Pan-Canadian Quality Assurance Recommendations for Interpretive Pathology

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CANADIAN PARTNERSHIP AGAINST CANCER

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Pan-Canadian Quality Assurance Recommendations for Interpretive Pathology

On behalf of the Quality Initiative in Interpretive Pathology Thought Leaders Group

Message from Dr. John Srigley, Expert Lead, Pathology, Canadian Partnership Against Cancer

I am pleased to introduce the **Pan-Canadian Quality Assurance Recommendations for Interpretive Pathology**. This document aims to enhance patient safety through promoting more consistent and high-quality pathology quality assurance across the country. This is Canada's first attempt at developing a framework of quality recommendations for interpretive pathology that could be implemented into existing and developing provincial quality assurance programs across Canada.

I would like to acknowledge the invaluable contributions of the **QIIP Thought Leaders Group** (see list at the end of the section) for their guidance and expertise in the production of this document.

To develop this document, we have worked closely with the Canadian Association of Pathologists to adopt a rigorous and comprehensive pan-Canadian approach to the development of consensus. There has been wide consultation with provincial, national and international leaders and quality experts. This opus is intended to be a living document which will be updated at regular intervals as new concepts and evidence emerges.

It is our hope that this document will act as an informational and a decision-making resource that can be embedded into provincial quality programs to ultimately create a culture of enhanced patient safety in institutions delivering pathology services.

I encourage you to review this document in its entirety and look forward to our future collaboration to improve the quality of diagnostic services in Canada.

Dr. John Srigley
Expert Lead, Pathology, Canadian Partnership Against Cancer

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There were also several additional individuals who contributed to the development of the recommendations, including **Dr. Raymond Maung**, Pathologist, Interior Health Authority**, Dr. Brian Jollymore**, Pathologist, Nova Scotia Health Authority**, Dr. Kelly Guggisberg**, Past President, Alberta Medical Association, Laboratory Physicians Section**, Dr. Catherine Ross,** Chair, Patient Safety and Quality Assurance Section, Canadian Association of Pathologists, **Dr. Aaron Pollett**, Provincial Head, Pathology & Laboratory Medicine Program, Cancer Care Ontario, **Dr. Janice Zeng**, Pathologist and Quality Lead, Trillium Health Partners, **Dr. Kathy Chorneyko,** Clinical Lead for Pathology, Quality Management Partnership (Ontario).

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PAN-CANADIAN QUALITY ASSURANCE RECOMMENDATIONS FOR INTERPRETIVE PATHOLOGY FRAMEWORK

Contents

1 Background and Preamble

The ability to provide patients with the best possible treatment for a wide variety of diseases rests on a foundation of high-quality diagnostics. Analyzing cells and tissues removed via biopsies and surgical resections yields key information required for diagnosis, prognosis, treatment planning and predicting each person's likely response to therapy. While this applies to patients with a variety of cancers, it is also true for those with non-neoplastic conditions such as kidney, liver, gastrointestinal and respiratory diseases.

In recent years, a number of events in Canada have raised questions regarding the quality of diagnostic interpretation and patient safety—both in the area of anatomical pathology and in diagnostic imaging. Some of these events have led to large-scale retrospective case analysis activities; others have been the subject of formal government investigations and judicial inquiries [1-3]. Additionally, the importance of improving diagnosis and reducing diagnostic discrepancies in health care was further highlighted in the recently released report by the Institute of Medicine, entitled "Improving Diagnosis in Health Care" [4]. Building a culture around high quality diagnostic services is a key enabler in enhancing patient safety [5].

Despite these recent events, laboratory medicine has been a leader in patient safety, quality assurance (QA) and quality improvement (QI) domains for the past 50 years. Public and commercial laboratories across the country are highly regulated and have vigorous quality programs to deal with the technical, clerical and administrative aspects of laboratory practice.

But while the technical and administrative aspects of these systems are generally well-understood and properly regulated, quality systems governing the interpretive aspect of laboratory practice—more specifically anatomical pathology and related disciplines—are less well developed and less standardized. For this reason, there is growing interest at the provincial, national and international levels, in developing a more standardized approach to QA in interpretive pathology.

The Pathology Testing Cycle

Quality systems in pathology and laboratory medicine are complex. The pathology testing cycle has traditionally been broken down into three phases:

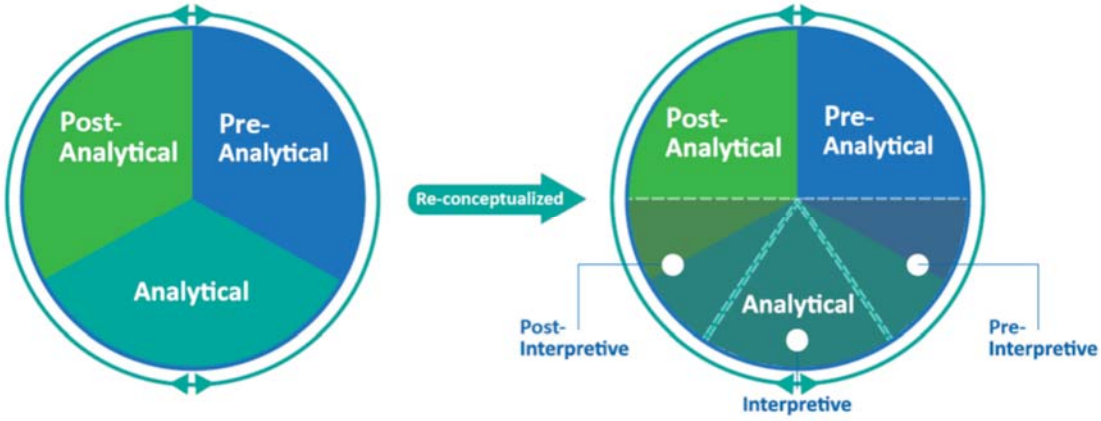
- The *pre-analytical phase* includes elements such as test selection, specimen procurement, documentation, requisitions, delivery, specimen preparation and fixation.
- The *analytical phase* includes both the technical aspect of the analysis related to the production of high-quality slides and the interpretive analysis generally carried out by a pathologist. The results of the analysis are documented in the pathology report and results communicated with the physician or surgeon.
- The *post-analytical phase* includes aspects of transcription, report delivery and interpretation by the requisitioning clinician.

Laboratory accreditation programs, which exist in each province, help to assure that the laboratories are running a high-quality and safe practice across all phases of the pathology testing cycle—at least at the technical, clerical and administrative level.

For the purpose of this **Quality Initiative in Interpretive Pathology (QIIP)** project, the pathology testing cycle has been re-conceptualized from the perspective of the pathologist as medical practitioner. This concept includes pre-interpretive, interpretive and post-interpretive phases (Figure 1).

- In the ***pre-interpretive*** phase, the pathologist assesses elements such as specimen identification, presence of clinical information, the quality and completeness of the gross description, and the quality of slides prepared.
- The ***interpretive phase*** involves the actual analysis of the case material. This covers the following key activities: correlation of the morphology with the clinical and imaging information; correlation with prior or concurrent pathology results; sharing the case with colleagues (peer review); taking additional blocks from the specimen; and utilization of ancillary techniques such as immunohistochemistry or molecular diagnostics to further work up the case. The product of the interpretive phase is the pathology report.
- The ***post-interpretive phase*** involves ensuring that the pathology report maintains proper patient identification and is timely, accurate and complete. This phase also deals with delivering the report to a referring physician(s). This may be done electronically, in hard copy and/or verbally (where appropriate).

Figure 1: The Pathology Testing Cycle



An up-to-date look at QA programs across Canada

Robust QA programs that incorporate technical, administrative and interpretive aspects of QA are integral to accurate pathological diagnosis, quality of care and patient safety. One of our initial steps in the QIIP project was to undertake a current state analysis of the various technical/administrative and interpretive QA programs that exist across the country [6].

All provinces have technical/administrative laboratory accreditation programs in place. Some are linked to physician regulatory bodies (e.g., British Columbia, Alberta) and others are independent of the regulators and are administered by the Institute of Quality Management and Healthcare (IQMH) and Accreditation Canada (e.g., Ontario, Newfoundland).

Jurisdictional QA systems related to interpretive pathology are more variable and less well developed. Only two provinces (Alberta and Prince Edward Island) have coordinated provincial-level quality assurance programs that relate to interpretive aspects of pathology. Several other provinces (Newfoundland and Labrador, New Brunswick, Nova Scotia, Quebec, Ontario, Manitoba and Saskatchewan) do not have existing QA programs but have plans to implement them in the near future. British Columbia does not have a program and there are no specific plans to implement such a program in this jurisdiction. Despite the absence of a provincial QA program in a number of provinces, some institutions in these provinces and organizations such as Diagnostic Services Manitoba have robust interpretive QA programs. Some provinces have also incorporated interpretive elements within their technical laboratory accreditation programs. For instance in British Columbia, components of its DAP (Diagnostic Accreditation Program) do deal with peer review of cases. In Manitoba, the College of American Pathologists (CAP) accreditation program is used. This program includes both technical/administrative aspects of the pathology testing cycle and some interpretive aspects.

How is Canada doing compared to other countries?

In other countries (specifically the United Kingdom, Australia, New Zealand, Ireland and the United States), colleges of pathology have assumed a significant leadership role in developing interpretive quality guidelines and recommendations.

The most developed of these is a Histopathology National Quality Improvement Programme overseen by the Faculty of Pathology of the Royal College of Physicians of Ireland. This program has established quality guidelines and recommendations and regularly monitors QA metrics in pathology. (These data are electronically submitted by all pathology laboratories to their governing college.)

In Canada, it is less clear where the responsibility for developing and maintaining interpretive pathology practice guidelines lies. This work is outside the scope of the Royal College of Physicians and Surgeons of Canada whose mandate relates mainly to post-graduate specialty certification and continuing professional development.

The Canadian Association of Pathologists (CAP-ACP) is the only national-level organization that represents anatomical pathology. In recent years, this group has been involved in guideline development, mainly through their patient safety and quality assurance (PSQA) section.

The Genesis of the Current Report

These QIIP recommendations emerged from a partnership between the Canadian Partnership Against Cancer (the Partnership) and CAP-ACP.

The goal of this partnership was to develop a comprehensive framework document for interpretive pathology QA. Key steps taken towards meeting that goal are described below:

- Establishing a national thought leaders group with representatives from each province and CAP-ACP
- The completion of a survey related to QA in pathology
- Conducting an environmental scan of the literature which yielded about 50 documents related to institutional, regional, provincial, national and international QA programs
- Providing input into CAP/Association of Directors for Anatomic and Surgical Pathology guideline on Interpretive Diagnostic Error Reduction Through Targeted Case Reviews
- Developing a quality framework for interpretive QA and utilizing a modified Delphi process to arrive at consensus regarding the recommendations presented in this document
- Seeking input from a wide range of stakeholders through targeted and public reviews to fine tune the recommendations presented herein

Statement of Scope

The quality framework recommendations presented in the following sections relate to the interpretive (medical consultative) aspect of pathology practice. While they principally apply to surgical pathology including contemporary ancillary techniques such as immunohistochemistry and molecular pathology, they are also very applicable to other subspecialty areas including cytopathology and morphologic hematology (blood films, bone marrows). These latter specialties have additional specialty-specific QA measures that are recommended through their respective specialty societies (e.g., Canadian Society of Cytology) and provincial accreditation bodies. Additionally, while this framework applies to the practice of pathology, there may be additional nuances not covered in this framework that need to be taken into consideration when addressing highly specialized practices (e.g., pediatric pathology, neuropathology, hematopathology).

The framework document firstly deals with the overarching foundational elements that need to be in place to support a quality system for interpretive pathology. Detailed elements of the pathology testing cycle from the perspective of the practicing pathologist are considered in some detail. This is followed by a section related to the internal Quality Assurance Policies and Procedures (QAPP) that need to be in place to assure interpretive QA. External quality assurance measures such as external quality assessment (proficiency testing) and pathologists' peer review assessment are then covered. Finally, there is a recommendation around the approach to situations where there has been an "expression of concern" raised regarding a pathologist's performance.

Please note that that the implementation of the framework recommendations contained within this report require considerable human, physical and technical/electronic resources. It is not the purpose of this report to specifically address the magnitude of resources required or to advocate for them. This set of recommendations is meant to provide guidance, intended to steer away from a 'blame and shame' approach. It should be contextualized according to local health system characteristics. In Canada, healthcare is delivered through 13 separate provincial/territorial systems. The incorporation of these recommendations into existing quality programs is left to individual jurisdictions to negotiate with their appropriate authorities. It is our hope that this document can be used as an important tool in discussions and negotiations with provincial bodies, as well as to create a culture of patient safety in institutions delivering pathology services across Canada.

2 Overarching Foundational Elements

2.1 Governance/Oversight – Jurisdictional

All pathologists share the aim of providing patients with safe, high quality pathology services. Good governance and a robust quality management system are fundamental to this aim. This system should include the measurement and reporting of rational standardized quality metrics for pathology. A provincial governance and quality management program can establish these metrics, develop benchmarks, and make system level recommendations that help ensure compliance with standards in interpretive pathology and QI activities at all localities [7-11].

The public is increasingly aware of the importance of high quality pathology services (and the consequences of failure in this regard [1, 12]), and so communication about this aspect of their care is important. Such communication can be enhanced by involving lay individuals on quality committees and boards of directors (at both the provincial as well as local level) and by other communication strategies that include best practices.

2.1.1 A governance structure should be in place to oversee and support the quality system for pathology services in each province or territory. This should include:

- **A quality system steering/oversight committee to provide overall governance of provincial pathology quality assurance (QA) programs and provide oversight of the institutional committees**
- **Development of an overarching quality plan for pathology**
- **Development of standardized nomenclature and quality metrics**
- **Communication with users of pathology services, including clinicians, patients and the public about the quality of pathology services**

2.2 Governance/Oversight – Institutional

Institutional-level quality oversight should be in place to ensure patient safety and professional medical practice. The rules and regulations for dealing with technical aspects related to specimen preparation are different than the interpretive aspect of the professional practice of medicine. For this reason, distinct oversight of these two components should apply. The interpretation of a specimen is a medical act and a corresponding system should be in place to address these aspects of QA.

A main role of a Professional/Interpretive Quality Committee will entail the development of a Pathology Professional Quality Management Plan. This plan should include:

- A purpose statement with goals, including:
  - Support for continuous QI
  - Encouraging timely, accurate and complete pathology reports
  - Help to minimize discrepancies and enhance patient safety

    - Rules that are fair and objective and that focus on improvement and education
    - Protection of professional and patient privacy
    - Meeting regulatory requirements and standards for good medical practice
- Policies and procedures that encompass the entire pathology workflow process, as well as procedures for monitoring related outcomes
- How all processes are regularly measured, monitored, and improved as necessary

This Professional/Interpretive Quality Committee and its activities should be consistent with provincial/territorial legal acts related to QA activities. Monitoring and reporting on performance should be a key activity within the Committee. Indicators should be based on approved policies and procedures that encompass the entire pathology workflow process [7, 9, 13, 14].

2.2.1 Each institution delivering pathology services should have the following in place:

- **A Laboratory Medical Director, or appropriate pathologist designate, fully supported by the organizational governance and able to fulfill fiduciary duties, who is accountable and responsible for the institutional quality program**
- **Appropriate oversight of both technical/administrative and interpretive activities. These components may fall under the umbrella of a single QA committee or be provided by two committees**
- **Technical/Administrative Committee:**
    - **A Laboratory QA Committee with authority to provide oversight for technical laboratory services from the health authority including the following element:**
        - **Implement a quality management system that includes policies and procedures for achieving optimal results and ongoing quality improvement**
- **Interpretive Committee:**
    - **A Professional/Interpretive Quality Committee, chaired by an appropriate pathologist, reporting to an institutional-level senior quality committee, that is responsible for implementing and monitoring of QA within the laboratory specialty; laboratory directors and laboratory/divisional heads implement and monitor the practice guidelines and/or standards developed including:**
        - **Development of a quality plan and implementation of QA policies**
        - **Regular review of QA metrics and monitoring of compliance**
        - **Reporting on the performance of the quality management system and areas for improvement**
        - **Provision of a forum for peer discussion and resolution of quality issues**
        - **Identification of acceptable QA targets/metrics**

2.3 Linkage to Existing QA Programs – Jurisdictional & Institutional

Governance and quality management structures vary between jurisdictions, organizations and institutions. Regardless of the structure in a given jurisdiction, the provincial QA plan for pathology services should be integrated with local and regional quality management structures. The goal is

to avoid inefficiency and duplication of effort and to ensure appropriate hierarchical reporting throughout health care organizations and governance bodies. In the event that the technical/administrative and interpretive quality committees are separate, the two should work closely together [7, 9].

2.3.1 The QA plan should integrate with other institutional and provincial quality management systems such as hospital quality of care programs, hospital accreditation and provincial laboratory accreditation programs.

2.3.2 All institutions providing pathology services should be accredited; the quality management processes for the technical work conducted should be compliant with national and provincial organizations and programs.

2.4 Human Resource Plan/Workload Measurement/Staffing

Adequate staffing (medical, scientific, technical and support staff) is a necessary though not sufficient requirement for the provision of timely, high quality pathology services [5]. The laboratory team should be made up of a sufficient number of qualified members with the appropriate expertise depending on the size and complexity of the organization and volume of laboratory services that are delivered. The responsibilities and accountabilities of all team members should be clearly outlined.

The modern healthcare workforce works collaboratively in a team based fashion, with clear descriptions of work and also with increasingly formalized performance expectations [8]. Appropriate training, skills and knowledge for the work required are critical, as is the determination of the specific staffing composition in an institution (e.g., the need for subspecialists, the appropriate supervision of pathologists' assistants (PAs) and residents, the conduct of quality management activities, administrative duties, committee participation, etc.).

A robust workload measurement system is vital to ensuring adequate resourcing. Anticipating and planning for a foreseeable change in staffing needs is an integral component of a human resource plan. Health care budget constraints, changes in the level and type of service provision and in scope of practice, and the aging of the workforce as well as the overall aging of the general population are all factors that may be incorporated in human resource plans [15-17].

2.4.1 A human resource plan for medical, scientific, technical, and support staff should be in place to address the following:

- **Laboratory services, including administrative and academic responsibilities.**
- **QA activities in the laboratory**
- **Anticipating and responding to changes in staffing (e.g., staff turnover, retirement)**

2.4.2 An effective workload measurement system should include the following:

- **A transparent system that is based on the specimen volume and complexity, ancillary investigations (immunohistochemistry, molecular testing, etc.), reporting requirements and clinical information**
- **Activities related to QA, as well as patient care**
- **Other professional activities including administrative and academic ones**
- **Evaluation of laboratory and individual pathologist workload levels to ensure adequate staffing**

At the local and organizational level, it is possible to develop new ways of working that will free pathologists from tasks that can be done by other providers such as histotechnologists and PAs. This will allow pathologists to focus on interpretation and diagnosis [18]. For this reason, various authorities are asked to consider expanding the role of other professionals such as PAs, allowing them to do tasks traditionally performed by pathologists [19]. CAP-ACP has recently set up a certification process for pathologists' assistants in Canada. As such PAs should always be under the direction of a qualified pathologist who is medically and legally responsible for the work performed on her/his behalf.

2.4.3 For maximum efficiency, pathologists require adequate numbers of competent technical staff, secretarial staff and qualified and skilled pathologists' assistants (PAs).

2.5 Appropriate Training, Licensure, Credentialing and Continuing Professional Development for Pathologists

The public expects that pathologists will not only have achieved competence at the end of their period of formal training, but they will maintain that competence throughout their careers and will undertake only those professional activities for which they have appropriate expertise. Effective continuing medical education and professional development are necessary if pathologists are to keep up with and improve professional performance. They are also vital to ensure that pathologists can adapt to the changing needs of the work environment and to continue developing their professional careers [20].

Regulatory bodies, professional organizations and health care organizations are increasingly requiring formal demonstration of continuing education and professional development activities. Pathologists must meet the continuing education requirements of the Royal College of Physicians of Surgeons of Canada and their provincial regulatory bodies and associations, as applicable. Such activities are also important to conducting a safe and high quality pathology practice [20, 21]. These activities may be conducted through a variety of means, but all require dedicated resources.

2.5.1 Each institution should have a credentialing program in place to ensure appropriate training and certification of pathologists.

2.5.2 All pathologists should have the appropriate knowledge, skills and abilities required for the types of services they are expected to deliver. When appropriate expertise is not available, cases should be referred out.

2.5.3 Pathologists must participate in continuing education and professional development opportunities, to maintain their licensure, certification and privileges and to ensure quality of care. Continuing professional development should meet changing needs. These include needs related to assuming new roles within the department, the deployment of new technologies, changes in expected competency requirements and new laws and regulations. Such opportunities for growth should be supported by each pathologist's institution.

2.6 Privacy, Confidentiality, Disclosure and Duty to Report

Maintaining confidentiality is fundamental to providing the highest standard of patient care. Patients have a legal right to privacy and confidentiality regarding all aspects of their diagnosis and treatment, including how their health care information is maintained and shared. Physicians must act in accordance with all of their professional and legal obligations related to these patient rights and expectations.

Patients who understand that their information will remain confidential are more likely to provide their physicians with complete and accurate health information, which in turn, leads to better treatment advice [22, 23].

Disclosure of adverse events is based on principles of safety, openness, transparency, accountability and compassion. A patient safety culture should be advocated where there is a no "blame and shame" approach to the providers involved in the quality improvement and disclosure process. Healthcare providers have the legal and ethical obligation to disclose information to patients about events that have, or could, affect their health and risk of harm. Failure to disclose such information reflects upon the institution, providers, and the health system as a whole, and public confidence is undermined [24-26]. There is variation among jurisdictions with respect to which types of QA activities are legally protected.

2.6.1 Appropriate policies and procedures should be in place at all institutions delivering pathology services to address privacy and confidentiality of health information as well as disclosure and duty to report in cases of an adverse event.

- **Appropriate institutional policies should be in place to ensure the privacy and confidentiality of health information throughout the QA process**
- **Policies and procedures for disclosing any adverse events discovered during QA activities to patients should be in place, and should comply with legislative requirements in each province/territory, if applicable**

2.7 Informatics and Quality Documentation Systems

The modern pathology laboratory depends on a reliable information infrastructure to register specimens, record gross and microscopic findings, regulate laboratory workflow, formulate and sign out reports, disseminate them to the intended recipients across the whole health system, and support QA measures [27].

An effective information system with province- or territory-wide data on performance measures will provide information that can be used to make the system more efficient and drive decisions. An integrated information system will help ensure greater consistency in transfers of patient care between different centres within the same organization or transfers to different organizations in the same province or territory [18].

Documentation of all aspects of a quality management program is of the utmost importance. QA programs require the development of guidelines, terms of reference and various associated QA policies and procedures in surgical pathology. These documents should be prepared in a standard format to ensure consistency and completeness of documentation with appropriate version control. QA programs also require appropriate reviews and monitoring, which must be documented according to predefined policies and procedures. The results of reviews and monitoring should be regularly captured by quality management program managers and easily accessible for audits [7].

2.7.1 There should be a documentation system to capture all interpretive pathology activities, including QA activities.

2.7.2 There should be a laboratory information system (LIS) in place to support pathology case management.

- **Where possible, the LIS should be based on standard principles to allow for comparison of information contained between LISs and to facilitate communication with appropriate provincial or national collaborative programs.**

2.7.3 Access to documentation of QA activities should be restricted to appropriate individuals as per institutional/jurisdictional policies.

Support for synoptic reporting

Synoptic reporting has proven to be a best practice for medical reporting and electronic health records management. Electronic synoptic reports minimize medical record errors, streamline clinician workflows and improve the quality of patient care [28-31]. Synoptic reporting for various types of malignancies has become standard of care and is required by several provincial jurisdictions and accrediting agencies [19, 25, 32].

With synoptic reporting, both clinical and research relevant data elements can be captured. Such uniformity of data capture lends itself to subsequent ease of data viewing and extraction, leading to the rapid production of standardized, high-quality data. With more powerful capture of information, key data elements stored in the LIS relational database can be quickly accessed to provide the desired information for research and also for more personalized cancer management [33].

In order to achieve this, investments should be made to acquire the appropriate software and modules to generate synoptic reporting data and allow the integration of these data into existing laboratory information systems and the organizational and/or provincial electronic health records. Resources should be made available to pathology departments to enable training on the use of the synoptic software by all those involved and to provide ongoing technical support and necessary updates.

In order to prevent medical discrepancies and to assure the integrity of cancer databases, every newly diagnosed significant malignancy should be linked with one synoptic report [34, 35].

2.7.4 Each laboratory involved in reporting cancer cases should have appropriate and up-to-date software and modules to generate synoptic reports in a standardized format. This format ensures that information is captured in discrete data fields, and allows the integration of synoptic data into existing laboratory information and/or institutional health information systems.

2.7.5 The following tools and resources should be made available to all pathologists and other health care professionals who are involved in data entry to ensure a complete and efficient synoptic reporting system:

- **Adequate education, training, and technical support for the various functions of the synoptic reporting system**
- **A mechanism to integrate electronic synoptic pathology data into existing provincial and national e-Health infrastructure, such as provincial electronic health records and provincial cancer registries**
- **National standards and the most recent cancer protocols and checklists, and a synoptic software that is capable of integrating necessary updates**

Support for QA activities

QI depends on developing a culture of measurement and then using measurement findings to inspire change. To be able to improve quality, the system should have the capability to measure and monitor the quality of services and manage performance, including ways to give providers regular, constructive feedback on the quality of their work [18].

Data should be based on common definitions and indicators. There should be a reliable mechanism to collect, analyze and share data which allows us to measure the impact of changes in processes and practices [18]. Clearly, laboratories will require a number of infrastructure supports or resources to collect and submit quality indicator data. [7, 27, 36, 37].

2.7.6 The Information System (IS) should be enabled/in place to generate indicators to measure completeness and compliance with necessary clinical indicators.

2.7.7 The following resources and elements are essential to ensure successful implementation of a QA program:

- **Mechanisms to collect, analyze and share quality indicator data**
- **A suitable IS that can facilitate QA processes**
- **Sufficient personnel (professional and support staff)**
- **Information technology resources to develop and maintain the program**

Support for workload capture

In recent years, the field of pathology has evolved from providing a diagnosis to capturing and sharing other information related to prognosis, therapy and management. While advances in knowledge and the emergence of new immunologic, molecular and other techniques have increased accuracy, they have also increased the complexity of the diagnostic information.

The use of checklists has created more labour-intensive information gathering and reporting by pathologists. New QA processes, such as mandatory second opinions on cases of first-diagnosed malignancies and other QA measures have further increased demands on pathologists' time [38]. Hence, there is a need for a comprehensive system that is capable of objectively determining the pathologist workload.

The complexity level for each specimen is based not only on the time needed to sign out the case but also on the medical value to clinicians and patients, clinical urgency, degree of difficulty of interpretation and medico-legal responsibility [16].

Appropriate workload measurement should be in place. Such measurement may help determine appropriate resources needed to develop new approaches of working that will optimize the scope of practice for pathologists and other relevant health professionals [18].

A workload measurement system should also acknowledge the role that pathologists play in the academic and administrative mission of many hospitals [17]. Further, there is a portion of work that each pathologist performs that is not case-specific (i.e., involving direct clinical care and/or, generating a pathology report). This other work includes providing consultative services; taking part in research-related activities; performing various general office functions; and overseeing certain functions of the department and its activities (e.g., IHC laboratory, Pap screening programs, acquiring new equipment or LIS). Workload may also include participation in administrative meetings and multidisciplinary forums that guide patient management [17, 39].
All these activities should be factored in when determining the overall workload in a practice.

To increase efficiencies, every effort should be made to ensure that workload parameters are integrated into and can be retrieved from the LIS. Such efforts should enable the automated capture of these parameters from the LIS without the direct involvement of pathologists or supporting staff [15]. These systems provide the advantage of saving time, as well as increasing reliability and objectivity [15].

An adopted workload measurement system should meet the following criteria [16, 40]:

- It should allow for the collection, auditing, analysis, storage, documentation and communication of data
- It should be capable of covering the various aspects of a pathology practice, including personalized medicine and multidisciplinary patient-centred rounds, and reflecting the complexity of the work involved on an on-going basis. Consultations which have direct patient care implications include: QA/QI activities; academic (scholarly and teaching/training); and administrative and oversight activities
- It should be easily adapted to the practice patterns of an institution (e.g., the presence of pathologists' assistants and residents)

- If possible, it should allow benchmarking with other practices provincially and nationally

2.7.8 There should be adequate human, financial, and IT resources to implement and sustain a workload measurement tool designed to determine if pathology practices are appropriately resourced.

Support for new technology

To monitor and ensure quality of interpretive pathology services, there is a need for better intercommunication within and among local, regional and university laboratories. Most pathologists use traditional methods such as regular mail, phone and fax to inform colleagues of their analysis or diagnostic decision.

However, new technologies such as regional clinical information management systems, digital imaging and telepathology are starting to play a greater role in service delivery. This is achieved by linking all laboratories in a region or a province or territory into a virtual network to allow pathologists to share queries and expertise [18].

2.7.9 The laboratory should have adequate resources and qualified and competent medical and technical staff to implement emerging new technologies that could improve the quality of patient care whenever deemed necessary (e.g., digital pathology, telepathology, clinical information management systems).

2.8 Other Foundational Resources

A pathologist's work is associated with potential health hazards including injuries involving infectious human tissue and ongoing exposure to chemicals that may be carcinogenic (such work-related biohazards risks are covered extensively in other QA and laboratory accreditation documents). Pathologists also spend long periods of time using microscopes and computers [41]. In the pathologist's office, the association of prolonged microscope use with the development of chronic pain syndromes has been recognized for decades. Pathologists and other microscopists require adjustable and ergonomically designed workstations, chairs and microscopes in order to reduce their risk of developing a cumulative trauma disorder (CTD) [42-46].

2.8.1 There should be adequate resources (human, space, equipment, communication tools, other supports) in place to enable the pathologist to work in an optimal and safe environment.

- **Pathologists require a quiet office, with adequate space, efficient design, sufficient illumination and appropriate ventilation**
- **Workplace and equipment should be designed or positioned to reduce the risks of ergonomic distress disorders and accidents**

Isolation is another feature of pathology practice in many settings, which can be problematic to some individuals. All pathologists providing professional interpretations should be part of a

community of practice. While such a community may be located in close physical proximity, it can also be geographic (i.e., pathologists working within a particular region) or focused on a particular type of pathology practice (e.g., pathologists who specialize in looking at specimens from particular organs) [18].

2.8.2 Pathologists should not work in isolation. Their offices should ideally be located in close proximity to other colleagues or linked through technologies that facilitate sharing of cases and inter-professional communication, where possible.

Appropriate equipment

The process for selecting laboratory equipment should take into account the type of services provided, the knowledge and skills needed, occupational health and safety protocols, the latest research and evidence on advances in technology and cost/benefits ratio. Proper environmental conditions (e.g., temperature, humidity, and ventilation) are essential to ensure staff safety as well as the optimal function of equipment. Engineering departments and laboratory managers should have a complete and up-to-date record of equipment inspections, calibrations, maintenance and repairs [8].

2.8.3 Microscopes and equipment used in the laboratory should be of high quality and be cleaned and maintained on a regular basis. All equipment should be replaced/updated on a regular basis, as appropriate.

Communication tools

A comprehensive health record requires clinical, treatment and diagnostic data to be integrated and readily available to health care providers. To that end, accurate and timely communication are of the utmost importance in delivering high quality pathology services; hence, the communication system should support the pathologist in his/her work in the most efficient manner possible [47].

Means of communication that are frequently used by pathologists include: computers with a reliable internet connection; essential and current office software and email applications; telephone and voice messaging systems; paging systems and/or wireless services; and faxing and scanning equipment.

2.8.4 Pathologists should be provided with an appropriate communication system commensurate with the industry standard.

2.8.5 Information systems should be able to integrate pathology reports and diagnostic data into the institutional electronic health records and should be able to share this data between institutional-based pathology departments and community-based practices.

Decision support tools

Pathologists should stay up to date with current knowledge and practice to deliver high quality pathology services. Tools that aid pathologists to make an informed, evidence-based and accurate diagnosis include, robust Internet access, up to date textbooks and relevant pathology journals, and up to date evidence-based standards and clinical guidelines to improve practice. In addition, unrestricted access to "expert" consultants provincially and nationally is important for high-quality patient care.

2.8.6 All practicing pathologists should have access to the most current decision support tools to remain up to date on the most recent evidence and advances in the field to make an informed and accurate diagnosis.

2.8.7 There should be proper processes and adequate resources to perform ancillary testing and/or to seek second medical opinions, internally or externally.

3 Interpretive Pathology Testing Cycle

The interpretive pathology testing cycle can be broken down into activities that generally occur prior to slide analysis (pre-interpretive), those that occur during the diagnostic (microscopic) assessment including the consideration of prospective peer review and those occurring after a diagnosis has been made (post-interpretive). The latter include activities that should be undertaken prior to case verification and release and also those related to communication and report delivery.

The implementation of error reduction strategies is important for patient safety. Given the subjective nature of interpretive pathology, the expectation of a zero error rate is unrealistic; however, elements and processes can be in place to significantly reduce the chances of expected discrepancies and improve patient safety.

A series of patient safety checklists have been developed by Path2Quality which is a collaboration between the Laboratory Medicine Section of the Ontario Medical Association and the Ontario Association of Pathologists. These checklists are part of the Standards2Quality document (currently version 2.0, 2013) and are a useful way of breaking down the interpretive pathology testing cycle into a series of steps/activities that when followed will help to assure diagnostic quality and patient safety. The QIIP thought leaders have endorsed these checklists and with permission of Path2Quality they have been included as Appendix A.

3.1 Pre-Interpretive

Accrediting organizations require that each institution, in conjunction with the pathologists and appropriate medical staff departments, develop a written policy that addresses which specimens do not need to be submitted to the pathology department and which specimens may be exempt from a requirement for microscopic examination. In some jurisdictions, regulatory bodies have policies addressing tissues exempt from microscopic assessment. The institutional policy must be in compliance with the regulations [32, 48-50].

3.1.1 There should be policies and procedures in place to define specimens that are exempt from submission to the laboratory from the operating room and those specimens who do not require a microscopic assessment.

Identification errors can occur during any part of the testing cycle; however, most occur during the pre-analytic phase. The pathologist should be vigilant in reviewing the case materials before rendering a diagnosis and question any potential demographic or labelling problem that is encountered.

Certain unavoidable human factors can lead to identification errors. These include fatigue and distraction. Using technological supports (ranging from bar-coded specimen labels to radiofrequency identification tags) can be incorporated into protective systems that have the potential to detect and correct human error and reduce the frequency of errors in identifying patients and specimens [51].

Problems that have been shown to lead to errors include batch work, pre-labelling and the inability of laboratories to sufficiently segregate cases, specimens, blocks, and slides, so they are not mixed up at points of tissue transfer. The avoidance of batch work and the utilization of a pull system, as incorporated in lean production methods, are important principles. Accessioning and processing specimens and blocks one-by-one using bar code scanning prompts for identification can lower the rate of mislabelling errors [52].

It is important to understand that case mix-ups often result from failures along the patient care pathway. This pathway involves many individuals outside the laboratory. Therefore, significant improvement in correct specimen identification requires acceptance of this goal across an institution including its sources of referral. A substantial awareness campaign and the use of stringent standards and personnel expectations both within the laboratory and at specimen source are required to achieve this goal [53, 54].

3.1.2 Measures should be in place to minimize the risk of case mix-ups, including:

- **Multi-departmental (clinical departments in addition to anatomical pathology) policies that reduce the risk of case mix-ups**
- **A comprehensive bar-coding system, or similar positive patient identification system, to track specimens from time of collection through the pathologist's office to report release and electronic delivery**

It is important that the pathologist has a clear understanding of the macroscopic features pertaining to a case prior to microscopic interpretation. The gross features need to be clearly conveyed in the recorded description and there needs to be a detailed list of the blocks submitted for microscopic analysis. The CAP Laboratory Accreditation Program Anatomic Pathology Checklist recommends that: "All macroscopic tissue gross examinations are performed by a pathologist or pathology resident, or under the supervision of a qualified pathologist." (ANP.11600)[10]. The work of PAs or grossing technologists is considered a delegated medical act.

3.1.3 The gross examination must be performed by a pathologist or by a pathology resident or other qualified personnel, such as a PA or grossing technologist, who are under the supervision of a pathologist.

Patient and specimen identification are critical elements of patient safety in surgical pathology. Inadequate specimen identification may lead to patient injury from wrong diagnosis, wrong clinical management, or delay in diagnosis [52]. Studies have also shown that inadequate clinical

information for diagnosis, which is not uncommon (2-20% of all cases), results in clinically significant changed or amended diagnoses [55]. In addition, one area of increasing liability in surgical pathology is lack of clinical information or erroneous information [56].

The analytic phase of the anatomical pathology testing cycle begins with gross examination of the specimen and ends with the diagnosis. All aspects of technical preparation of the specimen, including histological sectioning and special staining need to be examined for their level of quality, because the accuracy of the final diagnosis is a measure of all of these sequential technical steps [53, 54].

3.1.4 Prior to the pathologist's assessment of a case, the following should occur:

- **Patient demographics, specimen identification and integrity should be reviewed and verified**
- **Clinical information included on the requisition should be reviewed; if any or all of this information is missing, its absence should be documented**
- **In cases where additional clinical information is deemed necessary, the pathologist should review the electronic medical records (where available), results of diagnostic imaging and/or laboratory studies or contact the referring physician or other appropriate personnel**
- **Discrepancies should be managed in line with the relevant Quality Assurance Policy and Procedure (QAPP)**
- **The quality of technical preparation should be monitored and any concerns, errors or deficiencies should be documented, with appropriate corrective actions put in place**

3.2 Diagnostic Assessment

Diagnostic assessment involves the pathologist analyzing slides microscopically (except for cases exempt from microscopic assessment) and correlating the findings with the clinical and macroscopic features in order to arrive at a diagnosis.

A review of all pertinent microscopic material is a standard of practice, with specific exemptions [10]. Sequential analysis of cytologic and histologic specimens may be critical in patient management and follow-up. Efforts must be made to routinely review pertinent current and previous material [10].

3.2.1 A pathologist must perform all microscopic examinations, with the exception of cervical cytology and peripheral blood smears. The cervical cytology and blood smears that must be reviewed by a pathologist should be determined based on guidelines from the Canadian Society of Cytopathology, the Canadian Hematology Society and other organizations.

3.2.2 Relevant clinical information must be correlated with the gross and histologic features. Relevant previous and concurrent pathology results/findings, including intra-operative consultations, should be sought prior to completing the case.

3.2.3 The pathologist should have access to and make use of additional studies as required before making the appropriate diagnosis. These could include, but are not limited to, additional blocks, block levels and special stains, immunohistochemistry, molecular tests and access to internal and/or external expert opinion/consultation.

3.3 Prospective Peer Review

The purpose of the prospective peer review process is to prevent patient harm and promote diagnostic quality. This is achieved by identifying potential diagnostic discrepancies before such discrepancies affect the quality of care and jeopardize patient safety. Peer review also identifies error-prone pathologists or systems and allows for appropriate corrective action. The results of the peer review may require a pathologist to seek additional clinical information or order additional ancillary testing (refer to 3.2.2 and 3.2.3). It is recognized that pathologists may be in solo practice; however, these pathologists should not practice in isolation. It is important for solo practitioners to engage in prospective peer review and this process may be enabled by new technologies (e.g., digital pathology).

The success of a peer review system requires that meaningful data be generated through an appropriate and acceptable review process, and that the system is routinely used because it has been thoroughly incorporated into everyday practice. It is also vital that participation in the program is unencumbered by potential civil litigation liability. (Since overall significant discrepancy rates in interpretive pathology are low, statistical analysis indicates that meaningful data can only be derived from targeted review of difficult or significant and unexpected diagnoses).

Analysis of patterns of pathologist discrepancies indicate that discrepancy rates drop precipitously when prospective consultation takes place [32]. The critical role of pathology peer review is to promote a systemic and individual pattern of consultative practice for difficult and significant and unexpected diagnoses, and to prohibit diagnosis in isolation. Furthermore, peer review should seek to identify systemic practices that are prone to discrepancies and/or vulnerable to catastrophic failure [32, 57-60]. Depending on specific circumstances, the peer review process may be done in a blinded or non-blinded fashion and may be prospective or retrospective through intra-departmental and/or external consultation.

3.3.1 There should be a review process in place for pathologists to seek peer consultation relevant to their practice setting in a timely manner. This would include intra-departmental and/or external consultation. The review process should work as follows:

- **Prospective peer review of diagnostic work in selected cases to minimize reporting discrepancy and eliminate significant errors before they affect patient care decisions or patient outcomes. Such peer review may also help to identify system flaws and individual pathologist's knowledge deficits, allowing corrective action to be taken**
- **Retrospective peer review, including multidisciplinary case rounds and case look-backs (during the process of evaluating current cases) to optimize patient care decisions and patient outcomes. Such retrospective peer review would help to identify systemic causes of discrepancies, especially false negative diagnoses, allowing corrective action to be taken**
- **All forms of intra- and extra-institutional peer review should include the principles of professionalism, independent analysis, formal documentation, prospective discrepancy identification, targeted review of difficult or significant and unexpected diagnoses, incorporation into normal laboratory work flow, resolution of diagnostic discrepancies, and protection from civil legal action**

3.4 Post-Interpretive– Pathology Report

Completeness and accuracy

Pathology reports are highly complex, and standardized processes are necessary to ensure accuracy, completeness, appropriate formatting/ usability and clinical relevance. Reports should be in a standardized format and structured (synoptic) reporting protocols should be used where appropriate [47, 61, 62].

3.4.1 Prior to verification, the pathologist should:

- **Re-confirm positive patient/specimen identification**
- **Check the report for accuracy, completeness and appropriate formatting/ usability**
- **Ensure the report is in a standardized format and contain standard terminology, scoring, grading and staging systems, and clear language is used**
- **Reconcile discrepancies between elements of the report**

Timeliness of the pathology report

Many factors contribute to the turnaround time of a report following review of an anatomical pathology specimen. Timely communication of results to the treating physician enables treatment or other medical interventions to begin and reduces patient anxiety caused by waiting to learn about the findings. Turnaround time for the reports of anatomical pathology specimens is a central concern of all anatomical pathology QA standards and programs [7, 18, 53, 63, 64].

3.4.2 The pathology report should be completed within a timeframe that is aligned with the clinical urgency, specimen type, and whether additional investigations and consultations are likely to be required.

Report delivery

Patient confidentiality is included in policies at all levels of health care and is also a standard in some accreditation programs across Canada (e.g., Accreditation Canada [8], provincial laboratory accreditation programs [25]). The communication of significant and unexpected results is also essential for prompt intervention in patient management [8, 25, 53, 64]. Ensuring the timeliness and accuracy of the report delivery and receipt processes is an essential part of the pathologist-treating physician communication process [65].

3.4.3 A number of procedures should be followed before the delivery of the report:

- **Patient confidentiality should be maintained**
- **There should be protocols for electronic and hard copy, where appropriate, delivery of reports to ordering physicians**
- **Significant and unexpected diagnoses and changes to the report that may impact patient management should be personally communicated to the treating physician as soon as possible**
- **There should be audits of receipt and integrity of electronic and hard copy reports**
- **Transcription, verification and delivery errors should be monitored and managed through a nonconforming event management system**

4 Interpretive Quality Assurance Policies and Procedures

This section deals with each specific quality assurance policy and procedure (QAPP) that should be present to support a robust internal QA program in the pathology laboratory.

4.1 QAPP-Intra-departmental Consultation

Prospective intradepartmental consultation involves a pathologist seeking an opinion from another pathologist within his/her own group; this can be done either through direct consultation or in the course of a case conference.

It is well established that internal consultation improves diagnostic accuracy and intra-departmental consultation has a significant impact on the final diagnosis. Similarly, identifying areas of disagreement and reaching consensus by intradepartmental consultation is a means for improving diagnostic accuracy. The documentation of these internal consults allows for the assessment of both the number and appropriateness of internal consults undertaken by the pathologists [7, 66, 67].

4.1.1 There should be policies and procedures in place to govern prospective intra-departmental consultation.

- **There should be a system to document intradepartmental reviews**
- **The results of intradepartmental reviews should be reported by the Professional/Interpretive Quality Committee on a regular basis; these data should be used to inform continuous quality improvement activities**

4.2 QAPP-Intra-operative Consultation

Correlation of intra-operative consult specimens with permanent preparations and their corresponding final diagnosis supports the measurement of individual and group diagnostic accuracy. Once discrepancies are identified, the potential cause of the frozen section discrepancies can be investigated, and measures can be implemented to help prevent similar occurrences. The impact of frozen section discrepancies on changes to diagnoses can also be investigated. There is evidence that long-term monitoring of frozen-permanent section correlation is associated with sustained improvement in performance.

A comprehensive QA report should include: the numbers of cases reviewed; the numbers and percentages of miscorrelations; the classification of discordances into interpretive discrepancies and other types of miscorrelations; the numbers and percentage of discrepancies; the numbers and percentage of deferrals; an analysis of factors leading to the discrepancies; and plans of action to deal with these factors.

4.2.1 There should be policies and procedures in place to govern intra-operative consultations.

- **There should be a system to document intra-operative consultations, and all discrepancies between the different techniques should be resolved and documented**
- **The results of intra-operative consultations should be reported by the Professional/Interpretive Quality Committee on a regular basis; these data should be used to inform continuous quality improvement activities**

4.3 QAPP-Internal Correlative Activities

When appropriate, current cases should be correlated with previous pathology reports from the same institution. If necessary, pertinent material should be retrieved and reviewed to help determine the appropriate diagnosis and to detect potential defects or diagnostic discrepancies.

Correlation of previous cytological and histological material and review of slides from significantly discordant cases targets a subset of cases with a higher-than-average discrepancy rate. Targeted reviews of these high-risk cases, will identify significantly more discrepancies and lead to significantly fewer cases being reviewed than would occur following a more random review, and is an effective way of identifying cognitive (human factors) errors that lead to patient harm.

This review also identifies factors that contribute to discrepancies and can serve to identify areas of potential discrepancies and to institute corrective action. The data obtained from such a targeted review also can be used to benchmark practices and target specific high-frequency discrepancies or discrepancies with high clinical impact. For example, the inadequacy rate for cytology specimens—especially those that are non-exfoliative such as fine needle aspiration—should be collected in an effort to improve patient care.

Correlation of cytological and subsequent histological diagnosis and review of cytological and histological slides in miscorrelating cases is an effective means of assessing diagnostic accuracy and identifying areas of diagnostic difficulty. In the United States, CLIA regulations mandate correlation of all gynaecologic cytology reports with a diagnosis of HSIL or carcinoma with the histopathology reports. The Canadian Society of Cytology guidelines for cervical-vaginal cytology also have this requirement. Additionally, cytological and histologic correlation of the fine needle aspiration is also considered a useful quality activity [7, 9, 47, 57, 67-75].

4.3.1 There should be policies and procedures in place to govern the comparison and correlation of a current case with previous surgical pathology and cytology reports and other material, if required.

- **There should be a system to document the correlation of previous and concurrent material with the final diagnosis; all discrepancies between the different techniques should be resolved and documented**
- **The Professional/Interpretive Quality Committee should report the results of internal correlative activities on a regular basis; these data can be used to inform continuous quality improvement activities**

4.4 QAPP-Internal Retrospective Reviews/Audits

Internal retrospective review can detect a number of discordances, including diagnostic and data elements that alter prognosis and treatment. The rate of discordance often varies with the tissue type reviewed. Data from documentation of internal reviews identifies factors that contribute to discrepancies; once collected, this information can be used to investigate the causes of these discrepancies and to institute corrective measures.

On a regular basis, areas perceived as being prone to diagnostic discordances may be selected for audit. Audits are appropriately performed when a pattern of diagnostic discrepancies is identified through look-back reviews, case conferences or other peer review activities.

Retrospective audits should be targeted toward problem areas (diagnoses with poor reproducibility of diagnostic criteria or involving ill-advised diagnostic procedures) and look-back reviews of past material when follow-up material is now available. Random retrospective reviews are not recommended as a routine QA activity as they have been shown to be non-productive especially when performed at a low percentage audit rate (e.g. 5%) [57]. While a random review program may provide the optics of effective peer review to the uninformed, it diverts limited professional resources away from effective strategies such as prospective intradepartmental consultation and focused retroactive reviews.

Focused reviews of specific surgical pathology and cytology areas, in which there is a perception of higher levels of diagnostic discordance and/or lack of standardization, are strongly recommended. Focused review detects problem areas of diagnostic discordance or lack of standardization. The data obtained from this focused review can be used to initiate measures to reduce discrepancies and standardize practice. Ideally, as highlighted in the literature, original diagnosis should be blinded for optimal results.

Pathologists should document correlation for all cases reviewed retrospectively for any reason (i.e., for rounds, tumour boards or at the request of a physician/patient) and review of previous material in the process of diagnosing a current surgical specimen. Report defects should be categorized using one of the established classification systems, such as the one advocated by the UK Royal College of Pathologists (see page 30) [76].

On a regular basis, a Professional/Interpretive Quality Committee should assess data from retrospective reviews. The assessment should include percentage of participation in the peer review program, percentage of discrepancies, classification into major and minor discrepancies, and assessment of medical consequences of discrepancies. All major discrepancies should be investigated.

Such audits should take place under the umbrella of a Professional/Interpretive Quality Committee. On a regular basis, this Committee should summarize data from all peer review activities, including retrospective reviews, in an anonymized report, which has been reviewed by the Laboratory Director (or equivalent) and all pathologists.

The report should include, but should not be limited to: number and percentage of cases reviewed, numbers of discrepancies, percentage of discrepancies, numbers and percentages of major discrepancies. Where possible it should provide analysis of factors leading to the discrepancies and suggest a plan of action to deal with these factors [7, 57, 67, 69, 70, 77-81].

4.4.1 There should be policies and procedures in place to govern internal retrospective reviews/audits.

- **There should be a system to document internal retrospective reviews/audits; all discordances between the original diagnosis and findings from the internal review/audit should be resolved and documented**
- **The Professional/Interpretive Quality Committee should report the results of internal reviews/audits on a regular basis; these data should be used to inform continuous quality improvement activities**

4.5 QAPP-External Consultation

External consultation involves a pathologist prospectively seeking an opinion from another pathologist outside of his/her professional group. External consultations may be requested for a variety of reasons including: the lack of a test or professional expertise on-site; and/or to resolve divergent opinions resulting from an intradepartmental consultation.

External pathology consultation is useful for patient management, especially in resolving difficult and controversial pathologic diagnoses. It can also help to ensure that institutional practice is consistent with national and international practice. The documentation of these external consults allows for assessment of number and appropriateness of external consults undertaken by the pathologists [82-85].

Analysis of patterns of pathologist error indicate that error rates drop precipitously when prospective consultation takes place [32]. The critical role of pathology peer review is to promote a systemic and individual pattern of consultative practice for difficult and significant and

unexpected diagnoses, and to prohibit diagnosis in isolation. Furthermore, peer review should seek to identify systemic practices that are prone to error or vulnerable to catastrophic failure.

NOTE: Unless the external consultation report identifies a malignancy where one was not identified previously, consultations should not generate a new synoptic report. Any changes to the original synoptic report should be documented as an amendment.

4.5.1 There should be policies and procedures in place to govern external consultations.

- **There should be a system to document external consultations**
- **The results of external consultations should be reported by the Professional/Interpretive Quality Committee on a regular basis; these data should be used to inform continuous QI quality improvement activities**

4.6 QAPP-External Reviews

An external review is a request for the review of a case by a laboratory or pathologist external to the one originally reporting a case. A pathologist, clinician, institution, or patient can retrospectively request such a review. It is important that the results of the external review are received by the primary pathologist and that any identified discrepancies be recorded as per the quality management policy. This activity is an important learning tool for pathologists and promotes quality improvement. When there is new information or a discrepancy identified, an appropriate addendum or amended report should be issued. In situations where the primary pathologist disagrees with the external review, an additional consultation may be requested.

NOTE: Unless the external review report identifies a malignancy where one was not identified previously, reviews should not generate a new synoptic report. Any changes to the original synoptic report should be documented as an amendment.

4.6.1 There should be policies and procedures in place to govern external reviews.

- **There should be a system to document external reviews; all discordances between the original diagnosis and external review should be resolved and documented**
- **The Professional/Interpretive Quality Committee should report the results of external reviews on a regular basis; these data should be used to inform continuous quality improvement activities**

4.7 QAPP-Urgent Diagnoses and Significant and Unexpected Findings

Significant and unexpected results requiring immediate treatment decisions to prevent morbidity or mortality must be communicated to the most responsible physician in a timely manner and documented—preferably in the LIS with the case.

A policy should outline which types of cases are considered urgent, significant and/or unexpected and describe the best methods for communicating these results to the attending/ordering

physician. Cases in which the diagnosis has been changed significantly in an amendment after sign-out should also be included.

Several existing documents have highlighted the importance of policies in this area. CAP and the Association of Directors of Anatomic and Surgical Pathology have formulated guidelines in this area. They recommend that each institution create its own policy regarding urgent diagnoses and significant, unexpected diagnoses in anatomical pathology. (This is a requirement on the CAP accreditation checklist.)

Such a policy should be separate from critical value policies in clinical pathology where expectations regarding a time frame for communication are different.

The terminology for anatomic pathology comprises the following:

- Urgent diagnoses (medical conditions which require treatment as soon as possible). These need to be communicated to the licensed caregivers as soon as possible so that treatment can be initiated
- Significant, unexpected diagnoses or findings (conditions which are clinically unusual or unforeseen and should be addressed at some point in the patient's course). These should be communicated to the licensed caregiver in a timely manner to ensure that s/he is aware of these unexpected results and ensure proper treatment

[7, 67, 86-88]

4.7.1 There should be policies and procedures in place to govern the communication of urgent diagnoses and significant and unexpected findings that will potentially require urgent care.

- **There should be a system to document the communication of critical results and unexpected findings; there should be a process to ensure that the message is received correctly**

4.8 QAPP-Revised (Addended, Amended) Reports

The adoption of a common set of definitions for revised reports is recommended across jurisdictions to ensure clarity and consistency. The pathologist may be confused when deciding whether to create an amended or an addendum report. Incorrect use of this terminology has the potential to contribute to patient harm. It can also interfere with the ability of the QI program to identify and correct problems by reviewing amended reports.

Various laboratory information systems may use different terminologies for addended and amended reports. As long as these categories are properly defined and used, the terminology of the institutions' laboratory information systems is acceptable.

The proposed definitions are as follows:

Addended [supplementary] Report: Adds information to a previously completed pathology report. This information does not change the diagnosis or any data elements related to the diagnosis (e.g., addition of ancillary test results).

Amended [corrected] Report: A change to information contained in the finalized report. The reason for the amendment must be included in the report. Reasons for amendments can be placed into two categories:

- Correction of information not related to the diagnosis (e.g., errors in transcription, patient identification, specimen site, report defects)
- Correction of diagnosis and/or other data related to the diagnosis. Amendments that may lead to a change in treatment must be communicated to the responsible physician

[7, 9, 67, 70, 76, 88-93]

Addendum (supplementary) reports often result from the acquisition of new information related to ancillary testing such as histochemistry, immunohistochemistry and molecular studies. While in most instances, the results of these studies lead to addended reports, in some situations, there is a significant change in diagnosis and hence an amended report is required. Likewise, retrospective reviews, for whatever reason, can result in either an addended or an amended report.

There is variation on how information systems deal with addended and amended reports. In some systems, addendum reports are listed at the end of the original report, requiring a recipient of the report to scroll to the bottom to find the additional information. Other LISs place the addenda at the top of the reports making it easier for the recipient to see the new information.

Some LISs exclusively utilize one of two terms, amended or corrected. Additionally in some practices the term corrected report is used in a more restrictive fashion for correction of information, not specifically related to the diagnosis (e.g. incorrect identification, transcription errors etc.) and the term amended report is used when there is a change in diagnosis or other data related to the diagnosis. For the purposes of this document, amended and corrected are considered equivalent terms and are not given more restrictive definitions.

In many LISs, amendments are given priority and replace the original report. Amendments of a diagnosis or other data with a significant impact on treatment must be communicated to the responsible physician in a timely manner to ensure that he/she is aware of the amendment and to ensure proper treatment.

Tracking amendment frequencies and the distribution of amendment types identifies problem areas in pathology diagnoses as well as factors that contribute to discrepancies. This information can be used to identify areas of potential discrepancies; to institute corrective measures; and to

evaluate the effect (or lack thereof) of these corrective measures. Addendum reports may be reviewed to see if they demonstrate deficiencies that need to be addressed.

Reports created by the Professional/Interpretive Quality Committee summarizing data from the retrospective reviews (aimed at the Laboratory Director or equivalent and all relevant pathologists) allows the Laboratory Director and staff pathologists to participate in the QI process. Each report should include, but is not limited to: numbers of amended reports reviewed, numbers of major and minor discrepancies, egregiousness (defined as being conspicuous or glaring) of discrepancies, analysis of factors leading to the discrepancies, and a plan of action to deal with these factors.

Report defects, deficiencies and discrepancies can be classified in a number of different ways [76, 90, 94]. The UK Royal College of Pathologists advocates a sensible hierarchal classification of microscopic discrepancies [76]:

- A diagnosis which one is surprised to see from any pathologist (e.g., an *obvious* cancer reported as benign). This type of error should be investigated
- A diagnosis which is fairly clearly incorrect, but which one is not surprised to see a small percentage of pathologists suggesting (e.g., a moderately difficult diagnosis, or missing a small clump of malignant cells in an otherwise benign biopsy)
- A diagnosis where inter-observer variation is known to be large (e.g., disagreements between two adjacent tumour grades, or any very difficult diagnosis)

4.8.1 There should be policies and procedures in place to define the process for revising report, including adding, modifying and correcting information, as well as classification of report defects, discrepancies, deficiencies and errors and a policy for their investigation and resolution.

- **Amended (corrected) reports should be assessed and results should be reported by the Professional/Interpretive Quality Committee on a regular basis; these data should be used to inform continuous quality improvement activities**
- **Amended reports that significantly alter synoptic report data fields should automatically overwrite those data fields within the synoptic report database**

4.9 QAPP-Turnaround Time

Turnaround times for surgical pathology reports are a critical component of quality practice because of their impact on patient care. Prompt diagnosis allows further investigation and treatment planning to be organized in a timely fashion and may reduce patient anxiety about their diagnosis.

The monitoring of turnaround times is an important element of many laboratory accreditation programs. Desirable turnaround times are documented in the current literature and by accrediting bodies. However turnaround times depend on local conditions which include case complexity,

infrastructure and/or the presence of a residency training program. Each institution should determine acceptable turnaround times based on desirable turnaround times documented in the literature and local conditions. Data can be used to analyze causes of unacceptable turnaround times and to modify systems to effect improvement [7, 9, 69, 70].

4.9.1 There should be policies and procedures in place to define acceptable and reasonable turnaround times based on local conditions, taking into account recommendations made by leading bodies and the needs of the clinicians.

- **Turnaround time for frozen sections, surgical pathology and cytology should be documented and evaluated regularly and reported by the Professional/Interpretive Quality Committee on a regular basis; these data should be used to inform continuous quality improvement activities**

4.10 QAPP-Completeness of Reporting

Measuring the completeness of pathology reporting is an important component of a departmental QA and QI plan. Such data can serve as one indicator for quality of care. Studies have shown that standardized reporting forms, including synoptic reports or checklists, are highly effective in improving report adequacy, particularly for cancer.

Synoptic reports contain all important diagnostic and prognostic factors that are laid out in a structured list or table with headers and responses. This relatively new style of reporting standardizes pathology reporting; improves overall report completeness; may help identify specific data points more easily compared to narrative or paragraphic reports; improves communication among healthcare providers; facilitates decision-making for treatment; facilitates secondary uses of pathology data for purposes such as tumour registries, quality reporting, stage capture, quality management and evaluation, patterns of care and outcome analysis, system planning and population research.

CAP requires complete reporting of cancer pathology cases for accreditation and has cancer reporting protocols for excisions of most cancers [9, 95-97].

4.10.1 There should be policies and procedures in place to measure the completeness of pathology reporting.

- **Completeness of reporting should be monitored by the Professional/Interpretive Quality Committee on a regular basis and this data should inform continuous quality improvement activities**

4.11 QAPP-Onboarding Pathologist Performance Assessment

Pathologists' performance in the context of their work environment should be evaluated on a regular basis. Particular attention should be given to new hires (including locums) and pathologists that have been away from practice for an extended period of time. While the interview and the

checking of references gives the employer some information about the newly hired pathologist, on rare occasions the information gathered on the new hire by these methods has been misleading. Performance appraisals may also be misleading.

Undertaking an audit when a new pathologist is first hired is one way to further ensure that the pathologist is performing at an appropriate level. A pathologist returning to practice after an extended leave of absence may have lost diagnostic skills and may not be knowledgeable of recent advances. An audit performed when the pathologist returns to work will ensure an appropriate level of performance and may identify areas of deficiency that need to be remediated. The pathologist being audited should be aware of the process and results of the review.

This audit is a management tool that should be monitored by the Professional/Interpretive Quality Committee. If the performance of the pathologist is in question, the laboratory director or appropriate designate requires access to all of the data.

4.11.1 There should be policies and procedures in place to ensure appropriate level of performance of all pathologists, particularly newly hired pathologists and pathologists returning to practice after a significant absence.

- **An audit, preferably targeted, should be performed on a proportion of cases reported by all recently hired pathologists or a pathologist returning to practice after an extended absence**
- **The results of the audit should be monitored by the Professional/Interpretive Quality Committee on a regular basis. These data should be used to inform continuous quality improvement activities. If the performance of the pathologist is in question, the Laboratory Director or designate requires access to all of the data. Pathologists should be aware of the auditing process and results.**

4.12 QAPP-Service Satisfaction

At appropriate intervals, feedback from consulting clinicians should be solicited with an aim to improve "product quality." Such feedback may potentially uncover problems that have not been identified by other QA activities. Feedback can be solicited through surveys, as well as by monitoring complaints and compliments. Monitoring client satisfaction is particularly helpful before, during and after implementing changes or new services.

4.12.1 There should be policies and procedures in place to monitor service satisfaction of those who use pathology services.

- **Feedback should be assessed by the Professional/Interpretive Quality Committee on a regular basis; these data should be used to inform continuous quality improvement activities, to help understand user needs and to determine overall service satisfaction**

5 External Quality Assurance (Assessment)

5.1 External Quality Assessment (Proficiency Testing)

External Quality Assessment (EQA), which is sometimes referred to as External Proficiency Testing (EPT) is an essential aspect of any laboratory operation. EQA is an inter-laboratory peer program that allows assessment of technical and diagnostic performance compared to other laboratories using the same methods, instrumentation, and analysis. EQA can provide laboratories and pathologists with the necessary information to help them:

- Maintain and improve technical and diagnostic quality
- Improve inter-laboratory and inter-pathologist agreement and raise standards
- Detect equipment faults, identify reagent problems, and identify diagnostic discordance
- Compare performance across different technical methods

[98-101]

5.1.1 All pathologists should participate in External Quality Assurance (EQA) programs, where available and appropriate, which have been designed to reflect the specific functions of the laboratory and the scope of practice of the pathologist.

- **The Laboratory Director and/or Professional Interpretive Quality Committee should review results of the EQA program periodically**

Class II IHC tests are prognostic and/or predictive tests that trigger specific treatment decisions independent of morphologic findings and classification. Thus, false positive or false negative results could lead to inappropriate therapy or inappropriate denial of specific therapies for individual patients [102]. Additionally, participation in EPT programs has been shown to correlate with improvement in inter-observer agreement [103] .

5.1.2 All laboratories performing Class II marker immunohistochemistry (IHC) should participate in external proficiency testing (EPT).

- **EPT programs for IHC should utilize validated test materials, be statistically and temporally relevant, have established parameters for acceptable performance, should have comparative results viewable by all participants**
- **Laboratories should report EPT performance results to the departmental QA Committee and to the appropriate regulatory/accreditation agency, if required**
- **All laboratories performing class II IHC testing should monitor biomarker positivity rates for comparison with nationally recognized standards, and report these rates to the departmental QA Committee and to the appropriate regulatory/accreditation agency, if required**

5.2 Pathologist Peer Review Assessment

A peer review assessment provides the pathologist with feedback about his/her practice. Peer review is based on observations by pathology colleagues and clinical colleagues and is used primarily as an educational tool to identify priorities for improvement of practice. Components of a pathologist peer assessment program may include:

- Completion of survey questionnaires by the pathologist, peers, referring physicians, and co-workers [104]
- Case review (15-25 cases) documenting components such as diagnostic accuracy [94]; report completeness, including appropriate use of synoptic report; appropriate use of second opinion, including documentation of any such consultation; report turnaround time; appropriate use of special stains, immunohistochemistry, and molecular tests; appropriate communication of urgent results to the responsible clinician[105, 106]

In some jurisdictions, pathologists may be chosen for peer review randomly or as part of a quality investigation or in some jurisdictions, when a pathologist reaches a certain age [107, 108].

5.2.1 Pathologists should participate in existing peer review assessments that are part of their licensing and regulatory body.

6 Approach to "Expression of Concern" Regarding a Pathologist's Performance

Surgical pathology reports have a significant influence on patient care and are the basis upon which most cancer patients' management plans are developed. It is acknowledged that diagnostic discrepancies in surgical pathology practice are not completely avoidable since surgical pathology interpretations reflect the opinions of individual pathologists. Significant subjectivity and inter-observer variation are also recognized sources of diagnostic discrepancy [94]. There is no established standard that defines an acceptable discrepancy rate [76, 94, 104, 109].

An "expression of concern" (EOC) regarding a pathologist's performance may originate from a variety of sources including a clinician or other healthcare provider within or outside the pathologist's facility, a pathology colleague within or outside the pathologist's facility, a patient, administration and regulatory bodies. It is important that all such EOCs are appropriately investigated based on the specific circumstances of the complaint. Expressions of concern may relate to a specific case or may relate to a series of cases in which a pattern of potential underperformance is alleged. The situation should be assessed by the Departmental/Program Chief/Medical Director who is ultimately responsible for professional quality within the organization or facility. The responsible leader must then decide on a course of action which in some instances may be simply reviewing a case of concern and discussing it with the responsible pathologist and the person raising the EOC. At times further internal or external consultation and/or review will be required. Regardless of the type of review, it is important that proper procedures are followed to ensure that the results are valid and that the pathologist in question has been treated in a fair and professional fashion. There are guidance documents from the CAP-ACP, the Royal College of Pathologists and the Royal College of Pathologists of Australasia that deal with these situations [76, 94, 105, 109, 110].

6.1.1 A policy that outlines how expressions of concern regarding a pathologist's performance are handled should be available at all institutions delivering interpretive pathology services.

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Appendix A: Patient Safety Checklists for Surgical Pathology

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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	Any standardized protocols employed by the professional group for reporting the specimen are adhered to.
4.4	The gross description, microscopic findings (if recorded), and any other information included support the pathologic diagnosis.
4.5	Any inadequacies or limitations of the specimen or its examination are documented.
4.6	The results of specialized studies are correlated with the morphologic diagnosis, documented and incorporated into the final diagnosis.
4.7	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.
4.8	The record of any intra-operative consultation performed is incorporated in the final report.
4.9	Any discordance between the final diagnosis and the gross description, intra-operative consultation and/or other tests performed, is reconciled and explained in the report.
4.10	Recommendations for further studies are included.
4.11	Significant, unexpected and critical findings are communicated promptly to the clinician and that communication documented.
4.12	All necessary sections of the report are completed (including required synoptic report fields).
4.13	No transcription or formatting errors are present.
4.14	All quality assurance processes employed during the course of specimen examination and reporting are documented.

4.15	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 Reports (including those with revisions or corrections) – if required
4.16	The reason for the addendum is clearly indicated in the report, and along with any background information and findings that may have served as its basis.
4.17	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.
4.18	The clinician is notified, if necessary and that notification documented.
4.19	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.	


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