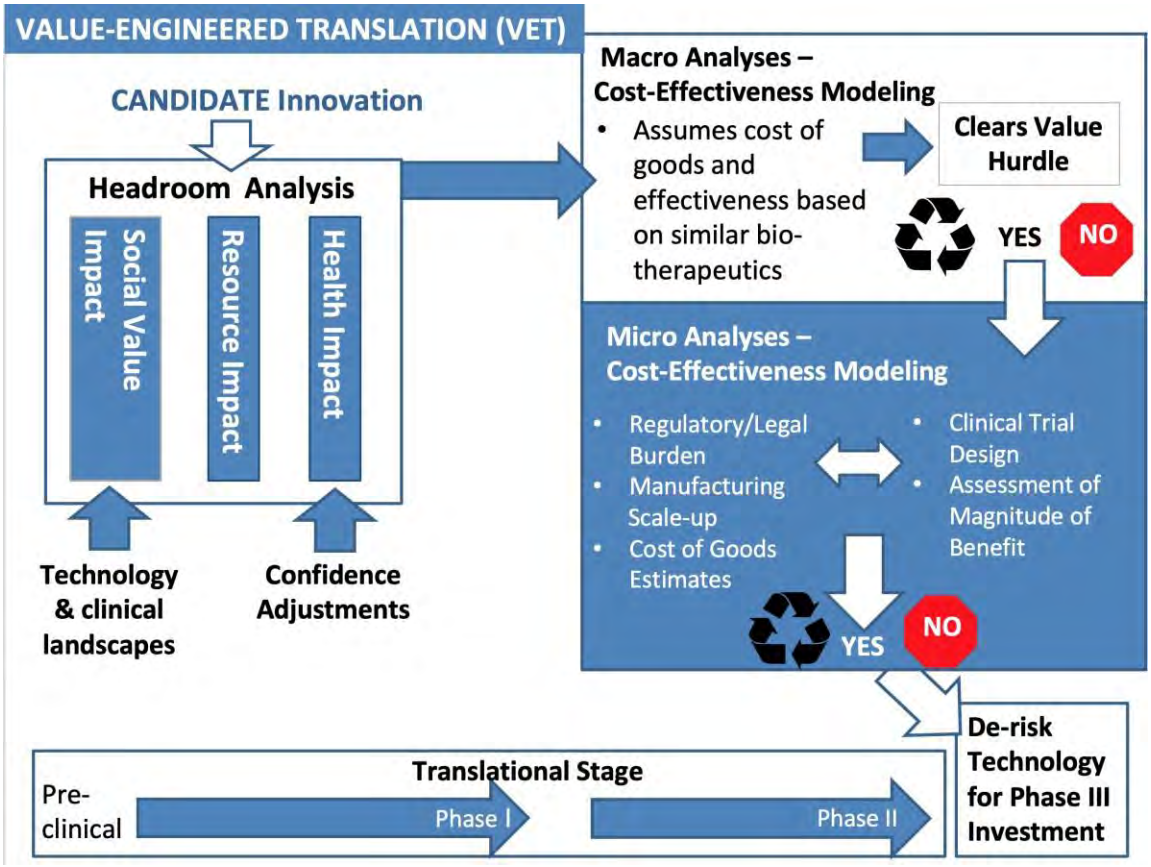
Dr. McCabe described how Alberta Health Services is moving from an industry push system to a health system pull approach, where clinical need drives innovation. AHS uses an Innovation to Action Lifecycle (I2A) which matches the needs of the system with the solutions that are available.



As a result of limited resources, priorities are set and the cycle includes understanding how an innovation may leave the pathway (de-adoption) before it is adopted. It is a structured, consistent and clear approach which innovators appreciate. Companies appreciate that they can knock on the door and get a quick 'yes or no'. The cycle is still in the early days of its use, with 76 innovations having been processed through the Innovation to Adoption Lifecycle (as of March 2019).

Early Evaluation Services

Alberta uses an approach called Value-Engineered Translation (VET) for SMEs (Small or Medium-sized Enterprises) to triage innovations in order to 'fail early and cheaply'. The approach aims to quickly understand if there is headroom for social value, resource impact, and health impact. If there is headroom, they will look at Macro Analyses through Cost-Effectiveness Modeling to understand if it can clear a hurdle. This may include bottom-up costing to understand the full cost (e.g. including manufacturing) of implementing the innovation. If the hurdle is cleared, will then move to Micro Analyses through Cost-Effectiveness Modeling, which includes Regulatory, Manufacturing, Cost of Goods, Clinical Trial Design, Assessment of Magnitude of Benefit.



Current Challenges

Dr. McCabe described the biggest challenge for Alberta is the co-ordination of stakeholders and organizations across the province to buy-in and re-buy-in to the system. It is a constant struggle to keep everyone engaged in the process.

Questions and Answers

Dr. McCabe fielded a number of questions from workshop participants, which included:

- How did Alberta come up with the decision not to use Prosigna over Oncotype DX based on the cost for change management, and did it generate a dollar amount for Prosigna that would have to be achieved to change?
    - Dr. McCabe estimated that the price of Prosigna would have to be half of what it currently is to make the change cost effective and overcome the health system issues.
- Creating an innovation approach needs a leader/owner that is measured and paid to own it. Were resources added to own the process in Alberta…how much was needed?

    - Dr. McCabe indicated that his entire career has been dedicated to this process. They were funded by Genome Canada grants to do this, with matching provincial/industry funds. The Real World Evidence Consortium was another $500k investment. It was a patchwork of money. All in, there was approximately $5 or 6 million invested in these efforts, and Dr. McCabe is trying to be the leader for this in Alberta.
    - Selling in electoral cycles is key because it can change so quickly.
- Change Management seems to be a critical component of adoption?
    - Dr. McCabe agreed that the cost of implementation is critical to be understood before funding decisions are made. There may be conditional reimbursement while the cost of implementation and change management is understood.
- If you had counterparts in the other large provinces and could spread out the risk of adopting a new innovation, would that decrease the cost of implementation and make adoption easier?
    - Dr. McCabe described that oncology has considerable agreement across provinces. Nevertheless, sharing data is viewed as an insurmountable barrier across provinces. It should not be, and it can be overcome through privacy agreements and data custodians. This would make Canada a very attractive place for conditional license technologies to launch because it could be a selling point for a first market for real world evidence. This should be a measure of success (being a first-choice market for launching new innovations).

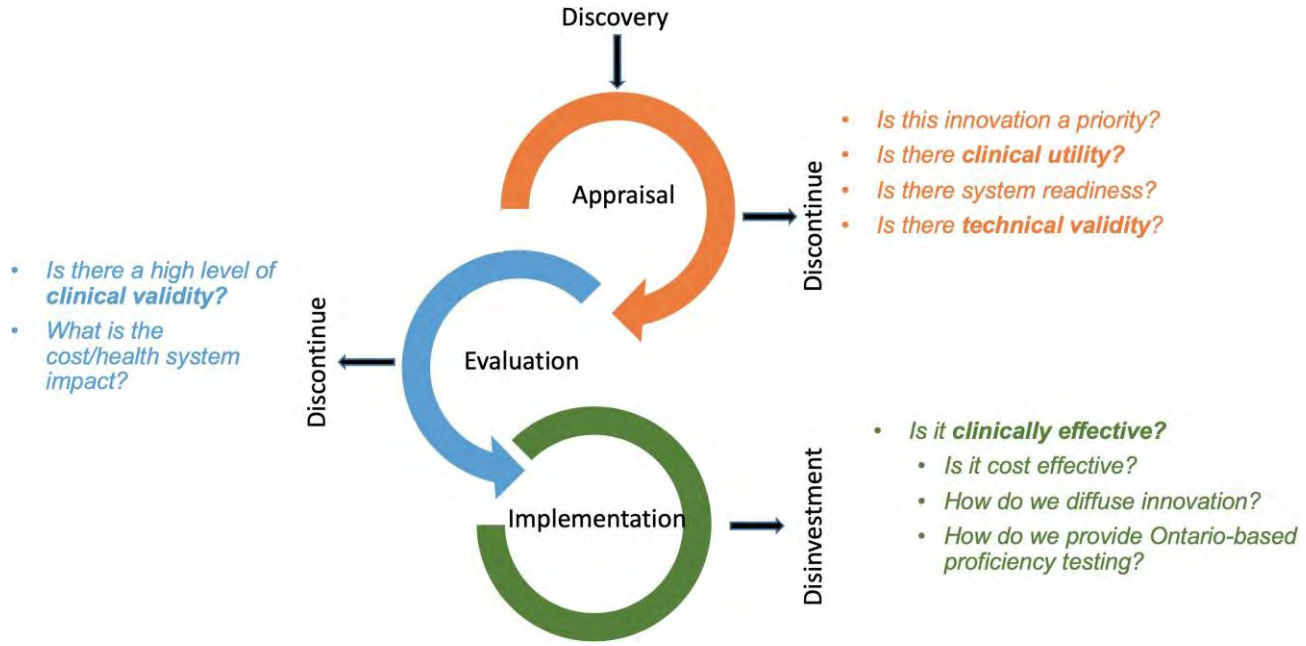
Overview of the Draft Innovation Framework

Drs. Christine Williams (OICR) and Harriet Feilotter (Queen's University) provided an overview and highlighted major messages of the Draft Innovation Framework.

The purpose of the framework is to develop a nimble, transparent framework and data requirements to evaluate and implement innovations that benefit cancer patients. The guiding principles for the framework include:

- Nimbleness
- Bias to be permissive (more 'small bets')
- Transparency (clear entry point; open governance; no privileged access)
- Discontinuation/Disinvestment (throughout the phases, based on insufficient evidence of benefit)
- Learning Health System Model (feedback loop between research, patient experience, decision-making)
- Leverage Existing Systems/Organizations (networks of partnerships; ongoing assessment of value)
- Broad Application (applicable to new & existing technologies; Ontario & global innovations)

The major questions that the multi-phase framework must answer are included in the following illustration:



Drs. Williams and Feilotter also described, at a high-level, each of the framework phases (Appraisal, Evaluation, and Implementation), and the gap, purpose, proposed process, recommended outcome, and details on who this is currently performed and funded by in Ontario. A detailed description of the framework can be found in Appendix 1).

Summary of Pre-Workshop Survey

An online survey was administered to all workshop participants (including those that could not attend the event) in order to obtain initial feedback on the draft innovation framework and help focus and refine the content and discussion for the workshop. Jason Pun, Principal Consultant at Intelligent Improvement Consultants (I2C), provided an overview of the survey results to the workshop participants. The full survey results can be found in Appendix 6.

Respondent Roles

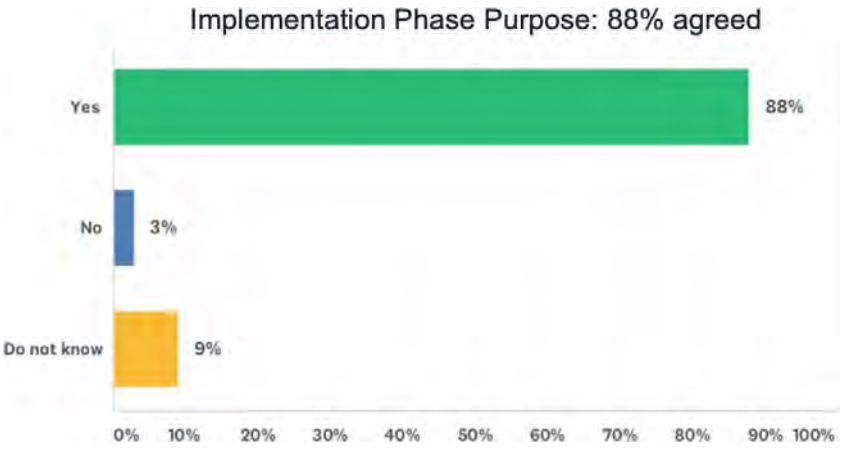
Most survey respondents identified themselves as 'health and cancer care system' and industry (30%), followed by researcher and clinician. Respondents were able to select multiple roles. Those that answered 'other' indicated: HTA Organization, not-for-profit funder, not-for-profit data platform support, consultant in Precision Medicine/Biomarkers, Government, health innovation expert.

Answer Choices	Responses
Health and cancer care system	12
Industry	12
Researcher	8
Clinician	7
Other (please specify)	6
Molecular geneticist/pathologist	4
Hospital/research leadership	4
Patient/Public	2
Total Responses:	40

In total, 82 people were sent the survey. A precise response rate could not be calculated, as some organizations responded as a group.

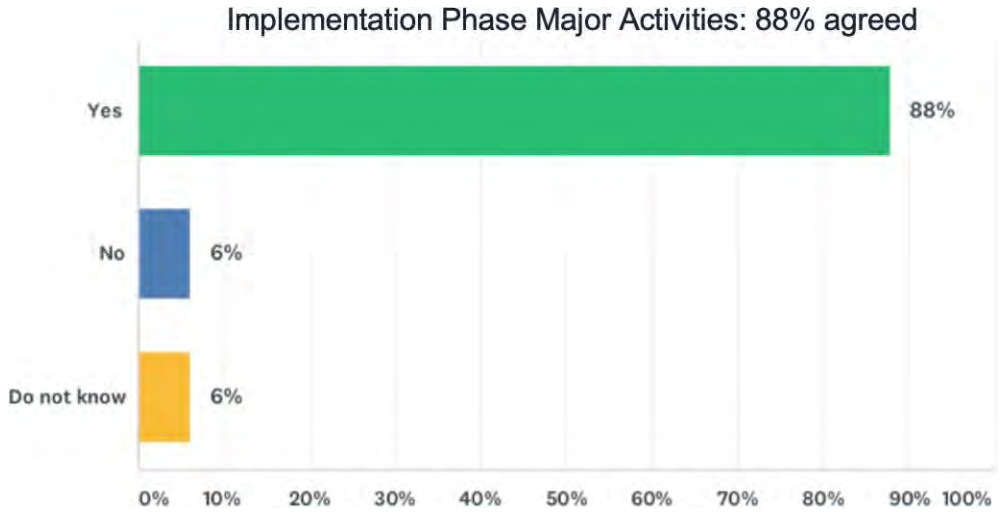
Innovation Framework Phases: Purpose and Major Activities

Respondents were asked to indicate if they agreed with the *purpose* of each phase of the draft innovation framework. ***For all phases, the large***



majority of respondents agreed with the stated purposes. Appraisal had a slightly lower level of agreement at 71%, with Evaluation at 87% and Implementation 88%.

Respondents were asked to indicate if they agreed with the major *activities* of each phase of the draft innovation framework. ***For all phases, almost 90% of respondents agreed with the proposed major activities.*** Appraisal had a slightly lower level of agreement at 87%, with Evaluation at 89% and Implementation 88%.



Innovation Framework Phases: How long should innovations be in each phase?

Most respondents believed that innovations should be in the Appraisal Phase for less than 6 months (64%), though many did not believe a restricted time period could be applied to all innovations.

There was not general agreement on the length of time for innovations to be in the Evaluation Phase, as many respondents believed it is dependent on: type/ category of innovation; disease; and need.

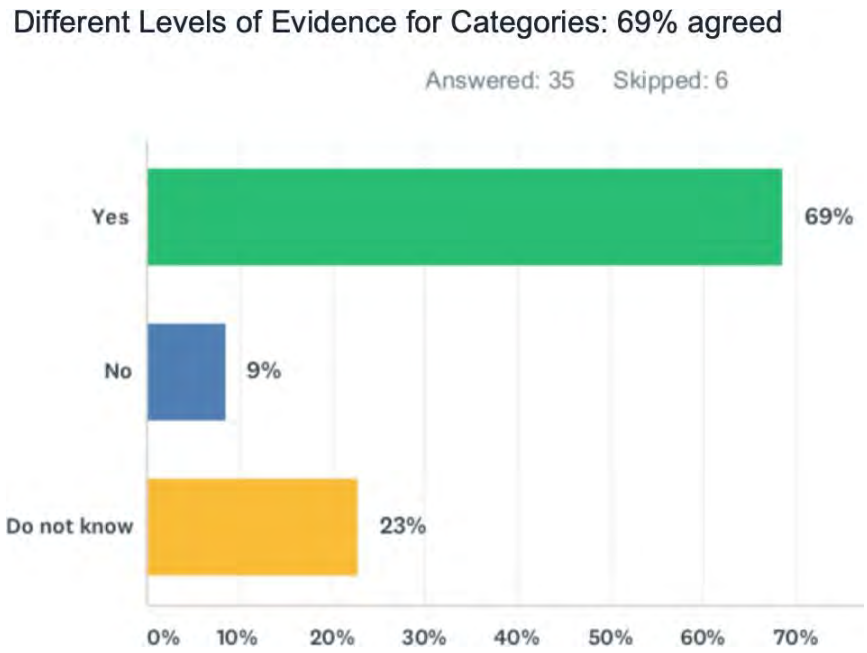
There was also not general agreement on the length of time for innovations in the Implementation Phase, as many respondents believed it is dependent on: type/category of innovation; disease; urgency; cost.

Innovation Framework Phases: Levels of evidence

Respondents were asked what minimum level of evidence should be required for innovations to be submitted for Appraisal and to pass Evaluation and move to Implementation. There ***was not strong agreement for any single minimum level of evidence***. Most respondents answered 'other', and provided comments including:

- Cannot be too rigid defining requirements, might miss beneficial innovations proceeding – need forum/committee to discuss the innovation
- It depends on:
  - Type of innovation
  - Disease (e.g. ultra-rare orphan could use N of 1 trial)
  - Clinical need
  - Payer expectations
  - The potential impact - positive or negative (patient safety)
  - Where the innovation is in the life-cycle
- Randomized Control Trials are required for later cycles requiring major policy decisions

A majority of respondents believed ***different levels of evidence need to be established for different categories*** of innovations.



Respondents were asked to comment about categories of evidence. Some indicated the framework should be flexible to accommodate what is feasible/appropriate for different innovations, and that a Randomized Controlled Trial would not be necessary to change an administrative or technical process but would be for a new drug or companion diagnostic. Some indicated that the categories would depend on:

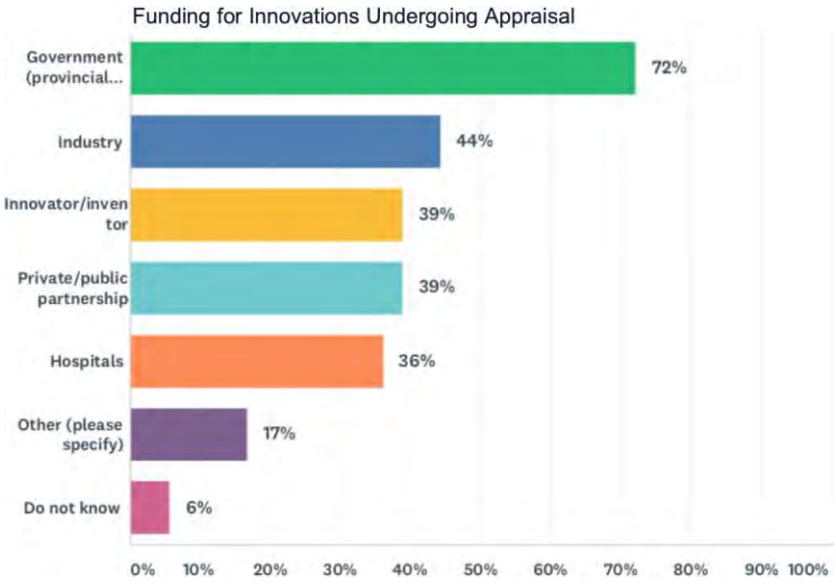
- Risk to the patient (safety)
- Cost of innovation
- Potential for impact
- Disease Type
- Target population (rare diseases for small populations will never have the level of evidence of more prevalent diseases)
- Patient/public values as to what is important to them and their needs
- Decision-makers' perspective
- Availability of resources/conflicting demands?

Other comments included:

- Categorization may not be able to avoid some exceptions so it might be better to set up guidelines to help think through what would be sufficient evidence.
- Should not categorize by modality (e.g. device, drug, etc.) or disease, rather, categorize on 2 axes: x axis is level of potential impact (# patients, burden of unmet need); y axis is level of change from standard of care. Innovations that are in upper right quadrant would need an emergent/iterative methodology because there will be a lot of variables and change management.

Innovation Framework Phases: Decision-making

Most respondents believed a ***multi-disciplinary committee*** of researchers, clinicians, health economists, policy experts, and laboratory experts should be involved with decision-making, followed by ***patients/families/ community representatives***. This was similar for entry into Appraisal, passing Appraisal, and passing Evaluation.

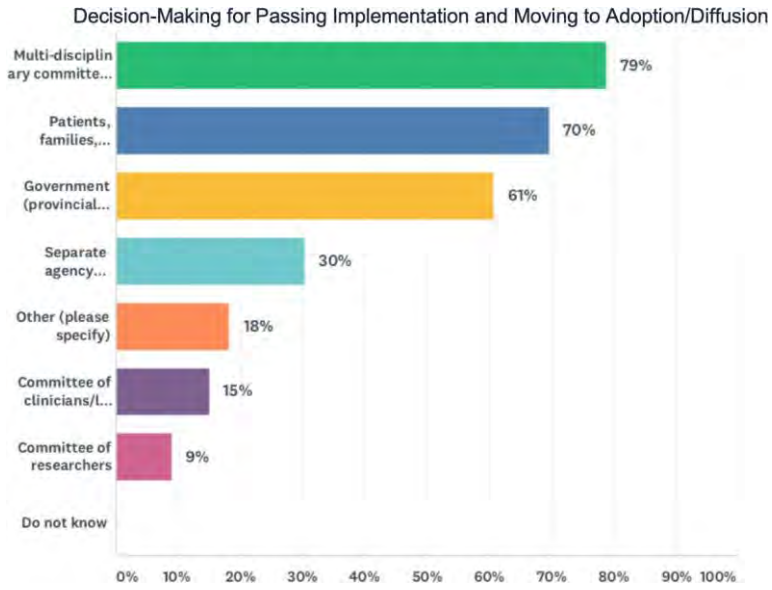


Innovation Framework: Funding, Governance and Oversight

Most respondents believed ***Government (provincial and/or federal) should fund*** Appraisal, followed by Industry, Innovator/inventor, Private/public partnership, and hospitals. This was similar for the Evaluation and Implementation Phases.

Almost 40% of respondents thought that a group of organizations should govern/oversee the innovation framework, followed by a single existing organization (25%). Some respondents thought a new organization should be created. Respondents that answered 'other' provided the following suggestions:

- A new organization that crosses all silos of healthcare and includes clinical experts and patients.
- Leverage expertise of existing organizations – new processes will be needed to mitigate against silo effects.



- A hybrid of new and existing players in the innovation ecosystem.
- Depends on who is bringing the innovation to market.
- Government has the biggest wallet but poor track record for reaching end points.
- Single new or existing organization to ensure clear accountability.

Performance Indicators

Respondents were asked to list the most important performance indicators for measuring the success of the innovation framework. Themes included indicators related to Patients, Providers, the Health System, and Economic Impact:

- Patient
  - Impact on patient Quality of Life
  - Improved patient journey
  - Quality of care
  - Overall survival
  - Patient safety
  - Access to innovations
  - Number of patients impacted in first 2 years (double digit growth by year 5)
- Provider
  - Provider utility
  - Stakeholder satisfaction
- Health System
  - Value for money (evidence generated supports use of the innovation
  - Utilization of precision medicine
  - Speed to bring innovations into practice (compared to other jurisdictions)
  - Rate of diffusion
  - Number of innovations introduced
  - Cost impact on healthcare system
  - Impact on system efficiency
- Economic
  - Return on Investment
  - Economic: Attraction of investment/innovators to Ontario
  - More rapid development and export of Ontario technologies
  - Increased movement of anchor companies to Ontario
  - Driving development of rich health data that enable AI and future technologies

- Recognition of Ontario as a leader in innovation

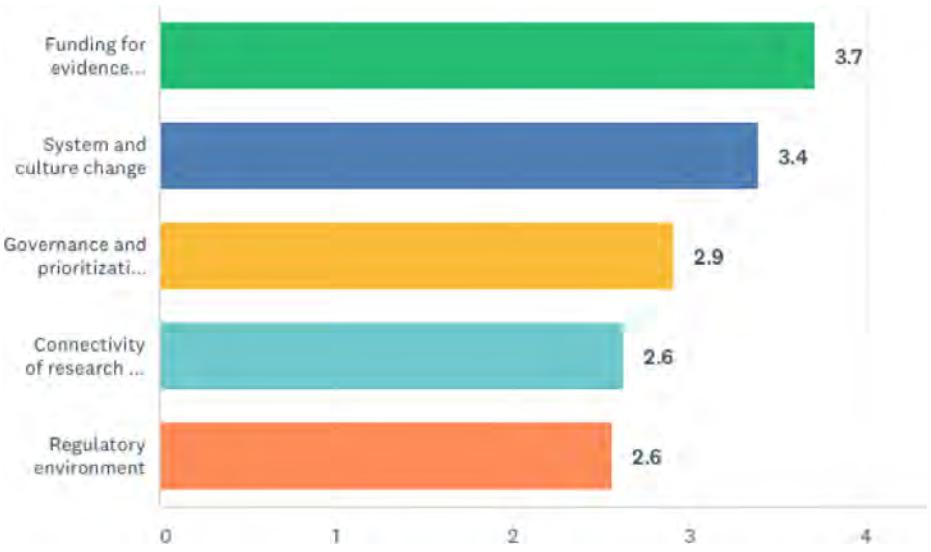
Challenges and Barriers

Survey respondents were asked to complete the following sentence: "From my perspective, the main challenge with adopting more innovation into cancer care in Ontario is…"

A number of themes emerged from the responses, including ***challenges with processes, funding, lack of evidence, problems with the current health system.***

- Process
  - Lack of a clear and predictable process to assess and approve innovations.
  - No owner of a process to approve innovations.
- Funding
  - Lack of funding to perform studies and create evidence-based guidelines.
- Evidence
  - General lack of evidence (published and real world) that is useful for decision-makers.
- Health System
  - Silos and lack of alignment between industry/innovators, regulators, HTA agencies, system planners, implementors, funders/payers.
  - Creating and maintaining productive collaboration.
  - Does not pull/direct research in areas of need.
  - Lack of resources to respond quickly.
  - Change management (physician education, courage to change).
  - Does not see innovation as an opportunity but a cost.
- Other
  - Finding early adopters to pilot innovations.
  - Lack of understanding of continuum of translational research.

Survey respondents were also asked to rank a series of five barriers to implementation of the innovation framework. Funding for evidence generation was ranked as the most important barrier, followed by System and culture change, Governance and prioritization of technologies, Connectivity of research and clinical data including privacy, and Regulatory environment.


Funding for evidence...
3.7
System and culture change
3.4
Governance and prioritizati...
2.9
Connectivity of research ...
2.6
Regulatory environment
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0
1
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4

Breakout Group Discussion Summary – Reviewing the Framework

Categories of Innovations and Evidence

What different categories of innovations should there be? Please define the categories with as much detail as possible.

Some breakout groups wanted to define 'innovation' prior to working on this question, for example:

> *"Anything new that redefines current standard of care and not in present clinical care."*

Breakout groups developed a few variations for categories of innovation. A few examples include:

Model A – Categorize by Type of Innovation

1. Biomarkers
2. Technology
3. Process

Model B – Categorize by Purpose of Innovation

1. Diagnostic
2. Predictive
3. Prognostic

Some groups also included Digital/Software solutions as a category, as well as the need to ensure that other technologies not yet imagined would not be excluded. Another concept that some groups included was the need to have a framework for prioritization of innovations and an acknowledgement that priorities may differ depending on clinician group. Prioritization could be based on disease burden.

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.

A number of concepts for types of evidence were discussed by the breakout groups. For example, one group provided feedback by some phases of the draft innovation framework:

Appraisal

- Need to consider if innovations have multiple uses (e.g. comprehensive genomic profiling is valuable in multiple cancers vs companion diagnostics that are specific for 1 or 2 drugs, or hot spot tests which look at one marker as opposed to many).
- Major stakeholders agree on level of interest in the innovation.
- Strong criteria by category of innovation.
- Potential clinical utility – will it change practice (acknowledge that it can take years to change)?

Evaluation

- Health Technology Assessment (HTA) that is comparison-based needs to be completed (compare to existing solutions).
- Clinical Utility (including evidence from other jurisdictions).

Some groups provided types of evidence by category of innovations:

Biomarker Innovations

- Basic science, clinical evidence proving clinical utility.
- Diagnostic yield (how many patients impacted).
- Clinical utility (will this change current care) including prognostic utility, therapeutic utility, and monitoring.
- Cost-effectiveness/system costs.
- How can it be implemented?
- Comparative-effectiveness using real world evidence to evaluate upfront and post-approval.
- Approvals in other jurisdictions.

Technology Innovations

- Basic science, clinical evidence proving clinical utility.

- Broad usage.
- Utility.
- Test to do diagnostic, prognostic, and treatment monitoring.
- Staying power/longevity.
- Better/faster/cheaper.
- Cost-utility.
- Systems feasibility.

Process

- Economic evidence.
- Why is it better?
- Look at process from start to finish. Review by experts.
- Need the right experts to review.

A number of other concepts for types of evidence were discussed by the breakout groups:

- Evidence-based framework similar to current (safety, clinical utility, validity, effectiveness) but with an analysis of value, where value needs to be defined for each innovation and informed by a multi-stakeholder committee.
- Current levels of evidence are too rigid and constraining.
- Do not discontinue innovations without learning from failures.
- Data liberation: standardized data formats and frameworks to integrate and disseminate data easily without an onerous process. Future-proof through country-wide consent policy and supporting legal protections. Digital support for Patient Reported Outcome Measures (PROMS).
- Global best evidence and frameworks: model impact of new innovation using real-world data, even if international data is an imperfect match to our local jurisdiction, especially at Appraisal and Evaluation stages for rapid assessment.
- Use clear scientific evidence that is validated and peer-reviewed.
- Collaborative data standards: evaluate and harmonize raw and 'polished' data from around the world with made-in-Ontario data, capture "data context" to broaden evidence pool and enable new research questions.
- Use a similar framework as pCODR.
- Value proposition to the system should be clear (value for money vs. risk).

Decision-Making

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?

Breakout groups supported the notion of a multi-disciplinary committee of experts and patients, which included (depending on the type of innovation), the following roles:

- Researchers
- Clinicians
- Clinician researchers
- Health economist
- Policy experts
- Laboratory experts
- Laboratory medicine/pathology
- Patients
- Family/community
- Patient advocates
- Government
- Payers

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***

There was support for the multi-disciplinary committee to be involved in decision-making throughout all aspects of the framework, with the caveat that payers and government could be included at the Appraisal Phase as observers but not decision-makers. It was felt that priority setting should be done at entry into Appraisal with patients (Citizen's Council in Ontario) and clinicians, with an agreed upon framework for setting priorities that allows for different types of evidence and input from different stakeholders.

Entry into Appraisal could be accomplished through the submission of an online application that would need to meet clinical utility criteria so that it could be determined if the Ontario health system needs/wants the innovation. The decision-making could be done by a smaller subset of the larger multi-disciplinary committee.

Passing Appraisal could be done through a monthly pitch meeting where innovators present their innovations to the multi-disciplinary committee to allow for a discussion between the committee and innovators (similar to University of Toronto UTEST). The process could include pre-reading packages for committee members, monthly half-day meetings with multiple pitches, and group discussion/adjudication at the end of the meeting. The committee would decide if the innovation will move into the Evaluation Phase, and the innovators could be informed if they are moving on soon after the meeting.

Disinvestment needs to be contextualized with opportunity cost and needs to look at the stewardship of the health system (broader than patients). Disinvestment of new therapies can be connected as a result of performance during implementation and comparison to previous standards of care.

Other thoughts on decision-making included learning from the current pCODR process in which a multi-disciplinary committee plays an advisory role with the funder being the final decision-maker. This could include different committees with the required expertise and skills for the advisory role, with different committee members needed for implementation. The process must be transparent. pCODR posts initial recommendations, which are available for critique and challenge to give confidence that the process is fair.

The need for better Real World Evidence (RWE) was discussed, and that without it, how can accurate disinvestment decisions be made? Also, the decision-making process must be nimble or we will continue to be stuck in the same predicament.

Oversight and Organization(s) conducting appraisal/evaluation/ implementation

What type of organization(s) should govern/oversee the innovation framework (is there an existing organization(s) that can do this)?

A breakout group described the need for an arm's length non-governmental organization (NGO), with dedicated staff, that is accountable to the Ministry of Health and Long-Term Care to oversee the framework. Funding for the review/evaluation should be from industry, similar to CADTH. It was thought that the NGO would own the process and be the ultimate decision-maker, but other organizations (CCO, CADTH, HQO, MOHLTC) would have a voice.

Another breakout group indicated the oversight committee should be small with the authority to make yes/no decisions and be incentivized to release new innovations into clinical practice, rather than acting as gatekeepers to inhibit innovation. Also, if the financial ask is small, then there should be a bias to permit these innovations through Appraisal and Evaluation.

Another breakout group provided the following functions for the oversight group (a single or group of organizations), which included:

- **Set policy** by convening panels and experts and coming up with concrete criteria for each of the phases of the framework.
- **Consultative** role that can provide the innovators with expert advice to guide the design of innovations.
- **Granting/Funding** of Appraisal and Evaluation studies (could be only funder or co-funder).
- **Evaluation and decision-making** based on the results of studies and the policy (priorities) with ability to make decisions for reimbursement or discontinuation. A decision to adopt across the province would not need to go to another organization for approval.

How should success of the framework be measured?

One breakout group presented four concepts for measuring success:

- Model Systems: Need a data model in place to quantify effect of injecting an additional dollar into the health system at specific points. Is there an overall saving of money and time?
- Data Process Expertise: Clear execution plan to move from A to B as well as creation of new ways to describe and communicate new analysis types. Easy querying of new data (e.g. demonstrate database expertise, not values trapped in flat Excel/Word data tables). Point to data sources, do not move or copy raw data.

- Communication and Outreach: Demonstrate co-piloting of innovations by non-inventors and users outside the initiating institution. Demonstrate Quality Management System and policies for data sharing.
- Define granular metrics: Learn these from Innovation Success stories.

Another breakout group indicated that the use of pre-defined performance metrics would help move Ontario up the ranking of adoption of innovative technologies so that the province would become earlier adopters. They also indicated de-prioritization or de-adoption (discontinuation) of redundant tests should be a measure, along with metrics on patient outcomes and cost-savings/efficiencies for the health system.

What organization(s) should be involved in evaluating/generating evidence for innovations? Integrate with your answer to categories of innovation if possible.

There is a need for a map of all of the organizations that are working in this area, that clearly delineates who is involved and what they do. A breakout group provided characteristics of organizations that should be involved in evaluating innovations, which included:

- Nimble: Data federators able to assess quick indicators of direction of effect, even if imperfect
- Incentivized: Champions evaluated for closing Research/Clinic loop.
- Well-Connected: Most care and outcome data are delivered in Community Hospitals - make this engagement cost-effective and non-disruptive to delivery of daily care.
- Technical: Organizations able to stream real-world data in real-time (e.g. Human Genome Project model).
- Collaborative: federal-level overseer focused on standards and capabilities across provinces at a patient-level (micro-focus) and linkages to global initiatives (macro-focus).

Others provided the following feedback on this question:

- Evidence Generation: Could come from anywhere – but after implementation RWE is generated within the system. As we get toward mature/widespread technology, we want more formal studies (e.g. evidence of reproducibility – ring testing, etc).

- Value for money assessment with immature data is the CADTH yes/no decision, but there needs to be follow up assessment as the technology is used more (RWE) and re-evaluation of how the technology is performing – monitoring and re-evaluation – de-prioritization or up-prioritization – by the NGO-type organization that evaluated the technology in the first place.
- Need to figure out how to evaluate evidence outside our own systems (inter-provincial/country, etc). Maybe more feasible with mature technology that has a common implementation substrate and we can just sub-in local pricing.

Breakout Group Discussion Summary – Barriers and Solutions

Funding for evidence generation and oversight of the innovation framework.

Funding for evidence generation

- Diversely funded into a single funding pool by several groups, including industry, research agencies, hospitals, provincial government (MOHLTC, economic development), and federal level ideally.
- No strings on funders, but funders have expectations of performance metrics, such as: volume of innovations assessed, milestones and impact, QoL achievement.

Where is the funding coming from?

- There needs to be policy change, and funding allocated to innovation in health.

Funding for oversight of the innovation framework

- A single point of accountability for dispersing the funds through the phases.
    - Important to ensure this body has clear ownership in partnership with other incentivized agencies.
- Funding for the evaluation phase (so it is not the valley of death):
    - Evaluation costs assessed at the initiation of evaluation.
    - Element of public/private partnership to reach certain maturity in the evaluation phase, and then expand private investment.
    - Separate evaluation phase, from gate-keeper phase to ensure no bias.
    - Need to consider alternative approaches in the evaluation phase, not focus only on proposed approach, but on best practices found worldwide.
- Metrics for key institutions for innovation – (e.g. 10% has to be allocated to innovation in the health system) - able to retain the savings they make
    - QOL with disease-recognition
- Incentives are Critical
    - Silos broken down through incentives for all parties (e.g. Lab and overall hospital budgets benefit) to adopt the innovation.
    - Some percentage of funds stays in the institution and some goes back to fund further innovation.

  - Want to build incentives to have private players early in the process.
  - Accountability for innovation has never been a requirement for hospitals or the health system.
    - This prevents the system from taking on innovation full force.

Governance and prioritization of technologies (health system does not pull/direct research in areas of need).

- Governance is *a priori* – how and which priorities get set determines all else downstream, including the funding.
- System-level governance is important (as opposed to clinical or institutional basis). Need for the governance to be transparent – large group, or small group with high transparency and input.
  - Transparency/openness and consultation is key to governance and prioritization.
- There is a need for more coordination.
- Importance of proactivity in priority-setting, not just reactive applications of frameworks based on submissions received.
- Other organizations have evaluation frameworks that can be leveraged - HQO, OTAC CADTH and pCODR approaches. Are there other frameworks from other industries?
- How do we put a fence around which tests should 'qualify' for system-level governance, as compared to institutional (hospital global budgets) decision-making around lab costs? What is 'net new' vs. addition that does not need full channel of assessment?
  - Partly by dint of history that genetic diagnostics have been hived off from global budget case-based clinical funding for lab tests.
  - Risk is that the testing is divorced from the rest of clinical care for a given case, meaning it is outside of the funding package for that case.
  - Important to align governance with funding mechanisms.
- Import for funder to be involved at prioritization stage so it has 'skin in the game' to meet targets and keep to them.

Connectivity of research and clinical data including privacy considerations.

Process and leadership for spelling out national data sharing strategy

- Privacy commissioner and centralized REB.
- Engage national PHIPA experts to codify rules for data sharing.
- Change in expectation, National Accreditation process and body.
- Measurement of current waste due to lack of data sharing, and financial gain from learning from current system.

Global and National standards e.g. GA4GH, ICGC, NIH

- GDPR has just published one-year assessment – perhaps can learn from this.

Direct to Patient Consent vs National Blanket Framework

- Dynamic digital computable consent.
- Legislative requirement for patients to consent at the door or assumed opt-in with opt-out option.
- Patient education (and public) – plain language education for how health data can be shared, used and protected.

Technical Solutions

- Change how consent is obtained, away from long-paper-based forms to digital consent.
- FAIR principles baked into each clinical and research protocol.
- Policy and data sharing software stacks.
- Data governance servers to enable fine-grained field-level access control.

Social comfort with comprehensive data

- Data access agreements and legal protections.
- Provincial vs federal funding as levers, national pharmacare strategy tied to standards.
    - Need to be able to integrate provincial data to understand what drugs to include.
- Strategic funding to incentivize private sector investment in a clear regulatory environment.
- Policy around collection and use of special access and compassionate use programs

- Body to say yes or no, process to come to a set of recommendations (national framework) – this is anonymized, this is sharable, etc.
- Dynamic consent, consent for specific purposes.
- Federated model, data remains where it is generated – stack that makes it sharable. Query platform that allows data visiting. Levels of access control depending on whether patient, clinician, researcher, etc.
- Create standards.
- Tie pharmacare to standards as an issue (government).
- Harmonized EMR system.
- Reframe the story of data sharing with the public.

System and culture change (silos and lack of alignment between industry/innovators, regulators, HTA agencies, system planners, implementors, funders/payers).

Ask what culture do I want to change?

- It is the non-collaborative nature of the culture, silos.
- Ministry is unresponsive – they are silent vs. the Drug Program.
- Industry is not trusted by the payer or the patients.
- Industry should be encouraged to work on changing the level of trust they have with patients and payers.
- High drug prices need to be understood.

Potential Solutions:

- An Internal Champion needs to be created – patient-oriented metrics must be assigned to an official at a high-enough level.
- Collaborative patient advocacy – patient groups that work along with known experts to influence the bureaucratic process
    - E.g. independent national pediatric cancer advocacy association
        - White paper written, approached gov't with the offering of helping them to improve patient care without involving more resources. These patient groups can offer ideas to introduce efficiencies into the system. This was effective in making a top-down mandate to change patient care.
- Key here is the common goal – successful example was the human genomics project.

- Everyone aligns to the common goal and silos break down when patient-associated metrics are being measured (e.g. B.C. – oncologists talk to lab people, they are required to talk to them).

Other comments included:

- Need to communicate the guidelines/rules for industry – there are ethical standards that the public is not aware of.
    - This would help change the lack of trust of industry.
- Need to pay attention to what the government of the day wants to do.
    - Current government is concerned with cost.
        - Need to explain how molecular biological tests will reduce cost – spin so that government understand how they win.
- Partnering with patient advocacy groups can be a way of influencing government.

Regulatory environment.

Defining the problem: There is a lack of clarity, old regulatory frameworks, older legislation that no longer works, political influence, media attention.

Solutions:

- Sharing of clinical data has too many barriers (e.g. cannot share OHIP numbers between databases)
    - Need to reduce institutional and provincial barriers to data sharing, contracting between institutions.
    - Prevent hospitals from not sharing data.
    - Create harmonized consent for patients to cover all aspects.
    - Accelerate Clinical Trials in Ontario model – needs more strength to enforce - there are many organizations that still have not signed up.
- Lack of transparency and rationale for restrictions on lab test licenses - process is unclear, there is no timeline for approval, hard to know where the application is and what is needed next (requests for multiple forms).
    - Need to streamline this process, educate, and provide transparency - difficult to have a nimble process if there's nowhere for technology to go.
- Proficiency testing (once a test is in use) can be a laborious process.
    - Incorporate the plans for this to align with proficiency testing processes.

- Simplify or eliminate designation of where a test needs to go.
    - Test outside of Ontario could be best option.
        - Would be easier if there was no need to go through special access process.
- There needs to be more clarity on what Health Canada is doing from a regulatory perspective.

General lack of evidence (published and real world) that is useful for decision-makers.

- Data vs. Evidence
    - Data is not evidence but is required – cannot set a bar of phase 3 trials for personalized medicine tests – especially for pediatrics.
        - Need to agree on the evidence level we need to reach.
    - Evidence is aimed at answering a question, can EXISTING data be collated to answer unknown questions?
- Why is there a lack of data and evidence?
    - Have the correct questions been asked?
        - Context: Better Evidence?
        - Harm and Benefit: What is the consequence of NOT acting? What are the potential harms of acting (to patients)?
- Collaborate with other jurisdictions
    - Should be able to take evidence from outside of Ontario for a short period of time (3, 4, 5 years) until local evidence can be generated.
    - Can there be multiple levels:
        - Enough to consider 'preliminary coverage': use province/national cooperation to provide some evidence
        - Toxicity, QoL
    - Collaboration remains a key element: Between institutions, provinces
        - Showcase our ability to work together and effectively
        - Single payer data set!
- Who are the 'decision makers'
    - Analytic
    - Clinical
    - Need a frame work that allows for modifications for smaller populations
- Barriers to Improving Evidence
    - Privacy REB/Rules: Challenge to sharing data: Advantage of Cancer Directed.

        - Need reality-based privacy rules.
    - Regulatory: Health Canada
- Tests/Assays are lab developed, NOT Pharma: Who drives that process, funds that process?
    - Test developers are not normally the skilled person to drive this process
    - Can pilot/gap grants drive this
    - Should Funding agencies that drive initial discovery also be expected bear part of the load to drive implementation, transfer to clinical world.
        - This is breaking down of 'silos'
- Pharma partnerships with Companion Diagnostics a challenge.
    - Lack of regulation in Canada.

6. Closing Remarks and Next Steps

Dr. Williams asked the participants to comment on the following question:

> ***How do we move forward and what should we do differently to make this a success?***

Participants provided the following comments:

- There is power in numbers, and there needs to be a united front of the different stakeholders in this workshop – nobody is going to be the hero – do not go into silos after the meeting.
- Should have a follow-up workshop with leadership from the various organizations.
- Canada is where white papers go to die – is there something that can be done differently, such as crisp messaging for decision-makers?
    - Agreement that there is no point in having any communication without an intended audience – the actual communication product could be different than the white paper.
- Pharma has typically worked in a silo – could have an exploratory meeting to see how we can work together?
    - There are a lot of innovations that do not have a current pathway forward.
- Need to establish a personal relationship with the person(s) you are trying to influence – need to work on personal face time with the officials we are trying to convince.
    - The patient voice can be the very strong.
- Sharing a summary document broadly, from this workshop, would help to validate what we are saying.
- There are many tangible stories about patients, lost opportunities, lost economic benefit that can be brought forward.
- There is a federal agency called Innovation Science and Economic Development (ISED) for bringing innovation to Canada (tasked with removing barriers), that could be engaged.
- Important to flag that a refreshed Canadian Cancer Control Strategy was released, and has been presented to the federal minister of health, and could be leveraged.
- Could add CIHI, Canada Health Infoway to the discussion from a privacy perspective.

Dr. Williams provided closing comments, which included an ongoing commitment from OICR and CCO as champions for the innovation framework.

The next steps, following this meeting, include the following tasks:

Task	Responsibility	Status
Workshop Participant Survey for 'other thoughts' (feedback, who's missing, other jurisdictions, other documents, other organizations, etc.).	OICR	Sent to Workshop Participants
Workshop Report documenting the meeting's process, presentations, discussion points and next steps.	Jason Pun (I2C)	Complete
Refinement of the draft innovation framework based on feedback/discussions.	OICR and CCO	In progress
Development of a White Paper describing the issue and solution (the audience for this paper needs to be considered)	OICR and CCO	In progress
Map of Existing Evaluation Organizations including mandates and accountabilities.	OICR	In progress
Project Charter for the remaining work to complete and implement the innovation pathway, including objectives, scope, deliverables, criteria for success, roles & responsibilities, risk analysis, key milestones, resources and performance measures.	OICR and CCO	In progress

7. Appendices

Appendix 1: Open to Innovation: Ontario Pathway Workshop – Background Document (separate document)

Appendix 2: Workshop Agenda

OICR
Ontario Institute for Cancer Research

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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)*

Collaborate. Translate. Change lives.

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*

Appendix 3: Invitation Letter to Participants

Dear XXXX,

The Ontario Institute for Cancer Research (OICR) and Cancer Care Ontario (CCO) are working together to address the difficult problem of how innovative technologies and processes can be more easily adopted into cancer care in Ontario to support health system transformation.

Please join OICR and CCO for ***Open to Innovation: Ontario Pathway Workshop*** on Tuesday, June 18, 2019 in downtown Toronto.

A one-day invited workshop will bring together key stakeholders from innovation to implementation science to discuss a pathway to facilitate adoption of new precision medicine tools into the Ontario cancer care system. Participants will discuss and review barriers and solutions as well as debate problem-solving methods and system processes. The overall goal of the workshop is to have a comprehensive understanding of system requirements to enable innovation adoption in the province of Ontario.

Registration is by invitation only. We will be engaging participants as active contributors during breakout sessions and, in some cases, subsequent work. Participation will be limited to 60-70 people; however if you feel there is a colleague who is critical to include, please contact Christine Williams (Christine.Williams@oicr.on.ca) or Nicole Mittmann (Nicole.Mittmann@cancercare.on.ca).

Registration and Location:
Event website and registration: https://events.oicr.on.ca/opw (*Registration is free*)

Location: Vantage Venues, 16th Floor, 150 King Street West, Toronto, ON M5H 1J9
Time: 8:00 a.m. - 3:45 p.m.

Best regards,

Christine Williams, PhD
Deputy Director, Ontario Institute for Cancer Research

Nicole Mittmann, MSc PhD
Chief Research Officer, Analytics and Informatics, Cancer Care Ontario

Appendix 4: Participant List

	FIRST NAME	LAST NAME	POSITION	ORGANIZATION	TYPE OF ORGANIZATION
1	Ryan	Demers	Senior Manager, Diagnostics	AstraZeneca	Pharmaceutical company
2	Mark	Oatway	Diagnostic Liaison	AstraZeneca	Pharmaceutical company
3	Josh	Silvertown	Senior Manager, Medical Affairs Strategist ? Oncology (TRK Fusion Canc	Bayer Inc	Pharmaceutical company
4	Heather	Logan	Senior Advisor, Pharmaceutical Reviews	CADTH	HTA agency
5	Aaron	Pollett	Provincial Head, Pathology and Laboratory Medicine	CCO	Cancer agency
6	Michael	Sherar	President & CEO	CCO	Cancer agency
7	Kelvin	Chan	Clinical lead, provincial drug reimbursement programs	CCO	Cancer agency
8	Andrea	Mackesy	Group Manager, Research, CCO Research Office	CCO	Cancer agency
9	Jennifer	Hart	Manager, Pathology and Lab Medicine	CCO	Cancer agency
10	Garth	Matheson	VP Analytics & Informatics	CCO	Cancer agency
11	Robin	McLeod	Vice President	CCO	Cancer agency
12	Arlene	Howells	Community rep	CCO	Patient & Family Advisor
13	Kathy	Smith	Community rep	CCO	Patient & Family Advisor
14	Siofradh	McMahon	Senior Manager, Clinical Translation and Regulatory Affairs	CCRM	Biotech company
15	Sara	Urowitz	Executive Director	CPAC	Cancer agency
16	John	Wallenburg	Chief Scientific Officer	Cystic Fibrosis Canada	Cystic fibrosis agency
17	Rebecca	McClure	Pathologist	Health Sciences North	Hospital
18	Caitlin	Taylor	Commercial Operations and Sales Segment Strategy	Illumina	Biotech company
19	Mena	Farag	Sr. Sequencing Specialist	Illumina	Biotech company
20	Kenneth	Evans	CEO	Indoc Research	Data management company
21	Chris	McCabe	CEO and Executive Director	Institute of Health Economics, Alberta	University
22	Jason	Pun	Principal Consultant	Intelligent Improvement Consultants	consultancy
23	Allan	Miranda	Head, JLABS Canada	J&J	Pharmaceutical company
24	Liz	Beecker	Director, New Product & New Business Development	J&J	Pharmaceutical company
25	Evelyn	Pyper	Real World Evidence Manager	Janssen	Pharmaceutical company
26	Barry	Elkind	Director, Business Development, General Diagnostics	Lifelabs	Diagnostic tests provider
27	Mike	Kadour	Lab Director	LHSC & St. Joseph's Health Care London	Hospital
28	Katherine	Kelly Gatten	Director, Science and Research Branch	Ministry of Economic Development, Job Creation and Trade	Ministry
29	Cynthia	Ho	Senior Program Consultant	MOHLTC	Ministry
30	Victor	Castellano	Policy Lead, Health System Planning	MOHLTC	Ministry
31	Jovan	Matic	Director	MOHLTC	Ministry
32	Maricon	Sanelli	Manager, Laboratories and Diagnostics Unit	MOHLTC	Ministry
33	Viola	Cheung	Policy Advisor	MOHLTC	Ministry
34	Chaim	Bell	Physician-in-Chief, Sinai Health System/CQCO member	Mount Sinai Hospital	Hospital
35	Rita	Kandel	Pathologist in Chief	Mount Sinai Hospital	Hospital

	FIRST NAME	LAST NAME	POSITION	ORGANIZATION	TYPE OF ORGANIZATION
37	Lindsay	Smith	Project Manager, GA4GH	OICR	Research organization
38	Laszlo	Radvanyi	President and Scientific Director	OICR	Research organization
39	John	Bartlett	Program Director, Diagnostic Development	OICR	Research organization
40	Christine	Williams	Deputy Director	OICR	Research organization
41	Sola	Dokun	Program Manager, OICR-CCO Health Services Research Network	OICR	Research organization
42	Lincoln	Stein	Head, Adaptive Oncology	OICR	Research organization
43	Lisa	Duncan	Event Staff-Registration / Executive Assistant	OICR	Research organization
44	Patricia	Falzon	Event Staff-Registration / Manager Events	OICR	Research organization
45	Trevor	Pugh	Director, PM-OICR Translational Genomics Lab	OICR	Research organization
46	Christopher	Needles	Senior Manager, Communications	OICR	Research organization
47	Julie	Wilson	Associate Director, PanCuRx	OICR	Research organization
48	Rebecca	Tamarchak	Director, Strategic Planning and Governance	OICR	Research organization
49	Tom	Mikkelsen	CEO	Ontario Brain Instutite	Research organization
50	Bettina	Hamelin	President & CEO	Ontario Genomics	Innovation catalyst
51	Kathy	Deuchars	Director, Ontario Personalized Medicine Network	Ontario Genomics	Innovation catalyst
52	Paul	Gibson	Associate Medical Director, Pediatric Oncologist	Pediatric Oncology Group of Ontario	Cancer agency
53	Monette	Greenway	Principal	Precision Rx-Dx Inc	consultancy
54	Ann	Humphreys	Principal and Co-Founder	Precision Rx-Dx Inc.	consultancy
55	David	Berman	Director, Queen's Cancer Research Institute	Queen's University	University
56	Harriet	Feilotter	Associate Professor of Pathology, Clinical Geneticist	Queen's University	University
57	Dvorah	Richler	Senior Manager, Strategic Partnerships and Policy, Personalized Health Care	Roche	Pharmaceutical company
58	Mike	Duong	Director, Personalized Healthcare and Evidence Generation	Roche	Pharmaceutical company
59	Zayna	Khayat	Future Strategist	SE Health	Social enterprise
60	Avram	Denburg	Physician, Division of Haematology/Oncology	SickKids	Hospital
61	Jim	Whitlock	Director, Garron Family Cancer Centre	SickKids	Hospital
62	Meredith	Irwin	Staff Oncologist	SickKids	Hospital
63	Marc	Clausen	Research Program Manager	St. Michael's Hospital	Hospital
64	David	Hwang	Professor	Sunnybrook Health Science Centre	Hospital
65	Karen	Keith	Senior Clinical Assays Specialist	ThermoFisher Scientific	Biotech company
66	Brad	Wouters	Excecutive Vice President, Science and Research	UHN	Hospital network
67	Tracy	Stockley	Head Department of Clinical Laboratory Genetics	UHN	Hospital network
68	David	Palma	Assistant Professor, Schulich School of Medicine & Dentistry	University of Western Ontario	University
69	Prateek	Lala	Acting Director, Applied Clinical Pharmacology	University of Toronto	University
70	Kenneth	Pritzker	CEO	York Medtech Ventures Inc.	Innovation catalyst

Ontario Pathway Towards Innovation in Cancer Care - Workshop
Pre and Post Workshop Participant Survey

August 6th, 2019

Table of Contents

1. Introductory Text for Post-Workshop Survey

Thank you once again for participating in the Ontario Pathway Workshop organized by OICR and CCO on June 18, 2019. We appreciate your time and thoughtful contributions to the pre-workshop survey and to the workshop discussions.
At the end of the workshop we committed to circulating a summary report to all participants and to providing an opportunity for additional ideas and feedback to be captured.
Consequently, attached to this email you will find:

- Ontario Pathway Workshop summary report
- A short post-workshop survey

Participating in this short survey is voluntary and anonymous and will take about 10 minutes to complete. Please click this link to start the survey http://dhfe felfafklmfaflehfereref. If you have any questions, please contact Sola Dokun at Sola.Dokun@oicr.on.ca or 647-260-7953. We would appreciate if you could send responses by **Friday, August 30, 2019**.
Thank you very much for your participation in this survey and for your commitment to promoting innovation in care for Ontario's cancer patients.

Best wishes,
Christine Williams
Deputy Director, OICR

2. Post-Workshop Survey Questions

1. The objectives of the OPW were to:

- Review the draft innovation framework.
- Identify solutions to barriers to implementation.
- Engage diverse stakeholders to initiate change management across the province.

   Were these objectives achieved during the workshop?

   Yes

   No

2. Please provide us with any comments or feedback on the workshop (see the attached summary report).

   [Comments]

3. Are there other stakeholders or organizations that we should engage to move this initiative forward in Ontario?

   [Comments]

4. Are there other jurisdictions we should consider as successful models?

   [Comments]

5. Are there other documents or reports that would be informative?

   [Comments]

6. Is there anything else you would like to add to make implementing a pathway for innovation in cancer care successful?

3. Introductory Text for Pre-Workshop Survey

Introductory Text [to be included on first page of web survey and email to participants]

The Ontario Institute for Cancer Research (OICR) and Cancer Care Ontario (CCO) are engaging key stakeholders in the cancer research and care communities to address the difficult problem of how to promote more innovative technologies and processes being adopted into cancer care in Ontario to support health system transformation.

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 purpose of this workshop we are focusing our discussion on innovations related to the delivery of precision medicine in oncology. For example, precision medicine tools such as molecular genetic testing and multi-omics, companion diagnostic, predictive and prognostic biomarker tests, and algorithms associated with precision medicine tools. The framework should, however, be applicable to other innovative technologies.

In addition to reviewing the pre-workshop materials we will be sending you, **we would like you to provide your initial thoughts and opinions on the draft Proposed Framework** in order to advance discussion on the day of the workshop. We understand this may be your first exposure to the framework, so if you must answer 'Do not know' to some questions, that is fine.

Participating in this survey is voluntary and anonymous. Your answers will be grouped with answers provided by the other workshop participants completing the survey. The survey may take 15 to 20 minutes to complete.

The survey is being administered by our workshop partner, Intelligent Improvement Consultants (I2C). If you have any questions/issues with the survey, please email or call Jason Pun at jpun@intel-icon.com or (416) 845-9771.

Thank you very much for your participation in this important survey.

Christine Williams
Deputy Director, OICR

4. Pre-Workshop Survey Questions

1. Please indicate what best describes the role you will be representing at the workshop (choose all that apply):
   - ☐ Researcher
   - ☐ Clinician
   - ☐ Molecular geneticist/pathologist
   - ☐ Patient/Public
   - ☐ Hospital/research leadership
   - ☐ Health and cancer care system
   - ☐ Industry
   - ☐ Other (please specify): _____

2. Please complete this sentence. "From my perspective, the main challenge with adopting more innovation into cancer care in Ontario is…

Validating the Proposed Framework

The draft Proposed Framework for the Evaluation and Implementation of Health Innovations has three phases: Appraisal, Evaluation, and Implementation. A diagram of the Proposed Framework was included in the survey invitation email sent by Christine Williams.

Appraisal Phase

3. The draft Proposed Framework for the Evaluation and Implementation of Health Innovations has three phases: Appraisal, Evaluation, and Implementation.

   The purpose of the **Appraisal Phase** is to:
   - Determine whether an innovation is worth evaluating (priority for the province, clinical utility, system readiness)
   - Provide a clear entry point into the evaluation phase

   In general, do you agree with the purpose of the **Appraisal Phase**?
   - ☐ Yes
   - ☐ No
   - ☐ Do not know

4. If you answered 'No' or 'Do not know' to the question above, how should the purpose of the **Appraisal Phase** be revised?

5. The **Appraisal Phase** process includes the following major activities:
    - Hybrid intake: invitations for priority solutions ("pull") AND submission of new innovations ("push")
    - Development of a checklist/guideline of required evidence
    - Establishment of a governance committee (including patients) for developing/determining priorities
    - Establishment of an adjudication committee for reviewing evidence

    In general, do you agree with the process/major activities of the **Appraisal Phase**?
    - ☐ Yes
    - ☐ No
    - ☐ Do not know

6. If you answered 'No' or 'Do not know' to the question above, how should the process/major activities of the **Appraisal Phase** be revised?

7. How long should innovations remain in the **Appraisal Phase** before continuing to the next phase or being discontinued?
    - ☐ Less than 3 months
    - ☐ 3 to 6 months
    - ☐ 6 to 12 months
    - ☐ 1 to 2 years
    - ☐ Other (please specify): _____
    - ☐ Do not know

8. What minimum level of evidence should be required for innovations to be submitted for **Appraisal** (choose one)?
    - ☐ **Performance specifications** (e.g. accuracy, sensitivity, specificity)
    - ☐ **N of 1 trial –** clinical trial in which a single patient is the entire trial
    - ☐ **Opinion or consensus** – authoritative opinion of expert committee on an innovation
    - ☐ **Qualitative of descriptive study** – provides background information on an innovation of interest, gathers qualitative data on human behaviour to understand why and how decisions are made
    - ☐ **Systematic review of qualitative or descriptive studies** – a synthesis of evidence from qualitative or descriptive studies
    - ☐ **Case-control or cohort study** – a comparison of subjects with or without use of an innovation, or observations of a group/cohort to determine outcomes of the use of an innovation
    - ☐ **Controlled trial without randomization** – an experiment in which subjects are nonrandomly assigned to an innovation group or control group
    - ☐ **Randomized controlled trial** – an experiment in which subjects are randomized to an innovation group or control group
    - ☐ **Systematic review or meta-analysis** – A synthesis of evidence from all relevant randomized, controlled trials
    - ☐ Other (please specify): _____

- ☐ Do not know

9. Based on your answer to the question above, is this level of evidence easily obtainable for innovative cancer technologies and processes in Ontario?
   - ☐ Yes
   - ☐ No
   - ☐ Do not know

10. If you answered 'Yes' to the question above, what are sources of innovative technologies and processes with this level of evidence?

11. If you answered 'No' to the question above, how do we build the necessary evidence?

12. Who should be involved with decision-making on which innovations/processes are accepted for **Appraisal** (select all that apply)?
    - ☐ Government (provincial and/or federal)
    - ☐ Separate agency arms-length from government
    - ☐ Committee of researchers
    - ☐ Committee of clinicians/laboratory experts
    - ☐ Multi-disciplinary committee of researchers, clinicians, health economists, policy experts, laboratory experts
    - ☐ Other (please specify): _____
    - ☐ Do not know

13. Who should be involved with decision-making on which innovations/processes pass the **Appraisal Phase** and move on to the **Evaluation Phase** (select all that apply)?
    - ☐ Government (provincial and/or federal)
    - ☐ Separate agency arms-length from government
    - ☐ Committee of researchers
    - ☐ Committee of clinicians/laboratory experts
    - ☐ Multi-disciplinary committee of researchers, clinicians, health economists, policy experts, laboratory experts
    - ☐ Patients, families, community representatives
    - ☐ Other (please specify): _____
    - ☐ Do not know

14. Who should provide funding for innovations undergoing **Appraisal** (select all that apply)?
    - ☐ Government (provincial and/or federal)
    - ☐ Hospitals

- ☐ Industry
- ☐ Innovator/inventor
- ☐ Private/public partnership
- ☐ Other (please specify): _____
- ☐ Do not know

Evaluation Phase

15. The draft Proposed Framework for the Evaluation and Implementation of Health Innovations has three phases: Appraisal, Evaluation, and Implementation.

    The purpose of the **Evaluation Phase** is to:
    - Critically evaluate evidence to determine whether an innovation should undergo pilot implementation with patients
    - Assess whether the innovation has a high level of clinical validity
    - Assess whether the innovation will positively impact patients and the health system
    - Evaluate real-world outcomes in real time

    In general, do you agree with the purpose of the **Evaluation Phase**?
    - ☐ Yes
    - ☐ No
    - ☐ Do not know

16. If you answered 'No' or 'Do not know' to the question above, how should the purpose of the **Evaluation Phase** be revised?

17. The **Evaluation Phase** process includes the following major activities:
    - Evaluate evidence (including clinical validity, safety, system impact, health technology assessment)

    In general, do you agree with the process/major activities of the **Evaluation Phase**?
    - ☐ Yes
    - ☐ No
    - ☐ Do not know

18. If you answered 'No' or 'Do not know' to the question above, how should the process/major activities of the **Evaluation Phase** be revised?

19. What type of organization(s) should evaluate innovations in this phase?
    - ☐ Existing organizations should be leveraged (e.g. HQO/OHTAC, MaRS Excite, CADTH, other)

- ☐ Create a new organization
- ☐ Other (please specify): _____

20. How long should innovations remain in the **Evaluation Phase** before continuing to the next phase or being discontinued?
    - ☐ Less than 3 months
    - ☐ 3 to 6 months
    - ☐ 6 to 12 months
    - ☐ 1 to 2 years
    - ☐ Other (please specify): _____
    - ☐ Do not know

21. What minimum level of evidence should be required for innovations to pass the Evaluation Phase and be submitted for Implementation (choose one)?
    - ☐ **Performance specifications** (e.g. accuracy, sensitivity, specificity)
    - ☐ **N of 1 trial –** clinical trial in which a single patient is the entire trial
    - ☐ **Opinion or consensus** – authoritative opinion of expert committee on an innovation
    - ☐ **Qualitative of descriptive study** – provides background information on an innovation of interest, gathers qualitative data on human behaviour to understand why and how decisions are made
    - ☐ **Systematic review of qualitative or descriptive studies** – a synthesis of evidence from qualitative or descriptive studies
    - ☐ **Case-control or cohort study** – a comparison of subjects with or without use of an innovation, or observations of a group/cohort to determine outcomes of the use of an innovation
    - ☐ **Controlled trial without randomization** – an experiment in which subjects are nonrandomly assigned to an innovation group or control group
    - ☐ **Randomized controlled trial** – an experiment in which subjects are randomized to an innovation group or control group
    - ☐ **Systematic review or meta-analysis** – A synthesis of evidence from all relevant randomized, controlled trials
    - ☐ **Other (please specify):** _____
    - ☐ Do not know

22. Based on your answer to the question above, is this level of evidence easily obtainable for innovative cancer technologies and processes in Ontario?
    - ☐ Yes
    - ☐ No
    - ☐ Do not know

23. If you answered 'Yes' to the question above, what are sources of innovative technologies and processes with this level of evidence?

24. If you answered 'No' to the question above, how do we build the necessary evidence?

25. Should different levels of evidence be established for different categories of innovations?
    - ☐ Yes
    - ☐ No
    - ☐ Do not know

26. Please briefly explain your response to the question above.

27. Should different levels of evidence be established for different therapeutic needs?
    - ☐ Yes
    - ☐ No
    - ☐ Do not know

28. Please briefly explain your response to the question above.

29. Who should be involved with decision-making on which innovations/processes pass the **Evaluation Phase** and move on to the **Implementation Phase** (select all that apply)?
    - ☐ Government (provincial and/or federal)
    - ☐ Separate agency arms-length from government
    - ☐ Committee of researchers
    - ☐ Committee of clinicians/laboratory experts
    - ☐ Multi-disciplinary committee of researchers, clinicians, health economists, policy experts, laboratory experts
    - ☐ Patients, families, community representatives
    - ☐ Other (please specify): _____
    - ☐ Do not know

30. Who should provide funding for innovations undergoing **Evaluation** (select all that apply)?
    - ☐ Government (provincial and/or federal)
    - ☐ Hospitals
    - ☐ Industry
    - ☐ Innovator/inventor
    - ☐ Private/public partnership
    - ☐ Other (please specify): _____
    - ☐ Do not know

Implementation Phase

31. The draft Proposed Framework for the Evaluation and Implementation of Health Innovations has three phases: Appraisal, Evaluation, and Implementation.

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

    In general, do you agree with the purpose of the **Implementation Phase**?
    - ☐ Yes
    - ☐ No
    - ☐ Do not know

32. If you answered 'No' or 'Do not know' to the question above, how should the purpose of the Implementation Phase be revised?

33. The **Implementation Phase** process includes the following major activities:
    - Generation of a checklist of outcomes required for system adoption
    - Establishment of an adjudication committee for reviewing evidence
    - Establishment of a Governance committee (including patients) for determining adoption of technologies
    - Identification of centres/networks to test and evaluate each technology (pilot testing)
    - Ongoing assessment- continual learning/improvement and data collection from the care setting
    - Develop implementation plan (e.g. Service Delivery Model, Quality Assurance guidelines, funding model)

    In general, do you agree with the process/major activities of the **Implementation Phase**?
    - ☐ Yes
    - ☐ No
    - ☐ Do not know

34. If you answered 'No' or 'Do not know' to the question above, how should the process/major activities of the **Implementation Phase** be revised?

35. What type of organization(s) should conduct evidence building in this phase?
    - ☐ Existing organizations should be leveraged (e.g. CCO's PET, Evidence Building Program, other)

- ☐ Create a new organization
- ☐ Other (please specify): _____

36. How long should innovations remain in the **Implementation Phase** before continuing to adoption and diffusion or being discontinued?
    - ☐ Less than 3 months
    - ☐ 3 to 6 months
    - ☐ 6 to 12 months
    - ☐ 1 to 2 years
    - ☐ Other (please specify): _____
    - ☐ Do not know

37. Who should be involved with decision-making on which innovations/processes pass the **Implementation Phase** and move on to adoption and diffusion (select all that apply)?
    - ☐ Government (provincial and/or federal)
    - ☐ Separate agency arms-length from Ministry of Health and Long-Term Care
    - ☐ Committee of researchers
    - ☐ Committee of clinicians/laboratory experts
    - ☐ Multi-disciplinary committee of researchers, clinicians, health economists, policy experts, laboratory experts
    - ☐ Patients, families, community representatives
    - ☐ Other (please specify): _____
    - ☐ Do not know

38. Who should provide funding for innovations undergoing **Implementation** (select all that apply)?
    - ☐ Government (provincial and/or federal)
    - ☐ Hospital
    - ☐ Industry
    - ☐ Innovator/inventor
    - ☐ Private/public partnership
    - ☐ Other (please specify): _____
    - ☐ Do not know

39. What type of organization(s) should govern/oversee the innovation framework?
    - ☐ A group of existing organizations
    - ☐ A single existing organization
    - ☐ Create a new organization
    - ☐ Other (please specify): _____

Additional Comments

40. Please rank the following barriers to implementing the innovation framework in Ontario in order of importance (1 = most important):
    - ☐ Funding for evidence generation
    - ☐ Governance and prioritization of technologies
    - ☐ Connectivity of research and clinical data including privacy considerations
    - ☐ System and culture change
    - ☐ Regulatory environment

41. In addition to those listed in the previous question, are there any other important barriers that must be overcome in order to implement the innovation framework?

42. What are the most important performance indicators for measuring the success of the innovation framework?

43. Is there anything else you would like to add about the draft innovation framework (other comments, what is missing, examples of systems/programs that have worked, etc.)?

Thank you for completing the survey. Results will be shared at the workshop. We look forward to seeing you on June 18th.

Ontario Pathway Towards Innovation in Cancer Care
Workshop Report

Appendix 6: Pre-Workshop Survey Results

June 18th 2019

Intelligent Improvement Consultants

Respondent Roles (select all that apply)

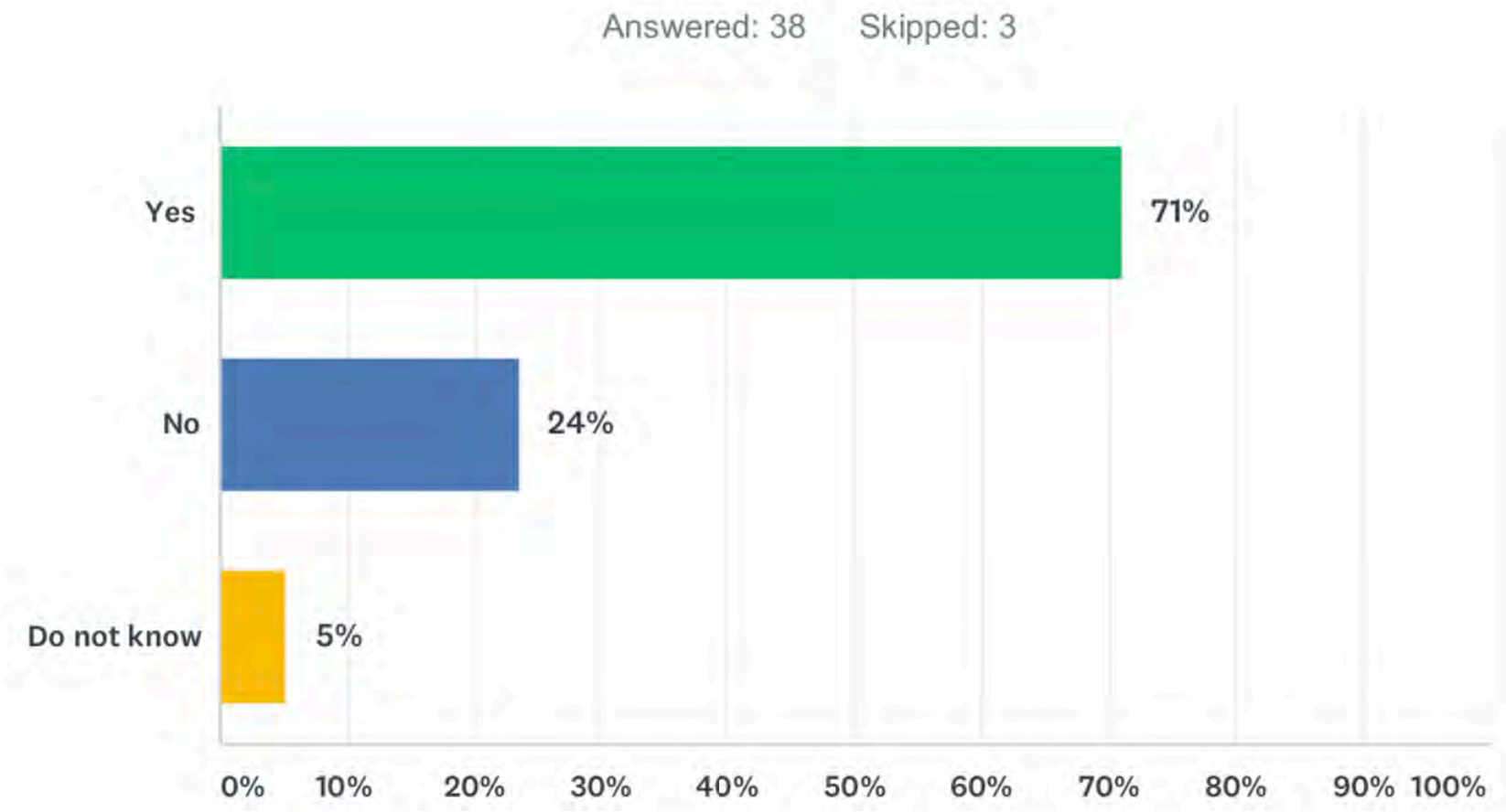
- Most respondents identified themselves as Health and cancer care system and/or Industry, followed by Researcher then Clinician.
- Some organizations responded as a group.

Answer Choices	Responses
Health and cancer care system	12
Industry	12
Researcher	8
Clinician	7
Other (please specify)	6
Molecular geneticist/pathologist	4
Hospital/research leadership	4
Patient/Public	2
Total Responses:	40

- Other: HTA Organization, not for profit funder, not for profit data platform support, consultant in Precision Medicine/Biomarkers, Government, health innovation expert

Appraisal Phase: Do you agree with the purpose?

- The majority of respondents agreed with the purpose of the Appraisal Phase of the draft framework.



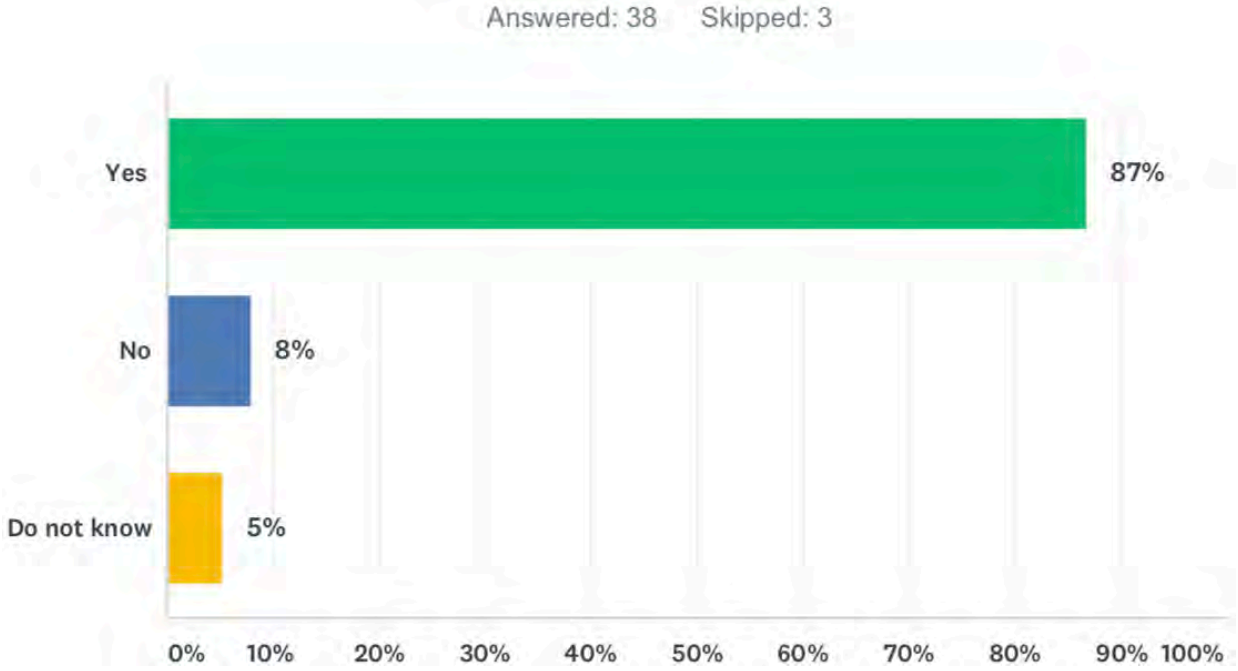
Appraisal Phase purpose: How should it be revised?

Respondents that did not agree with the purpose, or did not know, offered a number of suggestions for revisions:

- Difficult to answer linearly, each technology/clinical intervention/device needs a fairly unique path depending on life cycle
- Need to determine where product is in lifecycle and who major players are to determine next step
- Priority for patients should be defined (phase could be called “Prioritization”
- System readiness is a barrier that needs to be evaluated
- Should determine clinical validity before utility (define these terms)
- Should learn from how HQO performs HTA (e.g. OGAC committee)
- “Clear entry point” needs quantifiable measures
- Should align with the quadruple aim (pt outcomes, pt experience, provider satisfaction, cost effectiveness)

Appraisal Phase: Do you agree with the major activities?

- Almost 90% of respondents agreed with the major activities of the Appraisal Phase process, which included:
  - Hybrid intake: invitations for priority solutions (“pull”) AND submission of new innovations (“push”)
  - Development of a checklist/guideline of required evidence
  - Establishment of a governance committee (including patients) for developing/determining priorities
  - Establishment of an adjudication committee for reviewing evidence



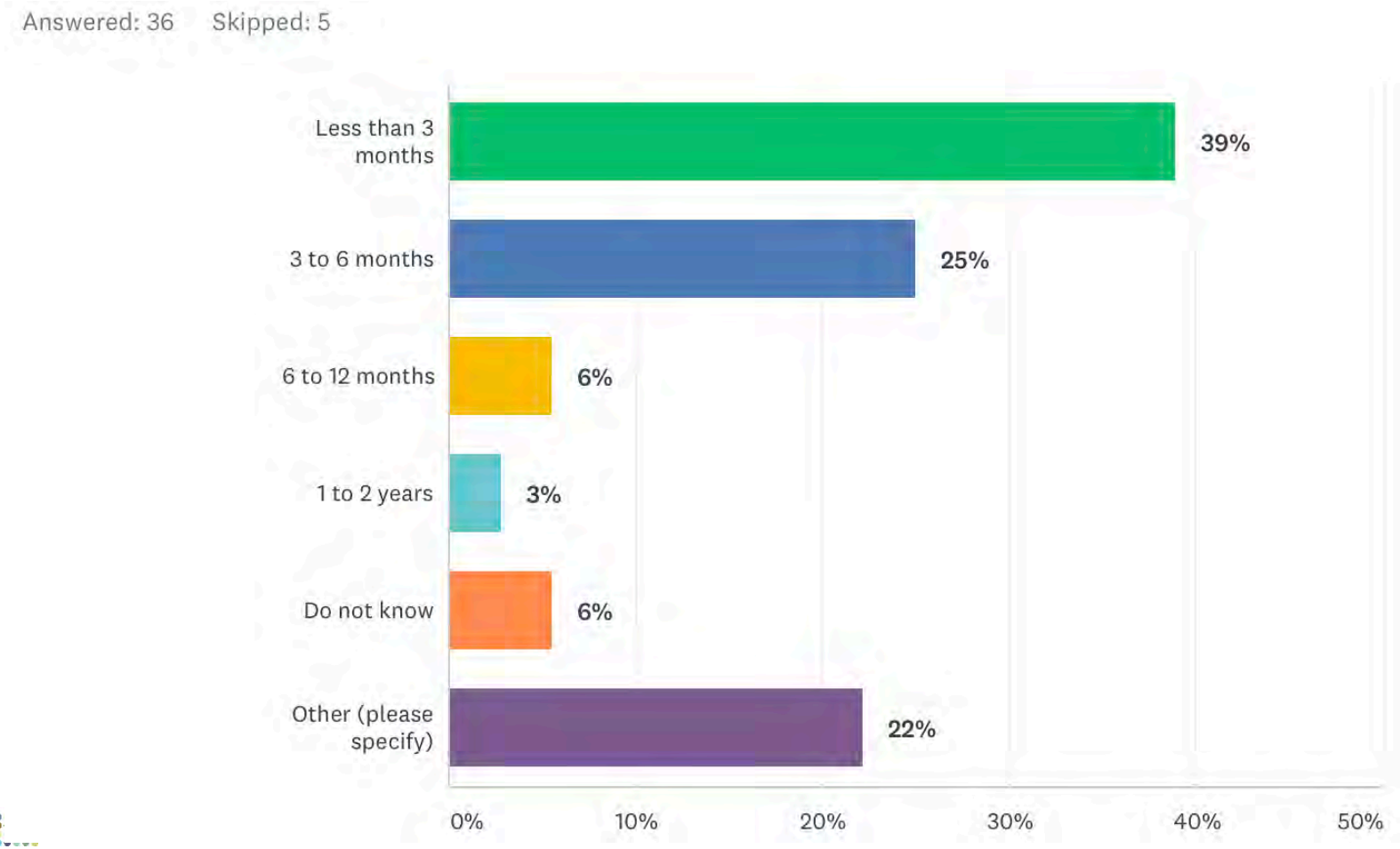
Appraisal Phase activities: How should they be revised?

Respondents that did not agree with the major activities, or did not know, offered a number of suggestions for revisions:

- Phase should be very short, just to understand where in the lifecycle (pre-regulatory, discovery, or post-regulatory for HTA)
- How to fit into existing structures/processes like HQO?
- How this works will depend on the prioritization framework and the vision for the innovation framework (e.g. improved commercialization, patient access/care, outcomes, value costs, all of these?)
- Should add input from prospective users/patients/stakeholders
- Suggest starting with mapping out existing process for evidence evaluation (national vs provincial processes)
- Should be a structured assessment akin to HTA, sized and scoped to the nature of the innovation

Appraisal Phase: How long should innovations be in this phase?

- Most respondents believed that innovations should be in the Appraisal Phase for less than 6 months (64%), though many did not believe a restricted time period could be applied to all innovations (see next slide).



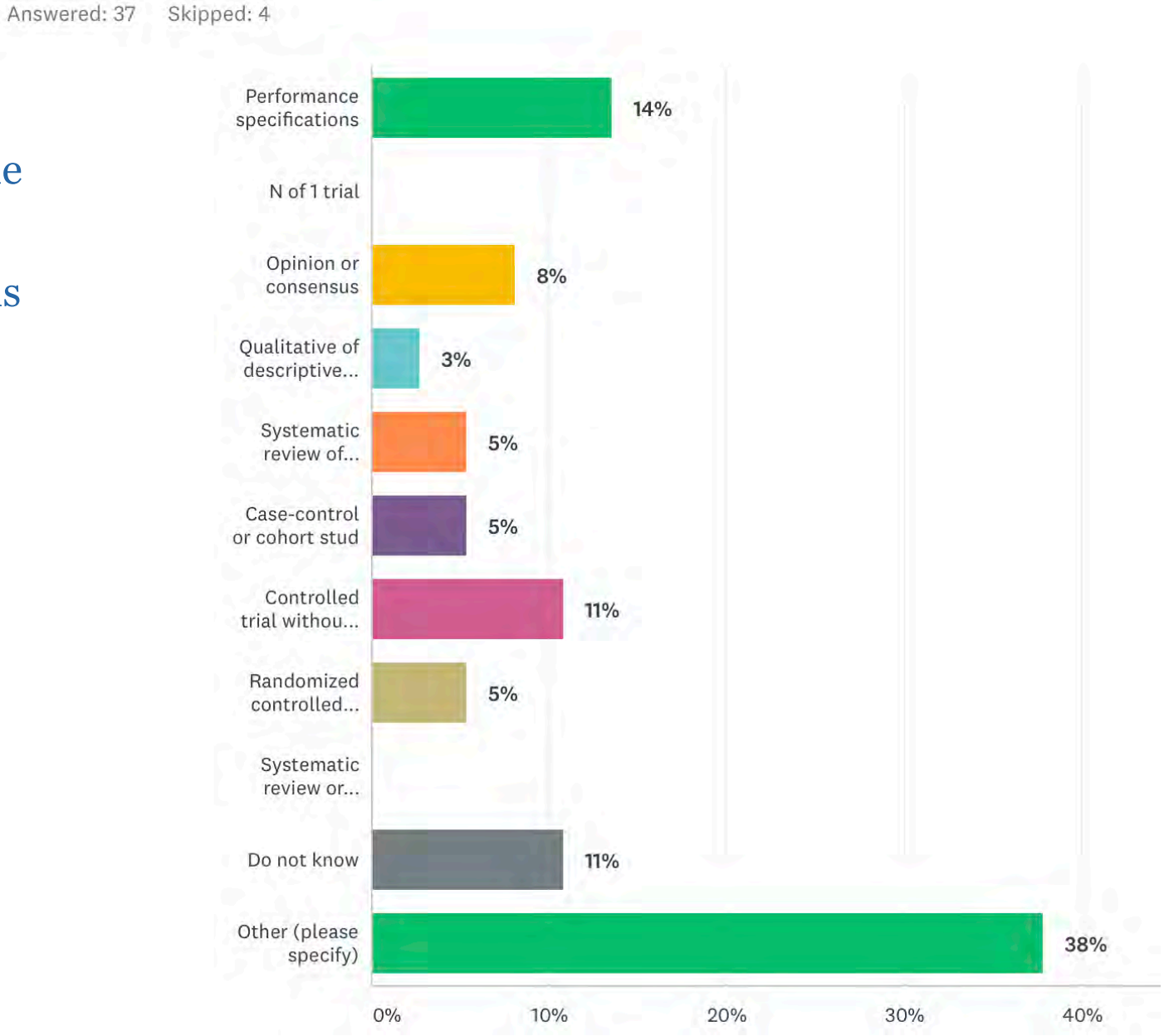
Appraisal Phase: How long should innovations be in this phase?

Respondents offered other suggestions for the Appraisal timeframe:

- Governance and adjudication committee will need to be managed carefully to keep timeline under 3 months
- 1 year, will have to manage data gathering back and forth with applicant
- As short as possible but will depend on evidence available for each innovation and the disease
- Many factors need to be considered – could be less than 3 months or ore than 2 years
- Arbitrary – don‘t want to lag, or rush with fixed deadlines to jeopardize patient safety
- Depends on category of innovation – could have different evidence thresholds and review processes – timeline should reflect categories
- As long as needed

Appraisal Phase: Minimum level of evidence to be submitted?

- There was not strong agreement for any single minimum level of evidence for innovations to be submitted to for Appraisal.
- Most respondents answered ‘other’.



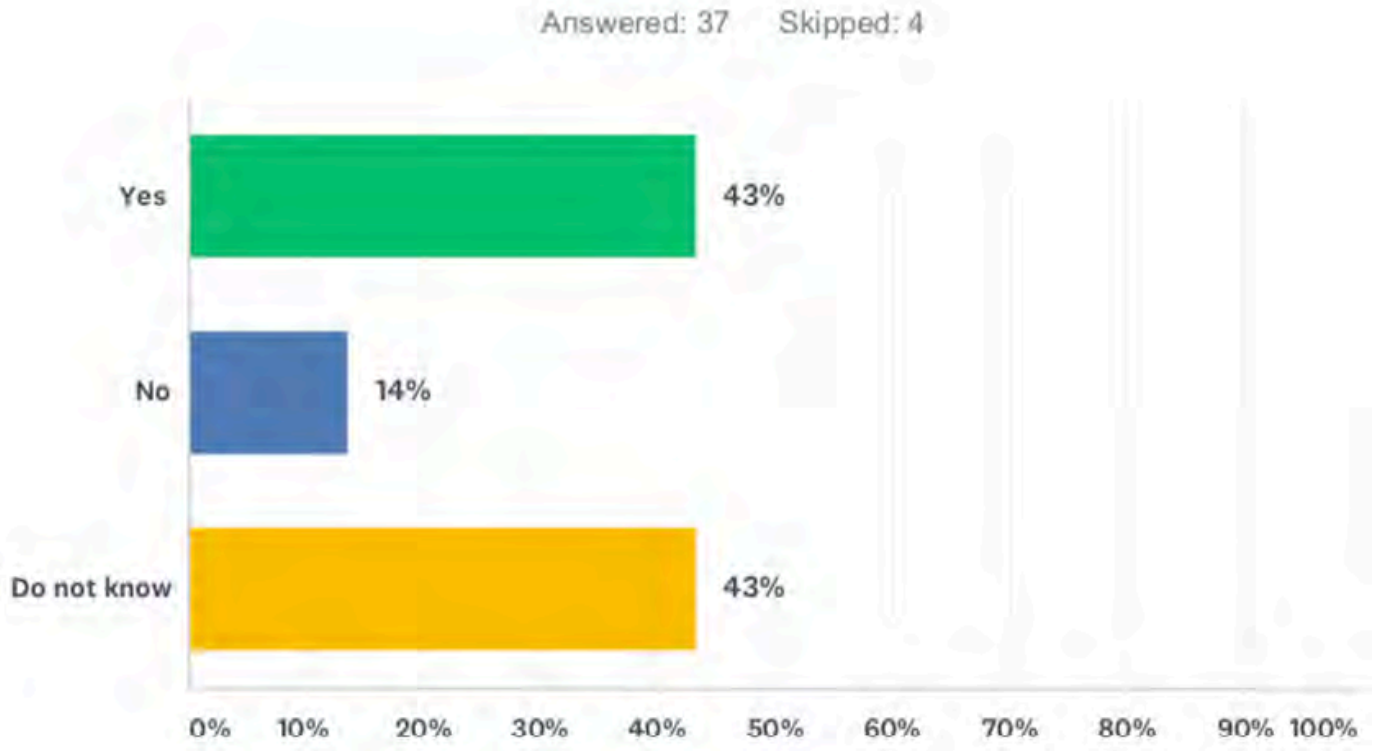
Appraisal Phase: Minimum level of evidence to be submitted?

Respondents that answered 'other' provided the following feedback on the minimum level of evidence:

- Cannot be too rigid defining requirements, might miss beneficial innovations proceeding – need forum/committee to discuss the innovation
- It depends on:
  - Type of innovation
  - Disease (e.g. ultra rare orphan could use N of 1 trial)
  - Clinical need
  - Payer expectations
  - The potential impact - positive or negative (patient safety)
  - Where the innovation is in the life-cycle

Appraisal Phase: Is the level of evidence you chose easily available in Ontario?

- Overall, some respondents (43%) thought that the level of evidence they chose was easily in Ontario, though an equal proportion did not know.



Appraisal Phase: Is the level of evidence you chose easily available in Ontario (by Q8 answer)?

- Though the absolute numbers were low, respondents that chose Performance specifications, Opinion or consensus, Case-control or cohort study, and Controlled trial without randomization, thought that evidence was easily available..

Level of Evidence	Yes	No	Do not know	TOTAL
Q8: Performance specifications	80%	0%	20%	26%
	4	0	1	5
Q8: Opinion or consensus	67%	0%	33%	16%
	2	0	1	3
Q8: Qualitative of descriptive study	0%	0%	100%	5%
	0	0	1	1
Q8: Systematic review of qualitative or descriptive studies	50%	0%	50%	11%
	1	0	1	2
Q8: Case-control or cohort study	100%	0%	0%	11%
	2	0	0	2
Q8: Controlled trial without randomization	100%	0%	0%	21%
	4	0	0	4
Q8: Randomized controlled trial	0%	100%	0%	11%
	0	2	0	2

Appraisal Phase: Sources of evidence, by level

- Respondents indicated the following sources, based on the level of evidence they chose:

Level of Evidence	Sources in Ontario
Performance specifications	Academia, Industry, Manufacturers specifications (product profiles), lab validation data, RWE
Opinion or consensus	Small non-randomized trials by cooperative groups (pediatrics), industry, academic and clinical research
Systematic review of qualitative/ descriptive studies	Innovators launch small initial studies of their technologies (1 or 2 could be sufficient)
Case-control or cohort study	Industry, Academic, Clinical research
Controlled trial without randomization	Administrative data sets, Observational studies, companion diagnostics studies, Academic/hospital research, Industry, Phase 2 cancer drugs with companion diagnostics

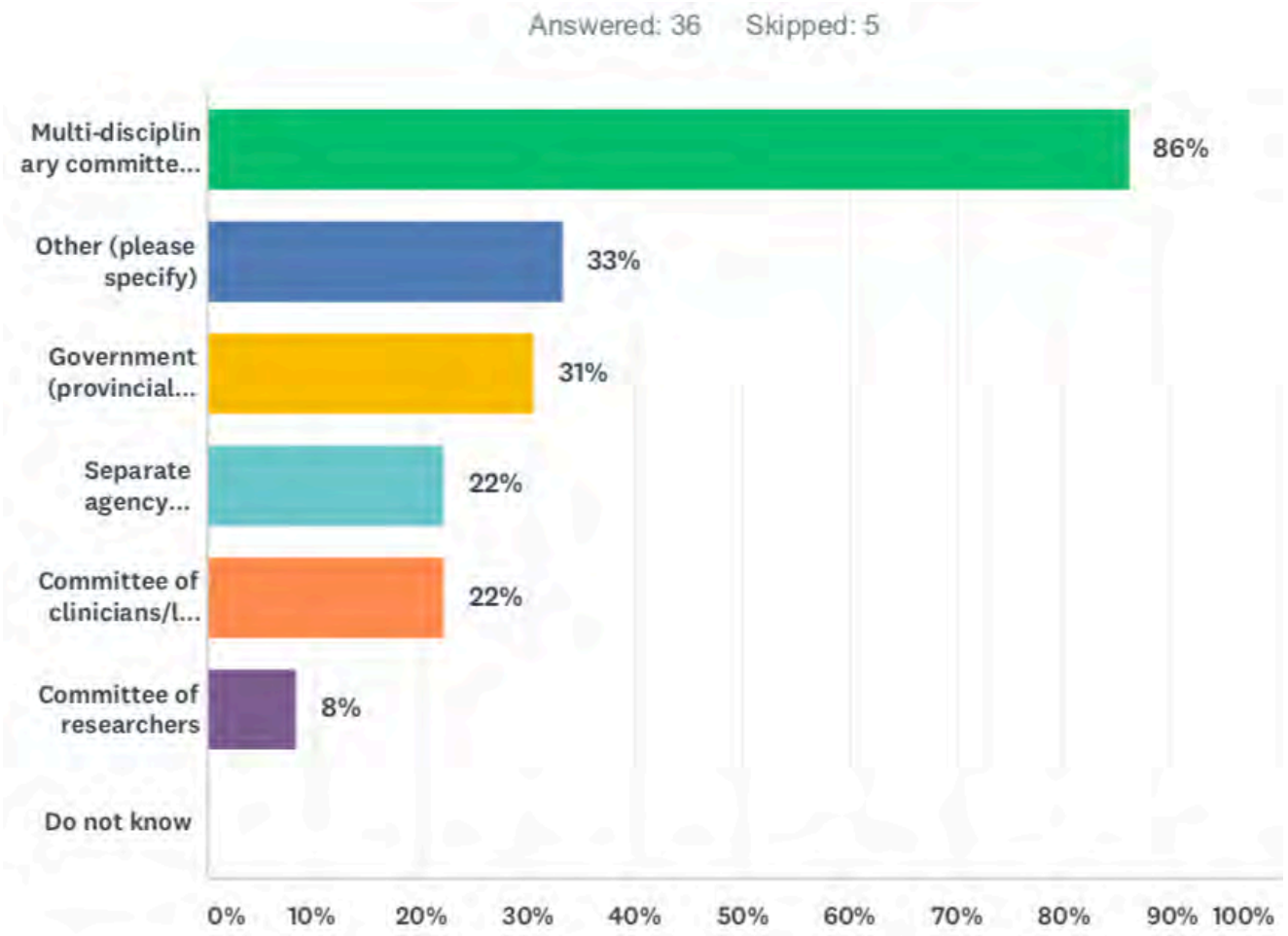
Appraisal Phase: How do we build the necessary evidence?

- Respondents that did not think Ontario had readily available evidence, offered the following suggestions on how to build the necessary evidence

Level of Evidence	Sources in Ontario
Unspecified	• Linked and accessible data within Ontario • Draw from other relevant provinces/jurisdictions • Pilot field evaluation studies (testing of technologies in the real world) • Data infrastructure and access policies/framework need to be enhanced and modernized to enable broader evidence generation capabilities • There are cycles of appraisal and evidence generation required to achieve each level of evidence. Capacity for early evidence generation based on a lower evidence bar is necessary in Ontario, e.g. availability of clinical sites for demonstration projects. The goal for earlier cycles is contextual evidence to trigger temporary policy decisions, the goal for later cycles is RCT-equivalent evidence to trigger longer term policy decisions.
Randomized controlled trial	Grants or private partnerships

Appraisal Phase: Who should be involved with decision-making on innovations accepted for Appraisal?

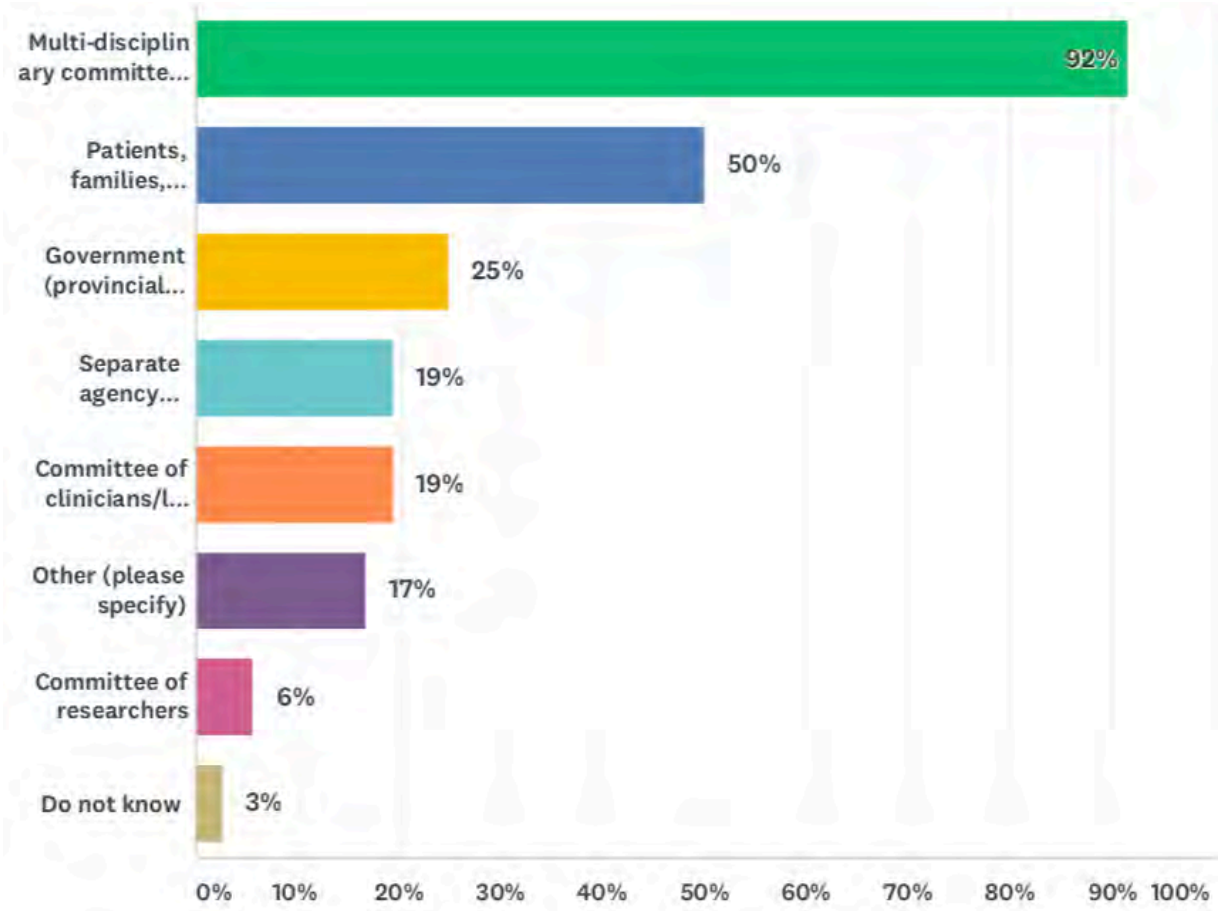
- Most respondents believed a multi-disciplinary committee of researchers, clinicians, health economists, policy experts, and laboratory experts should be involved with decision-making.



- Other included: Patients, Add patients to multi-disciplinary committee Committee (including HTA, regulator, funder, and payer), Government, Industry representatives, Industry experts.
- Note: patients was accidentally omitted from answer choices on this question.

Appraisal Phase: Who should be involved with decision-making on innovations passing Appraisal and moving to Evaluation?

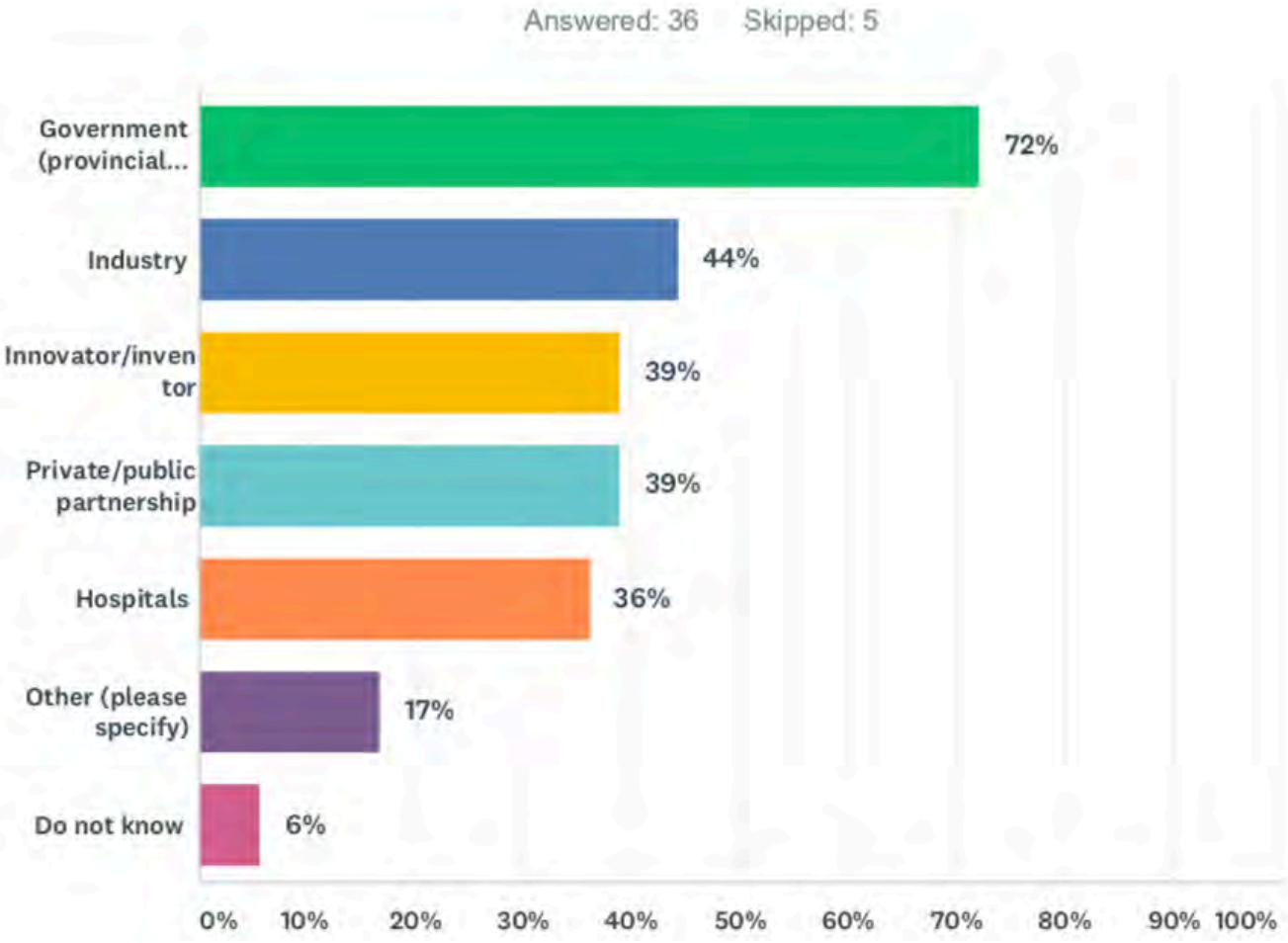
- Most respondents believed a multi-disciplinary committee of researchers, clinicians, health economists, policy experts, and laboratory experts should be involved with decision-making, followed by patients/families



- Other included: Funder of implementation, Committee (including HTA, regulator, funder, and payer), Industry representatives with relevant expertise, combination of multi-disciplinary committee and patients/family/ community advisors

Appraisal Phase: Who should provide funding for innovations undergoing Appraisal?

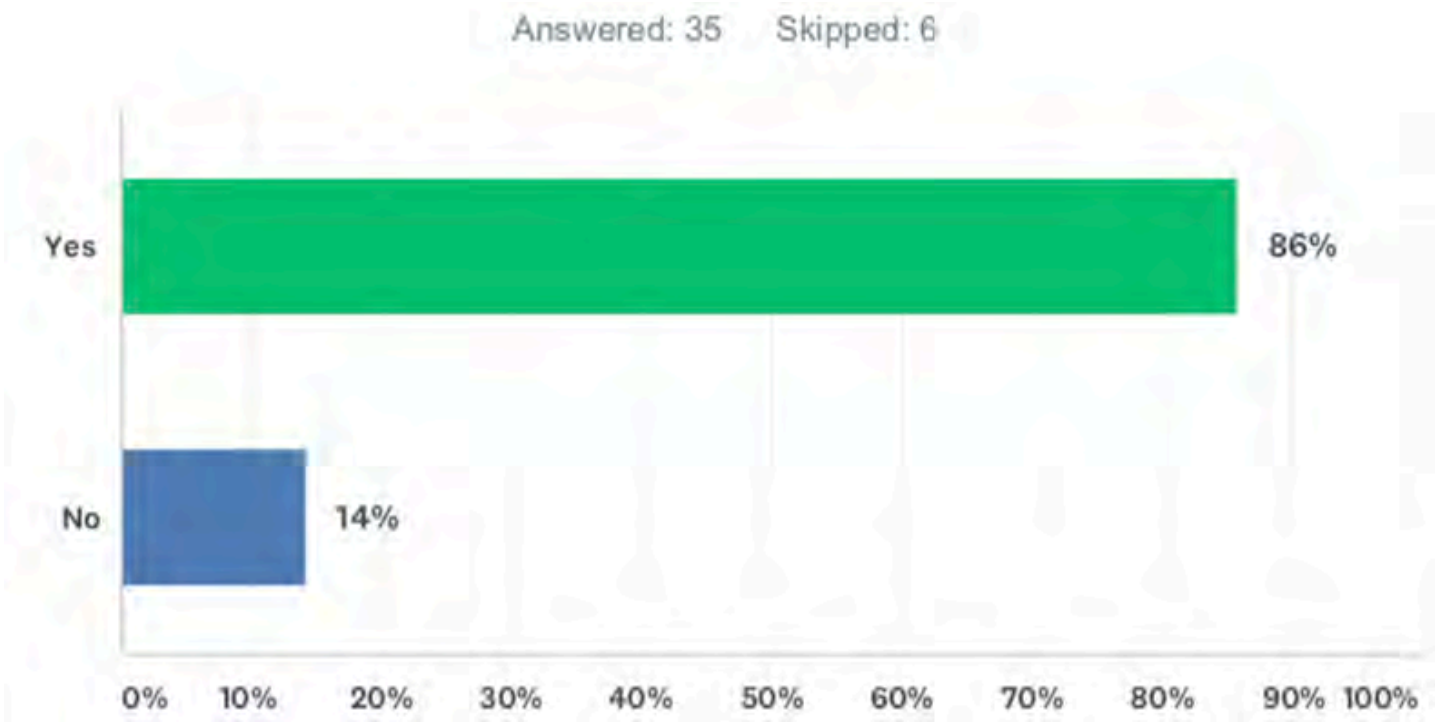
- Most respondents believed Government (provincial and/or federal) should fund Appraisal, followed by Industry, Innovator/inventor, Private/public partnership, and hospitals.



Other included: Shared funding with industry given the cost of evidence development, Government should provide given currently no funding for Appraisal, could be any of the answer choices provided conflicts of interest are managed, many are able and willing, different roles to play.

Evaluation Phase: Do you agree with the purpose?

- Most respondents agreed with the purpose of the Evaluation Phase of the draft framework.



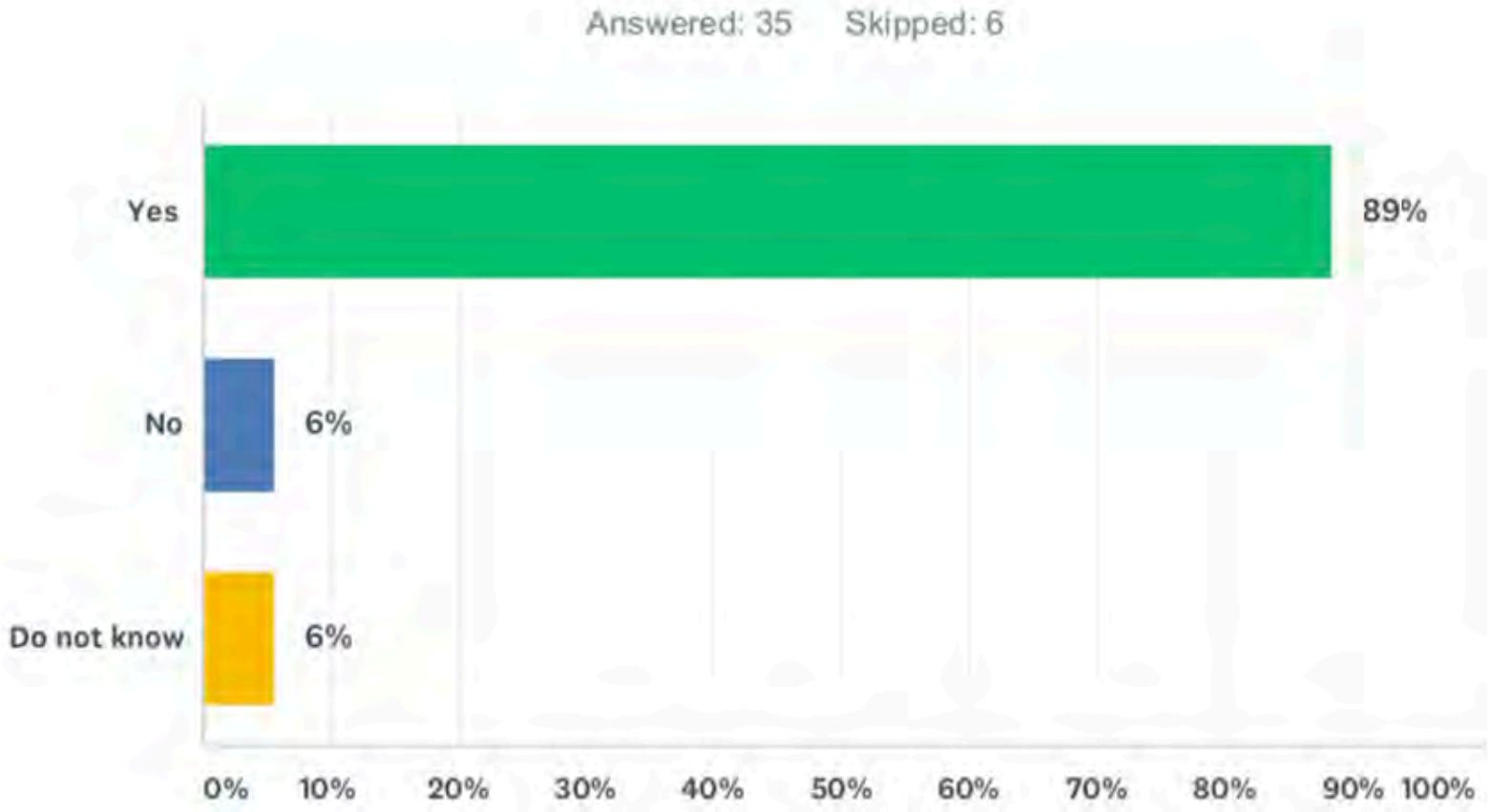
Evaluation Phase purpose: How should it be revised?

Respondents that did not agree with the purpose, or did not know, offered a number of suggestions for revisions:

- "Critically evaluate evidence" should be part of Appraisal Phase, which should then determine the type of evaluation that would be appropriate, then the type of innovation will determine the kind of evaluation and evidence required (some could be regulatory review, others filed study, others HTA).
- Should be about evaluating clinical utility, impact on patient care, long-term outcomes. Clinical validity should be determined first (in Appraisal). If there isn't validity, there is no need to move on to evaluating clinical utility.
- Too focused on 1.5 of the 4 legs of the quadruple aim. Clinical validity is important, but is not the only thing that matters. Patient outcomes (well beyond clinical, which is a system metric, not always a patient metric), patient and family experience/satisfaction, clinician experience/satisfaction all matter as much as clinical utility and cost effectiveness. suggest you anchor around quadruple aim.

Evaluation Phase: Do you agree with the major activities?

- Almost 90% of respondents agreed with the major activities of the Evaluation Phase process, which included:
  - Evaluate evidence (including clinical validity, safety, system impact, health technology assessment)



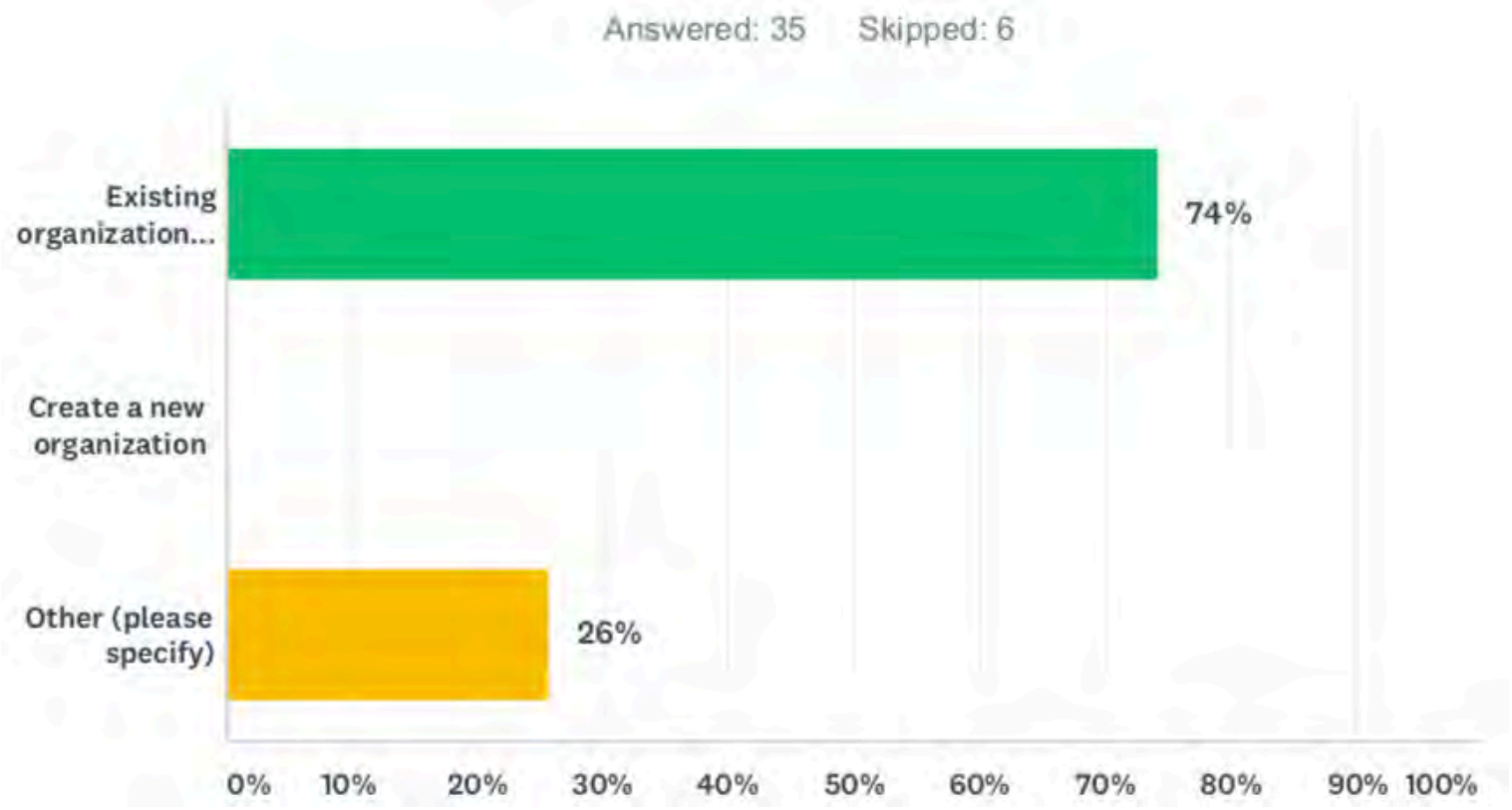
Evaluation Phase activities: How should they be revised?

Respondents that did not agree with the major activities, or did not know, offered a number of suggestions for revisions:

- Perhaps the same will not be needed for every technology. Fit for purpose and appropriate choice will be important.
- Should be merged with Appraisal.
- Need to include patient perspective and impact on patient Quality of Life.
- Should be clinical utility, not validity.
- Review what HQO and CCO currently do.

Evaluation Phase: What type of organization(s) should evaluate innovations in this phase?

- Almost 75% of respondents indicated Existing Organizations (e.g. HQO/OHTAC, MaRS Excite, CADTH, other) should evaluate innovations in the Evaluation Phase.



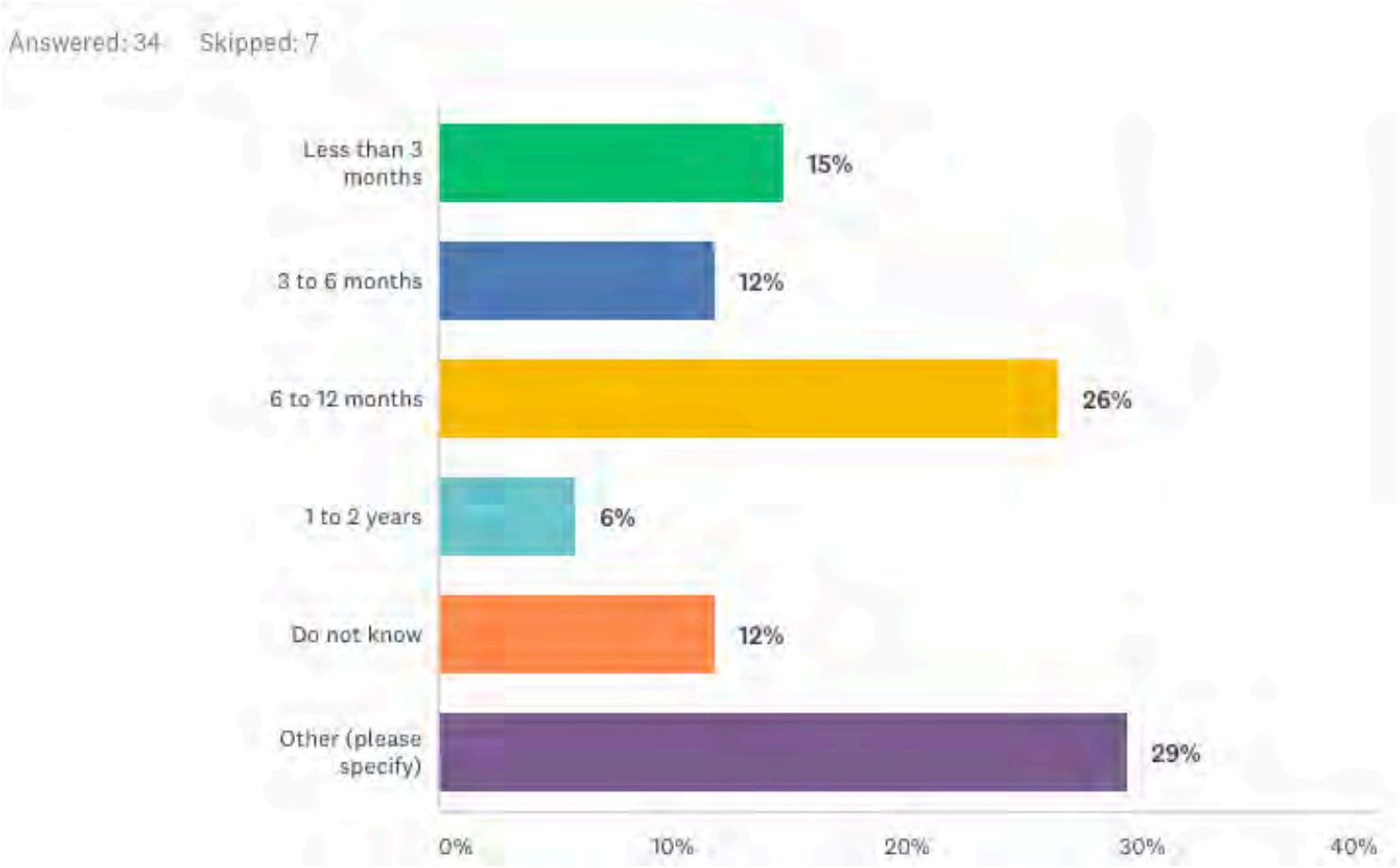
Evaluation Phase: What type of organization(s) should evaluate innovations in this phase?

Respondents that answered 'other' provided the following suggestions:

- Depends on the type of evaluation being conducted. If field testing is required, none of the example organizations could do this, but if it is HTA, listed organizations could be actively involved.
- Not against existing organizations, but mandates would have to be expanded (CADTH is strapped and would be challenged to do this work).
- Mix of existing and new, the new needs to move faster and use non-traditional data sources (no just for publication purposes).
- Create an evaluation committee/group from current organizations plus additional expertise, depending on the technology being assessed.
- Create a new special arm of an existing organization (e.g. OICR).
- Depends on level of evidence required. OHTAC/CADTH or equivalents could review RCT-level evidence to make policy recommendations, others could review earlier evidence to make recommendations on next steps for evidence generation.

Evaluation Phase: How long should innovations be in this phase?

- There was not general agreement on the length of time innovations should be in the Evaluation Phase.



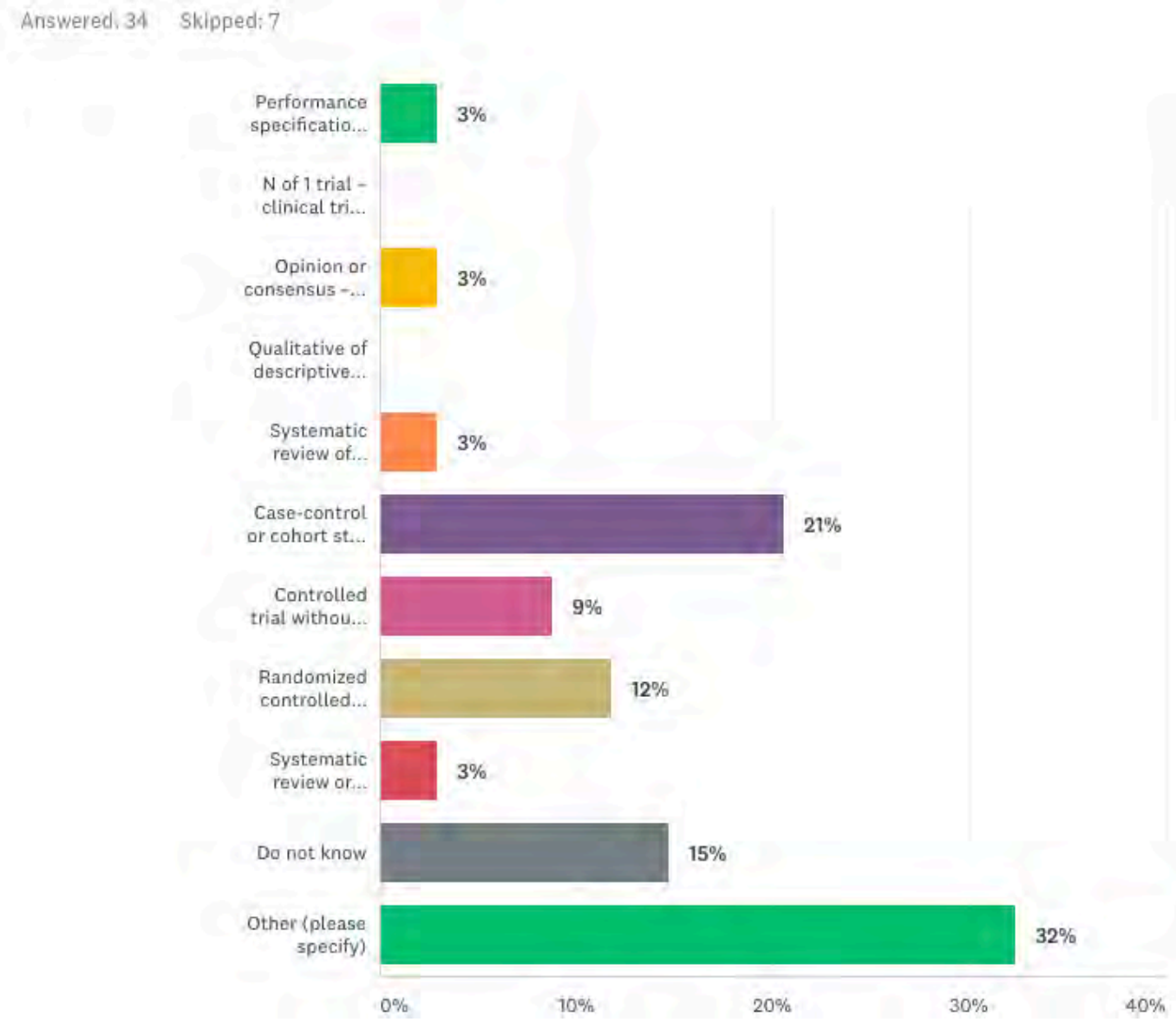
Evaluation Phase: How long should innovations be in this phase?

Respondents offered other suggestions for the Evaluation timeframe:

- Generally 12 to 24 months, but depends on technology being evaluated and type of evaluation being conducted. Will be challenging to match evaluation to the pace of innovation and product development. Longer processes means greater risk of implemented outdated technology.
- Depends on:
  - Type/category of innovation
  - Disease
  - Need
  - If Real World Evidence is required
- As short as possible.
- Take a 90 day approach – forces to be agile and nimble and cut bureaucracy the way it is done at current organzations.

Evaluation Phase: Minimum level of evidence to pass Evaluation and move to Implementation?

- There was not strong agreement for any single minimum level of evidence for innovations to be submitted to for Appraisal.
- Most respondents answered ‘other’.



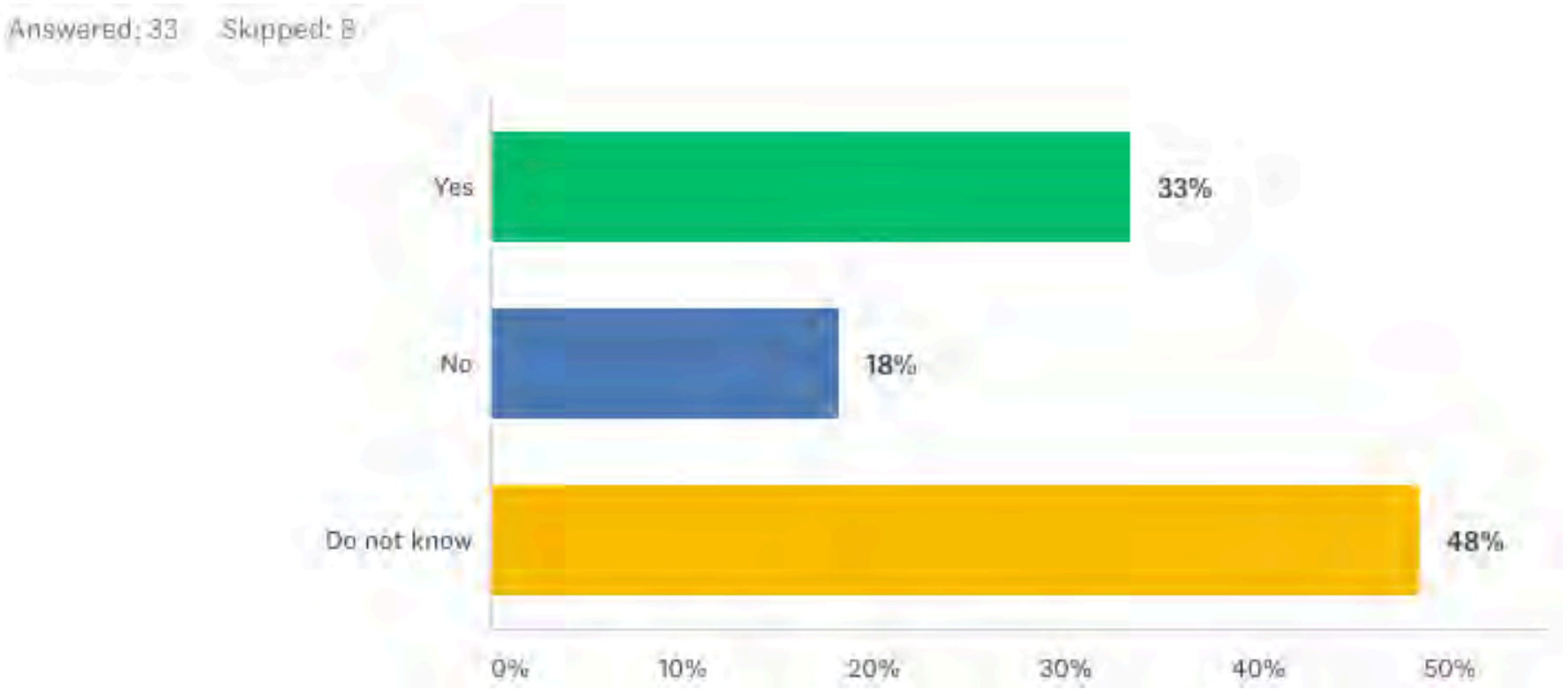
Evaluation Phase: Minimum level of evidence to pass?

Respondents that answered 'other' provided the following feedback on the minimum level of evidence:

- Pilot study
- Mix of elements, leveraging authoritative opinion of expert committee and a minimum case-control or cohort study
- RCT required for later cycles requiring major policy decisions.
- It depends on:
  - Type of innovation
  - Disease/health issue being addressed
  - Risk level

Evaluation Phase: Is the level of evidence you chose easily available in Ontario?

- Overall, some respondents (33%) thought that the level of evidence they chose was easily in Ontario, though a greater proportion did not know.



Appraisal Phase: Is the level of evidence you chose easily available in Ontario (by Q8 answer)?

- Though the absolute numbers were low, respondents that chose Opinion or consensus, Case-control or cohort study, Controlled trial without randomization, and Systematic review or meta-analysis, thought that evidence was easily available..

Level of Evidence	Yes	No	Do not know	TOTAL
Q21: Performance specifications	0%	0%	100%	5%
	0	0	1	1
Q21: Opinion or consensus	100%	0%	0%	5%
	1	0	0	1
Q21: Systematic review of qualitative or descriptive studies	100%	0%	0%	5%
	1	0	0	1
Q21: Case-control or cohort study	67%	0%	33%	27%
	4	0	2	6
Q21: Controlled trial without randomization	100%	0%	0%	14%
	3	0	0	3
Q21: Randomized controlled trial	0%	25%	75%	18%
	0	1	3	4
Q8: Systematic review or meta-analysis	100%	0%	0%	5%
	1	0	0	1

Appraisal Phase: Sources of evidence, by level

- Respondents indicated the following sources, based on the level of evidence they chose:

Level of Evidence	Sources in Ontario
Opinion or consensus	Expert opinion of scientific researchers/innovation authorities based on thorough review of all available sources of RW and CT evidence
Systematic review of qualitative/ descriptive studies	Published data, clinical studies, review articiles and commissioned studies (not yet published) by acknowledged experts in the field
Case-control or cohort study	Industry, Academic, start-ups, care model innovators (care delivery organizations and researchers), research studies, peer reviewed publications
Controlled trial without randomization	Incubators, small and big pharma, universities, industry, academia
Systematic review or meta-analysis	Published randomized controlled trials, real world evidence studies, industry, clinical researchers

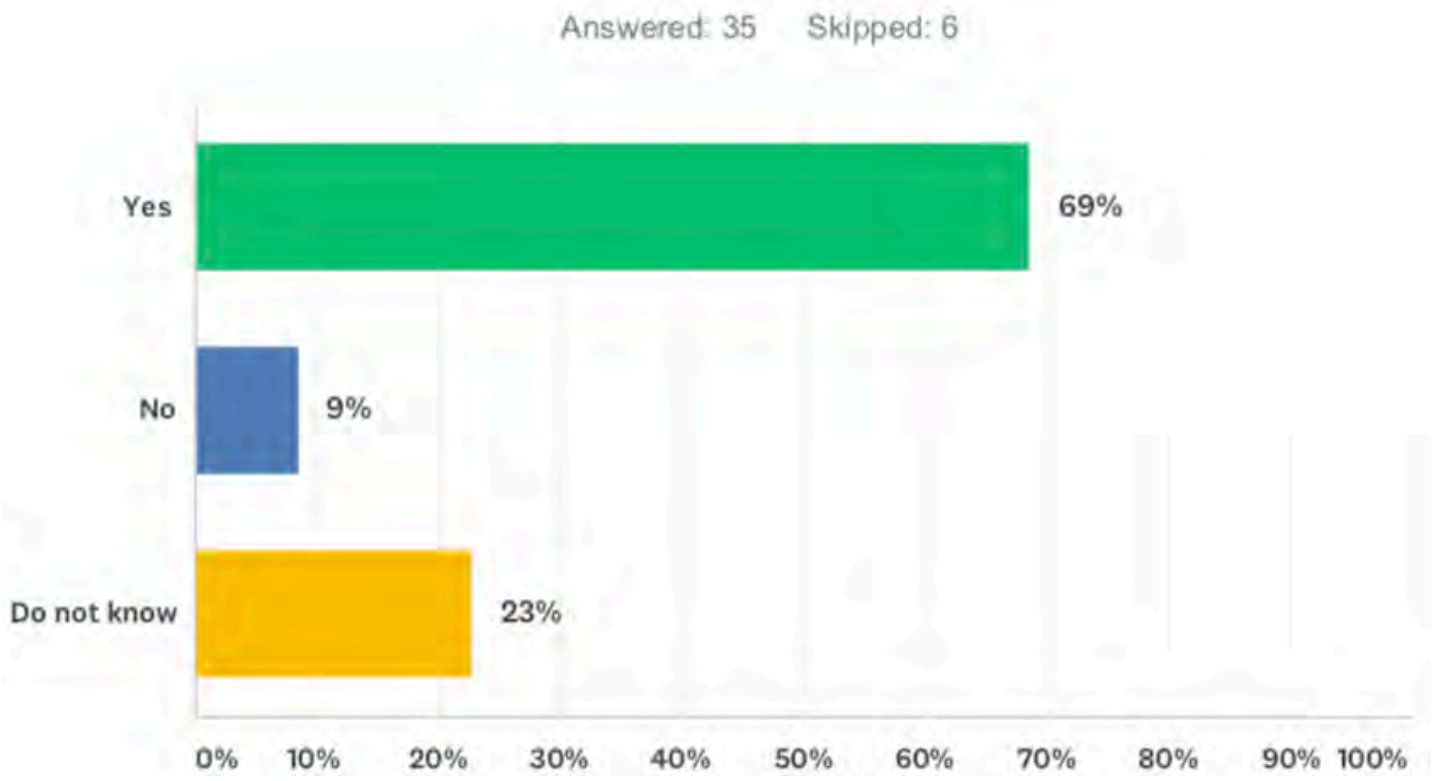
Evaluation Phase: How do we build the necessary evidence?

- Respondents that did not think Ontario had readily available evidence, offered the following suggestions on how to build the necessary evidence

Level of Evidence	Sources in Ontario
Unspecified	• Make it more efficient to start trials, fund trials, recruit and ensure trials are aligned to evidence needs • Clinical capacity, environment and incentives in Ontario required to facilitate different levels of evidence generation • Need a formal program akin to UK's NIHR HTA program
Case-control or cohort study	Many tools and infrastructure are already available (CADTH for drugs, ExCITE and OHTAC for devices, Women's College WIHB and Global Centre for eHealth Innovation for digital)
Randomized Controlled trial	MaRS ExCITE, public-private partnerships, find the gaps, find what the system needs urgently to pull in innovations, in short term focus on needs not wants

Evaluation Phase: Should different levels of evidence be established for different categories of innovations?

- Most respondents believed different levels of evidence need to be established for different categories of innovations.



Evaluation Phase: Should different levels of evidence by established for different categories of innovations – explain?

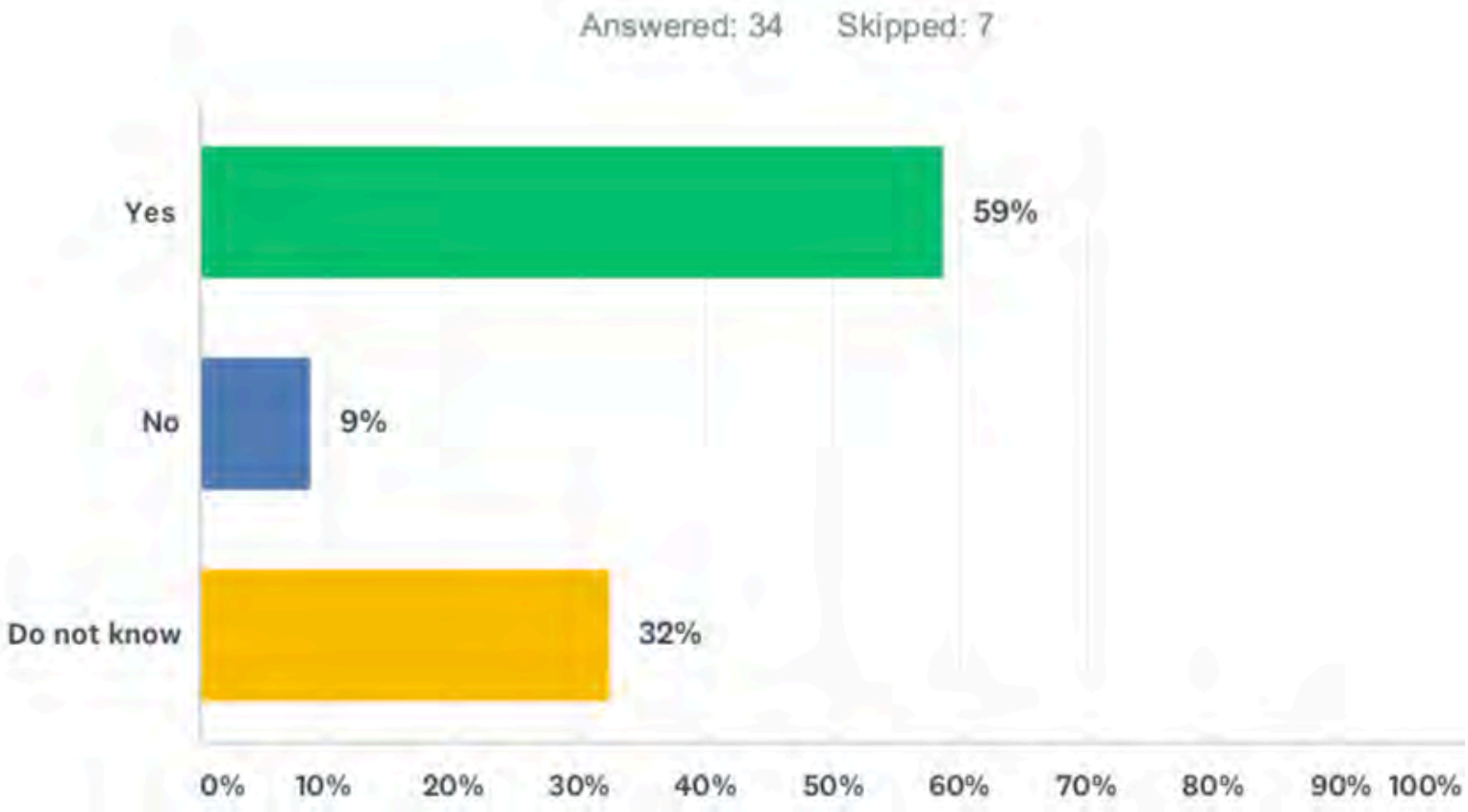
- Categories could depend on:
  - Risk to the patient (safety)
  - Cost of innovation
  - Potential for impact
  - Disease
  - Target population (rare diseases for small populations will never have the level of evidence of more prevalent diseases)
  - Patient/public values
  - Decision-makers' perspective
- Framework should be flexible to accommodate what is feasible/appropriate for different innovations.
- Don't need an RCT to change administrative or technical processes, but would for new drug or companion diagnostic.

Evaluation Phase: Should different levels of evidence by established for different categories of innovations – explain?

- Categorization may not be able to avoid some exceptions. Might be better to set up guidelines to help think through what would be adequate evidence.
- Should not categorize by modality (ie device, drug, etc) should not categorize by disease (breast, etc.) rather - categorize on 2 axis: x axis is level of potential impact (# patients, burden of unmet need); y axis is level of change from standard of care. The more you are north-east (ie high potential impact, high level of change to standard of care) - the more you need an emergent/iterative methodology because there will be a lot of variables, and the introduction of the innovation will require system-level change on many layers. You cannot treat these innovations like point solutions such as a biologic drug.

Evaluation Phase: Should different levels of evidence be established for different therapeutic needs?

- A majority of respondents believed different levels of evidence should be established for different therapeutic needs.



Evaluation Phase: Should different levels of evidence be established for different therapeutic needs – explain?

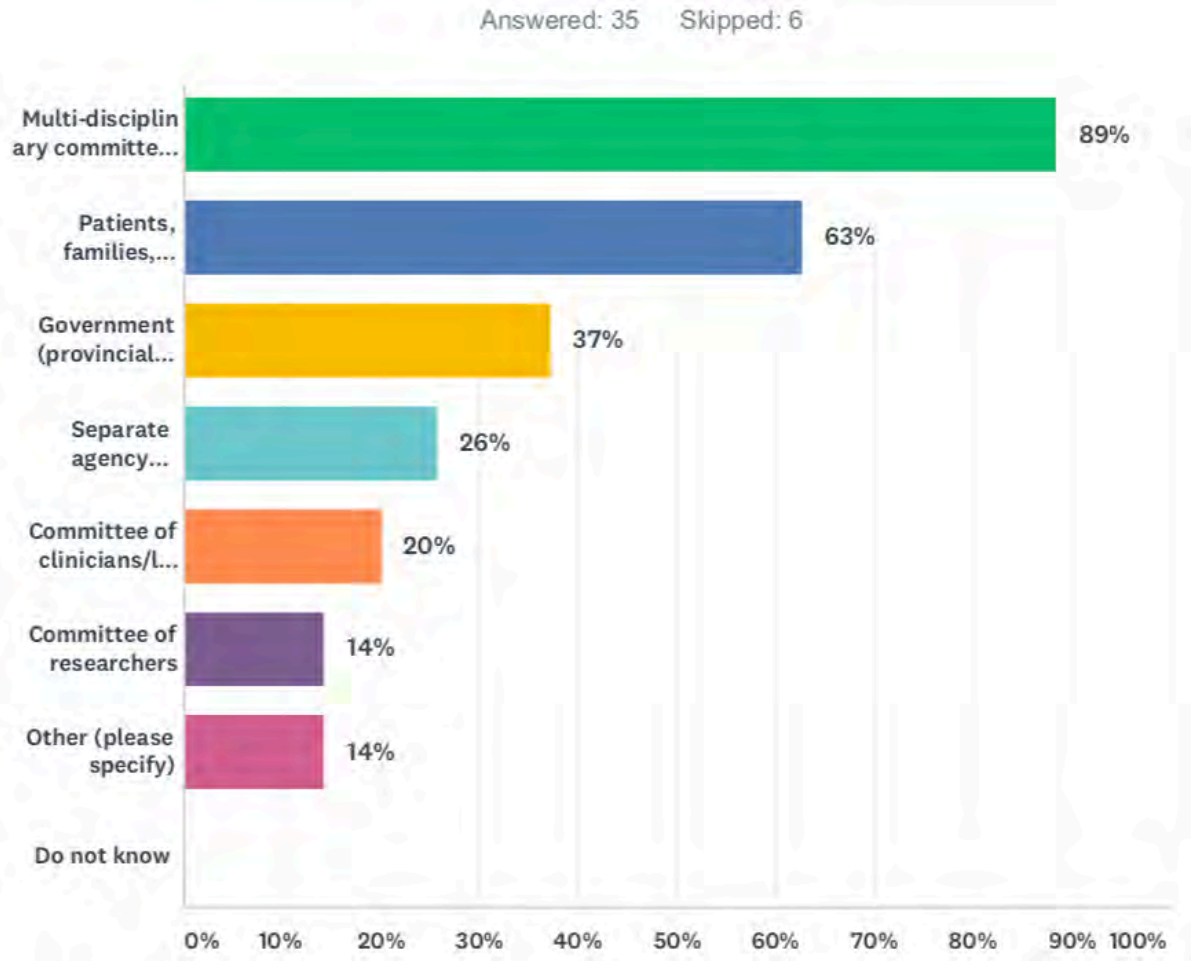
- Levels could depend on (many said this would be similar to previous categories question):
  - Risk/benefit to the patient (safety)
  - Cost of innovation
  - Potential for impact (unmet need, how effective is innovation)
  - Disease
  - Target population (lower bar for patients with no other options)
  - Patient/public values
- Must ensure equity and ethics in different levels of evidence

Evaluation Phase: Should different levels of evidence be established for different therapeutic needs – explain?

- Higher levels of evidence should be required for example for young children and people with an expected long life span where the risk is medium to high. Low levels would be acceptable if the targeted child or adult is seriously ill, has a low life expectance and there are few therapeutic alternates. Lower levels are also acceptable if the safety/health risks are low and there is high societal value (better health or low costs) - vaccines are a good example.
- Focus the level of evidence on the level of uncertainty of evidence, and the level of complexity of the potential solution in terms of changes to care models, workflow, patient behaviour, care setting, and funding models. The higher the change on these dimensions, the more rigorous and agile your evidence generation needs to be…..agnostic to therapeutic area or modality.

Evaluation Phase: Who should be involved with decision-making on innovations passing Evaluation?

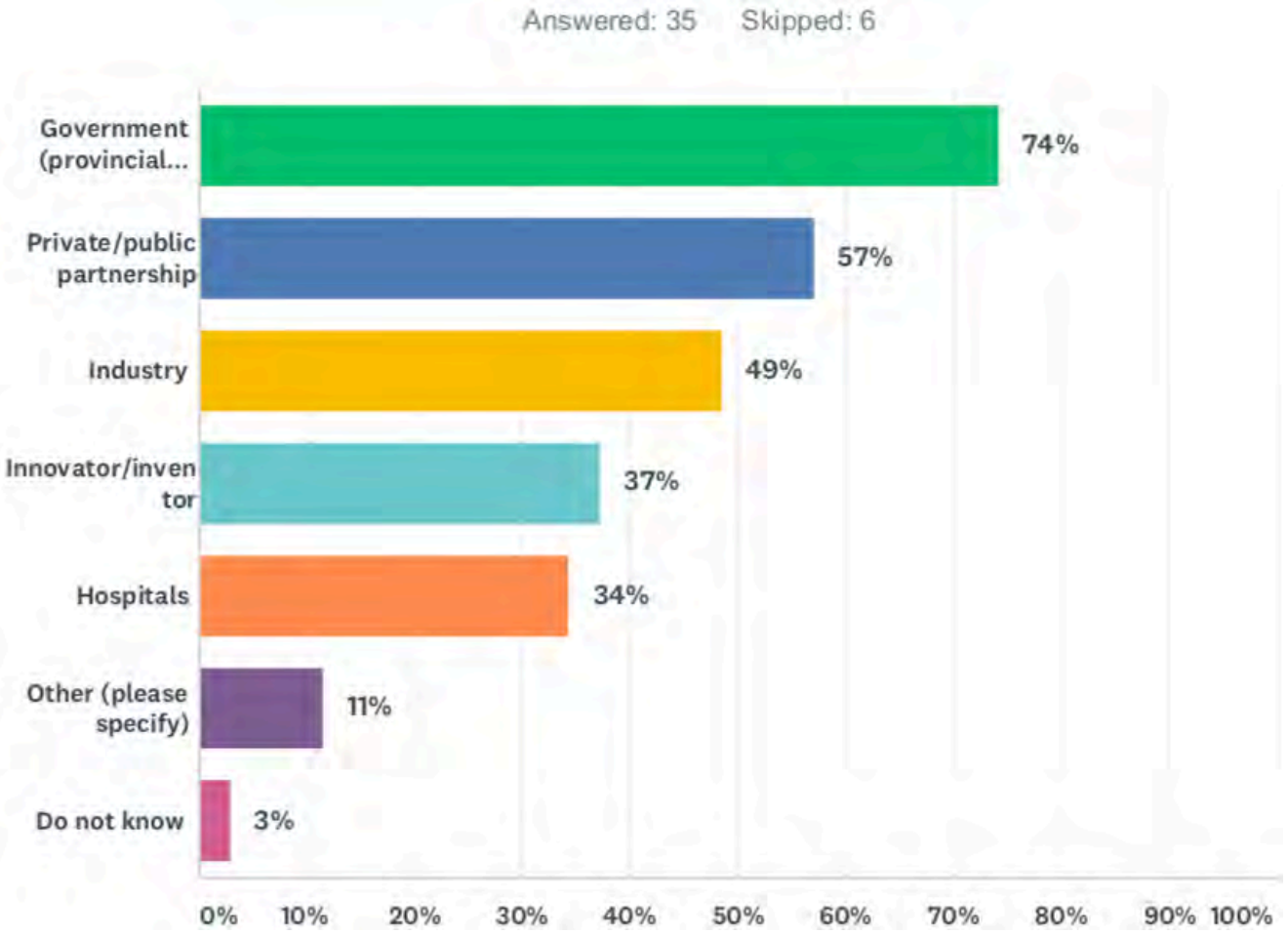
- Most respondents believed a multi-disciplinary committee of researchers, clinicians, health economists, policy experts, and laboratory experts should be involved with decision-making, followed by patients/families/community representatives.



- Other included: Industry, Government with input from multi-disciplinary committee, high-level of rigour and transparency required – participants should have credibility/expertise

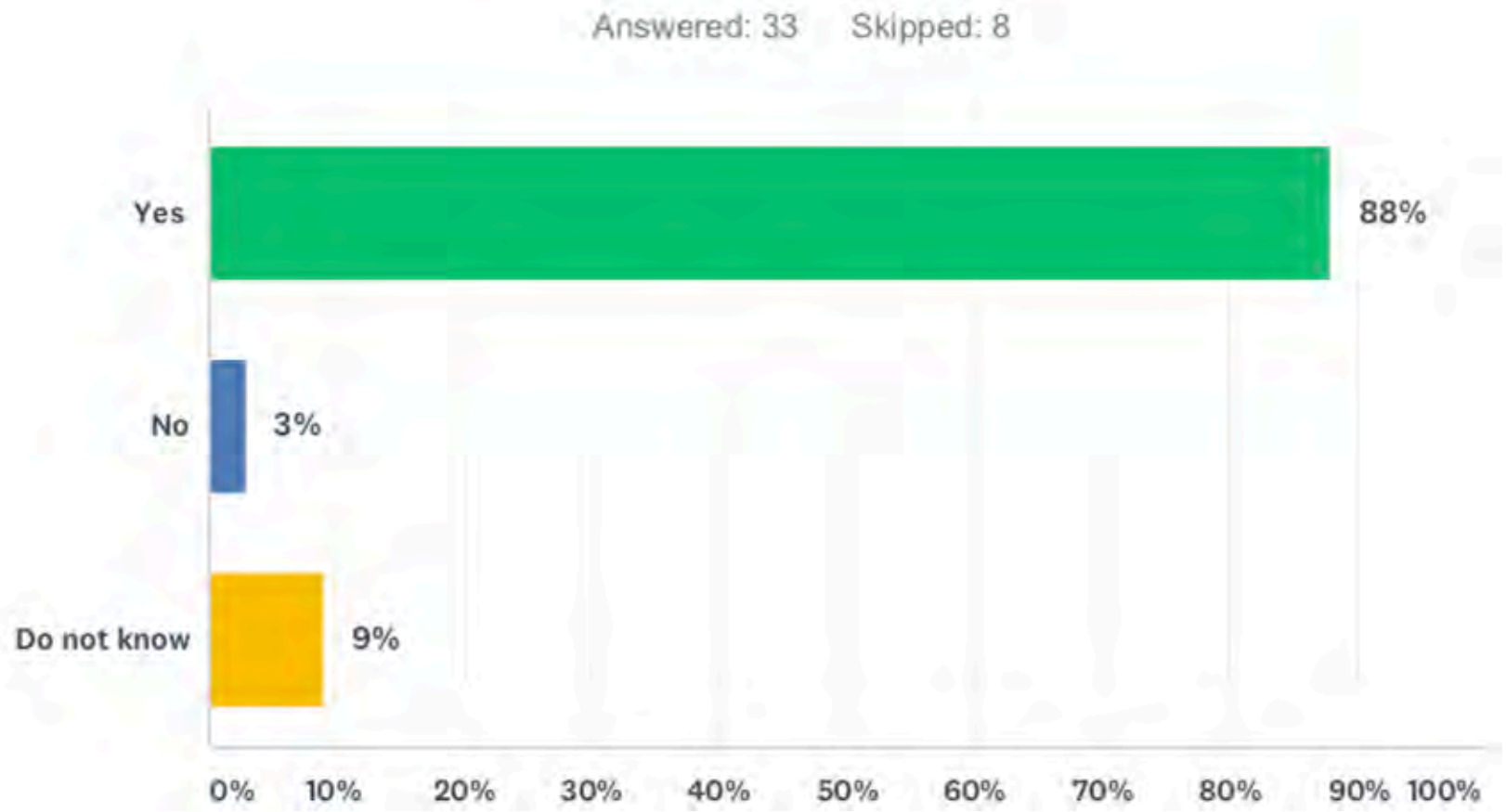
Evaluation Phase: Who should provide funding for innovations undergoing Evaluation?

- Most respondents believed Government (provincial and/or federal) should fund Evaluation, followed by Private/public partnership, Industry, Innovator/inventor, and hospitals.



Implementation Phase: Do you agree with the purpose?

- Most respondents agreed with the purpose of the Implementation Phase of the draft framework.



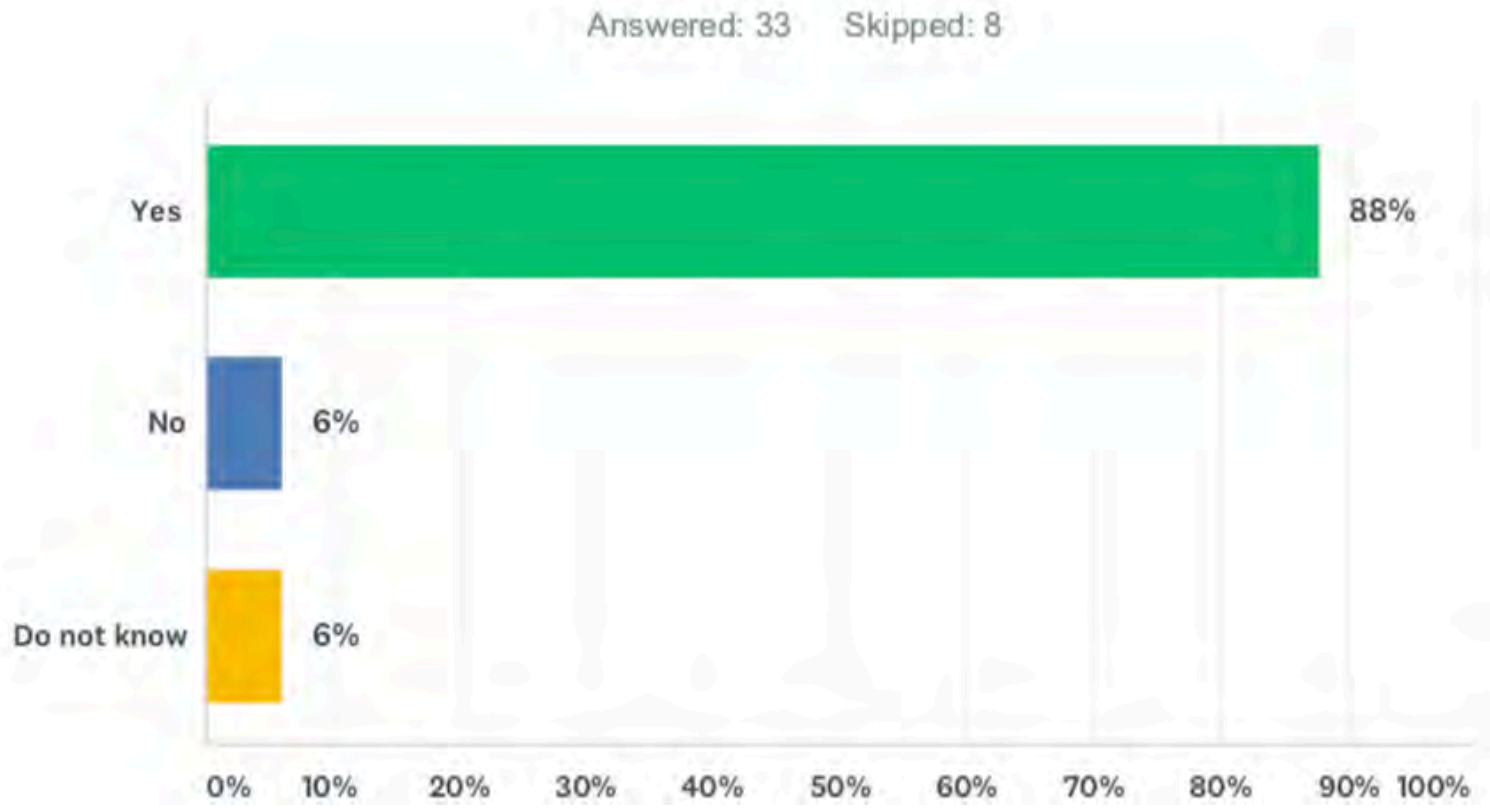
Implementation Phase purpose: How should it be revised?

Respondents that did not agree with the purpose, or did not know, offered a number of suggestions for revisions:

- Most of this is just HTA. I'm confused why we have two steps prior. I like the concept of step-wise approach, but there should be quick filter, HTA, then implementation.
- Is this an implement with evidence development approach, a paus to evaluate then either go or no-go?
- Funding model should be worked out earlier. If not done, and it's discovered too late, this stage is a waste of money.
- Cost effectiveness should be worked out earlier. Proof of principle/clinical effectiveness is appropriate for this phase.
- OTHAC and ExCITE have already developed good frameworks for this.

Implementation Phase: Do you agree with the major activities?

- Almost 90% of respondents agreed with the major activities of the Implementation Phase process.



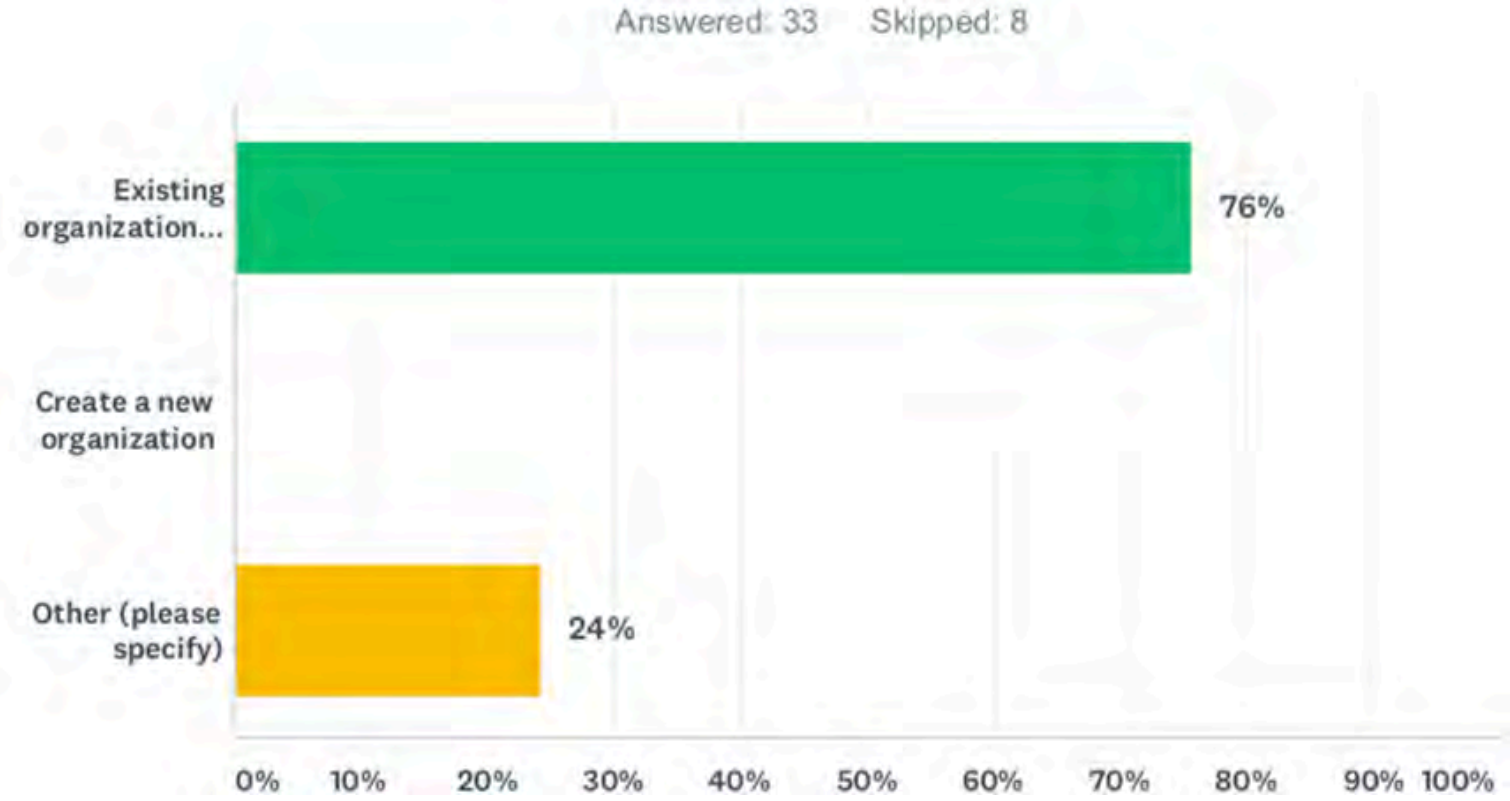
Implementation Phase activities: How should they be revised?

Respondents that did not agree with the major activities, or did not know, offered a number of suggestions for revisions:

- Effectiveness should be moved earlier. Implementation should be on it's own.
- Should implementation be step along the way to adoption? Or is this phase meant as an off ramp?
- This work has been done at length by OHTAC, ExCITE, and Alberta Health Services.

Implementation Phase: What type of organization(s) should conduct evidence building in this phase?

- Over 75% of respondents indicated Existing Organizations (e.g. CCO's PET, Evidence Building Program, other) should conduct evidence building in the Implementation Phase.



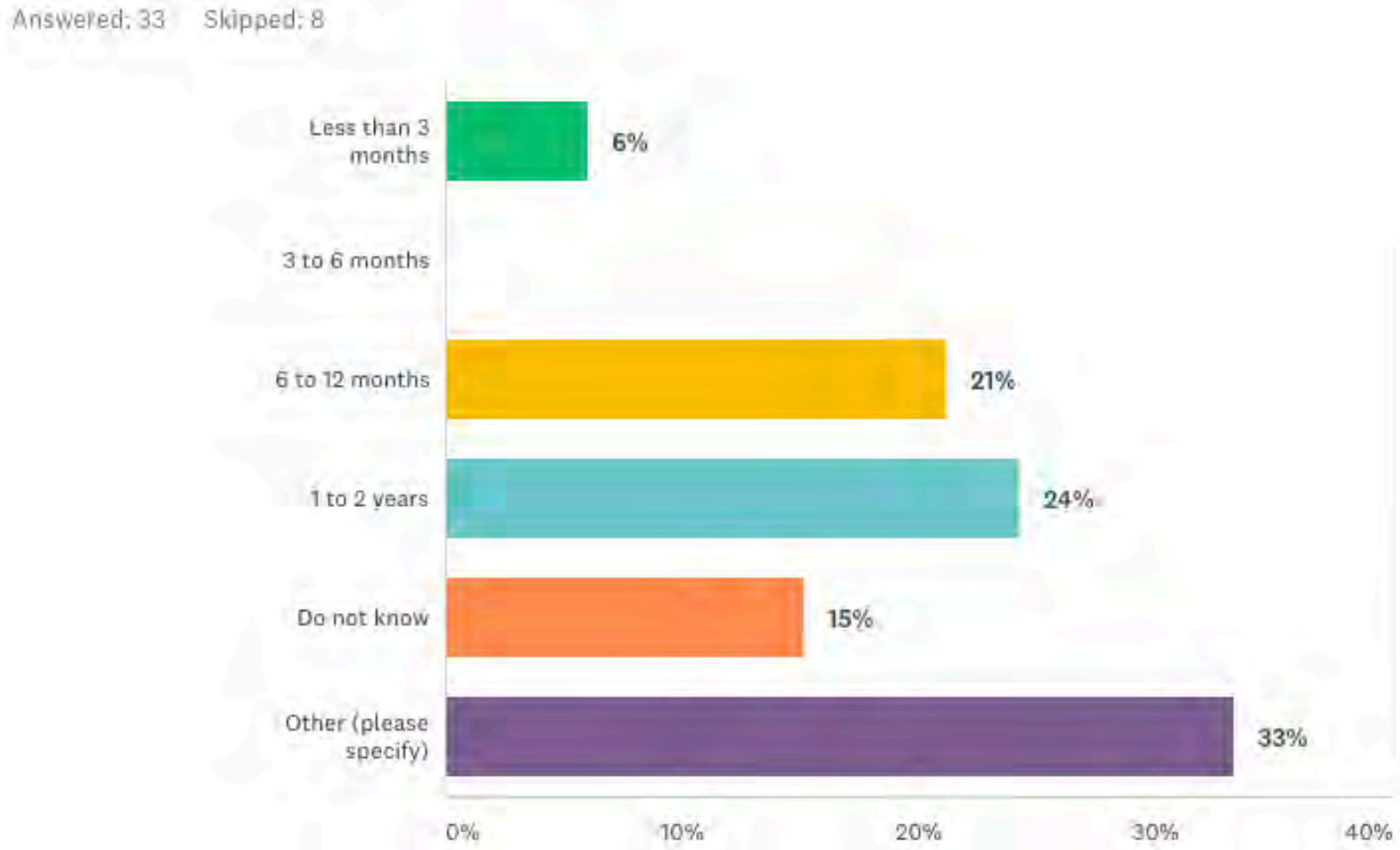
Implementation Phase: What type of organization(s) should evaluate innovations in this phase?

Respondents that answered 'other' provided the following suggestions:

- A specific implementation group including members from existing organizations and experts specific to the field. Group must cover all silos, so that implications across all aspects of healthcare are understood. Chaired by expert in the field. Mandate developed (by government organization) for these groups in terms of responsibility, accountability, timelines etc.
- Leverage existing organizations with experience/expertise
- Could be a specialized arm of an existing organization – CADTH, CCO?
- An organization with representation from all stakeholders in the process (researchers, clinicians, industry, lab directors, patients).

Implementation Phase: How long should innovations be in this phase before continuing to adoption/diffusion?

- There was not general agreement on the length of time innovations should be in the Implementation Phase.



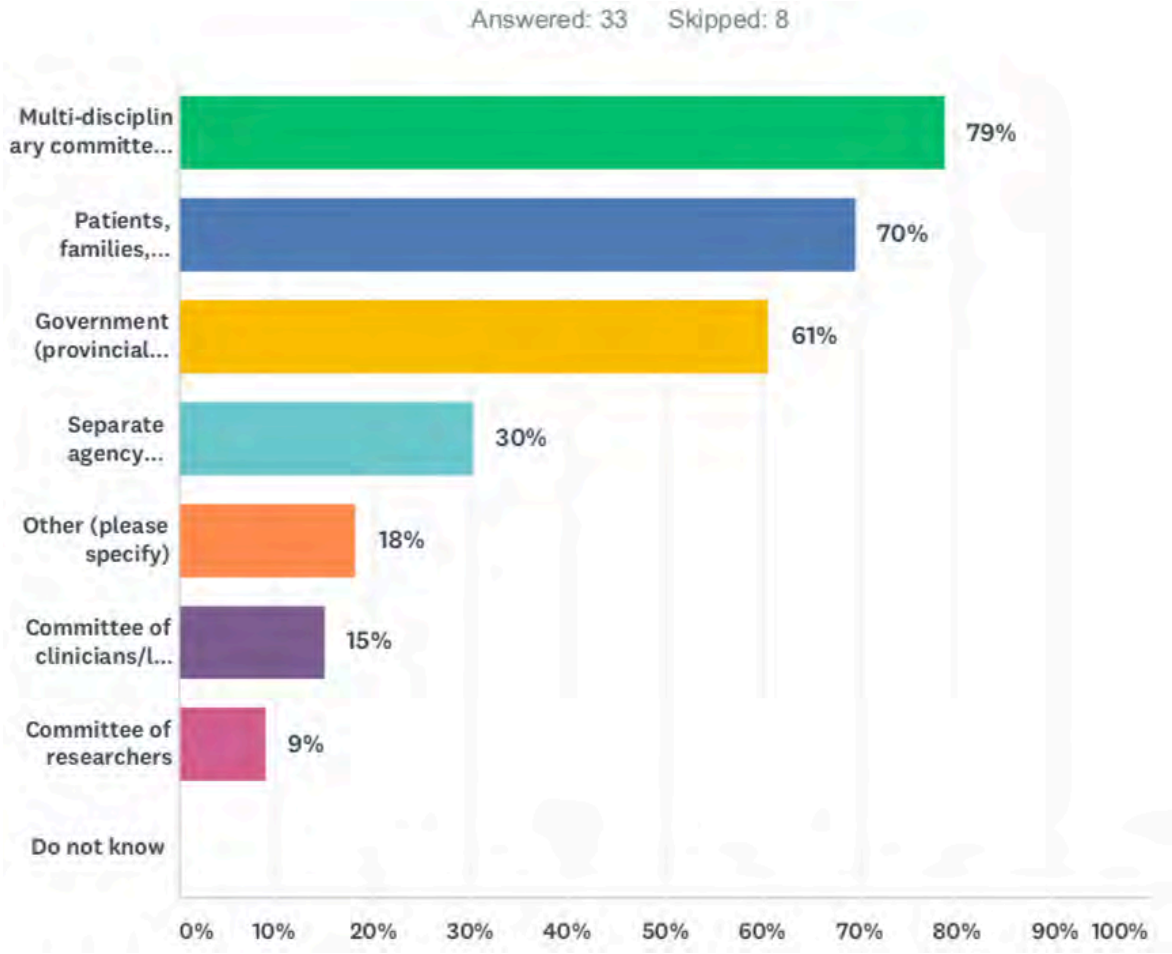
Implementation Phase: How long should innovations be in this phase?

Respondents offered other suggestions for the Implementation timeframe:

- Depends on:
  - Type/category of innovation
  - How long to establish clinical efficacy
  - Urgency
  - Potential risks and benefits
  - Complexity of innovation
  - Cost
  - Case-by-case
- Should not be rigid – it will vary, but try to cap at 18 months.
- Until clear evidence of benefit.

Implementation Phase: Who should be involved with decision-making on innovations passing Implementation and moving to adoption/diffusion?

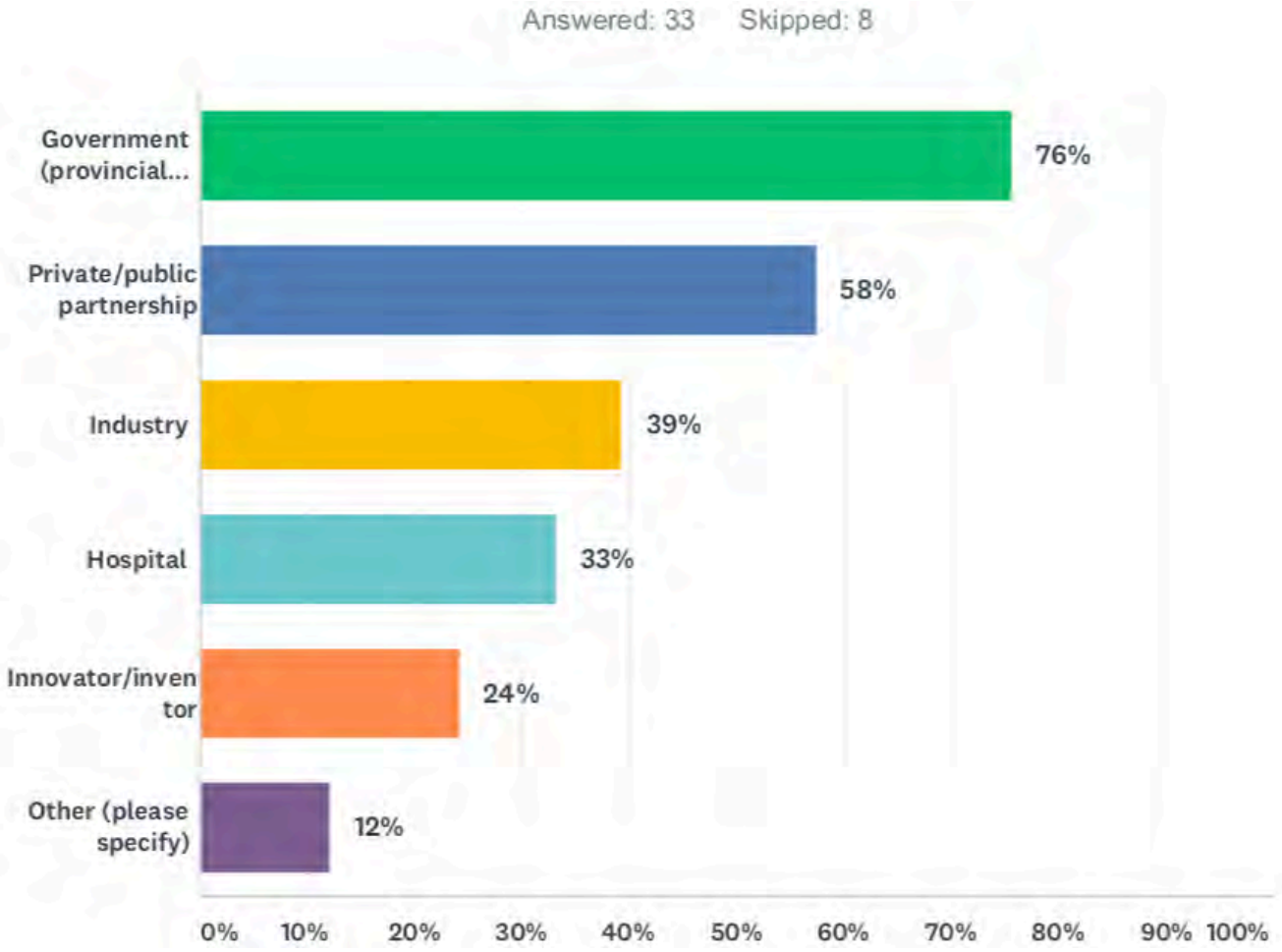
- Most respondents believed a multi-disciplinary committee of researchers, clinicians, health economists, policy experts, and laboratory experts should be involved with decision-making, followed by patients/families/community representatives.



- Other included: Whoever is going to fund (not necessarily government), must avoid siloes, Industry, include patients on multi-disciplinary committee, funding and clinical policy makers based on expert recommendations.

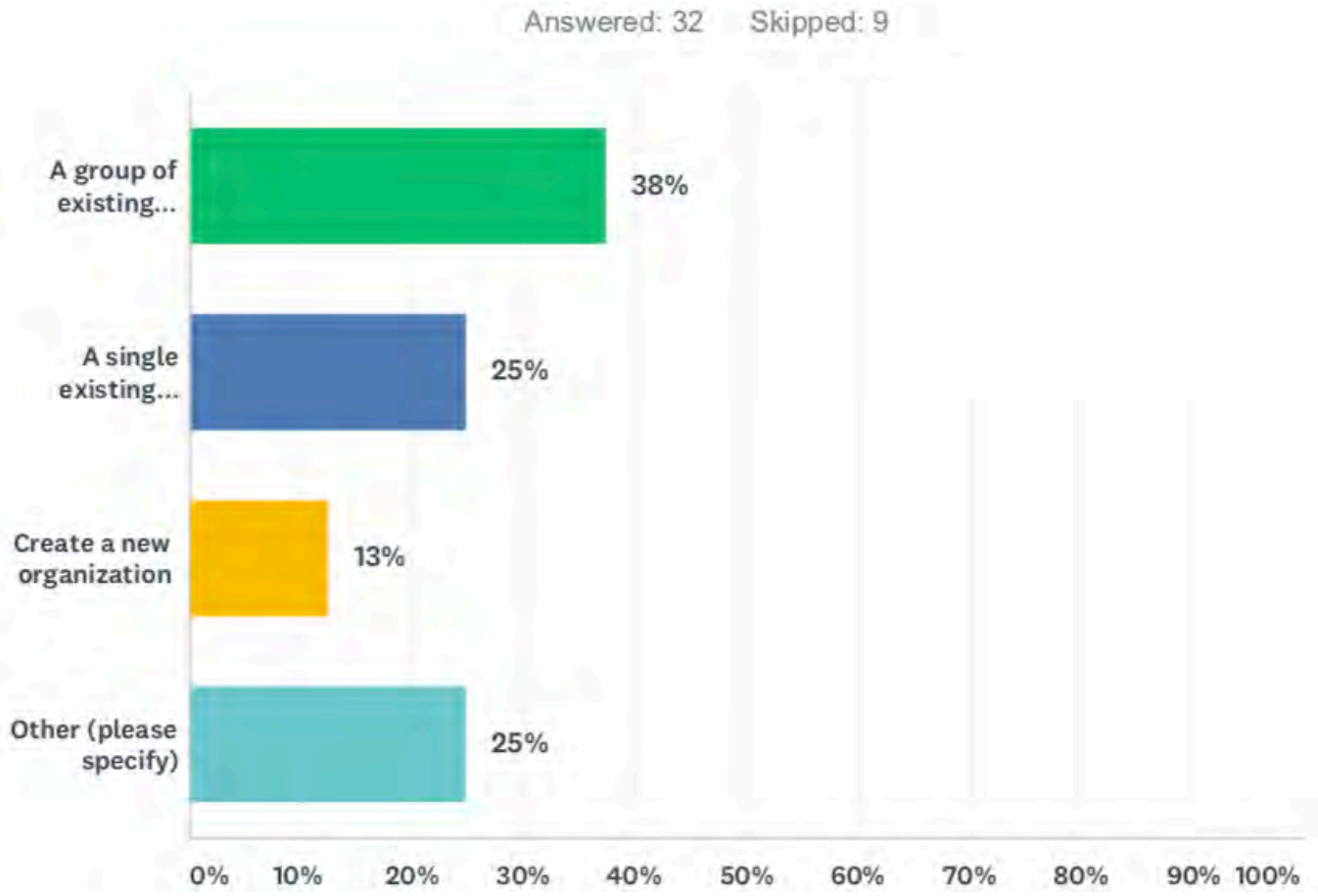
Implementation Phase: Who should provide funding for innovations undergoing Implementation?

- Most respondents believed Government (provincial and/or federal) should fund Implementation, followed by Private/public partnership, Industry, hospitals, and Innovator/inventor.



What type of organization(s) should govern/oversee the innovation framework?

- Almost 40% of respondents thought that a group of organizations should govern/oversee the innovation framework, followed by a single existing organization (25%). Some respondents thought a new organization should be created.



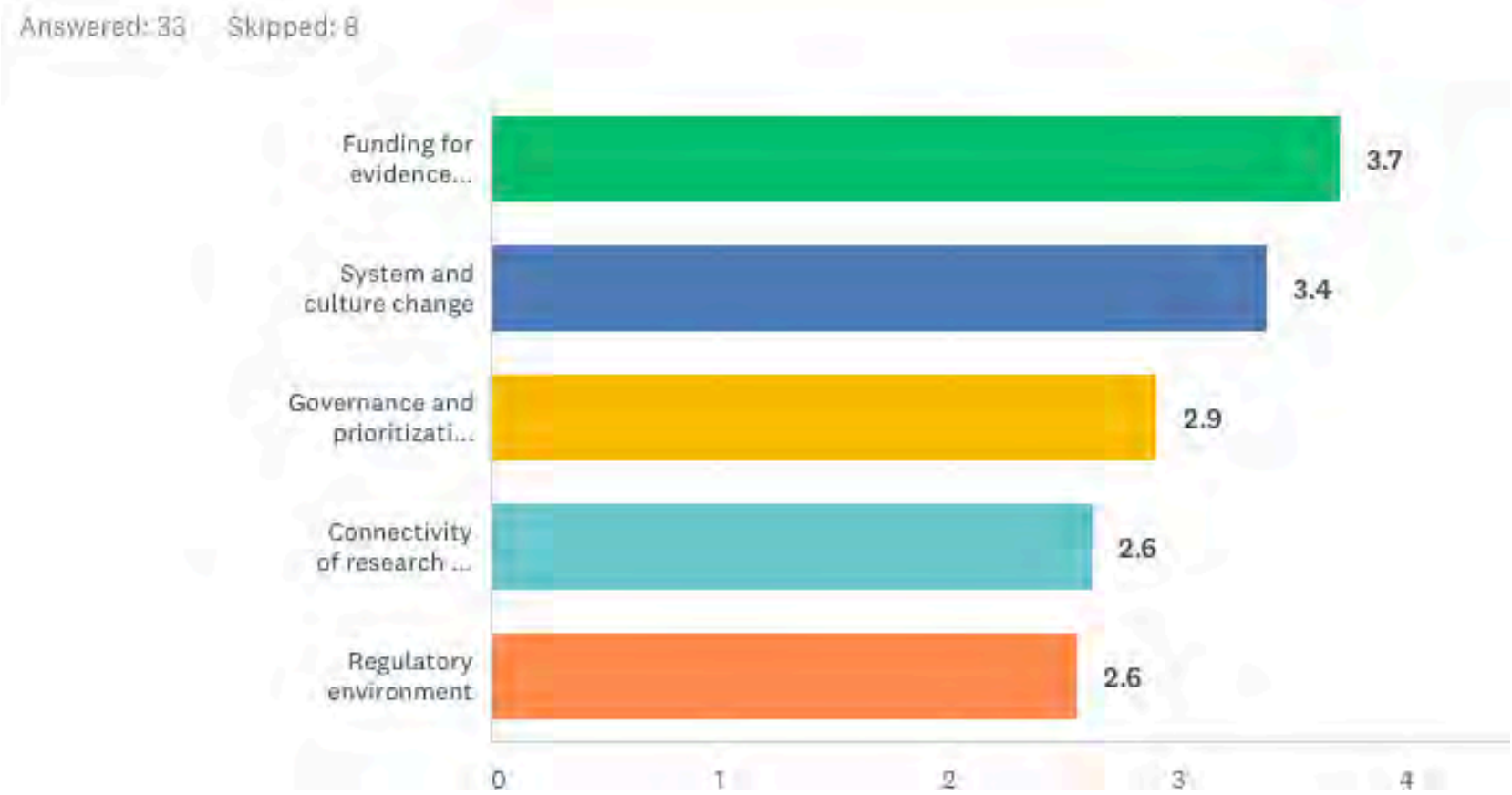
What type of organization(s) should govern/oversee the innovation framework?

Respondents that answered 'other' provided the following suggestions:

- A new organization that crosses all silos of healthcare and includes clinical experts and patients.
- Leverage expertise of existing organizations – new processes will be needed to minimize silos.
- A hybrid of new and existing players in the innovation ecosystem.
- Depends on who is bringing the innovation to market.
- Government has the biggest wallet but poor track record for reaching end points.
- Single new or existing organization to ensure clear accountability.

Barriers: Rank the following barriers to implementing the innovation framework in Ontario in order of importance

- Funding for evidence generation was ranked as the most important barrier, followed by System and culture change, Governance and prioritization of technologies, Connectivity of research and clinical data including privacy, and Regulatory environment.



Are there any additional important barriers to implementation?

- Funding of the innovation itself once it is available in high-unmet need/life-extending indications
- Silos in healthcare must be eliminated – implementation must occur across the whole system, personnel must be retrained not to think that their actions ONLY impact their area/organization.
- Political interference should be minimized, hence an arms-length from government arrangement.
- Speed of access: research conducted in competitive enclaves of secrecy and dis-connectivity (patenting of products?).
- Lack of a systematic approach for identifying innovations to test
- Organizational structures and processes.
- Should also focus on new care models that leverage technology, including funding models that can unlock value.

…the main challenge with adopting more innovation into cancer care in Ontario is…

- **Process**
  - Lack of a clear and predictable process to assess and approve innovations.
  - No owner of a process to approve innovations.
- **Funding**
  - Lack of funding to perform studies and create evidence-based guidelines.
- **Evidence**
  - General lack of evidence (published and real world) that is useful for decision-makers.

…the Main challenge with adopting more innovation into cancer care in Ontario is…

- **Health System:**
  - Silos and lack of alignment between industry/ innovators, regulators, HTA agencies, system planners, implementors, funders/payers,
    - Creating and maintaining productive collaboration.
  - Does not pull/direct research in areas of need.
  - Lack of resources to respond quickly.
  - Change management (physician education, courage to change).
  - Does not see innovation as an opportunity but a cost.
- **Other**
  - Finding early adopters to pilot innovations
  - Lack of understanding of continuum of translational research

What are the most important performance indicators for measuring the success of the innovation framework?

- Patient
  - Impact on patient Quality of Life
  - Improved patient journey
  - Quality of care
  - Overall survival
  - Patient safety
  - Access to innovations
  - Number of patients impacted in first 2 years (double digit growth by year 5)
- Provider
  - Provider utility
  - Stakeholder satisfaction

What are the most important performance indicators for measuring the success of the innovation framework?

- Health System
  - Value for money (evidence generated supports use of the innovation
  - Utilization of precision medicine
  - Speed to bring innovations into practice (compared to other jurisdictions)
  - Rate of diffusion
  - Number of innovations introduced
  - Cost impact on healthcare system
  - Impact on system efficiency
- Economic
  - Return on Investment
  - Economic: Attraction of investment/innovators to Ontario
  - More rapid development and export of Ontario technologies
  - Increased movement of anchor companies to Ontario
  - Driving development of rich health data that enable AI and future technologies
  - Recognition of Ontario as a leader in innovation

OPTICC Post-Workshop Survey Summary

The OPTICC workshop was held on June 18, 2019 at the Vantage Venues, Toronto. Among the 70 participants that attended the event, 19% completed the post-workshop survey that was open for 5 weeks. The low response rate was because the survey was conducted 8 weeks after the workshop.

More than half of the survey respondents (54%) felt the objectives of the workshop were achieved. The objectives were (1) to review the draft innovation framework (2) identify solutions to barriers to implementation and (3) engage diverse stakeholders to initiate change management across the province. ***When asked to provide feedback on the workshop***, respondents felt the workshop was well organized, productive and attracted diverse stakeholders from the ministry, academia, pharmaceutical and healthcare industry leading to generation of numerous recommendations. Furthermore, the workshop raised awareness of the challenges facing adoption of innovation in the province. ***Regarding other stakeholders or organizations that should be engaged to move this initiative forward,*** respondents mentioned senior representatives from the Ministry of Health and Long Term Care (MOHLTC), Clinical Trials Ontario (CTO), Ontario Health, CEOs and administrators from some of the leading hospitals/cancer care systems, representatives from diagnostic companies and clinical labs as well as the public and patient groups.

In terms of jurisdictions that should be considered as successful models, respondents named United Kingdom, Australia and France. Within Canada, British Columbia, Alberta and Quebec were considered as successful models. British Columbia and Quebec have pathways for evaluating new companion diagnostics associated with new therapies. Alberta was also considered to be ahead of Ontario in this space. According to respondents, ***other documents or reports that would be informative*** include publications from "Institut national d'excellence en santé et services sociaux" (INESSS) in Quebec and the Quebec Network for Personalized Healthcare.

Finally, ***respondents were asked if there was anything else they would like to add to make implementing a pathway for innovation in cancer care successful.*** Recommendations included;

1. Ensure the objectives of OPTICC align with the objectives of the new Ontario Health agency;
2. Avoid duplication of effort and focus OPTICC activities along selected priorities;
3. Keep up the momentum and buy-ins from diverse stakeholders involved in innovation adoption;
4. Organize more information campaigns and community/public outreach events to increase awareness of innovation adoption challenges in the province;
5. Synthesize a report showcasing the main outcomes of the OPTICC workshop and the next steps/strategy as well as an executive summary for the workshop attendees and the public;
6. Introduce innovation implementation as an integral part of hospital administration key performance indictors (KPIs);

7. Focus on clinical adoption of validated diagnostic tests in association with targeted therapies;
8. Create small working groups that will develop ideas/ solutions to be discussed by larger groups and;
9. In-depth consideration of how the industry will be engaged.

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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

Christine Williams	Ontario Institute for Cancer Research (OICR)
Nicole Mittmann	Canadian Agency for Drugs and Technology in Health (CADTH) Formely, Cancer Care Ontario (CCO)
Harriet Feilotter	Queen's University

Table of Contents

1 Problem Statement

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

2 Goal Statement

Shorten the distance between discovery and transformative patient care.

3 Quotes on Innovation in Ontario

"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.

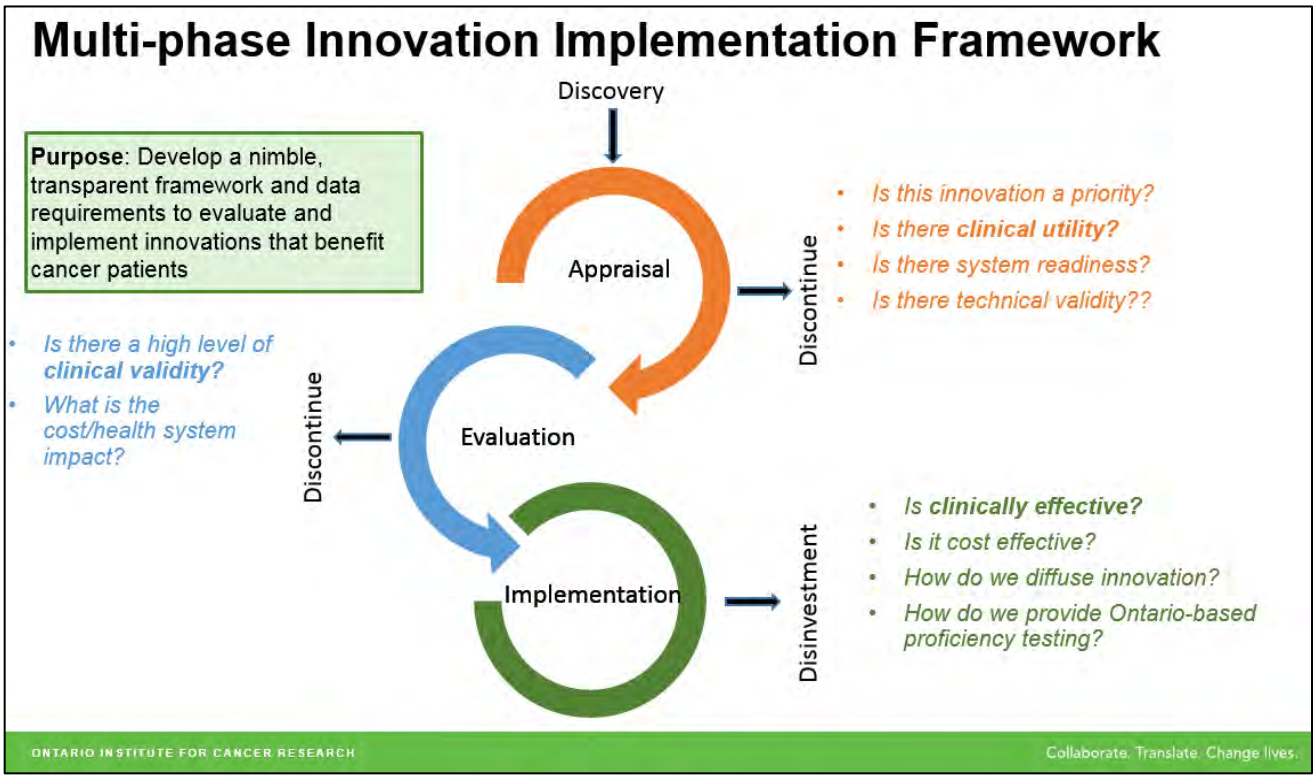
8.6 Principle 6: Leverage Existing Systems

- 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



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:
    - Service Delivery Model (e.g. centralized testing in one lab or decentralized in many labs)
    - Quality Assurance guidelines
    - 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)*

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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

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.*

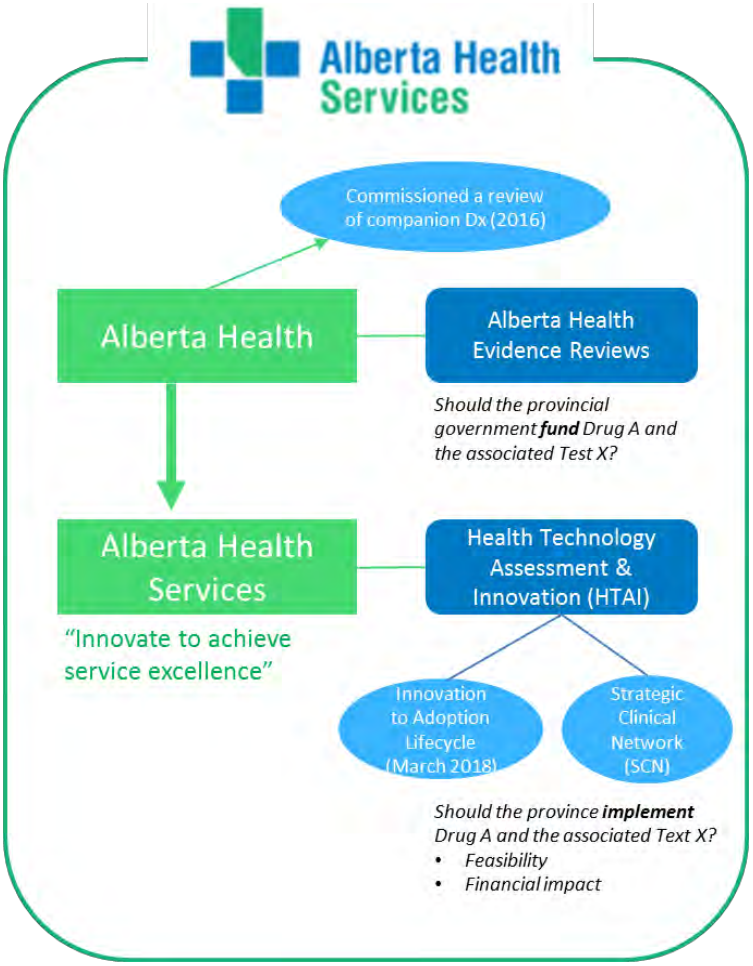
4. *System and culture change (silos and lack of alignment between industry/innovators, regulators, HTA agencies, system planners, implementors, funders/payers).*
5. *Regulatory environment.*
6. *General lack of evidence (published and real world) that is useful for decision-makers.*

Case Studies and Frameworks from Existing Innovation Groups

11.3 Canada - Alberta Health Services

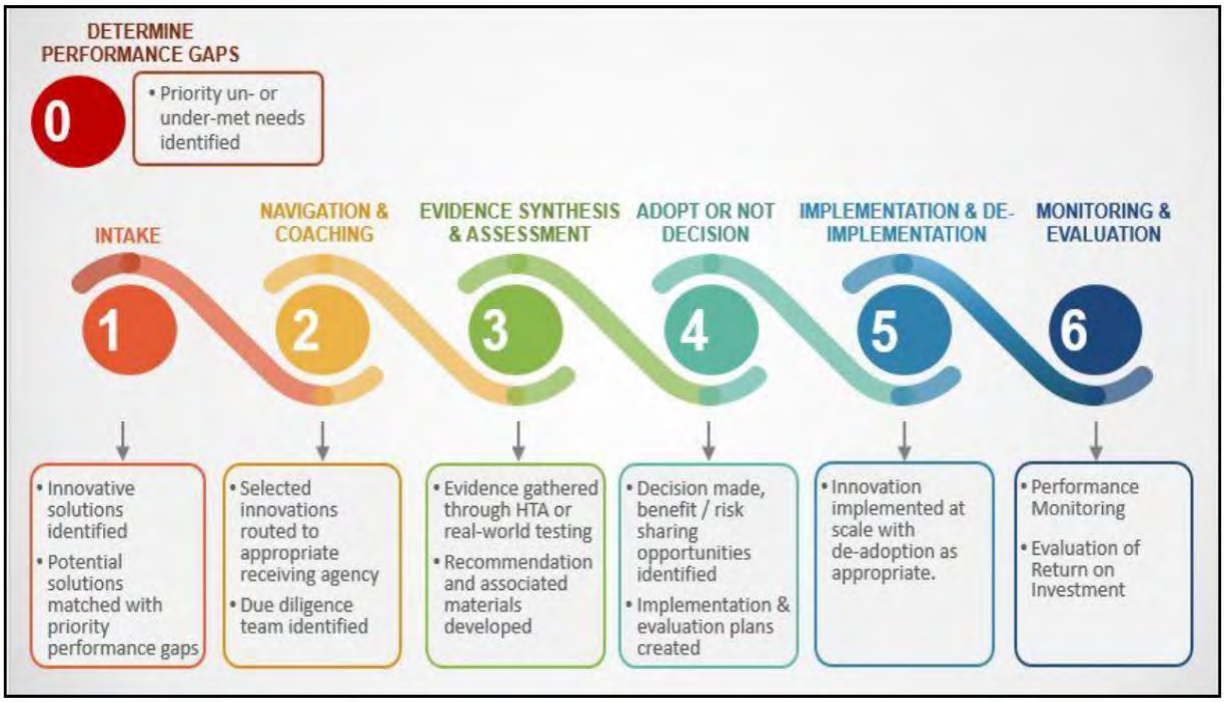
In 2004, the Government of Alberta introduced the Alberta Health Technologies Decision Process (AHTDP), a formalized HTA process to provide evidence to decision makers on whether a new health technology should be publicly funded. In 2017, AHTDP was undated and the review process was reduced from two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



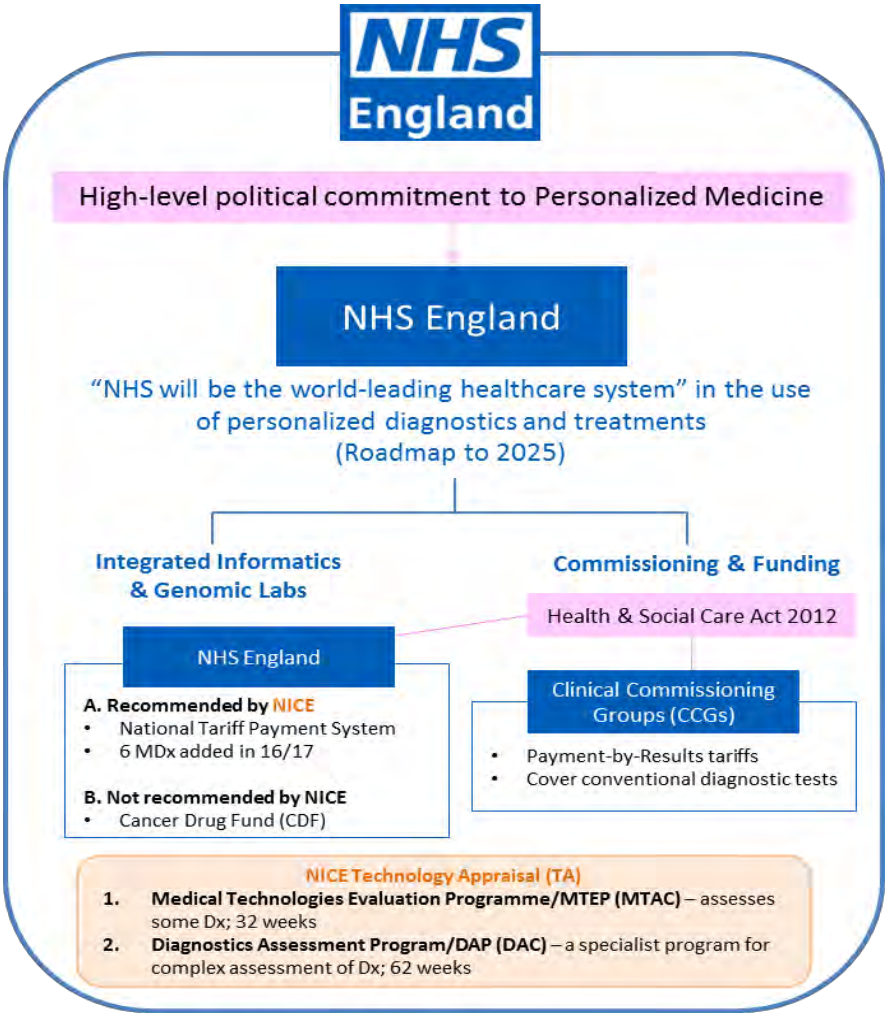
In addition to working with the Government of Alberta, SCN played a crucial role in the development of an innovation management process for AHS. SCN's Transformational Road Maps and other documents as well as the priorities identified by the Government of Alberta are used to identify areas of high priorities 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]



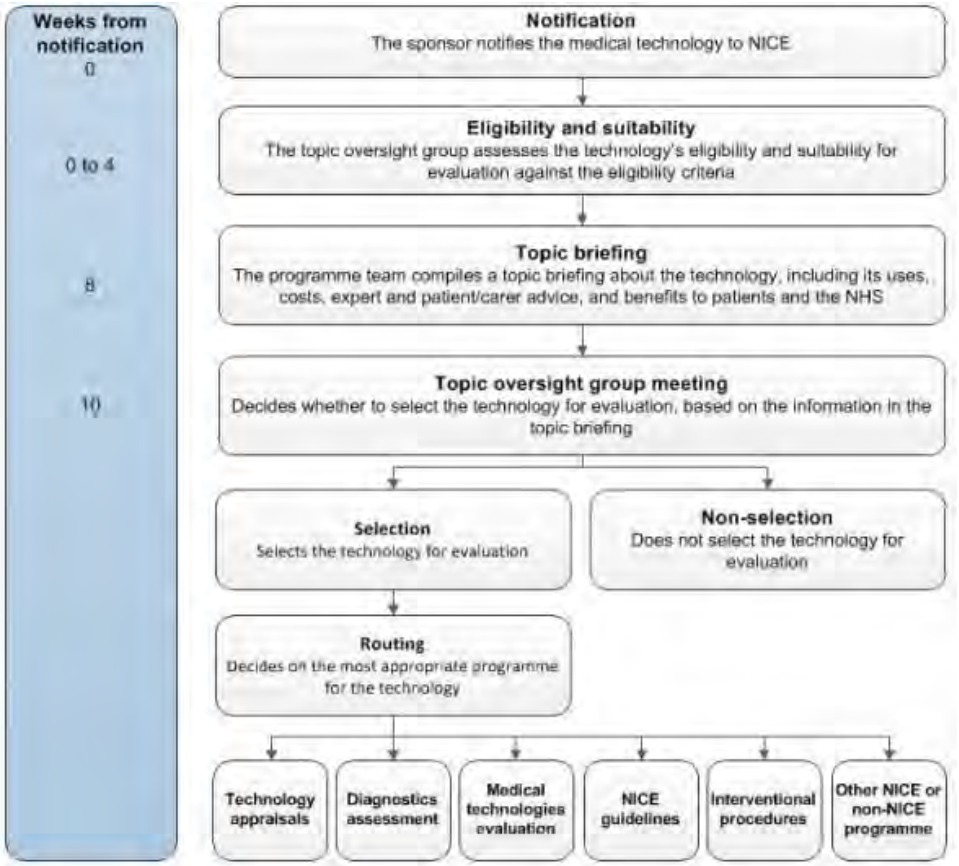
11.4 United Kingdom- National Health Service

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].

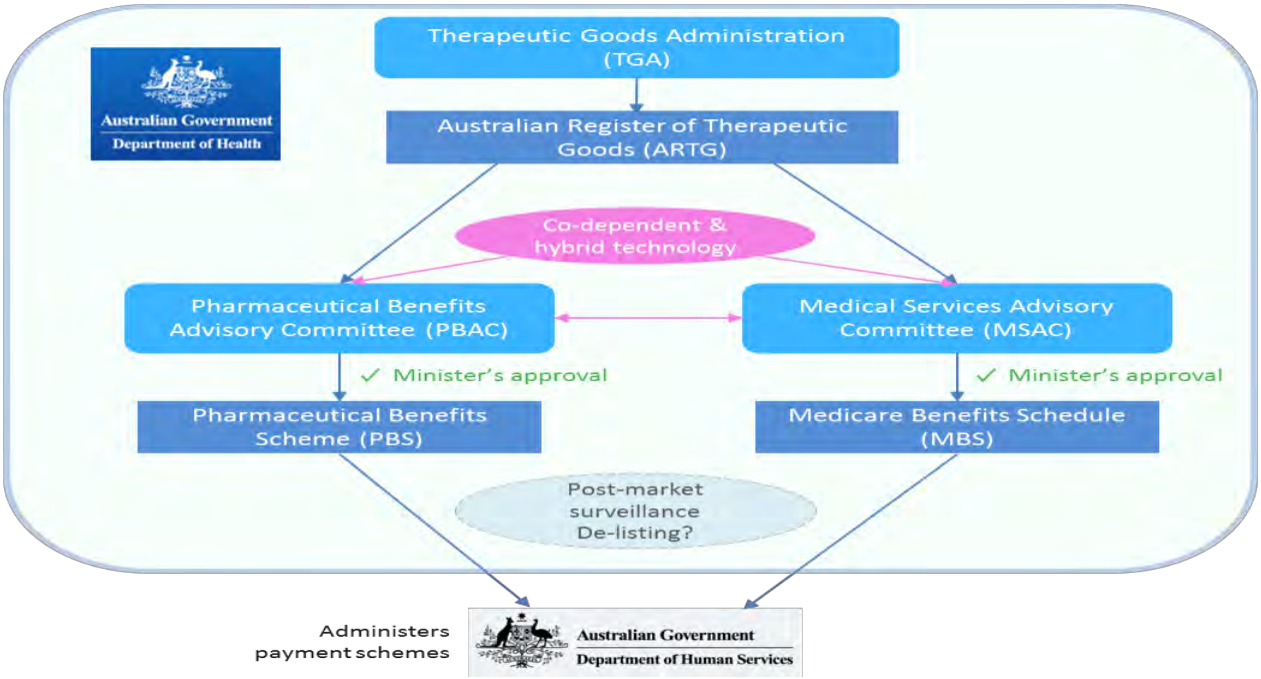
Kaiser Permanente (KP) has a well-established process for assessing, adopting and monitoring new innovative health technologies such as devices, equipment, diagnostics, and procedures. The process enables physicians of the Southern California Permanente Medical Group (SCPMG) to deliver the best care 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

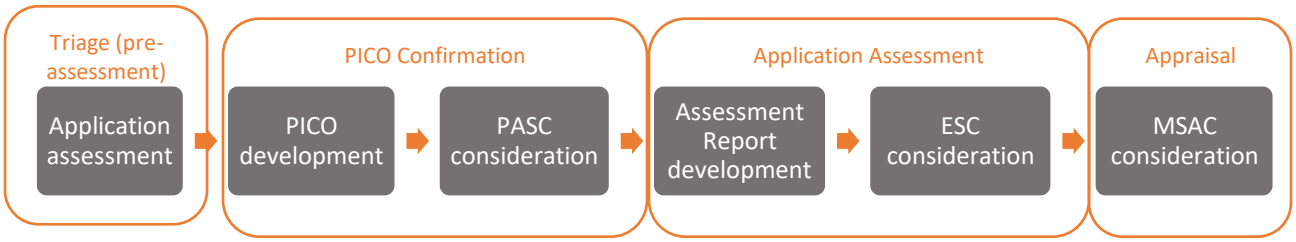
In Australia, the Government approves health technology for public funding under different programs including the Pharmaceutical Benefits Scheme (PBS) and the Medicare Benefits Schedule (MBS). The Medical Services Advisory Committee (MSAC) and the Pharmaceutical Benefits Advisory Committee (PBAC) perform 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.

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3. http://www.legislation.gov.uk/ukpga/2012/7/section/116/enacted

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