



Ontario Pathway Towards Innovation in Cancer Care (OPTICC)

February 5th, 2020 Version 3.0

Workshop Summary Report

Prepared by Intelligent Improvement Consultants, Inc.



Table of Contents

1. Executive Summary	3
2. Background / Introduction	5
3. Objectives of the Ontario Pathway Towards Innovation in Cancer Care Workshop	6
4. Approach	6
5. Outcomes and Discussion	9
Overview of Participants	9
Roundtable Discussion: Defining the Problem and the Need for a Solution	9
Perspectives from Other Jurisdictions: Learnings from Alberta Health Services	14
Overview of the Draft Innovation Framework	18
Summary of Pre-Workshop Survey	20
Breakout Group Discussion Summary – Reviewing the Framework	28
Breakout Group Discussion Summary – Barriers and Solutions	36
6. Closing Remarks and Next Steps	43
7. Appendices	45
Appendix 1: Open to Innovation: Ontario Pathway Workshop – Background Document (separate document)	45
Appendix 2: Workshop Agenda	46
Appendix 3: Invitation Letter to Participants	48
Appendix 4: Participant List	49
Appendix 5: Pre and Post Workshop Survey Questions	
Appendix 6: Pre-Workshop Survey Results	
Appendix 7: Post-Workshop Survey Results	

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

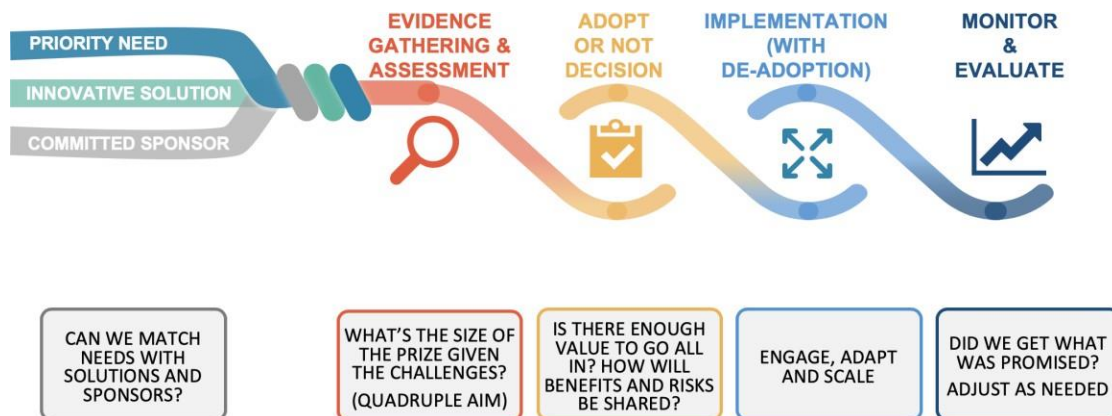
Dr. McCabe described the following innovation platforms in Alberta:

- 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

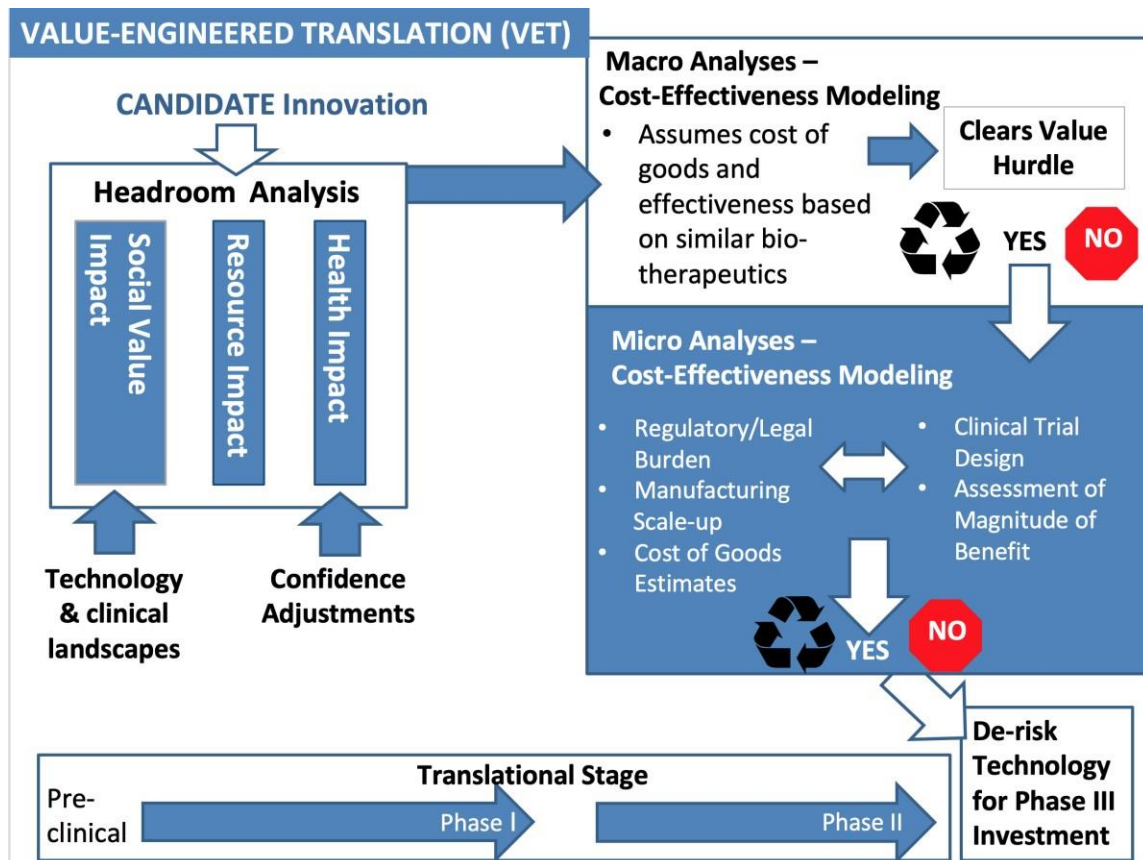
Dr. McCabe described how Alberta Health Services is moving from an industry push system to a health system pull approach, where clinical need drives innovation. AHS uses an Innovation to Action Lifecycle (I2A) which matches the needs of the system with the solutions that are available.



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).

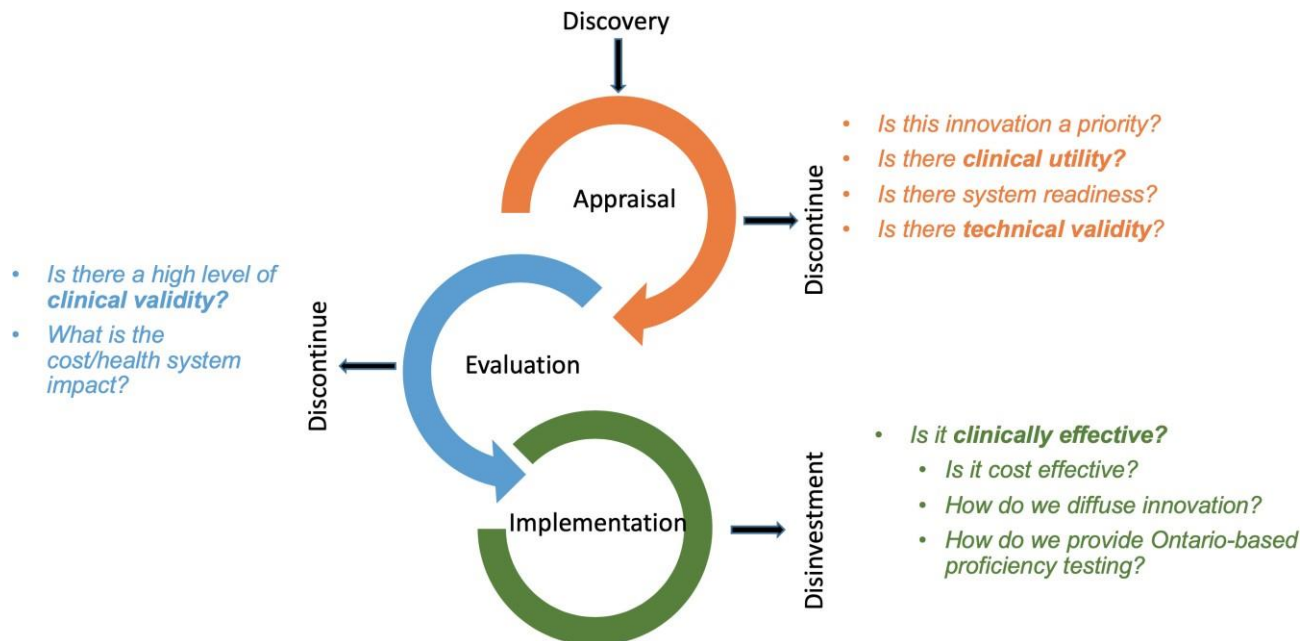
Overview of the Draft Innovation Framework

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.

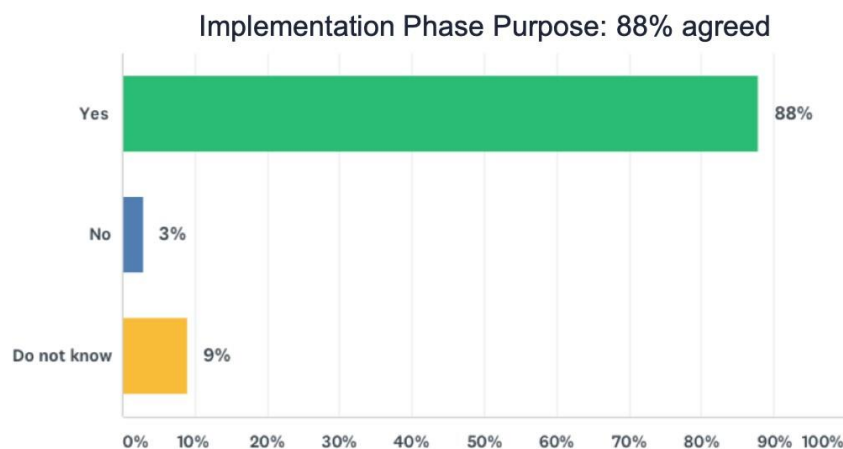
Answer Choices	Responses
Health and cancer care system	12
Industry	12
Researcher	8
Clinician	7
Other (please specify)	6
Molecular geneticist/pathologist	4
Hospital/research leadership	4
Patient/Public	2
Total Responses:	40

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

Innovation

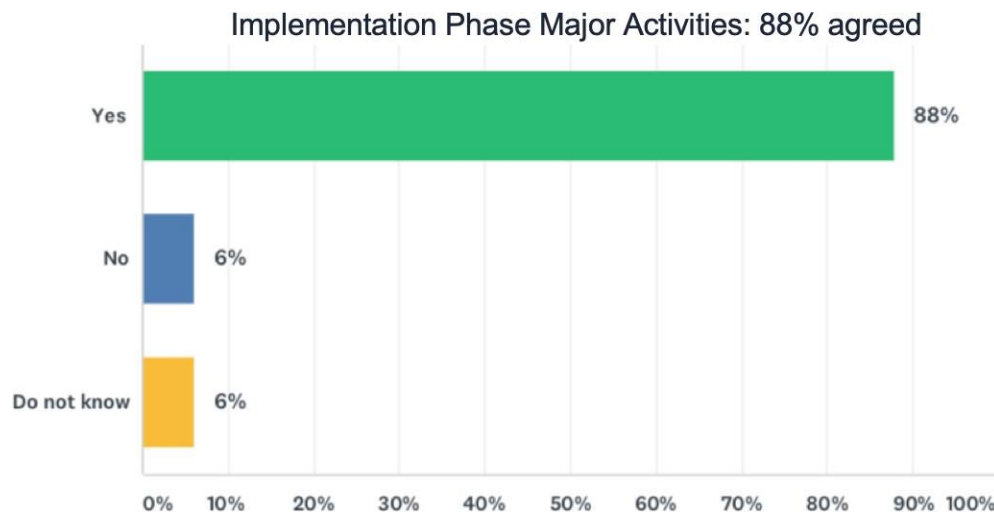
Framework Phases: Purpose and Major Activities

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.

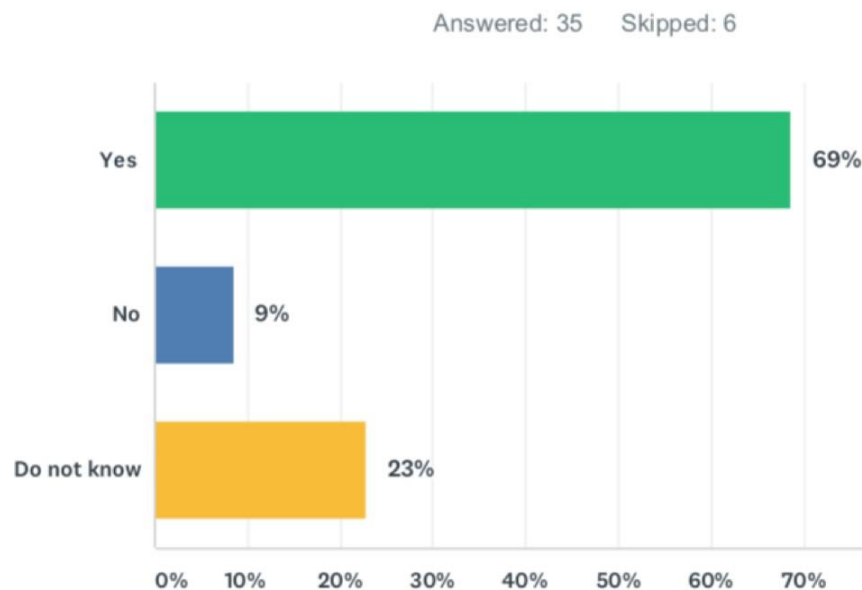
Innovation Framework Phases: Levels of evidence

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.

Different Levels of Evidence for Categories: 69% agreed



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:

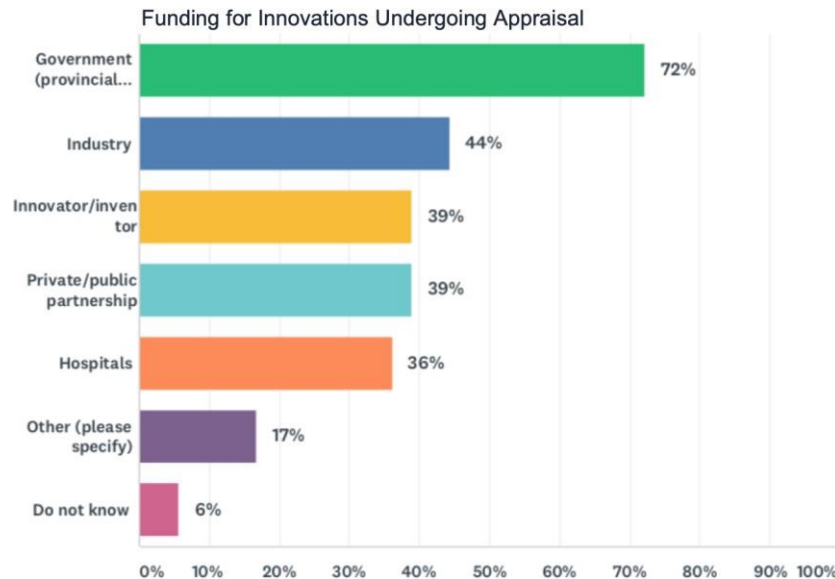
Funding,

Governance and Oversight

Most respondents believed

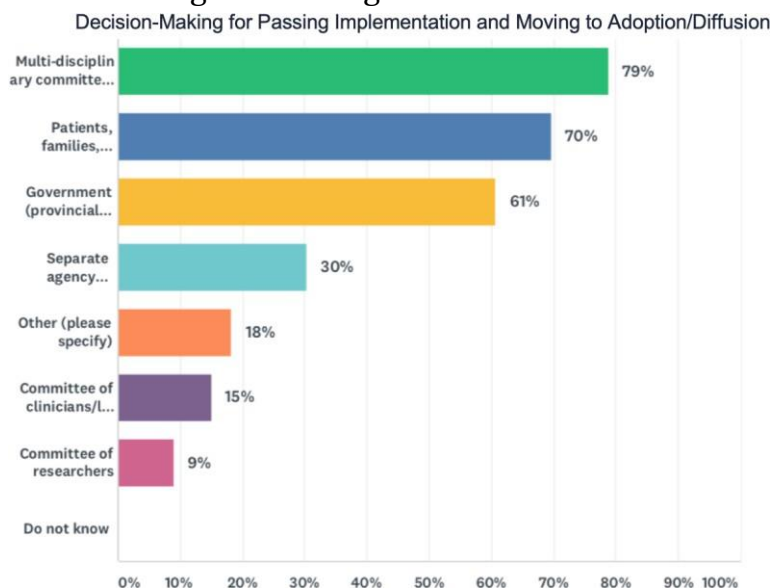
Government (provincial and/or federal) should

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

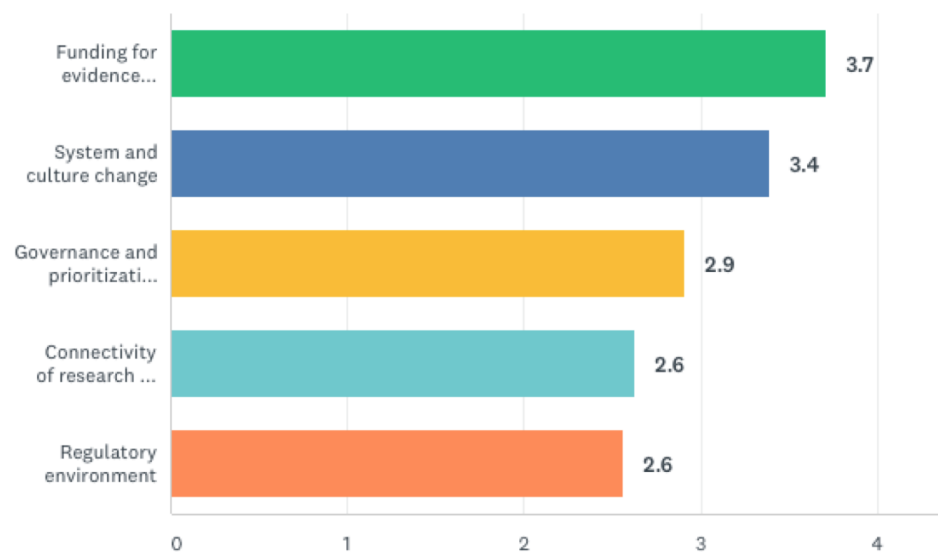
Challenges and Barriers

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.



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.
- Important 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



MaRS Centre
661 University Avenue, Suite 510
Toronto, ON M5G 0A3 Canada

Telephone 416-977-7599
Toll-free 1-866-678-6427
oicr.on.ca

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 <ul style="list-style-type: none"> Defining the problem from different perspectives: <ul style="list-style-type: none"> 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 <i>Lessons learned from Alberta Health Services</i> <ul style="list-style-type: none"> Q&A 	Christopher McCabe
10:10 – 10:25 a.m.	Proposed Framework for the Evaluation and Implementation of Health Innovations <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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	<i>Jason Pun (Facilitator)</i>
11:45 – 12:40 p.m.	Feedback and Discussion	<i>All</i>
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	<i>Jason Pun (Facilitator)</i>
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	<i>Jason Pun (Facilitator)</i>
2:20 – 3:15 p.m.	Feedback and Discussion	<i>All</i>
3:15 – 3:30 p.m.	Break	
3:30 – 3:50 p.m.	Next Steps and Actions	<i>All</i>
3:50 – 4:00 p.m.	Closing Remarks	<i>Christine Williams</i>

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 Cancer)	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 Institute	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	Executive 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	3
2.	POST-WORKSHOP SURVEY QUESTIONS.....	4
3.	INTRODUCTORY TEXT FOR PRE-WORKSHOP SURVEY	5
4.	PRE-WORKSHOP SURVEY QUESTIONS.....	6

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



Respondent Roles (select all that apply)

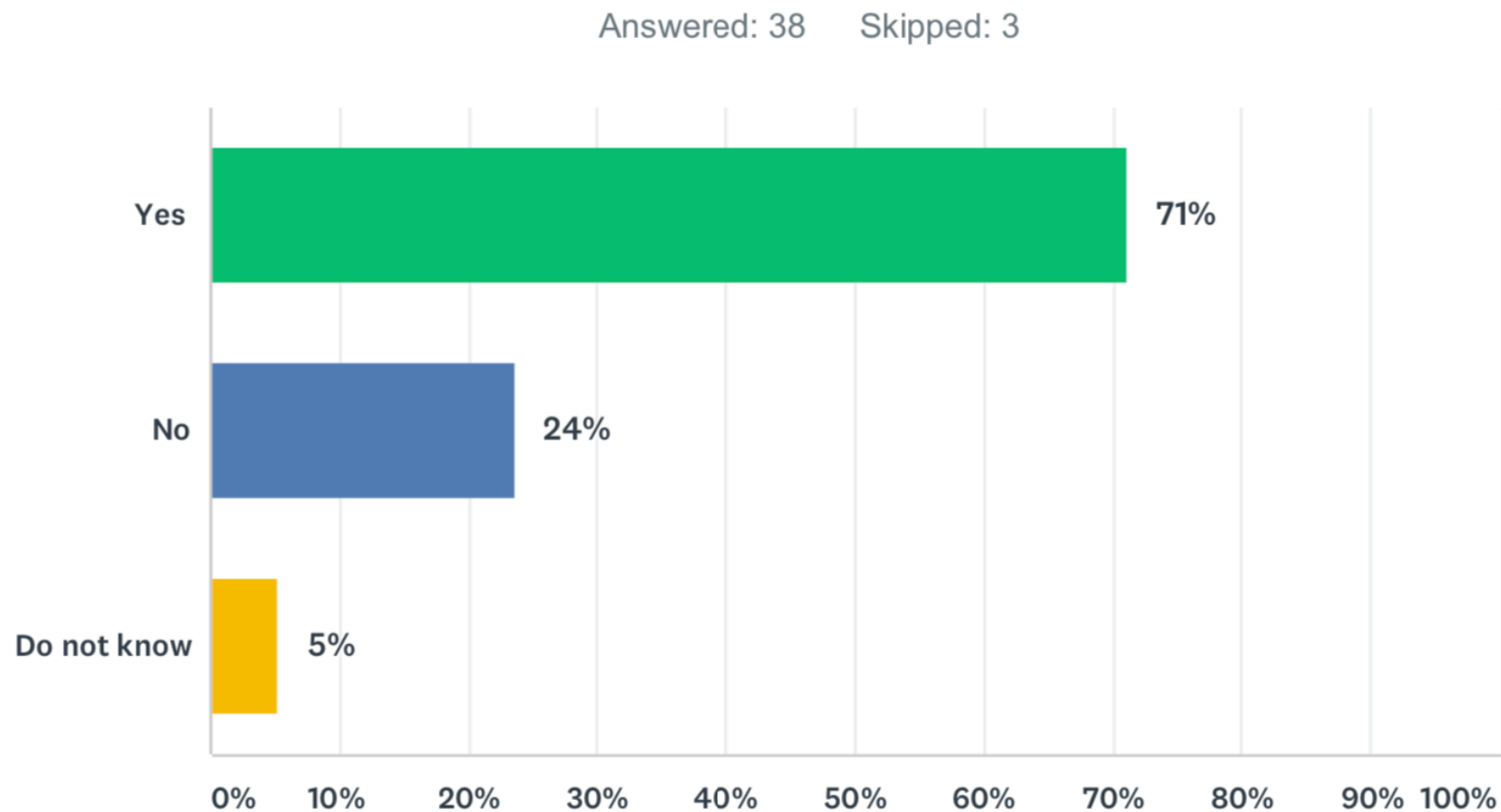
- Most respondents identified themselves as Health and cancer care system and/or Industry, followed by Researcher then Clinician.
- Some organizations responded as a group.

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?

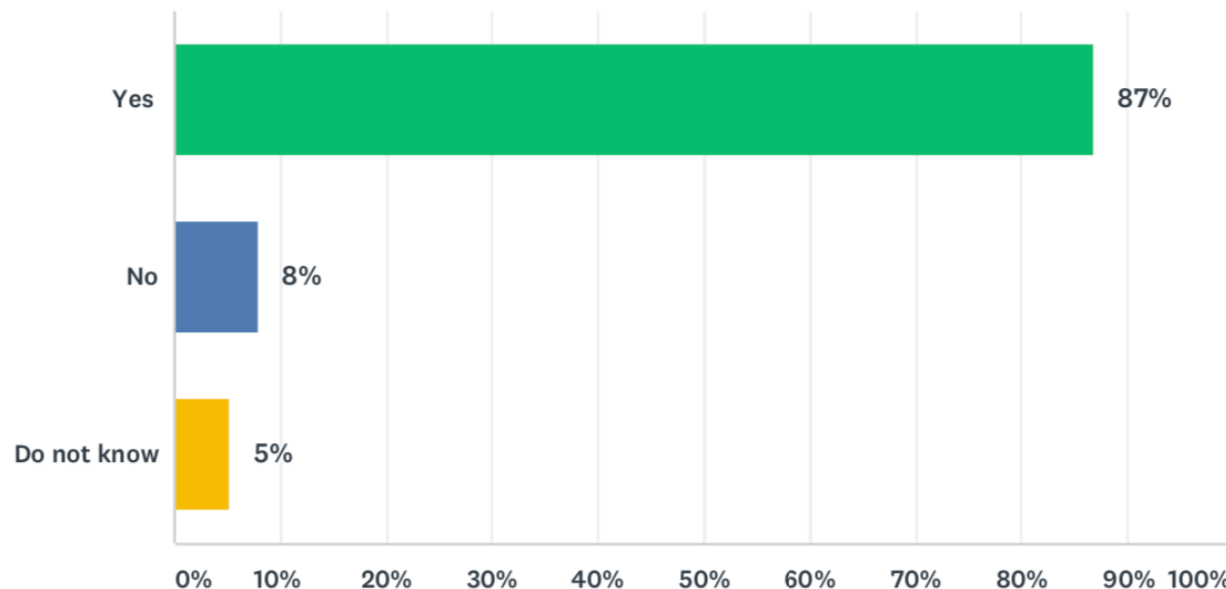
Respondents that did not agree with the purpose, or did not know, offered a number of suggestions for revisions:

- 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

Answered: 38 Skipped: 3



Appraisal Phase activities: How should they be revised?

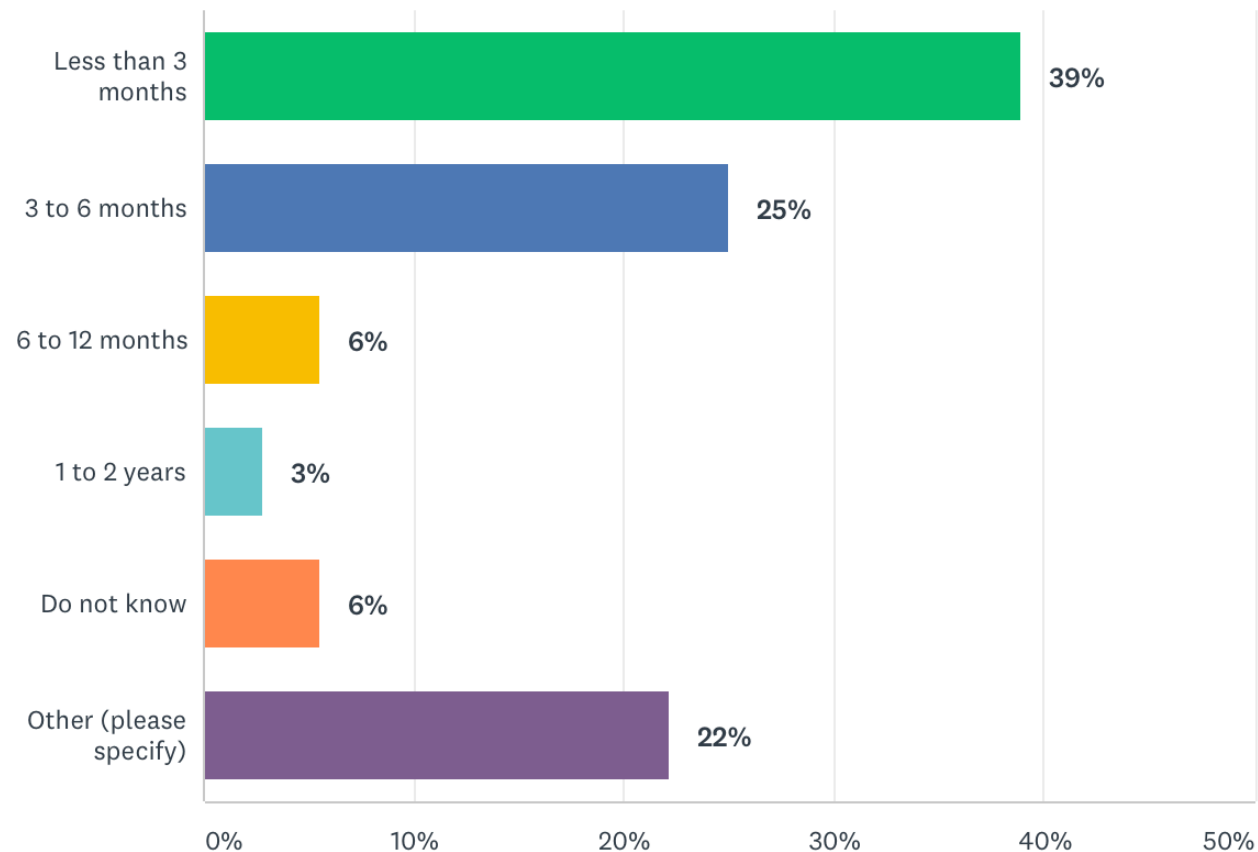
Respondents that did not agree with the major activities, or did not know, offered a number of suggestions for revisions:

- 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).

Answered: 36 Skipped: 5



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

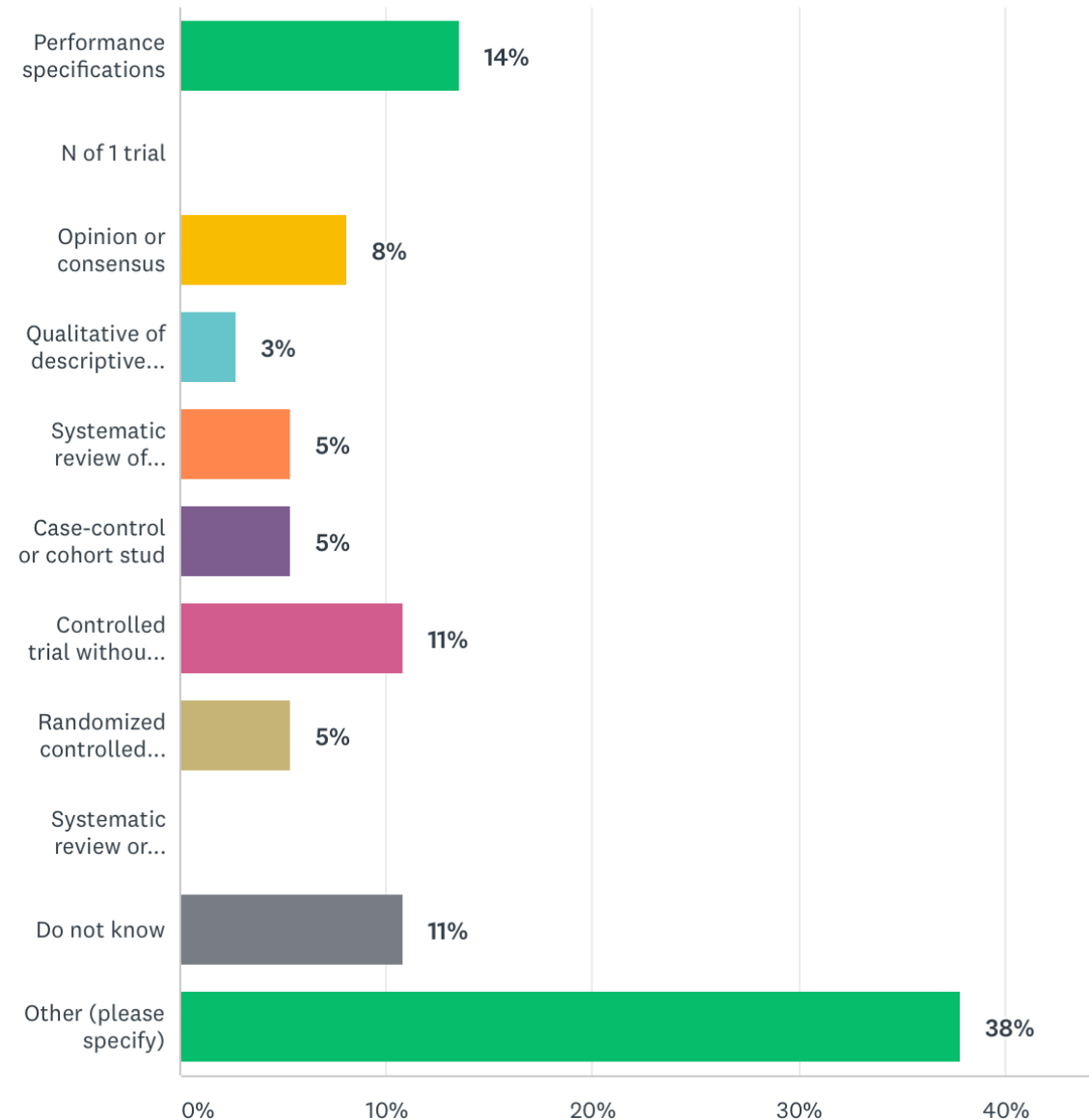
Respondents offered other suggestions for the Appraisal timeframe:

- 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 more 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?

Answered: 37 Skipped: 4

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



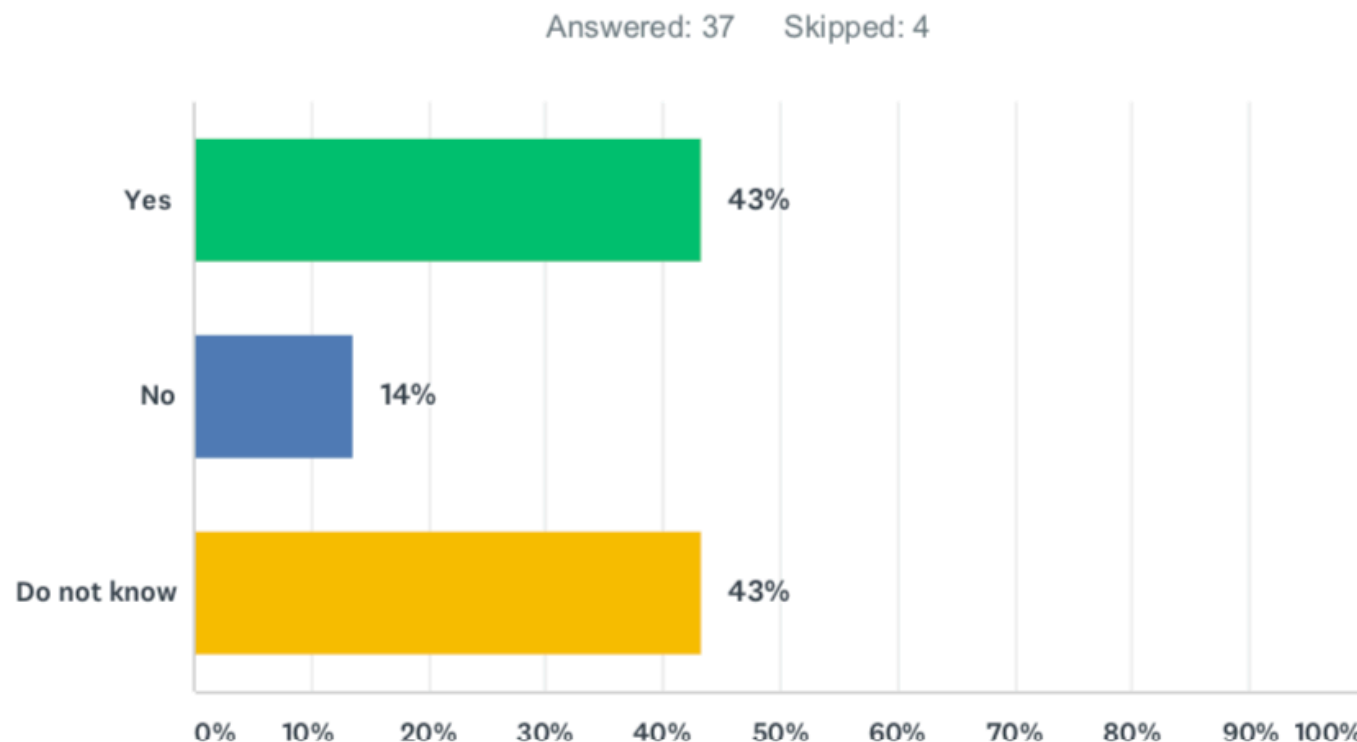
Appraisal Phase: Minimum level of evidence to be submitted?

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?

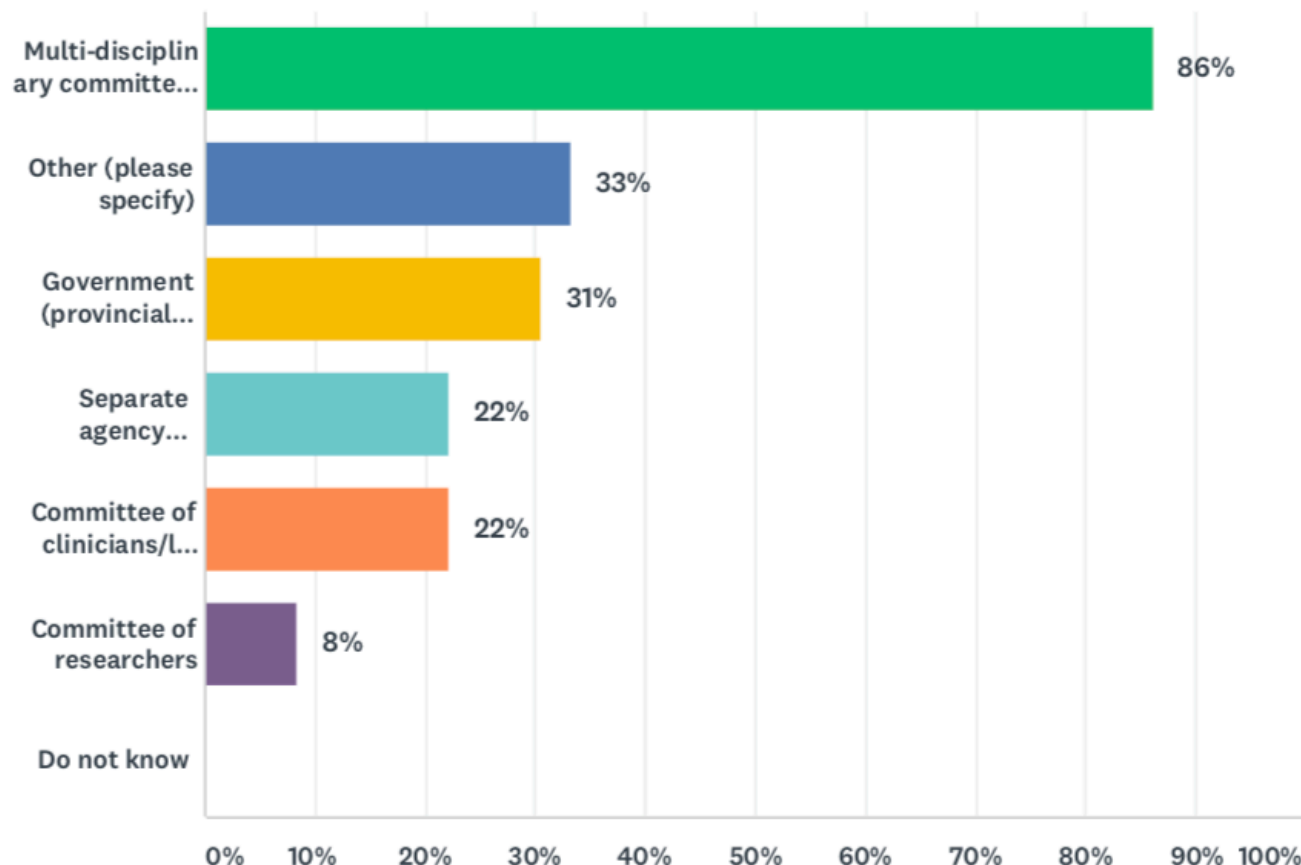
- Respondents that did not think Ontario had readily available evidence, offered the following suggestions on how to build the necessary evidence

Level of Evidence	Sources in Ontario
Unspecified	<ul style="list-style-type: none"> 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.

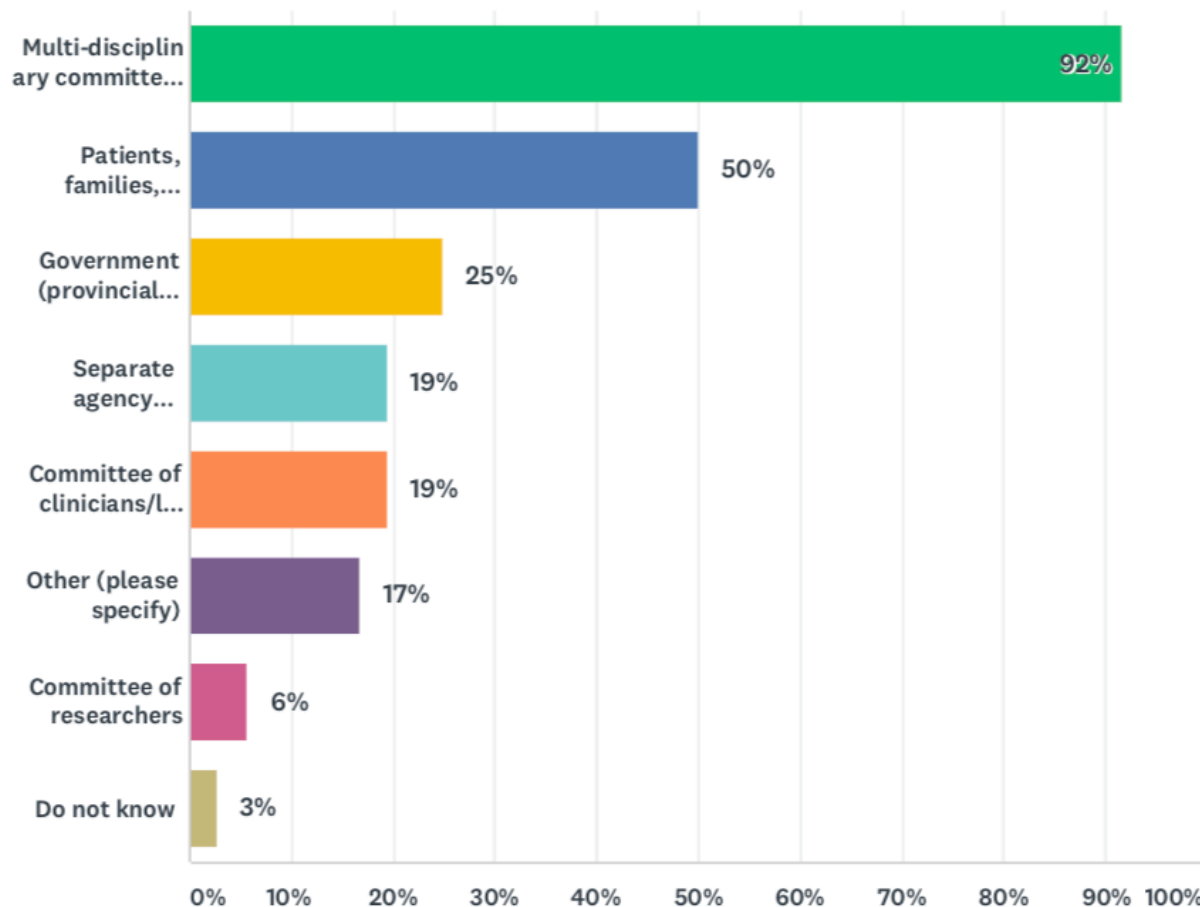
Answered: 36 Skipped: 5



- 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?

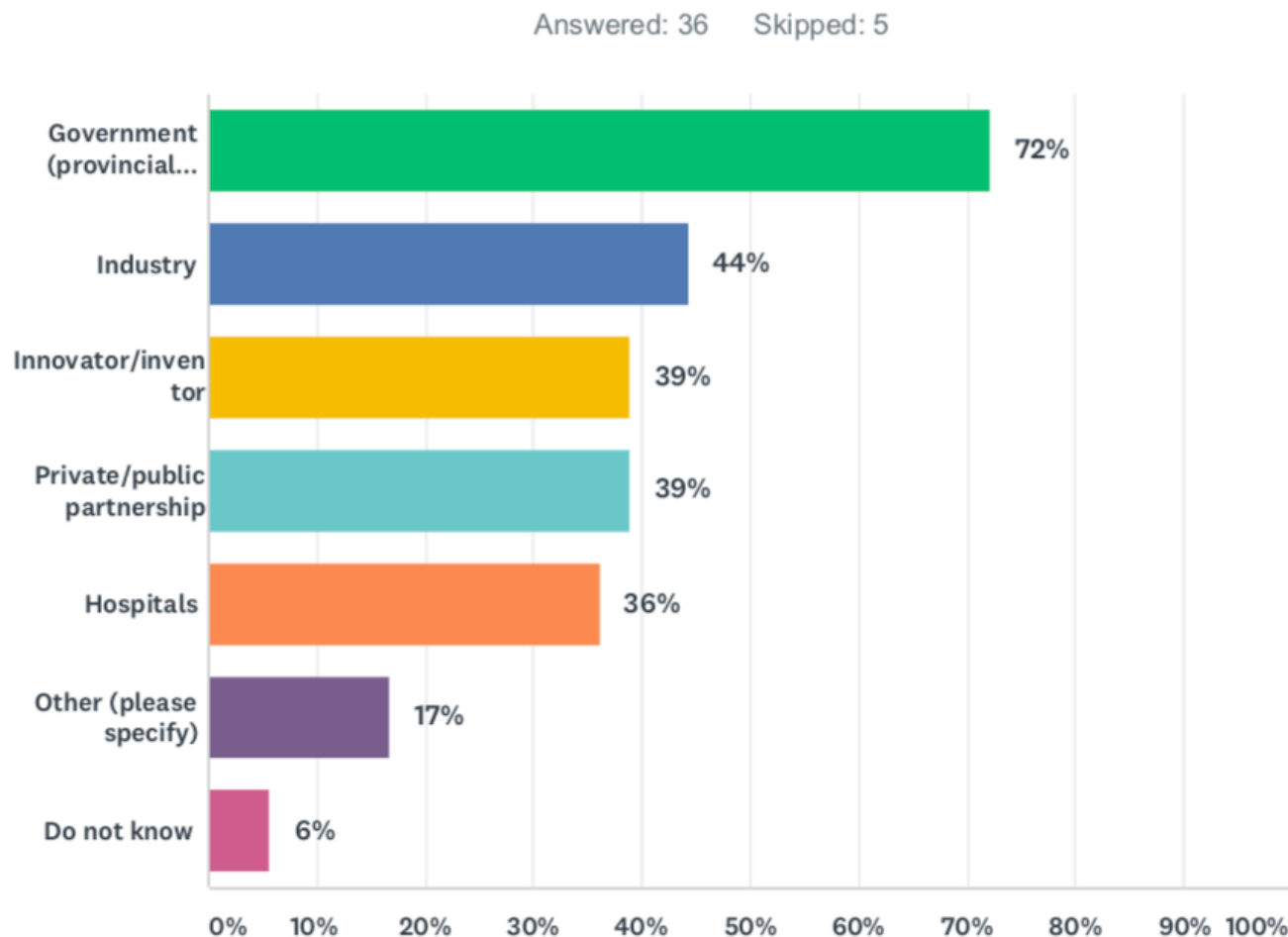
- Most respondents believed a multi-disciplinary committee of researchers, clinicians, health economists, policy experts, and laboratory experts should be involved with decision-making, followed by patients/families



- 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?

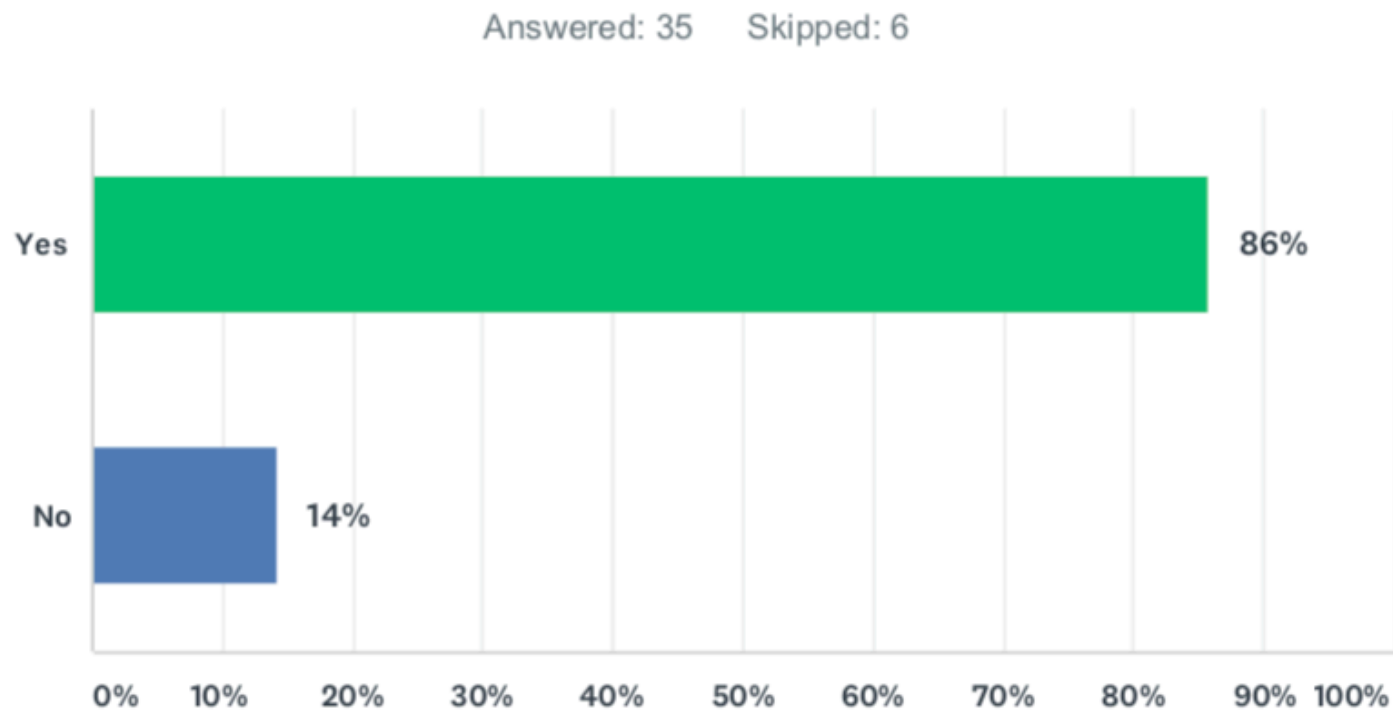
- Most respondents believed Government (provincial and/or federal) should fund Appraisal, followed by Industry, Innovator/inventor, Private/public partnership, and hospitals.



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.



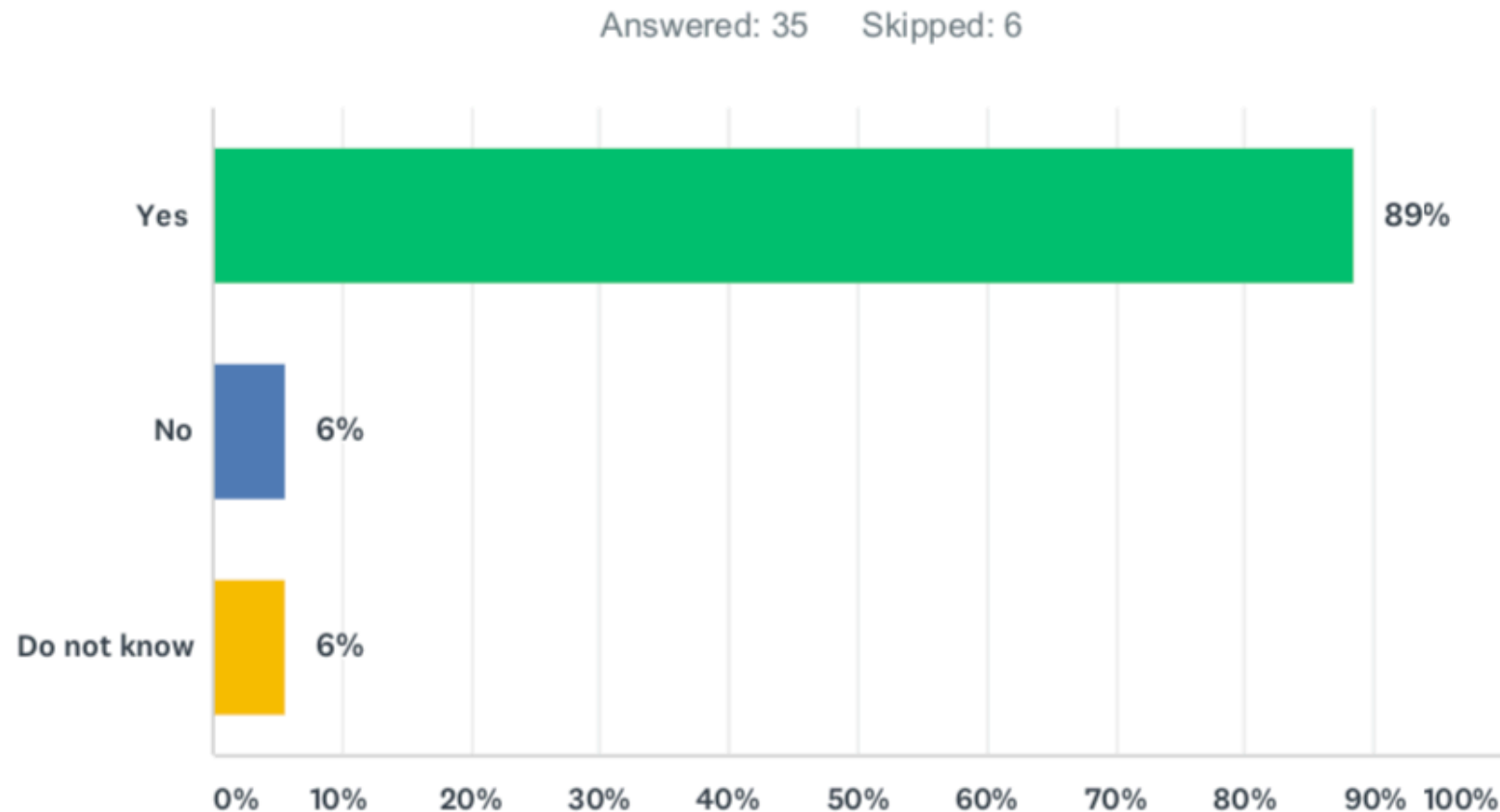
Evaluation Phase purpose: How should it be revised?

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)



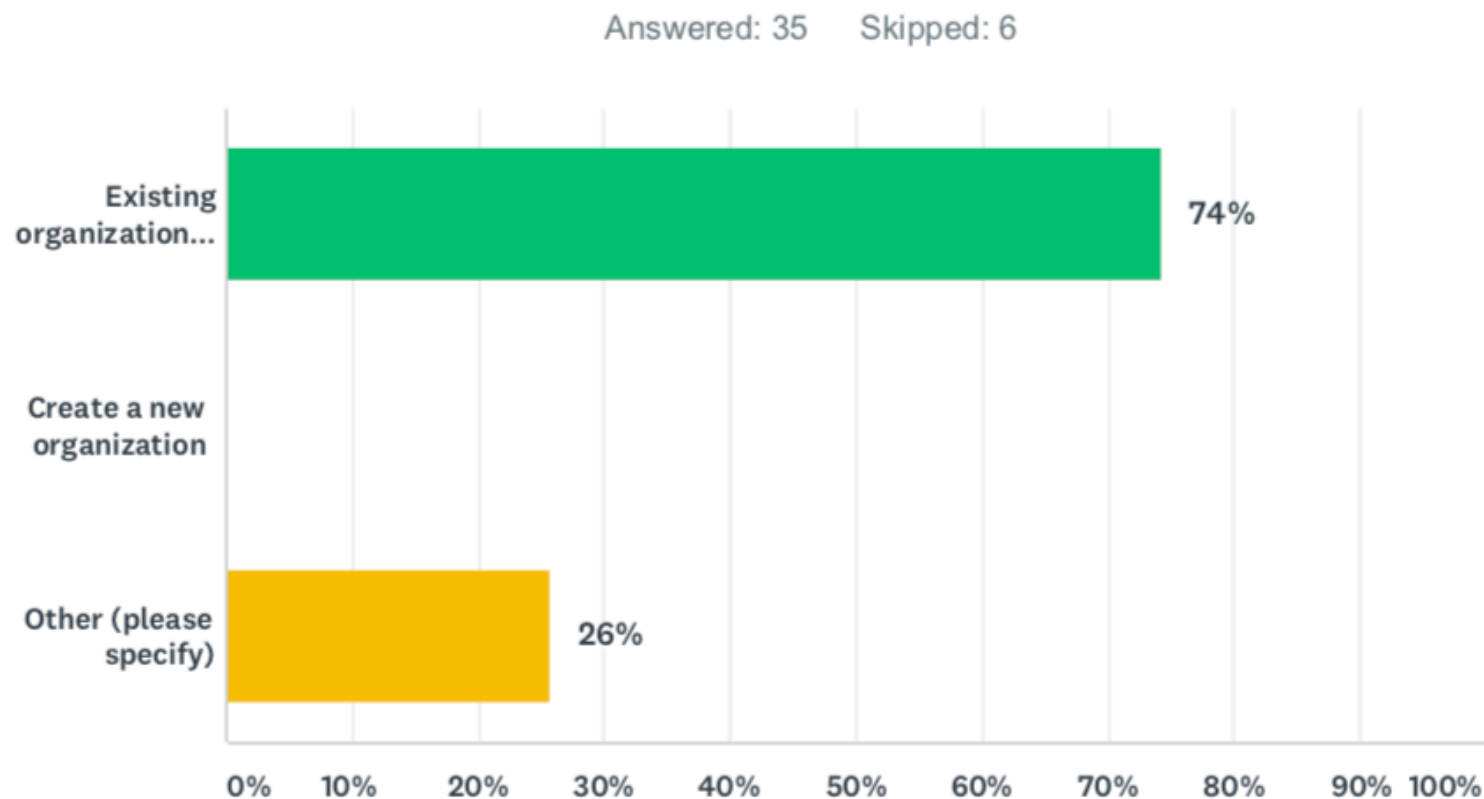
Evaluation Phase activities: How should they be revised?

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?

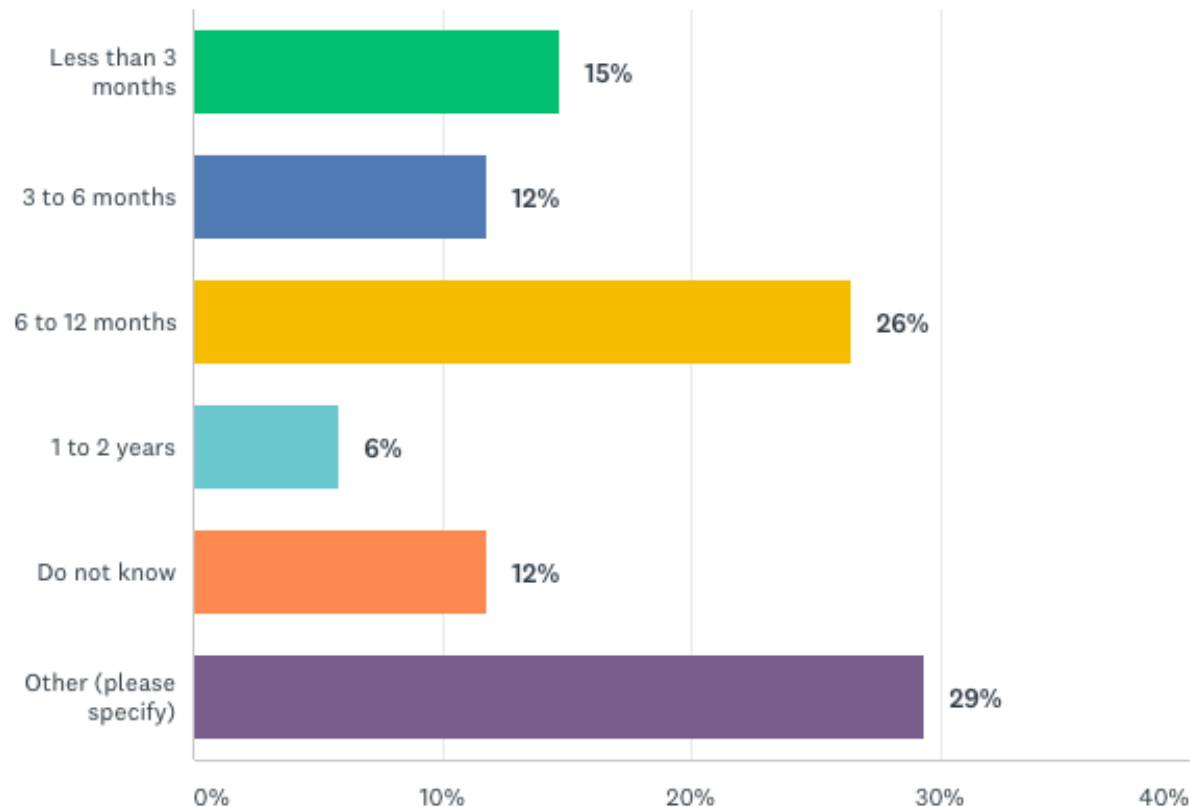
Respondents that answered 'other' provided the following suggestions:

- 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 (not 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.

Answered: 34 Skipped: 7



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

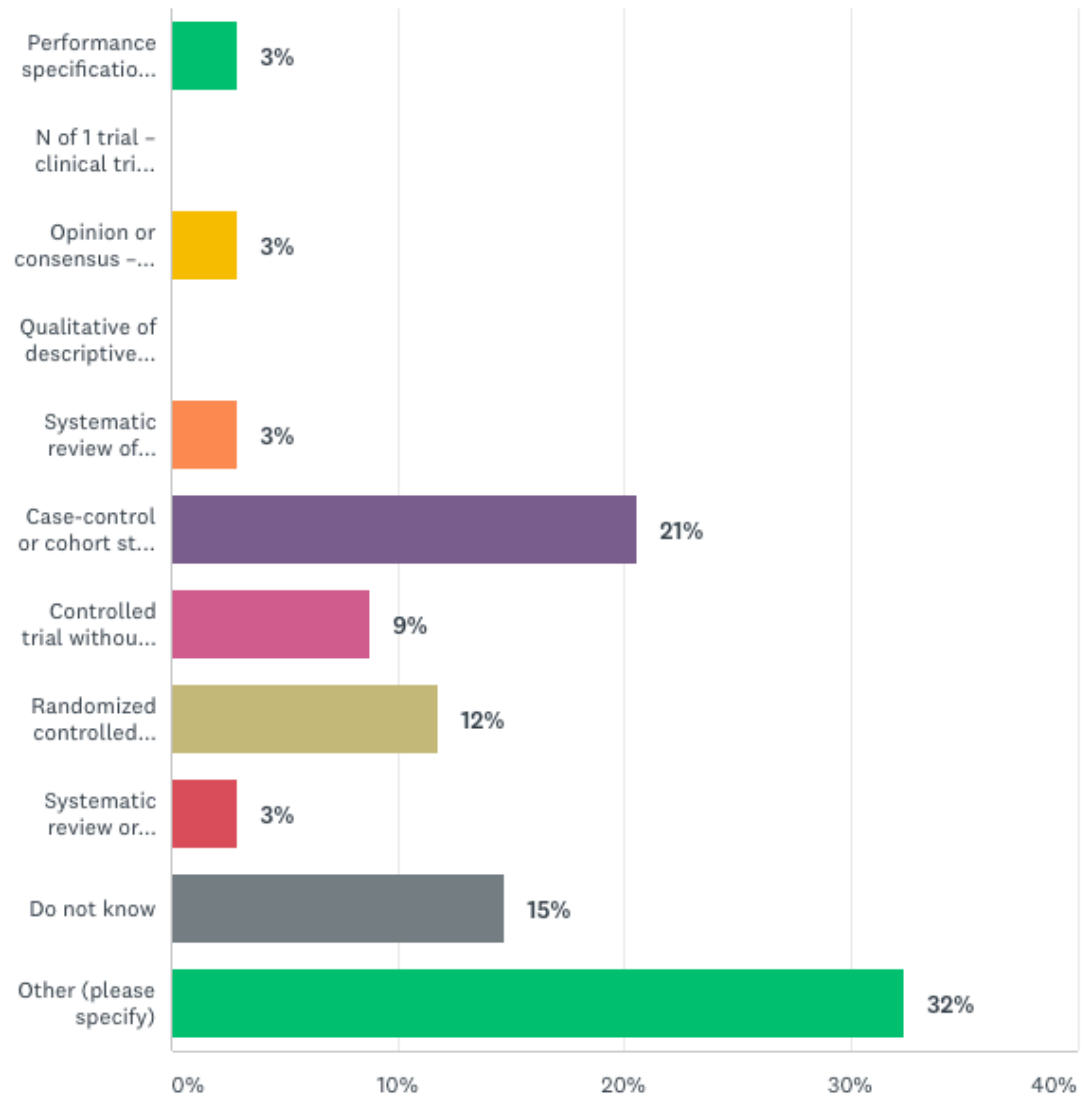
Respondents offered other suggestions for the Evaluation timeframe:

- 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 organizations.

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

Answered: 34 Skipped: 7

- 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?

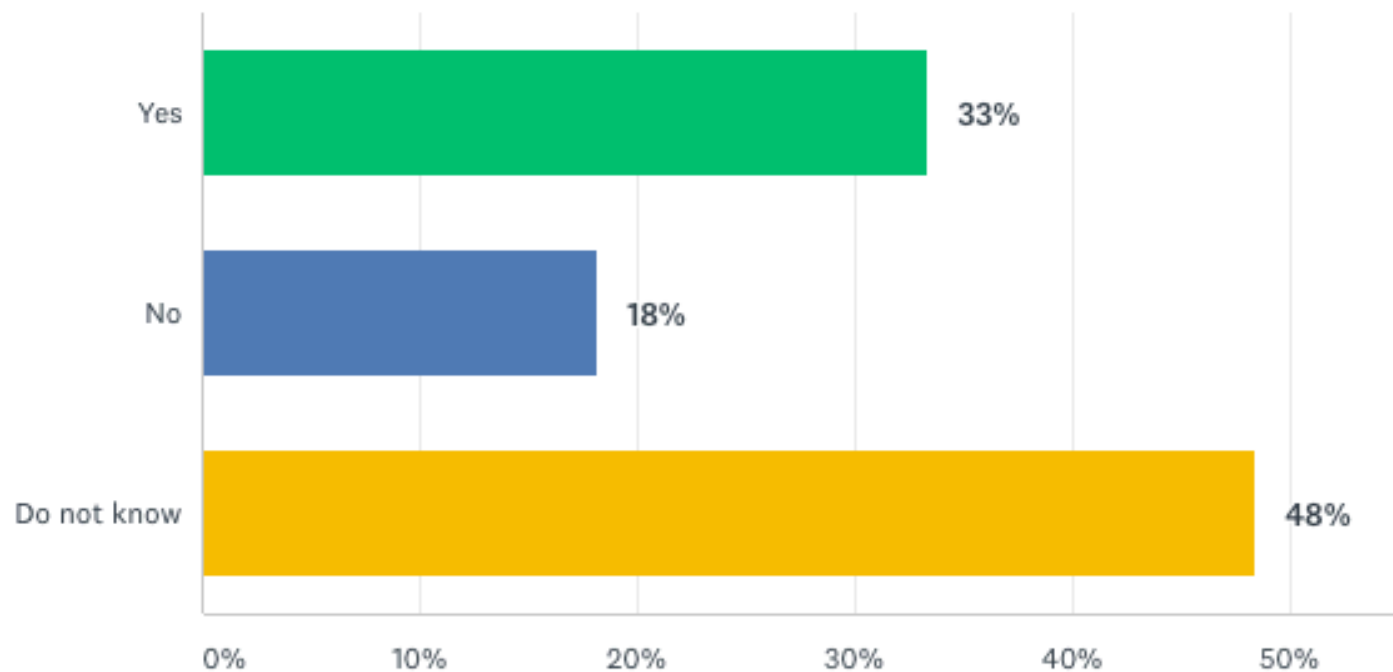
Respondents that answered 'other' provided the following feedback on the minimum level of evidence:

- 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.

Answered: 33 Skipped: 8



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 articles 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

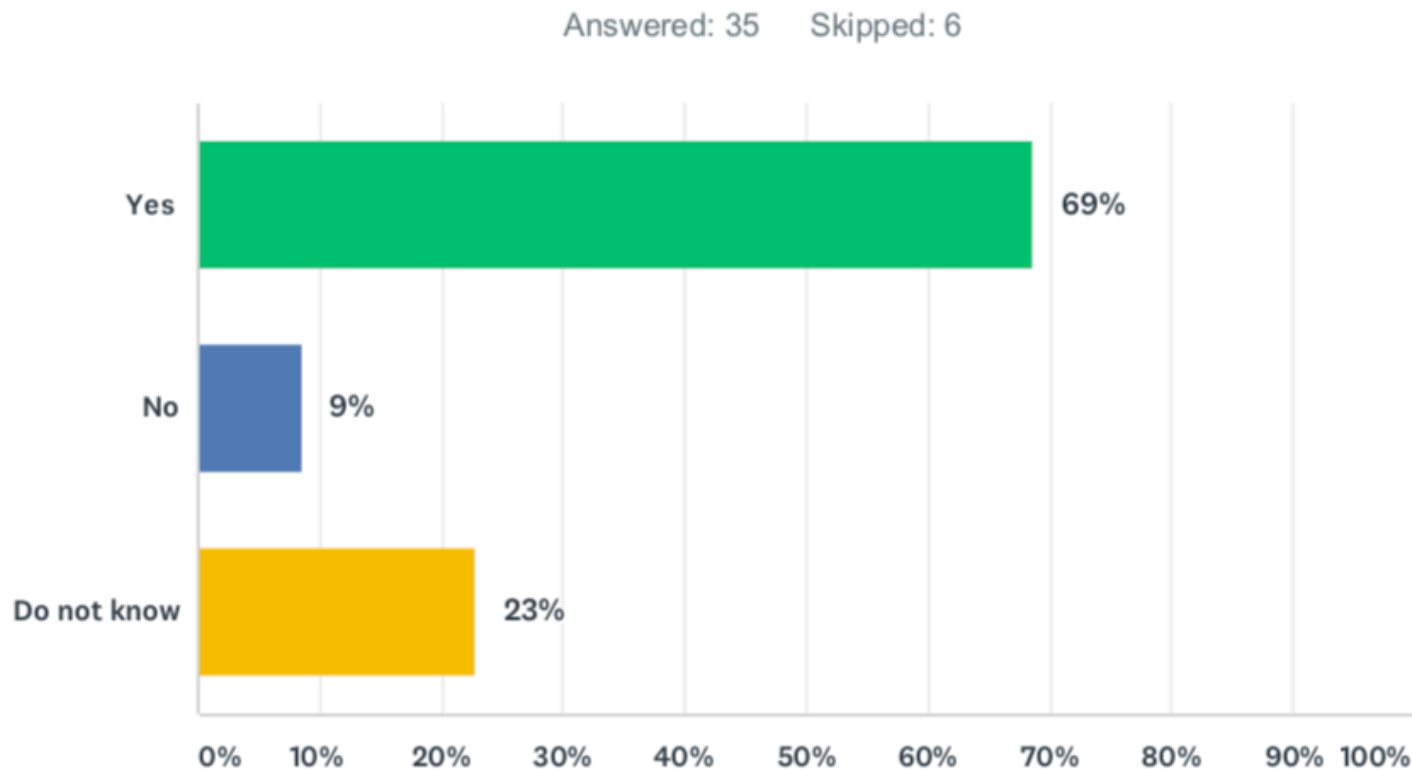
Evaluation Phase: How do we build the necessary evidence?

- 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	<ul style="list-style-type: none"> 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 WHB 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 be established for different categories of innovations – explain?

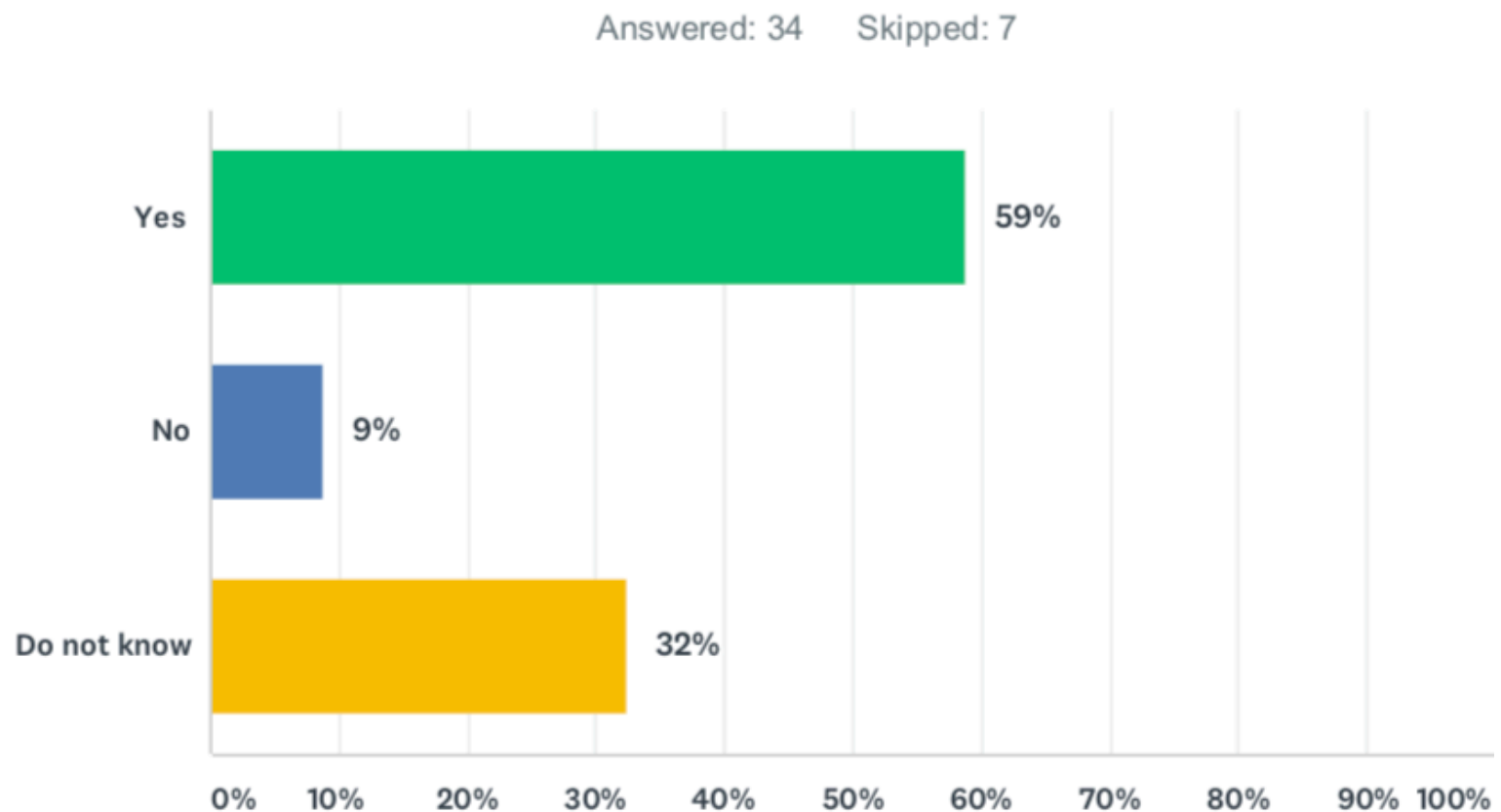
- Categories could depend on:
 - Risk to the patient (safety)
 - Cost of innovation
 - Potential for impact
 - Disease
 - Target population (rare diseases for small populations will never have the level of evidence of more prevalent diseases)
 - Patient/public values
 - Decision-makers' perspective
- 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 be 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

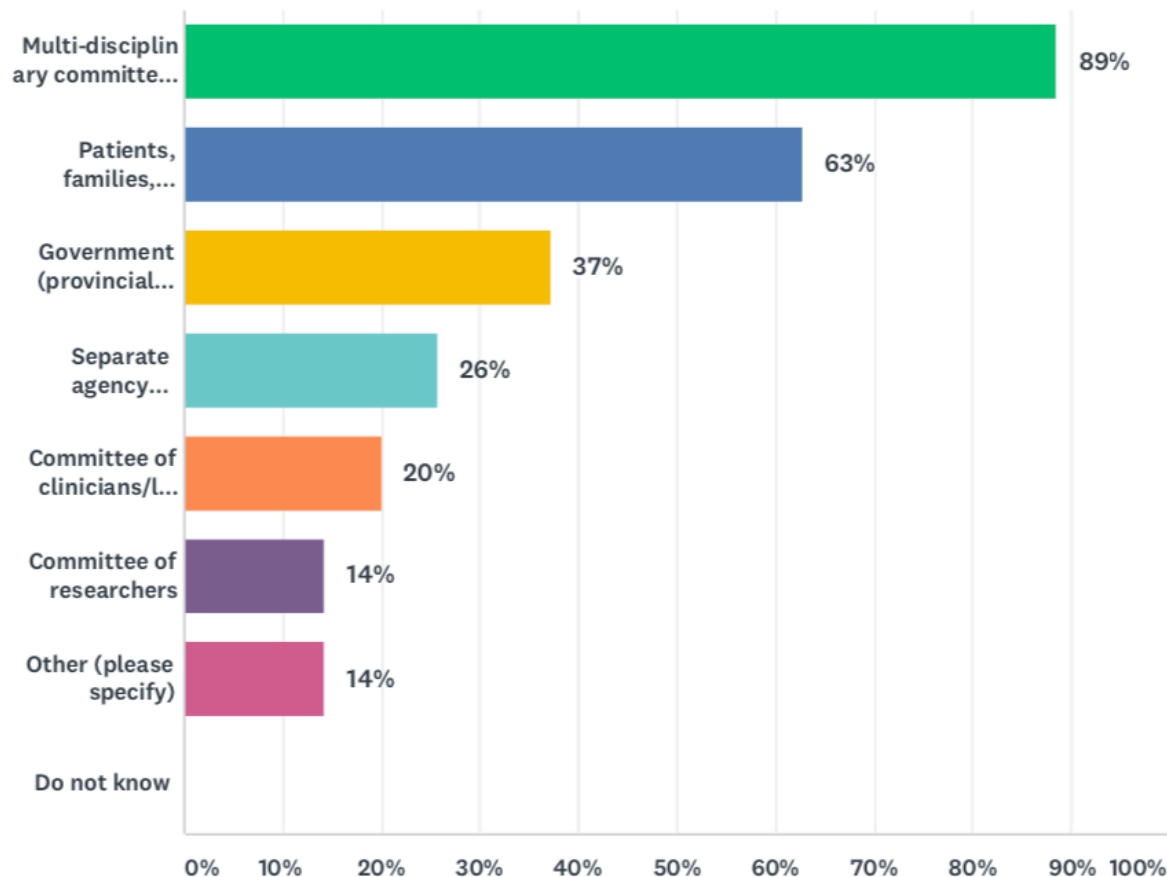
Evaluation Phase: Should different levels of evidence be established for different therapeutic needs – explain?

- 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 expectancy 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.

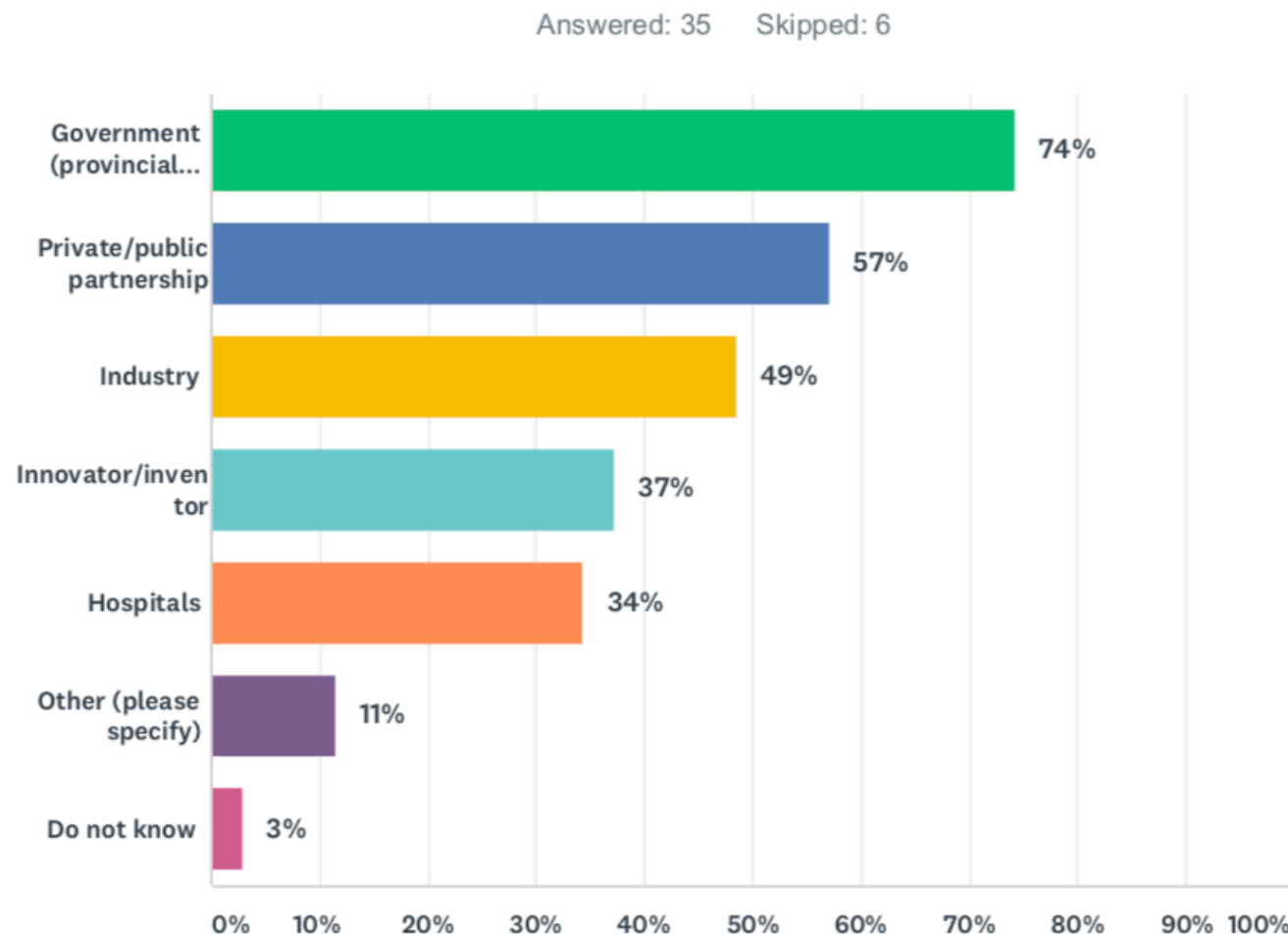
Answered: 35 Skipped: 6



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

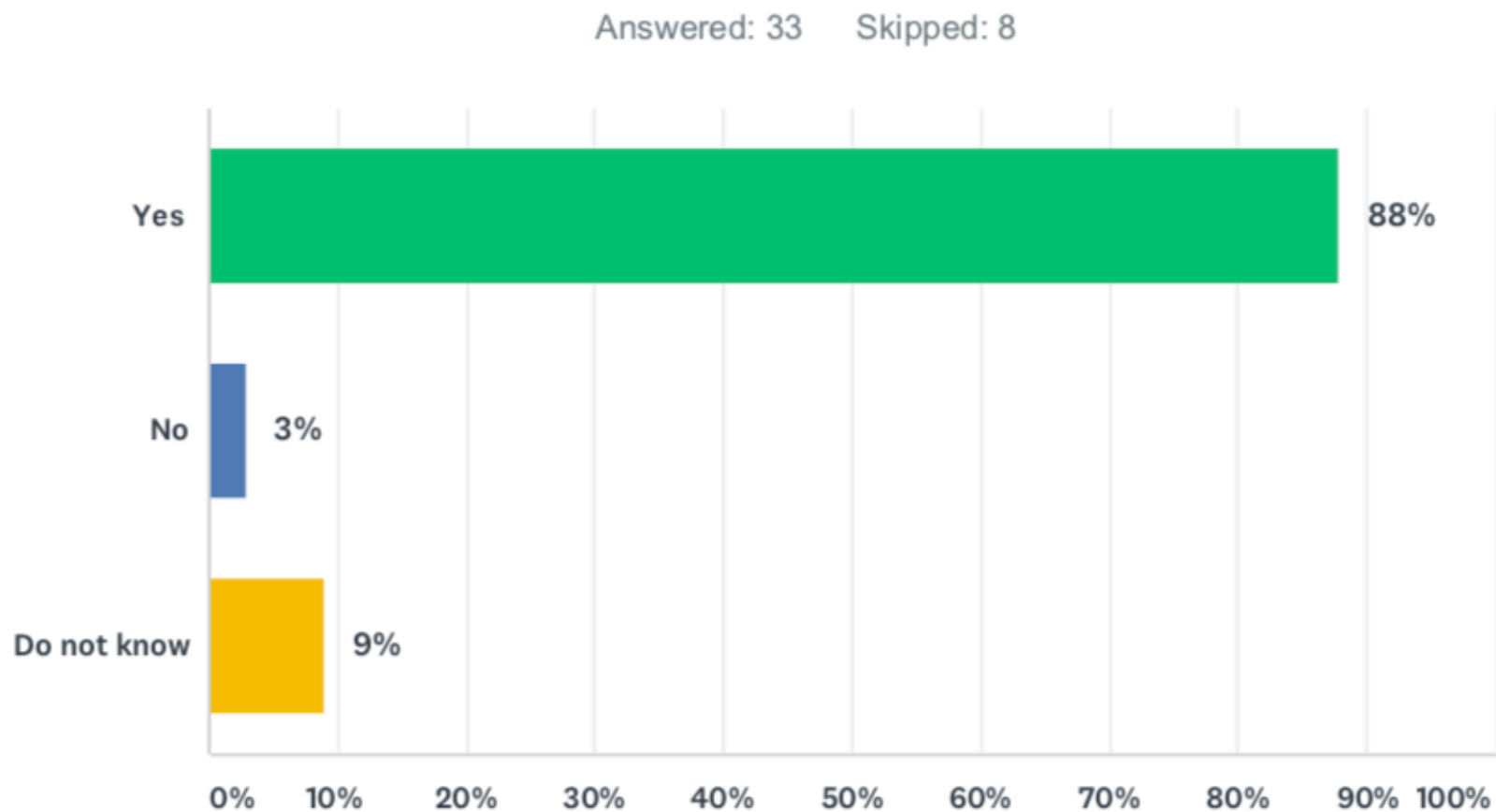
Evaluation Phase: Who should provide funding for innovations undergoing Evaluation?

- 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.



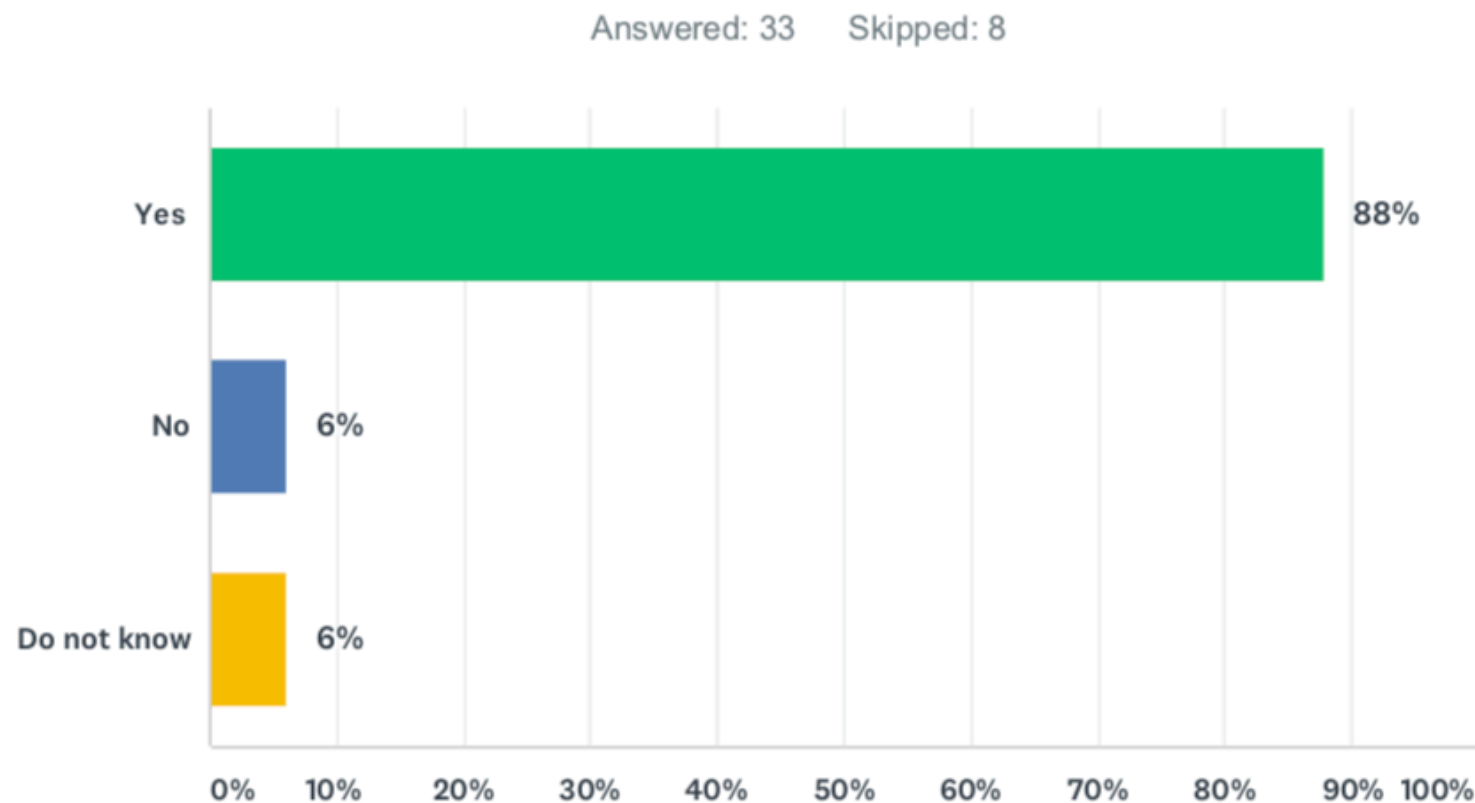
Implementation Phase purpose: How should it be revised?

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 pause 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.



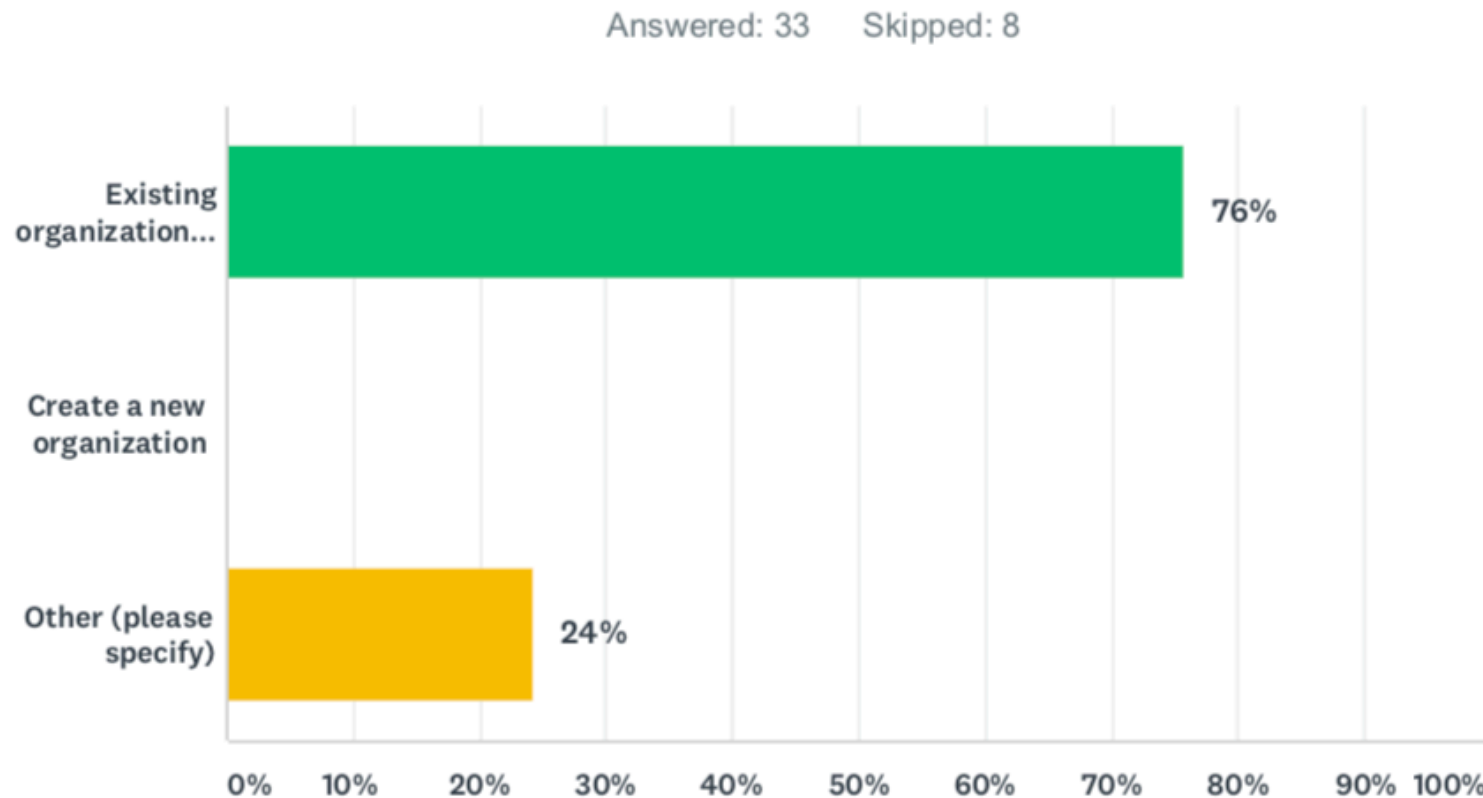
Implementation Phase activities: How should they be revised?

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?

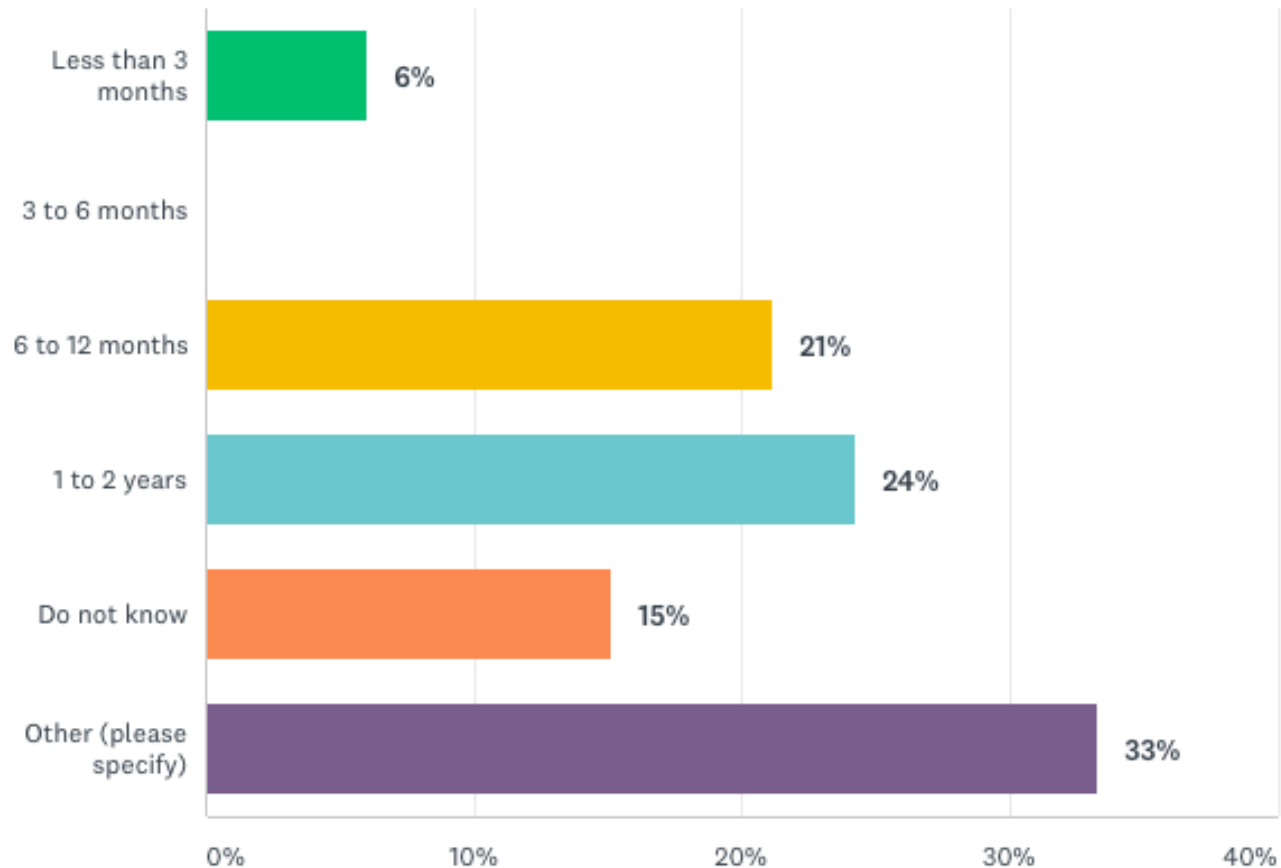
Respondents that answered 'other' provided the following suggestions:

- 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.

Answered: 33 Skipped: 8



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

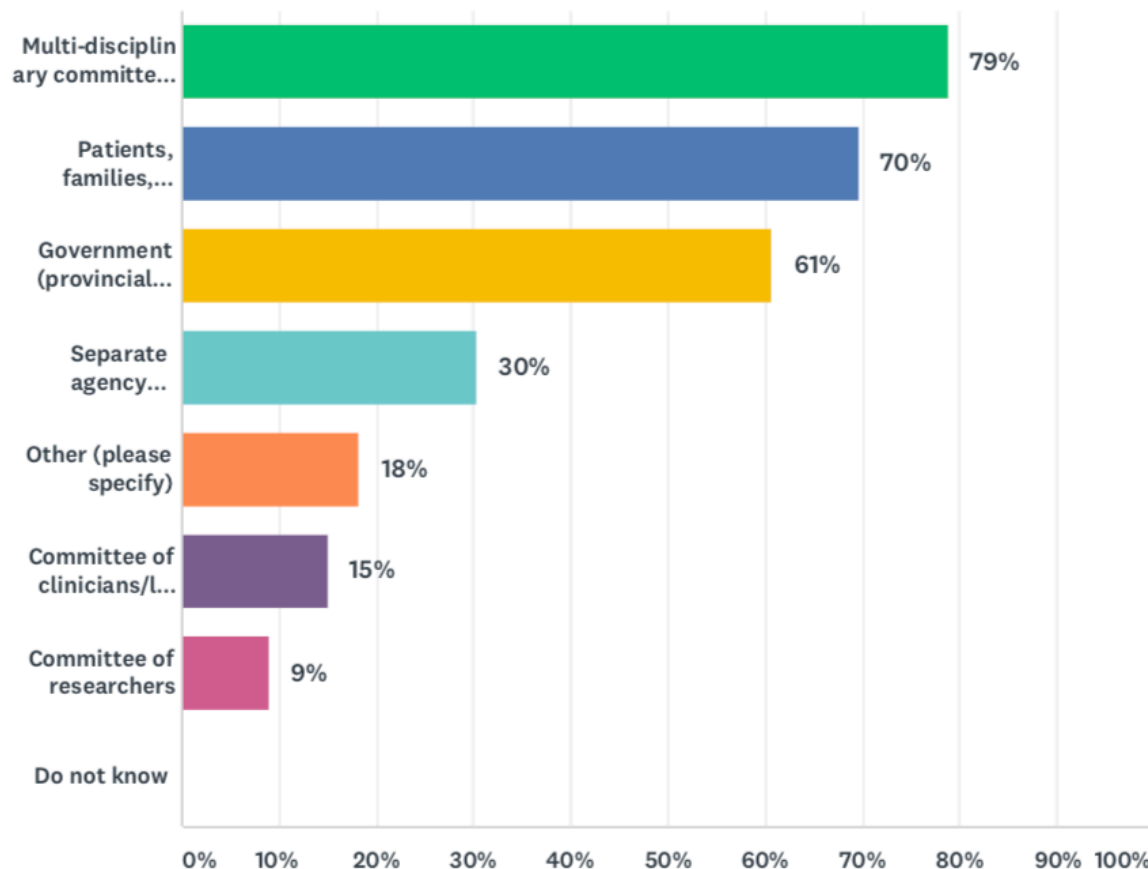
Respondents offered other suggestions for the Implementation timeframe:

- 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.

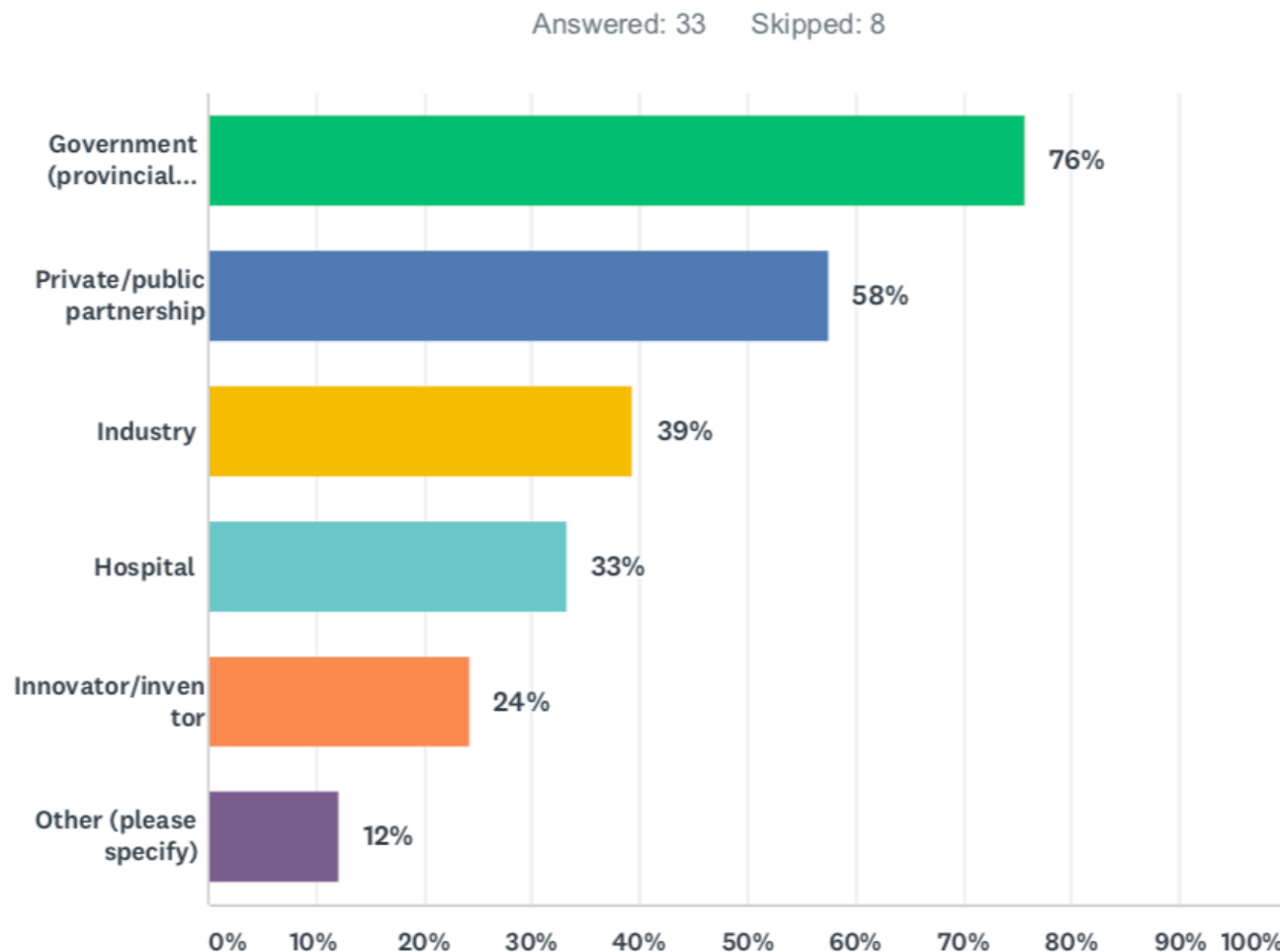
Answered: 33 Skipped: 8



- 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.

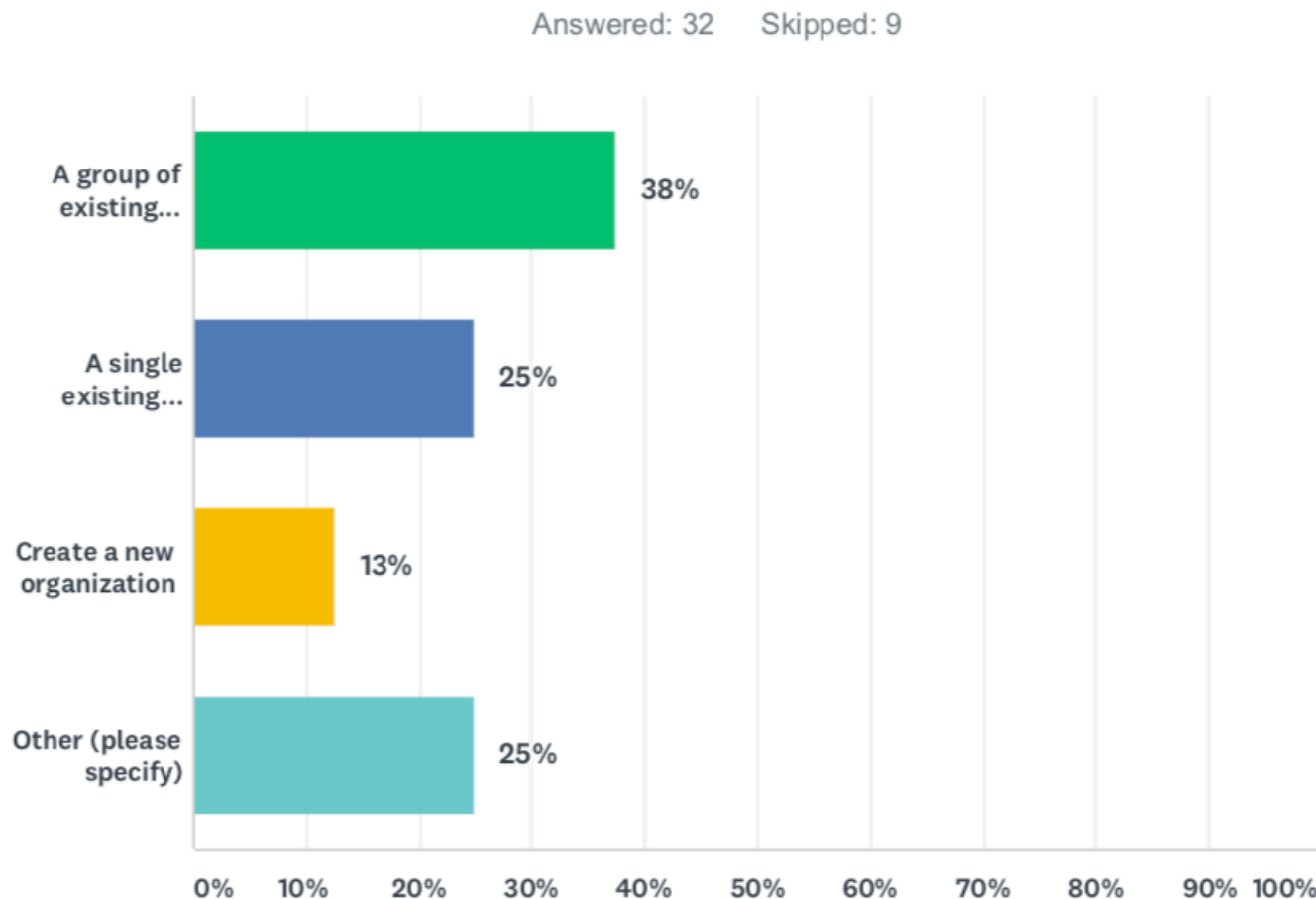
Implementation Phase: Who should provide funding for innovations undergoing Implementation?

- 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?

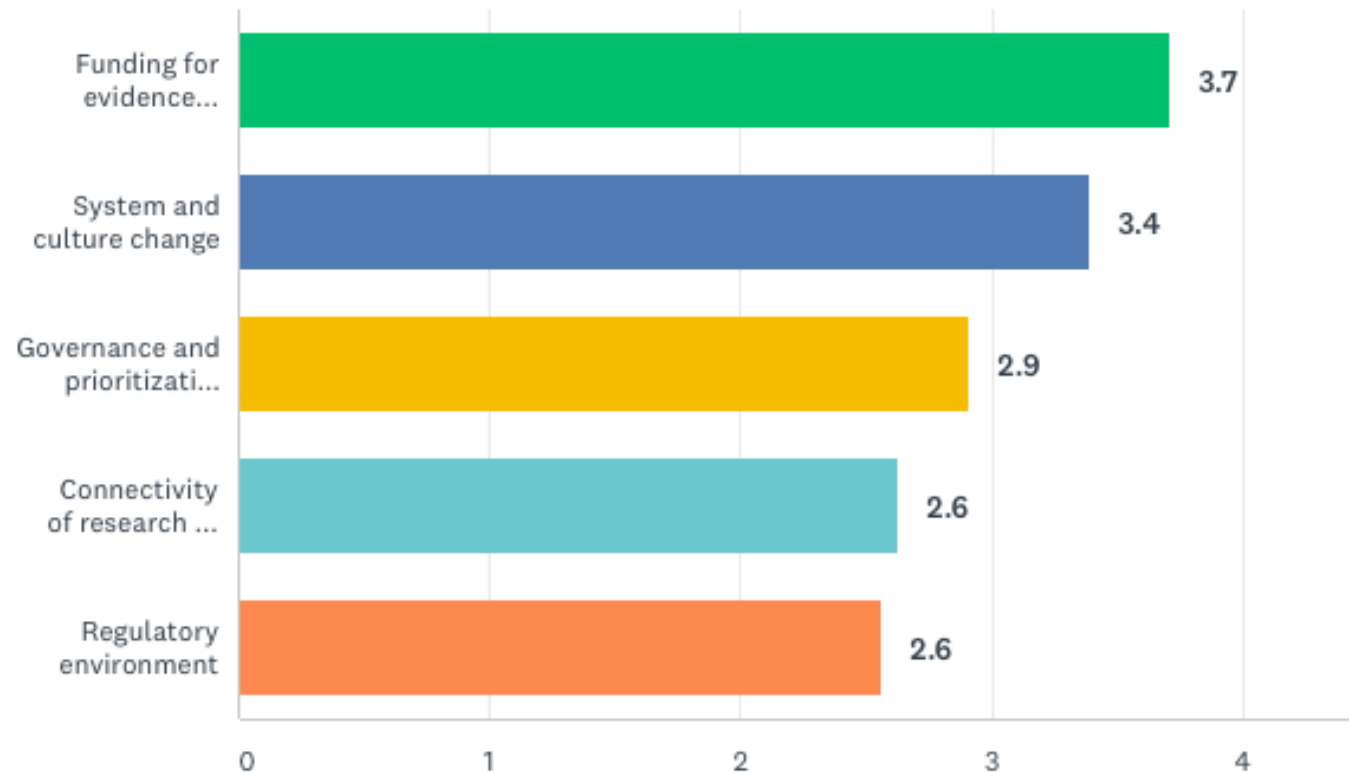
Respondents that answered 'other' provided the following suggestions:

- 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.

Answered: 33 Skipped: 8



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 disconnectivity (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 indicators (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.