

GE Healthcare

Pathology Innovation
Centre of Excellence (PICOE)

Digital Pathology: A New Frontier in Canadian Healthcare

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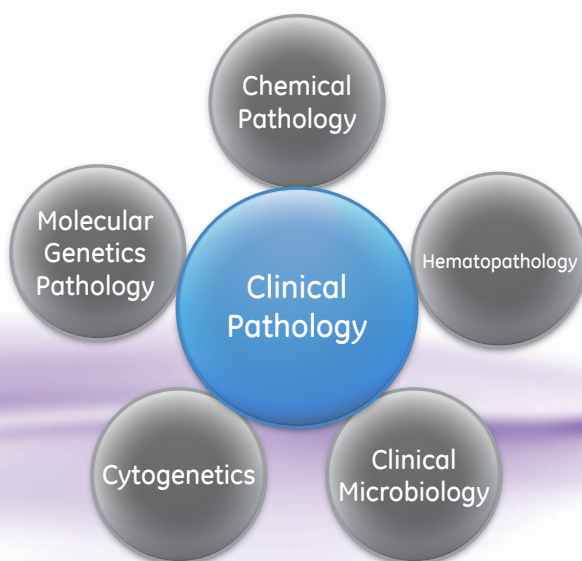
Pathology is the study of changes in tissues that are associated with disease. In medicine, pathology is divided into two specialties.

Clinical pathology deals with laboratory analysis of bodily fluids and tissues using chemistry, microbiology, hematology and molecular pathology.

Anatomic pathology involves examination of organs and tissues either by direct visual inspection, use of a microscope or more sophisticated tools. Subspecialties of anatomic pathology include surgical pathology (examination of surgical specimens and biopsies), cytopathology (examination of disease at the cellular level), molecular pathology (examination of molecules in organs, tissues and bodily fluids) and forensic pathology (whole body autopsies/post mortem examinations to determine the cause of death).

Anatomic pathologists are medical doctors who diagnose disease by examining cells, samples of tissues (biopsies) and organs. Pathologists have

traditionally accomplished this task through direct visual examination of specimens and the use of microscopes in conjunction with reviewing clinical information about the patients from whom the specimens were obtained. The pathologist determines whether or not an organ or tissue is diseased, provides a prognosis^{1,2} and sometimes even predicts the likelihood of response to particular therapies.¹ Pathologic findings guide crucial treatment decisions: whether or not an organ should be surgically removed, the choice of chemotherapy or radiation therapy and (in some cases) the decision to watch and wait. Intraoperative consultations (frozen sections) from surgeons require pathologists to examine tissue samples within 20 minutes while the patient is still in the operating room. Surgeons use frozen section diagnoses to fine tune their surgical plan for that patient.



Anatomic Pathology

The Current Process

Pathologists are skilled healthcare practitioners. Each newly certified member of the profession is a veteran of a decade of training: four years of medical school and five years of residency, followed by one or two years of postgraduate fellowship.³



The basic process of anatomic pathology has its roots in the nineteenth century, when the combination of examination with the naked eye and microscopic inspection was first used to arrive at a diagnosis.^{1,2} Although the past decade has seen equipment become more sophisticated, the eyes of an experienced pathologist still remain essential for diagnosis.

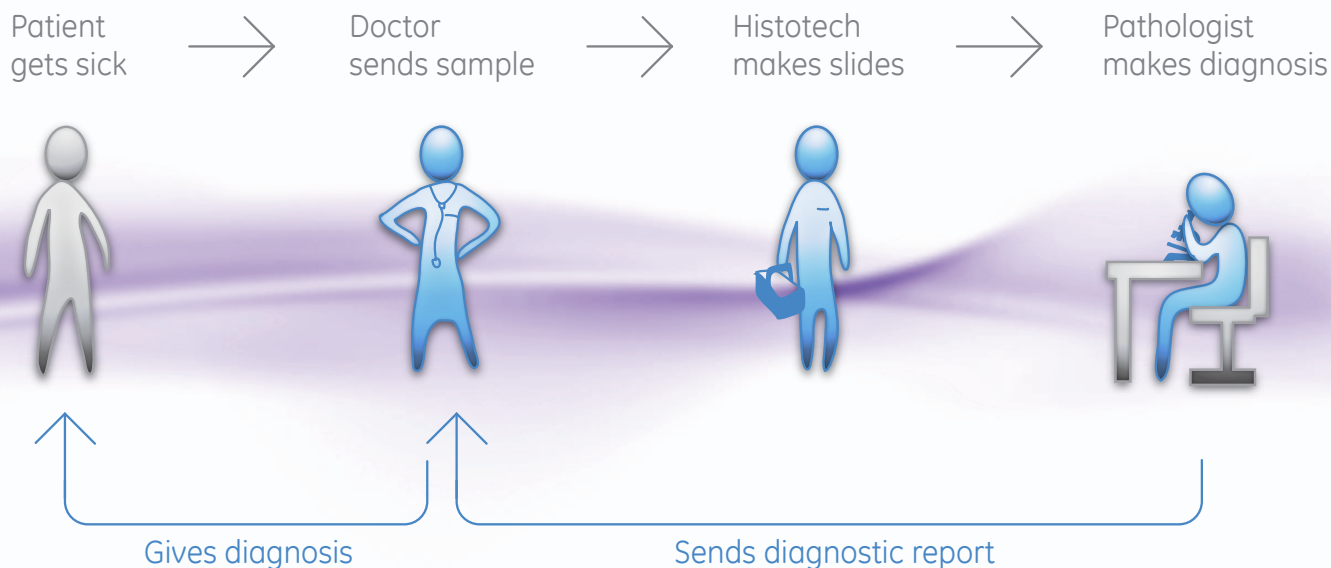
In a typical example, a physician who suspects disease will biopsy an affected area (perhaps a suspicious lump), removing a sample using a needle or by excision (cutting). The specimen is shipped to a histopathology laboratory where a pathologist assistant or specialized histotechnologist visually inspects and records the visible characteristics. A technician prepares the sample for microscopic inspection through a prescribed series of steps that usually includes fixation (to preserve cellular structure), dehydration and embedding the specimen in a block of paraffin wax.

This embedded specimen is sliced into thin sections which are mounted on glass slides and treated with stains that highlight different components of tissue, thereby facilitating inspection and diagnosis. Each slide is covered with a glass coverslip and is ready for a final stage of quality assurance. In addition to a visual inspection of quality of the sample (for staining, air bubbles, etc.) the laboratory must ensure that slides are properly labelled to match the paraffin block and the individual patient's paperwork. The process within the laboratory is meticulous to ensure quality and efficiency given the available tools. Pathologists rely on the highly specialized technical support team in the histopathology laboratory, to process tissue samples into high quality slides. A patient's case can include many slides.

As these slides flow through the laboratory they must be reconciled together at the end before being placed in trays and sent to the pathologist's office (typically via courier or an overnight delivery service).

A pathologist will review paperwork and clinical information before moving on to view slides using a microscope. After reviewing the slides, the pathologist will prepare a report (often dictated for later transcription) that provides a final tissue diagnosis. Once finalized, the report is sent to the patient's physician, who will use the findings to help determine an appropriate course of action.

Although pathologists spend years learning how to accurately diagnose disease, much of their time is spent in administrative work — moving slide trays, completing paperwork, matching slides to paperwork or entering data into a laboratory information system.



Histotech | A specialist who prepares and stains slides of tissue samples.

Attending pathologist | A pathologist who has completed residency and fellowship. An attending pathologist can supervise fellows and resident/registrar.

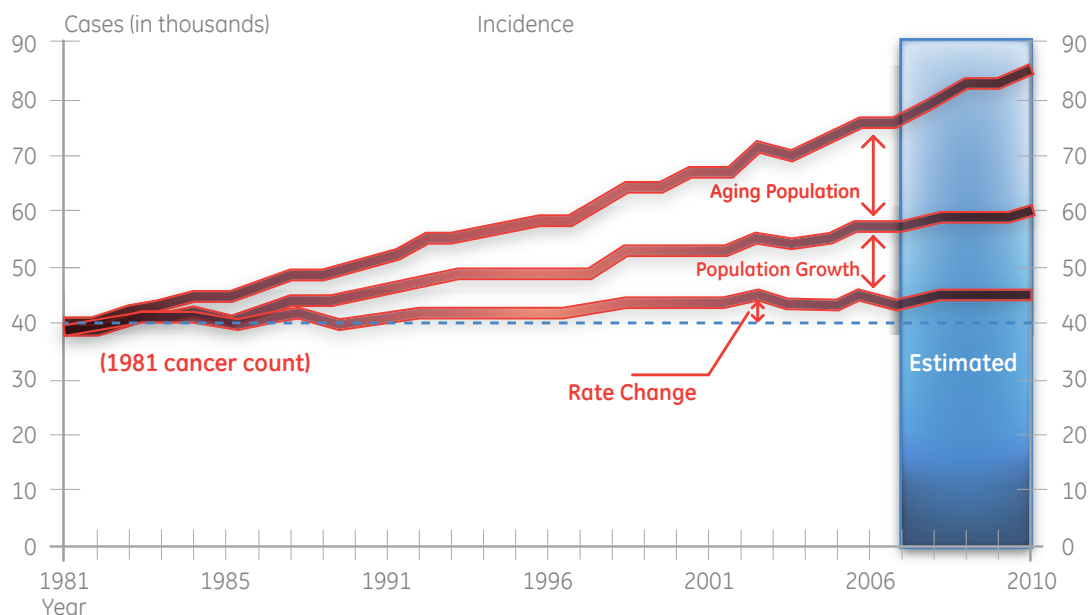
An Essential Element of Canadian Healthcare

Anatomic pathology is essential to delivering high-quality healthcare in Canada. An editorial in the Canadian Medical Association Journal acknowledged that “pathological analysis of tissues is the basis of most health care decisions regarding diagnosis and, increasingly, treatment. As well, it provides links to understanding disease processes”.⁴

Pathology influences not only diagnosis and treatment, but can also determine how quickly a diagnosis is reached and the amount of time spent in acute care. When all goes smoothly, the result is prompt diagnosis, and time in hospital is kept to a minimum. A disrupted or delayed workflow can delay diagnosis and possibly prolong hospital stays, which may result in increased direct costs due to lengthier hospitalization and

decreased productivity as patients are kept away from work and personal activities. Diagnostic or procedural errors can lead to unnecessary treatment, missed or delayed treatment and sometimes even death. Accurate pathologic assessment and an efficient workflow are essential to cost control, appropriate and timely treatment and delivery of high-quality healthcare.

In coming years, the importance of pathology can only increase. A pathologist is the only physician who can make the actual diagnosis of cancer.⁵ An aging population as well as population increase has been linked to a rising incidence of cancer. As long as current demographic trends continue we can expect more cases of cancer each year, and a consequent increase in the need for pathologists.⁶



Trends in new cases and deaths for all cancers and ages, attributed to cancer rate, population growth and aging population, females, Canada, 1981-2010⁶

Anatomic Pathology in Canada Today:

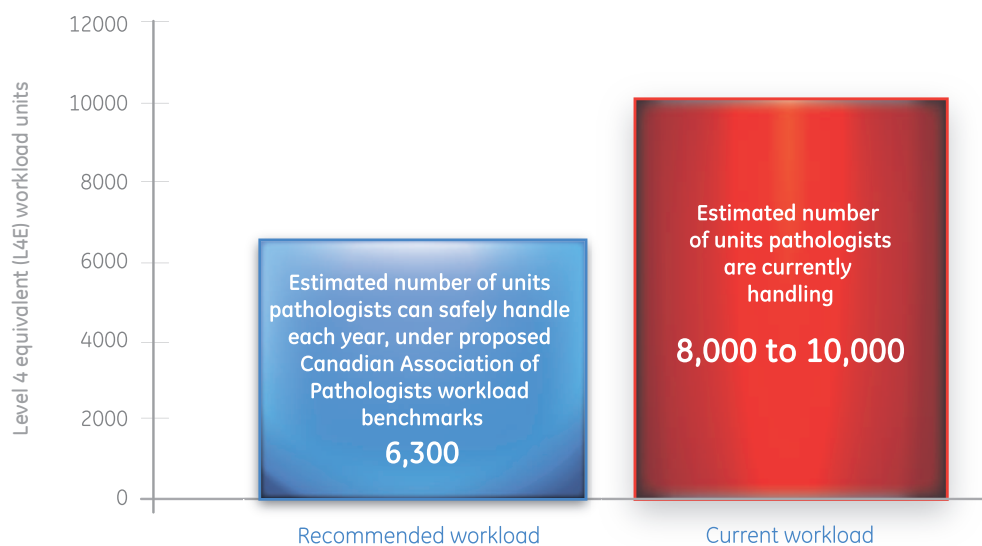
Limitations and Challenges

In Canada, the delivery of pathology services is facing growing challenges; challenges that have the potential to impact the delivery of accessible, high-quality, cost-effective services for patients.

Unequal access to care. Pathologists and labs tend to be clustered in and around major cities.⁷ People who live closer to cities find it easier to access these services. Delays occur when there is a greater distance between patients and pathologists, as is often the case with patients who live in rural areas.⁸ Greater distances mean slides must travel farther, increasing the turnaround time required to complete pathology procedures.

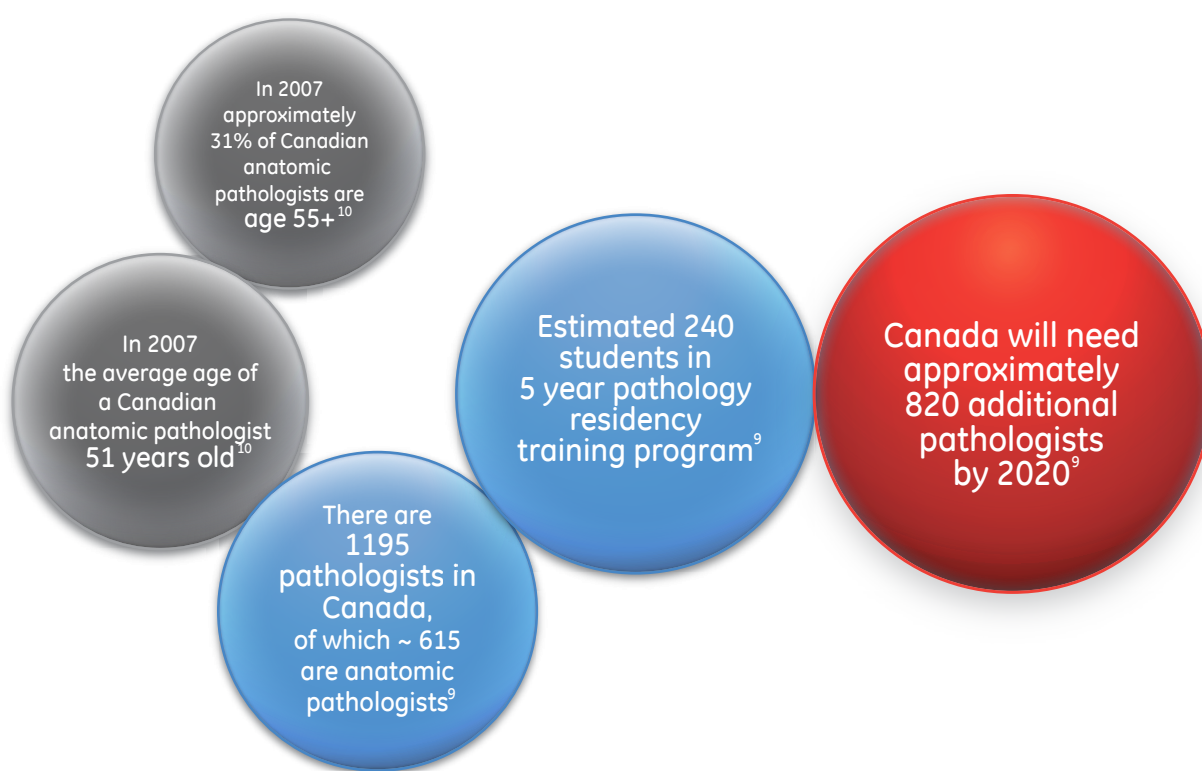
Lack of efficiency and limited cost-effectiveness. Compared to many other fields (radiology comes to mind), the pathology process is relatively inefficient. Laboratories are managed with many checkpoints in order to ensure accuracy and quality; however these are typically done with manual tools/techniques. After slides are prepared and shipped, the pathologist must undertake the time-consuming but important tasks of sorting, matching and carefully examining each individual sample for quality. These tests could have considerable impact on diagnosis and treatment plan of patients. Unfortunately, the current laboratory environment is not adequately funded to take advantage of technology advancements to increase quality, access and system productivity. The requirement that pathologists be located near the histology laboratories that prepare slides makes it difficult to centralize laboratories or decentralize pathologists, two measures that would allow the healthcare system to benefit from economies of scale.

An ever-increasing workload. Nowadays pathologist are tasked with a heavier workload. Advances in medicine have transformed pathology from a relatively simple assessment of the type and extent of a cancer to a complex process that can include extensive tissue sampling, exhaustive microscopic examinations and performing several related tests.⁴ Coupled with the rise in cancer cases, it is no surprise that some pathologists find themselves overburdened.



Recommended vs current workload for a Canadian pathologist⁹

A growing deficit of qualified professionals. The average Canadian pathologist is in his or her mid-fifties.⁹ Today, it is estimated that Canada needs an additional 370 pathologists, while only 240 students are currently enrolled in five-year residency training programs.⁹ By 2020, the country will need an additional 820 pathologists.⁹ This shortfall of pathologists means that positions will increasingly go unfilled, and the workload of each individual pathologist will increase. Many pathologists are already working past retirement age. Training more pathologists is at best a long-term solution, given the years of specialized study required to qualify.



Compromised quality of care. In recent years, there have been several cases in Canada where patient care has been seriously compromised as a result of pathologist error or lack of access to the expertise that sub-specialist pathologists provide. These events have had tragic consequences for patients and their families, and have undermined the confidence of Canadians in the quality of their public healthcare system.^{11,12,13,14,15,16,17} Studies have shown discordance between diagnoses of general vs. sub-specialist pathologists, thereby highlighting the value of providing a consultation network in pathology.¹⁸

Digital Pathology: A Potential Solution?

Digital pathology takes traditional pathology specimens – tissue samples mounted on glass slides – and transforms them into digital images that can be shared electronically by care providers.

While digital pathology has existed in some form since the 1980s, for most of this time the limitations have outweighed the benefits. Slow scanner speed, poor image quality, low network bandwidth and high cost have meant that digital pathology systems had no cost or efficiency advantage over the current process. Recent innovations in digital pathology technology have radically altered this picture by transcending these earlier limitations, thus opening new horizons in anatomic pathology.¹⁹

Digital pathology allows decentralization of pathologists and pathology departments, permits greater cost efficiencies through centralizing histology laboratories and greatly facilitates archiving and storage of information compared to traditional pathology. The result: specialized pathologists can provide care to remote regions, regional health systems can benefit from economies of scale and pathologists can process more cases with greater administrative efficiency and diagnostic consistency than ever before.¹⁹

Implementation of digital pathology technology has great promise for the future of anatomic pathology practice:

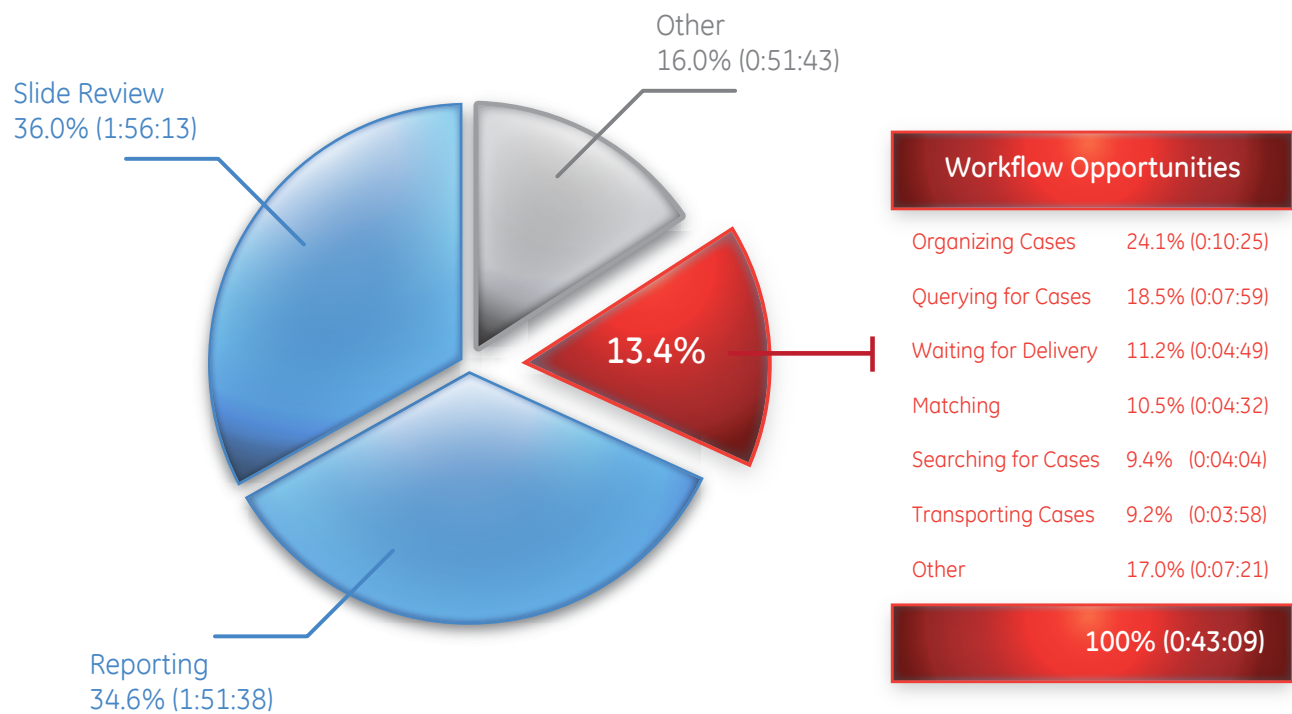
Quality of care. An investigation into issues related to quality of care and treatment of patients in Windsor, Ontario was initiated by the Honourable Deb Mathews, Ontario's Minister of Health and Long-Term Care. In the final report, the clinical and hospital leadership team appointed by the Minister recommended that digital scanning technology and remote review should be assessed as part of a provincial quality assurance system for pathology.²⁰

Connecting the pathology community and leveraging sub-specialist expertise has been shown to have a positive impact on accuracy of diagnosis by allowing cases to be reviewed by the most appropriate pathologist.¹⁸ New digital technologies have the potential to facilitate such pathology networks that could alleviate the limitations of the current practice.

Greater access to care. Having a pathologist onsite during surgical procedures can be critical. Pathologists may be called upon to determine the course of action required during surgery based on the analysis of tissue extracted with a required turnaround time of less than 20 minutes. This can create challenges for rural communities, which may only have a pathologist on site during intermittent periods of the week or month. This creates system challenges in scheduling surgeries, which has financial implications for the hospital and most importantly, an adverse impact on patient access to care. Even when a pathologist is available, lack of access to specialty consultation may impact diagnosis and treatment course. Telepathology provides the ability to transcend geography which means that pathologists can view slides anywhere they have access to a computer. This capability opens up opportunities for collaboration between distant colleagues or remote diagnosis by subspecialties – possibly helping to alleviate the chronic labour shortage in pathology.



Greater efficiency. Digital pathology has the potential to reduce the amount of time pathologists spend on administrative tasks that are inextricably linked to handling physical samples, and frees them to spend more time viewing cases. Time and motion studies show pathologists spend about 13% of their time performing administrative tasks which could potentially be eliminated by digital pathology.



Pathologist T&M study results breakdown of time working cases²¹

Reduced operating costs. Use of Digital Pathology systems can improve pathologist productivity. In some cases, as in the common Canadian scenario where a pathologist who practices at an urban centre provides support to remote communities, digital pathology eliminates the need for costly, time-consuming travel, freeing the pathologist to be even more productive. Increased productivity can mean a decrease in the large deficit of Canada's pathologists. Less dramatically, digital pathology eliminates the cost of transporting fragile glass slides from one location to another. Further cost savings may be realized by centralizing histology laboratories²², something that has been difficult to implement in the pre-digital era of pathology.

Future Possibilities

The potential of digital pathology to benefit Canadian healthcare (and most importantly, Canadian patients) has barely begun to be realized. Regional, provincial or national digital networks may make cross-country consultation a regular event, bringing the advantages of quality of care, better access, greater efficiency and cost savings to communities across Canada. These considerable benefits, however, may be only the beginning.

Advances in digital pathology technology currently under development open up possibilities that may transform the field of pathology. While glass slides will continue to be part of the process, high-speed, high-quality imaging will quickly transform these physical specimens into digital ones that can be viewed around the globe. Automated matching of case information with the digitized slides will reduce clutter and minimize the potential for error that can occur when physical slides and paperwork become separated. Central databases will store cases and samples in digital form, giving pathologists easy access to the information and creating an ever-growing resource that can be used for case sharing, collaboration and teaching. Moreover, once digital, computer algorithms could perform counting and finding functions on specimen images to assist pathologists in their diagnosis.

The delivery of pathology services has been complicated by an explosion of information related to the pathological diagnosis of cancers. The sheer volume of information specific to different cancers is driving a need for pathologists who are highly sub-specialized. The development of telepathology networks can facilitate rapid access to the expertise provided by sub-specialty pathologists. This, in turn, can only contribute to the improved delivery of timely, high-quality, cost-effective care for Canadian patients.

In time, digital pathology will benefit from the full power of computing. Computer-based algorithms can be created to assist pathologists in reaching a definitive diagnosis or to automate routine tasks, leading to even greater improvements in productivity and speed.

With the digitization of pathology, the idea of integrated diagnosis has the potential to be realized. Care providers across the continuum of care would have access to information in a more timely manner without geographical bounds. Studying the health economics and health outcomes of the impact of digitization is underway. Workflows for cancer diagnostics may change to impact outcomes, turnaround and greater system efficiencies.

Future healthcare practitioners may well look back on the coming decade as a crossroads in the history of pathology. Today's challenge is to make these possibilities a reality.



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