Standards2Quality*

Guidelines for Quality Management in Pathology Professional Practices

Version 3

Issued March 29, 2022

Developed by and for Laboratory Physicians in Ontario

Version 1 issued - March 31, 2011
Version 2 issued – Sept. 3, 2013

***A project of Path2Quality**

(A collaboration of the OMA Section on Laboratory Medicine and the Ontario Association of Pathologists)

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Appendices

INTRODUCTION TO VERSION 3

This document, Standards2Quality, professional practice guidelines, is Version 3 of the gold standard developed by the profession in 2011 that focuses on improving quality management systems that help guide the professional work of laboratory physicians in a high-functioning laboratory system. This updated version includes additional guidelines in the pre-analytic and post-analytic stages as well as advances in laboratory medical science, such as biomarker testing and digital pathology – thereby ensuring that the profession stays at the forefront of patient safety and the delivery of diagnostic pathology services are high quality, timely and responsive to the needs of the people of Ontario.

While Standards2Quality captures what laboratory physicians do, a companion document, Work2Quality, describes the resources that are required to successfully deliver on this quality imperative. One cannot exist without the other.

Adequate resourcing as envisaged by the Work2Quality Guidelines and other workload measurement systems begins with appropriate numbers of skilled and experienced laboratory physician staff who are working at optimal capacity but not overworked, which is counterintuitive from a patient safety standpoint. Within this context, effective workload management for laboratory physicians encompasses not only direct clinical service but many other activities; for example providing education and training to future generations of laboratory physicians and other staff, staying current, contributing to research, participating in committees and other administrative work.

As previous versions of S2Q have emphasized, in addition to adequate physician staffing, a high quality pathology service also requires other resources (see page 14/15). If these are not available then the expectations described in S2Q may not be reasonable or accomplishable. Either those professional staffing and infrastructure resource gaps would have to addressed, or the expectations of the professional group would need to be modified to deal with such a situation. At the time of this review, our health care system and our profession is challenged by the COVID pandemic and in particular is facing recovery plans to address the backlog of cancer screening and surgical cases, all of which will impact already stretched pathology departments. This is the challenge facing the Ministry of Health, the steward of Ontario's health care system resource allocation.

This is a living document continually in 'evolution', any limitations and inadequacies are solely the responsibility of the Path2Quality volunteers who worked to produce it. Feedback is encouraged, and may be directed to:

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SUMMARY OF CHANGES

General Changes:

- Updated terminology where applicable
- Updated references
- Streamlined guidelines and removal of redundancies where applicable
- Updated cytology and hematopathology sections

Foundational Elements:

- Addition of section for classification of report discrepancies based on clinical impact

Quality Assurance Guidelines:

- Case review guidelines revised to reflect prospective and retrospective reviews

Workflow Process Map:

- Enlarged for easier reading and streamlined to reflect changes made in the guidelines

New Additions:

- Total testing cycle to reflect importance of entire testing cycle on quality and patient safety.
- Pre-analytic Guideline
- Patient Education and Communication Guideline
- Digital Pathology Guideline
- Summary of Indicators

USING THE GUIDELINES

This document contains a number of linked sections and documents:

SECTION 1 – Pathology Professional Quality Management Program Guidelines

This section describes the guidelines that apply to the overarching quality management program that each professional group performing pathology should have in place, and includes suggestions for a committee to oversee the associated quality plan that should be developed by each professional group.

SECTION 2 - Foundational Elements

This section describes elements that broadly apply to the quality management system suggested in this document, or are applicable to many quality assurance policies and processes that a group should develop.

SECTION 3 – Total Testing Cycle and Workflow Process Map for Surgical Pathology

This section includes a schematic diagram outlining the total testing cycle and a process map that describes the main steps involved in the surgical pathologist's review of any case, and the main decision points before case sign-out.

The workflow processes described can be related to previously developed and updated Surgical Pathology Patient Safety Checklists (PSC). These checklists may be found in Section 4 of this document.

At points in the workflow processes various key quality assurance reviews are suggested as appropriate monitors of the quality of professional work. Each of these is further described in the associated quality assurance guidelines provided in Section 5.

SECTION 4 - Patient Safety Checklists for Surgical Pathology

These Surgical Pathology PSCs are analogous to those currently employed by surgical services, and those that are being developed by other disciplines. The four Surgical Pathology PSCs suggested are not intended to be used literally in the sign-out of every case, but instead are meant to be a reference standard that surgical pathologists may use to ensure that their day-to-day practice meets best practice.

SECTION 5 - Quality Assurance Guidelines for Surgical Pathology

This section describes a variety of guidelines to help monitor the quality of various aspects of the diagnostic work of surgical pathologists. Each has associated with it the description of its 'trigger' – some important step in the workflow process or a broader

quality goal. Each has a principle or purpose described for it, suggestions for related policies and processes, exceptions (if they exist), consideration of how individual practice type might influence the policy developed (if applicable), the responsibilities of the individual surgical pathologist and others in respect of the policy, and the monitors (indicators) that might be used to accomplish the activity in question.

SECTION 6 - Workflow Process Maps for Cytopathology

This is a section added in the September 3, 2013 Version 2 of the *S2Q Guidelines* and includes two workflow process maps. The workflow process map for "cytopathology – general" parallels the one for surgical pathology; where there are modifications or differences, those changes as highlighted. The other workflow process map for fine needle aspiration biopsy (FNAB) is entirely new and addresses the practice of pathologists performing FNABs by introducing FNAB patient safety checklists and quality assurance guidelines.

SECTION 7 - Patient Safety Checklists for Cytopathology

This is a section added in the September 3, 2013 Version 2 of the *S2Q Guidelines* and includes PSCs that parallel those provided in the Surgical Pathology section. Two Cytopathology PSCs for cytopathology work generally, and five further ones for fine needle aspiration biopsy (FNAB) work, are provided.

SECTION 8 - Quality Assurance Guidelines for Cytopathology

This is a section added in the September 3, 2013 Version 2 of the *S2Q Guidelines* and describes a variety of guidelines to help monitor the quality of various aspects of the professional work of cytopathologists.

Five guidelines are provided, describing unique quality assurance activities as they may apply to the work of cytopathologists. Three of these relate to work that cytopathologists may perform if they are responsible for the clinical acquisition of fine needle aspiration biopsy (FNAB) specimens.

SECTION 9 - Workflow Process Maps for Hematopathology

This is a section added in the September 3, 2013 Version 2 of the *S2Q Guidelines* and includes three workflow process maps. The workflow process map for blood films, flow cytometry and bone marrow aspirate and biopsy acquisition and interpretation parallel the surgical pathology and cytopathology workflow process maps.

SECTION 10 - Patient Safety Checklists for Hematopathology

This is a section added in the September 3, 2013 Version 2 of the *S2Q Guidelines* and includes PSCs that parallel those provided for surgical pathology and cytopathology.

SECTION 11 - Quality Assurance Guidelines for Hematopathology

The surgical pathology guidelines which are also applicable to hematopathology are listed.

SECTION 1
PATHOLOGY PROFESSIONAL QUALITY MANAGEMENT PROGRAM GUIDELINE

Trigger:

The need for laboratory physicians to provide high quality, efficient and effective surgical pathology services.

Principle/Purpose:

A pathology professional quality management program is essential if a professional group provides diagnostic interpretive pathology services. Oversight of the program should be the responsibility of the Professional Pathology Quality Management Committee (PPQMC) and should include a professional quality management plan. A Quality Management Plan will articulate how the group will ensure high quality patient centred care and patient safety in their professional practice. It will help to encourage effectiveness and responsiveness in the pathology services that a group provides, and ensures compliance with regulatory and organizational requirements of pathologists.

Policy:

To provide leadership in and support for quality assurance and improvement, pathologists should:

a) Establish a Pathology Professional Quality Management Committee (PPQMC)

Membership and Roles:

- A pathologist should serve as the Chair of the PPQMC and this individual should be chosen to reflect the organization of the professional group and should have an interest or experience in quality assurance and patient safety. Most often the Chair will be the Laboratory Director but may, in large professional groups, be a delegated responsibility.
- The Committee should be comprised of pathologists and be supplemented by others as appropriate and as required to perform its work.
- While oversight for the quality assurance of the professional work of pathologists is the jurisdiction of the PPQMC, the work of pathologists is closely linked to other quality assurance processes in the laboratory. Therefore it should be integrated into technical and other quality processes as determined by each facility's unique quality governance structure.

Responsibilities of the Committee:

The PPQMC will:

- Develop terms of reference that include appropriate governance elements – including (in conjunction with the host institution) articulation of the responsible body to which it will report.

- Establish sub-committees or working groups as required; for instance, with larger professional groups, it may be appropriate to define sub-committees or working groups to oversee the execution of the quality assurance plan for surgical pathology separate from that for cytopathology, and cytopathology separate from hematopathology, and so on.
- Meet on a regularly scheduled basis.
- Oversee the preparation of an annual pathology professional quality improvement plan and associated objectives.
- Establish plans to meet those objectives.
- Monitor, evaluate, improve upon, and report the performance with respect to the pathology professional quality improvement plan at least annually.
- Establish performance standards and benchmarks for the professional group.
- Ensure critical incident reporting meets local and provincial requirements and standards.
- Make recommendations to the responsible body regarding quality improvement initiatives and policies related to pathology.
- Advise on professional education to support continuous quality improvement.
- Ensure that best practice information supported by available scientific evidence is provided to pathologists in the group.
- Carry-out any other responsibilities provided for in regulation, or as determined by the responsible body.
- Operate in a non-punitive and non-coercive way, encouraging a culture of open and constructive communication.

Responsibilities of Laboratory Director and PPQMC Chair:

Depending on the structure of the professional group, the role of the Chair of the PPQMC may be delegated to an appropriate individual. However, the final responsibility for quality processes rests with the Laboratory Medical Director.

The Chair of the PPQMC is responsible for:

- Oversight of the development of the Pathology Professional Quality Management Plan
- Monitoring and regular review of the Pathology Professional Quality Management Plan
- Communication of the plan to all professional staff

The Laboratory Director should regularly assess whether there is appropriate professional time and infrastructure support for the Pathology Professional Quality Management Plan and its requirements. Where gaps are present, the Laboratory Director should continue to advocate for the professional group to ensure adequate resources.

Responsibilities of Pathologists:

Each pathologist should understand and participate in the Pathology Professional Quality Management Plan. This may be demonstrated by:

- Notifying the Laboratory Director and/ or PPQMC Chair in a timely manner of any critical incident, quality deficiencies, or problems with compliance with quality assurance policies and procedures.
- Participating in the quality improvement plan and in service satisfaction surveys and similar quality initiatives.
- Supporting their colleagues through professionalism in their work, and by maintaining a positive work environment that contributes to quality patient reports and outcomes.
- Supplying accurate and timely data as may be required for quality tracking purposes (for example, intra-operative consultation concordance or discrepancy).
- Adhering to regulations, and to established policies and procedures, performing self-checking, utilizing patient safety checklists, and paying attention to detail in the performance of their work.

Reporting Structure:

The PPQMC will:

- Provide regular reports to the Laboratory Director and Chief of Staff (for hospitals).
- Provide other regular reports to the responsible body as described in its terms of reference – these will vary from professional group to professional group according to their institutional situations.

b) Develop a Pathology Professional Quality Management Plan

The plan will articulate:

- A purpose statement which includes goals that:
    - Support continuous quality improvement.
    - Encourage timely, accurate and complete pathology reports.
    - Help to minimize error and enhance patient safety.
    - Are fair and objective as well as focused on improvement and education.
    - Protect professional and patient privacy.
    - Meet regulatory requirements and standards for good medical practice.
- Policies and procedures that encompass the entire pathology workflow process (es), as well as procedures for monitoring related outcomes.
- How all processes are regularly measured, monitored, and improved as necessary.

The plan will also:

- Consider the complexity, structure, responsibilities, and needs of each professional group’s circumstances and organization.
- Interface with other quality management programs such as Accreditation Canada Diagnostics, the institution’s quality and patient safety program, when appropriate.
- Establish quality objectives and priorities based on criteria such as problematic and high risk work processes.
- Assign responsibilities and timelines for action items.

- When possible, incorporate the input of patients, patient advisory groups, clients and other stakeholders that deal with patient outcomes.
- Communicate changes to policies and procedures, and the outcome of any monitoring activities in an open and transparent manner.
- Be reviewed at least annually for its effectiveness and to ensure it is up to date with current best practices. It should be modified and improved as required.

Practice Type Considerations

The Pathology Professional Quality Management Plan and its committee structure may need to be modified for professional groups with a small number of pathologists. In this circumstance, quality management may be a component of other institutional professional quality structures or a partnership with other pathology professional groups (if possible) may be necessary to meet the requirements for best practice.

Large groups may need to create structures and processes that provide for specialty or subspecialty specific quality assurance activities and reporting.

Monitors

Monitoring should be based on approved policies and procedures that encompass the entire surgical pathology work flow process and should also:

- Be performed on a regularly scheduled basis.
- Be conducted and reported against agreed criteria, with mandatory minimum goals identified.
- Incorporate the use of recent best practice benchmarking data related to the laboratory's practice.
- Take into consideration the professional group's practice environment; scope of testing, and available resources.
- Be useful in determining corrective, preventive, and improvement actions when required.

Other forms of oversight and monitoring of the professional work of the pathologists may include receipt of, and actions related to:

- Status reports related to corrective, preventive, and improvement activities.
- Reports and assessments from management and external/regulatory bodies.
- Quality indicators supplied by patient care or other services.
- Indicators used for monitoring should be defined, documented, controlled, analyzed, and improved as necessary to potentiate quality improvement initiatives.

The monitoring data for individual pathologists should be available to them for their review; such data should be maintained in such a way as to preserve individual confidentiality whenever possible, and be in accordance with the PPQMC policies and processes.

SECTION 2
FOUNDATIONAL ELEMENTS

This section describes some guidelines for the overarching principles that should apply to a quality management system for the professional work of pathologists. Additionally, those elements of professional quality assurance that are relevant to the all pathology professional reporting processes, or that apply to the multiple quality assurance guidelines are described. The goal of this work is to lay the foundation and embed within our daily work a strong safety and patient centred culture. Workplace culture describes the environment in which we work and relates to leadership, values, traditions, beliefs, interactions and behaviours that are present in an organization, facility or department. Culture influences patient safety directly by determining accepted practices and indirectly by acting as a barrier or enabler to the adoption of behaviours that promote patient safety. The components of culture include reporting, learning, flexibility as well as the concept of *just culture*, i.e. one in which system failures are fairly balanced with professional accountability.

Essential Attributes of Quality Management Programs

The quality management programs that professional groups devise to guide their pathology practices should focus on the goals of patient safety, and on high quality and efficient professional work processes and results reporting. The program should encourage all participating pathologists to actively contribute to these goals.

Quality assurance activities in the first instance should focus on critical hand-off points in work processes (i.e. points at which errors are prone to occur). To this end, every effort should be made to eliminate unnecessary work process variability, and all work processes should be regularly measured, monitored, and improved, as necessary.

The program should monitor work processes and outcomes in the form of aggregated data, and also be able to respond and deal with sentinel events and individual critical incidents.

All activities of a professional quality management program should be objective and aimed at constructive feedback to, and the improvement of the work of, the professional group and of the individual pathologists in that group.

The quality management system devised should be as comprehensive as possible. It should balance and guard the interests of the group and institution housing it, as well as those of the pathologists in that group. The quality management program should clearly articulate the roles and responsibilities of all involved, and include descriptions of dispute resolution processes. Indemnification, when appropriate, should be described for those organizing and maintaining the program.

Resources

A robust and multifaceted quality assurance program as described in this document cannot be accomplished without appropriate resourcing.

Equally important to supporting the work of Ontario's laboratory physicians are the following:

- Skilled and efficient technical and support staff;
- Efficient technical and professional work processes;
- Adequate laboratory equipment e.g. microscopes;
- Laboratory information systems that adequately support those work processes, as well as those that enable quality assurance and workload measurement;
- Readily available and effective decision support tools which facilitate access to timely quality data
- Time for continuing education
- Adequate time for teaching and research if applicable
- Time for supervision and oversight of pathologists' assistants and technologists
- Effective communication tools and technologies that enable laboratory physician-to-laboratory physician, and laboratory physician-to-clinician collaboration;
- Adequate physical space and office accommodations for professional staff practice.

If adequate infrastructure supports of the sort just listed are not available to a professional group, then the expectations described in either the S2Q or the W2Q *Guidelines* or other workload measurement systems may not be reasonable or accomplishable. Either those professional staffing and infrastructure supports would have to addressed, or the expectations of the professional group modified to deal with such a situation.

Physician Wellness

The health of our pathologist workforce and other laboratory professionals is paramount in creating a positive workplace and safety culture. Adequate supports as described above are a key element in supporting the health and well-being of laboratory staff. Selected literature about physician wellness can be found in references.

Integration with Other Quality Programs

These guidelines focus on professional practice of pathologists. It is assumed that pathologists work within accredited laboratories and the quality management processes for the technical work that supports them meets the high standards encouraged by organizations such as the Accreditation Canada – Diagnostics and the College of American Pathologists.

The program described in this document should integrate with more broadly-based institution-wide programs – in doing so, the form that the pathology professional quality management program takes at any institution may vary to meet broader institutional requirements and to support local clinical services.

Appropriate Training, Licensure, Credentialing and Continuing Professional Development of Pathologists

This document does not address the appropriate medical and specialty training and the examination of pathologists, which is the domain of the academic training programs and of The Royal College of Physicians and Surgeons of Canada (or equivalents), nor their licensure which in Ontario is the domain of the College of Physicians and Surgeons of Ontario.

Likewise, this document does not deal with the credentialing of pathologists which is the responsibility of the hospitals or other institutions for which they work. The requirement that pathologists continuously develop themselves professionally via continuing medical and other education, similarly, is not the subject of this document.

It is assumed that the pathologists working in the professional groups referred to in this document will have met all of the requirements prescribed by these regulatory and governing groups, and have the appropriate experience for the work that they perform. Members are encouraged to review on a regular basis and ensure compliance with provincial and national guidelines around scope of practice; for example Royal College of Physicians and Surgeons position statement – “Ensuring safe, high quality care: managing evolving scopes of practice of all health professionals”.

Any quality assurance program governing the professional work of pathologists should, however, describe the expectations of each of its pathologists with respect to the above, and ensure there is appropriate related documentation.

Documentation

Documentation of all aspects of the quality management program described is of paramount importance, whether related to individual patient cases or to the various policies, processes, monitors, and reviews suggested for such programs.

For individual patient cases, there should be a clear audit trail available that describes the contribution of various individuals (whether technical, support or professional) to the various components of the work and quality assurance processes. The pathologist responsible for the case should be clearly indicated, as should contact information for the institution or group performing the work.

All quality assurance program elements, including the overarching Pathology Professional Quality Management Program Guideline, the Pathology Professional Quality Management Committee terms of reference, and the various associated quality assurance policies and procedures should be appropriately documented, and have standard format, including indication of their author, date of issue or revision, and authorization. Document control processes that include an audit trail should be in place, and obsolete documents appropriately archived.

The results of quality assurance reviews and monitoring should likewise be documented according to predefined policies and procedures, and their integrity and confidentiality appropriately guarded. The results of reviews and monitoring should be regularly

reported in summary form to those governing the quality management program (e.g. hospital medical advisory or quality of care committees, or similar), according to predefined standards and at predefined intervals.

A policy and procedure manual describing the work of pathologists should be in place and describe the standard operating procedures for the work of the pathologists, including those responsibilities that are those of the individual pathologists and those that are the responsibility of the group. This manual should describe the recommended work processes, reporting standards, and similar, as well as the various associated quality assurance program elements.

Privacy, Confidentiality, and Duty to Report

All aspects of the quality management program described in this document must meet applicable statutory and regulatory requirements for privacy and confidentiality of patients' personal information. Likewise, the program should abide by the institutional policies for same.

Every effort should be made to keep confidential the results of individual performance assessments and monitors employed in the various quality assurance reviews described in this document. Where applicable, these should be anonymized.
When critical incidents are encountered, the institution's policies and procedures for dealing with these will be used, and may include, reporting to the Laboratory Director, to the Chief of Staff (in hospitals), to the Board's Quality of Care Committee (in hospitals), and similar. In all instances, the moral and ethical standards of the profession will be met, and the rules of all governing bodies, such as the College of Physicians and Surgeons of Ontario, adhered to. Additionally, the specifics of some forms of critical incident reporting are described in various forms of legislation, for instance Ontario's Excellent Care for All Act.

In Ontario, Quality of Care Information Protection Act (QCIPA) protection may be appropriate for some of the quality assurance reviews described here in accordance with current regulatory and facility standards.

External Consultation

Common circumstances in which external opinions are required include limited test menu and insufficient professional expertise on-site. Sometimes external consults are requested to resolve divergent opinions following intra-departmental consultation. Other prompts include a request by a clinician or patient for an external review. As part of a professional group's Pathology Professional Quality Management Plan, there should be defined policies and procedures for sending external consultations and reviews in these varied circumstances.

Responsibilities of a Pathologist Requesting an External Consultation:

A pathologist requesting an external consultation should ensure:

- The external laboratory and/ or consultant clearly understands the reasons for the consult and provide the external laboratory/ consultant with the preliminary report for the case.
- That the external consultant is provided complete and adequate clinical information. This may include seeking information not originally provided by the clinician who sent the specimen in the first instance.
- That representative materials are included for review. This may include some or all of the slides or other materials prepared from the specimen. Every effort should be made to guard the integrity of those slides and material (e.g., they will be transported to the external consultant in such a way as to minimize the risk of breakage or loss).

Every effort should be made to ensure that some diagnostic material is retained on-site, in order that, in the unusual circumstance of the loss of the consult material, it will not unnecessarily prejudice patient diagnosis. In only very unusual circumstances should all diagnostic material be sent to the consultant; in those cases, sending the material in two separate parts may deal with the possibility of the loss of one part. In the future, digital consultation may mitigate this issue.

Responsibilities of an External Consultant:

If a professional group offers an external consultation service and takes in consults from other groups or institutions there should be defined policies and procedures that govern that consultation work, and describe the expectations with respect to it. At a minimum:

- All materials provided by the originating pathologist or institution should be reviewed; or, alternatively, the consultant's report will make clear which selected materials were reviewed;
- The consultant should review the original report, and if questions exist regarding clinical history or other aspects of the report, the originating surgical pathologist or institution should be contacted for clarification;
- Ideally, the consultant should be part of a sub-specialty team. In difficult cases, other members of the team should also review the case;
- The consultant should provide a timely and complete opinion, and in some instances provide detailed comment;
- The consultation report should embody all the elements described elsewhere in this document (e.g. a record of quality assurance processes used by the consultant);
- In the event that the external consultant remains unsure of the diagnosis, further consultation to another experienced consultant should be considered;
- If a definitive diagnosis was rendered by the original pathologist, and if there is a discrepancy between the original and consult diagnoses, the case should be reviewed by a second pathologist, if available, and this should be recorded in the consultation report. A detailed comment should be included with the consultant's diagnosis. Furthermore, consideration should be given to the need for verbal communication to the original pathologist;

- The materials sent in consultation should be kept intact and in good order;
- The materials sent to the consultant should be returned to the originating pathologist or institution, unless there is expressed consent to do otherwise;
- Every effort will be made to guard the integrity of those slides and material referred (e.g. they will be transported back to the requesting pathologist in such a way as to minimize the risk of breakage or loss);
- The consultant should have backup when away, ideally other members of his/ her professional group; and
- A consultant pathologist should not abandon his/ her consultation practice without fair warning to the community served. Every effort should be made to find alternative solutions.

Guidelines for Dealing with Report Diagnostic Discrepancies*

* *It is recognized that in the literature and in different facilities other terminology may be used when discussing report discrepancies. For the purposes of this document discrepancy is synonymous with the terms defect, discordance and error.*

If report diagnostic discrepancies are revealed by any of the forms of review the professional group employs, there should be in place a policy and predetermined processes for their investigation and resolution, and for the documentation of the same.

At a minimum, the pathologist who becomes aware of a report discrepancy should:

- Discuss the report discrepancy with the pathologist responsible for the report in question, to determine if there is agreement that the report contains a report discrepancy;
  - If they agree that there is a report discrepancy, they will attempt to determine why the report discrepancy arose, the clinical impact of the report discrepancy, and the appropriate action;
  - If they disagree that there is a report discrepancy, resolution may be sought by various means, for instance:
    - Consultation with others in the professional group;
    - Consultation with the Laboratory Director;
    - External consultation.

This discussion and follow- up should be documented.

At a minimum, when a report discrepancy is determined to be present, the pathologist responsible for the report in question should:

- Directly communicate with the clinician for those patients whose treatment or clinical management may need to be modified;
- If appropriate, document the above in an amendment (please see QA guideline Addendum and Amended Reports) to the original report;
- If an amended report is issued, ensure that any originally issued reports are clearly marked in such a way as to ensure that they are not confused or misinterpreted as the final report for the case.

At a minimum, the policy and procedure should outline:

- Processes for the various pathologists involved to follow, including mechanisms for dispute resolution;
- Criteria to determine when notification of clinicians should take place;
- Criteria to determine when amended reports should be issued;
- Criteria to determine when the Laboratory Director should be notified;
- Criteria to determine if critical incident reporting, including notification of the Chief of Staff, or equivalent, is required;
- How the pathologist responsible for the report in question will be notified, when that pathologist is not immediately available;

- Documentation and tracking of report discrepancies including those that are not considered to warrant communication with the clinician, addendum report, etc.;
- How professional group improvement plans will be based on the above.

Monitors

Minimum Requirement:

Number of cases where review of laboratory reports and/or materials revealed report discrepancies compared with number of all cases in same time period for the professional group overall classified according to clinical impact (see below).

Optional:

Number of cases where review of laboratory reports and/or materials revealed report discrepancies for an individual pathologist compared with number of all cases in same time period for the individual pathologist classified according to clinical impact (see below).

Classification of Report Diagnostic Discrepancies

Although there is not yet agreement in the literature about how best to classify report discrepancies, Ontario pathology professional quality leaders under the auspices of the Quality Management Partnership (a partnership of Cancer Care Ontario, now Ontario Health, and the College of Physicians and surgeons of Ontario), reviewed various classification schemes and suggested guiding principles for classification and simple classification system based largely on clinical impact. This terminology was developed with the following guiding principles:

- The emphasis is on impact to patient care rather than on the evaluation of the performance of a pathologist. The impact of a diagnostic discrepancy on patient care cannot reliably predict or make inferences about the performance of a pathologist. For example, a discrepancy may be so incongruous that it may raise concerns about a pathologist's competence; however, it may have no impact on patient care. Furthermore, a discrepancy may have clinical impact; however, it may be a very difficult diagnosis which even experts may disagree upon, or it may be an entity where there is high inter-observer variability, so that a discrepancy may occur for even a highly competent pathologist.
- Laboratory Directors and Chiefs of Pathology, as part of their quality improvement process, may assign a numerical value to discrepancies and determine a specific discrepancy rate. However, each case(s) should be assessed in the context in which it occurred.
- Discrepancy may be related to and influenced by many factors (for example, case mix, technical, and workload), and therefore calculation of discrepancy rates in isolation cannot be used to judge or compare facility or individual performance.
- While this classification schema standardizes terminology around the classification of discrepancy, determining and monitoring the reason for discrepancy is equally if not more important for quality improvement and patient care. For example, in cases of frozen section, determination of whether discrepancy is due to sampling, technical preparation, misinterpretation or lack of clinical data would indicate where quality improvement efforts should be directed. Similarly the etiology of external review discrepancy should be determined and monitored for quality improvement purposes.
- It is recognized that in many instances the patient impact may not be known and cannot be easily determined without a great deal of effort and resources that may not be available to pathologists and pathology departments. There may also be differences of opinion as to the degree of discrepancy which makes definitive categorization impossible. For these reasons, a category of "Can Not be Determined" is available. Monitoring and determining the etiology of discrepancy in this category is of equal importance for quality improvement.

Proposed Terminology

Concordance/Agreement - a report conveys same/similar message or diagnosis

Discrepancy - any disagreement or lack of consensus between two different reviews or modalities, for example difference of opinion between two pathologists or difference between frozen section diagnosis and permanent section. Any disagreement which may result from additional information or testing which was not available at the time of the original diagnosis; for example, additional immunohistochemistry or molecular testing.

Proposed Classification of Discrepancy:

A. Near miss: no patient impact or potential for patient impact due to timely intervention.

Examples:
- Discrepancy at intradepartmental consultation detected before sign-off.
- Case reviewed at multidisciplinary rounds results in upstaging of tumor before therapy is instituted
- An external review of a case involving inflammatory bowel disease, results in reclassification prior to therapy.
- Typographical error such as “malignancy present” instead of “No malignancy present” is noticed within first few days of release of report before communication to patient.

B. Discrepancy with minor patient impact: did not trigger an irreversible surgical procedure, harmful therapeutic intervention or result in serious complication or morbidity.

Examples:
- Intraoperative consultation of an ovarian lesion as benign A and changes to benign B
- Change in diagnosis which results in further diagnostic investigations and/or a minor delay in therapy

C. Discrepancy with major patient impact: loss of life, limb, major organ or serious complication/morbidity due to inappropriate or delayed therapy due to discrepant diagnosis.

Examples:
- Breast biopsy diagnosed as malignant but following lumpectomy and sentinel lymph node biopsy, permanent sections show a benign lesion
- Tissue contaminant on a small biopsy results in misdiagnosis of cancer and an unnecessary surgery

D. CND-Can Not Determine Patient Impact, due to lack of clinical follow-up or clinical information. These cases should be documented as patient impact may become apparent at a later date and they may be important for facility and/or individual quality improvement. **Data on cases which are classified as CND**

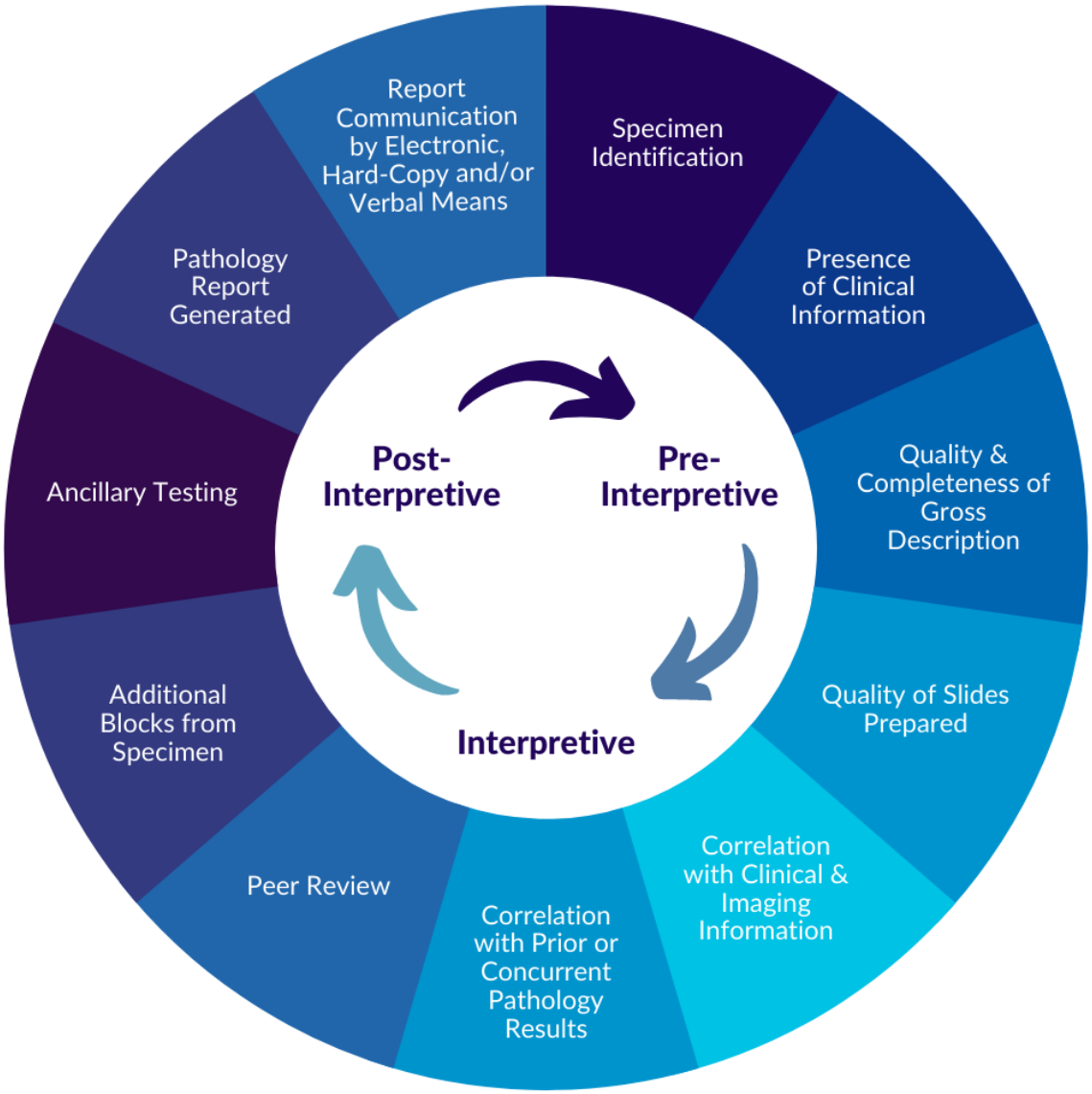
should be followed by the facility on a regular basis to ensure this category is being appropriately utilized.

Examples:

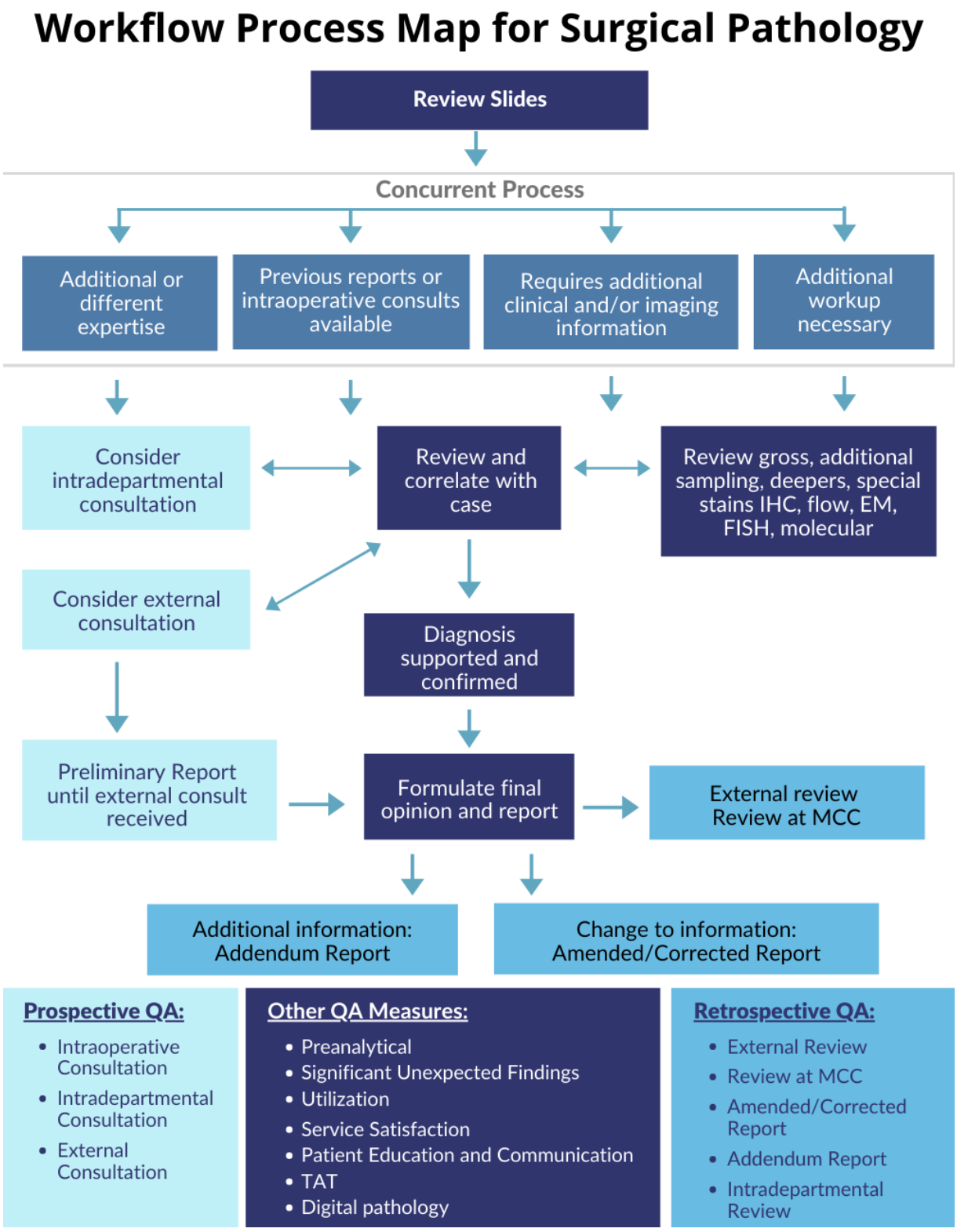
- Upon review of a liver biopsy the degree of fibrosis changes. Upon communication to attending physician there is no change to management however, long term follow up not available.
- Prostate biopsy on review is classified as Gleason 7 rather than Gleason 9 however, due to patient co-morbidities there is no immediate change in management.

SECTION 3

TOTAL TESTING CYCLE



WORKFLOW PROCESS MAP FOR SURGICAL PATHOLOGY



SECTION 4
PATIENT SAFETY CHECKLISTS FOR SURGICAL PATHOLOGY

1.0	GROSS EXAMINATION PATIENT SAFETY CHECKLIST
1.1	The patient identifiers and other information provided on the requisition match those on the specimen container, and match any other related patient record (e.g. in the laboratory information system).
1.2	The specimen submitted is appropriate for examination and is not on the organization's examination exemption list.
1.3	The gross examination is performed by a pathologist, a pathology resident, or by other qualified personnel who are under the supervision of a pathologist.
1.4	Pertinent previous clinical history, diagnostic imaging and laboratory reports are available for review.
1.5	The referring physician or appropriate other personnel is contacted for additional information, if required.
1.6	A standardized protocol or guideline is used for the dissection, description, and histologic and other sampling of the specimen.
1.7	If a pathology resident or other personnel performs the examination, they will review unusual or unexpected findings with the pathologist.
1.8	When unusual findings or situations are encountered, the pathologist exercises professional discretion to perform those studies indicated.
1.9	Tissue for special procedures or research protocols is obtained at the direction of the pathologist, does not compromise patient care, and is performed according to institutional policies, including institutional review board (IRB) requirements.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

2.0	INTRA-OPERATIVE CONSULTATION PATIENT SAFETY CHECKLIST
2.1	Pertinent previous clinical history, diagnostic imaging and laboratory reports are available for review.
2.2	The referring physician or appropriate other personnel is contacted for additional information, if required.
2.3	Specimens from concurrent consultations are kept separate.
2.4	Tissue for frozen section or other rapid analysis is selected taking into account the possible need for fixed tissue or subsequent studies.
2.5	Each frozen section slide or other preparation created is labeled with two unique patient identifiers.
2.6	Frozen section slides or other preparations are of sufficient quality for intra-operative diagnosis.
2.7	If a verbal report is given, the referring physician or delegate is contacted directly by the pathologist.
2.8	The patient's identification is checked before delivery of any verbal report.
2.9	Results provided verbally are read-back by the referring physician, or delegate, and checked for accuracy by the pathologist.
2.10	The performance of an intra-operative consultation, its results, any verbal communication to the referring physician, and the date and time of any communication are permanently documented in the report for the specimen.
2.11	Following the intra-operative consultation, tissue is submitted for further studies as required.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

3.0	PRE-INTERPRETATIVE PATIENT SAFETY CHECKLIST
	Patient Demographics
3.1	The patient demographics are consistent with the submitted specimen.
	Patient Clinical History
3.2	Pertinent previous clinical history, diagnostic imaging and laboratory reports are available for review.
3.3	The referring physician or appropriate other personnel is contacted for additional information, if required.
	Case Material Correctness
3.4	Slides and other preparations created are uniquely and permanently identified with adequate and legible information.
3.5	The patient record (including any transcribed portions), the specimen requisition and slides, and any other case materials match.
	Gross Description
3.6	The specimen type matches the requisition and other records.
3.7	The description is complete, understandable and follows established protocols.
3.8	The description contains adequate information regarding tissue type/ material, number of tissue/ material pieces, dimensions and/or weight of tissue/ material, any lesions, and other information for pathologic diagnosis.
3.9	Appropriate sections are taken, or other preparations made, for the type of specimen submitted.
3.10	There is documentation of the sections taken or other preparations made in the report.
3.11	Annotated specimen drawings, photographs, radiographs, and similar (if required), are available for review.
3.12	The individual responsible for the gross description is documented.
	Slide and Other Preparation QC/QA
3.13	The material in the slides or other preparations matches the gross description.
3.14	Slides and stains, and other preparations, are of sufficient quality.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

4.0	POST-INTERPRETATIVE PATIENT SAFETY CHECKLIST
	Provisional (Preliminary) Report – if required
4.1	The report describes what work or other information is pending/ incomplete, and why the report is not a final/ completed one.
4.2	The report clearly indicates that the findings are preliminary and may be modified at the time of issuing the final/ completed report.
	Pathology (Final) Report
4.3	All components of the Final Report are consistent with one another, and patient identifiers in the Final Report have been checked and matched with the content of the report.
4.4	Any standardized protocols employed by the professional group for reporting the specimen are adhered to.
4.5	The gross description, microscopic findings (if recorded), and any other information included support the pathologic diagnosis.
4.6	Any inadequacies or limitations of the specimen or its examination are documented.
4.7	The results of specialized studies are correlated with the morphologic diagnosis, documented and incorporated into the final diagnosis.
4.8	For reports that include tests that provide independent predictive information, details of specimen processing, and the test and the scoring methods used are included in the report.
4.9	The record of any intra-operative consultation performed is incorporated in the final report.
4.10	Any discrepancy between the final diagnosis and the gross description, intra-operative consultation and/or other tests performed, is reconciled and explained in the report.
4.11	Recommendations for further studies are included.
4.12	Significant, unexpected findings are communicated promptly to the clinician and that communication documented.
4.13	All necessary sections of the report are completed (including required synoptic report fields).
4.14	No transcription or formatting errors are present.
4.15	All quality assurance processes employed during the course of specimen examination and reporting are documented.
4.16	The pathologist responsible for the report (including any preliminary report/s) is clearly indicated in the report, along with contact information for the institution/professional group.
	Addendum (Supplementary) and Amended (Corrected) Reports – if required
4.17	The reason for the addendum or amendment is clearly indicated in the report, and along with any background information and findings that may have served as its basis.

4.18	The information in the original report and the original diagnosis are reviewed and changed if required. If a change is made, that change is clearly identified.
4.19	The clinician is notified, if necessary and that notification documented.
4.20	The original report is retained and can be retrieved – ensuring that it cannot be mistaken as the active/ final report.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

SECTION 5
QUALITY ASSURANCE GUIDELINES FOR SURGICAL PATHOLOGY

Quality Assurance Guideline
Pre-Analytical Factors

Trigger: Any event which occurs prior to specimen analysis and which may impact quality.	
Principle/Purpose	The pre-analytical phase begins at the time of specimen collection and ends with specimen analysis. Pre-analytic factors have profound effects on the processing of pathology specimens. As these errors are difficult to capture in the later phases of the testing cycle, it is important that systems are in place to detect these errors and that personnel are vigilant against these errors. The downstream effects may be significant. Pre-analytic factors may be divided into several categories A. External to the pathology laboratory, and includes: • Patient identification, with appropriate labelling of specimens and requisitions; • Inclusion of appropriate clinical history; • Identification of most responsible physician (MRP) and other physicians involved in the patient's care. B. Internal and external to the pathology laboratory including ischemic and fixation times C. Internal to the laboratory including issues related to fixative type and decalcification. External pre-analytical factors are more difficult to control, and require collaboration and communication with clinical service administration. Internal pre-analytical factors are more within the control of the pathology laboratory. **A. Factors external to the pathology laboratory:**

	There is no substitute for a correctly labelled specimen, accurate clinical information, and correct identification of physicians related to a patient's care. Absence of these elements may lead to problems in specimen identification, diagnostic misinterpretation, delays, inappropriate use of limited health care resources, and breakdown in communication of results, which can lead to significant critical and adverse events. Correcting systemic deficiencies requires consistent, persistent messaging between the laboratory directors to related personnel. **i. Specimen receipt and labelling, including criteria for specimen acceptance and rejection** This is covered extensively in accreditation protocols included in the references. **ii. Relevant clinical information** Inclusion of all accurate, relevant clinical information is critical for the evaluation of all pathologic specimens. This information should include: • Description of findings, including unusual features of the clinical presentation; • History of prior tumours, immunosuppression, prior radiation or chemotherapy, and transplantation; • Relevant prior material, including biopsies or resections from external institutions; and • Relevant medication history. Pathologist access to electronic health records is also necessary, however it is not a substitute for clinical information and appropriate communication with the most responsible physician. **iii. Indication of most responsible physician and other clinicians in the patient's circle of care.** The most responsible physician (MRP) must be clearly identified on the requisition. The MRP is the first point of contact for critical results and for communication of any pertinent information. While a physician signature is useful, institutions are shifting towards integrated hospital and laboratory information systems with electronic documentation, which may obviate the need for a physical signature. Care must be used in identifying physicians in the circle of care. When incorrect physicians are identified on the report, this constitutes a breach of patient privacy and confidentiality, and should be handled in accordance with appropriate local protocols.

	B. Factors internal and external to the pathology laboratory Ischemic and fixation times have profound implications for preservation and retrieval of antigens and nucleic acids, and consequently for diagnosis and management of various diseases. Although the laboratory does not generally have complete control over specimen transport and similar factors, the laboratory can exert control over the portions of (cold) ischemic time and fixation time that elapse within the laboratory. Cold ischemic time is defined as the time from devitalization of the tissue to initiation of formalin penetration which may require large specimens to be opened or sliced into appropriate thickness of sections in order to ensure adequate formalin penetration. Prolonged ischemic time may lead to irreversible degradation of antigens and nucleic acids. Current guidelines recommend ischemic times be kept to one hour or less. Fixation time is defined as the time that a specimen is adequately exposed to fixative. Most guidelines suggest an optimal fixation time between 6-72 hours. **C. Factors internal to the pathology laboratory** The laboratory can typically control the nature of the fixative and decalcification methods. These factors may influence antigen and nucleic acid retrieval which are important for prognostic and predictive testing in cancer diagnoses.
Policy	As part of the Pathology Professional Quality Management Plan and/or the facility overarching quality management plan there should be a policy that outlines the processes for and documentation of pre-analytic factors (external and internal).
Exceptions	There may be different pre-analytic factors which a facility may choose to monitor however pre-analytic factors affect all facilities.
Practice Type Considerations	All facilities which offer anatomical pathology services should have a policy addressing pre-analytic factors. Facilities which do not perform immunohistochemistry or molecular testing on site will still need to have processes in place to ensure ischemic times and fixation times meet current standards.
Responsibilities of Case Pathologist	All pathologists should participate in departmental quality assurance around pre-analytical factors.
Monitors	Many of these proposed metrics may already be prepared as part of standard laboratory practice, and may fall under the operational/technical rather than the professional quality assurance

	domain. They are nevertheless repeated here as they apply to all patients passing through the pathology laboratory. These metrics include but are not limited to: • Specimen rejection rates per time period (looking for areas which may need focused intervention regarding appropriate specimen labelling); • Determination of proportion of specimens which have absent, insufficient, incorrect, or otherwise inappropriate clinical history; • Monitoring ischemic and fixation times, particularly for breast specimens These metrics may be useful when analyzed on a routine basis, or as part of a more targeted analysis during a near-miss or critical incident.

Quality Assurance Guidelines for Case Reviews

Overview	
Evaluation of pathology cases (case reviews) are a very important element in the practice of quality interpretive pathology. There is evidence that the performance of case reviews detect discrepancies and pathologist groups that perform case reviews have a lower error rate than if they do not perform case reviews. By definition, a case review happens when the report and/or slides from a case (either in whole or in part), are reviewed by a second pathologist (reviewer) after the primary pathologist responsible for sign out of the report has reviewed the case (case pathologist). In 2016 the College of American Pathologists released evidence based guidelines related to interpretative diagnostic error reduction and recommended that pathologists should have documented case reviews relevant to their practice setting. There is a lack of clear evidence that one type of review is better than any other and the ones chosen should be those that best suit the pathologist or group practice and which have the best chance of identifying discrepancies with minimal negative impact on report turnaround time and resources. In any of the circumstances in which a case is reviewed, documentation of the review is an important part of the Quality Management Program. The performance of case reviews should be continuously monitored and the results documented to ensure that the program is functioning as intended and there is appropriate compliance. If case reviews demonstrate poor agreement within a defined case type, steps should be taken to improve agreement. In instances where discrepancies are identified requiring amended reports and clinical communication, documentation and resolution of these cases may utilize the Guidelines for Dealing with Diagnostic Discrepancies (see page 20) and other institutional policies. This version of the S2Q has been revised to provide a functional framework for approaching case reviews based on whether a review is prospective (performed before case sign out) or retrospective (performed after case sign out) and whether it is performed by a pathologist within the case pathologist's group/institution (intra-departmental) or outside of it (external).	
Prospective Reviews	In these types of reviews the guidance for the reviewer and the case pathologist focus primarily on appropriate documentation of the opinions provided and resolution of any discrepancies prior to release of the report. In the case of external prospective review, a preliminary report may be issued indicating further opinion and final diagnosis is to follow. Prospective reviews aim to achieve diagnostic agreement prior to making patient care decisions and evidence shows that prospective reviews can reduce discrepancy rates and amended report rates. A pathologist may also review a concurrent specimen not yet reported. This happens when multiple samples are taken from a patient at the same time (or in short proximity) and are submitted for multiple laboratory assessments (pathology,

	cytopathology, hematopathology). The review of concurrent cases is performed for diagnostic purposes and is done prospectively (prior to case sign out). The documentation and management of this type of review would follow that outlined for intradepartmental prospective reviews. The College of American Pathologists recommends that case reviews be performed in a timely manner to avoid having a negative impact on timeliness of patient care. This is achieved most often by an intradepartmental prospective review whenever possible.
Retrospective Reviews	These types of reviews occur after the case has been signed out. As with prospective reviews, these can be performed by a pathologist within the case pathologist's group/institution (intradepartmental retrospective review) or outside of it (external retrospective review). These sorts of reviews include instances where in the course of completing a surgical pathology case, a pathologist may need to review previous pathology reports and slides either within the pathologist's group/institution (intradepartmental) or at an external institution. Unlike prospective reviews, it is more likely that there may be a need to resolve discrepancies, issue amended or addendum reports and communicate with the appropriate clinical staff as needed.
Review of Clinical Information	Pathologists routinely review patient clinical information in order to conduct a proper pathologic assessment. This clinical information may take many forms including patient demographics, laboratory results (biochemistry, hematology, microbiology), radiology reports and operative finding just to name a few. It also routinely includes the review of previously signed out laboratory reports (surgical, cytopathology, hematopathology, etc.). While the practice of reviewing relevant clinical information, including previous or concurrent laboratory reports, is an important foundational element for high quality practice in pathology and an integral part of the surgical pathology workflow process map it is difficult to capture as a quality assurance process. Whenever possible these activities should be included in workload metrics.
Accordingly, the guidelines in this section are organized using this framework: **Prospective Reviews:** - Intradepartmental Prospective review (formerly Intradepartmental Consultation) - External Prospective Review (formerly External Consultation) **Retrospective Reviews:** - Intradepartmental Retrospective Review (formerly Previous/Concurrent Laboratory Reports and Retrospective Reviews) - External Retrospective Review (formerly External Review)	

Quality Assurance Guideline - Intradepartmental Prospective Review

Trigger: Consider intra-departmental review.	
Principle/Purpose	Peer review is a commonly used method of ensuring diagnostic accuracy in pathology. This guideline refers to those intra-departmental reviews that occur before case sign-out. Intra-departmental prospective review (intradepartmental consultation or second review) occurs when a pathologist seeks an opinion from other pathologist/s within their own professional group. This may involve either a direct request from one pathologist to another to consult on all or selected slides/ material from a case. It may also involve review of all or selected slides/ material in the course of a case conference or similar. Intra-departmental review should be encouraged and facilitated. Consultation with intra-departmental colleagues should lead to improved decision-making, uniformity in use of diagnostic terminology, grading systems and criteria, and should increase the compliance with quality assurance processes. Teamwork, continuing education, and exchange of ideas and expertise should be enhanced.
Policy	As part of the Pathology Professional Quality Management Plan, there should be a policy that outlines the procedure for prospective case reviews with intra-departmental colleagues, including the documentation of those consults. This policy should refer to both individual pathologist intra-departmental consultation and case conference type scenarios, if both are employed by the group. The Pathology Professional Quality Management Plan may provide guidance as to the types of cases that are appropriate for prospective review if applicable. It is difficult to specify for all situations the types or proportions of cases that should be subject to intra-departmental prospective review. This will vary depending on factors such as practice type, experience level and expertise and clinical impact of a diagnosis (please see Practice Type Considerations below). Generally, the case pathologist should seek an intra-departmental prospective review: • If there is any doubt about a diagnosis or a clinically significant finding.

	• For critical diagnoses. • In cases where there is known diagnostic interobserver variability that has an impact on patient management. • For rare disorders that have clinical importance. A professional group should determine which sorts of cases require mandatory intra-departmental prospective review and which are discretionary.
Exceptions	• If there is no other pathologist with appropriate expertise on-site, or if the question at hand is not resolvable on-site, the case should be referred-out for external consult and/or testing. • Showing a slide to a colleague “out of interest” is not considered an intra-departmental consultation (for the purposes of “consultation” some form of permanent documentation is required of the consulting pathologist).
Practice Type Considerations	• The types of cases that are considered appropriate for intra-departmental consultation may vary depending on factors such as practice type, typical caseload of the professional group, knowledge and experience of the pathologist, and clinical impact of the diagnoses. The case types identified for review may be modified, for instance, when new diagnostic procedures or terminologies are introduced, or with the introduction of new pathologists. • Groups that report a wide variety of case types with a relatively low incidence of malignancy may choose to have a policy stating that all first-time diagnoses that may lead to a significant clinical intervention should be subject to consult prior to case sign-out (e.g., new diagnoses of malignancy). These groups may also choose to directly refer certain types of cases for external consultation. • Groups with a subspecialty-based practice and/ or a relatively high incidence of malignancies may choose to focus consultations on cases where the diagnosis is likely to result in significant clinical actions or is prone to diagnostic variability. Certain cases may require mandatory subspecialty review required by provincial or other guidelines.
Responsibilities of the Reviewing Pathologist(s)	• The intra-departmental consult pathologist/s should review all relevant patient material and clinical information related to the case, as needed. The reviewing pathologist may choose to perform the review ‘blinded’. • The opinion of the intra-departmental consult pathologist should be documented as per department policy, for the case pathologist to consider when finalizing the report. The manner of documentation (hard copy, internal electronic copy) will depend on the local preference and the Laboratory Information System capabilities.

	• The intra-departmental review pathologist's electronic signature may be required depending upon the group's reporting policy.
Responsibilities of Case Pathologist	• After the review, the case pathologist should determine the best diagnosis, based on all the data available at the time. The need for further review, including external consultation should be considered. • The case pathologist should document that a consultation took place, and the involvement of other pathologist/s in the final patient report. It is acknowledged that depending on local preference the name of the consulting pathologist/s may or may not be included in the patient report; in any case, if that name is used, it will only be so with the express consent of the reviewing pathologist (that consent may be deemed received if the local policy is to include such names).
Monitors	The Pathology Professional Quality Management Committee should collect and review data on intra-departmental reviews, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time. **Minimum Requirements:** • Number of intra-departmental prospective reviews by professional group (including individual pathologist and case conference types of consults), compared with number of all cases in same time period **Indicator Examples:** ○ % of cases with individual pathologist type consultation ○ % of cases with case conference type consultation **Optional:** • Number of intra-departmental prospective reviews by individual pathologist, compared with number of all that individual's cases in same time period • Number of intra-departmental consults by specific anatomic site or disease type, compared with number of all such cases in same time period **Indicator Examples:** ○ % of individual pathologist's cases with individual pathologist type consultation ○ % of cases of specific anatomic site or disease type that had an intra-departmental consultation **Frequency:** • Quarterly (or as appropriate for the group)

Quality Assurance Guideline - External Prospective Review

Trigger: Refer out appropriate cases for testing and consult that cannot be performed on site.	
Principle/Purpose	External prospective review (or external consultation) occurs when a pathologist seeks an opinion from another pathologist external to their professional group prior to a final signed out report has been issued or a final diagnosis has been issued. If a preliminary sign out of the case is required in order to send the case to an external institution for review, the signed out report should clearly state the case is being sent for an external consultation and a consultation report expected. External prospective reviews may be required due to lack of test menu or professional expertise on-site, or to resolve divergent opinions following an intra-departmental review.
Policy	As part of the Pathology Professional Quality Management Plan, there should be a policy that outlines the procedure for requesting external prospective review, including the review and documentation of the resulting consultation opinion. The Pathology Professional Quality Management Plan should provide guidance as to the types of cases that are appropriate for external prospective review if applicable. The external prospective review should by definition be sought prior to final report sign-out. A preliminary report noting that an external consultation is being sought may need to be provided. The selection of an external consultant and/or laboratory should be based primarily upon the quality of the service that will be provided. Prior to selection, and on an ongoing basis, the professional group should ensure that external consultants and laboratories are qualified to perform the requested services/ tests. The involvement of an external pathologist and/ or laboratory and the results of the external prospective review should be documented in the final report. The professional group should have tracking and audit processes, to ensure that external reviews are sent as described, and that the related consultation reports are received, documented, and retained. Monitoring for outstanding cases should occur on a regular basis.

	For quality assurance purposes, the external review should be forwarded to the case pathologist for review, whether or not the case pathologist is the one to finalize the report.
Exceptions	None.
Practice Type Considerations	• The types of cases requiring external prospective review may depend on the typical case types of the department, its test menu, and the availability of intra-departmental expertise.
Responsibilities of Case Pathologist	• It should be clearly communicated that an external consultation is being sought, with likely a resultant diagnostic delay. This can take the form of a preliminary signed out report released, verbal or written communication and documentation with the requesting clinician. • When a case is being sent-out to an external institution, the case pathologist should follow the responsibilities outlined in the Responsibilities of a Pathologist Requesting an External Consultation in Foundational Elements • Once the external consultation report is received, the case pathologist should document the involvement of the external laboratory/ pathologist, with their opinion, in the final case report.
Monitors	The Pathology Professional Quality Management Committee should collect and review data on external prospective reviews, for the professional group. As data is collected, it should be compared to established benchmarks and trended over time. **Minimum Requirements:** • Number of external prospective reviews by professional group, compared with number of all cases in same time period **Indicator Examples:** ○ % of cases sent for external prospective review/consultation **Optional:** • Number of external prospective reviews by individual pathologist, compared with number of all that individual's cases in same time period • Number of external prospective reviews by specific anatomic site or disease type, compared with number of all such cases in same time period **Indicator Examples:** ○ % of individual pathologist's cases with external prospective review

	○ % of cases of specific anatomic site or disease type that had external prospective review **Frequency:** • Quarterly (or as appropriate for the group)

Quality Assurance Guideline- Intradepartmental Retrospective Reviews

Trigger: Previously finalized cases and/ or their clinical outcomes may be reviewed retrospectively in a variety of circumstances.	
Principle/Purpose	Intra-departmental retrospective reviews occur after cases have been signed-out. These reviews occur within the case pathologist's group/institution. They can occur in a variety of circumstances, and serve a variety of purposes. It may take the form of a review of the original case material. For example Multidisciplinary Case Conferences (MCC), correlation with a current case, request for review by a clinician or patient, research, as well as other random or focused reviews. These can be individual cases or groups of cases (case sets) as part of planned reviews. Such planned reviews may focus on aspects of the analytic phase, including professional interpretation (e.g., processes employed and resulting diagnoses), or on pre- and post-analytic processes (e.g. part of activities related to test development or validation). Analysis of patient outcomes is another form of intra-departmental retrospective review. This type of review may include chart review, communications with clinicians about patient outcome, culture results, imaging follow-up or other clinical information. The review process may include examination of or for: • Completeness or adequacy of patient identifiers. • Completeness or adequacy of clinical history provided. • Use of other relevant clinical and diagnostic data. • Adequacy of specimen sampling. • Review of relevant previous surgical pathology and cytopathology material; this could include previous reports only or a review of all of the case material • Review of elements of the pathology report (gross and microscopic description; final diagnosis and comments; report format, clarity or typographical errors, etc.). • Other elements determined appropriate. A benefit of retrospective focused 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/or other materials as part of an intra-departmental retrospective

	review may generate educational feedback about the original cases. If case reviews demonstrate poor agreement within a defined case type, the pathologist group/institution should take steps to improve agreement.
Policy	As part of the Pathology Professional Quality Management Plan, various types of intra-departmental retrospective reviews and follow-up should be performed, and their documentation and reporting for quality management purposes should be described. The policies on managing the discovery of report discrepancies should be clearly outlined in the Quality Management Plan. See also Guidelines for Dealing with Report Discrepancies, Classification of Report Discrepancies, Addendum report and amended report The choice of case type or circumstances in which an intradepartmental retrospective review is conducted should be relevant to the pathologist group/institution practice setting. They should best suit the pathologist or group/institution type of practice and have the best chance of identifying discrepancies while having as minimal negative impact on resources as possible.
Exceptions	Discrepancies may occur because an intra-departmental retrospective review employs diagnostic material or techniques not available at the time of the original case sign-out (e.g. additional recut slides, additional immunohistochemistry, or other ancillary studies). In some cases it may be that the previously signed out reports and other materials originate from another institution or professional group. If report discrepancies are found in such material, they should not be included in quality assurance monitoring for the professional group dealing with the current case. They should be brought to the attention of the other institution or professional group, in order that the report discrepancies may be part of that other group's quality reporting program.
Practice Type Considerations	Groups/institutions with resource limitations of various kinds (e.g. numbers of pathologists, lack of subspecialty trained pathologists) may have to consider external assistance to perform some forms of retrospective review intended for quality assurance or other purposes. This may include collaboration with other institutions in order to obtain follow-up outcomes.
Responsibilities of the Reviewing Pathologist	• If an intra-departmental retrospective review reveals any discrepancies from the original report, the policies and processes for the professional group in the management of report discrepancies outlined in the Quality Management Plan should be employed. • This process should be employed for all types of cases and circumstances in which a retrospective review was performed. .

	• When retrospective reviews are part of formal and planned reviews for quality assurance purposes:
	  ○ Case selection criteria should be predetermined to maximize the random nature of the case selection.
	  ○ Case/ report elements that should be assessed, and the criteria against which they will be compared should be predetermined.
	  ○ Particularly, as part of the above, criteria for determination of concordance/ discordance should be predetermined.
	  ○ Where possible, the reviews should be performed blindly, with the identifiers for the original sign-out pathologist masked.
	  ○ Where possible, the reviews should not be performed by the pathologist originally responsible for case sign-out.
	• In the setting of retrospective reviews for test development or validation, or as part of research protocols or projects, and similar:
	  ○ There should be a predefined policy about whether patients will or will not be identified if significant new information is revealed.

Responsibilities of Case Pathologist	• When report discrepancies are revealed, the case pathologist should participate in their investigation and resolution, according to the policies and processes in the Quality Management Plan for managing report discrepancies. • To determine if an addendum or amendment of the original pathology report is required, the case pathologist should refer to the policies and processes of the professional group for addendum and amended reports.
Monitors	The Pathology Professional Quality Management Committee should collect and review data on report discrepancies revealed by retrospective reviews, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time. **Minimum Requirements**: • Number of cases where retrospective review revealed report discrepancies of various kinds, compared with number of all cases in same time period, for professional group overall **Indicator Example:** ○ % of cases with report discrepancies of various kinds, for professional group overall

	Optional: • Number of cases where retrospective review revealed report discrepancies, compared with number of all cases in same time period, by individual pathologist • Further analysis of the above by specific anatomic site or disease type, or for other attributes **Indicator Example:** ○ % of cases with report discrepancies of various kinds, by individual pathologist **Frequency:** • Quarterly (or as appropriate for the group)

Quality Assurance Guideline - External Retrospective Review

Trigger: Previously finalized cases are reviewed externally (outside the case pathologist's practice) in a variety of circumstances.	
Principle/Purpose	External retrospective reviews occur when there is a request by a pathologist, clinician, institution (e.g. cancer clinic), or patient to have a previously signed out case reviewed by a laboratory or pathologist/(s) external to the one in which the case was originally reported. External retrospective reviews may be required to clarify information for patient treatment or may be a pro forma requirement of an institution. They may also be requested by a clinician or patient as a second opinion. External retrospective review is distinguished from "external prospective review" in which external consultation occurs before a final case report or final diagnosis is issued and is at the request of the case pathologist. An external retrospective review occurs after a final diagnosis is rendered and a final case report issued.
Policy	As part of the Pathology Professional Quality Management Plan, there should be a policy that outlines the processes for handling requests for review of cases by an external pathologist or institution including the documentation and review of those results. When the results of an external retrospective review are received, the original report should be reviewed and compared with the external institution's report of the case. The request and performance of an external retrospective review should be documented for the case in question. Depending on the outcome of the review, the result may be documented through internal documentation, addendum or may require an amended report. The professional group should have tracking and audit processes in place to ensure that external reviews are sent, the external review reports are received, documented, and retained, and any material requested to be returned is accomplished. Monitoring for outstanding cases should occur on a regular basis. For quality assurance purposes, the external review should be forwarded to the case pathologist for review, whether or not the case pathologist finalizes the report.

	See also Guidelines for Dealing with Report Discrepancies, and Guidelines on Classification Discrepancies, QA Guideline – Addendum report and amended report
Exceptions	None.
Practice Type Considerations	This guideline applies to all types of practice.
Responsibilities of Case Pathologist	• When a request for an external review is received the case pathologist should review the original material and determine the appropriate slides and/ or blocks and/ or other material to be sent for external review. • When the external review is returned the case pathologist should review the consultant's opinion and document that review. • To determine if an addendum or amendment of the original pathology report is required, the case pathologist should refer to the policies and processes of the professional group for addendum and amended reports. • When report defects or discordances are revealed, the case pathologist should participate in their investigation and resolution, according to the policies and processes for the professional group according to the Quality Management Plan for managing report discrepancies.
Monitors	The Pathology Professional Quality Management Committee should collect and review data on report defect and discordances revealed by external reviews, for the professional group. As data is collected, it should be compared to established benchmarks and trended over time. **Minimum Requirements:** • Number of cases where external review revealed report defects or diagnostic discordances, compared with number of all cases in same time period, for professional group overall **Indicator Example:** ○ % of cases with report defects or diagnostic discordances, for professional group overall **Optional:** • Number of cases where external review revealed report defects or diagnostic discordances, compared with number of all cases in same time period, by individual pathologist • Further analysis of the above by specific anatomic site or disease type

	Indicator Example: ○ % of cases with report defects or diagnostic discordances, by individual pathologist **Frequency:** • Quarterly (or as appropriate for the group)

Quality Assurance Guideline - Intra-operative Consultation

Trigger: Review and correlate intra-operative consults (IOC) with current case.	
Principle/Purpose	Intra-operative consultations include rapid interpretations with gross and, in many cases, microscopic examinations. Other techniques (including cytopathology) may be employed, depending on specimen type. The correlation of intra-operative consultation materials with more permanent preparations and their associated final diagnoses is necessary to resolve discrepancies between the different techniques. Review of discrepancies aids in the measure of intra-operative consultation performance and improves recognition of morphologic alterations related to the various techniques employed. Rates of deferred diagnoses should also be reviewed as the rates vary depending upon expertise, types of specimens and resections encountered by a professional group.
Policy	As part of the Pathology Professional Quality Management Plan, there should be a policy that outlines the processes for, and the documentation of, the comparison of intra-operative consultation results with final diagnoses. The review should include an analysis of the turnaround times required for intra-operative consultations. The review should include an analysis of those diagnoses deferred, and the appropriateness of that deferral. Deferred diagnoses should not be considered discordant results. See also Guidelines for Dealing with Report Discrepancies, and Classification of Discrepancies.
Exceptions	• Certain specialized studies or cases, such as Moh frozen sections, may be exempt from the process.
Practice Type Considerations	• This guideline applies to all types of practice where IOC are performed.
Responsibilities of Intra-operative	• Refer to Intra-operative Consultation Patient Safety Checklist prior to providing a report to the clinician.

Consult Pathologist	
Responsibilities of Case Pathologist	• When practical (this may depend on the size of the professional group) it is preferable that the case pathologist be another pathologist (and not the same individual as the intra-operative consult pathologist) • The case pathologist should compare both the intra-operative consult report and materials with the permanent material. • This review and comparison should be documented in the final case report and should include comment on any inconsistencies or discrepancies. • When report defects or discrepancies are revealed, the intra-operative consult pathologist and/or case pathologist should participate in their investigation and resolution, according to the policies and processes the professional group usually employs.
Monitors	The Pathology Professional Management Committee should collect and review data on the appropriateness, accuracy of intra-operative consults and deferral rates, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time. **Minimum Requirements:** • Number of cases where review of the intra-operative consultation revealed report diagnostic discrepancies, compared with number of all IOC cases in same time period, for professional group overall • Number of cases where intra-operative consultation diagnosis is deferred (sub-classified as appropriate or inappropriate), compared with number of all IOC cases in same time period, for professional group overall • Times from specimen receipt to intra-operative consult report (may be defined by the group as verbal or written report to the clinician), for professional group overall **Indicator Examples:** ○ % of cases with report diagnostic discrepancies for professional group overall ○ % of cases with deferred diagnosis (sub-classified as appropriate or inappropriate), for professional group overall ○ Mean turnaround time, for professional group overall **Optional:** • Number of cases where review of the intra-operative consultation revealed report diagnostic discrepancies of

	various kinds, compared with number of all cases in same time period, by individual pathologist. • Number of cases where intra-operative consultation diagnosis deferred (sub-classified as appropriate or inappropriate), compared with number of all cases in same time period, for individual pathologist. • Time from when intra-operative material available to pathologists (specimen receipt) to intra-operative consult report, for professional group overall. • Times from when intra-operative material available to pathologists (specimen receipt) to intra-operative consult report, by individual pathologist. • Further analysis of the above by specific anatomic site or disease type, or for other attributes. **Indicator Examples:** ○ % of cases with report defects or diagnostic discrepancies of various kinds, by individual pathologist ○ % of cases with deferred diagnosis (sub-classified as appropriate or inappropriate), by individual pathologist ○ Mean turnaround time, by individual pathologist **Frequency:** • Monthly (or as appropriate for the group)

Quality Assurance Guideline - Addendum and Amended Report

Trigger: Addendum and Amended reports are issued**.**	
Principle/Purpose	After case sign-out, new information may become available that should be documented in the report for future reference, or some other revision or correction in the original report may be required. An **amended (corrected or revised)** report is issued to correct errors or discrepancies in the originally signed out report. Typically an amended report will result in change in final diagnosis or other significant change from the original report (change in patient's identification, specimen type/site or correction of transcription error). An amended report is replacing the previously signed out report in patient permanent medical records. An **addendum** (**supplementary or additional**) report is used when new information needs to be added after the pathology report has been released (e.g., addition of results of ancillary testing). By definition, the addition of new information does not change the diagnosis and does not replace the original report. When issued following a provisional report, the addendum report may actually represent the final report. In this case, the requirement for an addendum report may be anticipated at the time of provisional report sign-out. Although different terminology may be in use in various laboratory information systems, it is important that professional groups properly define and use these categories. Monitoring and review of amended reports can provide information for quality improvement opportunities.
Policy	As part of its Pathology Professional Quality Management Plan, the professional group should have a policy that outlines the criteria for addendum and amended reports. 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. If a diagnosis is amended this should be clearly indicated in the report, preferably with an explanation of the background for the amended report.

	An amended report should be issued as soon as possible. It should be explained clearly in the report that it is replacing a previously generated report. This should apply to all paper reports as well as to data that are displayed in laboratory information systems or other clinical information systems. When an amended report might impact patient care, it must be communicated to the responsible clinician (e.g. by verbal communication), and that communication must be documented in the report. Computer records should allow for the retention of the original and amended reports. In the event that computer system cannot capture amendments, an audit log may be used, and its existence referred to in the amended report. The original report shall not be erased, made illegible or deleted from the record. The original report will be kept in such a way as to ensure that it is not confused with the amended report. An important part of the policies governing issuing amended reports should include defined policies and procedures for notification of the Laboratory Director (or depending on a group's policies, the Chair of the PPQMC), and through the Laboratory Director (or Chair, PPQMC) initiation of critical incident and similar reporting where appropriate. Remedial, corrective, and/or preventative action should be implemented, if required. Based on the host organization's incident reporting process, amended reports may also have to be documented for risk management, root cause analysis and quality improvement purposes via that organization's processes. See also Guidelines for Case Reviews, Guidelines for Dealing with Report Discrepancies and Classification of Report Discrepancies.
Exceptions	None.
Practice Type Considerations	This guideline applies to all types of practice.
Responsibilities of Case Pathologist	The pathologist follows the professional group's policy for issuing addendum and amended reports, completing all related documentation, and following all related quality assurance processes.
Monitors	The Pathology Professional Quality Management Committee should collect and review data on amended reports for the professional group and for individual pathologists. As data is collected, it should be compared to established benchmarks for the professional group and trended over time.

	Minimum Requirements: • Number of amended reports, compared with number of all cases in same time period, for professional group overall. Amended reports should be classified according to patient impact (near miss, minor, major or cannot determine). **Indicator Example:** ○ % of amended reports of various kinds, (change in diagnosis or other changes to original report such as patient information, specimen type or transcription errors), classified by patient impact for professional group overall. **Optional:** • Number of amended reports, compared with number of all cases in same time period, by individual pathologist. • Number of addendum reports for the professional group overall. • Further analysis of the above by specific anatomic site or disease type, or for other attributes. For example, a facility may consider performing an audit of types of addendum reports over a defined time period to ensure appropriate classification of addendum vs amended. **Indicator Example:** ○ % of amended reports of various kinds, by individual pathologist **Frequency:** • Monthly (or as appropriate for the group)

Quality Assurance Guideline - Significant Unexpected Findings/Urgent Diagnoses

Trigger: Some diagnoses or results may seriously affect patient outcome, and require immediate communication to the clinician.	
Principle/Purpose	Significant unexpected diagnosis is a pathologic diagnosis that is clinically unusual or unforeseen and needs to be addressed in a timely manner although not urgently. This may include: unexpected malignancy (e.g. a finding of malignancy in an orthopedic specimen when the clinical notes do not mention the possibility of malignancy). Cases in which malignancy is reasonably within the differential diagnosis do not qualify as a significant unexpected diagnosis. Urgent diagnosis is a pathologic diagnosis that in most cases should be addressed as soon as possible. This may include: malignancy involving a critical site (spinal cord, SVC); transplant rejection; identification of possible pathogenic organisms from an immunosuppressed patient or critical site (e.g. CSF, orbit). Terminology for these cases may be variable across facilities. Other terminologies include critical values, alert values, significant pathologic findings, or critical pathologic findings. Regardless of terminology, there should be a common understanding that these are cases which require expedited notification of the most responsible physician or delegate since urgent patient management may be needed to prevent morbidity or mortality. Alternatively, such diagnoses/ results may be clinically unusual or unforeseen (significant, unexpected) and need to be emphasized to the clinician so that they may be addressed during the patient's current course of care. Significant unexpected finding/urgent diagnosis result reporting can impact clinical decision making, patient safety and operational efficiency. A clearly defined process for significant unexpected finding and urgent diagnosis result notification will improve the quality of patient care and enhance patient safety.
Policy	As part of the Pathology Professional Quality Management Plan, there should be a policy that outlines the types of diagnoses/ findings which are considered significant unexpected and urgent in the practice/s of physicians served by a surgical pathology group.

	There should be a defined procedure for timely communication of these diagnoses/ findings to the physician most responsible for the care of the patient involved. Not all situations appropriate for consideration as a significant unexpected finding and urgent diagnoses/ results can be anticipated in this guideline. The criteria for defining these cases should be done with input from the organization's clinical staff and clients. On a case by case basis, the discretion of the pathologist is necessary. Significant unexpected findings and urgent diagnoses should be communicated directly by a method appropriate for the situation (verbal, fax, encrypted or secure electronic communication) to the appropriate individual. It should be ensured that the message was received correctly. Faxing the report as the only means of communication should be discouraged, unless it is ensured that the fax report was received appropriately. The communication of these results should be documented. The documentation should include the date and time of the communication, method of communication and to whom the communication was made. The documentation should be included in the pathology report or in laboratory files. The communication and documentation processes for significant unexpected findings and urgent diagnoses/ results should be standardized within the department. The method of direct communication may vary among organizations but, if methods other than verbal communication are used, mechanisms should be in place to ensure that the communication is compliant with privacy regulations and is received by an appropriate individual.
Exceptions	None.
Practice Type Considerations	• Pathologists in all organizations should reach consensus with their clinical colleagues about what types of diagnoses are deemed significant unexpected and urgent and policy development should be based on the organization's clinical service needs and best practice. **The following are additional examples of urgent diagnoses:** 1) Retrospective review where the diagnosis is significantly changed and may result in a change to patient management. 2) A corrected/amended report where the diagnosis is significantly changed, and may result in a change to patient management.

	3) A report where the intraoperative consultation and final diagnosis are significantly discordant and may result in a change to patient management. 4) Presence of normal tissue not native to site sampled, suggesting organ perforation. 5) Presence of large blood vessel in needle core biopsy. 6) Significant organisms. **The following are additional examples of significant unexpected findings:** 1) Presence of molar pregnancy in routine products of conception. 2) Presence of malignancy in routine cholecystectomy specimen.
Responsibilities of Case Pathologist	The discretion of the pathologist is necessary to determine additional diagnoses/findings that should be communicated to the physician either urgently or in an expedited manner if significant and unexpected.
Monitors	The Pathology Professional Quality Management Committee should collect and review data on reporting of significant unexpected findings and urgent diagnoses for the professional group. As data is collected it should be trended over time. It is recognized that it is not possible to do extensive auditing to determine whether all cases which meet the definitions of significant unexpected or urgent are reported as such, however at minimum there could data around the number of cases reported in these categories. **Minimum Requirements:** • Number of cases where significant unexpected findings and urgent diagnoses were reported, compared with number of all cases in same time period, for professional group overall **Indicator Examples:** ○ % of cases where significant unexpected findings were reported, for professional group overall ○ % of cases where urgent diagnoses were reported for professional group overall **Optional:** • Further analysis of the above by specific anatomic site or disease type, or for other attributes **Frequency:** • Quarterly (or as appropriate for the group)

Quality Assurance Guideline - Utilization and Compliance

Trigger: Technical and other supportive services are utilized responsibly.	
Principle/Purpose	Biomarkers and ancillary tests may be performed on patient material to guide treatment options and potentially identify a heritable genetic condition. Underuse of ancillary tests and procedures may provide insufficient information for appropriate patient care. Overuse may result in inappropriate costs and resource depletion.
Policy	As part of the Pathology Professional Quality Management Plan, there should be a policy that describes when and how ancillary tests and procedures should be employed for various types of cases, and processes for monitoring same. As part of the Pathology Professional Quality Management Plan, there should be a policy that describes report formatting, and the various elements expected in pathology reports for varied types of cases; the plan should include processes for monitoring same. The Pathology Professional Quality Management Committee should develop, where appropriate, diagnostic algorithms or so-called tissue pathways, based on available “best evidence” that help guide policies for the above. Pathologists should stay up to date on methodology and reporting of established biomarkers and other ancillary tests that have implications for treatment, prognosis or identification of a heritable genetic condition. In some tumour sites/diagnoses, testing should be initiated by the original pathologist. In other circumstances, testing may be initiated by the treating oncologist or other member of the healthcare team. If testing is not available at one’s institution, pathologists should be aware of regional testing centres and refer the case in the appropriate circumstances. In Ontario, pathologists should have access to a list of tests funded through Ontario Health-Cancer Care Ontario and incorporate this testing into their workflow. Surgical pathology laboratory protocols should be designed to include considerations pertaining to pre-analytical requirements of biomarker tests that will be subsequently ordered.

	If pathologists are responsible for ordering a reflex test, a quality assurance protocol should be in place in order to monitor compliance in order to mitigate delays. When ordering tests for diagnostic work up, consideration should be given to appropriate utilization of the tissue for future potential use for predictive and prognostic biomarkers. If sending a case for biomarker testing at an external laboratory, the results of the test should be integrated with the original diagnostic report. Biomarker test results should be reported in a synoptic report template by the reporting institution if one is available through OH-CCO. If a synoptic template is not available, the results should be reported in a standardized fashion with all data elements required for clinical care, so that the reports are readily understood, clinically relevant, and suitable for quality monitoring. If biomarker testing is being performed externally, the referring institution should issue a supplementary report to indicate the availability of these results.
Exceptions	Cases that do not follow standard work processes may be excluded from analysis by the professional group. For example, biomarkers not performed on site may be reported in synoptic report format by an external laboratory in which case monitoring compliance would be the responsibility of the external laboratory.
Practice Type Considerations	• Laboratories should perform immunohistochemical and molecular tests for which they have been appropriately licensed and have the appropriate volume of cases. They should participate in external quality assurance programs. • The required ancillary tests and procedures may not be available to all professional groups. External consultation may be needed to accomplish the required case workup. • The laboratory and professional group providing the ancillary testing in external consult must be appropriately credentialed for this work. • The professional group may choose to monitor specific types of cases and diagnostic algorithms/ ‘tissue pathways’ depending on clinical needs, perceived issues, or changes in practice.
Responsibilities of Case Pathologist	The case pathologist should ensure that appropriate diagnostic algorithms/ tissue pathways are followed and that appropriate ancillary tests/ procedures are employed, or requested in external consultation. The case pathologist should ensure that the formatting of their surgical pathology reports is at the standard defined by their

	professional group, and that the various elements expected in them are included.

Monitors	The Pathology Professional Quality Management Committee should collect and review data on compliance with diagnostic algorithms/ tissue pathways, ancillary test/ procedure utilization, and on report formatting and completeness, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time.
	
	Minimum Requirements:
	• Number of cases where selected ancillary tests/ procedures defined by various protocols were used, compared with number of all cases in same time period, for professional group overall.
	  ○ Example: % of cases where selected ancillary tests/ procedures defined by various protocols were used, for professional group overall.
	• Number of cases where selected report type had appropriate format and was complete, compared with number of all cases in same time period, for professional group overall.
	  ○ Example: % of cases where selected report type had appropriate format and was complete, for professional group overall.
	• Turnaround time for biomarkers being performed within the institution should be monitored.
	• If biomarker testing is being performed externally, the referring institution should have a process to monitor receipt of outstanding results.
	
	Optional:
	• Number of cases where selected ancillary tests/ procedures defined by various protocols were used, by individual pathologist
	• Number of cases where selected report type had appropriate format and was complete, compared with number of all cases in same time period, by individual pathologist
	  ○ Further analysis of the above, determined by needs of the professional group
	
	Indicator Examples:
	  ○ % of cases where selected ancillary tests/ procedures defined by various protocols were used, by individual pathologist
	  ○ % of cases where selected report type had appropriate format and was complete, by individual pathologist
	
	Frequency:
	• Quarterly (or as appropriate for the group)

Quality Assurance Guideline - Turn Around Times

Trigger: Turn around times are monitored.	
Principle/Purpose	Turn around time (TAT) is a key indicator of the total testing cycle (see page 25) and begins when a decision is made to obtain a tissue sample. It is reflective of system efficiency in providing a pathology result for further patient management. TATs may vary due to a number of factors such as: case volume and type, concurrent urgent and routine requests, number of laboratory staff and pathologists, subspecialty expertise, availability of intra-departmental tests and expertise, the available information technology, geographical location, the need for trainees as well as the type of laboratory (community, academic etc.). Measuring TATs can help to identify gaps in the system for example adequate staffing or technology which can assist laboratory administration to develop business cases and to advocate for additional resources as needed.
Policy	As part of the Pathology Professional Quality Management Plan, there should be a policy that outlines the processes for monitoring turn around times on a regular basis. Since pathology samples are procured in one location and transported to a central laboratory for processing, it is recommended that overall TAT should be measured from the time a sample is taken to the time a report is available. Additional time points should also be measured to allow for quality improvement if needed. For example the time from when a sample is taken to when it is received in the laboratory may identify opportunities for quality improvement in delivery of samples to the laboratory. The time a specimen is received in the laboratory to the time a report is issued is reflective of surgical pathology work processes. This turn around time may be analyzed further, according to constituent work processes, e.g., those portions which are the responsibility of technical and other support staff and those that are the direct responsibility of the surgical pathologists involved. Used in this manner, it is reflective of the efficiency of the surgical pathology service. It should be specified whether turn around times are measured in calendar or working hours or days.

Exceptions	Cases such as those sent for external consultation and cases that, as part of a group's standard protocols, may not follow standard work processes may be excluded from analysis by the professional group.
Practice Type Considerations	• Depending upon the complexity of an individual case, additional time may be allowed for adequate acquisition of clinical information, reviewing previous reports and materials, ensuring adequate fixation, employing special techniques or testing, or obtaining internal or external consultation. • The professional group may choose to monitor specific types of cases depending on clinical needs and perceived issues/ changes in their practice.
Responsibilities of Case Pathologist	Delays that may impact patient care should be communicated to the clinician, and that communication documented in the report.
Monitors	The Pathology Professional Quality Management Committee should collect and review data on turn around times, for the professional group and for each pathologist. As data is collected, it should be compared to established provincial, national or other benchmarks as appropriate for each facility and trended over time to identify quality improvement opportunities. **Minimum Requirements:** • Time from specimen collection to case sign out for professional group • Times from specimen receipt in the lab to case sign-out for professional group overall • Cumulative number of cases signed out by professional group, by day after specimen receipt • Other TAT reports required by other agencies e.g. TAT for synoptically reported cancer resections. **Indicator Examples:** ○ Mean turn around time from specimen collection to case sign out for professional group ○ Mean turn around time from specimen receipt to case sign out for professional group overall ○ Cumulative percent of cases signed out by professional group, by day after specimen receipt **Optional:** • Separate reporting for distinct specimen or report types**;** for example biopsy and resection specimens • Times from specimen receipt to case sign-out, by individual pathologist • Cumulative number of cases signed out by individual pathologist, by day after specimen receipt • Times from when cases available to pathologists to case sign-out, for professional group overall

	• Times from when cases available to pathologist to case sign-out, by individual pathologist **Indicator Examples:** ○ Mean turn around times from specimen receipt to case sign out by individual pathologist ○ Cumulative percent of cases signed out by individual pathologist, by day after specimen receipt ○ Further analysis of the above by specific anatomic site or disease type, or by other attributes **Frequency:** • Quarterly (or as appropriate for the group)

Quality Assurance Guideline
Digital Pathology

Trigger:
To provide guidance and minimum requirements in implementation of a digital pathology system for diagnostic purposes for surgical pathology in your laboratory.

Principle/Purpose

With increasing literature supporting non-inferiority of whole slide imaging methods to conventional glass microscopy, in addition to the expanding list of vendors in North America with regulatory approval to market digital pathology systems for primary diagnosis, this document aims to discuss the key steps involved in the implementation process.

Relevant definitions:
Digital Pathology is the all-encompassing term that comprises the usage of digital imaging and telecommunications technology for the acquiring, sharing, transmission and/or storage of pathology images and/or other related data for diagnosis (intra-operative consultation/frozen section, consultation, quality assurance and primary diagnosis), education, and research. **Telepathology** refers to the use of digital technology to review glass slides that are in a different physical location.

The College of American Pathologists (CAP) defines **telepathology for clinical purposes** as "the practice of pathology, in which the pathologist views digitized or analog video or still image (s), and renders an interpretation that is included in a formal diagnostic report or documented in the patient record."

Whole slide imaging (WSI) uses an automated device composed of a scanner (hardware comprised of a robotic microscope and digital camera) with in-built software that allows the device to use compound algorithms to 'stitch' serial digital images together to produce a 'virtual' replica of the glass slide. These virtual images can be archived, retrieved, and shared through appropriate network access. The important components include:

S#	Important components	Some parameters to consider
1.	Scanner	Scan time, magnification, resolution, plan, depth of field or "z stacking", stitch error/striping, tissue coverage
2.	Viewer/Monitor	Display resolution, brightness and contrast, display environment

	<table><tr><td>3.</td><td>Image management software</td><td>Robust and protected link between on-site and remote sites, link with local LIS (laboratory information system), archiving and retrieval options</td></tr><tr><td>4.</td><td>Image analysis/ diagnostics</td><td>Not in the scope of this guideline</td></tr><tr><td>5.</td><td>Network connectivity</td><td>Network speed, privacy and data protection</td></tr></table> **Validation** - A process to demonstrate a new method performs as expected for its intended use and environment prior to using it for patient care. Even if a given digital pathology system has received regulatory approval, individual institutions using these systems must perform their own validation studies specific to their intended use of the technology. **Verification** – Confirming performance requirements, as specified by a manufacturer, have been satisfied.
Policy	**<u>Steps in implementation:</u>** ***I. Pre-implementation phase:*** 1. Evaluate needs and objectives - requires identification of a specific clinical need(s) for digital pathology 2. Involve all relevant stakeholders (laboratory management, IT/LIS, technical specialists, pathologists etc.) 3. infrastructure and budget considerations 4. Risk assessment for privacy and security 5. Proposal formulation - requires a detailed understanding of current analogue workflow and how it will change when digital pathology is introduced for a specific application ***II. Implementation phase:*** **<u>1. Validation and verification:</u>** There are several guidelines to assist laboratories with validation of digital pathology systems for clinical use, the most recent of which was released in May 2021 from the College of American Pathologists (CAP). This includes 3 evidence-based strong recommendations and 9 good practice statements (GPS). The basic elements are summarized below (see references for full details). 1.1. **Strong Recommendation 1** - The validation process should include a sample set of at least 60 cases for one application that reasonably reflects the expected spectrum and complexity of specimen types and diagnoses to be encountered during routine practice.

	Comment: The validation process should include at least 20 cases for each additional application (e.g., immunohistochemistry, special stains). 1.2. **Strong Recommendation 2** - The validation study should establish diagnostic concordance between digital and glass slides for the same observer (i.e., intraobserver variability). The mean concordance rate based on currently available literature is 95%, which is not inferior to concordance data when glass slides are reviewed on different occasions with a washout period. This non-inferiority data formed the basis of US FDA approval of the first WSI system for primary diagnosis in 2017. Concordance < 95% does not constitute a failed validation, it is merely an average benchmark based on current evidence. 1.3. **Strong Recommendation 3** - A washout period of at least two weeks should occur between viewing digital and glass slides. General practice statements (GPS) are statements having a high level of certainty that the recommendation will do more good than harm (or the reverse), but where there is little direct evidence. 1.4. **GPS1** - All pathology laboratories implementing WSI for clinical diagnostic purposes should carry out their own validation studies. Health Canada, US FDA or CE Mark approval does not remove the need for individual validation. 1.5. **GPS2** - Validation should be applicable to the intended clinical use and clinical setting in which WSI will be employed. If a new application for WSI is contemplated, and it differs materially from the previously validated use, a separate validation should be performed. 1.6. **GPS3** - The validation study should closely emulate the real-world clinical environment in which the technology will be used. **Comment:** "Perfect" cases should not be used for validation. Rather, a realistic day-to-day workload of straightforward to challenging cases should be used. 1.7. **GPS4 -** The validation study should encompass the entire WSI system. It is not necessary to separately validate each individual component (e.g., computer hardware, monitor, network, scanner). 1.8. **GPS5** - Laboratories should have procedures in place to address changes to the WSI system that could impact clinical results.

	1.9. **GPS6** - Pathologists adequately trained to use the WSI system must be involved in the validation process. 1.10. **GPS7** - The validation process should confirm all of the material present on a glass slide to be scanned is included in the digital image. 1.11. **GPS8** - Documentation should be maintained recording the method, measurements, and final approval of validation for the WSI system for an intended clinical application. 1.12. **GPS9** - Pathologists should review cases/slides in a validation set in random order. This applies to both the review modality (i.e., glass slides or digital) and the order in which slides/cases are reviewed within each modality. 2. **Technical support:** This includes: 2.1. IT/LIS integration and communication 2.2. Equipment maintenance 3. **Establish Quality Management system:** These include standard Quality Management essentials with specific attention to: 3.1. System to document important performance indicators (see monitors) 3.2. Establishing Quality assurance program: External and/or Internal or alternative 4. **Orientation and training of all staff members** 5. **Storage and archival needs:** Retention policies for images and reports need to be established by each individual laboratory based on their unique considerations. A well-discussed policy explaining the final decision should be provided. 6. **Liability and licensure consideration:** Discussion with CMPA and ensuring all applicable licensing requirements in the jurisdiction involved in the telepathology encounter are fulfilled. The CPSO and CMPA have no concerns specific to the use of digital pathology for clinical purposes. Generic documents describing the principles for telemedicine/telehealth activities are available from each organization. Regulatory agencies such as Health Canada, the US FDA and CE Mark regulate vendors, their manufacturing processes and the marketing claims they make about their products. They do not regulate pathologists or the practice of pathology. Regulatory approval of digital pathology systems is not required to use them in clinical practice, however it

	is incumbent upon those using these systems to insure they have been validated and verified for specific applications prior to use for patient care. 7. **<u>Documentation:</u>** Examples include: 7.1. Documentation of training and orientation 7.2. Individual pathologist intra-observer variability 7.3. Standard Operating Procedures (SOPs) 8. **<u>Execution</u>** ***III. Post-implementation Phase:*** 1. Assess efficiency through audits/quality assurance (external and/or internal) 2. Collect data regarding performance indicators 3. User feedback and troubleshooting 4. Expand to new applications
Exceptions	Cytopathology and wet hematopathology (peripheral blood films, bone marrow aspirates), image analysis/diagnostics with assistance from artificial intelligence/machine learning
Practice Type Considerations	• This is a rapidly evolving aspect of pathology and this document will require regular updating to account for changes in technology and new evidence to guide its use in clinical practice. • Revalidation is required whenever a significant change is made to any component of the WSI system. **Comment:** Deciding what constitutes "significant" change requires robust communication between relevant stakeholders.
Responsibilities of Case Pathologist	While the Laboratory Director is responsible for the proper implementation and maintenance of the digital pathology system, the individual reporting pathologist is responsible for cases signed out by them using this technology. Therefore, the facilities and individual reporting pathologists should follow quality assurance guidelines or requirements akin to those they undertake for reporting of conventional glass slides.
Monitors	• Review of minimum of 10% of all consultations and diagnosis made by telepathology • Turn around time for sign-out and intra-operative consultations • Concordance rate between frozen and permanent section • Percentage of cases deferred to glass slide review with reason for deferral

	• Percentage of slides requiring re-scanning

Quality Assurance Guideline
Patient Education and Communication

Trigger: Most hospitals and private laboratories now provide patients access to their pathology report.	
Principle/Purpose	The pathology report is a critical part of the patient's medical record. Historically, patients learned what was in their report from their doctor. Today, many patients use online patient portals to access and read their pathology report directly. However, the highly technical language and complex structure of the report prevents many patients from making meaningful use of this information. Patient centred care encourages active collaboration and shared decision making between patients and their medical team. In order to be an active participant in their care, patients must not only have timely access to their medical records, but they must also be able to understand them. Strategies that help patients read and understand their pathology report are associated with increased patient engagement and improved overall satisfaction. Importantly, an engaged and informed patient is more likely to catch an error before it has a chance to cause harm. **Recommendations for creating a patient centred pathology report** The modern pathology report should aim to communicate clearly with both doctors and patients. The language should be clear and adhere to accepted classifications and definitions. The organization of the report should make it easy to find the most important information quickly. 1. If possible, the diagnosis section should be placed at the beginning of the report so that it is easy to find. 2. The diagnosis section should provide a summary and overall impression of the case. The name of the diagnosis should be placed near the top of this section. Additional information deemed critical by the case pathologist can be included under the main diagnostic line. 3. Highly technical language including microscopic descriptions should be limited to subsequent sections of the report. 4. When necessary, multiple specimens can be itemized and described in the microscopic description section of the report.

	5. All sections of the report should be proofread for grammatical, typographic, and spelling errors. The report should also be reviewed for clarity and internal consistency. This is particularly important when an abnormality identified on gross examination is not subsequently substantiated on microscopic examination. 6. The pathologist should consider providing an explanation in the Comments section for diagnostically challenging cases and cases with significant interobserver variability, when the diagnosis is preliminary, and when additional tests are pending. 7. When applicable, the pathologist can choose to provide links to patient-centred pathology resources including pathology terminology within the pathology report. 8. Quality assurance activities performed should be clearly documented in the report.
Exceptions	While these recommendations apply to all pathologists, it is acknowledged that not all hospitals currently make pathology reports available to patients. Moreover, pathologists and administrators should collaborate with patients and/or patient advisory groups to determine the best method for communicating pathology results to patients.
Workload Measurement	Pathologists have not traditionally interfaced directly with patients. However, patients who access their pathology report may wish to speak to their pathologist about the results. Pathology workload measurement systems should incorporate metrics to capture pathologist-patient interactions
Responsibilities of Case Pathologist	Pathologists should view their report not as 'test result' but as an opportunity to communicate important medical information directly with the patient. As physicians, all pathologists have a responsibility to make sure that their report can be understood by both patients and other members of the health care team.
Monitors	The Professional Quality Management Committee should assess pathology reports for clarity while performing existing quality activities such as the review of amended reports and addendums. Specific feedback should be provided to the case pathologist when required and improvement should be monitored. Local patient advisory committees can also be approached to review selected reports and provide feedback including suggestions for improvement. Feedback on report clarity can be included into local service satisfaction surveys (see section on Service Satisfaction).

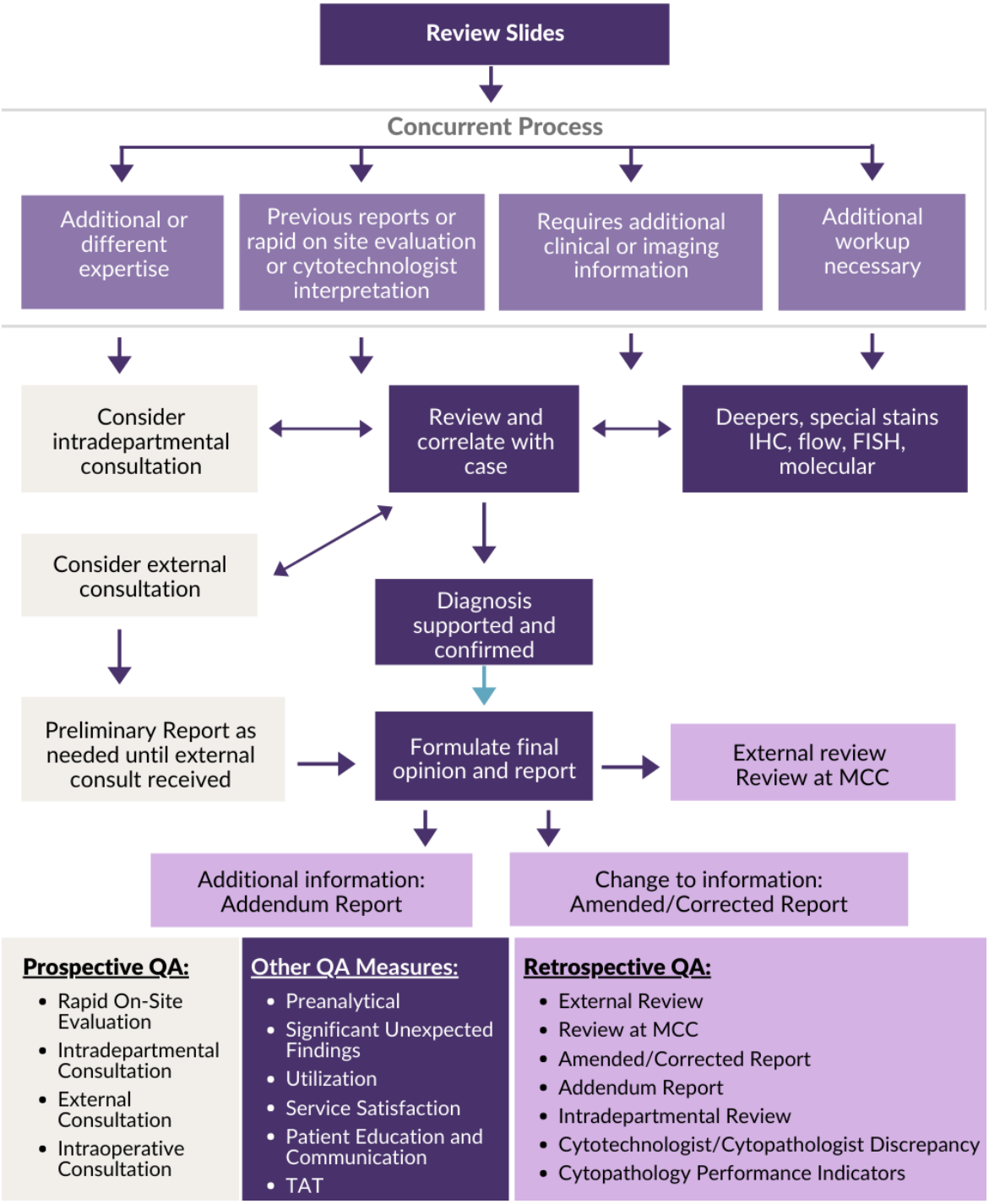
Quality Assurance Guideline - Service Satisfaction

Trigger: Consider intra-departmental review.	
Principle/Purpose	Communication with, and feedback from, those who use pathology services should provide a continuing framework for understanding user needs, implementing appropriate improvement initiatives, and determining overall service satisfaction. Monitoring is particularly helpful before, during and after implementing changes or new services related to pathology.
Policy	As part of the Pathology Professional Quality Management Plan, there should be a policy that outlines the processes that will be employed to monitor and improve service satisfaction. The PPQMC should identify the current and future needs and expectations of stakeholders, including objective measures of service satisfaction. Service satisfaction may be monitored through surveys, the monitoring of complaints and compliments, and other sources of feedback. Various aspects of pathology services may be rated and monitored, including: • Professional interaction for consultation. • Clerical and technical staff interaction/ attitude. • Perception of diagnostic accuracy and report usefulness. • Pathologist's responsiveness to questions and concerns. • Pathologist's accessibility for intra-operative and other forms of consults. • Tumor board and case conference presentations. • Teaching conferences and courses. • Notification of critical diagnoses/ results. • Timeliness of reports. • Patient interactions Open-ended questions should be included in surveys, to gain more information regarding services. Satisfaction surveys may be expanded beyond the organization and used on a regional basis, if appropriate.
Exceptions	None.

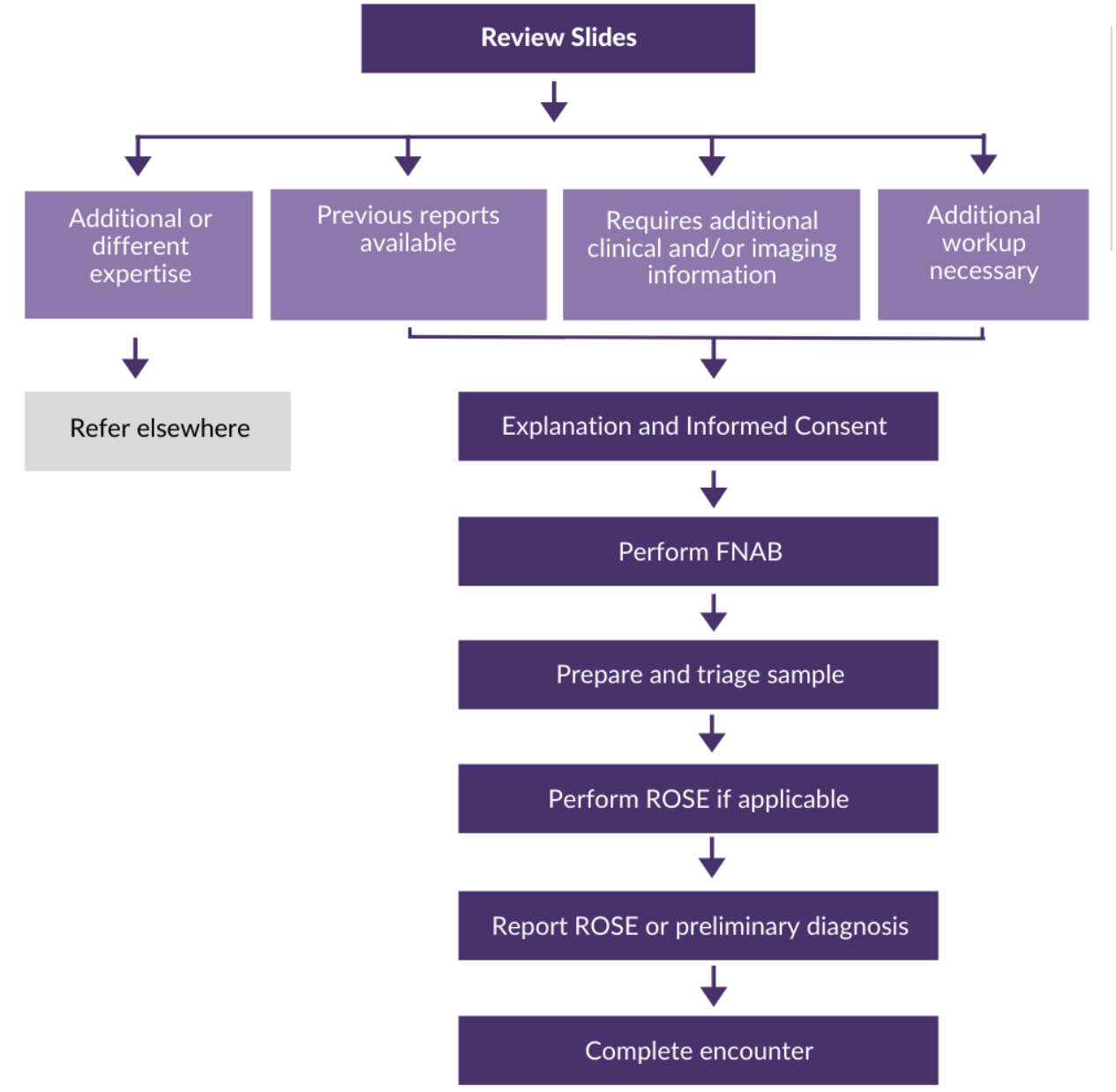
Practice Type Considerations	An effective way of obtaining user/ stakeholder feedback when pathology resources are limited may be to develop focused surveys. Surveys may be targeted to a subset of user/ stakeholder groups, based on specific requirements, expectations and/ or associated risks.
Responsibilities of Case Pathologist	Every pathologist should take the opportunity to understand users/ stakeholders concerns about service. They should communicate to the laboratory medical director any concerns raised to them by clinical staff as well as positive comments or compliments. They should participate, through departmental meetings or other venues as appropriate to each facility, in the monitoring and process improvement activities which may result from feedback.
Monitors	The Pathology Professional Quality Management Committee should collect and review data on service satisfaction, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time. **Minimum Requirements:** • A process to document and discuss positive comments and complaints to the professional group, and of suggestions for improvement • An annual survey to adequately understand user needs, improvement opportunities, and determine overall service satisfaction. **Optional:** • Focused surveys of the satisfaction of specific user groups or of satisfaction with the reports for specific anatomic sites or disease types **Frequency:** • Annual (or as appropriate for the group)

SECTION 6
WORKFLOW PROCESS MAPS FOR CYTOPATHOLOGY

A - CYTOPATHOLOGY - GENERAL



B - FINE NEEDLE ASPIRATION BIOPSY (FNAB) ACQUISITION AND/OR RAPID ON-SITE EVALUATION BY CYTOPATHOLOGISTS



Prospective QA:

- Intradepartmental Consultation (on ROSE)

Other QA Measures:

- Service Satisfaction

Retrospective QA:

- Rapid On-Site Evaluation (ROSE)
- Unsatisfactory Rates for FNAB

SECTION 7
PATIENT SAFETY CHECKLISTS FOR CYTOPATHOLOGY

A – CYTOPATHOLOGY – GENERAL

1.0	PRE-INTERPRETATIVE PATIENT SAFETY CHECKLIST
	Patient Demographics
1.1	The patient demographics are consistent with the submitted specimen.
	Patient Clinical History
1.2	Pertinent previous clinical history, diagnostic imaging, procedural record, and laboratory reports are available for review.
1.3	The referring physician or appropriate other personnel is contacted for additional information, if required.
	Case Material Correctness
1.4	Slides and other preparations created are uniquely and permanently identified with adequate and legible information.
1.5	The patient record (including any transcribed portions), the specimen requisition and slides, and any other case materials match.
1.6	The specimen type and site match the requisition and other records.
	Slide and Other Preparation QC/QA
1.7	The final number of slides matches the electronic report and if applicable, adequacy assessment information.
1.8	Slides and stains, and other preparations, are of sufficient quality.
1.9	The collection and submission of the cytopathology specimen is optimal and follows laboratory collection and submission guidelines.
1.10	The processing of the cytopathology specimen is optimal and follows laboratory processing guidelines.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

2.0	POST-INTERPRETATIVE PATIENT SAFETY CHECKLIST
	Provisional (Preliminary) Report – if required
2.1	The report describes what work or other information is pending/ incomplete, and why the report is not a final/ completed one.
2.2	The report clearly indicates that the findings are preliminary and may be modified at the time of issuing the final/ completed report.
	Cytology (Final) Report
2.3	The specimen site and diagnosis are included in the report.
2.4	The microscopic findings (if recorded), and any other information included support the pathologic diagnosis.
2.5	Any inadequacies or limitations of the specimen or its examination are documented.
2.6	Reason(s) for an unsatisfactory diagnosis is/are included in the report.
2.7	The results of ancillary studies are correlated with the morphologic diagnosis, documented and incorporated into the final diagnosis.
2.8	For reports that include tests that provide independent predictive information, details of specimen processing, the test and the scoring methods used are included in the report.
2.9	The record of any preliminary diagnosis is documented in the final report. The rendering of a preliminary diagnosis is optional and may be dependent on the group's practice.
2.10	The record of any adequacy assessment is documented in the final report (for internal or external viewing only).
2.11	Consider a comment or disclaimer if immunohistochemical studies have been done on cell block with antibodies have not been validated for alcohol fixed material.
2.12	Any diagnostic discordance between the preliminary and final diagnoses is explained in the final report.
2.13	Recommendations for further studies are included.
2.14	Significant, unexpected and critical findings are communicated promptly to the clinician and that communication is documented.
2.15	All necessary sections of the report are completed (including required synoptic report fields).
2.16	No transcription or formatting errors are present.
2.17	All quality assurance processes employed during the course of specimen examination and reporting are documented and retrievable in the laboratory information system (or other quality assurance records used by the group).
2.18	The pathologist responsible for report (including any preliminary report/s) is clearly indicated in the report, along with contact information for the institution/professional group.

	Addendum (Supplementary) or Amended (Corrected) Reports – if required
2.18	The reason for the addendum or amendment is clearly indicated in the report, along with any background information and findings that may have served as its basis.
2.19	The information in the original report and the original diagnosis are reviewed and changed if required. If a change is made, that change is clearly identified.
2.20	The clinician is notified, if necessary and that notification is documented.
2.21	The original report is retained and can be retrieved – ensuring that it cannot be mistaken as the active/ final report.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

B – FINE NEEDLE ASPIRATION BIOPSY (FNAB) ACQUISITION BY CYTOPATHOLOGISTS

1.0	PALPABLE LESION FNAB PATIENT SAFETY CHECKLIST
1.1	The FNAB is deemed appropriate (lesion is accessible and palpable) and safe to perform, based on clinical and/ or imaging findings. No contraindications to FNAB are identified with respect to the patient or the lesion.
1.2	The procedure is explained and patient consent obtained.
1.3	The patient identifiers and other information on requisition, specimen container and sample labels match the patient's identifiers (in accordance with institution's patient identification policy).
1.4	The site and laterality of the lesion are confirmed from the clinical referral information and/ or the imaging findings.
1.5	The patient's position is optimal to expose the target lesion, stabilize the patient and reduce risk of complications.
1.6	The biopsy site is prepared appropriately: cleansed and local anaesthetic applied, if used.
1.7	The target lesion is stabilized with palpation, using appropriate technique.
1.8	The target lesion is sampled using appropriate tools (needle alone; syringe and needle without suction; syringe, holder and needle with negative pressure).
1.9	The target lesion is sampled using palpation for needle placement and adequate needle excursions.
1.10	A patient safety checklist is used for documentation, if part of institutional policy.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

2.0	ULTRASOUND GUIDED FNAB PATIENT SAFETY CHECKLIST
2.1	The FNAB is deemed appropriate (lesion is accessible and visualized on imaging) and safe to perform, bases on clinical and/ or imaging findings. No contraindications to FNAB are identified with respect to the patient or the lesion.
2.2	The procedure is explained and patient consent obtained.
2.3	The patient identifiers and other information on requisition, specimen container and sample labels match the patient's identifiers (in accordance with institution's patient identification policy).
2.4	The site and laterality of the lesion are confirmed from the clinical referral information and the imaging findings.

2.5	The patient's position is optimal to expose the target lesion, stabilize the patient and reduce risk of complications.
2.6	The ultrasound machine parameters are ideal for visualization of target lesion.
2.7	Sonographic criteria are identified to classify target lesion as benign, indeterminate, or malignant.
2.8	The biopsy site is prepared appropriately: cleansed and local anaesthetic applied, if used.
2.9	The target lesion is sampled using appropriate tools (needle alone; syringe and needle without suction; syringe, holder and needle with negative pressure).
2.10	The target lesion is sampled using either parallel or perpendicular approach with adequate needle excursions.
2.11	A patient safety checklist is used for documentation, if part of institutional policy.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

3.0	**SAMPLE PREPARATION AND TRIAGE PATIENT SAFETY CHECKLIST**
3.1	The sample is optimally prepared by making smears and/or needle rinse(s) with use of appropriate techniques for bloody and/or scant specimens.
3.2	The fixative (if used) and staining methods are optimal for air-dried versus wet-fixed material.
3.3	The need for material for ancillary testing (e.g. flow cytometry, microbiology) and/or cell block preparation is considered and, if deemed appropriate, is collected in the appropriate preservative(s) and/or transport media.
3.4	The option of collecting material for cell block preparation for future molecular studies is considered.
3.5	A patient safety checklist is used for documentation, if part of institutional policy.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

4.0	**PATHOLOGIST-PERFORMED RAPID ON-SITE EVALUATION PATIENT SAFETY CHECKLIST**
4.1	The patient identifiers are checked prior to delivery of any verbal report.
4.2	The performance of a rapid on-site evaluation, its results, any verbal communication to the referring physician, and the date and time of any communication are permanently documented in the report for the specimen.
4.3	Standardized terminology is used for reporting results.

4.4	Where there is no standardized terminology for a particular site, descriptive diagnoses that clearly communicate the findings are used.
4.5	A patient safety checklist is used for documentation, if part of institutional policy.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

5.0	**POST FNAB PATIENT CARE PATIENT SAFETY CHECKLIST**
5.1	Local complications at the biopsy site are minimized by persistent pressure with sterile pads and subsequent sterile coverage of the puncture site.
5.2	Patient is examined for post-biopsy complications and appropriately managed if complications identified.
5.3	Patient is advised of potential side effects/complications and where to seek medical assistance for side effects/complications.
5.4	Resuscitative equipment and personnel for CPR are available in the event of cardiac arrest.
5.5	Arrangements for discussion of results and subsequent management are undertaken with patient.
5.6	Physical exam findings and procedural note are documented.
5.7	A patient safety checklist is used for documentation, if part of institutional policy.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

SECTION 8
QUALITY ASSURANCE GUIDELINES FOR CYTOPATHOLOGY

A - COMPARISON WITH SURGICAL PATHOLOGY GUIDELINES

Quality Assurance Guidelines Relevant to Cytopathology
Intradepartmental Prospective Review
External Prospective Review
Intradepartmental Retrospective Review
External Retrospective Review
Intraoperative Consultation
Addendum and Amended Reports
Significant Unexpected Findings/Urgent Diagnoses
Utilization and Compliance
Turn Around Times (TAT)
Patient Education and Communication
Service Satisfaction

B - GUIDELINES SPECIFIC TO CYTOPATHOLOGY

Guidelines specific to cytopathology – see following pages
Rapid On-site Evaluation
Cytotechnologist-Cytopathologist Discrepancy
Performance Indicators
FNAB Patient Consent
FNAB Unsatisfactory Rate

Quality Assurance Guideline - Rapid On-Site Evaluation

Trigger: Review and correlate rapid on-site evaluation on a cytopathology specimen with final diagnosis on current case.	
Principle/Purpose	Rapid on-site evaluation (ROSE) includes microscopic examination by either a cytotechnologist (CT), a cytopathologist (CP), or both of an FNAB or other cytopathology sample for ensuring sample adequacy and appropriate sample triaging for ancillary testing. A CP may choose to render an adequacy statement or a preliminary diagnosis in accordance with their professional group's policy. The correlation of ROSE with further preparations and their associated final diagnoses is necessary to resolve discrepancies between the different preparations and provide education to the interpreters of the ROSE material. Review of discordances aids in the measure of consultation performance and improves recognition of morphologic differences between different preparations.
Policy	As part of the PPQMP there should be a policy that outlines the processes for, and the documentation of, the comparison of ROSE results with the final diagnosis. Adequacy criteria must be defined for each site sampled. ROSE reporting terminology must be clearly defined. See also Guidelines for Intradepartmental Retrospective Reviews, Guidelines for Dealing with Report Diagnostic Discrepancies, and Guidelines on Classification of Report Diagnostic Discrepancies.
Exceptions	Certain specialized cases, such as cyst contents, may be exempt from the process.
Practice Type Considerations	Some professional practices lack resources/personnel to offer ROSE services.
Responsibilities of Case Pathologist	• Refer to Pathologist-Performed Rapid On-site Evaluation Patient Safety Checklist prior to reporting to clinician. • When report defects or discordances are revealed, the case pathologist should participate in their investigation and resolution, according to the policies and processes the professional group usually employs. • When practical (depending on the size of the professional group), it is preferable that the case pathologist not be the same individual as the ROSE pathologist.

	• The case pathologist should compare the ROSE consult report and materials with the permanent material. • The review and comparison for a ROSE may be documented in the final report at the discretion of the case pathologist, in alignment with the professional group's policy in this matter.
Associated Documents	• Pathology Professional Quality Management Program Guideline • Professional Quality Management Committee Terms of Reference • Foundational Elements

Quality Assurance Guideline - Cytotechnologist-Cytopathologist Discrepancy

Trigger: Intradepartmental and/or external consultation for cytotechnologist (CT) –cytopathologist (CP) diagnostic discrepancies are monitored.	
Policy	As part of the PPQMP, there should be a policy outlining the process for further CP intradepartmental or external CP consultation for discrepancies. The professional group defines the criteria for minor and major discrepancies and defines criteria for further CP consultation. The classification of discrepancies may be derived from one of the published standards.
Exceptions	None.
Practice Type Considerations	Solo or small group practices may have to consider external consultation for major CT-CP discrepancies.
Responsibilities of Case Pathologist	Consider further CP consultation for major discrepancies.
Monitors	The PPQMP should review the use of consultation for discrepancies (See Classification of Report Diagnostic Discrepancies). Correlation of cytopathology and surgical pathology diagnoses should occur. **Minimum Requirements:** • Use of consultation for major discrepancies: # cases • Outcome of consultation for major discrepancies: concordance with cytopathologist interpretation • Reasons for major discrepancies (e.g. interpretation, cell block interpretive expertise, use of ancillary testing, complexity of case) **Frequency:** Quarterly (or as appropriate for the group)
Associated Documents	• Pathology Professional Quality Management Program Guideline • Professional Quality Management Committee Terms of Reference • Foundational Elements

Quality Assurance Guideline - Performance Indicators

Trigger: Performance indicators are monitored.	
Principle/Purpose	Performance indicators relevant to cytopathology are key indicators of the performance of each cytopathologist and the professional group. Monitoring may be particularly helpful after implementing change, establishing a new service; or for a new pathologist joining the practice.
Policy	As part of the PPQMP there should be a policy outlining processes for monitoring specific performance indicators relevant to cytopathology on a regular basis.
Exceptions	None.
Practice Type Considerations	Institutions/groups with resource limitations may have to consider external assistance with performance indicators. Solo or small group practices may have to consider external benchmarks rather than internal peer performance for comparison. The professional group may choose to monitor very specific performance indicators depending on resources, needs and changes to their practice.
Monitors	The PPQMP should collect and review performance indicator data for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time. **Minimum Requirements:** • Unsatisfactory rates (percentages) for gynecologic and separately for non-gynecologic cases • Major diagnostic category rates (percentages) for gynecologic cases • Major diagnostic category rates (percentages) for non-gynecologic cases overall and major specimen types, especially if published benchmarks available (e.g. Thyroid Bethesda System categories I-VI). • ASC:SIL ratio for gynecologic cases (ASC includes ASC-US and ASC-H; SIL includes low, high grade and ungraded SIL)

	• Examination of reasons for non-correlation between ROSE and final sign-out diagnosis (includes unsatisfactory diagnostic categories). • TAT from specimen collection to sign out for the professional group • TAT from specimen receipt in the lab to sign out for the professional group **Indicator Examples:** ○ Unsatisfactory FNAB rate for professional group and by individual cytopathologist ○ ASC:SIL ratio of professional group and by individual cytopathologist **Frequency:** Quarterly (or as appropriate for the group)
Associated Documents	• Pathology Professional Quality Management Program Guideline • Professional Quality Management Committee Terms of Reference • Foundational Elements

Quality Assurance Guideline - Patient FNAB Consent

Trigger: At fine needle aspiration biopsy (FNAB) written patient consent is obtained.	
Principle/Purpose	Standardization of patient consent will help ensure all the appropriate elements for informed consent have been included. The explanation of the procedure and the meaning of the consent should be easily understood by the patient.
Policy	As part of the PPQMP, there should be a policy which describes the particulars of the standardized patient consent, which should comply with institutional policies and standards. If a written consent form is used it should include risks and benefits of the procedure, patient identifiers (full name, date of birth), site of biopsy, name of physician performing FNAB, patient's signature and printed name, and date of signing. A statement regarding patient understanding of the procedure and of the risks and benefits of FNAB should be included. Any signed written consent form shall be included in the patient chart along with the procedure note. If only verbal consent is obtained the same elements should be included in the patient's permanent chart, along with the procedural note. Completion of patient consent may be documented in a patient safety checklist.
Exceptions	None.
Practice Type Considerations	In practices where the patient is unable to render informed consent for the procedure, then the appropriate health care surrogate decision maker may render the consent. Examples may include a patient who is a minor or an unconscious patient. Some pathology practices do not offer pathologist FNAB services.
Responsibilities of Pathologist Aspirator	Explanation of the FNAB procedure and its risks and benefits. Any patient questions or concerns are addressed. Assessment of the patient's ability to render informed consent must be considered. Use of a health care surrogate decision maker may be more appropriate for informed consent. The FNAB is performed only after informed consent has been obtained and documented.
Monitors	As an option, the PPQMP may choose to monitor or audit the completion and documentation of consent by pathologist aspirator(s).

Associated Documents	• Pathology Professional Quality Management Program Guideline • Professional Quality Management Committee Terms of Reference • Foundational Elements

Quality Assurance Guideline - FNAB Unsatisfactory Rates

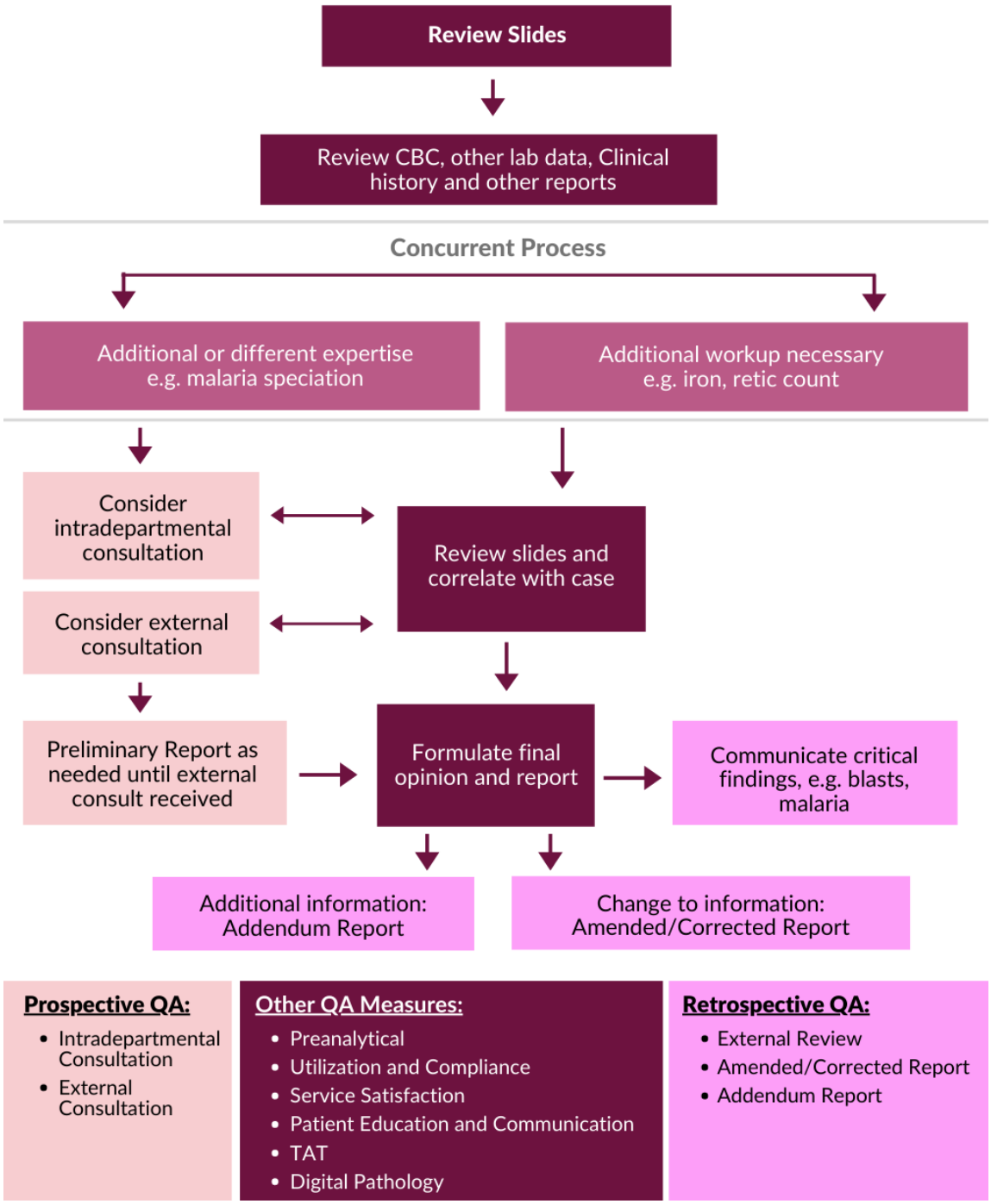
Trigger: Unsatisfactory rates for FNAB cytopathologist aspirator are monitored.	
Principle/ Purpose	Unsatisfactory rates are key indicators of the performance of the FNAB aspirator. Unsatisfactory rates reflect patient safety and quality of care provided by the FNAB aspirator. A clearly defined process for feedback of unsatisfactory rates will improve the quality of patient care and enhance patient safety.
Policy	As part of the PPQMP, there should be a policy which outlines the processes for monitoring unsatisfactory rates on a regular basis, for pathologist performing FNABs. Confidential feedback to aspirators on their unsatisfactory rates is an expectation. Unsatisfactory criteria for samples should be clearly defined.
Exceptions	None
Practice Type Considerations	Some pathology practices do not offer pathologist FNAB services. Unsatisfactory rates may be offered to clinician aspirators. Some groups may choose to also monitor rates of samples which have been interpreted as adequate at the time of FNAB, but for which further sampling and work-up is still required.
Responsibilities of Aspirator Pathologist	Documentation of reason(s) for unsatisfactory sample at time of FNAB.

Monitors	The PPQMP should collect and review data on FNAB unsatisfactory rates for the pathologist aspirator group overall and for each pathologist aspirator.
	
	As data is collected, it should be compared to established benchmarks (if available) and trended over time.
	
	Minimum Requirements:
	• number of unsatisfactory FNABs compared with total number of FNABs
	  ○ by pathologist aspirator group overall
	  ○ by each pathologist aspirator

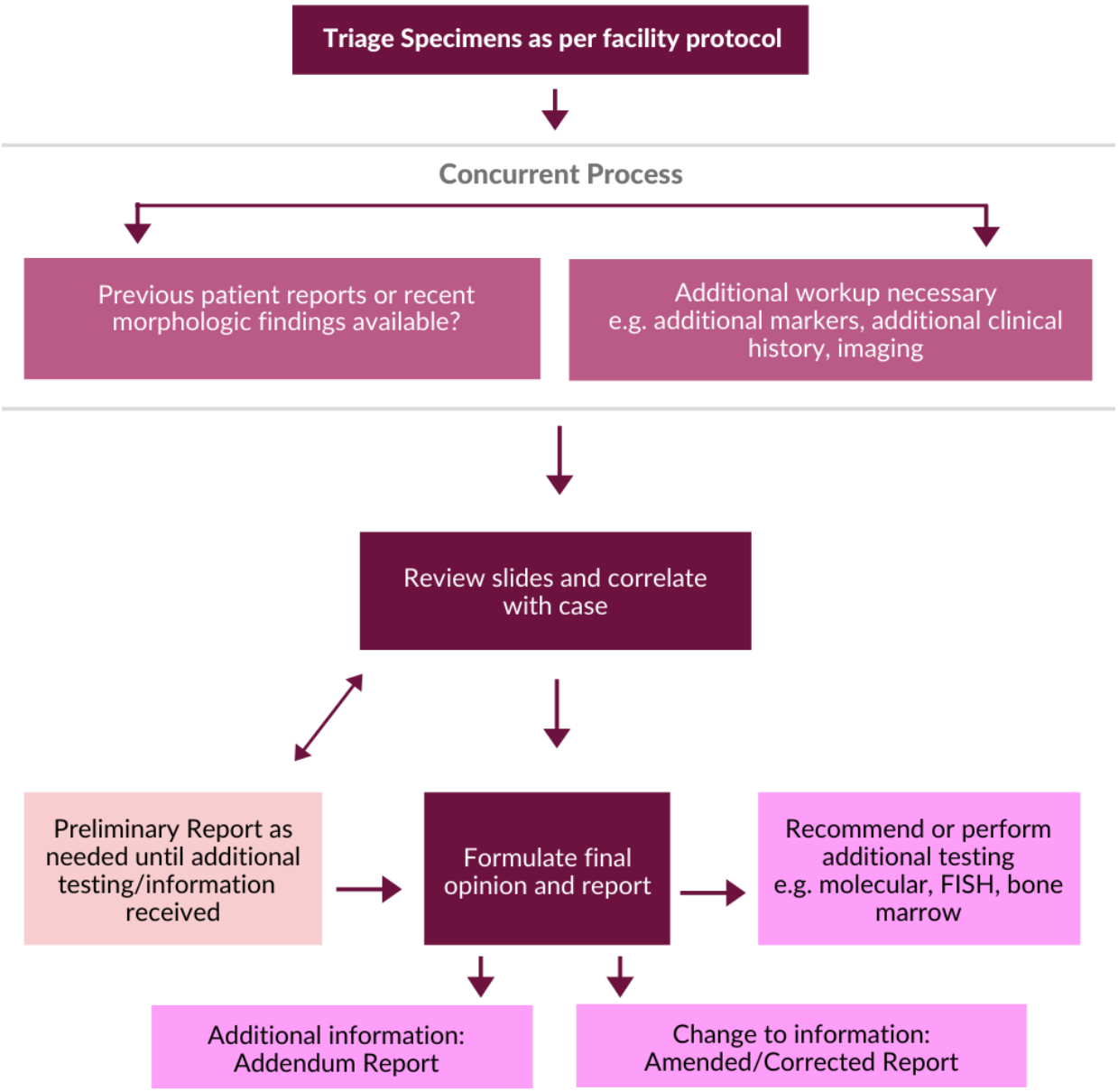
	Indicator Examples: • % of unsatisfactory FNABs for aspirator group overall and each pathologist aspirator **Optional:** number and % of unsatisfactory FNABs by site ○ by pathologist aspirator group overall ○ by each pathologist aspirator ○ reasons for unsatisfactory samples **Frequency:** • every 6 months or as appropriate for group
Associated Documents	• Pathology Professional Quality Management Program Guideline • Professional Quality Management Committee Terms of Reference • Foundational Elements

SECTION 9
WORKFLOW PROCESS MAPS FOR HEMATOPATHOLOGY

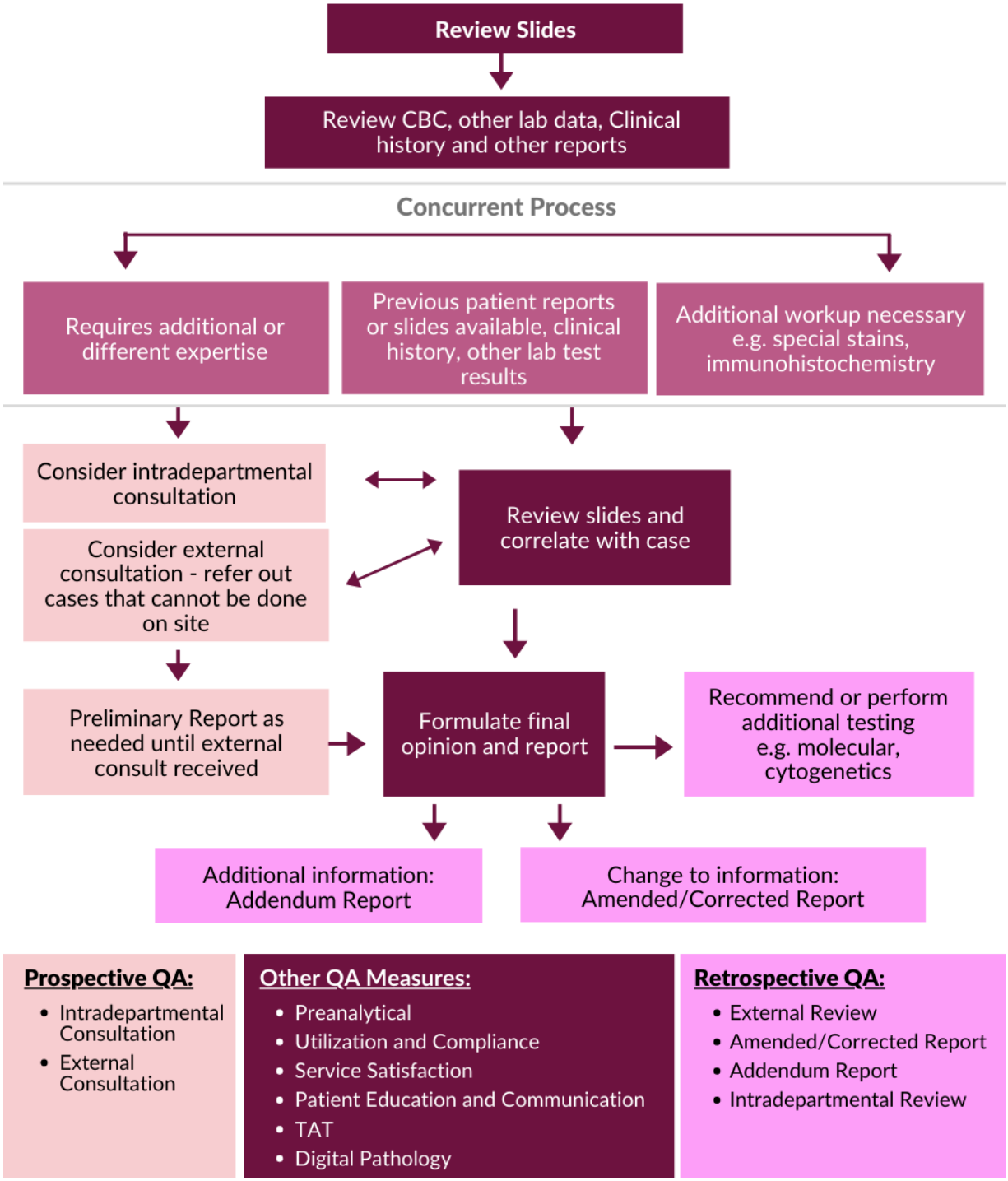
A - PERIPHERAL BLOOD FILM



B - FLOW CYTOMETRY



C - BONE MARROW ASPIRATE AND BIOPSY INTERPRETATION



SECTION 10
PATIENT SAFETY CHECKLISTS FOR HEMATOPATHOLOGY

A – PERIPHERAL BLOOD FILM

1.0	**PRE-INTERPRETATIVE PATIENT SAFETY CHECKLIST (This PSC is to be used as a guide, and may not be applicable to every blood film reviewed).**
	Patient Demographics
1.1	The patient demographics are consistent with the submitted specimen.
	Patient Clinical History
1.2	Pertinent previous clinical history, diagnostic imaging, procedural record, laboratory reports and previous slides are reviewed if available.
1.3	The referring physician or appropriate other personnel is contacted for additional information, if required and if available.
	Case Material Correctness
1.4	Slides and other preparations created are uniquely and permanently identified with adequate and legible information.
1.5	The patient record (including any transcribed portions), the specimen requisition and slides, and any other case materials such as flow cytometry, molecular testing or cytogenetics match.
	Slide and Other Preparation QC/QA
1.6	Slides and stains, and other preparations, are of sufficient quality.
	Pathologist Slide Review

1.7	Microscopic Description – Systematic review of specimen is undertaken at low, medium and high powers and attributes of the smear assessed:
	• Low (x10)
	  ○ Quantity and distribution of cells
	  ○ Scanning of feathered edge and slides for large parasites or platelet clumps
	• Medium (x20-40)
	  ○ Quantity, morphologic features of all cell lines, inclusions
	• High (x63 dry, x100 oil immersion)
	  ○ Organisms e.g. malarial speciation
	Pathologist should also ensure that the CBC results and peripheral blood findings correlate.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

2.0	POST-INTERPRETATIVE PATIENT SAFETY CHECKLIST
	Final Report (peripheral blood film, bone marrow aspirate and biopsy)
2.1	Any standardized protocols employed by the professional group for reporting the specimen are adhered to.
2.2	The microscopic findings (if recorded), and any other information included support the pathologic diagnosis.
2.3	Any inadequacies or limitations of the specimen or its examination are documented.
2.4	The results of specialized studies are correlated with the morphologic findings, documented and incorporated into the final report.
2.5	Any discordance between other tests performed, is reconciled and explained in the report.
2.6	Recommendations for further studies are included.
2.7	Significant, unexpected and critical findings are communicated promptly to the clinician and that communication documented.
2.8	No transcription or formatting errors are present.
2.9	All quality assurance processes employed during the course of specimen examination and reporting are documented.
2.10	The pathologist responsible for report (including any preliminary report/s) is clearly indicated in the report, along with contact information for the institution/professional group.
	Report Structure
2.11	The blood film report includes the following: • Pertinent morphologic findings including a qualitative description with correlation to CBC abnormality if applicable • Diagnostic summary including differential diagnosis and recommendations for further investigation if applicable. The bone marrow aspirate and biopsy report include the following: • Morphologic findings and ancillary studies as applicable. • Final diagnosis which correlates all relevant findings and ancillary testing. • Comments and recommendations if applicable.
	Addendum (Supplementary) and Amended (Corrected) Reports – if required
2.12	The reason for the addendum or amendment is clearly indicated in the report, and along with any background information and findings that may have served as its basis.
2.13	The information in the original report and the original diagnosis are reviewed and changed if required. If a change is made, that change is clearly identified.
2.14	The clinician is notified, if necessary and that notification documented.

2.15	The original report is retained and can be retrieved – ensuring that it cannot be mistaken as the active/ final report.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

B – FLOW CYTOMETRY

1.0	PRE-INTERPRETATIVE PATIENT SAFETY CHECKLIST
	Patient Demographics
1.1	The patient demographics are consistent with the submitted specimen.
	Patient Clinical History
1.2	Pertinent previous clinical history, diagnostic imaging, and laboratory reports are available for review.
1.3	The referring physician or appropriate other personnel is contacted for additional information, if required and available.
	Case Material Correctness
1.4	Slides, histograms and other preparations created are uniquely and permanently identified with adequate and legible information.
1.5	The patient record (including any transcribed portions), the specimen requisition, histograms and slides, and any other case materials match.
1.6	Slides and stains provided with the case, if applicable, are of sufficient quality.
	QA Checklist For Pathologist Written Report
1.7	Sections of the report should include: • Patient Demographics • Hospital or Division sending the sample • Type of Specimen • Clinical information • Sample quality • Findings and interpretation (See 2.7) • Recommendations if applicable

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

2.0	POST-INTERPRETATIVE PATIENT SAFETY CHECKLIST
	Final Report
2.1	Any standardized protocols employed by the professional group for reporting the specimen are adhered to.
2.2	The morphologic findings (if applicable) and any other information included support the diagnosis.
2.3	Any inadequacies or limitations of the specimen or its examination are documented.
2.4	Any discordance between the final diagnosis and other tests performed, is reconciled and explained in the report.
2.5	Recommendations for further studies are included.
2.6	Significant and unexpected findings are communicated promptly to the clinician and that communication documented.
2.7	All necessary sections of the report are completed (including synoptic report fields). See 1.7
2.8	No transcription or formatting errors are present.
2.9	All quality assurance processes employed during the course of specimen examination and reporting are documented.
2.10	The pathologist responsible for report (including any preliminary report/s) is clearly indicated in the report, along with contact information for the institution/professional group.
	Report Structure
2.12	A flow cytometry report might include the following: • Morphologic description (if sample provided). • Results of gating procedure – report the population gated and the percent identified. • Immunophenotype of any atypical/abnormal population including significant positive or negative markers and fluorescence intensity. • In the absence of an abnormal population, the report should contain a brief description of the major cell groups analyzed and any relevant negative results. • Diagnostic conclusions, including differential diagnosis and recommendations for follow up studies, if indicated.
	Addendum (Supplementary) and Amended (Corrected) Reports – if required.
2.13	The reason for the addendum or amendment is clearly indicated in the report, and along with any background information and findings that may have served as its basis.
2.14	The information in the original report and the original diagnosis are reviewed and changed if required. If a change is made, that change is clearly identified.
2.15	The clinician is notified, if necessary and that notification documented.

2.16	The original report is retained and can be retrieved – ensuring that it cannot be mistaken as the active/ final report.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

C – BONE MARROW ASPIRATE AND BIOPSY INTERPRETATION

1.0	**PRE-INTERPRETATIVE PATIENT SAFETY CHECKLIST**
	Patient Demographics
1.1	The patient demographics are consistent with the submitted specimen.
	Patient Clinical History
1.2	Pertinent previous clinical history, diagnostic imaging, and laboratory reports are available for review.
1.3	The referring physician or appropriate other personnel is contacted for additional information, if required.
	Case Material Correctness
1.4	Slides and other preparations created are uniquely and permanently identified with adequate and legible information.
1.5	The patient record (including any transcribed portions), the specimen requisition and slides, and any other case materials such as flow cytometry, molecular testing or cytogenetics match.
	Gross Description
1.6	The specimen type matches the requisition and other records.
1.7	The description is complete, understandable, and follows established protocols.
1.8	The description contains adequate information regarding tissue type/material, number of tissue/material pieces, dimensions, and other information for pathologic diagnosis.
1.9	Appropriate sections are taken, or other preparations made (touch preparation, smear or squash, clots section) for the type of specimen submitted.
1.10	There is documentation of the sections taken or other preparations made in the report.
	Slide and Other Preparation QC/QA
1.11	The material in the slides or other preparations matches the gross descriptions.
1.12	Slides, stains and other preparations are of sufficient quality.
	Microscopic Description – Bone Marrow Aspiration
1.13	Review of CBC and examination of blood film – preferably obtained along with current bone marrow specimen. Qualitative – systemic review of specimen at low, medium, and high power.

	• Low (x10)
	  ○ Number of particles.
	  ○ Cellularity.
	  ○ Assessment of megakaryocytes (quantity).
	  ○ Identification of low incident cells or clumps (e.g. carcinoma).
	• Medium (x20-40)
	  ○ Content of fragments.
	  ○ Morphologic features of all cell lines.
	• High (x63 dry, x100 oil immersion if necessary)
	  ○ Fine morphologic details
	
	Quantitative – differential cell count with quantitation of erythroid, granulocytic, lymphocytes, plasma cells, and blasts with calculation of myeloid to erythroid ratio.
	
	• 200 cell differential is recommended if not essential to the diagnosis.
	• 500 cell differential is recommended when precise percentage is needed or if abnormal cell counts are close to diagnostic thresholds.
	• If a sample is dilute, in the absence of particles, or particles with very reduced cellularity, consider reporting only qualitative data.
	
	Comparison with previous bone marrow specimens.
	Interpretation of any special stains.
	Assessment of iron stores, presence and quantity of ring sideroblasts.

	Microscopic Description – Bone Marrow Biopsy

1.14	Two to four sections should be routinely reviewed.
	Systematic review of the specimen at low, medium and high power.
	
	• Low (x2.5-10)
	  ○ Adequacy of specimen.
	  ○ Assessment of cellularity and bone marrow architecture.
	  ○ Presence of focal lesions.
	• Medium (x20-40)
	  ○ Bone structure.
	  ○ Hematopoietic activity and morphologic detail.
	  ○ Blood vessels.
	  ○ Nature of focal lesions.
	• High (x63 dry)
	  ○ Fine cellular detail (if applicable)
	  ○ Fungus or protozoal infections.
	
	Review of any special stains – cytochemical, immunohistochemical, etc.

	• Reticulin stain should be graded according to a standardized published system.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

2.0	POST-INTERPRETATIVE PATIENT SAFETY CHECKLIST
	Provisional Preliminary Report – if required
2.1	The report describes what work or other information is pending/ incomplete, and why the report is not a final/completed one.
2.2	The report clearly indicates that the findings are preliminary and may be modified at the time of issuing the final/complete report.
	Pathology Final Report
2.3	Any standardized protocols employed by the professional group for reporting the specimen are adhered to.
2.4	The morphologic findings and any other information included support the pathologic diagnosis.
2.5	Any inadequacies or limitations of the specimen or its examination are documented.
2.6	Unified reporting of the bone marrow aspirate and biopsy is recommended.
2.7	The results of specialized studies, if available, are correlated with the morphologic diagnosis, documented and incorporated into the final diagnosis.
2.8	For reports that include tests that provide independent predictive information, details of specimen processing, and the test and the scoring methods used are included in the report.
2.9	Any discordance between the final diagnosis and other tests performed is reconciled and explained in the report.
2.10	Recommendations for further studies are included.
2.11	Significant, unexpected and critical findings are communicated promptly to the clinician and that communication documented.
2.12	All necessary sections of the report are completed (including required synoptic report fields).
2.13	No transcription or formatting errors are present.
2.14	All quality assurance processes employed during the course of specimen examination and reporting are documented.
2.15	The pathologist responsible for the report (including any preliminary report/s) is clearly indicated in the report, along with contact information for the institution/professional group.

	Addendum (Supplementary) or Amended (Corrected) Reports
2.16	The reason for the addendum or amendment is clearly indicated in the report, and along with any background information and findings that may have served as its basis.
2.17	The information in the original report and the original diagnosis are reviewed and changed if required. If a change is made, that change is clearly identified.
2.18	The clinician is notified, if necessary and that notification documented.
2.19	The original report is retained and can be retrieved – ensuring that it cannot be mistaken as the active/final report.
	Report Structure – Bone Marrow Aspirate

2.20	The report for a bone marrow aspirate includes the following:
	• Clinical details.
	• Major CBC findings (WBC, Hgb, Plt, MCV, reticulocytes).
	• Peripheral blood findings.
	• Aspirate findings including:
	  ○ Adequacy of specimen.
	  ○ Cellularity.
	  ○ Quantitative and qualitative description of each cell lineage including any abnormal cells, maturation of the granulocytic and erythroid lines should be reported.
	  ○ Results of iron stains or other cytochemical stains.
	• Correlation of morphologic findings with other investigations, if available (e.g. flow immunophenotyping, FISH, molecular).
	• Comparison with previous pathologic material.
	• Diagnosis assessment and summary including differential or definitive diagnosis (where applicable) with reference to international consensus guidelines and suggestions, opinions, or recommendations for further investigations.
	• Document communication with clinician, if applicable.
	• List of pending investigations.

	Report Structure – Bone Marrow Biopsy
2.21	The report for a bone marrow biopsy includes the following: • Macroscopic description including specimen length and adequacy for diagnosis. • Microscopic description including assessment of cellularity, bone structure, hematopoietic activity, and any abnormal infiltrate or artifact. • Assessment of any special stains. • Comparison of current findings with results of any pertinent ancillary tests that support findings or diagnosis (e.g. flow cytometry, FISH). • List of any pending investigations.

	• Diagnostic assessment and summary with integration of morphologic findings with results from other tests, correlation with clinical findings, and recommendations for further investigation.
	Report Structure – Integrated Bone Marrow Report
2.22	An integrated bone marrow report is recommended where the same hematopathologist or pathologist reports the flow cytometry, blood film, aspirate and core biopsy and integrates these with the clinical and molecular/ancillary data for final diagnostic interpretation.

If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.

SECTION 11
QUALITY ASSURANCE GUIDELINES FOR HEMATOPATHOLOGY

A – COMPARISON WITH SURGICAL PATHOLOGY GUIDELINES

Quality Assurance Guidelines Relevant to Hematopathology
Intradepartmental Prospective Review Applies predominantly to bone marrow aspirate and biopsy. Should be considered for peripheral blood smear interpretation however these may generate fewer reviews and there may not be the same ability to document a second review on the report.
External Prospective Review
Intradepartmental Retrospective Review
External Retrospective Review
Addendum and Amended Reports
Significant Unexpected Findings/Urgent Diagnoses Includes communication of significant unexpected findings/urgent diagnoses found on peripheral blood smear interpretative review.
Utilization and Compliance (for example, Ontario Health/Cancer Care Ontario guidelines for Acute Leukemia, Myelodysplastic and Myeloproliferative Disorders)
Turn Around Times (TAT) Also includes monitoring of TAT for peripheral blood smear interpretative comments.
Digital Pathology
Patient Education and Communication
Service Satisfaction

APPENDIX A
SUMMARY OF SURGICAL PATHOLOGY INDICATORS

Suggested Minimum Indicators
Pre-Analytical
% of breast excisions with ischemic time in acceptable range (Accreditation Requirements)
% of breast excisions with formalin fixation time in acceptable range (Accreditation Requirements)
Intra-operative Consultation
% of cases with intra-operative consultation discrepancies for professional group
% of deferred cases at intra-operative consultation for professional group
Mean Turn Around Time for intra-operative consultation for professional group
Prospective Review (Intradepartmental and External Consultation)
% of Intradepartmental Prospective Reviews for the professional group (individual pathologist and case conference types)
% of Intradepartmental Prospective Reviews by specific anatomic site or disease type
% of cases sent for External Prospective Reviews for the professional group
Retrospective Reviews (Intradepartmental or External)
# of cases with report discrepancies resulting in near miss for the professional group
# of cases with report discrepancies resulting in minor patient impact for the professional group
# of cases with report discrepancies resulting in major patient impact for the professional group
Addendum and Amended Report
% of Amended reports classified by patient impact for the professional group
Significant Unexpected Findings and Urgent Diagnoses
% of cases where urgent diagnoses were reported for professional group
Turn Around Time
Mean turn around time from specimen collection to case sign out for professional group
Mean turn around time from specimen receipt in lab to case sign out for professional group
Cumulative % of cases signed out by professional group by day after specimen receipt in lab
Mean turn around time for biomarker tests
Service Satisfaction/Patient Education and Communication
# of complaints received by the professional group
# of compliments received by the professional group

Suggested Optional Indicators
Pre-Analytical
% of specimens with absence, insufficient or incorrect clinical history
% of all tumour resections with ischemic times which meet standards
% of all tumour resections which meet formalin fixation standards
Intra-operative Consultation
% of cases with intra-operative consultation discrepancies for individual pathologist
% of deferred cases at intra-operative consultation for individual pathologist
Mean turn around time for intra-operative consultation for individual pathologist
Prospective Review (Intradepartmental and External Consultation)
% of Intradepartmental Prospective Reviews by individual pathologist (individual pathologist and case conference types)
% of cases sent for External Prospective Review by individual pathologist
Retrospective Reviews (Intradepartmental or External)
# of cases with report discrepancies resulting in near miss for individual pathologist
# of cases with report discrepancies resulting in minor patient impact for individual pathologist
# of cases with report discrepancies resulting in major patient impact for individual pathologist
# of cases with report discrepancies of undetermined patient impact for individual pathologist
Addendum and Amended Report
% of Amended reports classified by patient impact by individual pathologist
% of Addendum Reports for professional group
% of Addendum Reports by individual pathologist
Turn Around Time
Mean turn around time from specimen receipt to case sign out by individual pathologist
Cumulative percent of cases signed out by individual pathologist by day after specimen receipt
Digital Pathology
Concordance/Discordance from 10% review of all telepathology consultations/diagnoses
Turn around time for sign out of cases – intra-operative consultation and routine
Concordance between intra-operative consultation and permanent section
% of cases deferred to glass slide review with reason for deferral
% of slides requiring re-scanning

APPENDIX B
GLOSSARY

TERM	DEFINITION
Academic practice	Professional practice carried out in an institution that is attached to a university/ teaching centre. This type of practice is often subspecialty based and a referral centre.
Accreditation Canada Diagnostics	Agency which provides oversight of laboratory accreditation.
ADASP	Association of Directors of Anatomic and Surgical Pathology.
AP	Anatomic Pathology.
Blinded review	A review that takes place without knowledge of clinical information or previous opinions.
CAP	College of American Pathologists.
Case	A pathology specimen or group of specimens from a single patient procured at the same diagnostic or operative procedure
Case Pathologist	The pathologist most responsible for a case
Case conference	A conference where cases are reviewed. In the context of surgical pathology a case conference usually involves reviewing material with colleagues, often using a multi-headed microscope or image projection.
CLSI	Clinical And Laboratory Standards Institute.
Correlation	Pathologic findings are within the same category of interpretation (e.g., grading of a tumour, or assessment of a margin, or the diagnoses agree or match). Correlation can involve separate interpretations on the same specimen or initial and subsequent material from the same patient.
Consensus	An opinion or position reached by a group as a whole.
Consulting pathologist	The pathologist whose opinion is sought by the case pathologist. This pathologist can be internal or external to the organization. Also referred to as Review Pathologist.
Critical diagnoses	In surgical pathology, critical diagnoses are those that require expedited notification of the most responsible physician or delegate, as urgent patient management may be needed to prevent morbidity and mortality. (Synonyms include: critical value, alert value, significant pathologic findings, and critical pathologic findings).
Cytohistologic discrepancies	A difference in interpretation with respect to cytologic and histologic specimens from the same patient.
Deferral	A diagnosis is not provided and is deferred until after subsequent testing.
Deferral rate	The number of cases with a deferred diagnosis compared to the total number of cases in the same group.
Deferral rate - appropriate	The number of cases with a deferred diagnosis where this deferral was considered an appropriate course of action, compared to the total number of cases within the same group.
Deferral rate - inappropriate	The number of cases with a deferred diagnosis where a more definitive interpretation could have been rendered, compared to the total number of cases within the same group.

Digital Pathology	**Digital Pathology** is the all-encompassing term that comprises the usage of digital imaging and telecommunications technology for the acquiring, sharing, transmission and/or storage of pathology images and/or other related data for diagnosis, education, quality assurance and research. The College of American Pathologists (CAP) defines **telepathology** as "the practice of pathology, in which the pathologist views digitized or analog video or still image (s), and renders an interpretation that is included in a formal diagnostic report or documented in the patient record." Telepathology comes under the niche of the digital pathology umbrella.
Disagreement	A difference of opinion as to the interpretation of a case.
Discrepancy/discrepant	Description of a difference between the original interpretation and that after a second review.
External consult	External consultation occurs when a case pathologist seeks an opinion from a pathologist external to the case pathologist's professional group.
External review	External review occurs when there is a request by a pathologist (other than the case pathologist), clinician, or patient for case review by a pathologist external to the case pathologist's professional group.
False negative	A negative test result for patient or specimen that is positive for the condition or constituent in question.
False-positive	A positive test result for a patient or specimen that is negative for the condition or constituent in question.
Frozen section	One form of an intra-operative consultation that includes rapid microscopic interpretation of pathology material that is frozen quickly to produce the tissue section for microscopy.
Guideline	A consensus recommendation for best practice that should be used if an advanced level of practice is desired.
Internal audit	A review of cases or results within a professional group.
Interpretation	A professional opinion or diagnosis.
Inter-departmental case conference	A conference that involves clinicians or other health care professionals external to the surgical pathology department.
Intra-departmental consultation	When a pathologist seeks an opinion from another pathologist in their professional group. This may involve either a direct request from one pathologist to another to review all or selected slides from a case. It may also involve review of all or selected slides during a case conference.
Intra-operative consultation (IOC)	A rapid consultation by a pathologist (often while the patient is still in the operating room) that may include gross evaluation of the specimen, frozen section, examination of cytopathology preparations (e.g., touch imprints), or sampling of the specimen for special studies (e.g. molecular pathology techniques, flow cytometry).
Intra-operative Consultation Pathologist	Pathologist performing/ responsible for an intra-operative consultation.
Laboratory Director	A licensed physician who is a suitably qualified specialist in laboratory medicine who is responsible for the administration of the scientific and technical operation of a laboratory, including the supervision of tests and the reporting of results of the tests.
LAP	Laboratory Accreditation Program of the CAP.

LIS	Laboratory Information System.
MAC	Medical Advisory Committee.
Minimum requirements	These are basic or baseline monitors or indicators that should be used or in place. Depending on the type of practice/ scenario additional monitors or indicators may be employed.
Misidentification	The identity of the patient or the type of specimen is incorrect.
MOHLTC	Ministry of Health and Long Term Care
Original pathologist	The pathologist who previously finalized a case that is being reviewed.
Optional requirements	Additional actions that may be performed in addition to minimum requirements.
Patient Safety Checklist	A listing of actions to be performed in a given clinical setting, in order decrease the risk of adverse events by fostering a patient safety mindset and encouraging communication.
Peer review	Review of a case by laboratory physicians within the same type of practice.
Preliminary diagnosis	An interpretation that contains some but not all of the information required in the final report.
Preventive action	A proactive process for identifying opportunities for improvement rather than reaction to the identification of problems or complaints (i.e., non-conformances). In addition to review of the operational procedures, preventive action might involve analysis of data, including trend and risk analysis, external quality assurance, and the monitoring of quality indicators.
Prospective Review	A review that occurs before a case has been finalized.
Quality assurance	A set of activities intended to establish confidence that quality requirements will be met. It is one part of quality management.
Quality control	A set of procedures intended to ensure that a product or performed service adheres to a defined set of quality criteria.
Quality improvement	Anything that enhances an organization's ability to meet quality requirements. It is one part of quality management.
Quality management	All activities of the overall management function that determine quality policy objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance, and quality improvement within the system. Quality management is focused not only on final quality, but also the means to achieve it.
QA Pathologist	A pathologist responsible for carrying out and reviewing a quality assurance (QA) activity and its results.
QMP - LS	Quality Management Program - Laboratory Services
Referring pathologist	A case pathologist who requests a second opinion on a case, usually from an external consultant.
Regional/community practice	Professional practice carried out in a regional or community based organization/ laboratory.
Report defect	An error or omission in a report.
Requirement	Need or expectation that is stated, generally implied or obligatory.
Retrospective review	A review that occurs after a case has been finalized.
Review	An activity undertaken to ensure the suitability, adequacy, effectiveness and efficiency of the subject matter to achieve established objectives.

Review pathologist	A pathologist who is reviewing or giving a second opinion on a case.
Revision	Introduction of all necessary changes to the substance and presentation of a document to ensure its continuing suitability, adequacy, effectiveness to achieve established objectives.
Risk management	Clinical and administrative activities undertaken to identify, evaluate, and reduce the risk of injury to patients.
Service satisfaction	The degree to which lab services meet or surpass the expectations of physicians, clinical personnel and patients.
PPQMC	Pathology Professional Quality Management Committee.
PPQMP	Pathology Professional Quality Management Program
Standard	The minimum requirement for a procedure, method, staffing resource, or laboratory facility that is required before accreditation can be attained.
Subspecialty expertise	Focused or additional expertise in a specific area of medicine/ pathology.
Telepathology	The College of American Pathologists (CAP) defines **telepathology** as "the practice of pathology, in which the pathologist views digitized or analog video or still image (s), and renders an interpretation that is included in a formal diagnostic report or documented in the patient record." Telepathology comes under the niche of the digital pathology umbrella.
Turn around time (TAT)	From the patient perspective, TAT begins when a decision is made to obtain a tissue sample to when they receive the results of a report. Within the lab, it may be analyzed for its constituent work processes; for example, time from when sample is taken to time a report is available, time from when sample is received in the lab to time a report is available. The units used to measure TATs should be specified, e.g., calendar or working hours or days.
Whole slide imaging (WSI)	**Whole slide imaging (WSI)** uses an automated device composed of a scanner (hardware comprised of a microscope and digital camera) with in-built software that allows the device to use compound algorithms to 'stitch' serial digital images together to produce a 'virtual' replica of the glass slide. These virtual images can be archived, retrieved, and shared through appropriate network access.

APPENDIX C
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Note: New references used for Version 3 are bolded.

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APPENDIX D
PROCESS AND RESULTS OF CONSULTATION WITH LABORATORY PHYSICIANS IN ONTARIO

Central to the principles guiding the *Standards2Quality* project was the desire for active consultation and transparency. Laboratory physicians were made aware of the work of Path2Quality, and its efforts to draft quality assurance guidelines for professional practice in the area of surgical pathology, on multiple occasions and via a number of methods. For instance, this work was described at the Annual General Meetings of the Ontario Medical Association (OMA) Section on Laboratory Medicine and the Ontario Association of Pathologists (OAP). It was highlighted in a number of preparatory emails directed to each of those associations' members.

Once the Guidelines were available in draft form they were circulated in hard copy to all laboratory physicians in the OMA database. Excluded were laboratory physicians who did not practice in Ontario, or who were retired.

A total of 495 laboratory physicians were sent the Guidelines (it is estimated that about 420 of these individuals practice either surgical pathology or cytopathology). Included with the Guidelines was a brief questionnaire about the Guidelines, and an opportunity to provide free text comments. Addressed return envelopes with prepaid postage were provided. Responses were in confidence, and physicians desiring to respond anonymously did so.

Eighty (80) questionnaire responses were received. The response rate was, as a result, at least 16.2% (some responses received were submitted on behalf of groups of physicians, so the total number of individual physicians responding is not fully known). Seventy (70) percent of the responses included free text comments.

The questionnaire consisted of nine statements about the Guidelines and an agreement rating was requested for each statement. The rating choices included: "1 (strongly disagree)", "2", "3", "4", or "5 (strongly agree)" for each statement. The following describes the aggregate of the questionnaire ratings (compiled by the *Standards2Quality* project's secretariat/ technical support):

Survey Statement About Circulated Draft Guidelines	Mean Response	Median Response	Mode Response
Purpose is clearly defined	4.6	5	5
Well organized & easy	4.4	5	5
Complete - no gaps	4.0	4	5
Consistent with literature	4.2	4	5
Appropriate for Ontario	4.1	4	5
Clearly distinguished requirements	3.9	4	5
Sufficient information to develop a plan	4.1	4.5	5
I would use them	4.3	5	5
I would recommend them	4.2	5	5

Standards2Quality project's secretariat/ technical support also compiled the free text comments provided by respondents. These comments were anonymized and reviewed in detail by the Path2Quality Executive. While some respondents had reservations about portions of the document, virtually all respondents expressed a positive interest in the work, and most a recognition that the Guidelines would likely be useful to them in their own practices and/ or at the provincial level.

The comments received about the *Guidelines* ranged from suggestions for formatting and typographic improvements to others of a more substantive nature. In some cases the latter highlighted issues (e.g., the resource implications of the *Guideline*s) considered out of scope by the Path2Qualtiy Executive (note that there has since been a separate effort by Path2Quality, *Work2Quality*, which has at least in part addressed this issue).

Where possible, the comments provided were used to enhance the *S2Q Guidelines*. All comments and responses were made available for review by any interested laboratory physicians in the Province. After the various consultation and enhancement efforts, the first version of the *S2Q Guidelines* was issued at the end of March, 2012.

The *S2Q Guidelines* have been presented at a number of scientific meetings, including the 2011 Annual meeting of the Canadian Association of Pathologists, and the Annual Meeting of the College of American Pathologists in 2012.

In January, 2013 directors of Ontario's laboratories were surveyed to examine for the effect of the *S2Q Guidelines*. Thirty-nine (39) laboratory directors completed the survey; 26.5% said their quality management program had improved a great deal in the interim, and 50.0% somewhat (14.7% neutral, and 5.8% not at all); 38.2% said the *S2Q Guidelines* had helped a great deal in quality management improvement, and 44.1% somewhat (11.8% neutral, and 2.9 not); 2.9% said the *S2Q Guidelines* had helped a great deal securing resources for QM, and 14.7% somewhat (26.5% neutral, and 50.0% not). In the interim since the *Guidelines* were first issued, the number with no formal quality management program dropped from 22.2% to 13.9%.

It appears the *S2Q Guidelines* have been well received and have been useful to pathologists in Ontario. Interest in their extension had been evidenced earlier; in relation to that, in early 2012 Path2Quality struck working groups to extend the *S2Q Guidelines* to cytopathology and hematopathology. With the output of those working groups, *the Guidelines* were reviewed by Path2Quality and further enhanced, for issue as the current Version 2.

APPENDIX E
NATIONAL AND INTERNATIONAL EXPERTS CONSULTED FOR THE MARCH 31, 2011 *S2Q GUIDELINES*

Before issuing the first version of the *S2Q Guidelines* he Path2Quality Executive approached each of the individuals listed below and requested their comments on the draft *S2Q Guidelines*. The group represents a selection of national and international experts with an interest in, and knowledge of, the various quality management programs in place for surgical pathologists - in Canada or in other jurisdictions. Honoraria were provided to these individuals, to recognize the considerable time commitment required to review the Guidelines.

In general the comments provided by these experts were laudatory and supportive. Where possible, the comments provided were used to enhance the Guidelines currently being circulated to other stakeholders. Some comments will have to await the next phase of this project before they are dealt with.

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The Path2Quality Executive acknowledges and thanks Ms. Barb Lemay, ART, MLT, CQM/OE, CQA, (JAAS Quality Management) and Ms. Kathy Bugeja, MBA, (SPI Group) for their technical support and other help in the drafting of the *Guidelines.*

Further, grant support from Cancer Care Ontario and resourcing from LifeLabs' Medical -Scientific group provided substantial help with the first version of the *Guidelines*.

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Kindly provided by Kourtney Reich, Brant Community Healthcare System, Communications.