Provincial Quality Management Programs

for Colonoscopy, Mammography and Pathology in Ontario

March 2015

Quality Management Partnership

THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

Ontario
Cancer Care Ontario
Action Cancer Ontario

"I believe the work of the QMP is important for patients as it will improve health outcomes, patient safety and the overall patient experience. It is important for providers as it will help to streamline processes, encourage collaboration and ensure consistency across the spectrum of providers. It is important for the Ontario healthcare system as it will improve transparency, efficiency and the overall quality of care provided in the province."

Jill Carmichael Adolphe, expert advisory panel member and patient/service user

Quality Management Partnership Phase 2 Report
Published March 2015

Message from the Partnership Executive

In March 2013, when the Ministry of Health and Long-Term Care asked Cancer Care Ontario (CCO) and the College of Physicians and Surgeons of Ontario (CPSO) to form the Quality Management Partnership (the Partnership), the two organizations came together as partners with the goal of improving the quality and consistency of care in three health service areas: colonoscopy, mammography and pathology.

Working together, we built the internal teams to conduct the work, formed expert advisory panels consisting of providers, patients/service users and other health service experts to inform our efforts, and consulted with broad groups of stakeholders to better understand the landscape and potential impacts of our recommendations. Through these efforts, our understanding of the work needed to improve quality in the three services – as well as the impact this type of partnership can have on provincial health systems – has grown exponentially.

As we conclude this phase of the work to design quality management programs, it is clear that the Partnership is not just between CCO and CPSO, but with the many providers, patients/service users, healthcare leaders and administrators who have so generously shared their time, expertise and feedback with us throughout this process.

This report reflects our continued commitment to work together with our partners across Ontario's health system. Together, we will develop the processes, structures, standards and guidelines that will help us achieve our goals of increased quality of care and improved patient safety, increased consistency in the quality of care provided across facilities and improved public confidence through increased transparency.

As we move forward in the next phase of this journey, we will continue to engage our partners and stakeholders to align the work of the Partnership with other quality initiatives across the system, and to strengthen the role that patients/service users play in guiding our work.

We thank everyone who participated in and contributed to this effort and we look forward to taking these next steps with you to make healthy change happen.

Michael Sherar
President and CEO
Cancer Care Ontario

Dr Rocco Gerace
Registrar
College of Physicians
and Surgeons Ontario

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1.0 Executive Summary

1.1 Background

Ontario has embarked on a transformation journey to improve the quality of health care delivered in the province and ensure that patients/service users[1] can access high-quality, safe and effective services when they need them, regardless of where they live or receive their care.

It was in this context that, on March 28, 2013, Susan Fitzpatrick, then Assistant Deputy Minister, Negotiations and Accountability Management at the Ministry of Health and Long-Term Care (MOHLTC) announced the formation of the Quality Management Partnership (the Partnership) between Cancer Care Ontario (CCO) and the College of Physicians and Surgeons of Ontario (CPSO). She directed the Partnership to work closely with stakeholders to develop quality management programs (QMPs) for three health service areas: colonoscopy, mammography and pathology. The two organizations have experience with quality initiatives in these health service areas and are well positioned to lead the development of consistent approaches to quality for all providers and facilities across Ontario. The Partnership will not make changes to physician regulation, and CPSO will continue to be the sole regulator of physicians in Ontario.

1.2 Process

The Partnership began its work in April 2013, guided by the Partnership Steering Committee, chaired by the President and CEO of CCO and the Registrar of the CPSO and with membership from senior executives from the two organizations. System-level guidance and advice was provided to the steering committee through a Healthcare System Reference Group, which had representation from leading experts and key Ontario healthcare organizations.

The Partnership recruited a provincial clinical lead for each health service area and established three expert advisory panels that included physicians and other health professionals who practice in the health service area, administrators and patients/service users. Between September 2013 and March 2014, the panels developed a preliminary sketch of the design for QMPs and identified 12 early quality initiatives that will move the province towards QMPs. The Partnership began a preliminary analysis of the information management and information technology (IM/IT) impacts of the QMPs and the legislative and regulatory requirements for the early quality initiatives. After consultation with stakeholders, a Phase 1 report detailing this work was submitted to the MOHLTC in March 2014.

Between April and December 2014, the panels developed detailed design recommendations for the three QMPs. Preliminary analyses of the IM/IT and legislative and regulatory impacts were completed, the early initiatives were started, and implementation and operations planning began, including developing an evaluation framework. During this time, some initiatives began that may change the landscape for quality management in the future. They include Health Quality Ontario's project to design a province-wide physician peer review program for all facilities where diagnostic imaging services are provided, and its review of current oversight programs for out-of-hospital premises and independent health facilities. During implementation, the Partnership will align with any system changes that have occurred as a result of these initiatives.

A major focus during Phase 2 was a broad stakeholder consultation process. Overall, stakeholders were supportive of the Partnership's work and the QMP recommendations. However, some concerns were raised around resourcing for the QMPs and how data will be collected consistently across the province, reported and appropriately interpreted. Stakeholders also stressed the importance of aligning with existing initiatives and recommended that the Partnership proceed with implementation in a thoughtful manner, phasing in the QMPs over time.

1.3 Goals and Principles

The Partnership has three goals for the QMPs:

- Increase the quality of care and improve patient safety
- Increase the consistency in the quality of care provided across facilities
- Improve public confidence by increasing accountability and transparency

To guide its work, the Partnership adopted the principles that the QMPs will be:

- Required for all providers and facilities that provide the health service

1 Many people who use the health services – colonoscopy and mammography in particular – are not sick and have the procedures for routine screening purposes only. Therefore, this report refers to people who use the health services as "patients/service users".

- Patient-centred
- Focused on fostering quality and protecting the public interest, while balancing confidentiality with transparency
- Based on collaboration and alignment
- Value-added
- Supportive and educational
- Appropriately resourced to support implementation

1.4 Quality Management Programs

The QMPs will be provincial and mandatory for all providers and facilities. They will be supportive, enhance transparency and encourage quality improvement while providing mechanisms and escalation processes to appropriately manage quality concerns.

The QMPs will promote safe, high-quality care and benefit patients/service users, providers and the healthcare system by:

- Establishing provincial standards that will be consistently applied across all care settings where these services are provided
- Reporting on quality at the provider, facility and regional levels and providing clear lines of accountability for quality of care and patient safety
- Addressing current inconsistencies and gaps in quality assurance programs and processes

The Partnership will support and foster a culture of continuous quality improvement by putting in place a supportive network of clinical leads for each health service area at the provincial, regional and facility levels. The leads will be responsible for monitoring quality and engaging with providers and facilities to support continuous quality improvement and managing quality concerns if they arise. All leads will be practicing physicians with expertise in the health service area. The provincial and regional leads will be selected through an open and transparent process. The facility will be responsible for identifying their facility lead and aligning this role with existing accountability structures and processes for quality. The leads will receive leadership support to orient them to their new responsibilities and will be encouraged to work collaboratively in carrying out their roles.

Each QMP will be guided by a provincial committee that is chaired by the QMP provincial lead and includes the QMP regional leads, other relevant clinical leads and non-physician providers, patients/service users and other subject matter experts as required. Efforts will be made to ensure that the committee members include representation of the relevant facility types. The provincial committees will:

- Provide overall guidance and leadership for the QMPs
- Advise on program priorities, recommendation refinement and future areas of expansion
- Provide recommendations for improvement opportunities across the health service area
- Support change management and knowledge translation and exchange across the province

The following core processes will be foundational to the QMPs and were considered by each of the expert advisory panels as they made detailed recommendations specific to their health service areas:

Defining standards, best practice guidelines and indicators

Defining quality involves establishing the standards, best practice guidelines and indicators to provide a foundation for quality reporting, assurance and improvement processes. The expert advisory panels used their knowledge, skills and judgment to recommend guidelines, standards and indicators that, if applied across the province, will facilitate consistent, high-quality care in Ontario. The Partnership assessed the evidence that supports each standard, guideline and indicator using its own scale that considered the extent to which the recommendations are supported by published evidence and literature, and adopted in other jurisdictions.

Defining quality involves establishing the standards, best practice guidelines and indicators to provide a foundation for quality reporting, assurance and improvement processes.

Facilitating the uptake and adoption of provincial standards and best practice guidelines

To streamline processes, align with existing quality initiatives and prevent duplication, the QMPs will work with other programs and organizations to integrate the recommended provincial standards and best practice guidelines into existing inspection, assessment or accreditation programs. In many cases this will involve expanding or modifying an existing program, but when a gap is identified in an

inspection, assessment or accreditation program, the QMPs will look to fill that gap by collaborating with existing organizations. The provincial committees will advise on, support and monitor the adoption of the QMP standards and guidelines.

Generating and distributing quality reports

Measuring and reporting quality indicators at the provider, facility, regional and provincial level is critical to understanding the current level of quality, making informed decisions around quality improvement investments and monitoring the effectiveness of quality improvement efforts over time. Quality reporting also promotes transparency and accountability for the broader health system to help support and drive quality improvements.

The provincial committees will be responsible for reviewing and monitoring aggregate quality reports. Responsibility for reviewing individual provider- and facility-level data will be limited to QMP leads because they have the relevant clinical knowledge and expertise to appropriately interpret these data.

QMPs will foster a culture of quality improvement by assisting providers, facilities and regional leaders to develop the skills, knowledge and resources they need to deliver high-quality care.

Quality reports will be issued to providers, facilities and the QMP leads and will be used as an input into a quality management process that:

- Monitors quality at all levels
- Supports continuous quality improvement discussions with providers and facilities
- Identifies providers and facilities where there may be a quality issue
- Provides clear lines of accountability for validating and exploring the cause of the issue and recommending and confirming that quality improvement activities are completed

Supporting quality assurance and continued quality improvement

The QMPs will foster a culture of quality improvement by assisting providers, facilities and regional leaders to develop the skills, knowledge and resources they need to deliver high-quality care. These resources will include educational supports for providers, process improvements for facilities and regions and may include system-level initiatives at the provincial level. QMP leads at the appropriate level will support and facilitate quality improvement.

"Quality of care means to me that my care stands out and is directed specifically to ensure my needs are consistently met. I am a partner in the decision making – the provider is not just doing to or for me, but with me."

Joanne MacPhail, patient/service user

It is possible that quality reporting and monitoring will highlight occasions where quality standards are not being met such that there is a potential threat to patient safety. Recognizing this, the Partnership is developing a process to identify and act on these cases in a timely and responsible way. This process will be integrated with and support existing local facility quality management processes. The process will address clinical and facility concerns requiring improvements. The focus will be on optimizing patient safety and providing accountability for quality concerns in the rare instances when quality improvement is no longer effective. This may lead to referral to the CPSO for a more structured interaction, if required.

QMP enablers

IM/IT infrastructure is required to enable data collection and quality reporting for the three health service areas. Existing data and IM/IT infrastructure and processes will be used wherever possible to minimize the burden of data collection. Opportunities for greater clinical information sharing and standardized clinical reporting will continue to be explored.

Legislative and regulatory changes may be required to support the Partnership's goals and move forward with the Partnership's work, both in the short- and long-term. Initially, CCO can rely on its existing authority as a prescribed entity under the Personal Health Information Privacy Act (PHIPA) to collect, use and disclose many of the quality indicators identified by the expert advisory panels. More analysis and work with the MOHLTC, CCO and the CPSO will be undertaken to establish and propose the necessary legislative and regulatory changes required to mandate participation in the QMPs and address legislative gaps.

1.5 Patient-Centred Approach

A key principle for the Partnership is to be patient-centred. The Partnership delivers on this principle by:

- Having patients/service users involved in the design and delivery of QMPs
- Measuring patient experience in order to engage patients/service users in providing feedback on the care they received and support improved patient-centred care at the provider and facility levels
- Working with patient/service user and public representatives to develop a communications strategy that will provide accurate, relevant and timely information to patients and the public

Patients/service users have participated on the expert advisory panels and assisted in the development of recommendations for the design of the QMPs. In addition, patients'/service users' views and experiences were actively sought during the consultation process. The Partnership's focus on providing patients/service users with accurate, relevant and timely information to enable them to be engaged in their care arose, in large part, as a response to patient/service user advice and feedback.

QMPs must be seen by patients/ service users to improve the quality of the care they experience in ways that matter to them.

Going forward, patient-centredness will be strengthened. Patients/service users will be more deeply involved in Partnership governance, sitting on the provincial committees as well as a newly created Citizens' Panel that reports directly to the Partnership steering committee. Measuring patient experience will be an early focus of activity, with an IM/IT solution already in progress. More broadly, as the QMPs are implemented, patients/service users will be a key stakeholder group that is targeted for engagement and communication.

Overall, the QMPs must be seen by patients/ service users to improve the quality of the care they experience in ways that matter to them.

1.6 Implementation

Impact and resourcing are key considerations when planning to implement an initiative of this size and complexity, and the Partnership consistently heard this from stakeholders. The Partnership is proposing a phased, multi-year implementation approach that prioritizes and sequences activities based on their importance for delivering high-quality care, the availability of resources to support implementation and stakeholder support. Early implementation activities will focus on establishing and supporting the network of QMP provincial, regional and facility leads and the provincial committees to lead the changes required to enable this method of quality management in health care across the province. Evidence-based methods and best practices will be used to guide implementation and change management activities. Stakeholder engagement and communications activities will continue throughout the planning and implementation phases. Implementation activities will start in 2015/16.

1.7 Evaluation

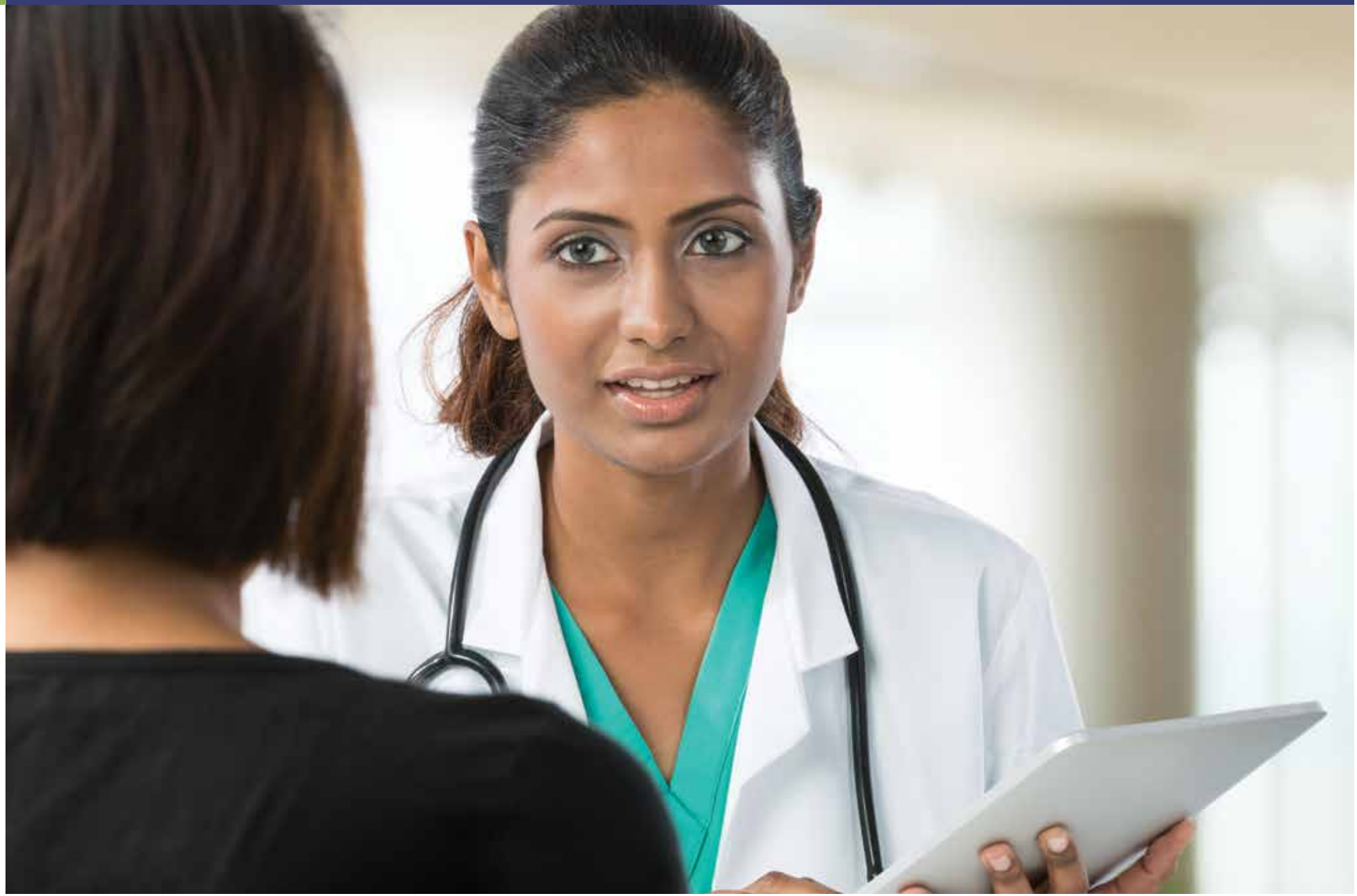
The QMPs represent a new way of driving quality improvement in Ontario and significant resources have been dedicated to help ensure their success. The Partnership is committed to evaluating the effectiveness of the QMPs over time. This evaluation will provide valuable feedback to the Partnership to enable course corrections during implementation and build evidence about the best ways to improve quality in health care.

In order to evaluate the effectiveness of the QMPs, a framework has been developed to assess whether the Partnership achieves its goals for the QMPs, which are:

- Increase the quality of care and improve patient safety
- Increase the consistency in the quality of care provided across facilities
- Improve public confidence by increasing accountability and transparency

Given that implementation will be phased in over time, the evaluation will also be staged. The first stage will focus on exploring the extent to which the foundational elements of the programs are in place and obtaining qualitative feedback on the progress of the Partnership to support course correction during implementation. The second stage will be more summative in nature, and will evaluate the extent to which the Partnership has achieved its overall objectives, the QMPs as an approach to improve quality of care and the value for money provided by the Partnership.

2.0 Introduction



2.1 The Transformation Journey

Ontario has embarked on a transformation journey to improve the quality of health care across the province. There are a number of reasons the province has decided to go down this path, including:

- Ensuring that people get the right care, at the right time, in the right place
- Increasing transparency and accountability across the healthcare system
- Actively engaging patients in their health care

Patient safety is a key component of quality care. Patients/service users expect – and deserve – to receive high-quality, safe and effective care. All healthcare providers want to deliver the best quality care, yet research shows that too often the ideals of high-quality, safe and effective care are not realized, despite providers' best intentions. The Canadian Adverse Events Study,[2] published in 2004, found that adverse events occurred in 7.5 per cent (185,000) of hospitalizations in Canada, and 38 per cent (70,000) of these adverse events were preventable. Ten years later, despite intensive efforts and investments, it does not appear that care is reliably safer than it was.[3]

High-quality, safe and effective care is based on evidence and best practice.

High-quality, safe and effective care is based on evidence and best practice. Facilities and providers may not realize that the care they deliver does not meet standards until they receive reports that show where they are meeting benchmarks and where they need to improve. This type of audit and feedback is optimized when it is presented by a colleague or supervisor, delivered both orally and in writing, and includes clear targets and an action plan.[4] Expanding reporting and ensuring that educational quality improvement supports are in place will increase transparency and accountability across the healthcare system in fundamental ways.

Reducing variability by basing care on evidence and best practice has other benefits as well. Costs decrease as waste and duplication are eliminated, adverse events are minimized and patient outcomes are improved.[5] Providers and facilities must deliver consistent, evidence-based and cost-effective care to Ontarians wherever they live and whether they are treated in a hospital or community setting.

Every actor in the healthcare system has a role to play in providing high-quality care. Patients have a role in defining what quality means to them and, with adequate support, being active and engaged in their care if they so choose. The healthcare system can empower patients to be actively involved in their care by ensuring they have access to relevant and useful tools and information. In practice, this will involve increased transparency – subject to required privacy and confidentiality protections – so that patients have access to accurate, relevant and timely information about the safety and quality of care in Ontario.

The healthcare system can empower patients to be actively involved in their care by ensuring they have access to relevant and useful tools and information.

2.2 Creation of the Partnership

It was in the context of this transformation that Susan Fitzpatrick, then Assistant Deputy Minister, Negotiations and Accountability Management at the Ministry of Health and Long-Term Care (MOHLTC), announced the creation of the Quality Management Partnership (the Partnership) on March 28, 2013, in a memorandum that was widely distributed across the healthcare system (see Appendix A).

In the memorandum, the MOHLTC asked Cancer Care Ontario (CCO) and the College of Physicians and Surgeons of Ontario (CPSO) to work together to develop provincial quality management programs (QMPs), initially for three health service areas: colonoscopy, mammography and pathology. The two organizations have experience with quality initiatives in these three health service areas, and are well-positioned to lead the development of consistent approaches to quality for all providers and facilities across Ontario. The MOHLTC directed the Partnership to work in close collaboration with

2 Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. The Canadian Adverse Events Study: The incidence of adverse events among hospital patients in Canada. CMAJ. 2004;170(11):1678-86.
3 Baker GR. An opportunity for reflection. Healthcare Quarterly. 2014;17: 1-2.
4 Ivers N, Jamtvedt G, Flottorp S, Young JM, Odgaard-Jensen J, French SD, et al. Audit and feedback: effects on professional practice and healthcare outcomes. Cochrane Database Syst Rev. 2012;6:CD000259.
5 James BC, Savits LP. How Intermountain trimmed health care costs through robust quality improvement efforts. Health Affairs. 2011;30(6):1-7.

clinical experts, system partners and all other relevant stakeholders, including patients/service users.[6] It must be noted that the Partnership will not make changes to physician regulation, and CPSO will continue to be the sole regulator of physicians in Ontario.

Colonoscopy, mammography and pathology were chosen as the initial focus for several reasons. First, these three service areas already share a foundation of quality management activity upon which the Partnership can build. Second, incidents in each of the three health service areas have revealed quality and safety concerns that have shaken public confidence. Third, there is a perception that the quality of care differs depending on where the services are provided, underlining the need to ensure that all Ontarians have access to consistent, high-quality care in all facilities providing these services. Finally, the Partnership supports Ontario's Patients First: Action Plan for Health Care (2015) and its broad quality agenda that focuses on continuous improvement and transparency across the health system.

The two organizations have experience with quality initiatives in these three health service areas, and are well-positioned to lead the development of consistent approaches to quality for all providers and facilities across Ontario.

2.3 Partnership Goals

In keeping with the MOHLTC's transformation agenda, the Partnership has identified three goals for the provincial quality management programs (QMPs):

- Increase the quality of care and improve patient safety
- Increase the consistency in the quality of care provided across facilities
- Improve public confidence by increasing accountability and transparency

2.4 Work to Date

The Partnership began its work formally in April 2013. During the first few months, the Partnership engaged three clinical leads (one for each health service area), and established three expert advisory panels. The relevant health professional associations circulated requests for letters of interest and were involved in interviews for the leads; the associations made recommendations on lead hiring and on physicians to sit on the panels. For more information on the clinical leads and membership of the expert advisory panels, see Appendix B.

Between September 2013 and March 2014, the panels developed a preliminary sketch of the design for provincial QMPs and initiated implementation of 12 early quality initiatives to move the province towards provincial QMPs. For more information on these early initiatives, see Appendix C.

The Partnership also commenced an analysis of potential information management and information technology (IM/IT) solutions, and the legislative and regulatory impacts of the early quality initiatives. After consultation with stakeholders, the Phase 1 report detailing this work was submitted to the MOHLTC in March 2014.

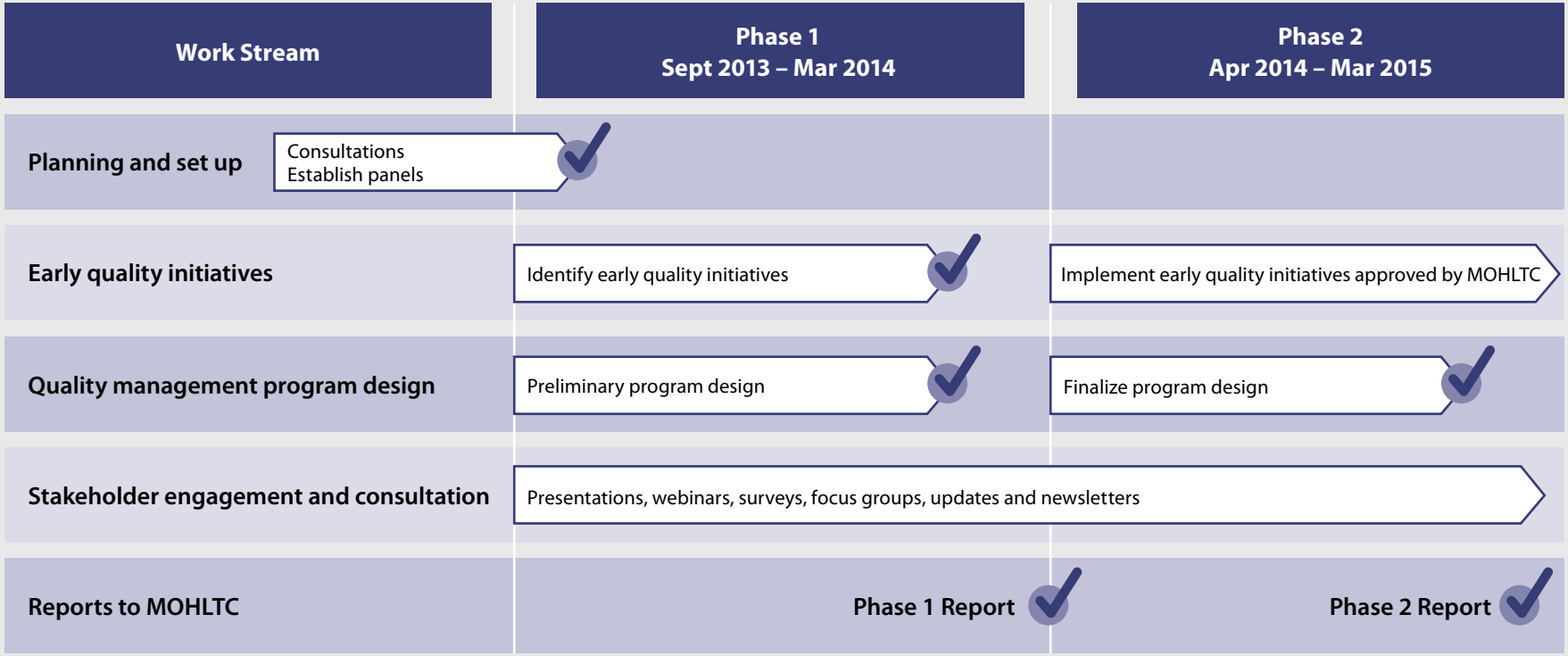
In April 2014, the Partnership began the second phase of its work. Between April and December 2014, the panels developed detailed design recommendations for the provincial QMPs and initiated implementation of the early quality initiatives. Broad consultations were held from October through December 2014 to gather feedback from key stakeholders and this input was considered as the Partnership refined and finalized the recommendations for the QMPs. The Partnership also completed its analysis of IM/IT impacts.

The Partnership acknowledges that during this same time period, some parallel initiatives have been occurring that may change the landscape for quality management in the future. They include Health Quality Ontario's project to design a province-wide physician peer review program for all facilities where diagnostic imaging services are provided, and its review of current oversight programs for out-of-hospital premises and independent health facilities. During implementation, the Partnership will align with any system changes that have occurred as a result of these initiatives.

Figure 1 shows a high level workplan and timelines for work completed during Phases 1 and 2.

6 Many people who use the health services – colonoscopy and mammography in particular – are not sick and have the procedures for routine screening purposes only, leading some to argue that "service users" is a more appropriate label than "patients". This report uses the terminology patients/service users to refer to people who use the health services.

Figure 1 **High-level workplan and timelines**



3.0 Approach and Methodology

3.1 Guiding Principles

Based on the Ministry of Health and Long-Term Care's (MOHLTC's) direction, literature on quality management and advice from healthcare leaders in Ontario and other jurisdictions, the Quality Management Partnership (the Partnership) adopted the principles below to guide its work.

Provincial quality management programs (QMPs) will be:

1. **Required for all providers and facilities that provide the health service** – The QMPs will apply to all providers and all facilities that provide the health service in Ontario. This will ensure the same standard of quality is applied to all care settings across the province.

2. **Patient-centred** – Patients/service users will continue to be involved in the design and delivery of the QMPs. The programs will support and enable patients/service users who wish to be engaged in their care by providing them with accurate, relevant and timely information.

3. **Focused on fostering quality and protecting the public interest, while balancing confidentiality with transparency** – The Partnership will rely on evidence and data to demonstrate where quality is being achieved and where support for improvement is needed. Data collection, use and disclosure will occur in a controlled manner that is compliant with legislative requirements and supports high-quality, safe and effective health care.

4. **Based on collaboration and alignment** – The Partnership will continue to consult closely with providers and health service organizations to identify opportunities to collaborate to embed best practices across the province. Where possible, the Partnership will support and augment existing programs and processes rather than duplicate what already exists or reinvent the wheel.

5. **Value-added** – The Partnership will add value by creating a clear accountability structure for quality while supporting knowledge transfer and exchange. The Partnership will use evidence to drive improvement efforts, enhance and reinforce quality initiatives already underway and develop capacity for spreading best practices across the province.

6. **Supportive and educational** – The Partnership will foster a culture of continuous quality improvement to support providers to learn and continuously improve. The Partnership will work with providers and other stakeholders to develop reasonable processes for quality improvement and continuing professional development. In order to enhance patient safety, existing regulatory and/or funding frameworks will remain an option when required.

7. **Appropriately resourced to support implementation** – The timelines and approach to implementing the QMPs will require an assessment of the impact on facilities and the availability of resources. The QMPs will be phased in to ensure that appropriate resources are in place to support successful implementation.

3.2 Governance

The Partnership is guided by a steering committee that is chaired by the President and CEO of Cancer Care Ontario (CCO) and the Registrar of the College of Physicians and Surgeons of Ontario (CPSO), with membership from senior executives from the two organizations. The committee gains system-level guidance and advice from a Healthcare System Reference Group, which is chaired by the President and CEO of Health Quality Ontario and has representation from key Ontario health organizations, system leaders and academic researchers.

For steering committee and the Healthcare System Reference Group membership, see Appendix D.

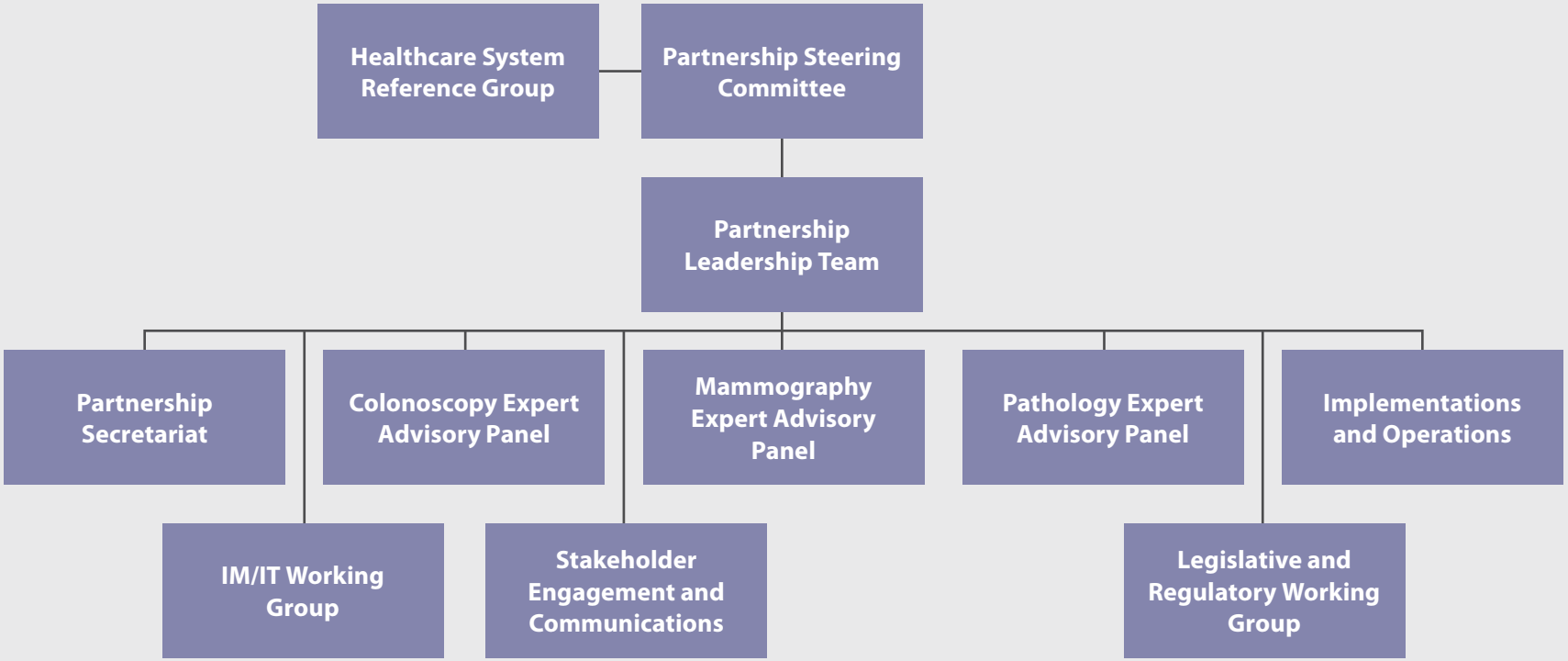
Three clinical leads have provided strong clinical leadership for the Partnership's work. The clinical leads chaired their respective expert advisory panels, which included physicians, other health professionals who provide the service, healthcare administrators and patients/service users.

Working groups were established to develop IM/IT solutions, assess the need for potential legislative and regulatory changes, plan stakeholder engagement activities and begin implementation planning. The work of the Partnership is supported by a secretariat.

A Leadership Team, chaired by a CCO and a CPSO senior executive and with representation from the clinical leads, working group members and a staff secretariat, oversees the day-to-day work of the Partnership.

A high-level overview of the governance structure is in Figure 2.

Figure 2 **Governance structure**



3.3 Components of a Quality Management Program

The Partnership recognized that the three health service areas are quite different. Mammography is one of several diagnostic imaging modalities and is used primarily by radiologists to screen for and diagnose breast cancer and other breast conditions. Colonoscopy is generally performed by gastroenterologists and surgeons and is an essential tool in screening, diagnosis and treatment of gastrointestinal concerns. Pathology is unique in that it addresses an entire professional practice, rather than a specific health service such as mammography and colonoscopy

Given the diverse nature of the health service areas, the Partnership recognized the need for a common framework to guide the development of provincial QMPs. Based on a review of the literature, advice from the expert advisory panels and consultation with stakeholders, the Partnership determined that the QMPs must have the five components shown in Figure 3.

Quality defined

Defining quality facilitates consistency in the delivery of care across the province and provides a foundation for quality reporting and quality assurance activities. Quality definitions include standards, best practice guidelines, indicators and targets/thresholds that are informed by evidence, widely accepted, clearly articulated and applicable to all providers and facilities that provide the service.

- **Provincial standards:** Recommendations about minimum acceptable levels of quality for

providers and facilities based on evidence and best practice. Standards must be monitored to ensure compliance.

- **Best practice guidelines:** Recommendations about acceptable levels of quality based on evidence and best practice. Guidelines describe what providers and facilities should do to achieve quality care.
- **Indicators:** Quantitative measures to monitor and evaluate quality and measure whether improvements are made over time.
- **Targets/thresholds:** Expected levels of achievement for indicators. In order to be achievable, targets are generally developed after a period of data collection and analysis to document current achievement.

Figure 3 **Quality management program components**

The Partnership considered existing evidence-based standards and guidelines that are already in place in Ontario, Canada and other jurisdictions and recommended those that, if endorsed, could have a positive impact on quality in the province. Defining quality will be an on-going activity and will proceed with expert clinical guidance and in consultation with stakeholders as new evidence is developed.

Quality reporting

A key component of provincial QMPs is an integrated data-gathering infrastructure to facilitate the production and distribution of reports to measure provider- and facility-level quality indicators consistently across the province. Measuring and reporting quality indicators is critical to understanding the quality of care provided, making informed decisions about quality improvement investments and monitoring achievement over time. Reporting also promotes transparency and accountability for quality across the system.

In order to reduce the burden of additional data collection, the Partnership considered existing data currently reported in Ontario that could be used to report evidence-based quality indicators for the three health service areas. In many cases, the data that are needed to generate the recommended quality indicators are already being gathered. In other cases, additional data collection will be required. The IM/IT and legislative and regulatory working groups are developing strategies to permit CCO to collect and report the required indicators on behalf of the Partnership. It will take time and resources before all the required data collection processes and technology are in place across the province.

Quality assurance
Quality assurance programs and processes establish clear accountability for ensuring that quality is being achieved. These programs and processes periodically assess achievement, providing a consistent way to monitor adherence to standards across all providers and facilities.

Defining quality will be an on-going activity and will proceed with expert clinical guidance and in consultation with stakeholders as new evidence is developed.

A number of quality assurance programs and processes are already in place for each of the health service areas. The Partnership considered where to recommend addressing inconsistencies and/or filling gaps in order to ensure a consistent, comprehensive approach to quality assurance for all providers and facilities.

Quality improvement
The Partnership will support and foster a culture of continuous quality improvement and require participation in quality improvement activities for providers and facilities that do not meet minimum standards. For providers, quality improvement often involves educational support to improve clinical skills and abilities. For facilities and regions, quality improvement often involves process improvement that may occur within the facility or region itself, or may target processes between facilities or regions.

Sufficient programs and supports must be in place to foster quality improvement. The Partnership considered the range of quality improvement activities available to providers and facilities in Ontario and identified gaps for consideration.

Quality by design
System-level changes may be required to improve quality for the province overall. Quality management should include processes for identifying and evaluating potential changes to healthcare system design in Ontario that will support significant quality improvement across the system. The Partnership is already learning about potential quality by design recommendations through its work on early quality initiatives identified in Phase 1 and will develop these further as its work proceeds.

3.4 Designing Quality Management Programs

The expert advisory panels developed detailed design recommendations for provincial QMPs based on the five components outlined above. The panels were instructed to consider adopting existing evidence-based standards and guidelines and building on current quality initiatives where possible. They focused on addressing inconsistencies and filling gaps in order to ensure a consistent, comprehensive approach to quality for all providers and facilities across the province.

All five components are essential for effective quality management. The detailed recommendations in this report focus on quality defined, quality assurance, quality reporting and quality improvement, with minimal emphasis on quality by design.

The initial work of the Partnership has involved establishing a core program that defines minimum standards, monitors achievements against those standards and puts in place supports to ensure that all providers and facilities can achieve minimum standards by engaging in continuous quality improvement. Implementing provincial QMPs of this size and complexity will require a phased, multi-year approach, and once strong programmatic foundations are laid, detailed work on health system design recommendations will proceed.

The approach to designing QMPs that the Partnership has developed can be applied to other health service areas in future.

Quality assurance programs and processes establish clear accountability for ensuring that quality is being achieved.

3.5 Consultation and Engagement

Throughout Phase 1, the Partnership consulted closely with stakeholders and this focus continued in Phase 2. In particular, during Phase 2, a strategic communications plan was developed to help inform stakeholders on the purpose of the Partnership and to obtain feedback on selected recommendations for the QMPs. Specific engagement activities targeted to providers, administrators and patients/service users were developed.

Providers and health system administrators were informed of emerging recommendations from the expert advisory panels through various activities and they provided early feedback on the design recommendations. The Partnership's broader engagement work came through a consultation process with in-person and online components. The consultation process was designed to engage thought leaders from organizations and associations representing key stakeholders. The goal was to gain stakeholder input about select Partnership recommendations and identify potential challenges the Partnership may encounter.

The Partnership also ensured that patient/service user voices were heard. This was facilitated through patients/service users who served on the expert advisory panels, as well as CCO's Patient and Family Advisory Council. Patients/service users provided input and advice on what is important to them as it relates to quality in these three health services. Patients/service users also provided feedback online.

For an in-depth description of the consultation process, see Appendix E.

> "As a patient I can contribute an essential perspective to discussions about a delivery system that in the end concerns me. It is absurd to consider healthcare improvement without involving patients."
>
> Jacques Lupien, expert advisory panel member and patient/service user

4.0 Stakeholder Feedback and Insight

The Quality Management Partnership's (the Partnership's) consultation and engagement activities provided opportunities for stakeholders to comment on its goals, selected recommendations for the quality management programs (QMPs) and potential implementation challenges. The consultation and engagement activities yielded meaningful feedback that has been analyzed, carefully considered and incorporated when feasible. This section provides an overview of the stakeholder feedback that was obtained.

4.1 Patients, Service Users and Members of the Public

Patients, service users and members of the public were asked about their expectations for a quality management program and were invited to share their experiences in the three health service areas. Stakeholders noted that consistent standards of care, patient experience measures and quality reporting are important aspects of a quality management program. They identified timely access to services, adequate follow-up, clear communication and access to information about the quality of the facilities where they receive care as important components of high-quality care. Some emphasized that it is important for them to be adequately informed so that they can be involved in decisions made about their care.

The feedback obtained from the consultation and engagement activities adds to the Partnership's growing understanding of stakeholder perspectives and concerns and will be considered as the Partnership moves forward with implementation planning for the QMPs.

4.2 Health Service Area Providers and Health System Administrators

Providers and administrators appreciated the opportunity to provide feedback and were generally supportive of the concept of the QMPs and the Partnership's goals, but they also used this opportunity to provide constructive feedback. Although there was some specific feedback regarding particular recommendations and indicators, most of the feedback was related to implementation considerations. Many of these were common across stakeholder groups and are described below.

Resourcing

Stakeholders are supportive and interested in improving quality; however, adequate and sustained resourcing at the local level was identified as a critical success factor for implementation of the QMPs. Participants emphasized that both human and financial resources are needed to support local infrastructure, information management and information technology (IM/IT) solutions, capital expenses (e.g., equipment) and additional professional and administrative human resource needs.

Data quality and data interpretation

Stakeholders stressed that the indicators selected for each of the QMPs must be accurately measured to enable the Partnership to drive quality improvement. Clear indicator definitions are required to facilitate accurate data collection and reporting. Participants indicated that comparing data across facilities that serve different populations (e.g., proportion of screening vs. non-screening patients) could result in misinterpretation of the data. There was also feedback that there may be unintended consequences of collecting and reporting selected indicators, driving providers and facilities to do things that could negatively influence quality (e.g., changes in practice patterns, redistribution of services). There was feedback that the data could be used in a punitive fashion or for matters unrelated to quality improvement.

Stakeholders indicated that knowledge translation should be supported to allow providers, facilities and regions to learn from each other, and that sharing information across the three health service areas could provide opportunities for learning.

Quality improvement and continuing professional development supports must be made available

Stakeholders emphasized that the focus of the QMPs should be continuous quality improvement. To achieve this objective, adequate support and capacity for quality improvement will be required. Participants indicated that continuing professional development and training opportunities that are peer-driven and non-punitive are needed to facilitate remediation and continuous improvement. Furthermore, there should be equal access to appropriate learning opportunities, regardless of the type of facility. Stakeholders were concerned about the capacity of small facilities to implement quality improvement because they may have greater challenges with resourcing and expertise. Stakeholders also stressed that buy-in from administrators will be needed to support local initiatives. Stakeholders indicated that knowledge translation should be supported to allow providers, facilities and regions to learn from each other, and that sharing information across the three health service areas could provide opportunities for learning.

Phase implementation and move slowly

Although participants generally agreed that the QMPs have the potential to improve quality, they also recognized the impact that implementation will have on providers and facilities. Participants advised the Partnership to continue to engage stakeholders to understand the impact of the programs. They emphasized that an iterative, multi-phased approach would allow learnings to be incorporated and integrated into future phases. There was support expressed for prioritizing recommendations and indicators; stakeholders also suggested pilot-testing before broadly implementing across the province.

> "I believe as service users we have a responsibility to contribute to the ongoing improvement of the system … I feel that I was able to contribute to this initiative and bring a different perspective to the table."
>
> Jacquie Brown, expert advisory panel member and patient/service user

Align with existing quality and continuing professional development initiatives

Stakeholders recognized that there are numerous quality and continuing professional development initiatives in Ontario, and identified integration and alignment with these initiatives as a critical success factor for implementation.

Stakeholders noted that consistent standards of care, patient experience measures and quality reporting are important aspects of a quality management program.

Transparent selection process for provincial and regional QMP leads

Stakeholders suggested that the effectiveness of the quality management model will depend on the interests and skill sets of the individuals in the QMP lead positions, and recommended that the quality management model be evaluated. Stakeholders emphasized that the QMP leads must be recruited using a transparent and robust process to ensure that the most appropriate candidates are selected and that there is representation from all facility types in the province. Candidates must have experience in quality management and be passionate about quality improvement. The feasibility of merging QMP clinical lead roles with existing lead roles should be considered to facilitate integration and alignment; capacity and expertise are also important factors to consider.

Scalability of clinical leadership structure

Despite general agreement that the quality management model has the potential to improve quality, there was concern that a three-tiered structure might be too bureaucratic in practice. Some stakeholders advised that quality is best managed locally, and that regional and provincial oversight is not required. Stakeholders also indicated that there may be insufficient expertise within facilities and regions to allow recruitment of all QMP leads, and that this model may not be easily scalable if more QMPs are developed in the future.

The feedback obtained from the consultation and engagement activities adds to the Partnership's growing understanding of stakeholder perspectives and concerns and will be considered as the Partnership moves forward with implementation planning for the QMPs.

For a detailed summary of the stakeholder feedback, see Appendix F.

5.0 Quality Management Program Design

5.1 Overview of a Quality Management Program

The Partnership has developed quality management programs (QMPs) to increase the quality and consistency of care across facilities, improve patient safety and increase accountability and transparency across the healthcare system. To support the design and implementation of QMPs across three different health services areas, the Partnership identified a common approach to governance and to processes to define quality, monitor change and support quality improvement. Common supporting enablers – information management and information technology (IM/IT) solutions and privacy, legislative and regulatory requirements – have also been identified.

The QMPs will be provincial programs that are mandatory for all healthcare providers and facilities that provide the identified health services. The QMPs will be supportive in nature, enhance transparency within the Ontario health system and encourage quality improvement, while providing mechanisms

The programs will establish system-wide provincial standards that will be consistently applied to all providers and facilities for the health service areas.

and escalation processes to appropriately manage quality and patient safety concerns.

The QMPs will promote the delivery of safe, high-quality and consistent care in Ontario, and will benefit patients/service users, providers and the healthcare system in a number of ways. The programs will establish system-wide provincial standards that will be consistently applied to all providers and facilities for the health service areas. Transparency will be enhanced through provincial reporting on quality at the provider, facility and regional levels, and providing clear lines of accountability for the quality of care and patient safety. The programs will address current inconsistencies and gaps in quality assurance programs and processes by building on and leveraging existing programs where possible.

The common program is described in this section. Additional details specific to the three programs are described in Sections 6 (colonoscopy), 7 (mammography) and 8 (pathology).

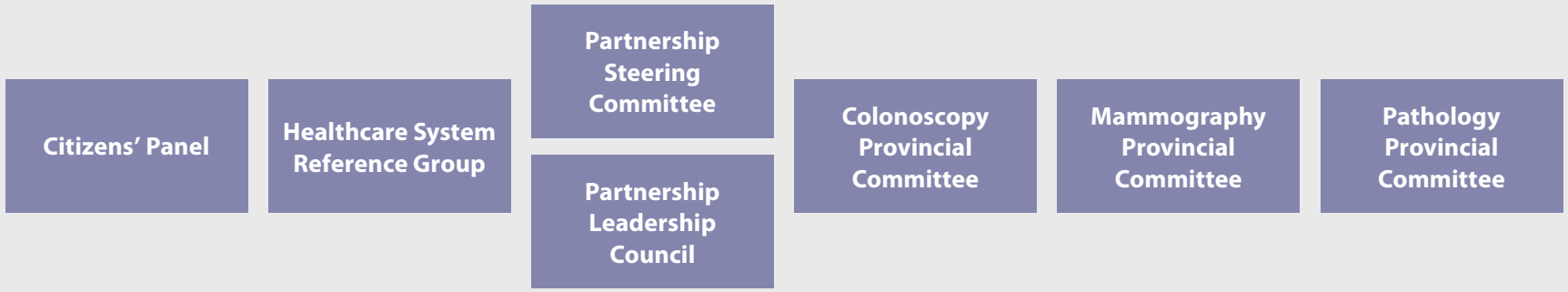
5.2 Governance, Roles and Responsibilities

Partnership governance

Partnership governance will facilitate effective leadership and decision-making for successful delivery of the three QMPs. Through different governance tables, system leaders, clinical experts and other key stakeholders, including patients/service users, will provide guidance on program priorities and activities. Governance will be further augmented by extensive stakeholder engagement with key organizations to obtain advice and to collaborate on program delivery.

The proposed Partnership governance structure is depicted in Figure 4.

Figure 4 **Partnership governance structure**



The Partnership Steering Committee will continue to be co-chaired by the President and CEO of Cancer Care Ontario (CCO) and the Registrar of the College of Physicians and Surgeons of Ontario (CPSO), and will involve executives from both organizations as well as the new QMP provincial leads. The steering committee is accountable for program delivery and is the final decision-making table for the Partnership.

The Partnership leadership council will oversee the day-to-day operations of the three programs and involve senior management from both organizations. It will be accountable to the steering committee.

The Citizens' Panel with patients/service users will be established to provide guidance from the public's perspective on the QMPs overall, as well as on patient engagement, patient experience indicators and public reporting. Some patients/service users will also participate in QMP provincial committees. The panel will provide guidance directly to the steering committee.

The Healthcare System Reference Group will continue to involve senior leaders from key organizations involved in healthcare service delivery and quality management. The chair of the Citizens' Panel will also participate in this group. This group will provide expertise and guidance directly to the steering committee.

A provincial committee for each QMP will be established and will be chaired by the QMP provincial lead. The committees will consist of QMP regional leads and other experts, further described below. The committees will be accountable to the steering committee for both program operations and ongoing program expansion and refinement.

Program governance

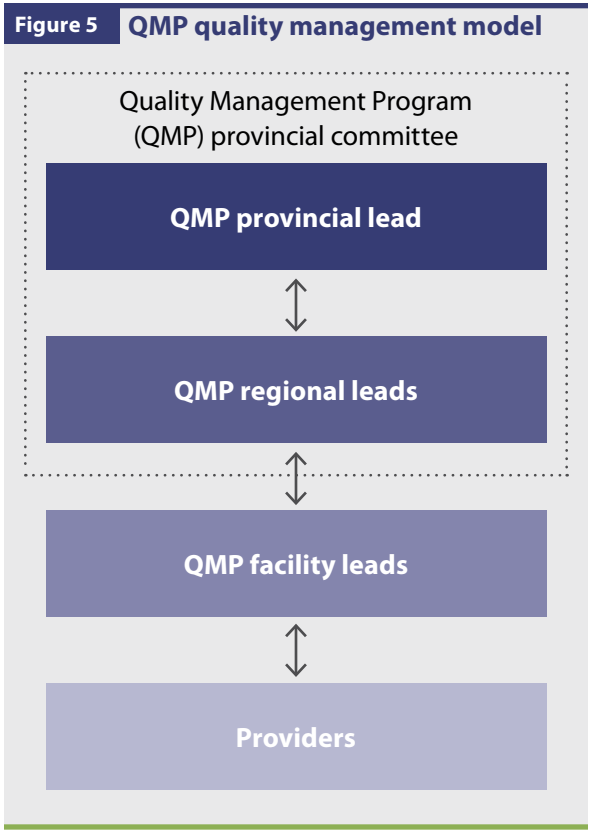
A primary aim of the QMPs is to foster a culture of continuous quality improvement in which providers and facilities are able to improve the quality of care they deliver. The Partnership will support and foster this culture by establishing a supportive network of clinical leads at the provincial, regional and facility levels. All leads will be physicians with expertise in the health service area. Together, the QMP leads will strengthen accountability for quality at all levels and promote consistency and transparency in the three health service areas. They will support and facilitate quality improvement at their respective level, reviewing quality reports and encouraging providers and facilities to participate in quality improvement activities. The leads will receive leadership support to orient them to their new responsibilities and will be encouraged to work collaboratively in carrying out their roles.

The proposed program governance, illustrated in Figure 5, shows how the leads will function within a provincial network that extends to the individual provider.

The provincial committee will provide overall guidance and leadership for each QMP. The committee will:

- Advise on program priorities, refinements of recommendations and future areas of expansion
- Provide recommendations for quality improvement opportunities across the health service area
- Support change management and knowledge translation and exchange across the province

Figure 5 QMP quality management model



Each committee will be chaired by the QMP provincial lead and will include:

- QMP regional leads
- Other relevant program leads (e.g., Radiologist-in-Chief for the Ontario Breast Screening Program)
- Relevant non-physician providers (e.g., nurses, medical radiation technologists or MRTs, pathologists' assistants) with health service area expertise and knowledge
- Patients/service users
- Other subject matter experts as required

Efforts will be made to ensure that the committee members include representation from each facility type for the health service area (e.g., academic hospitals, community hospitals, independent health facilities or IHFs, out-of-hospital premises or OHPs, private laboratories).

The provincial and regional leads will be selected through an open and transparent process. The recruitment and selection processes for these leads and other committee members will be designed and executed with input from stakeholders. The facility will be responsible for identifying their facility lead and aligning this role with existing accountability structures and processes for quality.

5.3 QMP Core Processes

Core processes have been identified to support the QMPs. The Partnership will continue to work with stakeholders to refine and develop these processes to ensure successful implementation for the three QMPs. The proposed processes are:

- Defining standards, best practice guidelines and indicators
- Facilitating the uptake and adoption of provincial standards and best practice guidelines
- Generating and distributing quality reports
- Supporting quality assurance and continued quality improvement activities

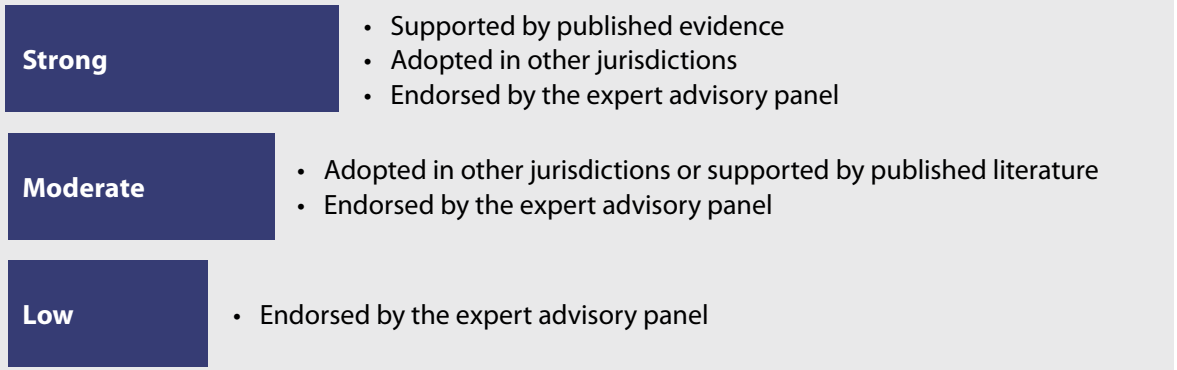
Defining standards, best practice guidelines and indicators

Defining quality involves establishing the standards, best practice guidelines[7] and indicators to provide a foundation for quality reporting, assurance and improvement processes. The expert advisory panels used their knowledge, skills and judgment to recommend guidelines, standards and indicators that, if applied across the province, will facilitate consistent, high-quality care in Ontario. To build on existing programs and reduce duplication, the panels focused their efforts on assessing existing standards and guidelines that are either recommended or implemented in Ontario or other provincial, national or international programs or organizations.

Once the panels had made their recommendations, the Partnership assessed the evidence that supports each standard, guideline and indicator. It was recognized that existing scales to assess levels of evidence are not suitable[8] for this task because they do not assess adoption in other jurisdictions. For this reason, the Partnership devised its own scale to assess the extent to which the recommendations are supported by published evidence and literature, and adopted in other jurisdictions. (See Figure 6.)

The QMP provincial committee for each health service area will conduct regular reviews of emerging literature and evidence in order to consider whether updates to the provincial standards, best practice guidelines and indicators are needed. The committees will also regularly consider which standards, guidelines and indicators will be incorporated into QMP quality reports, further described below.

Figure 6 QMP evidence rating scale



7 Best practice guidelines were only recommended for pathology.

8 Existing rating scales are often used in systematic reviews to assess the strength of results from a research study or clinical trial based on the study design and the endpoints that are measured. They do not include consideration of the adoption in other jurisdictions.

"Personally, I was surprised and disappointed that I did not have the best polyp detection rate … I have been motivated to improve my procedural skill and intra-procedural attention to a complete exam, in order to improve my performance next year."

Dr. Doug Hemphill, expert advisory panel member and gastroenterologist

Provincial quality reporting promotes transparency and accountability for the broader health system to help support and drive quality improvements.

Facilitating uptake and adoption of provincial standards and best practice guidelines

In an effort to streamline processes, align with existing quality initiatives and prevent duplication, the Partnership will work with other programs and organizations to integrate the recommended provincial standards and best practice guidelines into existing inspection, assessment or accreditation programs. In many cases this will involve expanding or modifying an existing program, but when a gap is identified in the existence of an inspection, assessment or accreditation program, the QMPs will look to fill that gap by collaborating with existing organizations.

On a regular basis, the QMP provincial committee for each health service area will review the current level of uptake and adoption of provincial standards and guidelines and identify any further efforts needed to increase uptake and adoption of new and existing standards and guidelines.

Generating and distributing quality reports

Measuring and reporting quality indicators at the provider, facility, regional and provincial levels is critical to understanding quality, making informed decisions about quality improvement investments and monitoring the effectiveness of quality improvement efforts over time. Provincial quality reporting promotes transparency and accountability for the broader health system to help support and drive quality improvements.

Quality reports will be produced on two levels of indicators:

- **Provider-level indicators:** Measure outcomes of individual providers (e.g., cancer detection rate)
- **Facility-level indicators:** Measure processes (e.g., wait times) and implementation of standards (i.e., binary [yes/no] or per cent adherence) at the facility level

The reports will be issued regularly to providers, facilities and the QMP leads and will provide information on quality indicators at each level in both identified individual and aggregate peer comparator format. The provincial committees will be responsible for reviewing and monitoring aggregate quality reports. Responsibility for reviewing individual provider- and facility-level data will be limited to QMP leads because they have the clinical knowledge and expertise to interpret these data. See Table 1 for further information on who will receive information at each level.

The network of QMP leads will provide independent clinical review and follow-up of quality reports and/or other identified quality concerns that require clinical leadership. The reports will be used as an input into a quality management process that:

- Monitors quality at the provider, facility, regional and provincial levels
- Supports continuous quality improvement discussions with all providers and facilities
- Identifies providers and facilities that may have a quality issue
- Provides clear lines of accountability for validating and exploring the cause of the issue and recommending and confirming that quality improvement activities are completed

Table 1 **Distribution and review of quality reports**

	Providers	QMP Facility Leads	QMP Regional Leads	QMP Provincial Leads
Provider Indicators	Their own identified provider data (e.g., cancer detection rate)	Identified provider data for providers in their facility	Identified provider data for providers in their region	Identified provider data for all providers
	Peer comparator data (e.g., cancer detection rate for all providers in Ontario)	Peer comparator data	Peer comparator data	Peer comparator data
Facility Indicators	Identified facility data for their facility (e.g., wait times for facility A)	Identified facility data for their facility	Identified facility data for facilities within their region	Identified facility data for all facilities
	Facility comparator data (e.g., wait times for all facilities in Ontario)	Facility comparator data	Facility comparator data	Facility comparator data

Note: At this time, pathology quality reporting will be limited to facility-level indicators.

Supporting quality assurance and continued quality improvement

To foster a culture of quality improvement, the QMPs will assist providers, facilities and regional leaders to develop the skills, knowledge and resources they need to deliver high-quality care. QMP leads at the appropriate level will support and facilitate quality improvement.

- **At the provider level, continuing professional development will be used to support continued learning and clinical improvement.** All providers will be encouraged to access quality improvement supports. The QMP will play a role in identifying and facilitating access to educational opportunities for the health service areas.

- **At the facility level, process improvement activities will most often occur within a facility or between facilities.** Facilities will be encouraged and supported to identify and conduct quality improvements. This may include supportive processes to identify root causes and solutions for quality improvement recommendations. QMP regional leads will have the ability to facilitate learning by sharing best practices from peer facilities across the region and providing a supportive network of clinical resources.

- **At the regional level, process improvement activities will most often occur across facilities.** The QMP regional lead will work with the local facilities and the QMP provincial lead to identify opportunities for quality improvement and mechanisms to share best practices from across the province and provide a supportive network of clinical resources.

- **At a provincial level, system-level initiatives may be identified to improve quality.** In order to continually drive quality improvement, there may be large transformational initiatives needed in each of the three health service areas. With access to provincial quality information and a broad-reaching clinical network, the QMP provincial committee will be positioned to identify system-level initiatives and seek advice from other relevant experts, when needed, to recommend system-level improvements.

While the majority of providers and facilities provide excellent, high-quality care, it is also possible that quality reporting and monitoring will highlight occasions where quality standards are not being met such that there is a potential threat to patient safety. Recognizing this, the Partnership is developing a process to identify and act on these cases in a timely and responsible way. This process will be integrated with and support existing local facility quality management processes.

The process will address clinical and facility concerns requiring improvements. The focus will be on optimizing patient safety and providing accountability for quality concerns in the rare instances when quality improvement is no longer effective. This may lead to referral to the appropriate regulator for a more structured interaction, if required. The Partnership will continue to refine this process into the implementation phase.

"From the time our GP made the call for my husband to have a colonoscopy, we already had a lot of anxiety … Sharing our personal experience, I hope, will improve the experience of future patients and their families so they don't have to go through what we went through."

Anne Newman, caregiver/service user

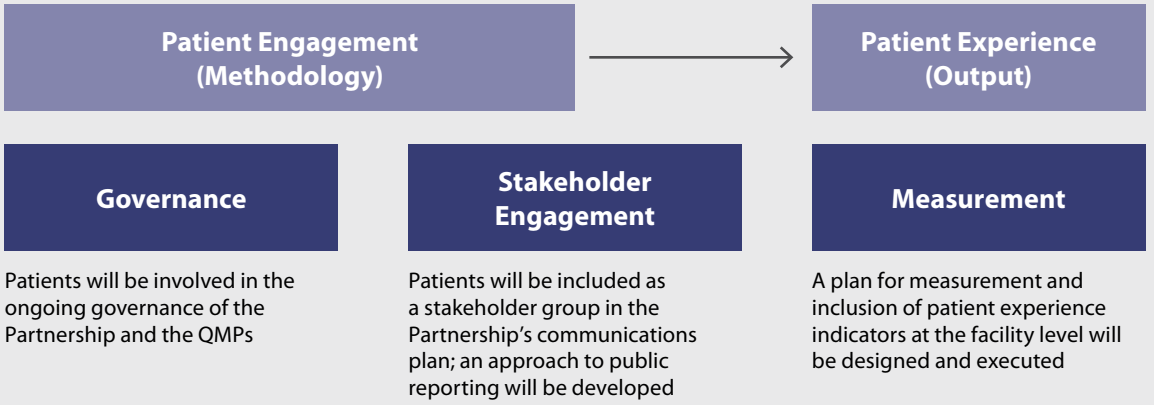
5.4 Patient-Centred Approach

A key principle for the Partnership is to be patient-centred and improve the quality of care for patients/service users in ways that are important to them. The Partnership delivers on this principle in several ways:

- Having patients/service users involved in the design and delivery of QMPs
- Measuring patient experience in order to engage patients/service users in providing feedback on the care they received and support improved patient-centred care at the provider and facility levels
- Working with patient/service user and public representatives to develop a communications strategy that will provide accurate, relevant and timely information to patients and the public

To date, patients/service users have served as members of the expert advisory panels and assisted in the development of recommendations for the design of the QMPs. Their views were actively sought during the consultation process. In fact, patient/service user feedback was a major driver of the Partnership's recommendations on providing patients/service users with accurate, relevant and timely information to enable them to be engaged in their care.

Figure 7 **An overview of the Partnership's multi-pronged approach to patient-centredness**



As the Partnership continues its work, patient-centredness will be maintained through a multi-pronged approach, as outlined in Figure 7. This approach uses patient/service user engagement as a methodology to improve patient experience at the facility level.

As the Partnership moves towards implementation, patients/service users will be more deeply involved in its governance structure. Patients/service users will continue to provide advice and feedback to each health service area, with representatives on each of the provincial committees. In addition, a newly created Citizens' Panel will obtain broader input from members of the public on key issues. The Citizens' Panel will report its recommendations directly to the Partnership Steering Committee.

Measuring patient experience will be an early focus of activity, with an IM/IT solution already in progress. Development of these indicators and the approach to data collection will require significant input from patient/service user representatives at various governance tables.

More generally, as the QMPs are implemented, patients/service users will continue to be counted as a key stakeholder group to be considered in all engagement and communication activities.

Overall, the QMPs must be seen by patients/service users to improve the quality of the care they experience in ways that matter to them.

5.5 Enablers

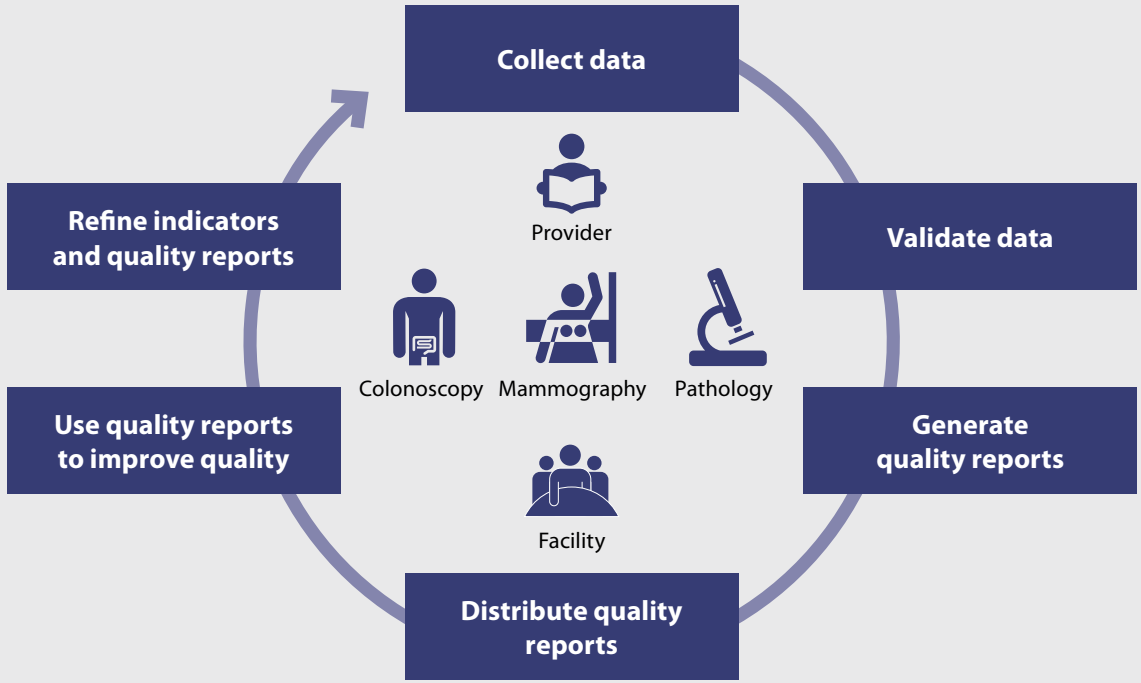
Implementing IM/IT Solutions

Quality Reporting

The Partnership will implement and maintain IM/IT solutions to enable quality reporting for each of the QMPs. These solutions will adhere to the following principles outlined in the Partnership's IM/IT Strategy (see Appendix G):

- **Clinical workflow alignment** – Data collection requirements will align with existing/best practice clinical workflow
- **Common data standards** – Data collection requirements will align with existing relevant provincial, national or international data standards and be consistently applied across all care settings in Ontario
- **Data quality** – Data collection solutions and processes will ensure high data quality
- **Value added** – Reports will be designed to meet user needs and support quality assurance and quality improvement activities

Figure 8 **QMP quality reporting cycle**



- **Leverage existing solutions** – Existing provincial, regional and/or local data collection and reporting infrastructure will be leveraged and shared across related programs wherever feasible

The IM/IT solutions will enable the QMP quality reporting cycle depicted in Figure 8. Data will be collected and validated before quality reports are generated and distributed. The ongoing use of quality reports will facilitate quality improvement activities and the refinement of indicators and quality reports. Over time, the accuracy, comparability and usability of the data that are collected will also improve.

The IM/IT solutions to enable quality reporting will integrate several components, depicted in Figure 9, and will include:

- A tool to collect real-time feedback from patients about their experience; these data will be used to generate patient experience indicators

- A data submission portal to be used by all facilities participating in the QMPs to submit facility information
- An eReports portal to be used by all providers and facilities participating in the QMPs to access their QMP quality reports
- Existing health service area-specific systems to be used by facilities to collect colonoscopy, mammography and pathology data
- Expanded Ministry of Health and Long-Term Care (MOHLTC) data feeds to include all relevant fee codes, provider and patient data across all ages and facilities to support data validation processes

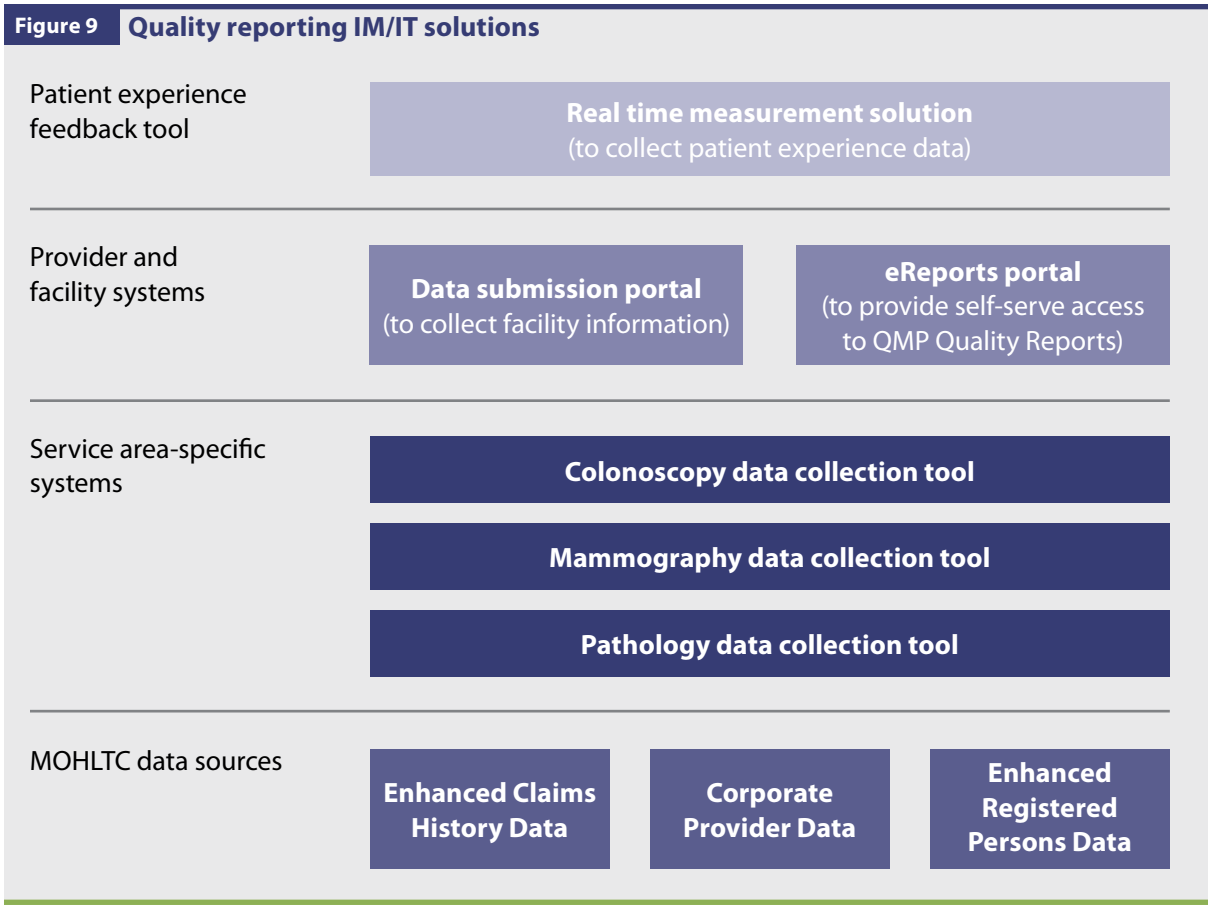
Clinical Reporting Standards

Clinical reporting standards determine the content, structure and format requirements for capturing patient health record information and clinical reporting. These standards facilitate consistency, usability and comparability of patient data and clinical reports across providers, facilities and the province. The Partnership will assess the current state of clinical reporting standards and IM/IT solutions to enable these standards for each service area and make additional recommendations.

Clinical Information Sharing

Clinical information sharing is the ability to access patient clinical reports, images, videos and other related information to support clinical decision-making and/or quality assurance and improvement processes. The Partnership will explore opportunities to use existing eHealth initiatives and infrastructure for clinical information sharing and make additional recommendations.

Figure 9 **Quality reporting IM/IT solutions**



Legislative and Regulatory Requirements

The Partnership formed a legislative and regulatory working group that included counsel and staff from both CCO and CPSO and sought advice from the MOHLTC as well as stakeholders such as the Ontario Hospital Association and the Ontario Medical Association. The working group's purpose was to assess the scope of legislative and regulatory changes required to support the Partnership's goals and to move forward with the Partnership's work, both on a short-term and long-term basis.

The collection, use and disclosure of the quality indicators identified by the expert advisory panels were identified as a priority for a legislative and regulatory assessment. On behalf of the Partnership, CCO will be accountable for data collection and reporting functions. A legal review of the mandate of the Partnership as against CCO's current authorities determined that the mandate of the Partnership is largely aligned with CCO's objects under the Cancer Act and its authority as a Prescribed Entity under the Personal Health Information Protection Act, 2004 (PHIPA) as well as with the scheme and objects of PHIPA. A legal review determined that CCO can initially rely on these authorities to begin the work set out by the Partnership to collect and report the quality indicators identified by the expert advisory panels.

The working group also reviewed legislative and regulatory changes required to make participation in the QMPs mandatory for healthcare providers and facilities, and to identify existing legislative gaps that exist related to the implementation of the QMPs. More analysis and work with the MOHLTC, CCO and the CPSO will be undertaken to establish and propose the necessary legislative and regulatory changes required to mandate participation in the QMPs and address other legislative gaps, for example those related to the inspection of hospital facilities.

6.0 Colonoscopy Program Details

6.1 Colonoscopy Overview

"As a nurse participating as an expert advisory panel member, I feel that the recommendations in the Phase 2 report will contribute to the goal of improving consistency in the quality of care provided across all facilities."

Kay Rhodes, expert advisory panel member, nurse and OHP administrator

A colonoscopy is a visual inspection of the rectum and colon that is performed using a colonoscope, a long, flexible lighted tube with a camera at the end. Colonoscopies may be performed for a variety of indications, including colorectal cancer screening, follow-up of abnormal screening tests, symptoms such as abdominal pain or rectal bleeding, or surveillance of individuals with chronic conditions, such as inflammatory bowel disease, previous polyps, or prior history of colorectal cancer. During colonoscopy, polyps that may develop into colorectal cancer or have become cancerous can be removed/biopsied, and other abnormalities may be treated. The majority of colonoscopies are performed by general surgeons and gastroenterologists in one of three settings: out-of-hospital premises (OHPs), independent health facilities (IHFs) and hospitals.

Quality management is essential for colonoscopy to ensure safe, high-quality care and a positive patient/service user experience. Colonoscopies carry a low risk of bowel perforation and bleeding. Polyps and cancers may be missed – a result that can have a significant impact on patient/service user morbidity and mortality. Colonoscopy is an invasive procedure that carries a risk of infection if equipment is not properly sterilized between uses. Because colonoscopy is usually performed under sedation, there is a risk of complications if the patient/service user has co-morbidities, such as respiratory or cardiac problems. Furthermore, if a patient/service user has a negative colonoscopy experience, he or she may not return for repeat examinations that are necessary to manage health concerns and/or conditions.

Currently, the scope of the provincial quality management program (QMP) in this health service area is colonoscopy rather than all endoscopic procedures. Early on in its work, the Colonoscopy Expert Advisory Panel recommended expanding the scope to include all upper and lower gastrointestinal endoscopic procedures to ensure that the quality of colonoscopy is managed in the context of excellence in endoscopy care overall, and to foster a rational approach to facility assessment that is efficient and cost-effective. Some recommendations only make sense when applied to endoscopy as a whole. This recommendation was included in the Phase 1 report.

In addition, the Partnership's colonoscopy QMP is being developed at the same time that the gastrointestinal (GI) endoscopy quality-based procedure (QBP) initiative is being rolled out, and the two programs are aligned but distinct. QBP is a component of health system funding reform and uses evidence-informed rates that are associated with the quality of care being delivered. QBP has developed interim quality standards for colonoscopy, as well as other GI endoscopy services offered in hospitals, OHPs and IHFs. The QBP standards were reviewed prior to release and endorsed by the Colonoscopy Expert Advisory Panel. Expanding the scope of the QMP to all endoscopy will strengthen the alignment of QMP with QBP.

Quality management is essential for colonoscopy to ensure safe, high-quality care and a positive patient/service user experience.

The colonoscopy QMP is based on a patient-focused continuum of care, rather than on the procedure itself. This means that the correct

procedure is done for the right indications, that colonoscopies are performed and interpreted correctly, that results are communicated to patients and referring physicians, and that follow-up happens after the procedure. This will ensure that patients receive appropriate and seamless care along their care pathway in a timely fashion. The panel noted that focusing only on the colonoscopy procedure decreases continuity of care, leading, in the worst case, to procedure repetition, missed follow-up and mismanagement of existing conditions.

> "I believe that the Quality Management Partnership is on the right path to making important changes that will support providers and facilities in taking advantage of continuous quality improvement opportunities and to ensure consistent quality standards across the province."
>
> Dr. Doug Hemphill, expert advisory panel member and gastroenterologist

6.2 Colonoscopy Provincial Standards

The Colonoscopy Expert Advisory Panel made recommendations on standards that will be mandatory in order to standardize colonoscopy quality across the province. The standards, in boxes below, are preceded by background and rationale. For further information on the evidence assessment for the standards and indicators see Appendix H.

Facility inspections and assessments

Periodic assessment ensures that facilities meet appropriate standards. The College of Physicians and Surgeons of Ontario (CPSO) is mandated by the Ministry of Health and Long-Term Care (MOHLTC) to carry out regular inspections and assessments of all OHPs and IHFs to ensure that they adhere to guidelines that have been developed for the services offered. OHPs providing colonoscopy must adhere to the Out-of-Hospital Premises Inspection Program (OHPIP) program standards, which contain general and colonoscopy-specific guidelines. As OHPs are grandfathered into IHFs as part of the QBP initiative, they will continue to be inspected through the OHPIP and be subject to any additional IHF requirements.

Hospital endoscopy units are not required to undergo analogous regular inspections and assessments. Hospital accreditation is voluntary, and may not focus specifically on colonoscopy services. Recognizing that standards should apply to all facilities, the Colonoscopy Expert Advisory Panel recommended that an assessment program be developed for hospitals based on the OHPIP. The panel felt that the OHPIP is a robust and well-founded inspection program that, with some adaptations, can be used for hospital-based colonoscopy services. Other jurisdictions have common standards and inspection processes for colonoscopy services regardless of the size or type of facility.

Colonoscopy Standard 1
All facilities must participate in regular inspections and assessments to ensure they meet appropriate standards. An inspection program based on the OHPIP must be developed for hospitals.
Level of Evidence: Moderate

All Ontarians should receive a comparable level of colonoscopy care regardless of the facility that provides the care.

Minimum standard of care and equipment

All Ontarians should receive a comparable level of colonoscopy care regardless of the facility that provides the care. Establishing a minimum standard of care and equipment provides all patients/service users with the same procedure regardless of what facility they are seen in, and ensures that patients/service users will not have to undergo a repeat colonoscopy in a different setting for routine procedures, such as small polyp removal. It requires all endoscopists to have the expertise to manage complications and recognize when transfer to an alternative level of care is needed, and ensures that the transition to a new facility is expedited in an efficient, patient-centred manner. The Colonoscopy Expert Advisory Panel recommended that a minimum standard of equipment and expertise be required of all facilities.

Colonoscopy Standard 2

All facilities that provide colonoscopy must have the equipment, and endoscopists working in those facilities must have the expertise, to:

- Recognize abnormalities and perform biopsies
- Tattoo to identify appropriate abnormalities for follow-up
- Remove polyps at least 1 cm in diameter
- Manage complications resulting from interventions, including knowing when to use clips and/or other hemostasis, and when transfer to another level of care is required
- When transfer is initiated, provide written documentation, supplemented by oral communication with the receiving physician

Level of Evidence: Low

Indication for colonoscopy

Colonoscopies must be performed for clinically valid reasons that are recommended by current evidence-based guidelines. Overuse of the procedure is a drain on healthcare resources, can lead to longer wait times for people who truly need the procedure and places patients/service users at unnecessary risk. The Colonoscopy Expert Advisory Panel recommended that all colonoscopies be performed for an appropriate indication and that the indication be clearly documented on the colonoscopy report.

Colonoscopy Standard 3

Colonoscopies must be performed for an appropriate, clearly documented indication that is consistent with current evidence-based guidelines.

Level of Evidence: Strong

Centralized repository for colonoscopy information

Endoscopists require access to previous procedure reports, images and pathology findings in order to determine whether the findings have changed in the intervening period. Before each procedure, the endoscopist should review clinically relevant details from past procedures, if any, but this is not always possible, particularly if the endoscopist did not perform the previous procedures. It is unrealistic to expect patients/service users to recall their clinical history, particularly when years may pass between colonoscopies. Recognizing the importance of endoscopists having detailed clinical information about past procedures, the Colonoscopy Expert Advisory Panel recommended that a provincial electronic repository be developed to provide access to this information.

Colonoscopy Standard 4

A centralized electronic repository must be developed to include past procedural reports and relevant pathology findings, as well as images and/or video related to the procedure.

Level of Evidence: Low

Ensuring follow-up happens

After a colonoscopy, appropriate follow-up is essential, such as the communication of an appropriate interval before the next colonoscopy, or establishing further treatment based on findings. The expert advisory panel heard from stakeholders that referring physicians receive reports that vary greatly in the level of detail provided about the procedure. Recognizing the importance of referring physicians having comprehensive information in order to manage patients/service users across the continuum of care, the Colonoscopy Expert Advisory Panel recommended that every colonoscopy facility inform the referring physician of the procedure results. This information must include any colonoscopy findings and follow-up recommendations. If samples were sent for pathology, the referring physician must also be notified of results and any recommended next steps.

Colonoscopy Standard 5

Facilities must inform referring physicians of the results of all procedures and any associated pathology, including any findings and follow-up recommendations.

Level of Evidence: Moderate

Standardized reporting

Inconsistent use of language on colonoscopy reports and unclear or missing information can compromise the quality of care. Standardization of electronic reports, including mandatory reporting elements and standard phraseology, facilitates uniform data capture and improved data analysis. It also provides the ability to analyze achievement to show where there is variability in the provision of care and identify where quality improvement efforts are needed. The Colonoscopy Expert Advisory Panel recommended that standardized reporting elements be used to improve clarity and consistency of information. The panel felt strongly that electronic reporting was essential to achieving standardized reporting, and is a prerequisite for submitting information to a centralized electronic repository, but they noted that implementation will need to be carefully planned to ensure appropriate support is provided.

This recommendation aligns with the Phase 1 early quality initiative that a standardized report to the referring provider be created.

Colonoscopy Standard 6
All facilities must adopt electronic and standardized reporting.
Level of Evidence: Low

Digital photographic documentation

During a colonoscopy, abnormalities in the colon are detected visually and may be biopsied and/or treated. Supplementing written documentation of abnormalities with images is widely accepted as an important quality measure and should be standard across all facilities. Requiring these images to be digital ensures that they can be collected and placed into an electronic repository as a resource for consultation activities and continuity of care. The Colonoscopy Expert Advisory Panel recommended that digital images be captured and stored centrally to document relevant landmarks and findings.

Colonoscopy Standard 7
Facilities must have equipment to record digital photographic evidence of relevant landmarks and lesions.
Level of Evidence: Low

Mechanical irrigators

During colonoscopy, irrigation may be required to effectively wash the colon in order to visualize the mucosa (interior lining of the colon) and any lesions. Adequate visualization of the mucosa is essential to a quality colonoscopy. The Colonoscopy Expert Advisory Panel felt strongly that mechanical irrigation is efficient and effective and should be the standard of care, and recommended that mechanical irrigators be available for use in every case, if needed.

Colonoscopy Standard 8
Mechanical irrigators must be available for every case and be used when necessary in order to allow adequate visualization of the mucosa and lesions.
Level of Evidence: Low

Infection control

All facilities have standards for proper infection control and sterilization of medical equipment. Facilities inspected under the OHPIP must adhere to the *Best practices for cleaning, disinfection and sterilization in all health care settings, 3rd edition*.[9] The American Society for Gastrointestinal Endoscopy has position statements on infection control, as do most jurisdictions. Exogenous infections transmitted during endoscopy are extremely rare, and generally result from failure to follow accepted guidelines for the cleaning and disinfection of gastrointestinal endoscopes, underscoring the importance of meticulous attention to endoscope reprocessing. Automated endoscope reprocessors (AERs) provide more consistent, thorough cleaning than manual techniques and may lead to a reduction in variability.

Because of the importance of infection control for both provider and patient safety, and the recognition that well-maintained equipment can reduce overhead costs, the Colonoscopy Expert Advisory Panel recommended standards for equipment and for personnel:

Colonoscopy Standard 9
All facilities providing colonoscopy must use automated endoscope reprocessors (AERs).
Level of Evidence: Low

Infection control processes should be equally rigorous across all facilities. Formalized training for all scope technicians must include instruction on scope handling, mechanics, infection control procedures and personal protective equipment (PPE). While training provided by the manufactures with respect to the equipment is excellent, feedback from stakeholders suggested that technicians with additional training in PPE and infection control procedures would reduce risk of contamination for the facility and improve patient and provider safety. At least 10 community colleges across the province currently offer programs in sterile/medical device processing.

Colonoscopy Standard 10
All personnel involved in reprocessing must participate in a formalized training program beyond that provided by the manufacturers.
Level of Evidence: Low

Training and assessment of colonoscopy nurses

Nurses are essential members of the care team that provides colonoscopy, and have specialized skills to perform their role within the endoscopy unit. A certification program creates consistency in the quality of care offered to patients/service users, strengthens patient safety and offers an environment for reviewing and updating best practices in colonoscopy nursing. Currently there is no standardized certification or assessment program specific to nurses working in endoscopy units because the national gastroenterology certification program is focused on the entire field of gastroenterology, not specifically endoscopy.

9 Provincial Infectious Diseases Advisory Committee (PIDAC). Best practices for cleaning, disinfection and sterilization of medical equipment/devices. Toronto: Ontario Agency for Health Protection and Promotion (Public Health Ontario); 2013.

Therefore, the Colonoscopy Expert Advisory Panel recommended that a voluntary certification program be developed for nurses, with input from provincial and national endoscopy specialty nursing organizations. In the future, the program could become mandatory.

Colonoscopy Standard 11
A certification program for endoscopy nurses must be developed.
Level of Evidence: Moderate

Competency-based orientation is a learner-focused method of providing nurses with the requisite knowledge and skills to perform/assist competently in an endoscopy unit. The Colonoscopy Expert Advisory Panel recommended that endoscopy facilities use this method for all nursing staff at the time of hiring. In addition to common core competencies across the province, facilities will be required to define competencies specific to each nurse on the team because these duties and responsibilities can vary greatly between facilities.

Colonoscopy Standard 12
Endoscopy units or facilities must provide competency-based orientation to all nursing staff at the time of hiring.
Level of Evidence: Low

Regular review ensures that competencies are being maintained and that nurses have the knowledge, skills and judgment to safely perform/assist with procedures carried out in an endoscopy unit. It also gives nurses the opportunity to align their annual personal development plans with practice improvement goals. Annual nursing reviews are especially valuable for verifying the competencies of part-time nursing staff. The Colonoscopy Expert Advisory Panel recommended that all nurses have annual reviews.

Colonoscopy Standard 13
Every facility providing endoscopy must undertake an annual nursing competency review.
Level of Evidence: Low

After hours nursing support

It is best practice, and considered essential to patient safety and quality of care, to have nurses experienced in endoscopic procedures perform/assist in endoscopy units, regardless of the time of day that the procedure takes place. The presence of experienced nurses is especially important for procedures during an emergency or urgent issue. After hours, it is current practice to pull nurses without such experience from other tasks to assist in urgent or emergency case procedures. The Colonoscopy Expert Advisory Panel recommended that nurses with endoscopy experience be available on-call in facilities where after-hours emergency and urgent services include endoscopy.

Colonoscopy Standard 14
Nurses with experience in endoscopy must be available on-call in facilities where after-hours urgent and emergency endoscopic procedures occur.
Level of Evidence: Low

In order to provide the highest quality care, it is essential that all aspects of pre-procedural, procedural and post-procedural care be delivered in an efficient, effective and patient-centred manner.

Global Rating Scale

In addition to regular assessments and inspections, other tools are available that can be used as valuable quality assurance/quality improvement tools. The panel noted in particular the global rating scale (GRS), a validated tool that captures clinical indicators of quality and the patient/service user experience. The GRS, originally developed in the United Kingdom in 2004, has been adopted by New Zealand, Scotland and the Republic of Ireland. Over 100 facilities currently participate in Canada. British Columbia is a leading early adopter of GRS, mandating that all facilities use it. In early 2014, Newfoundland and Labrador also adopted the GRS comprehensively, mandating that all facilities that provide colonoscopies use the GRS. The GRS allows peer comparison within regions, the province and across the country. The Colonoscopy Expert Advisory Panel recommended that all facilities use the GRS to drive their quality assurance and quality improvement efforts.

Colonoscopy Standard 15
All facilities must use the global rating scale (GRS) as a quality assurance/quality improvement tool.
Level of Evidence: Strong

Patient/service user privacy

In order to provide the highest quality care, it is essential that all aspects of pre-procedural, procedural and post-procedural care be delivered in an efficient, effective and patient-centred manner. Respect for patient/service user privacy is a requirement of patient-centred care and an important aspect of patient/service user experience, and should be reflected in the physical environment where the health service is offered. Due to space constraints, patients/service users are often asked personal health details where other patients/service users can overhear, which can lead to reluctance and/or embarrassment at having to discuss personal information in such an environment. The Colonoscopy Expert Advisory Panel recommended that confidentiality be respected by ensuring that patients/service users are able to discuss their symptoms and history in sufficient privacy. The panel also felt that the pre-procedure assessment area should be separate from the post-procedure recovery area.

Colonoscopy Standard 16
All facilities providing colonoscopy services must ensure that the environment provides sufficient privacy to patients to maintain their confidentiality. Ideally, the pre-procedure assessment area must be separate from the recovery area.
Level of Evidence: Moderate

Discharge information

Patients need to understand what was found during a colonoscopy and what the next steps should be. They also need to be aware of potential post-procedure warning symptoms that would cause them to seek immediate physician follow-up. Providing oral information is insufficient because after sedation the patient may not understand or remember everything they were told. In addition, if follow-up is required in an urgent or emergency situation, written information could provide valuable history to the physician attending the patient. The Colonoscopy Expert Advisory Panel recommended that all patients/service users receive essential clinical information in writing when they are leaving the facility after their colonoscopy.

This recommendation aligns with the early quality initiative for a standardized patient discharge report.

Colonoscopy Standard 17
All colonoscopy patients, on discharge, must receive written information regarding the procedural findings, plans for treatment and follow-up, worrisome symptoms to watch for and steps to be taken.
Level of Evidence: Moderate

6.3 Colonoscopy Quality Management Program

To support the design components and implementation of consistent QMPs across the three health service areas, the colonoscopy QMP will fundamentally reflect the common program described in Section 5. However, the Colonoscopy Expert Advisory Panel noted a few unique considerations for colonoscopy.

To prevent overlap and duplication in roles, the Colonoscopy Expert Advisory Panel has recommended that:

- At the provincial level, there will initially be separate roles for the QMP provincial lead

and the CCO provincial endoscopy lead. It is anticipated there will be opportunity to combine roles in the future.

- At the regional level, regional colorectal screening GI endoscopy leads currently responsible for quality initiatives will also assume the responsibilities of the QMP regional leads.
- At the facility level, QMP facility leads will be practicing endoscopists and the local quality lead (where existing).

For quality reports, the Colonoscopy Expert Advisory Panel has recommended that individual physician data be handled differently for smaller facilities as an interim measure. The QMP facility lead for larger facilities will be responsible for managing quality for endoscopists in their facilities; for smaller facilities, the QMP regional lead will receive and follow up on quality reports for endoscopists. As the colonoscopy QMP matures, this recommendation will be re-evaluated and may be altered if needed. In addition, a fulsome review process to establish if facilities are classified as small or large will be developed during implementation.

Finally, the Colonoscopy Expert Advisory Panel recommended that endoscopists who work in more than one facility receive their overall totals for each indicator, as well as their indicators stratified by each facility they work in. QMP provincial, regional and facility leads will receive individual indicators, with overall totals as well as indicators stratified by each facility the endoscopist works in.

10 For indicators that monitor the frequency of rare occurences, a rate cannot be accurately calculated, so a number will be reported.

11 Tinmouth J, Kennedy E, Baron D, Burke M, Feinberg S, Gould M, et al. Guideline for colonoscopy quality assurance in Ontario. Toronto: Cancer Care Ontario; 2013. Program in Evidence-based Care Evidence-based Series No:15-5 .V2.

Colonoscopy QMP indicators

Table 2 Colonoscopy provider-level indicators

No.	Indicator	Target/Auditable Outcome*
C1	**Total Colonoscopy Volume** Total colonoscopy volume in a year **Level of Evidence:** Moderate	≥ 200 colonoscopies
C2	**Inadequate Bowel Preparation** Percentage of outpatient colonoscopies with poor bowel preparation, using the scale: • Very good to excellent preparation • Adequate preparation with colonic irrigation • Inadequate preparation **Level of Evidence:** Strong	Auditable outcome
C3	**Outpatient Polypectomies** Percentage of outpatient colonoscopies in which ≥ 1 polyp(s) were removed. **Level of Evidence:** Strong	Auditable outcome
C4	**Outpatient Cecal Intubation** Percentage of outpatient colonoscopies where the cecum or terminal ileum (TI) was reached. **Level of Evidence:** Strong	95% in patients with adequate bowel preparation and no obstructing lesions
C5	**Polypectomy Associated Bleeding** Number of outpatient colonoscopies with polypectomy where the patient was admitted to hospital with lower gastrointestinal bleeding within 14 days of the procedure. **Level of Evidence:** Strong	< 1 per 100 colonoscopies resulting in clinically significant bleeding requiring hospital admission
C6	**Outpatient Perforations**[10] Number of perforations among outpatient colonoscopies performed. **Level of Evidence:** Moderate	< 1 per 1,000 colonoscopies
C7	**Colorectal Cancer (CRC) Detection** Number of outpatient colonoscopies where CRC was detected. **Level of Evidence:** Moderate	N/A
C8	**Post-Colonoscopy CRC (Interval Cancer)** Number of persons who had a colonoscopy negative for CRC in whom CRC was diagnosed within the subsequent 6 to 36 months. **Level of Evidence:** Moderate	Auditable outcome
C9	**Adenoma Detection** Percentage of colonoscopies in which ≥ 1 adenoma was identified and removed **Level of Evidence:** Strong	TBD

*Note: Targets are supported by evidence. Auditable outcomes are monitored for quality assurance purposes when there is insufficient evidence to recommend a target. The targets and auditable outcomes currently indicated for provider-level reporting are based on the *Guidelines for Colonoscopy Quality Assurance in Ontario*[11].

Table 3 **Colonoscopy facility-level indicators**

No.	Indicator	Target/Auditable Outcome*
C10	**Outpatient Cecal Intubation** Percentage of outpatient colonoscopies performed where the cecum or terminal ileum (TI) was reached **Level of Evidence:** Strong	TBD
C11	**Colonoscopies Performed by Endoscopists Meeting Volume Standard** Percentage of colonoscopies performed at each facility by endoscopists who have performed 200 or more colonoscopies in total in the reporting year **Level of Evidence:** Moderate	TBD
C12	**Colonoscopy Within Eight Weeks of Positive Fecal Occult Blood Test (FOBT)** Percentage of Ontario screen-eligible individuals, 50-74 years old, who had an abnormal FOBT result and follow-up colonoscopy within six months, who underwent colonoscopy within eight weeks. **Level of Evidence:** Moderate	TBD
C13	**Colonoscopy Within 26 Weeks for Family History** Percentage of colonoscopies within the 26-week benchmark for individuals with family history of colorectal cancer defined by the family history colonoscopy indication in the Colonoscopy Interim Reporting Tool **Level of Evidence:** Moderate	TBD
C14	**Positive FOBT Follow-Up Rate** Percentage of Ontario screen-eligible individuals, 50 to 74 years old, who had an abnormal FOBT result and underwent colonoscopy within six months. **Level of Evidence:** Moderate	TBD
C15	**Tier 1 and Tier 2 Adverse Events** Numbers of Tier 1 and Tier 2 adverse events. Tier 1 Events: • Death within the premises • Death within 10 days of a procedure performed at the premises • Any procedure performed on wrong patient, site or side • Transfer of a patient from the premises directly to a hospital for care Tier 2 Events: • Number and type of infections occurring in the premises • Unscheduled return to the procedure room for an unexpected event • Unplanned stay at the premises for medical reasons that is longer than 12 hours post-procedure • Unscheduled treatment of a patient in a hospital premises Note that currently only OHPs report Tier 1 and 2 events to CPSO. Further work will be required to implement adverse event reporting in hospitals and IHFs. **Level of Evidence:** Moderate	TBD

6.4 Colonoscopy QMP Considerations

Implementation

The expert advisory panel and other stakeholders recommended the following considerations for the successful implementation of a colonoscopy QMP:

- **Sufficient capacity, resources and support will be required for the implementation of the colonoscopy QMP.** There is conceptual support to move forward with the program, however implementing the recommendations into practice will be limited by the current availability of resources. A detailed review of the program impact and required resources will be needed as part of the initial phase of implementation. For example, the current support for QMP facility and/or regional leads to execute quality improvement projects and the potential of the program to increase workloads will need to be fully assessed, as well as the costs of purchasing new equipment such as digital photo documentation.

- **Successful uptake and adoption of the QMP will depend on integration and close alignment with existing quality management processes and programs.** To ensure alignment and avoid duplication, the QMP must complement and integrate into existing quality management structures and processes in hospitals, OHPs, and IHFs, and align with related programs such as the QBP. As the QMP is implemented, the Partnership must maximize relationships and opportunities for integration and alignment.

- **Support, commitment and adoption of the colonoscopy QMP will be enhanced through the use of quality data that accurately reflects the quality of care being provided.** In order to obtain early stakeholder buy-in and commitment from the colonoscopy community, the ability to demonstrate that quality indicators will be used to reflect the quality of care being provided will be important. A careful process of indicator definition, data acquisition, data stabilization and review will be essential to support the buy-in from the colonoscopy community.

Future Work

The Colonoscopy Expert Advisory Panel recommended the following areas for future consideration that may have an impact on the quality of services provided for colonoscopy.

- **Patient/service user experiences are an important measure of quality.** There are currently no well-established and validated indicators that the Colonoscopy Expert Advisory Panel could recommend for the colonoscopy QMP. Indicators for patient/service user experience will be established and included in facility-level reporting in the future, after a process of data acquisition, stabilization and review.

- **Challenges with respect to access for colonoscopy services in rural and remote areas.** A number of system design considerations were highlighted by the panel to address challenges with respect to equity of access to colonoscopy services in rural/remote areas of Ontario. There was concern that there may be differences in quality in rural/remote areas, though there are currently no mechanisms to assess this. Future work should include reviewing access to colonoscopy services in rural and remote areas and ensuring that a consistent standard of quality care is being provided.

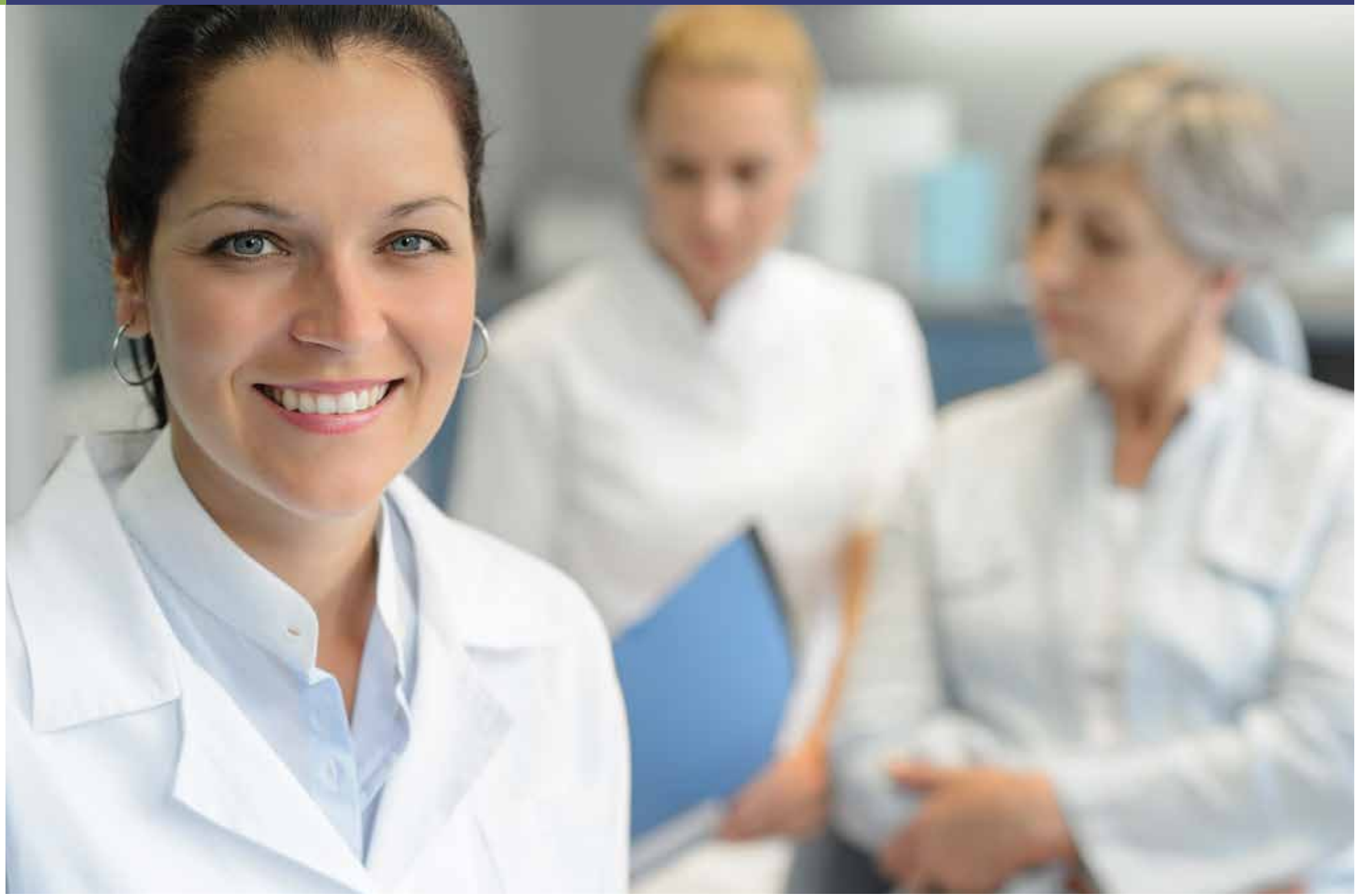
- **Use of sedation and anesthesia for colonoscopy services.** There is considerable variability in the use of sedation during colonoscopy (and for other endoscopy procedures). The panel recommended that the impact of sedation variability on quality outcomes be further assessed. This is currently being reviewed as part of the QBP initiative; the findings of that work, and any new and emerging evidence, will be considered by the colonoscopy QMP.

- **Availability of quality improvement educational resources and tools for providers.** Providers have limited quality improvement resources and tools at the local level. To support continuous quality improvement, work will need to be conducted to ensure that providers and facilities are aware of and have access to the appropriate resources and knowledge (e.g., courses, communities of practice, peer-to-peer support, provincial conferences).

- **Expanding the scope of the colonoscopy QMP to include pediatric care.** Pediatric endoscopy/colonoscopy care has its own special considerations, and indicators and standards may need to be adjusted to reflect this specialized area of practice. A detailed analysis and review of the program by experts in pediatric endoscopy is required to assess the suitability and applicability of the standards and indicators as they relate to pediatric care.

- **Cross-collaboration between the pathology and colonoscopy QMPs.** Facilitated through the work of the Partnership, there is an opportunity for cross-collaboration between the colonoscopy and pathology programs. For example, after a biopsy or polypectomy, pathology results are necessary to allow endoscopists to reach a diagnosis and recommend follow-up. Standardized terminology for pathology results will facilitate clear communication between the pathologist and endoscopist to reach a diagnosis and recommend next steps. Future work will include a review of current processes and communication mechanisms, with an opportunity to standardize specimen and referral submissions, and pathology results to support integrated quality care between the two areas of specialty.

7.0 Mammography Program Details



7.1 Mammography Overview

"The development of a quality management program for mammography could result in improved quality in the delivery of mammography services for individuals across the province, regardless of facility or provider, through the extension of best practices (OBSP) to all mammography."

Ivana Marzura, expert advisory panel member and patient/service user

A mammogram is a set of images obtained from a machine that uses low-dose X-rays. These images are used to detect breast cancer and evaluate changes in the breast. Mammography may be performed as a screening test for asymptomatic women, including women with a prior history of breast cancer, or as a diagnostic test to evaluate abnormal clinical or imaging findings. In Ontario, mammograms are performed by medical radiation technologists (MRTs) and interpreted by radiologists in hospitals and independent health facilities (IHFs).

Quality management is essential for mammography to ensure that images are of sufficiently high-quality and that regulatory requirements for mandatory testing for X-ray safety are being followed. In the context of screening for breast cancer, mammography has benefits, harms and limitations. One of its benefits is that it can find cancers early when they can be more easily treated and cured; one recent evidence review concluded that using mammography to screen for breast cancer resulted in a 21 per cent reduction in breast cancer mortality in women aged 50 to 69.[12] Harms include a slight radiation exposure, false positive results that lead to anxiety and unnecessary imaging, biopsies and surgery; and over-diagnosis (detecting and treating cancers that would not have caused harm during a person's lifetime). Limitations of mammography include false negative results – cancers that are missed at screening.

Currently, the scope of the QMP in this health service area is mammography. The Mammography Expert Advisory Panel designed a QMP for mammography that incorporates the continuum of care, and not just the mammography procedure itself. This means that, in addition to ensuring that mammography is performed and read correctly, the QMP will also ensure that results are communicated to patients and referring physicians, and that follow-up happens after an abnormal mammogram, so that patients receive appropriate and seamless care. The panel has noted that focusing only on the procedure risks losing this continuity of care, leading, in the worst case, to missed follow-up and, potentially, missed cancers.

Quality management is essential for mammography to ensure that images are of sufficiently high-quality and that regulatory requirements for mandatory testing for X-ray safety are being followed.

Early in its work, the Mammography Expert Advisory Panel recommended expanding the scope to include all breast imaging because the imaging dimension of breast cancer diagnostic processes are interdependent, often requiring a radiologist to correlate and interpret results from several breast imaging modalities (mammography, ultrasound, magnetic resonance imaging or MRI) and procedures (e.g., various types of image-guided biopsies). This recommendation was included in the Phase 1 report.

12 The Canadian Task Force on Preventive Health Care. Recommendations on screening for breast cancer in average-risk women aged 40–74 years. CMAJ. 2011;183(17):1991–2001.

7.2 Mammography Provincial Standards

The Mammography Expert Advisory Panel made recommendations on standards that will be mandatory in order to standardize mammography quality across the province. The standards, in boxes below, are preceded by background and rationale. For further information on the evidence assessment for the standards and indicators, see Appendix I.

Access to care

Access is widely recognized as a key aspect of quality, and patients/service users who need mammography must be able to access it. Ontario needs to have adequate capacity to provide convenient and timely access to mammography, breast ultrasound and breast MRI in order for patients/service users to be properly assessed, within a reasonable distance from where they live. The Mammography Expert Advisory Panel recommended that patients/service users have timely, equitable access to breast imaging services, but acknowledged that at the current time there are no accepted metrics for assessing timeliness or equity of access for mammography services.

Mammography Standard 1
The healthcare system must provide patients/service users with timely, equitable access to breast imaging services.
Level of Evidence: Moderate

Informed patients/service users

Supporting patients/service users to be actively engaged in their care is increasingly recognized as an important dimension of quality for health care, and is a priority focus for the Ministry of Health and Long-Term Care (MOHLTC) and Cancer Care Ontario (CCO). The healthcare system needs to be structured to support all patients/service users through mammography and follow up, and support and enable patients/service users who want to take an engaged and active role in their care by providing them with information in a format that is useful to them. Facilities can provide information in many ways, ranging from oral instructions and/or pamphlets provided at the mammography visit describing potential outcomes and next steps, to electronic portals that give patients/service users access to their test results and other information relevant to their care. The Mammography Expert Advisory Panel recommended that patients/service users be supported to be engaged and active in their care through provision of timely, comprehensive, accurate and accessible information.

Mammography Standard 2
Patients/service users who wish to be engaged and active in their care must be supported to do so.
Level of Evidence: Moderate

In order to provide the highest quality care, it is essential that all aspects of care, including the mammography procedure itself, be delivered in an appropriate, seamless and patient-centred manner. This means that the mammogram is performed and read correctly, the mammography results are communicated to patients/service users and referring physicians, and timely follow-up occurs after an abnormal mammogram, optimizing the continuity of care and reducing the risk of missed cancers. Timely communication of results is essential

In order to provide the highest quality care, it is essential that all aspects of care, including the mammography procedure itself, be delivered in an appropriate, seamless and patient-centred manner.

to quality and reduces patient/service user anxiety. The Ontario Breast Screening Program (OBSP) sends women their mammography results directly by letter to help ensure that they are informed of their results. In the absence of result letters, it is the responsibility of the referring health professional to communicate mammography results and recommended next steps to the patient/service user. The Mammography Expert Advisory Panel recommended that patients/service users receive their mammography results and understand the next steps.

Mammography Standard 3
There must be mechanisms in place to ensure that patients/service users receive their mammography results in a timely way and understand recommended next steps.
Level of Evidence: Moderate

Ensuring follow-up happens

Timely follow-up of abnormal results is essential to quality. It ensures that a definitive diagnosis is reached and that patients/service users receive treatment as soon as possible. Follow-up is enhanced when roles and responsibilities of all parties – particularly

the referring physician and reading radiologist – are clearly defined and communicated. The Mammography Expert Advisory Panel recommended that mechanisms be in place to ensure that follow-up happens after abnormal results.

Mammography Standard 4
There must be mechanisms in place to ensure that patients/service users who have abnormal results receive timely follow-up.
Level of Evidence: Moderate

Screening in an organized program

In Ontario, there is currently no unified, coordinated quality management program for mammography that applies to all providers and all facilities. Ideally, the provincial quality management program for mammography will be based on a set of standards that are consistent for, and consistently applied to, all providers and facilities. There are many initiatives and processes in place that provide a strong foundation for the mammography QMP to build on, particularly the OBSP.

The OBSP is an organized screening program that extends the benefits of organized screening (e.g., inviting women to participate in screening and reminding participants when it is time for their next screening test) to eligible women. Eligibility for the OBSP and other provincial organized screening programs is based on evidence and clinical practice guidelines that identify which groups would receive the most benefits and the least harms from screening.

The Mammography Expert Advisory Panel recognized that it would not be appropriate to expand the populations of women who are eligible for the OBSP because this would be contrary to evidence. However, the panel felt that the OBSP provides high-quality screening to Ontario women and that it should be expanded to all mammography sites so that all those who are eligible can be screened through the program.

Mammography Standard 5
All women who choose to undergo screening mammography and meet the criteria must be screened in the Ontario Breast Screening Program (OBSP).
Level of Evidence: Moderate

Expanding OBSP quality assurance to all sites

Once all sites are participating in the OBSP, they will be required to participate in the program's enhanced quality assurance processes, detailed below.

Mammography equipment uses low-dose x-rays, and like all x-ray equipment, must be properly maintained through regular quality control testing in order to remain safe and effective. Quality control detects and identifies equipment-related problems before they affect clinical images, and must be carried out regularly at frequencies ranging from daily to semi-annually. This is required by the equipment manufacturer, Health Canada's Radiation Protection and Quality Standards in Mammography: Safety Code 36 and the Healing Arts Radiation Protection Act (HARP). The Mammography Expert Advisory Panel reinforced these requirements in a recommendation.

Mammography Standard 6
Regular quality control must be performed on all mammography units.
Level of Evidence: Strong

Medical physicists conduct regular inspections to assure proper functioning of mammography units and the associated viewing chain (i.e., work stations). Physicists also conduct inspections when equipment is new, when problems are suspected and after servicing or maintenance of the equipment. All OBSP sites require regular physics inspection services in order to confirm that required quality control has been carried out and to assess and maintain mammography image quality. The reports generated under the OBSP physics inspection program can be reformatted to demonstrate adherence to HARP and the Canadian Association of Radiologists – Mammography Accreditation Program (CAR-MAP), an accreditation program for mammography run by the Canadian Association of Radiologists. The Mammography Expert Advisory Panel recommended regular physics inspections for all mammography units.

Mammography Standard 7
All mammography units and work stations must be regularly inspected by a qualified medical physicist with training in mammographic systems.
Level of Evidence: Strong

CAR-MAP verifies that radiologists and MRTs have the training, education and experience to perform mammography, that the equipment has been inspected by qualified medical physicists, and that images produced by the equipment are clinically satisfactory for interpretation. The OBSP requires all participating sites (hospitals and IHFs) to be accredited under CAR-MAP; all IHFs are also required by the CPSO IHF Assessment Program to maintain this accreditation. Hospitals that do not participate in

OBSP, however, are not required to be accredited by CAR-MAP. In order to ensure that all facilities are held to the same standards, the Mammography Expert Advisory Panel recommended that all facilities ensure that each mammography unit is currently CAR-MAP accredited and that each MRT and each radiologist at their facility is currently CAR-MAP accredited.

Mammography Standard 8
All facilities must maintain Canadian Association of Radiologists – Mammography Accreditation Program (CAR-MAP) accreditation.
Level of Evidence: Moderate

MRTs are responsible for correctly positioning the breast to produce a high-quality mammogram that will reduce recalls for technical problems and maximize cancer detection. Image reviews assess an MRT's positioning technique and identify where they are performing well and where they may need to improve. The OBSP conducts regular image reviews for MRTs who work in participating sites. Recognizing the value of this personalized assessment and feedback in improving MRT performance, the Mammography Expert Advisory Panel recommended that all MRTs who perform mammography have regular image reviews along with assistance to achieve improvement, if required.

Mammography Standard 9
All medical radiation technologists (MRTs) performing mammography must have regular image reviews.
Level of Evidence: Low

Peer review

Peer review is a way for physicians to assess and provide feedback on each other's skills. It is important that a radiologist's mammographic interpretations only be assessed by another radiologist who also reads mammograms. There are many types of peer review.

Retrospective peer review is a quality assurance process that provides valuable learning opportunities for reading radiologists. The OBSP does post-screen (interval) cancer reviews on cancers that occur after a normal/benign screening episode; this is a type of retrospective peer review. The Mammography Expert Advisory Panel recommended that OBSP interval cancer reviews be expanded to all reading radiologists.

Mammography Standard 10
Retrospective peer review of interval cancers must occur for all reading radiologists.
Level of Evidence: Moderate

Peer assessments for radiologists are a useful non-punitive tool that can be used for quality assurance purposes. Peer assessments provide supportive education to improve the quality of care and ensure patient safety. CPSO conducts peer assessments to promote continuous quality improvement by providing physicians with feedback to validate appropriate care and show opportunities for practice improvement. The CPSO is developing peer assessments for radiology. These assessments must be value added and non-duplicative (i.e., they must not assess aspects of quality that are assessed through other processes).

Mammography Standard 11
CPSO peer assessments must be used for radiologists in Ontario.
Level of Evidence: Low

Prospective peer review is a promising quality assurance process that may improve overall quality and provide educational opportunities for the reading radiologists. There is interest across Canada in developing prospective peer review for radiology in order to improve diagnostic imaging quality overall; in Ontario, Health Quality Ontario is developing a peer review program for all aspects of diagnostic imaging. The Mammography Expert Advisory Panel felt that a prospective peer review system for screening mammography should ideally be developed and should be embedded within this broader diagnostic imaging initiative.

Mammography Standard 12
A prospective peer review system should ideally be developed for screening mammography.
Level of Evidence: Moderate

Standardized mammography reports

The interpretation of the mammogram and the clarity of the mammography report are essential to high-quality care. They ensure that referring physicians understand the radiologist's assessments and act on their recommendations. Inconsistent use of language and unclear or missing information and recommendations can all detract from the utility of the mammography report. The Mammography Expert Advisory Panel recommended that reports use standard elements to improve clarity and

comprehensibility of the information they contain, and that the radiologist/facility must provide the referring health professional with either a normal or an abnormal breast imaging report (i.e., incorporating mammography, breast ultrasound, breast MRI and, if done, image-guided biopsy) in a timely manner, ideally using standard elements in all reports. Standardization will be enhanced through the use of information technology to track and report on all breast imaging.

Mammography Standard 13
Mammography reports must be standardized.
Level of Evidence: Moderate

Image and report repository

MRTs and radiologists need access to prior mammograms and reports when viewing or reporting a current mammogram in order to decide if a finding has changed in the intervening period, but there are a number of barriers to achieving this. The lack of an image and report repository that is accessible by all facilities means that images and reports must often be shipped or carried by the patient, often on CDs that can be unreadable or poorly presented in the Picture and Archiving System (PACS) in the receiving site. Recognizing the value of fast and easy accessibility to images and reports across the healthcare system, the Mammography Expert Advisory Panel recommended that all breast images and reports be available through a provincial repository.

Mammography Standard 14
All breast images and reports must be integrated into a provincial repository to allow imaging and report sharing.
Level of Evidence: Low

The interpretation of the mammogram and the clarity of the mammography report are essential to high-quality care.

Digital mammography

Clinically, digital and film screen mammography are both acceptable for screening. However, digital mammography has significant advantages over film screen mammography, including quicker image acquisition, more efficient image archiving, better image portability, improved integration with other imaging modalities (ultrasound and MRI) and elimination of hazardous chemicals used in developing films. In addition, film screen imaging is becoming obsolete as manufacturers abandon production of necessary supplies and equipment. Although clinically equivalent to film screen mammography, digital mammography has sufficient advantages over film screen, which led the Mammography Expert Advisory Panel to recommend that all mammography be digital.

Mammography Standard 15
All mammography must be digital.
Level of Evidence: Moderate

Facility inspection and assessment

The CPSO is mandated by the MOHLTC to carry out regular inspections and assessments of all IHFs. The purpose of these inspections and assessments is to ensure that IHFs adhere to standards and guidelines that have been developed for the services offered. IHFs that provide mammography must adhere to the Diagnostic Imaging Clinical Practice Parameters and Facility Standards, which contain general diagnostic imaging standards and guidelines, as well as standards and guidelines specific to mammography. Hospitals are not required to undergo regular inspections and assessments; hospital accreditation is voluntary and may not focus specifically on mammography services. Recognizing that standards and guidelines should apply to all facilities, regardless if they are IHFs or hospitals, the Mammography Expert Advisory Panel recommended that an assessment program be developed for hospitals, with the caveat that any new program must be value added and non-duplicative.

Mammography Standard 16
All facilities must participate in regular inspections and assessments to ensure they meet appropriate mammography standards.
Level of Evidence: Low

7.3 Mammography Quality Management Program

To support the design components and implementation of consistent QMPs across the three health services areas, the mammography QMP will fundamentally reflect the common program described in Section 5. However, given the unique nature of this health service area, the Mammography Expert Advisory Panel noted a few considerations for mammography.

To prevent overlap and duplication in roles, the Mammography Expert Advisory Panel has recommended that:

- The QMP provincial lead will work closely with the OBSP Radiologist-in-Chief, who will sit on the provincial mammography quality committee. This will foster continued alignment between the QMP and the OBSP.
- OBSP regional breast imaging leads (RBILs) will take on additional responsibilities to cover Partnership responsibilities. This will reduce overlap in responsibilities between OBSP and QMP regional leads. This role expansion will require expanding RBILs' time commitments and/or hiring additional RBILs.

The Mammography Expert Advisory Panel recommended that radiologists who work in more than one facility receive their overall totals for the indicators, as well as their indicators stratified by each facility they work in. Regional and provincial leads will receive individual radiologist totals for indicators (overall total and stratified by each facility the radiologist works in), but facility leads will receive the total individual radiologist's indicators and those for that facility, not any other facilities.

Mammography QMP indicators

For provider-level screening reports, the Mammography Expert Advisory Panel recommended that well-established national indicators and targets be used. Current targets apply to screening eligible women in an organized program, so in future, after a process of data acquisition, stabilization and review, targets will be established for all screening (i.e., screening inside and outside the OBSP).

Table 4 Provider-level mammography screening indicators

No.	Indicator	Target[13]
M1	**Abnormal Calls** Percentage of mammograms identified as abnormal at the screening episode **Level of Evidence:** Strong	< 10% initial screens < 5 % re-screens
M2	**Positive Predictive Value** Percentage of abnormal cases with completed follow-up found to have breast cancer (ductal carcinoma in situ or DCIS, or invasive) after diagnostic work-up **Level of Evidence:** Strong	≥ 5% initial screens ≥ 6% re-screens
M3	**Invasive Cancer Detection** Number of invasive cancers detected per 1,000 screens **Level of Evidence:** Strong	> 5/1,000 initial screens > 3/1,000 re-screens
M4	**Ductal Carcinoma In Situ (DCIS) Detection** Number of DCIS cancers detected per 1000 screens **Level of Evidence:** Strong	Surveillance and monitoring purposes only
M5	**Tumour Size** Percentage of invasive cancers ≤ 15 mm **Level of Evidence:** Strong	> 50%
M6	**Nodal Involvement** Percentage of invasive screen-detected cancers that are node-negative **Level of Evidence:** Strong	> 70%
M7	**Post-Screen Invasive Cancers (Interval Cancers)** Number of invasive breast cancers found after a normal mammography screening episode within 0 to12 months, and 12 to 24 months **Level of Evidence:** Strong	0 to 12 months: < 6 per 10,000 person/years 12 to 24 mos: < 12 per 10,000 person/years

For provider-level diagnostic mammography reports, the panel noted that there are currently no standardized national indicators and targets. Accordingly, the Mammography Expert Advisory Panel recommended that after a process of data acquisition, stabilization and review, the following indicators should be reported. Where targets do not exist, they will be established after a review of the evidence and the data.

13 Applicable only to mammography screening in an organized program for women aged 50 to 74.

Table 5 **Provider-level mammography diagnostic indicators**

No.	Indicator	Target
M8	**Malignant Biopsies** a) malignant core biopsies • Percentage of malignant core biopsies, out of all core biopsies for asymptomatic women • Percentage of malignant core biopsies, out of all core biopsies for symptomatic women b) malignant surgical biopsies • Percentage of malignant surgical biopsies, out of all surgical biopsies for asymptomatic women • Percentage of malignant surgical biopsies, out of all surgical biopsies for symptomatic women **Level of Evidence:** Strong	TBD
M9	**Positive Predictive Value** Percentage of recommended biopsies found to have breast cancer (ductal carcinoma in situ or DCIS, or invasive), out of all recommended biopsies **Level of Evidence:** Strong	TBD
M10	**Use of Breast Imaging Reporting and Data System or BI-RADS 3** Percentage of BI-RADS 3 called on diagnostic work-up, out of all diagnostic cases **Level of Evidence:** Strong	TBD
M11	**BI-RADS 3 Malignancies** Percentage of BI-RADS 3 calls that develop into cancer (DCIS or invasive), out of all BI-RADS 3 calls **Level of Evidence:** Strong	< 2%
M12	**BI-RADS 5 Malignancies** Percentage of BI-RADS 5 calls that develop into cancer (DCIS or invasive), out of all BI-RADS 5 calls **Level of Evidence:** Strong	> 95%

For facility-level indicators, the Mammography Expert Advisory Panel recommended that established wait time indicators be used to measure whether patients/service users are receiving timely follow-up after abnormal screens at the facility level. These indicators should mirror national and international indicators and targets to allow comparison with peers.

Table 6 **Facility-level mammography indicators**

No.	Indicator	Target
M13	**Wait Time to First Assessment** Time from abnormal screen to first diagnostic assessment **Level of Evidence:** Strong	≥ 90% within 3 weeks
M14	**Wait Time to Diagnosis without Tissue Biopsy (Core or Open)** Time from abnormal screen to definitive diagnosis without tissue biopsy **Level of Evidence:** Strong	≥ 90% within 5 weeks
M15	**Wait Time to Diagnosis with Tissue Biopsy (Core or Open)** Time from abnormal screen to definitive diagnosis with tissue biopsy **Level of Evidence:** Strong	≥ 90% within 7 weeks

7.4 Mammography QMP Considerations

Implementation

The Mammography Expert Advisory Panel and other stakeholders recommended the following considerations for the successful implementation of a mammography QMP.

- **Sufficient capacity, resources and support will be required for the implementation of the mammography QMP.** There is conceptual support to move forward with the program, however implementing the recommendations into practice will be limited by the current available resources (e.g., converting from film screen to digital mammography, participating in CAR-MAP, conducting physics inspections and participating in facility assessment processes). A detailed review of the program impact and required resources will be needed as part of the initial phase of implementation.

- **Successful uptake and adoption of the program will depend on integration and close alignment with existing quality management processes and programs.** To ensure alignment and avoid duplication, the QMP must complement and integrate into existing quality management structures and processes in hospitals and IHFs, and align with related efforts, such as the initiative to establish a peer review process for diagnostic imaging, led by Health Quality Ontario. As the QMP is implemented, the Partnership must further define the relationships and opportunities for integration and alignment.

- **Inclusion of diagnostic mammography introduces additional complexity and will need to be considered carefully.** The focus of the OBSP is screening mammography, while the QMP scope includes both screening and diagnostic mammography. While the QMP as designed builds on many aspects of the OBSP, introducing diagnostic mammography adds considerable complexity, particularly with regard to data collection and reporting. Information management and information technology (IM/IT) solutions that work for screening mammography may not be applicable to diagnostic mammography; this will only be compounded if the QMP scope expands to all breast imaging. Implementation will need to be managed carefully to ensure that the subtleties and complexities of the expansion to diagnostic mammography, and eventually all breast imaging, can be managed.

Future Work

The Mammography Expert Advisory Panel recommended the following areas for future consideration that may have an impact on the quality of services provided for mammography.

- **Patient/service user experiences are an important measure of quality.** There are currently no well-established and validated indicators that the Mammography Expert Advisory Panel could recommend for the mammography QMP. Indicators for patient/service user experience will be established and included in facility-level reporting in the future, after a process of data acquisition, stabilization and review.

- **Inclusion of emerging technologies and their impact on the quality of mammography services will need to be further considered by the program.** Newer technologies are in development that may change how breast imaging is performed. These emerging technologies will need to be assessed as to how they may impact the quality of mammography services. The Mammography Expert Advisory Panel noted two technologies that cannot be recommended due to insufficient evidence, but that will need to be re-assessed as more evidence becomes available.

    - Breast tomosynthesis is a promising new mammographic technology that has been shown in several studies to improve cancer detection in a screening environment and reduce recall rates compared to digital mammography alone.[14,15] Limitations include difficulties interfacing with some PACS, substantially longer radiologist read times and difficulty detecting clusters of calcifications. If further evidence supports adoption of tomosynthesis for screening, consideration will need to be given to compensation for tomosynthesis and its impact on radiologist workflow.
    - Computer-aided detection (CAD) is an image analysis method that uses computer algorithms to identify suspicious regions of an image. It may assist some radiologists when interpreting mammograms. There is currently no strong evidence to support or discourage its use, but if further evidence is developed in future, the mammography QMP will revisit this.

14 Skaane P, Bandos AI, Gullen R, Eben EB, Ekseth U, Haakenaasen U, et al. Comparison of digital mammography alone and digital mammography plus tomosynthesis in a population-based screening program. Radiology. 2013;267(1):47-56.

15 Rafferty EA, Park JM, Philpotts LE, Poplack SP, Sumkin JH, Halpern EF, et al. Assessing radiologist performance using combined digital mammography and breast tomosynthesis compared with digital mammography alone. Radiology. 2013;266(1):104-113.

8.0 Pathology Program Details

8.1 Pathology Overview

"I think the work we have done on the QMP will help establish consistent approaches for the whole province, reduce discrepancies in diagnoses and improve the overall standard of health care in Ontario."

Dr. Sandip SenGupta, expert advisory panel member, pathologist and laboratory medical director

Pathology is a specialty of medicine concerned with the study of the nature and causes of diseases through examination of organs, tissues, bodily fluids and whole bodies (autopsies). The work of a pathologist involves interpreting changes seen in tissue specimens (e.g., biopsies, surgical resections) to provide a diagnosis and/or diagnostic information that informs clinical decisions about treatment and management. The analytical work of a pathologist is one component of a total testing cycle which includes pre- and post-analytic processes. In Ontario, pathologists practice in hospitals, private community laboratories and public health laboratories and may practice in more than one of these settings. The pathology community has recognized the need to focus on quality improvement to advance performance and promote learning and education.

The profession has a history of leadership in the quality assurance domain. Since 2009, for example, pathologists have been proactively working towards developing a standardized quality assurance program for all surgical pathology laboratories in Ontario through Path2Quality, a collaborative initiative between the Ontario Medical Association Section on Laboratory Medicine and the Ontario Association of Pathologists. The focus of Path2Quality is on improving quality assurance programs and helping to guide the professional work of laboratory physicians. One of Path2Quality's work streams, Standards2Quality, has developed best practice guidelines for quality assurance that set out the policies and procedures that should be in place for professional pathologic interpretation. Defining the Standards2Quality Guidelines[16] is an excellent step, and the focus of the Pathology Expert Advisory Panel is on increasing uptake of the guidelines, which is currently uneven across facilities.

A provincial quality management program (QMP) for pathology will include recommendations for processes that are standardized and consistently applied to all providers and facilities. The Pathology Expert Advisory Panel endorsed *Standards2Quality for Quality Management in Pathology Professional Practices, Version 2* and used it as a foundation for developing provincial standards and best practice guidelines. The panel noted that implementation of these standards and guidelines must be predicated on appropriate infrastructure and resource support being made available. To that end, the panel had a preliminary examination of resource requirements through a high level discussion of Workload2Quality, the companion document to Standards2Quality, but no recommendation was made.

The pathology community has recognized the need to focus on quality improvement to advance performance and promote learning and education.

The scope of the pathology QMP is the analytic aspects of surgical pathology; the pre and post analytic processes are out of scope at this time, although they are very important in pathologic interpretation. In addition, forensic pathology and

16 Path2Quality. Standards2Quality: guidelines for quality management in pathology professional practices. V2. 2013.

the technical aspects of laboratory performance are out of scope. Quality management for forensic pathology occurs through another mechanism, and technical aspects of laboratory performance are addressed through the Ontario Laboratory Accreditation (OLA) program, led by the Institute for Quality Management in Healthcare (IQMH), which is mandatory for all pathology laboratories in Ontario.

In order to provide the highest quality care, it is essential for laboratories to have key foundational elements in place for quality assurance and improvement activities.

8.2 Pathology Provincial Standards and Best Practice Guidelines

The Pathology Expert Advisory Panel made recommendations on provincial quality standards and best practice guidelines that will help to standardize pathology quality across the province. Applicability of specific standards and guidelines will be determined by facility-specific practices. The standards and guidelines, in boxes below, are preceded by background and rationale. For further information on the evidence assessment for the standards and indicators, see Appendix J.

Foundational elements

In order to provide the highest quality care, it is essential for laboratories to have key foundational elements in place for quality assurance and improvement activities. One of the most effective ways this can be accomplished is to have an established quality management committee and a detailed quality management plan. The committee provides facilities with a venue to discuss and monitor quality issues, and implement quality improvement processes and projects. The plan allows facilities to focus on key quality deliverables on a regular basis, and provides overarching vision and scope for quality management at each facility. Recognizing the value of these foundational elements in ensuring safe, effective and reliable pathology services for all patients, the Pathology Expert Advisory Panel recommended that all facilities have a pathology professional quality management committee and a pathology professional quality management plan, as per the Standards2Quality Guidelines.

Pathology Standard 1
All laboratories in Ontario must have a pathology professional quality management committee.
Level of Evidence: Moderate

Pathology Standard 2
All laboratories in Ontario must have a pathology professional quality management plan.
Level of Evidence: Moderate

If report defects, discrepancies, discordances or errors are revealed by any form of review, a policy and predetermined processes must be in place for investigation, resolution and follow-up documentation. This must include a consistent scheme for classifying report defects, discrepancies, discordances and errors, and their subsequent investigation and resolution.

The Pathology Expert Advisory Panel recommended that a consistent classification scheme be used to report defects, discrepancies, discordances and errors in order to support standardized reporting. A standard regarding the appropriate follow-up investigation and resolution also needs to be established.

Pathology Standard 3
All laboratories must have a guideline for classification of report defects, discrepancies, discordances and errors, and a policy for their investigation and resolution.
Level of Evidence: Low

Secondary case reviews

An important method to facilitate the provision of high-quality care in pathology is through continual collaboration and secondary case review (i.e., double reads of a case). Prospective case review occurs when a second pathologist reviews a case prior to reporting in order to ensure accuracy of the diagnosis or other findings. Retrospective case review is a second read of a case after the pathologic diagnosis is rendered and is an important quality assurance mechanism within an institution. Both prospective and retrospective case reviews may be undertaken within a facility or between facilities; however, it is acknowledged that these reviews can have significant human resource implication.

The Pathology Expert Advisory Panel made a number of recommendations about secondary case review (below), recognizing that use of various

types of secondary review will be dependent on the details of the case and the expertise of the pathologists in the professional group – that is, all the pathologists in a facility who practice anatomical pathology.

Intra-departmental consultation

Intra-departmental consultation is a form of secondary prospective peer review. It may involve either a direct request from one pathologist to another or a consultation in the course of a case conference. Intra-departmental consultation leads to improved decision making; uniformity in the use of diagnostic terminology, grading systems and criteria; and increased compliance with quality assurance processes.

Due to the variability of cases, each facility should develop its own policy about which cases are considered mandatory for intra-departmental consultation. Groups that report a wide variety of cases may consider having a policy for review of all first time diagnoses that could lead to a significant clinical intervention. Subspecialty practice groups may choose to focus on cases that result in significant clinical action or are prone to diagnostic variability.

The Pathology Expert Advisory Panel recommends that laboratories have a policy that outlines the procedure for consultation with intra-departmental colleagues, as per the Standards2Quality Guidelines. All laboratories must collect and review data on intra-departmental consultation for the professional group.

Pathology Standard 4

All laboratories must have a policy that outlines the procedure for consultation with intra-departmental colleagues, including the documentation of those consults. Each laboratory must have a policy that outlines which cases require mandatory intra-departmental consultation and which are discretionary for the professional group.

Level of Evidence: Moderate

Pathology Standard 5

All laboratories must collect and review data on intra-departmental consultations, for the professional group.

Level of Evidence: Moderate

Pathology Best Practice Guideline 1

All laboratories should collect and review data on intra-departmental consultations, for each pathologist.

Level of Evidence: Moderate

External consultations

External consultation occurs when a pathologist seeks an opinion from a pathologist external to his or her group. This may happen if the pathologist has uncertainty about a case, lacks resources for ancillary investigations at their site or there are divergent opinions. External consultation occurs before a final diagnosis is rendered and therefore is a form of prospective secondary review. Guidelines outlining the responsibilities of a pathologist requesting an external consultation are critical to ensure that data and important clinical information are sent to the external consultant to allow for proper interpretation of the case in a timely manner.

Data on external consultations are a measure of secondary prospective review activity and provide confidence to clinicians and patients/service users that the diagnosis and information contained in the report is accurate.

The Pathology Expert Advisory Panel recommends that laboratories have a guideline outlining the responsibilities and procedure for a pathologist requesting an external consultation, as per the Standards2Quality Guidelines. These laboratories must also collect and review data on external consultations for the professional group.

Pathology Standard 6

All laboratories must have a guideline outlining the responsibilities of a pathologist requesting an external consultation to ensure data and important clinical information are sent to the external consultant to allow for proper interpretation of the case in a timely manner.

Level of Evidence: Moderate

Pathology Standard 7

All laboratories must have a policy that outlines the procedure for requesting external consultation, including the review and documentation of the resulting consultation opinion. The policy must provide guidance as to the types of cases that are appropriate for external consult.

Level of Evidence: Moderate

Pathology Standard 8

All laboratories must collect and review data on external consultations, for the professional group.

Level of Evidence: Moderate

Pathology Best Practice Guideline 2

All laboratories should collect and review data on external consultations, for each pathologist.

Level of Evidence: Moderate

Intra-operative consultations

Intra-operative consultations provide rapid information to surgeons during an operation to allow them to make appropriate intra-operative clinical decisions. Comparing intra-operative consultation results with the findings on permanent sections prior to final release of cases is necessary to resolve discrepancies between the two techniques. Rates of deferred diagnoses (diagnosis is not provided and is deferred until after subsequent testing) should also be reviewed because the rates vary depending upon expertise, types of specimens and resections encountered by a professional group. Monitoring data on intra-operative consultation provides confidence to clinicians and patients/service users that the process is reliable, accurate and appropriate.

The Pathology Expert Advisory Panel recommends that all laboratories whose facility provides operative services have a policy, as per the Standards2Quality Guidelines, that outlines the process for comparison of intra-operative consultation results with final diagnoses. These laboratories must also collect and review data on intra-operative consultations for the professional group.

Pathology Standard 9

All laboratories must have a policy that outlines the processes for, and the documentation of, the comparison of intra-operative consultation results with final diagnoses.

Level of Evidence: Moderate

Pathology Standard 10

All laboratories must collect and review data on the appropriateness and accuracy of intra-operative consults and deferral rates, for the professional group.

Level of Evidence: Moderate

Pathology Best Practice Guideline 3

All laboratories should collect and review data on the appropriateness and accuracy of intra-operative consults and deferral rates, for each pathologist.

Level of Evidence: Moderate

Previous/concurrent laboratory reports

Review of pertinent previous/concurrent laboratory reports from a current surgical pathology case ensures consistency and may help determine the most appropriate diagnosis for the current case.

The Pathology Expert Advisory Panel recommends that all laboratories have a policy, as per Standards2Quality Guidelines, that outlines the procedure for correlation of current surgical pathology cases with pertinent previous/concurrent laboratory reports. The collection and review of data for previous/concurrent laboratory reports is suggested as a best practice guideline at this time.

Pathology Standard 11

All laboratories must have a policy that outlines the procedure for correlation of current surgical pathology cases with pertinent previous/concurrent laboratory reports and, if required, related slides and other material.

Level of Evidence: Moderate

Pathology Best Practice Guideline 4

All laboratories should collect and review data on report defect and discordances revealed by review of previous/concurrent laboratory reports, for the professional group and for each pathologist.

Level of Evidence: Moderate

External reviews

External reviews occur when there is a request by a pathologist, clinician, institution or patient/service user to have a case reviewed by a different laboratory or pathologist than the one that originally reported the case. External reviews are a form of secondary review and may be requested to clarify information for patient treatment or as a pro forma requirement of an institution. Monitoring of diagnostic discrepancies revealed by external review can reassure patients/service users, pathologists, clinicians and institutions that diagnoses are accurate and can identify areas for quality improvement.

The Pathology Expert Advisory Panel recommends that all laboratories have a policy that outlines the processes for handling requests for review of cases by an external pathologist, as per the Standrds2Quality Guidelines. Laboratories must also collect and review data on report defect and discordances revealed by external reviews for the professional group.

Pathology Standard 12

All laboratories must have a policy that outlines the processes for handling requests for review of cases by an external pathologist, including the documentation and review of those results.

Level of Evidence: Moderate

Pathology Standard 13

All laboratories must collect and review facility-level data on report defect and discordances revealed by external reviews, for the professional group.

Level of Evidence: Moderate

Pathology Best Practice Guideline 5

All laboratories should collect and review data on report defect and discordances revealed by external reviews, for each pathologist.

Level of Evidence: Moderate

Retrospective reviews

Retrospective reviews occur after cases have been finalized. They may focus on aspects of the analytical, pre- or post-analytical phase. A benefit of retrospective reviews is that evaluation of case sets may produce more data and identify previously unrecognized areas of deficiency or discrepancy. Evaluation of reports, slides and other materials as part of a retrospective review may generate educational feedback about the original cases.

The Pathology Expert Advisory Panel suggests that all laboratories have a policy, as per the Standards2Quality Guidelines, for reviewing report defects and discordances revealed by retrospective reviews. The collection and review of data is suggested as a best practice guideline at this time.

Pathology Best Practice Guideline 6

All laboratories should have a policy that outlines the procedure for reviewing the professional group's data on report defects and discordances revealed by retrospective reviews.

Level of Evidence: Moderate

Pathology Best Practice Guideline 7

All laboratories should collect and review data on report defects and discordances revealed by retrospective reviews, for the professional group and for each pathologist.

Level of Evidence: Moderate

Corrected reports

Reports may be corrected for a number of reasons, including changes in demographic, provider or diagnostic information. Ensuring that the responsible healthcare provider is notified of corrections is important for patient care and safety. Monitoring corrected reports helps to identify quality improvement opportunities that can decrease corrected report rates. In addition, there must be consistency across laboratories as to how a corrected report is defined because currently there is significant variability in definitions.

The Pathology Expert Advisory Panel recommended that standardization and consistency across laboratories be facilitated through ensuring that policies clearly define and outline the processes and criteria for revising and reporting on corrected reports. Laboratories must also collect and review data on corrected reports and the reasons for the corrections, for the professional group.

Pathology Standard 14

All laboratories must have a policy that outlines:

- The criteria for revising or correcting reports, including those in which diagnoses are revised or corrected. This policy should include definitions of the terms employed by the group for such reports, criteria for their use, the procedures and documentation required to issue them and related follow-up quality assurance actions.
- When to directly inform the responsible clinician of the revision or correction (e.g., by verbal communication) and how to document that communication.
- The procedure for notification of the Laboratory Director (or, depending on a group's policies, the chair of the pathology professional quality management committee), and through the Laboratory Director (or chair of the pathology professional quality management committee) initiation of critical incident and similar reporting where appropriate.
- When revised or corrected reports have to be documented for risk management, root cause analysis and quality improvement purposes via the organization's processes.

Level of Evidence: Moderate

Pathology Standard 15

All laboratories must collect and review data on corrected reports and the reasons for the corrections, for the professional group.

Level of Evidence: Moderate

Pathology Best Practice Guideline 8

All laboratories should collect and review data on corrected reports and the reasons for the corrections, for each pathologist.

Level of Evidence: Moderate

Critical diagnoses and significant unexpected findings

Critical diagnoses (diagnoses that require expedited notification) and significant unexpected findings must be communicated to the appropriate healthcare provider to ensure timely management of important medical conditions in order to reduce risk of morbidity and mortality.

The Pathology Expert Advisory Panel recommends that all laboratories have a policy to define cases that should be classified as critical and a procedure to communicate diagnosis or findings in a timely manner. The collection and review of data are suggested as a best practice guideline at this time.

Pathology Standard 16

All laboratories must have a policy that outlines the types of diagnoses/findings that are considered critical in the practices of physicians served by a surgical pathology group.

Level of Evidence: Moderate

Pathology Standard 17

All laboratories must have a defined procedure for timely communication of these diagnoses/findings to the physician most responsible for the care of the patient involved. The communication of these results must be documented.

Level of Evidence: Moderate

Pathology Best Practice Guideline 9

All laboratories should collect and review data on reporting of critical diagnoses, results and alert values, for the professional group and for each pathologist.

Level of Evidence: Moderate

Turnaround times

Timely access to pathology results is essential for high-quality patient care. While there are a number of factors that can impact turnaround times, these times can be used to monitor the efficiency of laboratory work processes and can highlight resource limitations or issues in specimen handling or communication.

The Pathology Expert Advisory Panel recommends that all laboratories have a policy for monitoring turnaround times, as per the Standards2Quality Guidelines. Laboratories must also collect and review data for the professional group.

Pathology Standard 18
All laboratories must have a policy that outlines the processes for monitoring of turnaround times on a regular basis.
Level of Evidence: Moderate

Pathology Standard 19
All laboratories must collect and review data on turnaround times, for the professional group.
Level of Evidence: Moderate

Pathology Best Practice Guideline 10
All laboratories should collect and review data on turnaround times, for each pathologist
Level of Evidence: Moderate

Service satisfaction

Supporting patients/service users to be actively engaged in their care is increasingly recognized as an important dimension of quality for health care, and is a priority focus for the Ministry of Health and Long-Term Care (MOHLTC). In addition, feedback from clinicians who use pathology services helps provide knowledge of user needs, expectations and experience with a particular pathology laboratory. An example of enhancing service satisfaction is the pathology and colonoscopy early quality initiative, which focuses on investigating communication issues within pathology diagnostic reporting in order to make recommendations about the most effective way to structure pathology reports and report pathologic findings (see Appendix B).

The Pathology Expert Advisory Panel suggests all laboratories collect and review service satisfaction data, as per Standards2Quality, in order to identify improvement opportunities.

Pathology Best Practice Guideline 11
All laboratories should collect and review data on service satisfaction, for the professional group.
Level of Evidence: Moderate

Patient safety checklists for surgical pathology

The use of patient safety checklists in pathology helps ensure that all key aspects of a specific pathology process are followed. The use of checklists minimizes reliance on user memory in the face of complex and multi-step processes and procedures. Their use may also reduce variable input and inconsistency, and in doing so, increase workflow efficiency and, ultimately, minimize error and increase diagnostic accuracy.

The Pathology Expert Advisory Panel suggests that laboratories should have a best practice guideline, as per Standards2Quality, that supports the use of Patient Safety Checklists for Surgical Pathology.

Pathology Best Practice Guideline 12
All laboratories should have a process in place to ensure that the professional group is aware of Patient Safety Checklists for Surgical Pathology as a reference standard to ensure day-to-day practice meets best practice.
Level of Evidence: Low

The use of patient safety checklists in pathology helps ensure that all key aspects of a specific pathology process are followed.

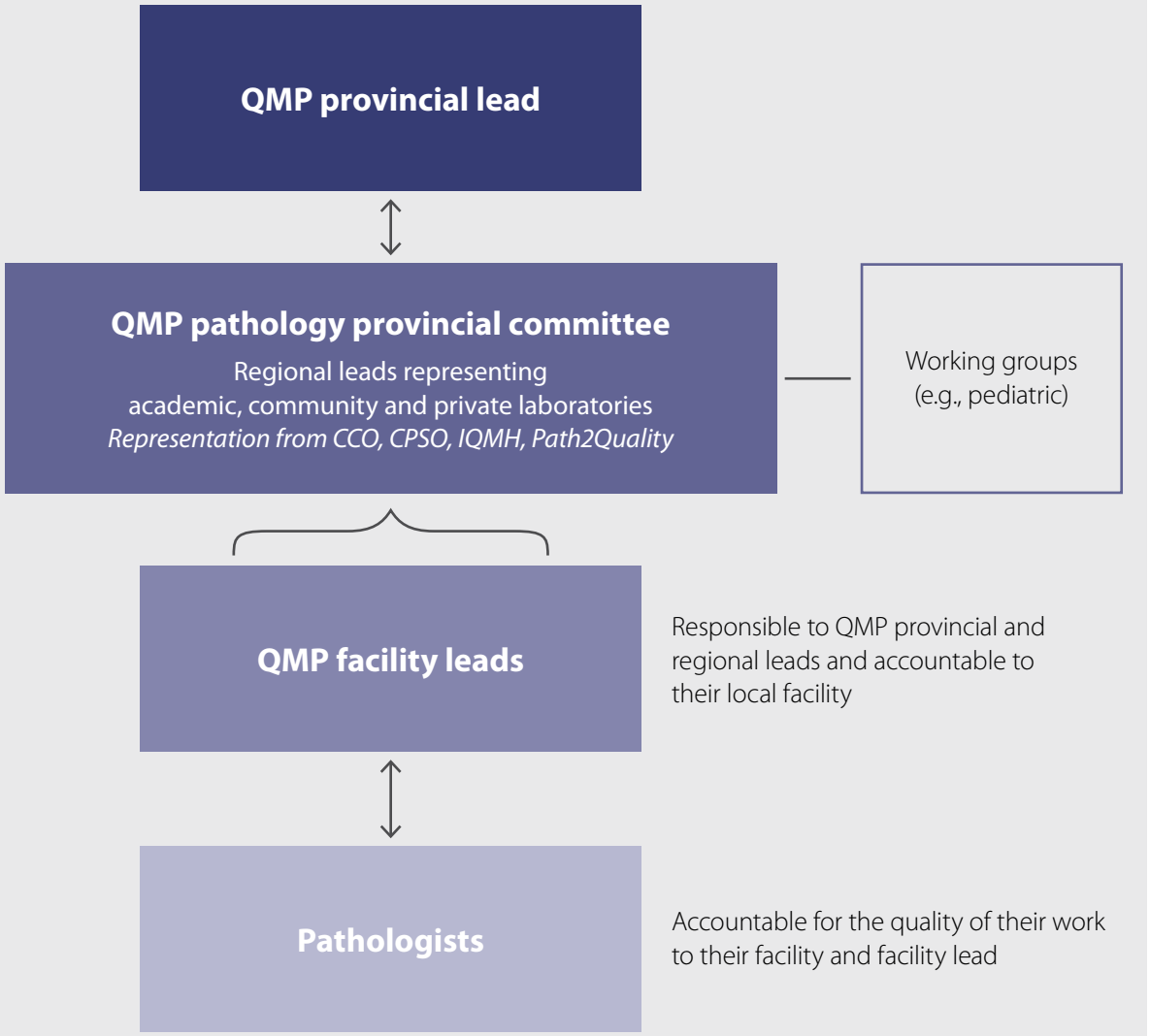
Pathology quality assurance program

A quality assurance program will be fundamental to support the implementation and adoption of the identified recommendations. The program will build on existing efforts in the field that address patient safety and quality for pathology, as well as the uptake of the provincial standards and best practice guidelines.

The Pathology Expert Advisory Panel has recommended that the quality committee determine the best manner and method for monitoring compliance to standards, as well as continually reviewing and maintaining the recommended standards.

Pathology Standard 20
Standards and best practice guidelines for internal quality assurance must be maintained and monitored.
Level of Evidence: Low

Figure 10 **Quality management model and structure for the pathology program**



8.3 Pathology Quality Management Program

To support the design components and implementation of common QMPs across the three health services areas, the pathology QMP will fundamentally reflect the common program described in Section 5. However, given the unique nature of this health service area, the Pathology Expert Advisory Panel recommended the following considerations for pathology.

The proposed quality management model will complement and integrate the existing quality structures currently in place. In Ontario, laboratory directors/chiefs of pathology service have primary responsibility for managing professional quality within their facilities. The quality management model will support, strengthen and enhance local accountability structures. Figure 10 illustrates the quality management model structure, which will be a subset of the overall governance for the program.

- The QMP pathology provincial committee will be chaired by the QMP provincial lead and primarily composed of pathologists. It will consist of the QMP regional leads with representation from various sectors (e.g., academic hospitals, community hospitals, private laboratories) as well as from other organizations such as Cancer Care Ontario (CCO), the College of Physicians and Surgeons of Ontario (CPSO), the Institute for Quality Management in Healthcare and Path2Quality.

- Working groups may be needed to focus on subspecialty areas (e.g., pediatric) and advise the provincial committee.

- QMP regional leads will also be QMP facility leads within their respective organizations. Because pathology is currently provided in both public and private facilities, both will need to have suitable representation. The Pathology Expert Advisory Panel has also identified the need for further consideration of how regions will be defined. For example, the work of pathology often crosses Local Health Integration Network (LHIN) boundaries, with hub and spoke models created between both large and small facilities, and academic and community facilities. This will need to be taken into account through the next phase of implementation to ensure successful uptake and adoption of the quality management model and structure, in particular at the regional level.

- QMP facility leads are the key individuals who will monitor and oversee quality at the local level. It is envisioned that the QMP facility leads, in many cases, will be chiefs of pathology or medical directors, but the role may also be delegated to another pathologist. The leads will require infrastructure support (i.e., clerical staff, information technology) in order to effectively execute their responsibilities. In addition, the potential for smaller sites to partner with larger facilities will be considered during implementation and may be guided by work done in other areas. Facility leads will be accountable to their local facility as per current accountability and legislative requirements, and responsible to the QMP regional and provincial leads (i.e., provincial committee) to provide and monitor data.

*Note: Targets are supported by evidence. Auditable outcomes are monitored for quality assurance purposes when there is insufficient evidence to recommend a target.

Pathology QMP indicators

Table 7 Pathology facility-level indicators

No.	Indicator	Target/Auditable Outcome*
Intra-Departmental Consultations		
P1	**Intra-Departmental Consultation** Number of facility-level intra-departmental consults for the professional group, out of all cases for the professional group. **Level of Evidence:** Moderate	TBD
External Consultations		
P2	**External Consultation** Number of facility-level external consults for the professional group, out of all cases for the professional group. **Level of Evidence:** Moderate	TBD
Intra-Operative Consultations		
P3	**Intra-Operative Consultation Accuracy** Number of accurate intra-operative consultations for the professional group, out of all cases for the professional group. **Level of Evidence:** Moderate	TBD
P4	**Intra-Operative Consultation Deferrals** Number of deferred intra-operative consultations for the professional group, out of all cases for the professional group. **Level of Evidence:** Moderate	TBD
External Reviews		
P5	**Defects and Discordances** Number of cases within the facility where external review revealed report defects or diagnostic discordances for the professional group, out of all reports reviewed externally by the professional group. **Level of Evidence:** Moderate	TBD
Corrected Reports		
P6	**Corrected Reports** Number of corrected reports stratified by reason for the professional group, out of all reports reviewed by the professional group. **Level of Evidence:** Moderate	TBD
Turnaround Times		
P7	**Turnaround Time** Average facility time from specimen receipt to case sign out for professional group overall for all surgical pathology cases. **Level of Evidence:** Moderate	TBD

- For provider-level indicators, the Pathology Expert Advisory Panel noted that there are currently no standardized, evidence-based national indicators. Accordingly, the panel recommended that future work will be required to define the indicators for provider-level reporting. This will include a process of indicator definition, data acquisition, stabilization and review, prior to establishing the provincial provider-level indicators.

- For smaller facilities, the Pathology Expert Advisory Panel has recommended that a process be put in place to ensure that facility-level data be reported in a way that ensures that individual physician data at these sites will remain anonymous, for example by grouping small facilities together for reporting purposes.

- For facility-level indicators, the Pathology Expert Advisory Panel noted that there are no standardized national thresholds and/or targets. Accordingly, the panel recommended that future work will be required to further define the indicators for data collection, and formally implement a process of data acquisition, stabilization and review, prior to establishing the provincial-level targets/thresholds.

In order to assess the uptake and adoption of the recommended provincial standards, all proposed standards identified in Section 8.2 above will be included for facility-level QMP reporting.

8.4 Pathology QMP Considerations

Implementation

The Pathology Expert Advisory Panel and other stakeholders recommended the following considerations for the successful implementation of the pathology QMP.

- **Sufficient capacity, resources and support will be required for the implementation of the pathology QMP.** There is conceptual support to move forward with the program, however implementing the recommendations into practice will be limited by the current available resources. A detailed review of the program impact and required resources will be conducted as part of the initial phase of implementation. For example a number of resources will need to be considered, which include the current shortage of pathologists and the potential of the program to increase workloads.

- **Successful uptake and adoption of the program will depend on integration and close alignment with local facility quality management processes.** The program as described has highlighted the need to complement and integrate into existing quality management structures and processes in both hospital and private laboratory environments. As the program is implemented, the Partnership will need to continue to work with local facilities to further define the relationship and ensure accountability for quality at the facility level is maintained.

- **Regional program governance will need to be considered based on the current delivery structures for pathology in order for a successful implementation of the quality management model.** The program as described has highlighted the need to review and consider how the quality management model, and in particular the role of the QMP regional leads, will be structured to optimally align with the current delivery models for pathology, including the existing hub and spoke models, as well as regional delivery relationships between academic, community and private laboratories. The QMP regional lead will be a QMP facility lead and will be well positioned to support facilities to implement the program. The recruitment and selection processes for all QMP leads and other committee members will be designed in a transparent process and executed with input from stakeholders. All QMP leads will be practicing pathologists.

Future Work

The Pathology Expert Advisory Panel recommended the following areas for future consideration, which may have an impact on the quality of services provided for pathology.

- **Pathology system-level design will need to be considered in parallel to the implementation of the pathology QMP program.** A number of system-level design considerations have been highlighted by the pathology community as foundations to advance quality, and the QMP will look to collaborate with other system players on these issues. For example:

- There are a number of different delivery models for pathology services in Ontario including the hub and spoke model, as well as regional delivery relationships between academic, community and private laboratories. The various delivery models will need to be considered with respect to how they may impact the program and the quality of pathology services.
- New technologies are emerging with the potential to positively impact quality for the pathology field. For example, the use of bar coding may be more fully considered as a process improvement opportunity for all facilities.
- The role and use of pathologists' assistants currently varies across the province. There is an opportunity to provide provincial recommendations to standardize and optimize their use in the pathology field moving forward.

- **Quality reporting for the program should include both facility-level and provider-level indicators.** There is concern among pathologists about sharing provider-level information because there are currently no standardized national indicators for pathology. The program as described has highlighted that provider-level reporting will not initially be reported. Accordingly, the panel recommended that future work will be required to define the indicators for provider-level reporting. This will include a process of indicator definition, data acquisition, stabilization and review, prior to establishing the provincial provider-level indicators. Data quality and reliability at the facility level will need to be carefully evaluated prior to sharing provider-level quality data.

- **Cross-collaboration should exist between the pathology and colonoscopy QMPs.** Facilitated through the work of the Partnership, there is an opportunity for cross-collaboration between the colonoscopy and pathology programs. For example, after a biopsy or polypectomy, pathology results are necessary to allow endoscopists to reach a diagnosis and recommend follow-up. Standardized terminology for pathology results will facilitate clear communication between the pathologist and endoscopist to reach a diagnosis and recommend next steps. Future work should include a review of current processes and communication mechanisms, with an opportunity to standardize specimen and referral submissions, and pathology results to support integrated quality care between the two areas of specialty.

- **Inclusion of external quality assessment (EQA) processes for interpretative pathology will need to be further considered by the program.** EQAs are any external means of assessing interpretive quality, and include inter-laboratory and inter-observer comparisons (e.g., slide/image surveys, diagnostic challenges, patterns of practice surveys). EQAs will need to be further considered by the program to assess the impact on the quality of interpretative pathology.

- **Pre- and post-analytic aspects of pathology.** The analytical work of a pathologist is just one component of a total testing cycle which includes pre- and post- analytic processes, and further work is needed on these other processes in order to assure patient safety and prevent potential adverse events. For example, work is needed to standardize labeling and requisitions in order to ensure that information is complete and accurate. Consideration should also be given to developing pre- and post-analytic quality indicators. Opportunities to further explore these issues with other collaborative partners should be considered.

9.0 Implementation Approach and Timeline

Successful and sustainable implementation of three quality management programs (QMPs) of this scope and complexity will require a phased, multi-year approach that is dependent on:

- Expanded legislative authority
- Collaboration with other organizations to adopt recommended standards and implement program elements
- Close alignment and coordination with related programs and initiatives across Ontario's health system
- Strong leadership and engagement of the stakeholders and organizations involved
- Sufficient capacity, resources and support for implementation activities

9.1 Scope and Approach

Implementing the QMPs represents a significant change for providers and facilities that includes adhering to new provincial standards, the introduction of a new facility lead role, and the establishment of new processes for quality assurance and improvement. Given the size of this change, stakeholders have advised the Partnership to phase implementation and move slowly.

During the first year of implementation, there will be eight priorities for the Partnership:

1. **Establishing the QMP leads and the QMP provincial committees:** The network of QMP leads and the provincial committees are the foundational structure for implementation planning and execution. The process for recruiting and selecting them will be open and transparent and involve key stakeholders. Once recruited, the Partnership will provide orientation, education and ongoing support to the leads and will help ensure that they can fulfill their roles and that the QMPs are ultimately successful.

2. **Reporting on quality:** The Partnership will produce a preliminary report on the quality of the three healthcare services in Ontario using existing colonoscopy and mammography data as well as the baseline report on pathology quality that is being produced as an early quality initiative.

3. **Prioritizing recommendations:** The Partnership has put forward a large number of recommendations in this report. It is recognized that these changes cannot be made all at once. In the first year, the Partnership will engage stakeholders and work with the QMP provincial committees to prioritize the recommendations based on their value in improving quality of care, feasibility and stakeholder support. This work will form the basis of a detailed, multi-year implementation plan.

4. **Engaging patients:** Patient engagement is critical for the success of the QMPs. During the first year, the Partnership will refine its approach to patient engagement, initiate the formation of the Citizens' Panel and begin work on patient experience measurement and developing the approach for public reporting.

5. **Initiating change management activities:** Early in implementation, the Partnership will develop a change management strategy and plan that focuses on building awareness of the QMPs, understanding the change that the QMPs represents for facilities and providers and providing supports to facilities and providers to begin implementation efforts for high priority recommendations.

6. **Collaborating with other programs and organizations:** The QMPs will not be successful without strong collaboration, alignment and engagement with other programs and organizations. The Partnership will begin working with programs and organizations to embed the QMP standards in existing accreditation, inspection and assessment programs, where possible, and develop communication, training and change management deliverables.

The QMPs will not be successful without strong collaboration, alignment and engagement with other programs and organizations.

7. **Developing IM/IT requirements:** The collection and reporting of accurate, timely and reliable data is a critical enabler of the QMPs. Much of the data required to calculate and report on the quality indicators recommended in this report is already collected from many facilities in Ontario. During the first year of implementation, the Partnership will develop a plan and begin work to enhance existing IM/IT infrastructure to collect additional data requirements. Stakeholders will be engaged during this process to ensure the burden of the additional data capture is minimized.

8. **Continuing work to expand legislative and regulatory authorities:** The Partnership will continue its work to assess options for legislative and regulatory changes to make participation in the QMPs mandatory, and to identify existing legislative gaps related to the implementation of the QMPs.

Stakeholder engagement, change management and communications activities will occur throughout the life of these programs to ensure stakeholders are supported.

Through the implementation planning process, the Partnership will continue to work closely with stakeholders to understand the impact, feasibility and priority of recommendations and develop a detailed implementation plan. While the design of the QMPs is consistent across the three health service areas, the priorities, implementation activities and timelines for each area will vary. This will be an important consideration for program planning and for ongoing stakeholder engagement and communications.

Figure 11 provides an overview of the Partnership's implementation approach for the QMPs. The cycle of program planning, implementation, evaluation and improvement is ongoing and iterative. Initially, program planning will involve an assessment of the feasibility, impact and priority of recommendations. Based on this assessment, recommendations will be scheduled for implementation, deferred for future implementation or developed further before being considered for implementation. Implementation will occur in phases and be based on priorities and availability of resources.

Evaluation activities will begin as programs are implemented. The framework for evaluation of the QMPs is described in Section 10. Throughout implementation, opportunities for improvement and course corrections will be identified to inform future implementation activities. Stakeholder engagement, change management and communications activities will occur throughout the life of these programs to ensure stakeholders are supported.

9.2 Timeline

Table 10 outlines key Partnership milestones for the first three years of the programs and assumes that Year 1 activities will start in 2015/16. Additional milestones for Years 2 and 3 will be determined in Year 1 as prioritization of recommendations, planning and early implementation activities are conducted.

Figure 11 **Partnership implementation approach**

Table 10 Key Partnership milestones

Year 1	Year 2 and 3
Core Programs	
• Complete early quality initiatives • Recruit and onboard provincial and regional leads • Appoint facility leads • Establish and kick-off provincial committees • Develop and implement program supports for QMP leads • Produce a preliminary report on quality for the three health service areas • Prioritize recommendations for implementation • Refine approach to patient engagement and initiate the establishment of the Citizens' Panel • Begin patient experience indicator development • Start collaboration with other programs and organizations to facilitate the adoption of recommended standards and guidelines • Finalize program evaluation plan	• Start QMP data collection and validation • Start generating and distributing quality reports to providers (if applicable) and to QMP leads • Start QMP lead review of quality reports • Continue to develop and refine indicator methodology for all recommended indicators • Complete work on recommendations that require additional assessment prior to implementation • Start program evaluation activities
IM/IT	
• Conduct privacy impact assessment and update/establish required data sharing agreements • Expand MOHLTC data feeds • Finalize data collection and reporting requirements • Begin designing, developing and testing data collection and reporting solutions	• Continue to design, develop and test data collection and reporting solutions for all recommended indicators including patient experience indicators • Deploy data collection and reporting solutions (leveraging existing solutions where possible)
Legislation and Regulation	
• Confirm legislative and regulatory changes required to enable programs • Initiate legislative and regulatory changes	• Complete legislative and regulatory changes required to enable programs
Change Management	
• Develop change management strategy and plan that focuses on awareness, education and supports for facilities and providers to implement standards and processes • Begin executing change management plan when MOH has approved the Phase 2 report for implementation	• Execute change management plan activities • Implement program supports

10.0 Evaluation Framework

10.1 Introduction

Quality management programs (QMPs) represent a new way of driving quality improvement in Ontario and significant resources have been committed to help ensure their success. The Partnership is committed to evaluating the effectiveness of the QMPs over time. This evaluation will provide valuable feedback to the Partnership to enable course corrections during implementation and to build evidence about the best ways to improve quality in health care.

Health Canada defines an evaluation framework as "a plan for conducting a future evaluation focusing on the issues to be addressed and, by implication, identifying the data needed to support the evaluation." The approach to developing a framework and plan to evaluate the Partnership and the QMPs is largely based on this definition.

Building on the stated goals of the Partnership, an evaluation framework has been developed to identify the scope and key questions to be addressed by the evaluation of the QMPs. Early in implementation, a detailed evaluation plan will be developed in parallel to the overall implementation plan that includes identification of indicators, data sources and timelines for the evaluation.

10.2 Scope of Evaluation

A framework has been developed to determine how the Partnership will evaluate the effectiveness of the QMPs and assess if the Partnership has created QMPs that:

- Increase the quality of care and improve patient safety
- Increase the consistency in the quality of care provided across facilities
- Improve public confidence by increasing accountability and transparency

Given that implementation will be phased in over time, the evaluation will be staged. The first stage will focus on exploring the extent to which the foundational elements of the programs are in place and obtaining qualitative feedback on the progress of the Partnership to support course correction during implementation. The second stage will be more summative in nature, and will evaluate the extent to which the Partnership has achieved its overall objectives, the QMPs as an approach to improve quality of care and the value for money provided by the Partnership.

The Partnership is committed to evaluating the effectiveness of the QMPs over time.

10.3 Evaluation Framework

Approach

A broad range of input was received that informed the development of the framework and plan. An ad hoc advisory committee met between January and March 2015 to provide subject matter expertise and strategic advice on the development of an evaluation framework and plan. In addition, numerous stakeholders within the partner organizations provided input and direction that was invaluable for refining and confirming all aspects of the evaluation framework and plan, including the overall scope, the evaluation questions, indicators and measurement strategies.

Below is an outline of the components that will be used to develop the evaluation framework and plan.

Logic model

A logic model was developed that articulated the overall goal of the Partnership, the anticipated long-term and medium-term outcomes of the Partnership and the key activities intended to realize the outcomes. Each of the outcomes identified in the logic model can be linked to the evaluation questions and indicators in the framework.

Guiding principles

Development of the framework was informed by a set of principles to manage the scope, select the evaluation questions and develop the indicators. The principles include:

- Focus on high-level evaluation questions and indicators that provide an aggregate view of Partnership effectiveness
- Favour evaluation questions and indicators that evaluate the impact of the QMPs
- Engage stakeholders when building the framework and plan
- Develop evaluation questions and indicators that are applicable to each of the QMPs
- Embed patient perspectives throughout the framework

Domains

The evaluation framework is informed primarily by the Partnership's goals for the QMPs, which are to:

- Increase the quality of care and improve patient safety

- Increase the consistency in the quality of care provided across facilities
- Improve public confidence by increasing accountability and transparency

Based on these overarching goals, some medium- and long-term objectives were articulated.

Evaluation questions

Evaluation questions have been developed to explore the extent to which the objectives of the QMPs and the Partnership are being met.

Indicators

Each evaluation question will be accompanied by one or more indicators that are intended to measure and detect change in performance.

Data sources

The potential data source for each indicator will be identified. It is expected that the evaluation will include a blend of quantitative and qualitative data sources.

Time period

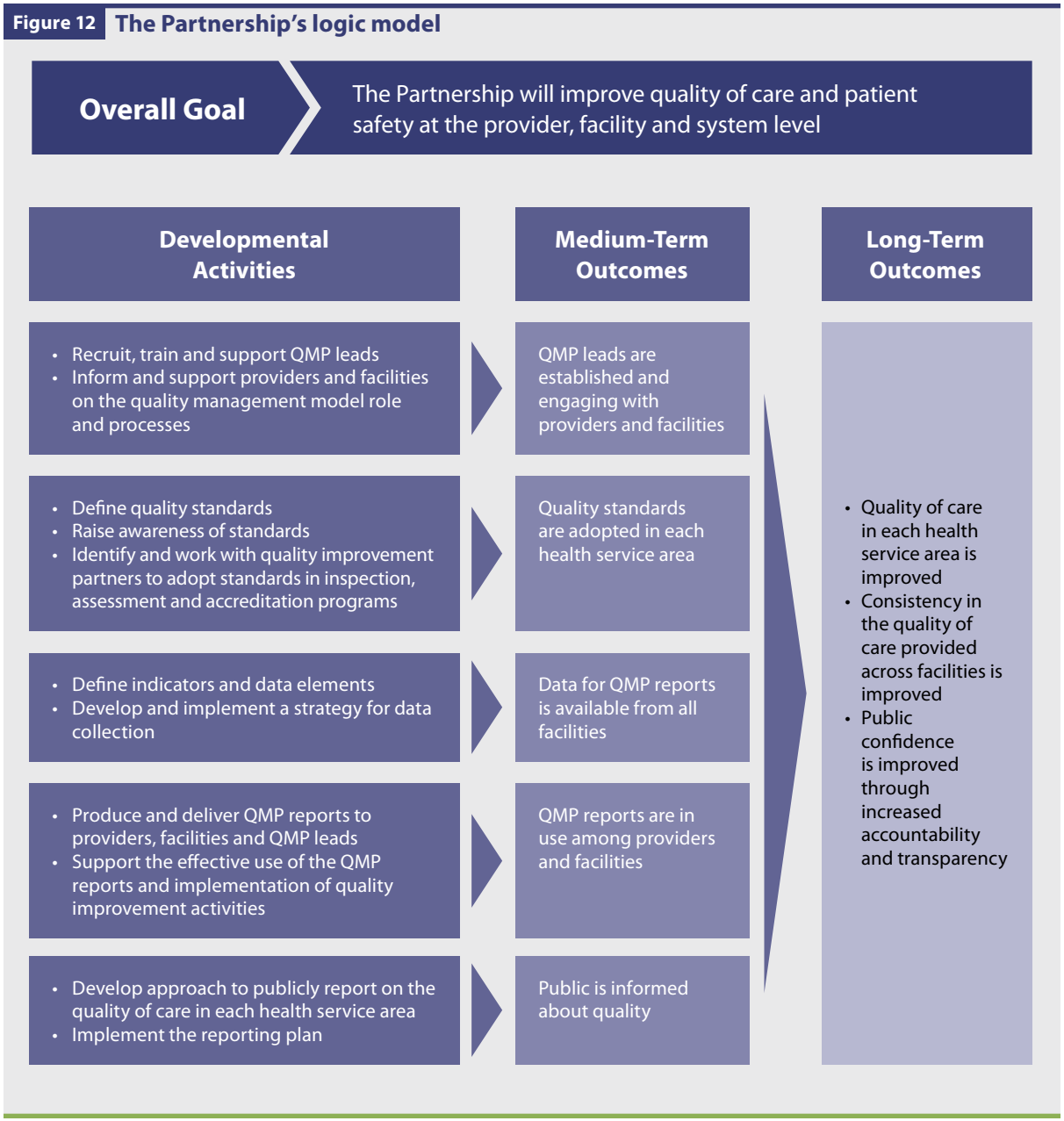
The evaluation will track performance across multiple years. Once indicators are identified, efforts will be made to establish baselines as early in the implementation phase as possible. The ability to report performance and the quality and reliability of the data will evolve over time.

The evaluation plan will incorporate all of the above components into a multi-year plan.

Logic model

A logic model is a planning tool used to clarify and graphically display what the program intends to do and what it intends to accomplish.

Figure 12 **The Partnership's logic model**



The Partnership's logic model (Figure 12) links the overall goals with ongoing and future activities, and provides the basis for the development of the evaluation framework. The medium- and long-term outcomes are addressed by the framework's evaluation questions. Medium-term outcomes (those that can be achieved within three years) are focused primarily on assessing processes and data availability. Long-term outcomes (those that will be achieved within three to five years or beyond) are focused on measuring the impact and value of the Partnership.

Evaluation questions

A number of evaluation questions have been developed to answer whether each medium- and long-term objective has been achieved. The evaluation questions examine the extent to which a positive change has been observed, rather than pose a specific hypothesis.

The first stage of the evaluation will focus on the medium-term outcomes identified in Figure 12. Table 11 identifies a number of evaluation questions to assess performance towards achieving these objectives.

Conducting a province-wide evaluation of the QMPs will be complex and occur in stages to align with the phased implementation of the QMPs across the three health services.

Table 11 Medium-term outcomes and evaluation questions

Anticipated Outcomes	Evaluation Questions
QMP leads are established and engaging with providers and facilities	• To what extent has the quality management model been implemented across the three health services? • How has the quality management model enhanced continuous quality improvement efforts in the three health service areas?
Quality standards are adopted in each health service area	• To what extent have the recommended quality standards been adopted in the three health service areas? • How have the recommended quality standards improved quality in the three health service areas?
Data for QMP reports is available from all facilities	• To what extent are data for the QMP reports available and consistently collected across all facilities?
QMP reports are in use among providers and facilities	• Has the use of QMP reports improved over time? • How have QMP reports enhanced continuous quality improvement efforts in the three health services?
Public is informed about quality	• To what extent has the Partnership publicly reported on the quality of care in the three health service areas?

The second stage of evaluation will gauge the overall effectiveness and value for money provided by the QMPs. The summative evaluation questions in Table 12 will help to assess whether the overall goals of the programs have been met.

Table 12 Long-term outcomes and evaluation questions

Anticipated Outcomes	Evaluation Questions
Quality of care in each health service area is improved	• To what extent has the quality of care improved in each of the health service areas?
Consistency in the quality of care provided across facilities is improved	• Has there been a reduction in variation in the quality of care provided by facilities in each health service area?
Public confidence is improved through increased accountability and transparency	• To what extent is public reporting taking place? • To what extent have the QMPs improved accountability and transparency among providers, facilities and regions?

10.4 Evaluation Plan

Conducting a province-wide evaluation of the QMPs will be complex and occur in stages to align with the phased implementation of the QMPs across the three health services.

As the Partnership moves into implementation, a key priority will be to develop a detailed evaluation plan. The plan will include the evaluation methodology, the required indicators and data sources, and timing of the evaluation activities based on data availability and the overall implementation plan of the QMPs. During the planning phase, the Partnership will explore the concept of involving an external, arms-length body during the summative evaluation stage to ensure objectivity.

11.0 Appendices

A Memorandum from Assistant Deputy Minister Susan Fitzpatrick

B Early Quality Initiatives

C Clinical Leads and Expert Advisory Panels

D Steering Committee and Healthcare System Reference Group

E Stakeholder Engagement and Consultations

F Detailed Stakeholder Feedback

G Evidence Assessment Approach

H Information Management and Information Technology (IM/IT) Strategy

I Colonoscopy: Supporting Evidence

J Mammography: Supporting Evidence

K Pathology: Supporting Evidence

Appendix A – Memorandum from Assistant Deputy Minister Susan Fitzpatrick

Ministry of Health and Long-Term Care

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HLTC3968IT-2012-1721

MAR 2 8 2013

MEMORANDUM TO: Relevant Stakeholders in Pathology, Colonoscopy and Mammography

FROM: Susan Fitzpatrick
Assistant Deputy Minister
Negotiations and Accountability Management Division

SUBJECT: Cancer Care Ontario and College of Physician & Surgeons joint quality management partnership

Ontario's Action Plan for Health Care directs a broad quality agenda focused on continuous improvement across all parts of the health care system. An important enabler to improvement has been demonstrated by comprehensive and system-wide quality management programs to support consistent best practices, appropriate care and optimal patient outcomes across areas of care.

In support of this, the Ministry has asked Cancer Care Ontario (CCO) and the College of Physicians and Surgeons of Ontario (CPSO) to jointly develop a provincial quality management program in three areas: mammography, colonoscopy and pathology. In these particular areas there is widespread agreement on the immediacy to address variability and gaps and ensure: (i) consistent, clinically-driven standards across the province; (ii)adequate supports, linkages and programs to promote adherence to those standards; and, (iii) system-wide reporting and measurement at all levels of care delivery. Mammography, colonoscopy and pathology share a foundation of substantial quality management activity already in the field from which to build on so it makes sense to focus on these three initially.

Elements of a comprehensive quality management program include:

1. A quality framework that sets out an integrated set of performance standards and quality measures at the provider, facility and system levels
2. An integrated data gathering infrastructure, reporting linked to quality improvement opportunities and rigorous health analytics to review data
3. Organized, peer-led approaches to performance improvement
4. Quality assurance processes – provider and site

The Ministry recognizes the interests and accountabilities that many groups, organizations and agencies have in these three areas. What is needed is to bring the shared intent and many good efforts already in place together into a single coherent provincial quality management program for each. This program will support other accountability structures already in the system with a particular focus on the clinical aspects of high quality care. The Ministry has asked two leadership organizations – CCO, given its leadership in continuous system quality improvement, and CPSO, given its leadership in quality assurance in physician practice as well as out-of-hospital premises and independent health facilities - to take lead responsibility to bring these programs together. CCO and CPSO will be accountable to plan and develop a program through extensive consultation and meaningful collaboration with clinical experts, other system partners and all other relevant stakeholders. The program's future success will depend, in part, on the degree of collaboration and integration that this initiative is able to foster.

Others including the Quality Management Program – Laboratory Services (under the Ontario Medical Association), the Ontario Hospital Association, various physician specialty organizations (e.g. the Path2Quality program), Health Quality Ontario and other provider groups and their regulatory organizations, will play a meaningful role in advising on the design and implementation of these total quality management programs, as well as helping to deliver aspects of the programs where appropriate. CCO and CPSO will be expected to fully access, coordinate and use the clinical and operational leadership and capacity already in the system.

This is a new approach in Ontario, built on success elsewhere, and we believe it can succeed here if it is planned in a spirit of open collaboration and a shared intent to 'get it right'. The first step will be a provincial consultation led by CCO and CPSO to inform program design. Consultations will begin early in the 2013/14 fiscal year.

Susan Fitzpatrick

Appendix B – Early Quality Initiatives

In March 2013, the Ministry of Health and Long-Term Care (MOHLTC) in partnership with Cancer Care Ontario (CCO) and the College of Physicians and Surgeons of Ontario (CPSO) formed the Quality Management Partnership (the Partnership) to jointly develop provincial quality management programs in three health service areas: colonoscopy, mammography, and pathology. With the guidance of the clinical leads and the expert advisory panels, preliminary design work for the quality management program for each service area was initiated in 2013/14 and will continue throughout 2014/15. During the first phase of design in 2013/14, the expert advisory panels recommended proceeding with a set of early quality initiatives to be started in 2014/15. These initiatives include:

Early Quality Initiatives	Target Date of Completion
Colonoscopy • Develop and trial a bowel preparation dosing reference tool. • Draft and evaluate guidelines for standardize endoscopy report for referring physicians. • Develop and evaluate guidelines for standardized patient discharge information. • Draft and evaluate a pre-procedure and post-procedure checklist. • Design and pilot a version 1 of the provider quality report for colonoscopy and draft recommendations. • Conduct Phase 1 feasibility assessment of an adenoma detection rate indicator.	2015/16
Mammography • Conduct a current state assessment of breast imaging service in Ontario. • Develop a plan to expand data capture to all sites providing screening mammography. • Develop a plan to expand the radiologist outcome report.	2014/15
Pathology • Produce a baseline pathology quality report. • Evaluate resources and provide recommendations to inform practices related to tissue exemption and tissue release. • Investigate communication issues within pathology diagnostic reporting in order to make recommendations about the most effective way to structure pathology reports and report pathologic findings with specific focus on polypectomies.	2015/16

Appendix C – Clinical Leads and Expert Advisory Panels

Dr David Morgan, QMP
Colonoscopy Clinical Lead

Dr David Morgan is Head, Service of Gastroenterology, and Deputy Chief, Department of Medicine, at St. Joseph's Healthcare in Hamilton. He also teaches at McMaster University. Dr Morgan is past president of the Canadian Association of Gastroenterology and the current treasurer of the Ontario Association of Gastroenterology. His research interests include dyspepsia, particularly with regards to effects of non-steroidal anti-inflammatory drugs.

Dr Rene Shumak, QMP
Mammography Clinical Lead

Dr Rene Shumak, assistant professor of medical imaging at the University of Toronto, is the Cancer Care Ontario regional breast imaging lead for three regions in the Greater Toronto Area. Dr Shumak was the Radiologist-in-Chief of the Ontario Breast Screening Program from 1999 to 2009 and again from December 2010 to July 2011, followed by six months as the special advisor to the Ontario Breast Screening Program. She has also served as head of Breast Imaging at Sunnybrook Health Sciences Centre and has participated in many research endeavors in the early detection of breast cancer.

Dr Katherine Chorneyko, QMP
Pathology Clinical Lead

Dr Katherine Chorneyko is Medical Director, Laboratory Services, at Brantford General Hospital. She served as the president of the Ontario Association of Pathologists (OAP) for two years and recently completed a term as president of the Brant County Medical Association. Dr Chorneyko completed her medical degree at the University of Western Ontario, followed by pathology training at the University of Ottawa and additional training in electron microscopy at McMaster University.

Colonoscopy Expert Advisory Panel	
NAME	**ROLE**
Dr David Armstrong	Gastroenterologist
Dr David Baron	Gastroenterologist
Dr Nancy Baxter	Provincial GI endoscopy lead, general surgeon
Mr Subi Bhandari	Patient/service user
Dr Catherine Dubé	ColonCancerCheck provincial lead, gastroenterologist (since May 2014)
Dr Stan Feinberg	General surgeon
Dr Michael Gould	Gastroenterologist (until May 2014)
Dr Jeff Habert	Primary care physician
Dr Doug Hemphill	Gastroenterologist
Dr Roger Hollingworth	Gastroenterologist (until Sep 2014)
Dr Hugh Kendall	General surgeon
Ms Judy Knighton	Nurse, OHP inspector
Dr Jeff Kolbasnik	General surgeon
Dr Matt Kurrek	Anesthetist
Ms Johanne Lin	Nurse
Mr Jacques Lupien	Patient/service user
Dr Angus Maciver	General surgeon
Mr Tom McHugh	CCO Regional Vice-President
Dr David Morgan (Chair)	QMP Colonoscopy Clinical Lead
Dr Iain Murray	Gastroenterologist
Ms Kay Rhodes	Nurse, OHP administrator (until Nov 2014)
Dr Peter Rossos	Gastroenterologist
Ms Jennifer Stretton	Nurse practitioner
Dr Jill Tinmouth	ColonCancerCheck Scientific Lead, gastroenterologist
Dr Chris Vinden	General surgeon

Mammography Expert Advisory Panel	
NAME	**ROLE**
Ms. Tina Bilodeau	Medical radiation technologist (MRT)
Dr Muriel Brackstone	Surgeon
Ms Jacquie Brown	Patient/service user
Dr Petrina Causer	Radiologist
Dr Anna Chiarelli	Scientific Lead, Ontario Breast Screening Program
Dr Pavel Crystal	Radiologist
Dr Belinda Curpen	Radiologist
Ms Michelle DiEmanuelle	Hospital CEO
Ms Joan Glazier	Provincial MRT Lead, Ontario Breast Screening Program
Mr Adrian Gorgey	Non-physician IHF administrator
Dr Mark Henderson	CCO Regional Vice-President
Dr Amanda Hey	Primary care physician
Dr Doris Jabs	Radiologist
Dr David Jacobs	Radiologist
Ms Ivana Marzura	Patient/service user
Ms Marlene McCarthy	MRT, IHF assessor
Dr Lori Moore	Radiologist
Dr Derek Muradali	Radiologist-in-Chief, Ontario Breast Screening Program
Dr Evan Roberts	Radiologist
Dr Jean Seely	Radiologist
Dr Rene Shumak (Chair)	QMP Mammography Clinical Lead
Dr Martin Yaffe	Medical Physicist

Pathology Expert Advisory Panel	
NAME	**ROLE**
Ms Jill Adolphe	Patient/service user
Ms Andrea Axente	Pathologists' assistant (until Jul 2014)
Ms. Judy Burns	CCO Regional Vice-President
Dr William Chapman	Pathologist
Dr Kathy Chorneyko (Chair)	QMP Pathology Clinical Lead
Mr Brian Chow	Pathologists' assistant (since Nov 2014)
Ms Sue Clipsham	Private laboratory administrator
Ms Heather Ead	Patient/service user
Mr Kevin Empey	Hospital CEO
Dr Danny Enepekides	Surgical oncologist (since Nov 2013)
Dr Tim Feltis	Pathologist
Dr Greg Flynn	Institute for Quality Management in Healthcare, pathologist
Dr Nusrat Hussain	Pathologist
Dr Suhas Joshi	Pathologist
Mr Iain Macri	Pathologists' assistant
Dr Meg McLachlin	Pathologist
Dr Bayardo Perez-Ordonez	Pathologist
Dr Aaron Pollett	CCO Provincial Head, Pathology and Laboratory Medicine Program, pathologist
Dr Corwyn Rowsell	Pathologist
Dr Sandip SenGupta	Pathologist
Dr David Shum	Pathologist
Dr John Srigley	Pathologist
Dr Jeff Tanguay	Pathologist

Appendix D – Steering Committee and Healthcare System Reference Group

Quality Management Partnership Steering Committee		
NAME	**TITLE**	**ORGANIZATION**
Dr Michael Sherar (Co-Chair)	President and CEO	Cancer Care Ontario
Mr Garth Matheson	Vice-President, Planning and Regional Programs	Cancer Care Ontario
Dr Linda Rabeneck	Vice-President, Prevention and Cancer Control	Cancer Care Ontario
Dr Robin McLeod	Vice-President, Clinical Programs and Quality Initiatives	Cancer Care Ontario
Ms Lynn Guerriero	Managing Director, Cancer Screening (until January, 2015)	Cancer Care Ontario
Ms Paula Knight	Vice-President, People, Strategy and Communications	Cancer Care Ontario
Dr Rocco Gerace (Co-Chair)	Registrar	College of Physicians and Surgeons of Ontario
Mr Dan Faulkner	Deputy Registrar	College of Physicians and Surgeons of Ontario
Mr Wade Hillier	Director, Quality Management Division	College of Physicians and Surgeons of Ontario
Dr Rene Shumak	QMP Mammography Clinical Lead	Quality Management Partnership
Dr David Morgan	QMP Colonoscopy Clinical Lead	Quality Management Partnership
Dr Katherine Chorneyko	QMP Pathology Clinical Lead	Quality Management Partnership

Healthcare System Reference Group	
ORGANIZATION	**REPRESENTATIVE**
Cancer Care Ontario	Dr Michael Sherar, President and CEO
College of Academic Hospitals of Ontario	Ms Karen Michell, Executive Director
College of Nurses of Ontario	Ms Anne Coghlan, Executive Director and CEO
College of Physicians and Surgeons	Dr Rocco Gerace, Registrar
Health Quality Ontario	Dr Joshua Tepper, President and CEO
Ontario Hospital Association	Mr Anthony Dale, President and CEO
Ontario Medical Association	Mr Ron Sapsford, CEO
Patients Canada	Dr Sholom Glouberman, President and CEO
INDIVIDUALS WITH HEALTHCARE QUALITY MANAGEMENT EXPERTISE	
Dr Adalsteinn Brown, Director, Institute of Health Policy, Management and Evaluation, University of Toronto	

Appendix E – Stakeholder Engagement and Consultations

Stakeholder Engagement: Laying the Groundwork for Consultations

The Quality Management Partnership (the Partnership) undertook an extensive process to engage and inform stakeholders prior to launching consultations. The goal of these engagement activities was to build awareness of the Partnership and the work of the expert advisory panels as they developed their recommendations. Activities included newsletters, updates on the Partnership website and presentations made by Partnership executive and clinical leadership where there were opportunities to provide early feedback on the design recommendations.

The following is a list of the organizations the Partnership engaged from April to November, 2014:

- Pathology and Laboratory Medicine Program, April 9
- Ontario Medical Association Executive Update, April 17
- Ontario Laboratory Directors' Summit, May 2
- Ontario Association of Medical Radiation Technologists Board Meeting, June 20
- Pediatric pathologists (including Sick Kids, Children's Hospital of Eastern Ontario and Kingston General), July 25
- Institute for Quality Management in Healthcare, July 29
- Path2Quality, August 6
- Ontario Hospital Association Board of Directors, August 13
- Independent Diagnostic Clinics Association, September 12
- Cancer Care Ontario Roadshow, South West Region, September 15
- General surgeons and gastroenterologists, September 16
- Ontario Hospital Association's Small, Rural and Northern Leadership Council, September 17
- Ontario Association of Pathologists Annual General Meeting, September 19
- Ontario Hospital Association's Physician Provincial Leadership Council, September 23
- Ontario Hospital Association webcast, September 26
- Cancer Care Ontario Roadshows:
  - Erie St. Clair, October 1
  - North East, October 7
  - Central East, October 16
  - Central West, October 17
- Ontario Association of Gastroenterology 18th Annual Conference, October 26
- Ontario Association of Medical Radiation Technologists, October 31
- Ontario Association of General Surgeons, November 1
- Ontario Hospital Association Health Achieve, November 3
- Cancer Quality Council of Ontario's Signature Event on Patient Safety, November 19
- Pathology and Laboratory Medicine Program, November 20
- Ontario Association of Medical Laboratories, November 20
- Local Health Integration Network CEO meeting, November 21

Consultations

The Partnership used a two-pronged approach to consultations, with both in-person and online methods, in order to engage with and listen to the concerns of stakeholders who would be directly impacted by future quality management programs (QMPs) in the three health service areas. The consultations were also designed to build strong relationships, and foster trust and support between the Partnership and the affected stakeholders and/or organizations in order to build a strong foundation for future work. The stakeholders engaged in consultations included:

- Providers in colonoscopy, mammography and pathology services, including physicians, nurses and technologists
- Health system leaders from across the health system, including associations that represent each health service area, Local Health Integration Networks (LHINs) and other quality programs
- Patients/service users and members of the public

The consultation program focused on two key strategies:

- Build awareness through open communications
- Collaborate and leverage key relationships to foster trust

These strategies ensured that all stakeholders had sufficient input into the design phase of the QMPs.

Build awareness through open communications

A variety of communication tools and methods were used to build awareness of the design phase work. This provided stakeholders with sufficient context about the Partnership to consider QMPs in their areas of care or expertise.

The communications strategy for the consultations was to promote the in-person approach as it had the ability to provide the greatest insight. The Partnership relied on collaborating organizations to decide who should attend the in-person consultations to represent them or their constituency. The collaborating organizations were provided with information to be broadly communicated through publications such as websites and newsletters. The Partnership used similar mechanisms as well as social media feeds and far-reaching publications such as the College of Physicians and Surgeons of Ontario's (CPSO's) newsletter.

Engaging patients/service users required a different approach, and the consultation team reached out to Cancer Care Ontario's (CCO's) Person-Centred Care team to ask the members of their Patient and Family Advisory Council and Patient and Family Advisory team to participate in the online survey and share their stories about what quality means to them. Excerpts from those stories are embedded in this report.

Collaborate and leverage key relationships to foster trust

Concurrent with building knowledge, key relationships were leveraged to gain early insights into challenges that may lie ahead.

Through regular contact with collaborating organizations during the fall, the Partnership strengthened and developed relationships necessary to make the consultations effective. Partnership staff worked closely with the collaborating organizations to share information and ensure that participants were well-prepared to engage in meaningful dialogue.

Partnership leaders and the clinical leads identified organizations that are thought leaders and influencers in the health service areas, as well as patient/service user representatives and health systems administrators. Where possible, the Partnership aligned its consultations with pre-scheduled association events to reduce travel and expenses for participants.

The Healthcare System Reference Group, made up of recognized and respected healthcare leaders, guided the Partnership to look at the impact of the QMPs across the health system. Because members of the Healthcare System Reference Group do not work within one of the health service areas, they ensured that much thought was given to how the QMPs will interact with existing quality programs in the sector. They were instrumental in shaping consultation content and ensuring that the consultations attracted key players from organizations, such as LHINs.

Patients/service users on the expert advisory panels and CCO's Patient and Family Advisory Council lent their voices to shape the content for the patient/service user and general public consultations. For example, they offered insights on what patients/service users understand when certain terms are used and how best to explain this phase of the Partnership's work to the general population.

Overview of the Consultation Process

The Partnership engaged stakeholders through facilitated in-person sessions and an online survey hosted on CPSO's website. Stakeholders were provided with tailored pre-reading material that described selected program components, as well as a subset of recommendations and quality indicators that the Partnership felt were relevant to the stakeholder group. Stakeholders were asked to comment on the Partnership's goals, the selected recommendations and indicators, and potential implementation challenges and opportunities.

In-person consultation process

Fourteen organizations participated in in-person consultations conducted by third-party facilitators. These consultations enabled collaborating organizations and their representatives from across the health service areas to speak directly with the Partnership executives and clinical leads.

The same questions were asked across all the in-person consultations within a health service area in order to highlight alignment and divergence between their views on:

- The program governance model
- Prioritization of select recommendations from the expert advisory panel
- Prioritization and support for select indicators for reporting
- Whether the recommendations collectively support the goals of the Partnership

Participants were provided with comprehensive background information that allowed them to offer their input and insights into the QMPs at this early juncture.

The following table outlines the organizations that brought 165 participants to the table to provide input via the in-person consultations.

Table 13 In-person consultation participating organizations

Colonoscopy	Mammography	Pathology	Health System Administrators
• Ontario Association of Gastroenterologists • Ontario Association of General Surgeons • Registered Nursing Association of Ontario	• Ontario Association of Radiologists • Independent Diagnostic Clinics Association • Ontario Association of Radiology Managers	• Ontario Association of Pathologists • Ontario Association of Medical Laboratories • Institute for Quality Management in Healthcare • Ontario Medical Association – Laboratory Medicine Section	• Health Quality Ontario (with LHINs) • Ontario Hospital Association • College of Nurses of Ontario • Ontario Medical Association

Online consultation process

For the online consultations, respondents were asked to identify themselves as either:

- A health system leader
- A provider in one of the three health service areas
- A patient/service user/member of the public

Based on this self-identification, the respondents were directed to the appropriate pre-reading and survey materials for their group. Respondents to the online survey for the health service areas were asked to rate and/or respond to questions about select indicators, standards and recommendations. Health system administrators were asked to provide more general feedback on select draft recommendations, standards and indicators for the health service areas, as well as feedback on the broader health system implications of the QMPs. Patients/service users were asked to provide their input in a more narrative format after they articulated their expectations of a QMP. The online consultation received feedback from a total of 245 respondents.

For detailed information on the content of the feedback, see Appendix F.

Appendix F – Detailed Stakeholder Feedback

Background

In late 2014, the Quality Management Partnership (the Partnership) engaged stakeholders through facilitated in-person sessions and through an online survey hosted on the College of Physician and Surgeons of Ontario's (CPSO's) website. Stakeholders were provided with tailored pre-reading material that described program components and selected draft recommendations and quality indicators relevant to their particular stakeholder group. The Partnership then asked stakeholders to comment on the Partnership's goals, the selected recommendations and indicators, and potential implementation challenges and opportunities.

In-person consultation sessions were held in November 2014 and the online survey was open from November 3 to December 12, 2014. Feedback was obtained from colonoscopy, mammography and pathology stakeholders, health system administrators, and patients/service users and members of the public. In total, over 400 individuals participated in the Partnership's stakeholder engagement and consultation activities. This appendix provides an overview of the feedback that was obtained from these stakeholder groups. For more information on the stakeholder engagement process, see Appendix E.

Patients, Service Users and Members of the Public

The Partnership engaged approximately 50 patients/service users and members of the public. In-person consultation sessions engaged patient/service representatives from the expert advisory panels for each of the health service areas as well as members of CCO's Patient and Family Advisory Council (PFAC).

The purpose of PFAC is to create a forum where patients and family members provide insight into how to improve the quality of the patient and family experience. The PFAC advises CCO on the direction and content of current and future strategies and initiatives.

The scope of the PFAC is to provide partnership and advice relevant to and based on patient/family member/caregiver experience in order to:

- Improve the patient and family cancer care experience
- Develop the vision and scope of Person-Centred Care at Cancer Care Ontario
- Generate areas of focus and priorities
- Advise on strategies for actively partnering with patients and families to design, plan and improve healthcare services (such as experience-based co-design)
- Review evaluation methods to help define the measurement of system-level success

Specific comments and feedback from patients/service users, some in abbreviated form, have been incorporated throughout the body of this report to further illustrate their expectations about quality and their experiences with colonoscopy, mammography and pathology services in Ontario.

The following are their full quotes:

"I believe the work of the QMP is important for patients as it will improve health outcomes, patient safety and the overall patient experience. It is important for providers as it will help to streamline processes, encourage collaboration and ensure consistency across the spectrum of providers. It is important for the Ontario health care system as it will improve transparency, efficiency and the overall quality of care provided in the province."
Jill Carmichael Adolphe, expert advisory panel member and patient/service user

"Quality of care means to me that my care stands out and is directed specifically to ensure my needs are consistently met … I am a partner in the decision making – the provider is not just doing to or for me, but with me. I am kept informed on what is happening, supplied the information I need to make good decisions that will ultimately affect my life. My care is respectful and responsive."
Joanne MacPhail, patient/service user

"As a patient I can contribute an essential perspective to discussions about a delivery system that in the end concerns me. It is absurd to consider healthcare improvement without involving patients."
Jacques Lupien, expert advisory panel member and patient/service user

"I believe as service users we have a responsibility to contribute to the ongoing improvement of the system, to act as equal partners to develop a system that recognizes the needs of users, providers and administrators and that enables high quality care to be consistently available. I feel that I was able to contribute to this initiative and bring a different perspective to the table. This supports the QMP's goal to be patient-centred."
Jacquie Brown, expert advisory panel member and patient/service user

"From the time our GP made the call for my husband to have a colonoscopy, we already had a lot of anxiety. When we got to the appointment, patients and family members were crammed into a small room. There was no privacy; we had to wait in a small, dark room with others all of whom were all worried about what comes next. Being in this environment certainly did not help with easing any anxiety that we were feeling. During the procedure my husband was gone for a very long time. No one communicated why. I was getting very worried. What I learned after was that during the procedure they removed a tumour and sent it off to pathology. The post care at the unit was also not a great experience. Sharing our personal experience, I hope will improve the experience of future patients and their families so they don't have to go through what we went through."
Anne Newman, caregiver/service user

"The development of a quality management program for mammography could result in improved quality in the delivery of mammography services for individuals across the province, regardless of facility or provider, through the extension of best practices (OBSP) to all mammography. Higher standards for facilities, staff, radiologists and imaging will be applied consistently across the province, leading to safer, more consistent and better quality images and readings. There will also be increased transparency and better engagement of individuals."
Ivana Marzura, expert advisory panel member and patient/service user

FEEDBACK SUMMARY

Participants were provided with the tailored background materials and were asked to share:

- Their expectations for outcomes of a quality management program
- Their personal experiences with the three health service areas

Participants indicated that consistent standards of care, patient experience measures and quality reporting are important outcomes of a quality management program. They identified timely access to services, adequate follow-up, clear communication and access to information about the quality of the facilities where they receive care as important components of high-quality care. Some also emphasized that it is important for them to be adequately informed so that they can be involved in the decisions that are made about their care and wellbeing.

Colonoscopy Stakeholders

Almost 100 colonoscopy stakeholders provided feedback regarding selected colonoscopy quality management program (QMP) draft recommendations and quality indicators. Most participants were either gastroenterologists or general surgeons; nurses, pathologists, anesthesiologists and others were also represented. The survey was publicly available on the CPSO website, and the in-person consultation sessions engaged the Ontario Association of Gastroenterology (OAG), the Ontario Association of General Surgeons (OAGS) and the Registered Nurses' Association of Ontario (RNAO).

Specific comments and feedback from colonoscopy providers have been incorporated throughout the body of this report, some in abbreviated form. The following are their full quotes:

"Personally, I was surprised and disappointed that I did not have the best polyp detection rate. (I carefully checked my ranking compared to my peers.) It may surprise non-physicians to learn doctors are confident, even arrogant, about their skills and abilities. I thought I had mastered this common procedure and lacked awareness of my own shortcomings. I have been motivated to improve my procedural skill and intra-procedural attention to a complete exam, in order to improve my performance next year."
Dr. Doug Hemphill, expert advisory panel member and gastroenterologist

"This process is overdue to standardize gastrointestinal procedures like colonoscopy protocols and practice all over the province, for safety to the public. As a nurse participating as an expert advisory panel member, I feel that the recommendations in the Phase 2 report will contribute to the goal of improving consistency in the quality of care provided across all facilities."
Kay Rhodes, expert advisory panel member, nurse and OHP administrator

"At our clinic, we'd like to improve our adenoma detection rate as a whole. There may be other factors influencing the group rate but we need to start to develop a plan to help every endoscopist, but especially low performers, improve their procedural quality. I believe that the Quality

Management Partnership is on the right path to making important changes that will support providers and facilities in taking advantage of continuous quality improvement opportunities and to ensure consistent quality standards across the province."

Dr. Doug Hemphill, expert advisory panel member and gastroenterologist

STAKEHOLDER FEEDBACK

All participants were provided with the same background materials and were asked to provide feedback regarding:

- The Partnership's goals
- The effectiveness of the quality management model, including the leads' roles
- Selected draft colonoscopy QMP recommendations
- Selected draft colonoscopy QMP indicators
- Factors for successful implementation of the colonoscopy QMP

Partnership goals and the quality management model

Overall, there was agreement that the quality management model will effectively foster accountability, support quality assurance and facilitate consistency and transparency. There was also agreement that the provincial, regional and facility leads will foster accountability and support quality assurance. Some commented that the effectiveness of the model will be dependent on the leads' interest and motivation, and noted that leaders in the field should be recruited to these roles to enable successful implementation. The potential for competitive bias within the model was noted; for example, if the regional lead is an out-of-hospital premises (OHP) owner, it could affect his/her interactions with other facilities/physicians in the region. There was less certainty as to whether the facility lead role aligns with existing roles and processes. Some stakeholders worried that the model adds complicated layers of oversight that may not effectively promote quality when put into practice, while others indicated that such a program is long overdue. Participants were also uncertain of the ability of the model to improve quality, stating that its effectiveness will depend greatly on how it is implemented.

Recommendations

Participants were asked to provide feedback regarding six of the colonoscopy QMP recommendations. Although there was some uncertainty about their overall scope and appropriateness, stakeholders were generally supportive of the selected recommendations.

There was agreement that there must be consistent standards across all facility types. However, there was some concern that if the OHP Inspection Program (OHPIP) standards are used as a foundation, not all of these standards would be relevant for hospitals. There was also support for requiring facilities to participate in a common quality assurance program that includes regular inspections and assessments, although some stakeholders questioned the need for inspection in addition to the existing hospital accreditation process. Furthermore, stakeholders indicated that the healthcare system should absorb the cost of this requirement rather than the individual facilities.

Conceptually, stakeholders agreed that personnel involved in reprocessing must participate in a formalized training program. However, concerns about the feasibility of this recommendation, were noted, specifically about the availability of appropriate training programs. Furthermore, they were apprehensive about who would be responsible for resourcing and oversight (i.e., who would pay for the training and who would monitor compliance).

There was also support for the use of the global rating scale (GRS), although there were concerns about the impact of the additional administrative burden associated with this quality improvement tool. Time would need to be allotted for GRS training and implementation, and its use would need to be evaluated on an annual basis.

Stakeholders were supportive of a centralized electronic repository, as well as synoptic reporting. They indicated that these recommendations have the potential to significantly improve colonoscopy quality and should therefore be prioritized. However, stakeholders acknowledged that although they would be transformative, these recommendations would be costly and technically challenging to implement.

Quality indicators and reporting

Participants were asked to provide feedback regarding selected recommended colonoscopy QMP quality indicators. Overall, stakeholders were in agreement with reporting the selected indicators as measures of quality. However, there were concerns regarding the additional administrative burden for providers and the care team due to data collection for quality reporting in general, and data collection related to the GRS in particular.

Data accuracy and suitability of the indicators to measure quality were also sources of concern. In particular, stakeholders were apprehensive regarding

data access (i.e., who will be able to see the data), data use (i.e., political and/or punitive use of quality data) and data interpretation (i.e., indicators need context to provide an accurate measure of quality). Stakeholders also cautioned that there may be unintended consequences that result from collecting and reporting the selected indicators such that providers and facilities may begin to change their practice in ways that could negatively influence quality (e.g., changes in practice patterns, redistribution of services).

Stakeholders were supportive of using outpatient cecal intubation as a quality indicator, although many respondents expressed concern about how cecal intubation would be verified. They indicated that billing code data and self-reporting are not adequate methods of measurement. Furthermore, there was concern that this could drive physicians to intubate the cecum when it is not indicated (e.g., non-screening cases, diagnostic cases). Stakeholders also indicated that this does not measure quality comprehensively because it does not account for anatomy, symptoms and patient disposition (e.g., not all patients have a cecum).

In general, stakeholders agreed that minimum total colonoscopy volume is an appropriate quality indicator; however, the stated benchmark (n=200) was criticized by some stakeholders as too high or too low to effectively measure quality. Others indicated that the volume standard was arbitrary and not based on evidence. There was a suggestion that the acceptable threshold be a range (e.g., 180 to 200) rather than a specific number.

There was support for using the ColonCancerCheck (CCC) screening program wait time indicators as measures of quality. However, it seemed to be unclear to stakeholders that the colorectal cancer (CRC) screening follow-up rate (i.e., percentage of screen-eligible individuals who receive colonoscopy within six months of abnormal fecal occult blood test or FOBT) is intended to be a measure of quality and not a standard of practice, and some commented that this window is too long to wait for colonoscopy. There was concern that this indicator does not account for wait times for symptomatic patients and individuals who are not screen-eligible, and could give the impression that screening patients are prioritized over patients who may need to be seen more urgently.

There was also moderate support for using the CCC screening program eight-week benchmark as a quality indicator. Some feedback indicated that the benchmark is unattainably short, while others indicated that it was too long to accurately measure quality. Stakeholders indicated that there are differences in endoscopy resourcing within certain regions that would make this benchmark more easily achieved in some areas (e.g., urban centres) compared to others (e.g., rural regions).

Stakeholders generally supported the use of Tier 1 and Tier 2 adverse event reporting for all facilities; however, some were apprehensive about comparing data across facilities due to differences in patient populations. Stakeholders indicated that hospital patients are typically older, sicker and more complicated than OHP patients. Therefore, hospital patients will experience more adverse events than OHP patients, regardless of the quality of the care they receive. Stakeholders were concerned that reporting adverse events could give the misleading impression that OHPs are safer than hospitals.

Lastly, there was support for using patient satisfaction as a quality indicator, although several respondents indicated that this is not a direct

measure of quality. For example, a patient who is heavily sedated may indicate a higher level of satisfaction, but this does not necessarily mean that the patient received a higher quality procedure.

Enablers of successful implementation

Participants emphasized that adequate resourcing is needed to support implementation. This includes local funding to mitigate additional administrative burden and system-level resourcing for information management and information technology (IM/IT) solutions that will build capacity for robust electronic medical record systems, central repositories, user friendly reports and straightforward data entry that minimizes administrative burden and allows for clinical outcomes to be reported (e.g., adenoma detection rate).

Educational resources to facilitate upskilling and remediation, as well as on-site implementation support (e.g., report and data entry software training), were also cited as enablers of successful implementation. In addition, stakeholders suggested that there should be opportunities to transfer knowledge between regions and facilities to allow groups to learn from one another. Differences in patient populations between hospitals and OHPs must be acknowledged to fairly evaluate quality across different sites. Lastly, stakeholders indicated that clear communication regarding plans for implementation will also facilitate successful implementation.

FEEDBACK SUMMARY

Although stakeholders expressed some implementation concerns, they were supportive of the quality management model and the selected colonoscopy QMP recommendations and indicators. Stakeholders commented that the effectiveness of the quality management model will depend on the leads' interest and motivation, and emphasized that leaders in the field should be recruited. There were concerns about the feasibility of particular recommendations, but overall they were well-received. Stakeholders did express some apprehension regarding implementation of the recommended quality indicators, citing concerns about data access, use and interpretation, as well as unintended consequences of collecting the data. Stakeholders identified adequate resourcing, including local and system level funding, as a critical success factor. Opportunities for knowledge translation between regions and facilities, contextualized data interpretation and clear communication regarding implementation plans were also cited as enablers of successful implementation.

Mammography Stakeholders

A total of almost 80 mammography stakeholders provided feedback regarding selected mammography QMP draft recommendations. Most participants were radiologists, medical radiation technologists (MRTs), hospital radiology unit managers or IHF managers. The survey was publicly available on the CPSO website and the in-person consultation sessions engaged the Ontario Association of Radiologists (OAR), the Ontario Association of Radiology Managers (OARM) and the Independent Diagnostic Clinics Association (IDCA).

STAKEHOLDER FEEDBACK

All participants were provided with the same background materials and were asked to provide feedback regarding:

- The Partnership's goals
- The effectiveness of the quality management model, including the leads' roles
- Selected draft mammography QMP recommendations
- Selected draft mammography QMP indicators
- Factors for successful implementation of the mammography QMP

Partnership goals and the quality management model

Overall, participants agreed that the quality management model will effectively foster accountability, support quality assurance and facilitate consistency and transparency. There was also agreement that the provincial, regional and facility leads will foster accountability and support quality assurance. However, some stakeholders believed that having provincial and regional leads was sufficient and that the three-tiered structure may result in excessive oversight.

Capacity to implement this structure was also a concern. Stakeholders indicated that there may be insufficient expertise within certain facilities and regions that would impede the recruitment of QMP leads, particularly at the facility level. Furthermore, providers already manage a heavy workload that may not accommodate additional duties and responsibilities.

Some commented that the effectiveness of the model will depend greatly on the leads' interest and motivation, and noted that leaders in the field should be recruited to these roles to enable successful implementation.

Stakeholders agreed that the facility lead role aligns with existing accountability structures. However, some feedback suggested that existing chiefs and quality advisors may not have the mammography expertise required to fulfill the facility lead role requirements. There was also a suggestion that there should be MRT facility leads in addition to radiologist facility leads.

Recommendations

Participants were asked to provide feedback on selected draft mammography QMP recommendations. Although some stakeholders were uncertain about the overall scope and appropriateness of the recommendations, they were generally supportive of the selected recommendations. Some stakeholders indicated that the recommendations are excellent in theory, but their effectiveness will depend greatly on the extent of buy-in and how the QMP is implemented.

Many stakeholders indicated that QMP recommendations appear to duplicate what

already exists. In particular, questions regarding the perceived overlap between QMP and the Ontario Breast Screening Program (OBSP) were commonly raised, with stakeholders indicating that the QMP appears to be duplicating OBSP activities. Stakeholders questioned why the Partnership had not recommended expansion of the OBSP eligibility criteria rather than creating a duplicative process within a new structure. The need for a new program was also questioned in the context of other existing quality programs (e.g., independent health facility or IHF assessments, hospital accreditation, Canadian Association of Radiologists – Mammography Accreditation Program or CAR-MAP).

Stakeholders were supportive of mechanisms to ensure that service users receive their mammography results in a timely way and understand recommended next steps. There was a suggestion that patients should be able to choose how they receive their results (e.g., via post, email, online). A need for more details about how this will be implemented was expressed (e.g., who is responsible, how will language barriers be addressed, how will patients without primary care physicians be managed). Stakeholders indicated that timely communication of results is only one facet of quality and is not reflective of the quality of the radiologist or the examination.

There was support for integration of all breast images into a provincial repository. Several stakeholders indicated that this is a valuable recommendation, although there were significant concerns regarding its feasibility. Specifically, stakeholders thought that this would be both an expensive and lengthy endeavor fraught with technical challenges (e.g., privacy, security, compatibility, reliability, validity and image quality). For stakeholders who supported prioritization of the more transformative recommendations (i.e., system changes with the greatest impact), the provincial repository was viewed as a priority. Other stakeholders indicated that although the transformative changes are important, they would be most challenging and instead suggested focusing on more attainable recommendations (e.g., bringing all screening into the OBSP).

Participants generally agreed with the recommendation that facilities maintain CAR-MAP accreditation. There were concerns raised that CAR-MAP is expensive, bureaucratic and inefficient. Other feedback indicated that the image assessment component is highly subjective and that assessments are too infrequent to be valuable. CAR-MAP's capacity to manage increased demand was also questioned.

Although there was some uncertainty about whether the proposed indicators are the most appropriate measures of quality, there was overall support for reporting individual outcomes. Stakeholders also agreed that facilities should receive regular reports on their quality outcomes. Stakeholders indicated that quality reporting facilitates transparency and helps with understanding the strengths and limitations of the healthcare system. However, stakeholders also indicated that quality reporting alone is not enough; there must also be quality improvement support to facilitate upskilling and remediation. Some stakeholders indicated that really powerful learning occurs when individual cases are reviewed in depth, ideally with someone who is very experienced in reading screening mammograms. Stakeholders indicated that hospital-based radiologists benefit from this kind of learning through multi-disciplinary rounds, but IHF-based radiologists do not have equivalent opportunities.

There was support for MRTs having regular image reviews. Some stakeholders indicated that the OBSP has demonstrated successful application of this quality improvement strategy. However, other respondents indicated that the OBSP process needs refinement to enable better management of MRTs who do not demonstrate improvement despite participating in prescribed quality improvement activities.

Participants were generally supportive of both retrospective and prospective peer review; however, some concerns were raised. Feedback suggested that retrospective peer review is one of the best strategies for quality improvement, but that protection against medico-legal ramifications is needed. For prospective peer review, there was a concern about the potential for disparity between first and second readings and how these situations would be resolved. Some feedback cautioned that prospective peer review could potentially result in unnecessary callbacks. There was concern that prospective peer review is both an expensive and time-consuming initiative that may only marginally improve quality.

Stakeholders were asked to provide feedback regarding the recommendation to introduce CPSO peer assessments for radiologists. There was support for this recommendation, although there was some feedback that questioned the need for this type of peer review if other forms of peer review are also introduced.

Enablers of successful implementation

Adequate funding was commonly cited as a critical success factor. Stakeholders indicated that resourcing is needed to fund equipment and

infrastructure (e.g., digital mammography, IM/IT solutions to support synoptic reporting and an image repository). Further resources are needed to support organizational infrastructure and QMP lead oversight (e.g., effective feedback loops, adequate opportunities for continuing professional development, remediation that is non-punitive and peer-driven and competent leadership at all levels).

Stakeholders also emphasized that the Partnership's role in quality management must be clearly defined and differentiated from that of the OBSP and other existing quality management programs. Lastly, there are many implementation details that will influence the extent to which the mammography QMP is successful (e.g., regarding peer review, what process will be implemented to resolve disagreements). These details must be carefully planned before anything is initiated.

FEEDBACK SUMMARY

Although stakeholders expressed some implementation concerns, they were generally supportive of the quality management model and the selected mammography QMP recommendations. Stakeholders were concerned that the three-tiered structure may result in excessive oversight and that limited local expertise and leadership may impede recruitment of the QMP leads. They also had concerns regarding implementation of some of the recommendations and called for thorough implementation planning to ensure that these concerns are addressed. Stakeholders identified resourcing for IM/IT and organizational infrastructure as a critical success factor for the mammography QMP. Adequate opportunity for quality improvement at the provider level and ensuring that processes are not duplicated were also identified as important enablers of successful implementation.

Pathology Stakeholders

More than 130 stakeholders provided feedback regarding the draft pathology QMP recommendations and quality indicators. Most participants were pathologists; primary care providers, technologists and assistants, managers and others were also represented. The survey was publicly available on the CPSO website and the in-person consultation sessions engaged the Ontario Association of Pathologists (OAP), the Ontario Association of Medical Laboratories (OAML), the Institute for Quality Management in Healthcare (IQMH) and the Ontario Medical Association Laboratory Medicine Section (OMA LMS).

Specific comments and feedback from a pathologist was in the body of this report in abbreviated form. The following is a full quote:

> *"We need to make important system design changes to improve patient care. I think the work we have done on the QMP will help establish consistent approaches for the whole province, reduce discrepancies in diagnoses and improve the overall standard of health care in Ontario."*
> Dr. Sandip SenGupta, expert advisory panel member, pathologist and laboratory medical director

STAKEHOLDER FEEDBACK

Participants were provided with the same background materials and were asked to provide feedback regarding:

- The Partnership's goals
- The effectiveness of the quality management model, including the leads' roles
- The draft pathology QMP recommendations and indicators
- Factors for successful implementation of the pathology QMP

Partnership goals and the quality management model

Feedback regarding the Partnership's goals and the quality management model was mixed. There was some agreement that the model will effectively foster accountability, support quality assurance and facilitate consistency and transparency.

Stakeholders were less certain about the role of the provincial and regional leads in fostering accountability and supporting quality assurance. Some stakeholders worried that the three-tiered model would lead to excessive oversight that is complicated and that does not necessarily promote quality. In particular, there was concern that the

regional leads will have no authority and therefore cannot accept responsibility for quality, limiting the effectiveness and value of this role. Moreover, if the facility leads are effective at the local level, the regional lead role may be redundant.

Despite the uncertainty regarding the value of the provincial and regional lead roles, there was agreement that the facility lead role would foster accountability and support quality assurance. Feedback suggested that quality is best managed locally rather than through centralized processes, although there were some questions raised about how the facility lead would interact with local quality management and accountability structures.

Participants also indicated that an assessment of the model's effectiveness is premature because its ability to improve quality will greatly depend on who is involved in the structure and how it is implemented. Stakeholders emphasized that the individuals who are recruited to the lead roles must be willing to work at the grass roots level and must be capable of considering the perspectives of various sub-specialties of pathologists. Furthermore, the leads must be recruited in a transparent manner to ensure that they are balanced, just and widely respected by the field. There was also some concern that the model may not effectively manage quality in small practices and regions because of limitations in expertise and leadership.

More generally, pathology stakeholders questioned the suitability of a partnership between Cancer Care Ontario (CCO) and the CPSO. In particular, there was considerable apprehension about the roles of the partner organizations and the perception of co-regulation.

Recommendations

Participants were asked to provide feedback on the draft pathology QMP recommendations for mandatory standards, best practice guidelines and quality assurance. Stakeholders were uncertain regarding the overall appropriateness of the scope and potential impact of the recommendations. Some indicated that the Partnership is redundant because there are existing structures and processes both provincially (e.g., IQMH, Ontario Laboratory Accreditation or OLA) and locally (e.g., department chiefs) that already address quality. Given this, stakeholders urged the Partnership to examine existing initiatives carefully so that efficient integration is achieved and duplication is avoided.

Some feedback indicated that the pathology QMP recommendations will improve visibility, consistency and transparency, and therefore represent a good starting point. However, stakeholders emphasized that the extent to which the recommendations will effectively improve quality can only be assessed after they are tested empirically and through formal program evaluation.

Stakeholders emphasized that the recommendations predominantly focus on the interpretive phase of pathology, which is just one component of the continuum of care. Other factors must be considered to comprehensively manage quality. These factors include pre-analytic activities (e.g. accurate labelling and processing, bar coding), post-analytic activities (e.g. communication of diagnosis) and system-level issues (e.g., workload, access to adequate clinical information, cost of external consults). Stakeholders suggested that the Partnership should prioritize recommendations that will have the greatest effect on patients (e.g., critical diagnoses and corrected report recommendations) as well as those that address system level factors (e.g., external consultation recommendations).

Stakeholders were supportive of the mandatory standard recommendations, but were less supportive of the best practice guidelines. Feedback indicated that the standards and best practice guidelines are reasonable, but inadequate resourcing (i.e., manpower, time, funding) would impede compliance. Some feedback questioned the appropriateness of using Standards2Quality (S2Q) as a basis of the pathology QMP recommendations because S2Q is meant to be interpreted in the context of adequate resourcing and is not meant to be used to measure pathologist competency. Feedback also indicated that there is a punitive undertone to the standards and best practices, with too much focus on the individual pathologist and not enough focus on system factors.

Stakeholders were uncertain about the appropriateness of the draft quality assurance recommendations. Feedback indicated that the recommendation regarding maintenance and monitoring of standards and guidelines was too vague and that more details are needed, including who is responsible for collecting and monitoring quality data, the plan for using the quality data, the extent of the administrative burden, the consequences of non-compliance and the plan for managing medico-legal consequences.

Stakeholders indicated that the External Quality Assurance (EQA) recommendation is too vague. Conceptually, EQA has the potential to address concerns with diagnostic accuracy, but its scope can be interpreted differently and it requires significant resources even for the simplest of cases. Thus, the intended scope and specifications of EQA must be known before its utility in quality improvement can be assessed.

Stakeholders provided mixed feedback regarding the recommendation to make provider- and facility-level quality data available to CPSO peer assessors. Some indicated that sharing this data with peer assessors would be reasonable once the data were proven to be reliable, while others insisted that quality data must be kept separate because of concerns about inaccurate interpretation.

Quality indicators and reporting

Participants were asked to provide feedback on the recommended set of quality indicators for the pathology QMP. Overall, stakeholders were supportive of measuring the recommended indicators and some indicated that many of them are already informally measured in some facilities. However, there were some concerns about formal implementation of the quality indicators. Stakeholders observed that the list of indicators is extensive and will require additional resources to facilitate data collection and monitoring. Feedback indicated that some of the indicators are influenced by other factors beyond the control of the pathologist and therefore may only be considered a quality indicator in a pathology laboratory that is adequately resourced (e.g., turnaround time is dependent on specimen complexity, workload, adequacy of clinical data). In particular, stakeholders were apprehensive about using turnaround time as a quality indicator since it is dependent on other system-level issues and because timely results are only one facet of quality (i.e., faster turnaround does not necessarily confer better quality).

There was some criticism that the indicators are based on expert consensus rather than evidence and that they have not been linked to improved patient outcomes. Furthermore, stakeholders were concerned that established benchmarks are unavailable and questioned whether appropriate benchmarks can be practically established (e.g., what is the appropriate rate for interdepartmental consult).

Stakeholders indicated that more work is needed to standardize definitions, terminology and metrics before comparisons between facilities can be meaningful. Feedback also indicated that it is not appropriate to measure these indicators at the level of the pathologist because of the complexity of factors that lead to the generation of the pathology report. Furthermore, stakeholders were concerned that quality reporting for individual pathologists could lead to unintended consequences (e.g., case skimming to select for the most straightforward cases).

Enablers of successful implementation

Participants frequently cited sustained and adequate resourcing at the local level, including both funding and manpower, as a critical enabler of successful implementation. They indicated that the recommendations would require devoted pathologist time and that this needs to be acknowledged and compensated appropriately. Additionally, clerical and administrative assistance are required for successful implementation.

Viable IM/IT solutions to support data collection and minimize administrative burden were cited as enablers of success. Other enablers identified that were identified included plans for evaluation (including a cost-benefit analysis), open and bidirectional communication and transparency regarding timelines and expectations and maintaining an educational emphasis. Lastly, stakeholders emphasized the need to implement slowly, recommending pilot-testing and phased implementation where possible.

FEEDBACK SUMMARY

Overall, stakeholders had mixed feedback regarding the Partnership's goals and the quality management model. Stakeholders agreed that the facility lead would be beneficial for quality improvement, but were less certain about the value of the regional and provincial leads. In particular, stakeholders indicated that the regional leads would have no authority in the facilities that they oversee, resulting in their inability to assume accountability for quality. Stakeholders were generally supportive of the mandatory standards and the quality indicators, but were less certain about the appropriateness of the best practice guidelines and quality assurance recommendations. Adequate resourcing at the local level was most frequently cited as a critical enabler of successful implementation. Other enablers that were identified included phased implementation, viable IM/IT solutions, clear communication about timelines and expectations and maintaining an educational focus.

Health System Administrator Stakeholders

A total of almost 60 health system administrators provided feedback regarding selected draft QMP recommendations and quality indicators. The survey was publicly available on the CPSO website and the in-person consultation sessions engaged the Ontario Hospital Association (OHA), the College of Nurses of Ontario (CNO) and the Ontario Medical Association (OMA). Feedback was also obtained from Health Quality Ontario (HQO) and representatives from the Local Health Integration Networks (LHINs) during a joint consultation session.

FEEDBACK SUMMARY

All participants were provided with the same background materials and were asked to provide feedback regarding:

- The Partnership's goals
- The effectiveness of the quality management model, including the leads' roles
- Selected draft QMP recommendations and quality indicators
- Factors for successful implementation of the QMPs

Partnership goals and the quality management model

There was general agreement that the quality management model will facilitate quality improvement at the provider and facility levels, and foster accountability and transparency within the healthcare system. Conceptually, stakeholders thought that the proposed model also has the potential to improve quality; however, there was concern that the model may not be effective in practice. More specifically, there were concerns that the three-tiered model is inefficient and overly complicated with too many levels of leadership that make accountabilities unclear.

Stakeholders indicated that the model's ability to improve quality cannot be accurately assessed before implementation because its effectiveness will depend on the suitability of the QMP indicators to measure quality, as well as the ability of the individuals involved to manage quality. Stakeholders emphasized that the QMP leads should be leaders in field, have experience in quality management, be passionate about quality improvement and be selected using a transparent recruitment process.

The feasibility of merging QMP lead roles with existing lead roles should be assessed; workload and capacity are important factors that must also be considered in this assessment. There was concern regarding the suitability of this model for smaller facilities because smaller sites may not have the same depth of resources as larger sites, making implementation more challenging.

Recommendations

Participants agreed that the draft recommendations for the QMPs have the appropriate scope and potential impact to increase accountability and consistency, and improve patient safety and transparency. Feedback also indicated that the QMP recommendations appropriately put the focus on the patient rather than on the efficiency of the procedure.

There were requests for more details regarding plans for integration and alignment of the QMPs within existing quality management and accountability frameworks. Furthermore, stakeholders indicated that the role of existing regional networks and centres, as well as accountabilities within these regional frameworks, must be clearly defined. Lastly, the Partnership was asked to provide the LHINs with additional details regarding their roles and responsibilities, including the process that the Partnership will use to work with the LHINs to implement the QMPs.

Quality indicators and reporting

There was support for measuring and reporting provider- and facility-level indicators to understand and improve quality. Additionally, stakeholders emphasized the importance of enabling adequate and appropriate responses to the quality data (i.e., to facilitate remediation and other quality improvement activities).

Stakeholders also provided feedback about indicator feasibility and appropriateness, emphasizing that the selected indicators must be accurate measures of quality that will enable the Partnership to influence quality. Stakeholders stressed that the indicators must also be clear and concise and that further work would be needed to define the indicators and establish benchmarks and targets. The feasibility of measuring the indicators at the facility and provider levels was also emphasized, as was the need to minimize the burden of data collection. There was support for the Partnership to focus on the collection of key indicators that are the most appropriate for measuring and influencing quality.

Stakeholders expressed concern about potential unintended consequences of measuring the proposed quality indicators. They thought that some of the indicators may drive providers and facilities to do things that could negatively influence quality. For example, if a small hospital cannot meet the minimum targets for the number of annual colonoscopies, this could cause the general surgeon to leave, resulting in the closure of the endoscopy unit and ultimately decreasing the accessibility of services for patients in that area. Lastly, stakeholders stressed the importance of including measures of patient experience as quality indicators.

Enablers of successful implementation

Participants emphasized that organizations will need resources to implement the QMPs. This includes adequate local funding to support technical (e.g., IM/IT solutions) and organizational (e.g., leaderships, physician and administrator buy-in and expertise) infrastructure. They indicated that particular consideration should be given to how to manage differences in capacity across facilities. For example,

small and/or remote facilities may not have the clinical leadership or depth of resources that are available at larger and/or urban facilities (e.g., clinical leadership, resources, administrative support) and therefore may require additional support to implement the QMPs. The Partnership was advised to consider providing training for facilities, as well as training for inspectors and assessors.

Allowing flexibility within the constraints of the fundamental quality framework was also recommended to allow facilities to make local adaptations that will facilitate implementation. Stakeholders recommended the use of phased implementation and pilot programs (when possible) to accommodate the learning curve and to allow for integration. They also suggested that there should be opportunities to transfer knowledge between regions and facilities to allow groups to learn from one another. System integration, avoidance of duplication, and building on existing programs and structures were also identified as factors that will facilitate successful implementation.

Participants emphasized the need for a thoughtful and deliberate communication strategy. The Partnership was advised to foster and sustain a quality improvement culture among providers. Stakeholders indicated that perceptions about quality improvement initiatives are almost as important as the design and content of the programs themselves. Accordingly, messaging about the Partnership and the QMPs should be considered very carefully.

Stakeholders also indicated that many of the recommendations and indicators establish minimum standards, which can foster a punitive tone. Thus, the Partnership will need to clearly articulate that the aim is to promote continuous improvement. Stakeholders also advised that communication to patients and members of the public must also be very strategic. Generally, patients and members of the public have a high level of confidence in the quality of the healthcare system, so overstating the need for the QMPs could cause anxiety.

The Partnership was advised to be transparent about its intended approach to quality management. In particular, the Partnership's guiding principles indicate that quality improvement will be achieved through educational and supportive measures, yet regulatory and funding frameworks have also been identified as strategies for managing quality. Stakeholders emphasized that if there are plans to use a multifactorial approach (i.e., education and support, as well as funding and regulatory frameworks), this should be explicit.

FEEDBACK SUMMARY

Feedback was generally supportive of the Partnership and the recommendations for the QMPs. Overall, health system administrators agreed that the recommendations for the provincial QMPs have the appropriate scope and potential impact to increase accountability and consistency and improve patient safety and transparency across Ontario. There was also agreement that the quality management model will facilitate quality improvement at the provider and facility levels and foster accountability and transparency within the healthcare system, although some feedback indicated that the model is complicated, the authorities unclear and its suitability for small sites/groups questionable. There was agreement that measuring and reporting provider- and facility-level indicators is critical to understanding and improving quality. Adequate resourcing at the local level to support both technical and organizational infrastructure was identified as a critical success factor. A deliberate and thoughtful strategy for communicating with stakeholders, including patients/service users and members of the public, was emphasized as an important component of implementation planning. Other enablers that stakeholders identified included the provision of training, alignment and integration, phased implementation and allowing facilities flexibility to make local adaptations.

Appendix G – Information Management and Information Technology (IM/IT) Strategy

Introduction

Information is a key enabler of quality and a critical tool for assuring and improving the quality of care. The ability to gather data, transform it and present it as useful information is the primary purpose of information technology and information management functions.

It is critical to ensure that the data collection process is aligned with, and supports, clinical work flow processes in order to minimize effort and ensure that the information provided to support quality processes is impactful and of high value. Information must be created, but it must also be used to effect the changes necessary to drive quality objectives. As the Quality Management Partnership (the Partnership) begins implementation, the application and use of information within the clinical quality management structure will evolve and be subject to quality improvement itself.

This appendix outlines the proposed strategy and plan to enable the Partnership with technology and information.

Principles

The Partnership IM/IT strategy adheres to the following guiding principles. All proposed and recommended solutions and implementation activities will adhere to these principles, which were set out early in the work of the Partnership. The application of these principles is highlighted throughout this strategy.

Table 14 Quality Management Partnership IM/IT guiding principles

Principle	Description
1. Clinical workflow alignment	• Data collection requirements will align with existing/best practice clinical workflow
2. Common data standards	• Data collection requirements will align with existing relevant provincial, national and/or international data standards wherever possible and be consistently applied across all care settings in Ontario
3. Data quality	• Data collection solutions and processes will ensure high-quality data
4. Value added	• Reports will be designed to meet user needs and support quality assurance and improvement activities
5. Build on existing technology and information assets and processes	• Existing provincial, regional and/or local data collection and reporting infrastructure will be leveraged and shared across related programs wherever feasible • No additional data collection will be required if an equivalent source already exists

Scope

There are three IM/IT strategy elements outlined below. The primary focus for this IM/IT strategy is quality reporting, one of the five components of a quality management program (QMP). However, as the expert advisory panels developed their recommendations, it became clear that IM/IT would be required to support other aspects of the QMPs beyond quality reporting. Therefore, this strategy also recommends approaches for addressing the panels' desire for clinical content standards for the patient chart or clinical record, as well as access to previous and/or related clinical images and reports in support of patient care.

Table 15 QMP IM/IT strategy elements

Strategic element	Definition
Quality reporting	• Quality reporting is the ability to provide regular quality reports at the provider, facility, regional and provincial levels.
Clinical reporting standards	• Clinical reporting standards determine the content, structure and format requirements for capturing patient health record information and clinical reporting. These standards facilitate consistency, usability and comparability of patient data and clinical reports across providers, facilities and the province.
Clinical information sharing	• Clinical information sharing is the ability to access patient clinical reports, images, videos and other related information to support clinical decision-making and/or quality assurance and improvement processes (e.g., audit, second read)

Quality Reporting Design and Implementation Approach

Report Design

The expert advisory panels have recommended over 30 quality indicators to be reported at the provider and facility level across the three health service areas. The indicators include structural indicators (e.g., existence of committees, equipment, training), process indicators (e.g., volumes, preparation rate, turnaround time, wait time) and outcome indicators (e.g., cancer detection rate, patient satisfaction). For the most part, the strategy for process and outcome indicators is to collect case-specific data at the point of care on a regular basis to produce reliable, consistent and meaningful information. Structural indicators are more likely to be populated through a less frequent data collection mechanism at a facility level. The proposed strategy is to use the same solution to access quality reports for all health service areas, with access to specific reports related to roles within the QMPs.

In all cases, the solution for data collection will focus on how to best support the current workflow and interface with existing solutions. Building on the CCO data management model, the data governance and stewardship model will be developed in parallel to the implementation.

Figure 13 QMP quality reporting cycle

Figure 13 depicts the cycle of quality reporting enabled by IM/IT solutions. Quality is enhanced and improved through the use of the information, refinement of the indicators and incorporation of improvements to both data quality and data integrity. Data review and validation are essential to the ongoing improvement of data quality and enhance consistency over time. The principle of data quality and the importance of common data standards are built into this cycle. All proposed QMP quality reports will move through this cycle.

Implementation of Reports

As the quality reports move to implementation, details of the specific indicator methodologies will need to be determined. Getting agreement on the exact definition of each indicator and which data elements will be required as part of the calculation is critical to achieving valid, value-added reporting. The process of bringing together clinical and administrative leaders and information management resources is important for ensuring the development and implementation of consistent data definitions and standards, and supporting the ability to compare between facilities and providers within a health service area.

The approach to implementation of quality reporting will be as follows:

1. Confirm indicator priorities and sequencing of development (if applicable)
2. Develop/refine indicator methodology
3. Expand data collection from the Ministry of Health and Long-Term Care (MOHLTC)
4. Refine and enhance Cancer Care Ontario's (CCO's) data collection tools
5. Expand data collection tools
6. Develop data integration and quality assurance processes and tools
7. Build reporting infrastructure
8. Pilot and test reports
9. Move to full reporting
10. Transition to operations

These steps will be detailed as part of the implementation plan for each health service area.

Quality Reporting Solution Overview

The following is the proposed solution for data collection and reporting in each of the three health service areas. In all cases, existing data collection tools and processes will be leveraged and expanded and quality reports developed in line with the principles of the IM/IT strategy.

In alignment with the principle of leverage, as a first step, the Partnership will look to expand the coverage of data received from the MOHLTC. Currently, CCO receives administrative data from the MOHLTC including service claims data and provider and patient identifiers. This set of data will be expanded to collect additional fee codes and scope of patients to support QMP quality reporting. This approach has no impact on clinical workflow and is a good way to get baseline information about clinical activity. Billing data reveals what happened, where, to whom and by whom. It does little in terms of relaying how well procedures were done or other descriptive information that is essential to assessing quality. In addition, billing data lags behind clinical activity data, and as such is a proxy of activity best used as a cross-reference mechanism to support data validation and accuracy analysis.

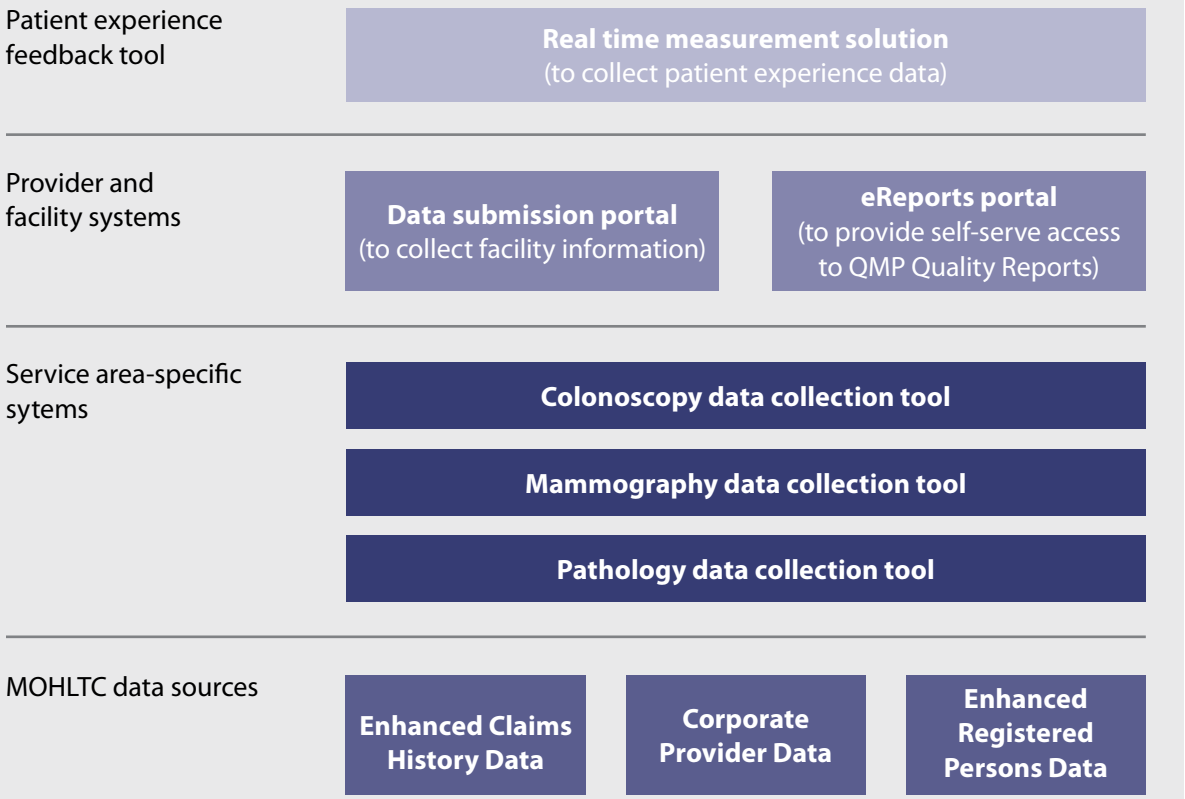
The data collected for billing and payment are not sufficient to meet the needs of quality management as qualitative detail about the service is required to understand the quality of care. The Partnership proposes to expand and enhance existing service-specific data collection tools already in use for clinical and/or administrative workflow.

The current solutions in place today for ColonCancerCheck (CCC) and the Ontario Breast Screening Program (OBSP) will provide the foundation for colonoscopy and mammography data collection; the ePath interface between provincial hospital and private laboratories and CCO will be explored to support population of pathology indicators. These systems will need to be refined and updated to meet the requirements of the QMPs.

Indicators that are reported less frequently and are based on summary data (e.g. number of policies in place, number of critical incidents reported) will be enabled through the QMP Data Submission Portal – a web-based form tool that can be presented for on-line entry – which will act as a survey input mechanism for facilities to securely share information on relevant practices and activities without personal health information.

A central point of access is envisioned for all QMP reports in the form of the QMP eReports Portal where providers and administrators will go to access reports relevant to their specific role in the program. The approach to collecting data for patient indicators will leverage the Real Time Measurement solution that is being developed by CCO and will be an important focus for the Partnership. The following diagram gives an overview of the technology and data sources expected to enable quality reporting requirements.

Figure 14 **QMP IM/IT strategy systems overview**



Quality Reporting from the Patient Perspective – Patient Experience Indicators

Patient experience is a key element of quality. The Partnership seeks to develop an approach to measure and act on patient experience for each of the QMPs.

The Partnership plans to leverage its new Citizens' Panel, as well as CCO's patient and family advisory structure, to develop specific metrics for assessing patient experience as it relates to colonoscopy, mammography and pathology. This process will be outlined and planned in the first year of implementation.

While the proposed quality reporting solution assumes expansion of existing administrative data currently collected from the MOHLTC and expansion of existing data collection tools in use today, there is little to build upon to collect data from a patient perspective. CCO is exploring the use of a solution to capture patient experience data related to cancer. This solution could potentially be used to support the capture of patient indicators for the Partnership. The feasibility of leveraging this solution will be assessed following the development of requirements in partnership with patients.

Quality Reporting Solution by Health Service Area

This section outlines the reporting requirements in each health service area. For each, the indicators identified by the expert advisory panels are listed and colour-coded to reflect the status of reporting today and potential for leverage for the QMPs, as follows:

- ***Green*** indicators are reported today within CCO and data could be expanded and/or the collection mechanism could be enhanced to support reporting for the QMPs. In all cases, data sharing agreements would need to be updated to reflect the new use of data. Also, the methodology for each indicator would need to be confirmed and each data element aligned to this methodology before moving forward with reporting.

- ***Yellow*** indicators reflect indicators where data are collected and reported on a very small or limited scale.

- ***Red*** indicators are not reported today and no data are currently collected to support populating these indicators.

Colonoscopy

The Colonoscopy Expert Advisory Panel identified nine indicators for measurement at the provider level and six indicators at the facility level. Table 16 outlines the proposed indicators and expected level of reporting.

Table 16 Colonoscopy indicators

No.	Indicator	Reporting Level
Provider-Level Colonoscopy Indicators		
C1	Total colonoscopy volume	Provider
C2	Inadequate bowel preparation	Provider
C3	Outpatient polypectomies	Provider
C4	Outpatient cecal intubation	Provider
C5	Polypectomy associated bleeding	Provider
C6	Outpatient perforations	Provider
C7	Colorectal cancer (CRC) detection	Provider
C8	Post-colonoscopy CRC (interval cancer)	Provider
C9	Adenoma detection	Provider
Facility-Level Colonoscopy Indicators		
C10	Outpatient cecal intubation	Facility
C11	Colonoscopies performed by endoscopists meeting volume standard	Facility
C12	Colonoscopy within 8 weeks of positive fecal occult blood test (FOBT)	Facility
C13	Colonoscopy within 26 weeks for family history	Facility
C14	Positive FOBT follow-up	Facility
C15	Tier 1 and Tier 2 adverse events	Facility

In order to populate these indicators, a number of data streams will be expanded. As a baseline for activity measurement, administrative claims, provider and patient data from the MOHLTC will be expanded to include all colonoscopy services from all facilities for all Ontarians. This will require enhancements to existing data feeds to CCO, including the expansion of ages, rostering information and fee codes. New and/or updated data sharing agreements will be required to support this expansion. These administrative data sets provide an excellent baseline to depict basic clinical activity based on billing data retrospective to about one year, depending on billing practice.

While these data provide an excellent baseline, they are not sufficient to be able to distinguish activity at the facility level for Out of Hospital Premise Facilities (OHPs) and independent health facilities (IHFs), nor are they timely or detailed enough to support the clinical quality indicator requirements. Building on the existing Colonoscopy Interim Reporting Tool (CIRT), an enhanced and expanded data collection tool for colonoscopy is proposed. The next version of CIRT will be expanded to all facilities performing colonoscopy. It is acknowledged that the current functionality of CIRT will need to be upgraded to support in-cycle updates to data, as well as more local reporting within the application, specifically with respect to wait time reports. Detailed CIRT requirements will be planned as part of implementation to ensure that changes meet the needs of facilities and current processes are maximized. Once all requirements have been finalized, it will be confirmed if the solution assumptions are correct.

For structural measures, a data submission portal is proposed to capture data on facility-based indicators on a less frequent basis (about once a year). Because the College of Physicians and Surgeons of Ontario (CPSO) has started to collect data on Tier 1 and Tier 2 adverse events from OHPs, it may be possible to collect these data in aggregate to support populating this indicator through a transfer to CCO. Hospitals may have the option to submit Tier 1 and Tier 2 adverse event data using the data submission portal. Details of the opportunity to leverage the CPSO solution will be explored during implementation.

Mammography

The Mammography Expert Advisory Panel identified seven screening indicators and five diagnostic indicators for measurement at the provider level and three indicators at the facility level. Table 17 outlines the proposed indicators and expected level of reporting.

Table 17 Mammography indicators

No.	Indicator	Reporting Level
Provider-Level Mammography Screening Indicators		
M1	Abnormal calls	Provider
M2	Positive predictive value	Provider
M3	Invasive cancer detection	Provider
M4	Ductal carcinoma in situ (DCIS) detection	Provider
M5	Tumor size	Provider
M6	Nodal involvement	Provider
M7	Post-screen invasive cancers (interval cancers)	Provider
Provider-Level Mammography Diagnostic Indicators		
M8	Malignant biopsies a) Malignant core biopsies • % of malignant core biopsies, out of all core biopsies for asymptomatic women • % of malignant core biopsies, out of all core biopsies for symptomatic women b) Malignant surgical biopsies • % of malignant surgical biopsies, out of all surgical biopsies for asymptomatic women • % of malignant surgical biopsies, out of all surgical biopsies for symptomatic women	
M9	Positive predictive value • % of recommended biopsies found to have breast cancer (DCIS and invasive), out of all recommended biopsies	Provider
M10	Use of Breast Imaging and Reporting Data System (BI-RADS) 3 • % of BI-RADS 3 called on diagnostic work-up, out of all diagnostic cases	Provider
M11	BI-RADS 3 malignancies • % of BI-RADS 3 calls that develop into cancer (DCIS or invasive), out of all BI-RADS 3 calls	Provider
M12	BI-RADS 5 malignancies • % of BI-RADS 5 calls that develop into cancer (DCIS or invasive), out of all BI-RADS 5 calls	Provider
Facility-Level Mammography Indicators		
M13	Wait time to first assessment	Facility
M14	Wait time to diagnosis without tissue biopsy (core or open)	Facility
M15	Wait time to diagnosis with tissue biopsy (core or open)	Facility

It has been proposed that the majority of these indicators can be populated by an enhanced and expanded version of the existing OBSP information system, the Integrated Client Management System (ICMS). Already planned as part of the OBSP expansion, the new ICMS includes technical upgrades that will enable interfacing with local clinical systems, an important prerequisite for expansion. Once all requirements have been finalized, it will be confirmed if the solution assumptions are correct.

The new ICMS will be designed to support the mammography QMP and will include extension of the age limits and indicators to cover all mammography services. The system will be deployed to all facilities performing mammography. Administrative data from the MOHLTC will also be expanded as a baseline to compare and validate mammography activity. As with colonoscopy, the administrative claims, provider and patient data from the MOHLTC will be expanded to include all mammography services from all facilities for all Ontarians. This will require enhancements to existing data feeds to CCO, including the expansion of ages, rostering information and fee codes. New and/or updated data sharing agreements will be required to support this expansion.

In order to leverage existing technologies, the proposed solution for diagnostic indicator data collection is ICMS. However, the final solution for diagnostic indicator data collection still requires further analysis of indicator definitions and methodologies before a technology solution can be confirmed. For structural measures, a data submission portal is also proposed to capture data on facility-based indicators on a less frequent basis for mammography.

Pathology

The Pathology Expert Advisory Panel identified seven indicators for measurement at the facility level. The development of the methodology is critical for these pathology indicators because data standards and expanded data collection will be required. In keeping with the principle of adding value, the list of priority indicators will be selected based on impact to patient care and the ease of data collection.

In order to assess the uptake and adoption of the recommended provincial standards, all proposed standards will be included for facility level QMP reporting. These indicators will be populated by data collected by means of a data submission portal. As with colonoscopy and mammography, this web-based form tool is well suited to capture these structural measures at a facility level.

Table 18 Pathology indicators

No.	Indicator	Reporting Level
Facility-Level Pathology Indicators		
P1	Intra-departmental consults	Facility
P2	External consultations	Facility
P3	Intra-operative consultation accuracy	Facility
P4	Intra-operative consultation deferrals	Facility
P5	Defects and discordances	Facility
P6	Corrected reports	Facility
P7	Turnaround time	Facility

The indicators listed in Table 18 will require record-level pathology data which could be captured through enhancements to the existing ePath system. ePath collects pathology reports from hospitals and private laboratories across the province representing over 90 per cent of all pathology reports. Changes to allow for the collection of non-cancer pathology reports, as well as requirements for new data specifications, will be explored. These changes are required to enable quality reporting on the recommended indicators related to turnaround times, accuracy, consultation, deferral, defect and discordance rates. New and/or updated data sharing agreements will be required to support this expansion. Once all requirements have been finalized, it will be confirmed if the solution assumptions are correct.

Quality Reporting System Architecture

Reporting includes three major components: aggregation of source data into a data mart; a method of presenting the information in a report; and a method of distributing the report, or providing access to it, for the intended recipient.

The reporting strategy includes implementation of a data mart that will be the repository for all QMP data. Data marts structure data to facilitate reporting; they are commonly referred to as On-line Analytical Processing (OLAP) and are designed specifically for reporting.

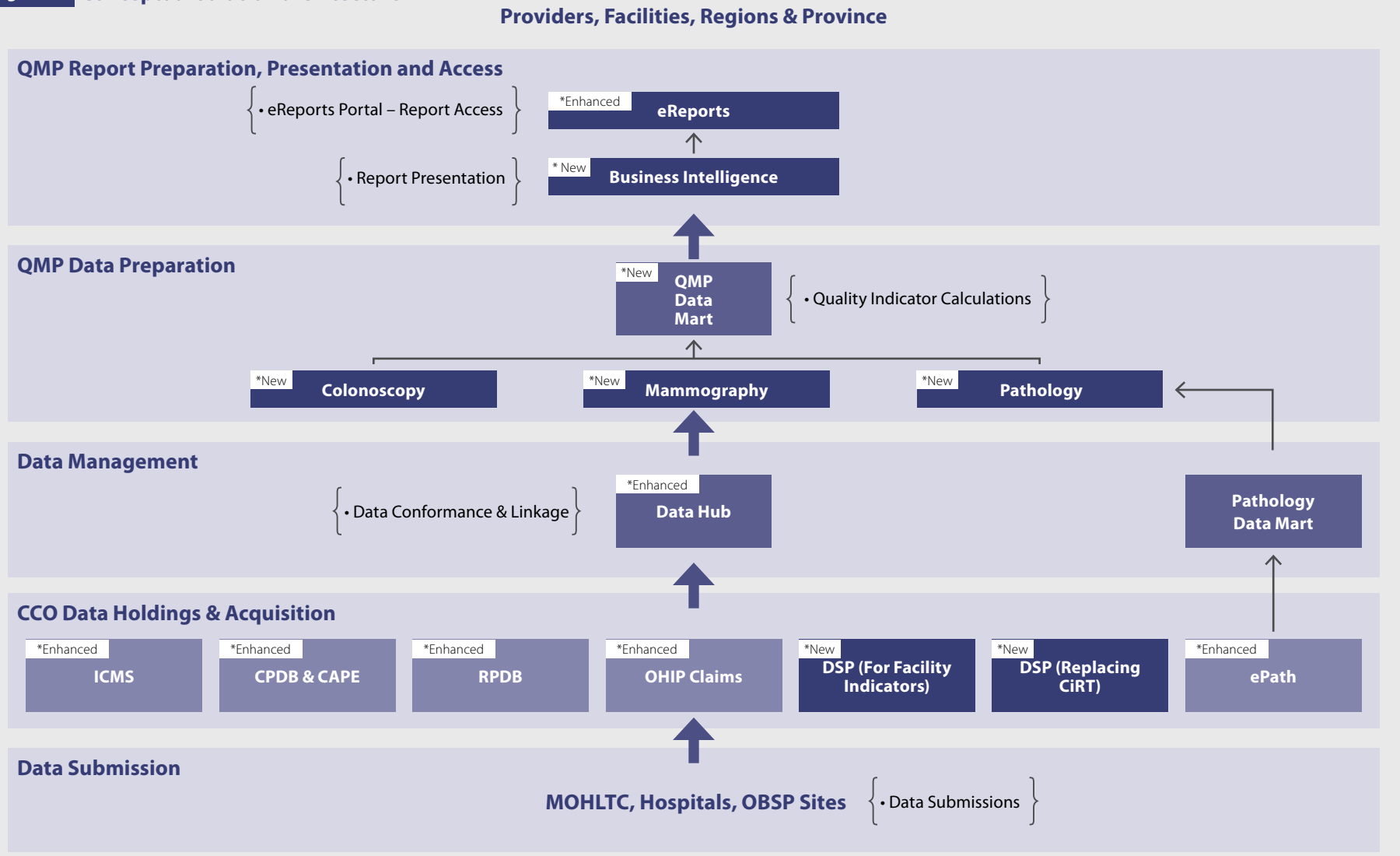
The second component includes the creation of reports to present the information. The QMP reports will leverage the information in the QMP data mart. There are a number of business intelligence tools licensed by CCO that can be used to build the new QMP reports.

The third component is a method of distributing or providing access to the reports. The proposed strategy is to leverage CCO's eReport platform that is currently providing thousands of primary care physicians with access to their practice-level Screening Activity Reports (SARs). eReport is integrated with eHealth Ontario's ONEID so that patient enrollment model (PEM) primary care physicians registered for ONEID can access their SAR.

High level conceptual solution architecture

Figure 15 is a conceptual view of the technical architecture envisioned for the QMP. This solution architecture will need to be updated once all solutions have been validated and confirmed as part of implementation.

Figure 15 **Conceptual solution architecture**



Clinical Reporting Standards

Clinical reporting standards define the clinical content, structure and format to be captured as part of the patient health record in order to support consistent quality of care and ease of use and interpretation by providers.

"Clinical content" refers to the data elements to be captured, "structure" refers to the valid values and format for discrete data fields, and "format" refers to the way the populated content is displayed on the final clinical report for use by providers in care and treatment. Each component is important as a mechanism to ensure consistency of care, ability to mine data for quality reporting and comparison purposes and clarity of communication of critical clinical findings.

Colonoscopy

The Colonoscopy Expert Advisory Panel recommended a standard colonoscopy report. There is already a body of literature supporting the type of clinical content to be considered for this standard report and there was an interest among the panel to see advancement of synoptic – or structured – reporting for colonoscopy. It is expected that the details of an approach to standard clinical reporting for colonoscopy will be pursued during implementation. The approach will include an assessment of the current state of colonoscopy reporting standards in Ontario and other leading jurisdictions, key roles required to support development and maintenance of such a standard and a recommended path forward for the Partnership.

Mammography

The Mammography Expert Advisory Panel recommended that all mammography reports be standardized. As with colonoscopy, the panel identified evidence supporting the type of clinical content to be considered as part of a mammography report. There is a nascent program in radiology synoptic reporting underway at CCO that could be expanded to support this standard. A detailed assessment and plan for the advancement of a clinical reporting standard for mammography will be developed during implementation.

Pathology

Pathology is one area where significant advancements have been made in terms of clinical reporting standards. Since 2009, the Canadian Association of Pathologists endorsed the College of American Pathologist (CAP) synoptic reporting checklists, and Ontario has taken a leadership role in advancing synoptic cancer pathology reporting.

CCO currently receives pathology reports from 100 hospital laboratories and two large private laboratories. The move to synoptic reporting for pathology has enabled improved coding of cancers for the Ontario Cancer Registry, the implementation of the reporting standard in the field has been variable based on the local vendor systems that have been deployed. As part of an early quality initiative that is underway, the Partnership proposed to further investigate and understand the current state, potential challenges and opportunities with the format of the synoptic pathology standards and how clinical information is presented for referring and follow-up with providers. This assessment will provide important insight to the other health service areas as part of their plans for clinical reporting standards.

Clinical Information Sharing

The availability and accessibility of related and historical clinical information is an enabler for clinical decision-making. The ability to view the progress of a mass over subsequent images or from the previous colonoscopy, mammography and pathology reports helps providers to better assess and recommend treatment for patients. In addition, the ability to share clinical information can support quality processes, such as second reads or clinical reviews. Each of the panels identified the ability to access related clinical information for patients as an important quality enabler. As the province continues to invest in eHealth solutions and the development of integrated local, regional and provincial clinical information repositories, this requirement will become a reality. In the interim, the Partnership may explore some specific clinical information assets for use.

Colonoscopy

The Colonoscopy Expert Advisory Panel recommended a centralized, electronic repository be developed to include past procedure reports and relevant pathology findings, as well as images and/or video related to the procedure. The Panel also recommended that all facilities adopt electronic and synoptic reporting.

Ontario is pursuing a regional integration strategy that involves leveraging local, regional and provincial assets and connecting existing information technologies in order to improve patient care and clinical efficiency. The initiative revolves around developing three eHealth clusters to implement regional integration hubs and, ultimately, province-wide information-sharing through a provincial hub.

It is proposed that the Partnership work with the provincial eHealth regional integration strategy to advance the panel's recommendations.

Mammography

The Mammography Expert Advisory Panel recommended that all mammography reports be digital and that all breast imaging and reports be integrated into a provincial repository to allow imaging and report sharing. All hospitals are currently part of the regional diagnostic image repositories and digital IHFs are moving to the repositories over the course of the current fiscal year. Integration of the regional repositories into one provincial diagnostic image repository (DIR) is currently underway.

In addition to leveraging the DIR to allow imaging and report sharing, it is proposed that the DIR be explored as a tool to enable the retrospective interval cancer review process recommended by the panel. Additional uses of the DIR will be explored in support of peer review and/or other quality assurance programs.

Pathology

The Pathology Expert Advisory Panel is keen to provide access to previous and possible concurrent pathology reports as a quality enabler for pathologists. The ability to view the progression of disease or related laboratory findings will ensure that pathologists have a full picture of each patient's case. The Ontario Laboratory Information System (OLIS) repository is a provincial initiative that connects hospitals, community and public health laboratories and providers to share laboratory test orders and results. The potential to leverage OLIS for the Partnership will be explored during implementation.

Summary of IM/IT Recommendations

The IM/IT recommendations are summarized below:

- Develop indicator methodology for provider and facility-level indicators
- Develop QMP requirements and leverage RTM solution for QMP patient indicators
- Assess ICMS feasibility for mammography diagnostic indicators/solutions
- Recommend pathology architecture/solution
- Design final data model and QMP architecture/solution
- Expand MOHLTC administrative data sets – age and fee codes
- Enhance and expand CIRT
- Enhance and expand ICMS
- Develop QMP facility data submission portal
- Develop QMP eReport portal for quality report access
- Conduct assessment of current state and recommendations for standard clinical reporting for colonoscopy and mammography
- Conduct early quality initiative to assess format and related communication and interpretation issues associated with current pathology reports
- Explore use of regional integration services for colonoscopy clinical information access
- Explore use of provincial DIR for mammography interval cancer review
- Explore use of OLIS for access to previous laboratory reports for pathology

High-Level Timeline

The following outlines the draft high-level timeline for the implementation of these recommendations. The IM/IT team will work with the Partnership to align the implementation of IM/IT recommendations.

Draft Year 1 Milestones (assumes that Year 1 activities will start in Fiscal 15/16):

- Amend MOHLTC data sharing agreement and expand data feeds to CCO
- Finalize indicator methodology, data collection and reporting requirements
- Complete privacy impact assessment and update/establish data sharing agreements
- Design pathology data collection solution architecture
- Develop and test colonoscopy data collection tool (leveraging CIRT)
- Develop and test mammography collection tool (leveraging ICMS)
- Develop and test facility information collection solution
- Establish data governance and data quality framework
- Complete early quality initiative to produce pathology baseline quality report
- Produce a preliminary report on quality for the three health service areas
- Analyze clinical reporting standards and clinical information sharing requirements

Draft Year 2 and 3 Milestones:

- Deploy colonoscopy data collection tool to all facilities
- Deploy mammography data collection tool to all facilities
- Deploy solution for facility information collection to all facilities
- Develop and test pathology data collection tool
- Deploy pathology data collection tool to all laboratories
- Develop and test patient experience data collection solution
- Deploy patient experience data collection solution to all facilities
- Begin to generate and distribute QMP quality reports
- Support local system integration with mammography data collection tool
- Develop strategy and recommendations to support standardized clinical reporting and clinical Information sharing for all service areas

Appendix H – Colonoscopy Supporting Evidence

The expert advisory panels used their knowledge, skills and judgment to recommend guidelines, standards and indicators that, if applied across the province, will facilitate consistent, high-quality care in Ontario. The Partnership assessed the evidence that supports each standard, guideline and indicator using its own scale that considered the extent to which the recommendations are supported by published evidence and literature, and adopted in other jurisdictions.

This appendix provides a summary of the colonoscopy evidence assessment and associated references.

Colonoscopy Provincial Standards

Colonoscopy Standard 1: All facilities must participate in regular inspections and assessments to ensure they meet appropriate standards. An inspection program based on the OHPIP must be developed for hospitals.

Background and Rationale: Periodic assessment ensures that facilities meet appropriate standards. Standards should apply to all facilities, regardless if they are OHPs, IHFs or hospitals. An assessment program must be developed for hospitals based on the Out of Hospital Premises Inspection Program (OHPIP), a robust and well-founded inspection program that, with some adaptations, can be used for hospital-based colonoscopy services. Other jurisdictions have common standards and inspection processes for endoscopy services regardless of the size or type of facility.
Level of Evidence: Moderate
Selected Jurisdictions:
- Canada (Ontario)[1]
- Australia[2,3]
- Ireland[4]

Colonoscopy Standard 2: All facilities that provide colonoscopy must have the equipment, and endoscopists working in those facilities must have the expertise, to:
- Recognize abnormalities and perform biopsies
- Tattoo to identify appropriate abnormalities for follow-up
- Remove at least 1 cm in diameter
- Manage complications resulting from interventions, including knowing when to use clips and/or other hemostasis, and when transfer to another level of care is required
- When transfer is initiated, provide written documentation, supplemented by oral communication with the receiving physician

Background and Rationale: Establishing a minimum standard of care and equipment provides all patients/service users with the same procedures regardless of what type of facility they are seen in, and ensures that patients/service users will not have to undergo a repeat colonoscopy in a different setting for routine procedures such as small polyp removal. It requires all endoscopists to have the expertise to manage complications and to recognize when transfer to an alternative level of care is needed, and ensures that the transition to a new facility is expedited in an efficient, patient-centred manner.
Level of Evidence: Low
Selected Jurisdictions: n/a

Colonoscopy Standard 3: Colonoscopies must be performed for an appropriate, clearly documented indication that is consistent with current evidence-based guidelines.

Background and Rationale: Colonoscopies should only be performed for reasons that are recommended by current evidence-based guidelines[5,6], and the reason for each colonoscopy must be clearly documented in the colonoscopy report[7]. The two most widely used guidelines for appropriate use of colonoscopies are from the American Society of Gastrointestinal Endoscopy (ASGE)[8,9] and the European Panel on the Appropriateness of Gastrointestinal Endoscopy (EPAGE), which is an open and free web-based tool.[10]
Level of Evidence: Strong
Selected Jurisdictions:
- Canada[7]
- United States[8,9]
- Europe[10]

Colonoscopy Standard 4: A centralized electronic repository must be developed to include past procedural reports and relevant pathology findings, as well as images and/or video related to the procedure.

Background and Rationale: Administrative databases, registries, and clinical databases are defined and differentiated by their purpose, and can be multi-purpose in their ultimate use. All three types of databases can be used to enhance quality through the appropriate interpretation of the data.[11] Endoscopists require access to previous

procedure reports, images and pathology findings in order to determine whether the findings have changed in the intervening period. A centralized repository, in the form of a clinical database, that is accessible by all endoscopists, will provide timely access to this information. In September of 2014, JAG and the Royal College of Physicians in the United Kingdom formally announced the launch of a National Endoscopy Database (NED).[12] While the purpose of this database is different (providing anonymized data to physicians on the number of procedures they performed and the outcomes), a regional electronic repository helps inform the use of colonoscopy/endoscopy as a system resource as well as providing information on outcomes.

Level of Evidence: Low

Selected Jurisdictions:

- United Kingdom[12]

Colonoscopy Standard 5: Facilities must inform referring physicians of the results of all procedures and any associated pathology, including any findings and follow-up recommendations.

Background and Rationale: It is essential that timely follow-up takes place after a colonoscopy finding that requires further care. The referring physician is generally responsible for ensuring that appropriate follow-up takes place, and the endoscopist must inform the referring physician of procedure findings and recommended next steps. This is particularly important when pathology was required and further follow-up needed. The use of precise and comprehensive colonoscopy reports[13] and the regular assessment of data contained in these reports may lead to better patient outcomes, fewer complications, improved coordination of care and greater patient satisfaction.

Level of Evidence: Moderate

Selected Jurisdictions:

- Canada (Ontario)[14,15]
- Australia[3]
- United States[8]

Colonoscopy Standard 6: All facilities must adopt electronic and standardized reporting.

Background and Rationale: Standardization of electronic reports, including mandatory reporting elements and standard terminology, facilitates uniform data capture and easier data analysis. It also provides the ability to analyze variability in the provision of care, identifying where quality improvement efforts are needed.[13,16-21]

Level of Evidence: Low

Selected Jurisdictions: n/a

Colonoscopy Standard 7: Facilities must have equipment to record digital photographic evidence of relevant landmarks and lesions.

Background and Rationale: Digital documentation of abnormalities and other landmarks provides a valuable supplement to written records, and facilitates collection of complete procedure records in an electronic repository.[8,16,22,23]

Level of Evidence: Low

Selected Jurisdictions: n/a

Colonoscopy Standard 8: Mechanical irrigators must be available for every case and be used when necessary in order to allow adequate visualization of the mucosa and lesions.

Background and Rationale: Adequate visualization of the mucosa is essential to a quality colonoscopy. Mechanical irrigators are both more efficient and better at clearing mucosa than manual irrigators and must be available for use in every colonoscopy.

Level of Evidence: Low

Selected Jurisdictions: n/a

Colonoscopy Standard 9: All facilities providing colonoscopy must use automated endoscope reprocessors (AERs).

Background and Rationale: Thorough cleaning and disinfection of colonoscopes after each colonoscopy is a recommended quality measure that is essential to patient safety. According to the American Society for Gastrointestinal Endoscopy (ASGE)[24], AERs can enhance efficiency and reliability of high-level disinfection (HLD) by replacing some manual reprocessing steps. Use of an AER may also reduce exposure of personnel to chemical germicides. This recommendation is based on the knowledge and expertise of the Colonoscopy Expert Advisory Panel.

Level of Evidence: Low

Selected Jurisdictions: n/a

Colonoscopy Standard 10: All personnel involved in reprocessing must participate in a formalized training program beyond that which is provided by the manufacturers.

Background and Rationale: Standards for proper infection control and sterilization of medical equipment are required.[25,26] Standards are clear, but a standardized training program of facility personnel to ensure consistent adherence to the

standards is needed. Infection control processes should be equally rigorous across all facilities. Formalized training for all scope technicians must include instruction on scope handling, mechanics, infection control procedures and Personal Protective Equipment (PPE).
Level of Evidence: Low
Selected Jurisdictions: n/a

Colonoscopy Standard 11: A certification program for endoscopy nurses must be developed.

Background and Rationale: Canada has a certification program offered through the Canadian Nursing Association for Gastroenterology but it does not specifically focus on colonoscopy or endoscopy. The American Board of Certification for Gastroenterology Nurses also includes endoscopic procedures as just one domain of several required for competency in gastroenterology nursing.[27,28] In Australia, the Quality Working Group for Improving Colonoscopy Quality in Australia recommended that an appropriate percentage of credentialed nurses be employed in each facility, and that this should be phased in gradually.[2] A voluntary national certification program for endoscopy/colonoscopy nurses should be developed and offered to nurses with at least one year of experience in endoscopy.
Level of Evidence: Moderate
Selected Jurisdictions: n/a

Colonoscopy Standard 12: Endoscopy units or facilities must provide competency-based orientation to all nursing staff at the time of hiring.

Background and Rationale: Competency-based orientation is a learner-focused method of providing nurses with the requisite knowledge and skills to perform/assist competently in an endoscopy/colonoscopy unit. In addition to common core competencies across the province, facilities will be required to define competencies specific to each nurse on the team, as these duties and responsibilities can vary greatly across facilities.[29,30]
Level of Evidence: Low
Selected Jurisdictions: n/a

Colonoscopy Standard 13: Every facility providing endoscopy must undertake an annual nursing competency review.

Background and Rationale: An annual review ensures that competencies are being maintained and that nurses have the knowledge, skills and judgment to safely perform/assist with procedures carried out in an endoscopy unit. It also gives nurses the opportunity to align their annual personal development plan with practice improvement goals. Annual nursing reviews are especially valuable for verifying the competencies of part-time nursing staff.[29,30]
Level of Evidence: Low
Selected Jurisdictions: n/a

Colonoscopy Standard 14: Nurses with experience in endoscopy must be available on-call in facilities where after-hours urgent and emergency endoscopic procedures occur.

Background and Rationale: It is important for nurses experienced in colonoscopy to assist with colonoscopy procedures, regardless of time of day that the procedure is performed. Endoscopy nursing is considered to be a specialized form of nursing, with specific knowledge, skills and abilities.[30-32] Given that on-call procedures are often a result of an emergency or urgent medical issue, to support patient safety, specialized endoscopy nurses should be? present for these procedures as procedural risk is higher. A study at the Queen Elizabeth II Health Sciences Centre in Nova Scotia[33] illustrated that therapeutics are required in almost half of all patients undergoing after-hours colonoscopy, and with the use of specialized equipment, endoscopy-trained nurses are necessary.
Level of Evidence: Low
Selected Jurisdictions: n/a

Colonoscopy Standard 15: All facilities must use the Global Rating Scale (GRS) as a quality assurance/quality improvement tool.

Background and Rationale: Originally developed in the United Kingdom, the Global Rating Scale (GRS) was created in 2004 as a quality improvement and assessment tool for the gastrointestinal endoscopy service. The GRS assesses 12 key aspects of the patient experience for colonoscopy procedures.[34] Clinical indicators of quality and patient/service user experience are fundamental to quality improvement, and using a tool validated by patients[34] such as the GRS[35-38] allows practitioners to monitor and measure progress towards improving quality.
Level of Evidence: Strong
Selected Jurisdictions:
- Canada[34] (compulsory in British Columbia and Newfoundland)
- Scotland[39]
- Ireland[4]

Colonoscopy Standard 16: All facilities providing colonoscopy services must ensure that the environment provides sufficient privacy to patients to maintain their confidentiality. Ideally, the pre-procedure assessment area must be separate from the recovery area.

Background and Rationale: Respect for patient/service user privacy is an important aspect of patient-centred care. Patients' perception of privacy strongly predicts their level of satisfaction.[40] Due to space constraints, patient/service users are often asked personal health questions in public areas, and may be reluctant or embarrassed to discuss personal details in such an environment. Every effort must be made to ensure that patient privacy and confidentiality is respected.

Level of Evidence: Moderate

Selected Jurisdictions:

- Canada (Ontario)[1]
- Austrailia[2,3]

Colonoscopy Standard 17: All colonoscopy patients, on discharge, must receive written information regarding the procedural findings, plans for treatment and follow-up, worrisome symptoms to watch for and steps to be taken.

Background and Rationale: It is important for patients to receive clearly communicated results of their colonoscopy with clear direction on the clinically recommended next steps.[7,8] Patients should also be aware of signs and symptoms of possible complications that would require them to seek immediate physician attention.

Level of Evidence: Moderate

Selected Jurisdictions: n/a

Provincial Provider-Level Colonoscopy Indicators

C1 Provider-Level Indicator:
Total Colonoscopy Volume

Definition: Total colonoscopy volume in a year

Background and Rationale: There is evidence that proficiency in endoscopic procedures is dependent upon continued practice and performance of adequate numbers of procedures.[41,42,43] There is also data to suggest that lower volume endoscopists have more complications[43]. However, there is some debate about the exact threshold (presently 200) to ensure competence. In addition, enforcement of a standard will have implications for rural and remote areas of the province.

Level of Evidence: Moderate

Selected Jurisdictions:

- Canada (Ontario)[44,45]
- Ireland[46]
- European[47]
- United Kingdom[48]

C2 Provider-Level Indicator:
Inadequate Bowel Preparation

Definition: Percentage of outpatient colonoscopies with poor bowel preparation. The following assessment scale must be used consistently throughout the province:

- Very good to excellent preparation
- Adequate preparation with colonic irrigation
- Inadequate preparation

Background and Rationale: Proper bowel preparation is important as it is associated with higher colonoscopy completion rates and adenoma detection rates.[8,13,15, 44-47,49,50]

Level of Evidence: Strong

Selected Jurisdictions:

- Canada (Ontario)[15, 44,45]
- Europe[47]
- United States[8,13,49]
- United Kingdom[50]
- Ireland[46]

C3 Provider-Level Indicator:
Outpatient Polypectomies

Definition: Percentage of outpatient colonoscopies in which ≥ 1 polyp(s) were removed

Background and Rationale: This indicator provides information on the presence or absence of polyps at the time of colonoscopy (unlike adenoma detection, which requires pathologic confirmation), and is captured in health administrative data.[8,51-54] Low PDR has been shown to be associated with more post-colonoscopy colorectal cancer (PCCRC).[42]

Level of Evidence: Strong

Selected Jurisdictions:

- Canada (Ontario)[15,44,45]
- Europe[47]
- United States[8]

C4 Provider-Level Indicator:
Outpatient Cecal Intubation

Definition: Percentage of outpatient colonoscopies where the cecum or terminal ileum (TI) was reached.

Background and Rationale: Cecal intubation is defined as passage of the scope beyond the ileocecal valve into the cecal pole or terminal ileum.[7, 44, 45] Lower endoscopist cecal intubation has been significantly associated with greater risk of a post-

colonoscopy colorectal cancer in a study using a large administrative database in Ontario.[42]

Level of Evidence: Strong

Selected Jurisdictions:

- Canada (Ontario)[7,15,44,45]
- United States[8,13]
- Europe[47,55]
- Australia[2]
- Ireland[46]

C5 Provider-Level Indicator:
Polypectomy Associated Bleeding

Definition: Number of outpatient colonoscopies with polypectomy where patient was admitted to hospital with lower gastrointestinal bleeding within 14 days of the procedure.

Background and Rationale: Bleeding post-polypectomy is a complication of colonoscopy which generarlly results in hospitalization. This complication leads to higher costs and use of resources, and adversely affects the patient experience. Reporting post-polypectomy bleeding ensures that providers are knowledgeable of all instances of perforation and have the opportunity to review their procedural reports in order to identify opportunities for improvement.

Level of Evidence: Strong

Selected Jurisdictions:

- Canada[15,44,45,56]
- Europe[47,55]
- Austrailia[2]
- United Kingdom[48]
- Ireland[46]
- United States[8]

C6 Provider-Level Indicator:
Outpatient Perforations

Definition: Number of perforations among outpatient colonoscopies performed.

Background and Rationale: A perforation is a complication of colonoscopy that will result in hospitalization. This complication leads to higher costs and use of resources, and may lead to death of a patient. Reporting perforations ensures that providers are knowledgeable of all instances of perforation and have the opportunity to review their procedural reports in order to identify opportunities for improvement.

Level of Evidence: Moderate

Selected Jurisdictions:

- Canada[15,44,45,56]
- Europe[47,55]
- Australia[2]
- Ireland[46]
- United States[8]

C7 Provider-Level Indicator: Colorectal Cancer (CRC) Detection

Definition: Number of outpatient colonoscopies where CRC was detected.

Background and Rationale: Colonoscopy is the gold standard for the diagnosis of colorectal cancer, therefore this is an important outcome to measure. CRC detection is a well-established indicator that is used widely.[57,58]

Level of Evidence: Moderate

Selected Jurisdictions:

- Australia[57]
- Ireland[46]
- Europe[47]

C8 Provider-Level Indicator: Post-colonoscopy CRC (Interval Cancer)

Definition: Number of persons who had a colonoscopy negative for CRC in whom CRC was diagnosed within the subsequent 6 to 36 months.

Background and Rationale: This indicator captures the occurrence of new or missed CRC diagnosed after colonoscopy, and often reported as a quality indicator for colonoscopy.[59-61] It is often defined as the proportion of persons with CRC who underwent a colonoscopy within six to 36 months prior to the diagnosis of CRC (those with a colonoscopy within 6 months of diagnosis are considered to be detected cancers).[45] Possible reasons for a post-colonoscopy CRC include missed lesions, incomplete removal of adenomas, and new rapidly growing lesions.[42,62,63]

Level of Evidence: Moderate

Selected Jurisdictions:

- Canada (Ontario)[15, 45]
- Europe[47]
- Ireland[46]

C9 Provider-Level Indicator:
Adenoma Detection

Definition: Percentage of colonoscopies in which ≥ 1 adenoma was identified and removed.

Background and Rationale: Adenoma detection is a specific and direct indicator of the quality of colonoscopy[64], because adenomas are known cancer precursors. It has been associated with important clinical outcomes such as post-colonoscopy colorectal cancers.[60] More recently, sessile serrated polyps (SSP), which are polyps with a distinct histology from adenomas, have been recognized as important cancer precursors.[65]

Level of Evidence: Strong
Selected Jurisdictions:
- Canada (Ontario)[15,44,45]
- Europe[47]
- Ireland[46]
- United States[8]

Provincial Facility-Level Colonoscopy Indicators

C10 Facility-Level Indicator: Outpatient Cecal Intubation

Definition: Percentage of outpatient colonoscopies performed where the cecum or terminal ileum (TI) was reached.
Background and Rationale: Cecal intubation is defined as passage of the scope beyond the ileocecal valve into the cecal pole or terminal ileum.[7,44,45] Lower endoscopy cecal intubation has been significantly associated with greater risk of a post-colonoscopy colorectal cancer in a study using a large administrative database in Ontario.[42]
Level of Evidence: Strong
Selected Jurisdictions:
- Canada[7,15,44,45]
- United States[8,13]
- Europe[47,55]
- Austrailia[2]

C11 Facility-Level Indicator: Colonoscopies Performed by Endoscopists Meeting Volume Standard

Definition: Percentage of colonoscopies performed at each facility by endoscopists who have performed 200 or more colonoscopies in total in the reporting year.
Background and Rationale: There is evidence that proficiency in endoscopic procedures is dependent upon continued practice and performance of adequate numbers of procedures.[41,42,43] There is also data to suggest that lower volume endoscopists have more complications[43]. However, there is some debate about the exact threshold (presently 200) to ensure competence. In addition, enforcement of a standard will have implications for rural and remote areas of the province.
Level of Evidence: Moderate
Selected Jurisdictions:
- Canada[44,45]
- Ireland[46]

C12 Facility-Level Indicator: Colonoscopy Within 8 Weeks of Positive FOBT

Definition: Percentage of Ontario screen-eligible individuals, 50-74 years old, who had an abnormal FOBT result and follow-up colonoscopy within 6 months, who underwent colonoscopy within 8 weeks.
Background and Rationale: The Canadian Association of Gastroenterology (CAG) has published a Canadian consensus on medically acceptable wait times, and has set benchmarks that recommend a colonoscopy be completed within two months for those with a positive FOBT.[66] CCO's ColonCancerCheck program has adapted this benchmark.[68]
Level of Evidence: Moderate
Selected Jurisdictions:
- Canada (Ontario)[68]

C13 Facility-Level Indicator: Colonoscopy Within 26 Weeks for Family History

Definition: Percentage of colonoscopies within the 26 week benchmark for individuals with family history of colorectal cancer defined by the family history colonoscopy indication in the Colonoscopy Interim Reporting Tool.
Background and Rationale: The Canadian Association of Gastroenterology (CAG) has published a Canadian consensus on medically acceptable wait times, and has set benchmarks that recommend a colonoscopy be completed within two months for those with a positive FOBT.[67] CCO's ColonCancerCheck program has adapted this benchmark.[67]
Level of Evidence: Moderate
Selected Jurisdictions:
- Canada (Ontario)[67]

C14 Facility-Level Indicator: Positive FOBT Follow-up Rate

Definition: Percentage of Ontario screen-eligible individuals, 50-74 years old, who had an abnormal FOBT result, who underwent colonoscopy within 6 months.
Background and Rationale: People with abnormal FOBT results must receive timely and appropriate follow-up in the form of timely colonoscopy to assess whether or not cancer is present.[47]
Level of Evidence: Moderate
Selected Jurisdictions:
- Canada (Ontario)[67]

C15 Facility-Level Indicator: Tier 1 and Tier 2 Adverse Events

Definition: Numbers of Tier 1 and Tier 2 adverse events.

Tier 1 Events:

- Death within the premises
- Death within 10 days of a procedure performed at the premises
- Any procedure performed on wrong patient, site or side
- Transfer of a patient from the premises directly to a hospital for care

Tier 2 Events:

- Number and type of infections occurring in the premises
- Unscheduled return to the procedure room for an unexpected event
- Unplanned stay at the premises for medical reasons that is longer than 12 hours post-procedure
- Unscheduled treatment of a patient in a hospital premises

Background and Rationale: OHPs are currently required to report Tier 1 and Tier 2 adverse events to the CPSO.[1] It is recommended that adverse events be reported for all facilities providing colonoscopies (including hospitals, OHPs, and IHFs).

Level of Evidence: Moderate

Selected Jurisdictions:

- Canada (Ontario)[1]

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Appendix I – Mammography Supporting Evidence

The expert advisory panels used their knowledge, skills and judgment to recommend guidelines, standards and indicators that, if applied across the province, will facilitate consistent, high-quality care in Ontario. The Partnership assessed the evidence that supports each standard, guideline and indicator using its own scale that considered the extent to which the recommendations are supported by published evidence and literature, and adopted in other jurisdictions.

This appendix provides a summary of the mammography evidence assessment and associated references.

Mammography Provincial Standards

Mammography Standard 1: The healthcare system must provide patients/service users with timely, equitable access to breast imaging services.

Background and Rationale: Access is widely recognized as a key aspect of quality, and patients/service users who need mammography must be able to access it.[1,2] Ontario needs to have adequate capacity to provide convenient and timely access to mammography, breast ultrasound and breast magnetic resonance imaging (MRI) in order for patients/service users to be properly assessed. Patients/service users should not have to travel too far to access these services.
Level of Evidence: Moderate
Selected Jurisdictions: n/a

Mammography Standard 2: Patients/service users who wish to be engaged and active in their care and outcomes must be supported to do so.

Background and Rationale: The healthcare system needs to be structured to support all patients/service users through mammography and follow up, and support and enable patients/service users who want to take an engaged and active role in their care by providing them with information in a format that is useful to them.[1,2] Facilities can provide information in many ways, ranging from oral instructions and/or pamphlets provided at the mammogram visit describing potential outcomes and next steps, to electronic portals that give patients/service users access to their test results and other information relevant to their care. Whatever method a facility uses, information must be timely, comprehensive, accurate and accessible.
Level of Evidence: Moderate
Selected Jurisdictions: n/a

Mammography Standard 3: There must be mechanisms in place to ensure that patients/service users receive their mammography results in a timely way and understand recommended next steps.

Background and Rationale: Timely communication of results is essential to quality and reduces patient/service user anxiety. The Ontario Breast Screening Program (OBSP) sends women their mammography results directly by letter to help ensure that they are informed of their results[3], and results notifications are recommended for all screening programs.[1,2] In the absence of result letters, it is the responsibility of the referring health professional to communicate mammography results and recommended next steps to the patient/service user.
Level of Evidence: Moderate
Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Ontario[4]
- Europe: Ireland, Norway, Sweden, Netherlands, United Kingdom[5]

Mammography Standard 4: There must be mechanisms in place to ensure that patients/service users who have abnormal results receive timely follow-up.

Background and Rationale: Timely follow-up of abnormal results is essential to quality and is recommended for all screening programs.[1,2] It ensures that a definitive diagnosis is reached and that patients/service users receive treatment as soon as possible. Follow-up is enhanced when roles and responsibilities of all parties – particularly referring physician and reading radiologist – are clearly defined and communicated.
Level of Evidence: Moderate
Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Ontario[4]
- Europe: Ireland, Norway, Sweden, Netherlands, United Kingdom[5]

Mammography Standard 5: All women who choose to undergo screening mammography and meet the criteria must be screened in the Ontario Breast Screening Program (OBSP).

Background and Rationale: Screening in an organized program provides high-quality screening[1,2] The OBSP provides high-quality screening to Ontario women, [3] but does not currently incorporate screening for all eligible women at all sites. Accordingly, an important early opportunity in mammography will be to expand OBSP to all sites and hence to all women who meet the program criteria.

Level of Evidence: Moderate

Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Nova Scotia, Northwest Territories, Ontario, Prince Edward Island, Quebec, Saskatchewan, Yukon[4]
- Europe: Ireland, Norway, Sweden, Netherlands, United Kingdom[5]

Mammography Standard 6: Regular quality control must be performed on all mammography units.

Background and Rationale: Quality control detects and identifies equipment-related problems before they affect clinical images, and must be carried out regularly at frequencies ranging from daily to semi-annually.[1,2,6,7,8,9]

Level of Evidence: Strong

Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Nova Scotia, Northwest Territories, Ontario, Prince Edward Island, Quebec, Saskatchewan, Yukon[4]
- Europe: Ireland, Norway, Sweden, Netherlands, United Kingdom[5]

Mammography Standard 7: All mammography units and viewing chain must be regularly inspected by a qualified medical physicist with training in mammographic systems.

Background and Rationale: Medical physicists conduct regular inspections to assure proper functioning of the units and the associated viewing chain (i.e., work stations). Physicists also conduct inspections when equipment is new, when problems are suspected and after servicing or maintenance of the equipment.[1,2,6,7,8,10]

Level of Evidence: Strong

Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Nova Scotia, Northwest Territories, Ontario, Prince Edward Island, Quebec, Saskatchewan, Yukon[4]
- Europe: Ireland, Norway, Sweden, Netherlands, United Kingdom[5]

Mammography Standard 8: All facilities must maintain Canadian Association of Radiologists – Mammography Accreditation Program (CAR-MAP) accreditation.

Background and Rationale: Accreditation helps ensure that facilities deliver high-quality mammography.[1,7,11] CAR-MAP accreditation confirms that mammography units produce clinically acceptable images, and that MRTs and radiologists are properly licensed for mammography. All facilities must ensure that each mammography unit is currently CAR-MAP accredited and that each MRT and each radiologist at their facility is currently CAR-MAP accredited.

Level of Evidence: Moderate

Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Nova Scotia, Northwest Territories, Ontario, Prince Edward Island, Quebec, Saskatchewan[12]

Mammography Standard 9: All medical radiation technologists (MRTs) performing mammography must have regular image reviews.

Background and Rationale: MRTs are responsible for correctly positioning the breast to produce a high-quality mammogram that will reduce recalls for technical problems and maximize cancer detection.[1,8] Image reviews assess an MRT's positioning technique and identify where he or she is performing well and where he or she may need to improve. The OBSP conducts regular image reviews for MRTs who work in the OBSP and mandates follow-up for MRTs who require assistance to achieve excellent positioning.[3] These image reviews must be expanded to all MRTs performing mammography.

Level of Evidence: Low

Selected Jurisdictions: n/a

Mammography Standard 10: Retrospective peer review of interval cancers must occur for all reading radiologists.

Background and Rationale: Retrospective peer review is a quality assurance process that provides valuable learning opportunities for reading radiologists.[1,2,8,13] The OBSP conducts regular interval

cancer reviews;[3] these must be expanded to all reading radiologists.

Level of Evidence: Moderate

Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Nova Scotia, Northwest Territories, Ontario, Prince Edward Island, Quebec, Saskatchewan[4]

Mammography Standard 11: College of Physicians and Surgeons of Ontario (CPSO) peer assessments must be used for radiologists in Ontario.

Background and Rationale: Peer assessments for radiologists are a useful non-punitive tool that can be leveraged for quality assurance purposes. Peer assessments provide supportive education to improve the quality of care and ensure patient safety.[11,13] The CPSO is developing peer assessments for radiology. These assessment programs must be value added and non-duplicative (i.e., they must not assess aspects of quality that are assessed through other processes).

Level of Evidence: Low

Selected Jurisdictions: n/a

Mammography Standard 12: A prospective peer review system should ideally be developed for screening mammography.

Background and Rationale: Prospective peer review is a promising quality assurance process that may improve overall quality and provide educational opportunities for the reading radiologists.[1,2,4,13] There is interest across Canada in developing prospective peer review for radiology in order to improve diagnostic imaging quality overall; in Ontario, Health Quality Ontario is developing a peer review program for all aspects of diagnostic imaging. A prospective peer review system for screening mammography should ideally be developed and embedded within this broader diagnostic imaging initiative.

Level of Evidence: Moderate

Selected Jurisdictions: n/a

Mammography Standard 13: Mammography reports must be standardized.

Background and Rationale: The interpretation of the mammogram and the clarity of the mammography report are essential to high-quality care and ensure that referring physicians understand the radiologists' assessments and act on their recommendations.[1,2] The radiologist/facility must provide the referring health professional with either a normal or an abnormal breast imaging report (i.e., incorporating mammography, breast ultrasound, breast MRI and, if done, image-guided biopsy) in a timely manner, ideally by requiring standard elements in all reports.[14] Standardization will be enhanced through the use of information technology to track and report on all breast imaging.

Level of Evidence: Moderate

Selected Jurisdictions:

- United States[14]

Mammography Standard 14: All breast images and reports must be integrated into a provincial repository to allow imaging and report sharing.

Background and Rationale: MRTs and radiologists need access to prior mammograms and reports when viewing or reporting a current mammogram in order to decide if a finding has changed in the intervening period.[1,2] Barriers to obtaining prior mammograms and reports include poor portability of film and/or CDs. Shipping of films and CDs is costly, and requiring pick-up by the patient/service user is inconvenient. Films are difficult to compare to images on monitors, and CDs often fail to display properly on different picture archiving and communication systems (PACS). All breast imaging and reports must be integrated into a provincial repository that allows image and report sharing between facilities and referring physicians across the province.

Level of Evidence: Low

Selected Jurisdictions: n/a

Mammography Standard 15: All mammography must be digital.

Background and Rationale: Clinically, digital mammography and film screen are both acceptable for mammography.[15] However, digital mammography has significant advantages over film screen, including quicker image acquisition, more efficient image archiving, better image portability, improved integration with other imaging modalities (ultrasound and magnetic resonance imaging or MRI) and elimination of hazardous chemicals used in developing films. In addition, film screen imaging is becoming obsolete as manufacturers abandon production of necessary supplies and equipment. For all these reasons, mammography must be digital.

Level of Evidence: Moderate

Selected Jurisdictions:

- Newfoundland and Labrador, Nova Scotia

Mammography Standard 16: All facilities must participate in regular inspections and assessments to ensure they meet appropriate mammography standards.

Background and Rationale: Periodic assessment ensures that facilities meet appropriate standards.[1] All independent health facilities (IHFs) must be regularly assessed by the CPSO.[11] An analogous assessment program should be developed for hospitals. These assessment programs must be value added and non-duplicative (i.e., they must not assess aspects of quality that are assessed through other processes).
Level of Evidence: Moderate
Selected Jurisdictions: n/a

Provincial Provider-Level Mammography Screening Indicators

M1 Provider-Level Screening Indicator: Abnormal calls

Definition: Percentage of mammograms identified as abnormal at the screening episode.
Background and Rationale: This is a well-established indicator used in jurisdictions across Canada and internationally.[1,2]
Level of Evidence: Strong
Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Nova Scotia, Northwest Territories, Ontario, Quebec, Saskatchewan[4]
- International: Australia, New Zealand, United Kingdom[16]

M2 Provider-Level Screening Indicator: Positive predictive value

Definition: Percentage of abnormal cases with completed follow-up found to have breast cancer (ductal carcinoma in situ or DCIS, or invasive) after diagnostic work-up.
Background and Rationale: This is a well-established indicator used in jurisdictions across Canada and internationally.[1,2]
Level of Evidence: Strong
Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Nova Scotia, Ontario, Quebec, Saskatchewan[4]
- International: Australia, New Zealand, United Kingdom[16]

M3 Provider-Level Screening Indicator: Invasive cancer detection

Definition: Number of invasive cancers detected per 1000 screens.
Background and Rationale: This is a well-established indicator used in jurisdictions across Canada and internationally[1,2]
Level of Evidence: Strong
Selected Jurisdictions:

- Canada: British Columbia, Manitoba, New Brunswick, Nova Scotia, Ontario, Quebec, Saskatchewan[4]
- International: Australia, New Zealand, United Kingdom[16]

M4 Provider-Level Screening Indicator: Ductal carcinoma In situ (DCIS) detection

Definition: Number of DCIS cancers detected per 1,000 screens.
Background and Rationale: This is a well-established indicator used in jurisdictions across Canada and internationally.[1,2]
Level of Evidence: Strong
Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Nova Scotia, Ontario, Quebec, Saskatchewan[4]
- International: Australia, New Zealand, United Kingdom[16]

M5 Provider-Level Screening Indicator: Tumour size

Definition: Percentage of invasive cancers ≤ 15 mm.
Background and Rationale: This is a well-established indicator used in jurisdictions across Canada and internationally.[1,2]
Level of Evidence: Strong
Selected Jurisdictions:

- Canada: British Columbia, Manitoba, New Brunswick, Nova Scotia, Ontario, Saskatchewan[4]
- International: Australia, New Zealand, United Kingdom[16]

M6 Provider-Level Screening Indicator: Nodal involvement

Definition: Percentage of invasive screen-detected cancers that are node-negative.
Background and Rationale: This is a well-established indicator used in jurisdictions across Canada and internationally[1,2]
Level of Evidence: Strong
Selected Jurisdictions:

- Canada: British Columbia, Manitoba, New Brunswick, Nova Scotia, Ontario, Saskatchewan[4]
- International: Australia, New Zealand, United Kingdom[16]

M7 Provider-Level Screening Indicator: Post-screen invasive cancers (interval cancers)

Definition: Number of invasive breast cancers found after a normal mammography screening episode within 0 to 12 months, and 12 to 24 months.
Background and Rationale: This is a well-established indicator used in jurisdictions across Canada and internationally[1,2]
Level of Evidence: Strong
Selected Jurisdictions:

- Canada: British Columbia, Manitoba, New Brunswick, Nova Scotia, Ontario, Saskatchewan[4]
- International: Australia, New Zealand, United Kingdom[16]

Provincial Provider-Level Mammography Diagnostic Indicators

M8 Provider-Level Diagnostic Indicator: Malignant biopsies

Definition:
a) malignant core biopsies

- % of malignant core biopsies, out of all core biopsies for asymptomatic women
- % of malignant core biopsies, out of all core biopsies for symptomatic women

b) malignant surgical biopsies

- % of malignant surgical biopsies, out of all surgical biopsies for asymptomatic women
- % of malignant surgical biopsies, out of all surgical biopsies for symptomatic women

Background and Rationale: This is a well-established indicator used in jurisdictions across Canada and internationally[1,2]
Level of Evidence: Strong
Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Nova Scotia, Ontario, Quebec, Saskatchewan[4]
- International: Australia, New Zealand, United Kingdom[16]

M9 Provider-Level Diagnostic Indicator: Positive predictive value

Definition: Percentage of recommended biopsies found to have breast cancer (ductal carcinoma in situ or DCIS and invasive), out of all recommended biopsies.
Background and Rationale: This is a well-established indicator of quality.[1,2]
Level of Evidence: Strong
Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Nova Scotia, Ontario, Quebec, Saskatchewan[4]
- International: Australia, New Zealand, United Kingdom[16]

M10 Provider-Level Diagnostic Indicator: Use of Breast Imaging Reporting and Data System or BI-RADS 3

Definition: Percentage of BI-RADS 3 called on diagnostic work-up, out of all diagnostic cases.
Background and Rationale: BI-RADS was developed by the American College of Radiology to standardize mammography reporting. BI-RADS 3 called on diagnostic work-up means that the abnormality is probably benign and that a shorter follow-up timeframe is required. It should be used infrequently.[14]
Level of Evidence: Strong
Selected Jurisdictions: n/a

M11 Provider-Level Diagnostic Indicator: BI-RADS 3 malignancies

Definition: Percentage of BI-RADS 3 calls that develop into cancer (DCIS or invasive), out of all BI-RADS 3 calls.
Background and Rationale: BI-RADS was developed by the American College of Radiology to standardize mammography reporting. BI-RADS 3 called on diagnostic work-up means that the abnormality is probably benign and that a shorter follow-up timeframe is required. It should be used infrequently.[14]
Level of Evidence: Strong
Selected Jurisdictions: n/a

M12 Provider-Level Diagnostic Indicator: BI-RADS 5 malignancies

Definition: Percentage of BI-RADS 5 calls that develop into cancer (DCIS or invasive), out of all BI-RADS 5 calls.
Background and Rationale: BI-RADS was developed by the American College of Radiology to standardize mammography reporting. BI-RADS 5 called on diagnostic work-up means that there is a very high chance that the findings indicate cancer.[14]
Level of Evidence: Strong
Selected Jurisdictions: n/a

Provincial Facility-Level Mammography Indicators

M13 Facility-Level Indicator: Wait time to first assessment

Definition: Time from abnormal screen to first diagnostic assessment.
Background and Rationale: This is a well-established indicator used in jurisdictions across Canada and internationally.[1]
Level of Evidence: Strong
Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Nova Scotia, Ontario, Quebec, Saskatchewan[4]
- International: Australia, New Zealand, United Kingdom[16]

M14 Facility-Level Indicator: Wait time to diagnosis without tissue biopsy (core or open)

Definition: Time from abnormal screen to definitive diagnosis.
Background and Rationale: This is a well-established indicator used in jurisdictions across Canada and internationally.[1]
Level of Evidence: Strong
Selected Jurisdictions:

- Canada: Alberta, British Columbia, Manitoba, New Brunswick, Nova Scotia, Ontario, Quebec, Saskatchewan[4]
- International: Australia, New Zealand, United Kingdom[16]

M15 Facility-Level Indicator: Wait time to diagnosis with tissue biopsy (core or open)

Definition: Time from abnormal screen to definitive diagnosis.
Background and Rationale: This is a well-established indicator used in jurisdictions across Canada and internationally.[1]
Level of Evidence: Strong
Selected Jurisdictions:
Canada: Alberta, British Columbia, Manitoba, New Brunswick, Nova Scotia, Ontario, Quebec, Saskatchewan[4]

- International: Australia, New Zealand, United Kingdom[16]

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Appendix J – Pathology Supporting Evidence

The expert advisory panels used their knowledge, skills and judgment to recommend guidelines, standards and indicators that, if applied across the province, will facilitate consistent, high-quality care in Ontario. The Partnership assessed the evidence that supports each standard, guideline and indicator using its own scale that considered the extent to which the recommendations are supported by published evidence and literature, and adopted in other jurisdictions. Members of the Canadian Partnership Against Cancer's Quality Initiative in Interpretive Pathology reviewed and provided input into this evidence assessment.

This appendix provides a summary of the pathology evidence assessment and associated references.

Pathology Provincial Standards, Best Practice Guidelines and Indicators

Foundational Elements
Pathology Standard 1: All laboratories in Ontario must have a pathology professional quality management committee.
Pathology Standard 2: All laboratories in Ontario must have a pathology professional quality management plan.

Background and Rationale:

In accordance with recommendations by the Canadian Association of Pathologists, and in accordance with the Excellent Care For All Act (ECFAA) legislation, the Ontario Laboratory Accreditation Requirements and the Public Hospitals Act, it is essential for laboratories to provide leadership in, and support for ,quality assurance and improvement.[1,2,3,4,5,6] One of the most effective ways this can be accomplished is to have an established quality management committee.

A pathology professional quality management committee is important for local facilities to have a venue to discuss and monitor quality issues and to implement quality improvement processes and projects in order to ensure safe, effective and reliable pathology services for all patients.

Such a committee would ideally have the following responsibilities:

- To monitor and report to the responsible body on quality issues and the overall quality of services provided in the healthcare organization, with reference to appropriate data
- To consider and make recommendations to the responsible body regarding quality improvement initiatives and policies
- To ensure that best practice information, supported by available scientific evidence, is translated into materials that are distributed to people providing services within the healthcare organization, and to subsequently monitor the use of these materials by these people
- To oversee the preparation of annual quality plans
- To carry out any other responsibilities provided for in the regulations[4]

In addition, an important recommendation for such a quality management committee is to have a detailed quality plan. The laboratory must have a documented quality management program to systematically ensure the quality of laboratory services.[3,7,8] A pathology professional quality management plan allows facilities to focus on key quality deliverables on a regular basis. A quality plan is most effective when it has a simple aim and speaks to its mission in a direct way.[3] The plan should ideally include an outline of specific areas of focus with specific mention of monitors that should be performed. Evidence-based benchmark levels, or minimum targets to be achieved, should be identified where possible. An institution should have a goal of improving on its own benchmarks as well as external benchmarks.

Level of Evidence: Moderate

Selected Jurisdictions:

- United States[3]

Secondary Case Reviews
Pathology Standard 3: All laboratories must have a guideline for classification of report defects, discrepancies, discordances and errors, and a policy for their investigation and resolution.

Background and Rationale:

A guideline for classification of defects, discrepancies, discordances and errors on retrospective review is important for patient safety to ensure that consistent terminology and definitions are used in a facility.[1] Multiple case reviews by more than one pathologist have resulted in overall lower diagnostic disagreement rates.[9]

Level of Evidence: Low

Selected Jurisdictions: n/a

Intra-Departmental Consultation

Pathology Standard 4: All laboratories must have a policy that outlines the procedure for consultation with intra-departmental colleagues, including the documentation of those consults. Each laboratory must have a policy that outlines which cases require mandatory intra-departmental consultation and which are discretionary for the professional group.

Pathology Standard 5: All laboratories must collect and review data on intra-departmental consultations, for the professional group.

Pathology Best Practice Guideline 1: All laboratories should collect and review data on intra-departmental consultations, for each pathologist.

P1 Facility Indicator: Intra-departmental consultation, defined as the number of facility level intra-departmental consults for the professional group, out of all cases for the professional group.

Background and Rationale:

When a pathologist prospectively seeks an opinion from another pathologist in their professional group prior to case sign-out, it is referred to as an intradepartmental consult. It may involve a specific request from one pathologist to another to consult on all or selected slides and material from a case. It may also involve consult on all or selected slides and material in the course of a case conference.[1]

Having a second pathologist review a case prior to reporting helps to ensure accuracy of the final diagnosis. Intra-departmental consultation leads to improved decision-making and uniformity in the use of diagnostic terminology, grading systems and criteria, and should increase compliance with quality assurance processes.[1]

An intradepartmental consultation serves as a second review of cases before verification and, as such, is a form of prospective peer review. Secondary review of cases may reduce the number of subsequent amended reports and, ideally, increase overall diagnostic accuracy.[8] Australian literature on internal quality assurance activities in pathology suggests several potential mechanisms for how a mandatory internal consultation and review process may increase patient quality and safety. Such a process may:

- Provide subconscious and conscious motivation to be more accurate
- Stimulate increased consultations among pathologists
- Foster uniformity in diagnostic reporting and thereby minimize inter-observer variability within a department
- Foster a "teamwork" mentality with shared-decision-making and continuous education, with the common purpose of increased quality[10]

However, although second reviews add value, the critical question remains how to determine which cases require review by a second pathologist.[9]

The ideal secondary review process (e.g., random versus targeted second review, blinded versus unblended review, focused review for selected cases such as all neoplasms) for intradepartmental consultation has yet to be determined in the literature. In one study, a focused secondary review process detected approximately four times more errors than a random review of five per cent of all cases.[11,12,13] However, the more focused the secondary review process, the more time consuming and costly, and the optimal ratio of cost for quality benefits remains to be seen. In addition, the ideal volume or target for intradepartmental consultation remains unknown. Renshaw et al found an intradepartmental consult rate intradepartmental consultation remains unknown. Renshaw et al found an intradepartmental consult rate at their centre of 20 per cent of total case volume, with a diagnostic disagreement rate of two per cent. Further studies are required to determine the optimal intradepartmental consult rate for optimizing diagnostic accuracy.[14]

Therefore, a formal process surrounding data information on intradepartmental consultation is recommended. Future directions include continued review of the literature to determine the optimal target intradepartmental consult rate and ideal type of secondary review process. The laboratory should also have a policy for handling intra-departmental consultations in the patient's final report.[15]

Level of Evidence: Moderate

Selected Jurisdictions:

- Ireland[16]
- United States[3,17]

External Consultations

Pathology Standard 6: All laboratories must have a guideline outlining the responsibilities of a pathologist requesting an external consultation to ensure data and important clinical information are sent to the external consultant to allow for proper interpretation of the case in a timely manner.

Pathology Standard 7: All laboratories must have a policy that outlines the procedure for requesting external consultation, including the review and documentation of the resulting consultation opinion. The policy must provide guidance as to the types of cases that are appropriate for external consult.

Pathology Standard 8: All laboratories must collect and review data on external consultations, for the professional group.

Pathology Best Practice Guideline 2: All laboratories should collect and review data on external consultations, for each pathologist.

P2 Facility Indicator: External consultation, defined as the number of facility level external consults for the professional group, out of all cases for the professional group.

Background and Rationale:

When a pathologist seeks an opinion from a pathology colleague external to their professional group, it is referred to as an external consultation. External consultations are typically sought to resolve differences in intradepartmental opinion, resolve cases of diagnostic uncertainty or receive professional expertise that is not available on-site. It is typically a formalized consultation process that requires a review of all the relevant slides and clinical information to render a second formal pathologic diagnosis, and is hypothesized to increase diagnostic accuracy and consensus.[1,18] Data on external consults is a measure of secondary prospective review activity and provides confidence to clinicians and patients/service users that the diagnosis and information contained in the report are accurate. Secondary pathology review is a commonly utilized methodology for the detection of potential errors and deficiencies in oncologic pathology reporting.[19]

External consultants are experts in a particular area of subspecialty. Since they are external to the institution of origin of the case, they do not necessarily have access to the important clinical information and other information data which is needed to properly interpret the case. Providing consistent and relevant information to an external consultant allows them to provide an accurate opinion in a timely fashion.

There are very few data about external consultation rate and diagnostic accuracy. In one study, there was an overall external consultation rate of 0.5 per cent, with the external consultation diagnosis in agreement with the referring pathologist's diagnosis in nearly three-quarters of the cases. However, in 15.9 per cent of the cases, the consultant added what was considered significant information.[18]

The optimal rate of external consultations is difficult to measure and there are few data on its effect on overall diagnostic accuracy. Certainly, second consultations come at the cost of increased turnaround times, decreased internal pathologist satisfaction rating with the overall diagnostic process and increased demands on pathologist workload.[18] More evidence is required before mandatory targets are set.

Overall, formal policies and procedures for collecting data on, requesting and defining which types of cases are appropriate for external consultations is recommended.[9] The laboratory should also have a policy for handling external consultations in the patient's final report.[15]

Level of Evidence: Moderate

Selected Jurisdictions:

- Ireland[16]
- United States[3]
- Manitoba[20]

Intra-Operative Consultations

Pathology Standard 9: All laboratories must have a policy that outlines the processes for, and the documentation of, the comparison of intra-operative consultation results with final diagnoses.

Pathology Standard 10: All laboratories must collect and review data on the appropriateness and accuracy of intra-operative consults and deferral rates, for the professional group.

Pathology Best Practice Guideline 3: All laboratories should collect and review data on the appropriateness and accuracy of intra-operative consults and deferral rates, for each pathologist.

P3 Facility Indicator: Intra-operative consultation accuracy, defined as the number of accurate intra-operative consultations for the professional group/ total cases for the professional group.

P4 Facility Indicator: Intra-operative consultation deferrals, defined as the number of deferred intra-operative consultations for the professional group, out of all cases for the professional group.

Background and Rationale:

Intra-operative consultations include rapid diagnostic interpretations of specimens (often gross frozen sections and cytology). They provide rapid information to surgeons during an operation that allows them to make appropriate intra-operative clinical decisions. Intra-operative diagnoses are subsequently compared with finalized diagnoses made from more permanent preparations and have been used as a marker of quality in pathology.[1]

The importance of close communication between surgeons, pediatric oncologists, pediatric radiologists, and pathologists cannot be

overemphasized. Frequently, this communication occurs before and during the intra-operative consultation and contributes to a better understanding of how the information from the frozen section will be used. Clinical decisions about staging with bone marrow biopsies and aspirates, line placement for chemotherapy and other pharmacotherapy, and further surgery may all be influenced by the frozen section result.[17]

Comparing intra-operative consultation results with the findings on permanent sections prior to final release of a case is necessary to resolve discrepancies between the two different techniques. When significant disparity exists between initial intra-operative consultation and final pathology diagnosis, it must be reconciled and documented in the surgical pathology report and in the departmental quality management file.[15,21] Monitoring data on intraoperative consultation provides confidence to clinicians and patients/service users that the process is reliable, accurate and appropriate.

An optimal target for intra-operative diagnostic discordance or deferral remains unclear, apart from the understanding that lower rates of diagnostic discordance are better. Discordance rates vary between sites as well as organ tissue in question.[1] It is recognized that there are certain cases that have high discordant rates, such as sentinel lymph node and surgical margin analysis.[22] In addition, there are cases where diagnosis is more often deferred intra-operatively. Rates vary considerably between sites and tissue section type, and range from 1.20 to 2.9 per cent in the literature.[22,23]

Regardless, evidence suggests that collecting and tracking this information is a starting point for lowering diagnostic discordance rates over time. In one study, tracking such data lowered diagnostic discordance rates below two per cent, and the trend to lower mean diagnostic discordance rates was associated with the amount of time spent in continuous monitoring.[24] In addition, studies emphasize the importance of close communication between surgeons, pathologists and other physicians involved in this process.[25] Hence, a process for collecting and reviewing the accuracy of intra-operative consults is recommended.

Level of Evidence: Moderate

Selected Jurisdictions:

- Ireland[16]
- United States[3,26]
- Manitoba[20]

Previous/Concurrent Laboratory Reports
Pathology Standard 11: All laboratories must have a policy that outlines the procedure for correlation of current surgical pathology cases with pertinent previous/ concurrent laboratory reports and, if required, related slides and other material.
Pathology Best Practice Guideline 4: All laboratories should collect and review data on report defect and discordances revealed by review of previous/ concurrent laboratory reports, for the professional group and for each pathologist.

Background and Rationale:

Comparing the current case with previous pathological information, including surgical pathology, cytology, hematology and other laboratory reports is an important aspect of delivering high quality care pathology. Review of pertinent previous/concurrent laboratory reports and/or related slides and other material as required from a current surgical pathology case ensures consistency and may help determine the most appropriate diagnosis for the current case.[1]

Level of Evidence: Moderate

Selected Jurisdictions:

- Ireland[16]
- Manitoba[20]

External Reviews
Pathology Standard 12: All laboratories must have a policy that outlines the processes for handling requests for review of cases by an external pathologist, including the documentation and review of those results.
Pathology Standard 13: All laboratories must collect and review facility-level data on report defect and discordances revealed by external reviews, for the professional group.
Pathology Best Practice Guideline 5: All laboratories should collect and review data on report defect and discordances revealed by external reviews, for each pathologist.
P5 Facility Indicator: External review defects and discordances, defined as the number of cases within the facility where external review revealed report defects or diagnostic discordances for the professional group, out of all reports reviewed externally by the professional group.

Background and Rationale:

An external review occurs when there is a request by a pathologist, clinician, institution or patient/service user to have a case reviewed by a pathologist in a facility external to the one in which the case was originally reported. External reviews are distinct from external consultations; the former occur after a final diagnosis

has been rendered, while the latter are second opinions prior to final diagnosis being rendered. External reviews may be routinely sought as part of an institution's mandatory quality assurance process or be requested as a secondary review and opinion.[1] As such, they are an additional mechanism of peer review for monitoring diagnostic accuracy and quality.

Monitoring of diagnostic discrepancies from external review can reassure patients/service users, pathologists, clinicians and institutions that diagnoses are accurate. They can also identify areas for quality improvement.

There is evidence to suggest that secondary review, regardless of whether prior to sign-out or after, improves the accuracy of pathology reports.[11,27] However, the optimal target for external review to increase diagnostic accuracy and maximize patient outcomes remains unknown.[9] Future directions include determining which cases require review by a second pathologist in order to maximize diagnostic accuracy.

Level of Evidence: Moderate

Selected Jurisdictions:

- Ireland[16]
- United States[3]

Retrospective Reviews

Pathology Best Practice Guideline 6: All laboratories should have a policy that outlines the procedure for reviewing the professional group's data on report defects and discordances revealed by retrospective reviews.

Pathology Best Practice Guideline 7: All laboratories should collect and review data on report defects and discordances revealed by retrospective reviews, for the professional group and each pathologist.

Background and Rationale:

Retrospective reviews occur after cases have been signed out, i.e., after a diagnosis is finalized. They are essentially a form of secondary peer review to determine whether there is diagnostic agreement between two separate pathologists interpreting the same sample. Hence, such data are an important measure of diagnostic accuracy. A guideline for classification of defects, discrepancies, discordances and errors on retrospective review is important for patient safety to ensure that consistent terminology and definitions are used in a facility.[1]

Overall, a formal process surrounding collecting information on retrospective reviews is recommended. Future directions include continued review of the literature to determine an optimal acceptable target for diagnostic agreement in focused or targeted retrospective reviews.[28]

Level of Evidence: Moderate

Selected Jurisdictions:

- Ireland[16]

Corrected Reports

Pathology Standard 14: All laboratories must have a policy that outlines:

- The criteria for revising or correcting reports, including those in which diagnoses are revised or corrected. This policy should include definitions of the terms employed by the group for such reports, criteria for their use, the procedures and documentation required to issue them and related follow-up quality assurance actions.
- When to directly inform the responsible clinician of the revision or correction (e.g., by verbal communication) and how to document that communication.
- Procedure for notification of the Laboratory Director (or, depending on a group's policies, the chair of the pathology professional quality management committee), and through the Laboratory Director (or chair of the pathology professional quality management committee) initiation of critical incident and similar reporting where appropriate.
- When revised or corrected reports have to be documented for risk management, root cause analysis and quality improvement purposes via the organization's processes.

Pathology Standard 15: All laboratories must collect and review data on corrected reports and the reasons for the corrections, for the professional group.

Pathology Best Practice Guideline 8: All laboratories should collect and review data on corrected reports and the reasons for the corrections, for each pathologist.

P6 Facility Indicator: Corrected reports, defined as the number of corrected reports stratified by reason for the professional group, out of all reports reviewed by the professional group.

Background and Rationale:

When new information becomes available after a case has been finalized and signed out, a correction, addendum or revision to the original report may be required. This new information may or may not have been anticipated prior to case sign-out. Collecting data on unanticipated addendum reports, in particular, may help identify and facilitate quality improvement opportunities and ideally result in preventive actions to reduce the release of incorrect reports.1 Ensuring a low level of corrected reports is desirable. Ensuring communication of corrections to the most responsible healthcare provider is important for patient care and safety.

Several retrospective studies have examined the frequency of errors in surgical pathology and reported amended report rates of 1.9 to 4.8 per 1000 cases.[28,29] These amended reports can have significant clinical impact. In a study of 480 corrected microbiology laboratory reports, as many as seven per cent of 480 corrected reports were associated with an adverse clinical impact; and of these 32 cases, 59 per cent involved delayed therapy, 25 per cent involved unnecessary therapy and 25 per cent were associated with inappropriate therapy. It is reasonable to recommend tracking and collecting these data in order to better understand the root cause and impact of corrected reports on clinical outcomes.

Therefore, a formal process surrounding data collection on corrected reports is recommended. Future directions include continued review of the literature to determine the optimal target of corrected, revised or amended reports that is considered acceptable, as well as impact on diagnostic accuracy overall on patient outcomes.

Level of Evidence: Moderate

Selected Jurisdictions:

- Manitoba[20]
- United Kingdom[30]
- Ireland[16]

Critical Diagnoses and Significant Unexpected Findings
Pathology Standard 16: All laboratories must have a policy that outlines the types of diagnoses/ findings that are considered critical in the practices of physicians served by a surgical pathology group.
Pathology Standard 17: All laboratories must have a defined procedure for timely communication of these diagnoses findings to the physician most responsible for the care of the patient involved. The communication of these results must be documented.
Best Practice Guideline 9: All laboratories should collect and review data on reporting of critical diagnoses, results and alert values, for the professional group and for each pathologist.

Background and Rationale:

Critical diagnoses (also known as critical values, alert values and significant results) are diagnoses that require expedited notification to the most responsible physician. They are either significant diagnoses or unexpected findings that require timely communication with patients and physicians involved in their clinical care in order to reduce the risk of patient morbidity or mortality.[1,31,32]

Communicating critical results in a clearly defined, standardized way has been shown to result in more effective and consistent pathologist performance by decreasing variation in individual pathologist practices and timely patient care, with increased perceptions of positive outcomes by hospital medical staff.[31] Processing of critical results may expedite clinical decision making, further testing, procedures and discussions with patients regarding their care.[28,31,32] One unresolved question is determining which results should be classified as critical. There is currently variation between institutions, and while certain diagnoses are, in general, thought of as critical, such as organ transplantation rejection, malignancy, vasculitis or certain infectious diseases, overall, there is still some pathologist discretion with respect to determining what defines a critical result.[32,33,34]

Therefore, a formal process for data collection on critical values is recommended. Future directions include continued review of the literature to determine the impact of critical values on overall patient outcomes. A discussion involving the pathology community might prove useful in an attempt to establish anatomic pathology critical value guidelines.[35]

Level of Evidence: Moderate

Selected Jurisdictions:

- United Kingdom[30]
- United States[36]

Turnaround Times
Pathology Standard 18: All laboratories must have a policy that outlines the processes for monitoring of turnaround times on a regular basis.
Pathology Standard 28: All laboratories must collect and review data on turnaround times, for the professional group.
Pathology Best Practice Guideline 10: All laboratories should collect and review data on turnaround times, for each pathologist.
P7 Facility Indicator: Turnaround time, defined as the average facility time from specimen receipt to case sign out for professional group overall for all surgical pathology cases.

Background and Rationale:

Turnaround times (TATs) refer to the amount of time from receipt of a specimen (such as a frozen section, biopsy or large specimen) to finalized report.[1,3,16] TATs reflect the efficiency of surgical pathology work processes and the capacity of a pathology facility to report case results in a timely manner. As such, they are an important quality indicator in pathology. Timely reports also decrease patient anxiety.[17]

Literature on the utility of TATs is varied. First, TATs are calculated via methods ranging from electronic data capture to manual collection, depending on the pathology facility. In some studies, the scope of TATs are expanded, to include communicating frozen section results to the surgeon, for example. Optimal TATs have yet to be determined and depend on the procedure in question; for example, frozen section block TATs have a typical benchmark target of 20 minutes, while a common TAT target for biopsies and more complex surgical specimens are within two days.[3,21] Moreover, for frozen sections, tissue type appears to impact TATs, with skin specimens having, overall, shorter TATs than oral/nasopharyngeal regions.[21] For biopsies and complex specimen TATs, a recent study concluded that a two-day TAT is a reasonable goal and was met in 91 to 95 per cent of routine biopsies and specimens. Longer biopsy TATs were associated with larger institutions with more surgical pathologists, resident trainees involved in cases, and fewer staff (e.g., technicians and transcriptionists).[3]

Despite these variations in practice and accepted threshold targets, TATs are a reflection of work process efficiency, and therefore their impact on the quality of patient care cannot be ignored. A formal process for data collection on TATs is thus recommended. Future directions include continued review of the literature to determine the impact of TATs on patient outcomes.

Level of Evidence: Moderate

Selected Jurisdictions:

- Ireland[16]
- United States[3]
- Ontario[37]

Service Satisfaction
Pathology Best Practice Guideline 11: All laboratories should collect and review data on service satisfaction, for the professional group.

Background and Rationale:

Feedback from those who use pathology services helps provide knowledge of user needs, expectations and experience with a particular pathology laboratory. As such, it is an important marker of quality of care from the user's perspective.[1,15]

It should be noted that service satisfaction may not necessarily relate to diagnostic accuracy, timeliness or cost of services. Service satisfaction is a complex metric that may include a user's expectations of the pathology laboratory process.[8] In addition, service satisfaction can refer to patient satisfaction; the opinion from other physicians, nurses and other staff who interact with a pathology lab; and the views of pathologists and staff who work at that particular laboratory.[17]

There is limited evidence on service satisfaction and its association with quality of care, diagnostic accuracy, and patient outcomes. Higher satisfaction rates are associated with shorter turnaround times, reflecting a value placed on efficient work processes as an indicator of quality.[18] Laboratory management accessibility and responsiveness were also highly regarded in several studies by nursing staff.[38] Despite the paucity of literature on the association between service satisfaction and quality of care outcomes, it is widely agreed that there is inherent value in collecting data on satisfaction from those who utilize the pathology service.

Level of Evidence: Moderate

Selected Jurisdictions:

- United States[17]

Patient Safety Checklists for Surgical Pathology

Pathology Best Practice Guideline 12: All laboratories should have a process in place to ensure that the professional group is aware of Patient Safety Checklists for Surgical Pathology as a reference standard to ensure day-to-day practice meets best practice.

Background and Rationale:
Patient safety checklists in pathology were modeled after surgical patient safety checklists and are designed to ensure that all key aspects of a specific pathology process were followed. The use of patient safety checklists minimizes reliance on user memory in the face of complex and multi-step processes and procedures. They may also decrease the issues of variable input and inconsistency, and in doing so, increase workflow efficiency and, ultimately, minimize error and increase diagnostic accuracy.[1,2]

The evidence that the use of checklists results in improved patient outcomes comes primarily from surgical literature rather than pathology. In surgical populations, checklists have been used as a patient safety and quality improvement tool and have been shown to reduce patient morbidity and mortality in surgical populations.[39] Unlike surgical safety checklists, however, pathology patient safety checklists are not intended to be utilized for every single case, but rather periodic checks for quality assurance purposes.

Level of Evidence: Low

Selected Jurisdictions:

- Canada[2]

Pathology Quality Assurance Program

Pathology Standard 20: Standards and best practice guidelines for internal quality assurance must be maintained and monitored.

Background and Rationale:
Standards2Quality (S2Q) is a set of recommended quality assurance processes and guidelines from which standards and indicators were derived by the Pathology Expert Advisory Panel. The Provincial Pathology Quality Committee will be responsible for determining who will maintain and monitor S2Q to ensure standards are being met.

Level of Evidence: Low

Selected Jurisdictions: n/a

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