

## Canada's pathology

Critical issues in Canadian anatomic pathology have surfaced like a crashing wave. Reports from the judicial inquiry into erroneous breast cancer estrogen and progesterone receptor testing,<sup>1</sup> the public inquiry into faulty forensic pathology,<sup>2</sup> and investigations into pathology misdiagnoses in New Brunswick<sup>3</sup> and, most recently, a pathologist's high error rate in Owen Sound, Ontario,<sup>4</sup> have occupied the minds of Canadian pathologists for months and eroded public confidence. But few would dispute pathology's importance. 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. As we wait for the recommendations that will emerge from these inquiries, it is critical to reflect in a general sense on why, with such a fundamental and essential role in patient care, it looks as though Canadian pathology laboratories are unravelling at the seams and, perhaps more importantly, what can be done about it.

Sir William Osler wrote "As is your Pathology, so is your Medicine." His words are as true today as they were in his time. Specimens submitted to a pathology laboratory are examined individually by a pathologist — a labour intensive, nonautomated process that requires scientific acumen and interpretive skills. Canada's population has grown, our understanding of disease has evolved, and screening programs and novel targeted therapies requiring confirmation of appropriate targets in tissues have been developed. With these advances, the pathologist's volume of work has increased and the complexity of each case has multiplied.<sup>5</sup> Gone are the days when a brief note describing the type of cancer, its extent and margins sufficed. Today, extensive tissue sampling, exhaustive microscopic examinations and ancillary tests, many of which determine therapy and predict outcome (such as estrogen receptor, progesterone receptor and human epidermal growth factor receptor-2/neu tests) as well as synoptic reporting are essential. All of these factors have overwhelmed the pathology laboratory. Unlike a clinic, which may book a limited number of patients per day, the pathology laboratory cannot restrict the number of patient specimens received.

Despite this environment of increased workload and complexity, Canadian laboratories deliver high-quality pathology results, and it would be incorrect to generalize from specific incidents to the overall state of pathology in the country. Most Canadian pathologists and technologists do an excellent job within tight timelines and against numerous confounding odds, including a severe and long-standing shortage of human resources. The Canadian Association of Pathologists estimates we will need about 500 pathologists over the next 10 years to keep up with the

current demands,<sup>6</sup> and the Canadian Society for Medical Laboratory Science states that more than 50% of medical technologists will retire over the next 8 years.<sup>7</sup>

Medical errors that may lead to adverse patient outcomes can occur anywhere, especially in an over-strained health care system. In 1999, an American Institute of Medicine report on patient safety prompted the examination of medical errors in all fields of medicine in the United States, including pathology. In response, the Joint Commission on the Accreditation of Healthcare Organizations as well as the College of American Pathologists revised and strengthened accreditation standards in laboratory medicine with respect to patient safety.<sup>8</sup> A number of variables have been identified that contribute to pathology errors, including preanalytical technical issues (e.g., tissue fixation time). Surprisingly, the importance of standardization and minimization of these technical variations has only recently been appreciated and is now being incorporated into practice guidelines.<sup>9</sup>

In Canada, some provincial laboratory accreditation and external proficiency testing programs are in place: Ontario has the Quality Management Program—Laboratory Services and British Columbia has the Diagnostic Accreditation Program. Unfortunately, proficiency testing varies from province to province. More important, Canada lacks an organization to deal with technical proficiency on a national scale. The Canadian Association of Pathologists recently created a National Standards Committee for Immunohistochemistry; however, this grassroots effort lacks official governmental standing or funding, and its recommendations will not be binding.

Although there is some momentum for technical quality-assurance programs, the Canadian health care system does not have a well-resourced approach to quality assurance of the analytical or professional component of anatomic pathology. It is accepted that peer review is an important method of error reduction.<sup>10</sup> This can take many forms (random retrospective review, prospective targeted review or interdepartmental conferences) and occurs to variable degrees in virtually all pathology departments, especially larger regional centres, academic hospitals and cancer treatment facilities. However, implementing and monitoring activities such as these requires a level of human resources most laboratories can ill afford, especially when already besieged with serious technical and professional staff shortages. Yet, the benefits could be far-reaching, and analyses of errors and discrepancies could uncover reasons for their occurrence that may have less to do with individual performance and far more to do with systemic problems, including human-resource issues, high workload pressures, pathologist fatigue and burnout, factors related to solo or small practices, or a lack of resources for ongoing continuing professional development.

Canadian laboratories are not unique in facing workload and human-resource issues or problems pertaining to medical error and patient safety.<sup>11</sup> However, they are unique in that they lack a national quality-assurance program such as exists within the College of American Pathologists, the British Royal College of Pathologists and the Royal College of Pathologists of Australasia. These organizations oversee and administer a wide variety of quality-assurance initiatives, and there is evidence to attest to the validity of these strategies in decreasing error rates.<sup>12</sup> External quality assessment or voluntary proficiency testing are components in all of these programs, and although there is considerable debate surrounding them, there is evidence to support their value in improving reporting consistency.<sup>13</sup>

All of us share the same goal — the delivery of the very highest quality of laboratory services in Canada. The judicial and public inquiries occurring in different parts of the country will make specific recommendations; however, we can start improving the system now with 3 broad first steps.

First, urgent attention to the serious human-resource issues should help alleviate long-standing staffing problems and improve future laboratory performance.

Second, local hospital administrations and provincial ministries of health should immediately fund quality-assurance efforts in the laboratory system. Far too often the laboratory is asked to develop these initiatives as well as absorb the impact of new clinical programs, changes in clinical practice, new therapies and new techniques without any consideration of appropriate additional resources.

And finally, we must create an appropriately resourced national body to promote excellence in the practice of laboratory medicine in Canada. Such an organization, similar to others around the world, would link together existing provincial laboratory accreditation programs and provide quality assurance to other regions. It could also set national standards and guidelines, establish voluntary professional proficiency quality assurance, coordinate educational activities, and advise and guide human-resource planning.

These 3 actions are absolutely essential if we are to continually improve and sustain a high-quality Canadian laboratory system. Laboratories provide time-critical information for patient care and even one error may have a devastating effect. By making quality assurance and patient safety a priority at all levels, we will be able to restore confidence in pathology to patients, clinicians and ourselves.

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