HQCA
Health Quality Council of Alberta

Rockyview General Hospital and Calgary Laboratory Services Diagnostic and Scientific Centre and Royal Alexandra Hospital: Review of the Quality of Anatomical Pathology Specimen Preparation and Interpretation 2010–11

October 2012

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FOREWORD

Anatomical pathology is a complex field. The people involved with this work are highly trained and the technology is increasingly sophisticated. The steps involved in the preparation and interpretation of tissue samples are many and complex. This review examined what went wrong when tissue samples from patients were either misprocessed in a laboratory or were misinterpreted by a pathologist. The review also explored organizational relationships of the health professionals involved.

In reading this report you will learn, in detail, about the course of events and circumstances that culminated in the misprocessing or misinterpretation of the anatomical pathology specimens at sites in Calgary and Edmonton. Such events are of great concern and warranted careful review – not to look back and lay blame, but to learn and look ahead. The report concludes with seven recommendations and associated steps for action that we believe will improve how anatomical pathology is performed in Alberta by the system and health professionals in whose hands we place our care. And we urge patients and their families to seek answers to their questions about their diagnoses and care. Our healthcare system is stronger when we are all better informed.

Many people contributed their time and talents to this review. I would like to thank the members of the review team who worked diligently to ensure the review was thorough and fair. On behalf of the team, I would also like to thank the many people who supported and co-operated in the review, many of whom shared their personal and sometimes difficult accounts of the events in question.

Dr. John Cowell, Chief Executive Officer, HQCA
Calgary, Alberta
October 31, 2012

EXECUTIVE SUMMARY

In late 2011, Alberta Health Services asked the Health Quality Council of Alberta (HQCA) to conduct an independent review of separate events in the practice of anatomical pathology (AP) that had occurred in Calgary and Edmonton. The Calgary events occurred in 2010 and 2011 at the Calgary Laboratory Services Diagnostic and Scientific Centre (DSC) and Rockyview General Hospital (RGH), and concerned problems in the preparation of 31 tissue specimens. The Edmonton events occurred in the summer of 2011 at the Royal Alexandra Hospital (RAH), where 159 tissue samples had been misinterpreted by a locum (temporary) pathologist.

This review was carried out by an appointed quality assurance committee (QAC) of the HQCA and in accordance with Section 9 of the *Alberta Evidence Act*. The names of people who appeared or were asked to appear will be kept confidential.

This review took a systemic view of the healthcare system and a systematic approach to the collection of information, analysis, and development of recommendations. Findings and recommendations are presented for system-level improvements for the delivery of healthcare in Alberta.

Cases at the Rockyview General Hospital and Calgary Laboratory Services Diagnostic and Scientific Centre

What happened to the patients?

In December 2010 the prostate biopsy specimens of nine patients were misprocessed at the DSC. This made it difficult to interpret the slides made from these specimens but opinions were eventually offered about all of them. No patient received an incorrect diagnosis that was then changed.

In January 2011 the tissue samples of 16 patients were misprocessed at the DSC, and in early March 2011 specimens from six patients were misprocessed at the RGH. Again, no patient was harmed in either situation and pathologists were able to provide timely interpretation of all 22 samples.

The first nine patients were informed of the problems with processing their tissue samples in late December 2010, shortly after the events occurred, while the patients from the January and March 2011 events were not contacted until early November 2011.

Sequence of events

Anatomical pathology (AP) services had been based in each of the four Calgary hospitals: Alberta Children's Hospital (ACH), Peter Lougheed Centre (PLC), Rockyview General Hospital (RGH), and Foothills Medical Centre (FMC). In the spring of 2008 Calgary Laboratory Services began a process that later led to a decision to centralize all AP laboratory services at the DSC.

The following table identifies the sequence of key organizational changes and events that took place in CLS or have directly affected it since 2008. The three misprocessing events that are the focus of this review are also identified in this table (shaded in grey).

Table 1: Chronology of key events at the RGH and DSC

Date	Key event
April 2008	▪ Changes were considered to the anatomical pathology service delivery model at Calgary hospitals. The CLS Executive sponsored a review of options.
April 2009	▪ CLS became a wholly owned subsidiary of AHS.
October 2009	▪ CLS Executive decided to centralize Calgary AP tissue processing services from the four hospitals to the DSC. ▪ Senior management changes occurred at CLS.
January to May 2010	▪ More management changes occurred at CLS. ▪ The CEO of AHS gave final approval to centralize AP services at the DSC.
Summer 2010	▪ Centralization began with three of the four sites (all but FMC) relocating, and problems with tissue processing started to emerge at the DSC site. ▪ Incorrect liquid was thought to have been used to fill an internal reservoir of a tissue processor affecting various specimens from 73 patients. Another and ultimately successful attempt was made to reprocess the tissues.
Late summer 2010	▪ Problems were found with the DSC facility and the plan to complete centralization was suspended until issues with space, ventilation, and various processes were resolved.
Fall 2010	▪ Because of complaints about the processing of prostate samples at the DSC, RGH pathologists requested services from former RGH staff only and proposed returning prostate tissue processing to the RGH.
Mid December 2010	▪ Misprocessing of prostate tissues occurred at the DSC, affecting the biopsy samples of nine patients. The biopsy samples were subsequently reprocessed. The processing problems made it difficult to interpret the slides and there were differences of opinion between RGH pathologists.
Late December 2010	▪ A decision was made to contact the nine patients to explain that there were problems with processing the tissue specimens and to let them know of the possible need for a repeat biopsy. Patients were called on December 23 and 24. Some of those contacted did not completely understand what they were being told and two of the patients were described as being extremely upset. ▪ Relationships between RGH pathologists and staff at the DSC became further strained. ▪ Meetings were held with pathologists to discuss complaints about disruptive interpersonal behaviours.
Early January 2011	▪ CLS initiated an internal quality review of AP centralization and attempts were made to improve relationships. ▪ Prostate tissue processing was moved back to the RGH on a trial basis.
Mid January 2011	▪ Misprocessing of various tissues occurred at the DSC, affecting the specimens from 16 patients. Pathologists were able to read the slides. It was felt there were no implications for the diagnosis or treatment of any of the 16 patients.
Late January 2011	▪ Opinions were eventually offered about all of the nine prostate slides (from the December event) after a prostate biopsy expert in the United States was consulted.
March 2011	▪ Misprocessing of various tissues occurred at the RGH, affecting the specimens from six patients. The specimens were reprocessed and pathologists were able to provide a diagnosis. There were no clinical implications to the six patients.
November 2011	▪ A decision was made to provide disclosure to patients connected to the January and March 2011 events, to let each patient know that there had been problems with tissue processing because of equipment malfunction. ▪ The HQCA review into anatomical pathology at RGH and the DSC in Calgary was announced. ▪ A tissue processor was loaded with three baskets instead of two, affecting various specimens from 25 surgical cases and an autopsy case. At the end of the processing cycle, problems with the tissues were discovered and the tissues were reprocessed satisfactorily. Pathologists were able to interpret all the slides.

Analysis

Patients

No specific patient factors can be said to have contributed to these events; however, there were inconsistencies in CLS's organizational approach to disclosure with respect to determining the necessity (no patients suffered harm or were nearly harmed), timing (either December 23–24 or several months after the events), or process of disclosure (including makeup of the disclosure team).

Personnel

As tissue processing services from each hospital were centralized to the DSC and progressed over the summer of 2010, space became increasingly limited, constraining work processes. Work schedules were changed, with some staff now working day and evening shifts, as well as six days a week instead of the previous five.

The first of the three problem events that are the focus of this review occurred on December 3, 2010 at the DSC, when the prostate tissue samples of nine patients were misprocessed. The slides contained 'artifacts' (irregularities). One pathologist deemed that two sets of slides were unreadable. Two RGH pathologists were able to interpret seven of the nine sets of slides and an international expert was able to interpret all nine.

In the second event, on January 19, 2011, the samples from 16 patients were misprocessed at the DSC when an internal reservoir of a tissue processor, a machine central to the work, was filled with the incorrect percentage of alcohol. Pathologists were able to interpret all the slides. There was a quick investigative response and a 'buddy' system was implemented for technical staff filling the reservoirs.

In the third event, on March 2, 2011, the samples from six patients were misprocessed at the RGH. Again there were some artifacts in the slides but the pathologists were able to interpret all the slides. Following another investigation, colour-coded labels were put on the processing liquid bottles to match the colour-coded labels on the corresponding reservoirs in the tissue processing machines.

Some of the RGH pathologists had expressed concerns about problems with tissue processing since it had been centralized from the RGH to the DSC. Problems were ongoing, would seem to be solved, and would then recur. Pathologists complained both verbally and in writing. There were episodes of verbal abuse directed at some of the non-medical staff by a few pathologists.

Environment and equipment

As centralization was occurring, it became clear that the allocated space was inadequate and the ventilation capacity insufficient to handle the fumes generated by the increased volume of tissue processing. After three of the hospital sites were moved to the DSC, centralization was stopped.

The problems that occurred with the tissue processors related to 'usability' of the machines. The problems included filling the machines' reservoirs with the incorrect liquids and entering incorrect information into the machines' control panel with no alarm sounding.

Organization

Considerable work was carried out in 2009 to prepare for centralization. In May 2010 the CEO of AHS gave the signal to proceed the next month. The ACH AP moved to the DSC in June 2010, followed a week later by PLC; the RGH move began in early July. Centralization was halted in September, ahead of the FMC move.

As it was described to the QAC, the plan for centralization had been treated as confidential because of the planned layoffs of non-medical staff, which meant frontline workers and many of the pathologists were not consulted before the move. The QAC heard concerns about poor communication, limited understanding of roles and responsibilities, and the poor handling of serious problems by various levels of CLS leadership.

Several internal and external factors affected CLS leadership during in the period when these events took place (2009–11). A new CEO of AHS was appointed in late March 2009. The next month CLS became a wholly owned subsidiary of AHS. Numerous senior management changes within AHS and CLS followed. During the course of this review, CLS underwent further organizational changes related to its relationship with AHS. In February 2012 the Board of CLS was almost entirely removed by AHS. Only one board member was left, a senior executive within AHS.

Regulatory

The QAC reviewed the process of accreditation of laboratories, which in Alberta is done by the College of Physicians & Surgeons of Alberta (CPSA). The CPSA Laboratory Program was reviewed and compared to four other provincial laboratory accreditation programs in Canada, Accreditation Canada, and laboratory accreditation programs outside Canada. The QAC considers that the CPSA program for accreditation of medical diagnostic facilities is a strong one by any measure, and is fully compliant with recognized general and laboratory discipline-specific international standards. Yet there are insufficient degrees of separation between the various steps and processes (i.e., accreditation, regulation, and the granting of privileges) and the organizations and roles involved (AHS, the CPSA, assessors, and pathologists) to ensure a process free from conflict of interest.

Cases at the Royal Alexandra Hospital in Edmonton

What happened to the patients?

In October 2011 two separate events occurred that triggered an internal AHS review of AP prostate core biopsy specimens read by a locum pathologist working at RAH during the summer of 2011. Discrepancies discovered with these specimens led to the internal review being expanded to include all specimens read by this pathologist (Pathologist A) during the locum period.

Of the 1,727 patients whose slides were read by Pathologist A between July and October 2011, 159 had undergone prostate core biopsies. Of these, 34 were found to have major discrepancies between the opinion of Pathologist A and the opinions of other pathologists. To the best of the QAC's knowledge, after secondary review of the slides, no patient wrongly received a diagnosis of cancer and no patient underwent an operation that was unwarranted.

The reports of the slides of the remaining 1,568 patients read by Pathologist A were classified on the basis of the type of specimen and the diagnosis as to a high, moderate, or low probability of the patients suffering harm. Of the 155 in the high-probability group, 14 had major discrepancies. (Two reports belonged to one patient.) Again, to the best of the QAC's knowledge, no patient underwent an operation that was unwarranted after secondary review of the slides.

Sequence of events

An experienced pathologist was hired as a locum at the RAH in the summer of 2011. During the four-month term, Pathologist A signed out a variety of cases, including prostate needle core biopsies.

Prostate biopsy specimens

A problem was discovered in **October 2011** after a patient who had undergone a prostate biopsy in Edmonton, with interpretation of the biopsy by Pathologist A, then chose (for personal reasons) to undergo treatment of prostate cancer in another province. There, the biopsy specimen was reviewed by a cancer pathologist who disagreed with the grading of the severity of the cancer given by Pathologist A. The cancer pathologist contacted the Department of Pathology at the RAH. At about the same time, a local urologist questioned the interpretation given by Pathologist A of another specimen.

As a result, in the first week of **November 2011**, a senior AHS pathologist had 18 prostate biopsy specimens previously signed off by Pathologist A randomly selected for peer review by RAH departmental pathologists. With this secondary review, there was disagreement about the diagnoses of the specimens of 12 patients. All RAH urologists were notified that their patients' biopsies were to be re-read and to temporarily defer all decisions about treatment.

Several rounds of secondary review followed. The 12 sets of prostate slides were reviewed by Pathologist B, who reported major discrepancies with Pathologist A's interpretation. Peer review of all 159 prostate biopsy specimens originally interpreted by Pathologist A was completed by three pathologists outside Edmonton. It was confirmed that no patients were wrongly given a diagnosis of cancer. Major discrepancies were found in 34 of the 159 specimens. These discrepancies were thought likely to result in a change in the plans for the patients' care, such as when no cancer was reported by Pathologist A but Pathologists C, D, and E found cancerous cells to be present. A decision was made to ask a fifth pathologist, elsewhere in Canada, to peer review the 34 specimens for which there were disagreements of clinical significance.

By **January 20** Pathologist F had found that all 33 specimens showed the presence of cancer of the prostate. (The slides for the patient receiving care out of province were not included.)

Attempts were then made by a senior RAH/AHS urologist to personally contact all 96 patients whose tissue sample reports had some degree of discrepancy between the opinion of Pathologist A and the expert reviewers.

Specimen review process

Based on discrepancies with the prostate specimens, a decision was made to review all of the work completed by Pathologist A. The reports were coded as high, moderate, or low priority for review, based on the possibility that the patient was at a high, moderate, or low probability for harm if the diagnosis

provided by Pathologist A was incorrect. Of the 1,568 patients, 155 were considered to be those with 'high' probability. Major discrepancies were found in 14 specimens.

Analysis

Patients

No specific patient factors can be said to have contributed to these events; however, the process of disclosure is also central to these events.

Once the misinterpretation of slides was discovered and reviews of the prostate specimens were underway, a senior urologist undertook disclosure for all the patients. The patients received their explanations from a clinician with a complete understanding of all the issues, including the effects that delay in diagnosis might have on prognosis and treatment options. Having the same individual inform every patient may have reduced the variability and confusion that can result from having different people provide disclosure. The QAC learned that the initial planning for disclosure did not follow any specified organizational model but was, however, based on the 'first principles of good care'.

Personnel

Pathologist A was newly retired from another institution in Alberta. During the four-month locum period, Pathologist A did not appear to have any difficulties with the work or the workload.

When determining the appropriate qualifications and experience required for a particular position, a human factors view of work is important. These work-related factors include workload, complexity of cases, and remaining current.

Increasing workload (and complexity of work) is described as a problem in pathology worldwide. However, it is difficult to determine what an appropriate workload is for pathologists. This question is important because there is case-to-case variability in difficulty and, as a result, variability in the amount of time a pathologist spends with each case. This is true for certain kinds of tissue specimens, including prostate needle biopsies, further increasing the workload.

Anatomical pathology experts perform a 'holistic' scan of the slide to detect what the diagnosis is and then search for anything else, whereas non-experts cannot distinguish important from less-important features of the slide and must search until they detect something. If workload is increased to the point where a pathologist feels that scanning time must be reduced in order to get through all the work, the non-expert could be more likely to misinterpret slides than would the expert.

Another work-related factor is that of remaining current with specific types of tasks. During the locum, Pathologist A signed out the prostate biopsy slides of more than 150 patients in four months. In contrast, in the previous two years Pathologist A had signed out the slides of fewer than 20 patients suspected of having prostate cancer. Are case numbers enough or are there other requirements, such as ensuring more-than-adequate knowledge of a specific subject?

Organization and regulatory

The QAC heard that when interviewing Pathologist A for the locum position, a physician administrator at AHS had discussed recent work history with Pathologist A and Pathologist A's ability to interpret various

types of tissues. No formal background checks were completed as to the amount or type of work the pathologist had carried out over the previous few years or how well qualified the individual was to complete the tasks required of the locum position. AHS has since reviewed procedures for the hiring of locums and will be adopting a more systematic approach. The QAC heard that for anatomical pathology locums, this approach will apparently include having a pre-determined number of specimens undergo a mandatory second reading by another pathologist.

The question of who should conduct detailed performance reviews of physicians in Alberta is important. At the time of these events there was no systematic approach to physician performance review by AHS. Since approval of the AHS Medical Staff Bylaws in 2011 all physicians who work in or for AHS will undergo performance review every three years.

In addition, every year when a physician applies for registration with the CPSA for a licence to practise medicine the physician is required to complete an online questionnaire. Questions include self-reporting of 'fitness to work' as well as participation in some form of educational program to maintain competence.

For new physicians the process includes background checks of education, training, and the possible existence of a criminal record. However, if a physician, who is already licensed in Alberta and in good standing with the CPSA, applies for a locum position then the CPSA may not become involved. An exception would be if the physician wished to work in a different area of practice or had been out of active practice for more than three years. In the case of Pathologist A this did not apply.

ISSUES, ANALYSES, AND RECOMMENDATIONS

Automated tissue processing machines

Issue

The automated tissue processing machines at the Calgary Laboratory Services Diagnostic and Scientific Centre (DSC) and Rockyview General Hospital (RGH) anatomical pathology (AP) laboratories are not optimally designed to avoid errors.

Analysis

In the time period under review (January 2010 to December 2011), it was learned that five separate instances of tissue processing errors occurred. Three of these occurrences involved the misprocessing of the 31 specimens that prompted this review. While the tissue processing machines are well designed to process tissues, the problems that occurred with the machines are best described as 'usability' issues. Design improvements in the tissue processing machines would reduce the opportunity for these errors to occur.

Calgary Laboratory Services has implemented corrective actions to address some of these issues; however, there is still opportunity to further reduce the potential for error.

1. RECOMMENDATION

Alberta Health Services (AHS) apply 'human factors' science to further mitigate usability issues associated with the use of AP automated tissue processing machines.

REQUIRED ACTIONS

- Undertake a formal human factors evaluation of the automated tissue processors at the DSC and RGH and other automated tissue processors throughout the province, including those of contracted laboratory service providers, and implement the required recommendations. These recommendations should, where possible, incorporate forcing functions, if re-engineering of the tissue processing machines cannot be undertaken.
- Set human factors standards for future purchasing of tissue processing liquids and automated tissue processing machines.
- In the long-term, advocate with the manufacturers for redesign of the automated tissue processing machines and tissue processing liquids (e.g., formalin and alcohol) to improve usability and lessen the probability of human error.

Calgary Laboratory Services (CLS) organizational structure

Issue

There continues to be lack of clarity related to CLS as a wholly owned subsidiary of AHS and the obligations of both organizations in that relationship. Recent changes in the CLS board structure and in

the reporting relationship for the CLS Chief Operating Officer (COO) to AHS have caused more uncertainty for CLS.

Analysis

In April 2006, CLS became a wholly owned subsidiary of the former Calgary Health Region. With the formation of AHS in 2009, CLS then became a wholly owned subsidiary of AHS. Early in 2012 the CLS Board was reduced to one member, who is also a member of the AHS Executive. This change has affected the reporting relationships of the CLS COO and physician leaders; the COO of CLS now reports directly to a vice-president of AHS and informs the CLS Board. These governance changes have resulted in a need for clarification of the expectations for individuals and the status of CLS itself, that is, if CLS is a 'department' within AHS. Clarity in all aspects of this structural change is critical, not only for the internal CLS leadership and staff, but also at a zone and provincial level.

In addition, concerns were expressed or noted about leadership at various levels of CLS including examples of poor communication, limited understanding of roles and responsibilities, and the manner in which highly charged situations were handled.

2. RECOMMENDATION

Alberta Health Services undertake an organizational review of all aspects of CLS to provide clear reporting and accountability structures within CLS and between AHS and CLS.

REQUIRED ACTIONS

- The organizational review include CLS governance; organizational structure; the leadership/executive requirements; reporting relationships, accountabilities, and authority; and the alignment of goals/priorities, funding/budget, communication channels, and human resources with those of AHS.
- Provide educational and mentoring support to individuals (both medical and non-medical) in leadership roles in CLS and in AHS Laboratory Services. This support should be aimed at helping individuals determine if they wish to remain in leadership roles and, if so, to enhance the knowledge, skills, and experience with various aspects of leadership, including setting priorities, responding to crises, and conflict resolution.

Centralization of AP services in CLS

Issue

The decision to centralize AP services in CLS remains unresolved.

Analysis

A decision was made in 2009 to centralize AP services in CLS. Despite considerable planning, including the development of a business case and plans for risk management, change management, communication, implementation, and resources, the completion of the centralization of AP services was put on hold in September 2010. Centralization was halted due to limitations with space and ventilation and various

problems with tissue processing, especially those related to prostate needle biopsy specimens. It was determined that centralization should proceed at a later date but not if patient care might be compromised and not until these specific issues had been addressed.

The QAC heard that the plan for centralization had been treated as confidential because of the planned layoffs. Input was therefore not sought from frontline workers or many of the pathologists about how aspects of centralization should be undertaken and achieved. A significant issue related to the centralization was the reluctance to discuss the situation openly and the desire to keep certain organizational information contained.

A Laboratory Assessment Report of CLS from the College of Physicians & Surgeons of Alberta (CPSA) in December 2011 noted that all CLS sites had problems with ventilation that would restrict any increase in workload capacity without significant renovation.

3. RECOMMENDATION

Alberta Health Services determine if centralization of all AP services in CLS should proceed from the perspective of patient care, the clinicians using the service, and the larger AHS AP laboratory strategy.

- Consider undertaking an operational review to examine service delivery models, type and volume of work, workload, current and future space and ventilation requirements, and equipment utilization for AP tissue processing and interpretation to assist in determining if centralization should proceed. The operational review would include effective staff and clinician engagement and communication strategies.

Disclosure of harm

Issue

The disclosure process following the events that occurred at the DSC, RGH, and Royal Alexandra Hospital (RAH) was inconsistent and did not appear to follow a specific organizational model.

Analysis

In the Rockyview General Hospital/Calgary Laboratory Services Diagnostic Scientific Centre events, disclosure was undertaken twice, once in December 2010 and once in early November 2011. There was no consistency in CLS's organizational approach to disclosure with respect to determining the necessity (no patients suffered harm or were nearly harmed), timing (either December 23–24 or several months after the events), or process of disclosure (including makeup of the disclosure team). The process resulted in confusion for some patients and the information provided was difficult for others to understand.

At the RAH, disclosure was undertaken and although no specific 'organizational' approach was followed, disclosure was completed on the basis of 'first principles of good care'.

4. RECOMMENDATION

Alberta Health Services ensure Laboratory Services staff and clinicians follow AHS disclosure policies and procedures.

REQUIRED ACTION

- Leadership and physicians in AHS Laboratory Services (including CLS) receive disclosure training, and evaluation of future episodes of disclosure is undertaken to ensure consistency with AHS guidelines.

Process for recruitment of locum pathologists

Issue

A thorough process for the hiring of the locum pathologist to fill a temporary vacant position at the Royal Alexandra Hospital (RAH) was absent.

Analysis

The pathologist who filled a locum position at the RAH was hired after a discussion with a senior individual at AHS. In part, because the pathologist had recently retired from another AHS hospital, no formal background checks were completed as to the amount or type of work the pathologist had carried out over the previous few years or how well qualified the individual was to complete the tasks required of the locum position.

A systematic review should be completed before a physician is granted a change in privileges, for example filling a locum position, to ensure the physician is capable of fulfilling the job requirements. Assumptions should not be made as to a physician's general and specific competence based on where a physician has trained or worked previously.

5. RECOMMENDATION

Alberta Health Services improve the process for the hiring of locum pathologists.

REQUIRED ACTIONS

- Develop a comprehensive approach to the granting of privileges, which should include checking the working background of the individual and the amount and type of work completed in a predetermined period.
- Develop and apply a systematic approach to the orientation/induction period of all newly hired pathologists, which would include review by another pathologist of all tissue specimen interpretations for a period sufficient to ensure that all types of tissues and an appropriate number of specimens are reviewed.

College of Physicians & Surgeons of Alberta (CPSA) accreditation

Issue

The current accreditation processes for AHS-owned, -operated, or -contracted medical diagnostic laboratories lacks sufficient separation between the organization conducting the accreditation and the laboratory being accredited.

Analysis

An important aspect of any accreditation process is that it is conducted by an external and fully independent organization. Currently, accreditation of AHS-owned, -operated, or -contracted medical diagnostic laboratories is conducted by the CPSA. Over the past four decades the laboratory accreditation program operated by the CPSA has evolved with changes in the local environment and international standards. The CPSA has shown a commitment to continuous improvement of its laboratory accreditation program by benchmarking its standards against the current international standards. The QAC considers that the CPSA program for accreditation of medical diagnostic facilities is a strong one by any measure and is fully compliant with recognized general and laboratory discipline-specific international standards.

AHS is the CPSA's only client for accreditation of public laboratories. The CPSA is dependent on AHS for funding its contract to perform the accreditation and consequently, this relationship raises questions about the CPSA's independence from AHS and its ability to make objective recommendations.

One of the difficulties for the CPSA is that the assessors who are used to accredit AHS laboratories are most often employed by or contracted by AHS to provide laboratory services. Although assessors come from different geographical areas of the province, they are still part of the organization being accredited. In addition, having the same individuals make repeated visits to the same site suggests the possibility that problems may not be noted because of 'familiarity' with a particular laboratory. The CPSA has contracted with a pathologist consultant from out-of-province to observe and report to AHS on the objectivity and thoroughness of the CPSA's laboratory accreditation process.

In Alberta, the CPSA is not only the accreditor of the laboratories but also regulates the pathologists who work in those laboratories. AHS, the sole public client of the CPSA for this program, in turn grants privileges to the pathologists who practise in the laboratories.

These various processes (i.e., accreditation, regulation of physicians, and the granting of privileges) need to have sufficient degrees of separation to avoid the potential for conflict of interest.

6. RECOMMENDATION

The CPSA, AHS and AH collaborate to implement an accreditation process for public medical diagnostic laboratories that mitigates the potential for conflict of interest.

REQUIRED ACTIONS

- Alberta Health assume responsibility for the signing and funding of the contract for accreditation of public diagnostic medical laboratories with the CPSA.
- The CPSA, as part of the accreditation contract and in addition to the external pathologist consultant, use assessors from other provinces and ensure that no assessor reviews a laboratory twice in succession.

Performance/assurance of competence of pathologists

Issue

The processes that support the regulation and assessment of the performance of individual pathologists that are conducted by the CPSA and AHS, respectively, need to be more closely integrated to fully support performance management and the assurance of competence of pathologists.

Analysis

Issues arose regarding the performance of Pathologist A at the Royal Alexandra Hospital and from this arose questions about how the performance of individual pathologists is determined.

Two distinct yet parallel systems exist in the province related to physician performance. One regulates the practice of medicine in Alberta (which is governed by the CPSA), and one grants privileges and assesses the performance of physicians who practise medicine within AHS's jurisdiction. The challenge is that these systems, which share a common purpose – determining and assuring the ongoing competence of physicians – are not integrated and consequently do not share vital information relevant to the assessment of physician performance and competence.

To strengthen the processes of regulation by the CPSA and privileging and performance management by AHS the ideal model is one developed jointly by AHS and the CPSA. This would not be a divesting of responsibility by the CPSA but an example of a shared model of responsibility. This model would coordinate the activities unique to AHS and to the CPSA as well as include the personal responsibility of each individual practitioner.

7. RECOMMENDATION

The College of Physicians & Surgeons of Alberta and Alberta Health Services create and implement a coordinated approach to assessing pathologists' competence and performance.

REQUIRED ACTION

- A provincial working group with representation from the CPSA, AHS leadership, and pathologists be tasked with the creation of a coordinated approach to the performance/assurance of competence of individual pathologists.

BACKGROUND

In the autumn of 2011 it came to the attention of the Health Quality Council of Alberta (HQCA) that between December 2010 and March 2011, problems occurred in the preparation of a total of 31 tissue specimens at the Calgary Laboratory Services Diagnostic and Scientific Centre (DSC)[i] and at Rockyview General Hospital (RGH). The problems with preparation then led to difficulties on the part of some pathologists at the RGH with interpretation of the specimens. After an initial investigation by Alberta Health Services (AHS) and discussions with the Minister of Health, AHS requested that an independent review of the problems at the RGH and the DSC be conducted by the HQCA under Section 14 of the *HQCA Regulation 130/2006*.

Shortly after the announcement of the review, in December 2011 it came to light that 159 anatomical pathology[ii] specimens at the Royal Alexandra Hospital (RAH) in Edmonton had been misinterpreted. A decision was then made to expand the scope of the DSC and RGH anatomical pathology review to include the issues identified at the RAH.

The review was to encompass the quality and safety of the processes and procedures, including interpretation, of anatomical pathology specimens collected and/or processed at the RGH and the DSC. Further, the review was to examine if appropriate standards, guidelines, and procedures were in place for the reading and interpretation of biopsies; the engagement and organization of health professionals who prepare and/or interpret anatomical pathology specimens; and if the necessary safeguards to ensure the accuracy of anatomical pathology procedures were in place at the RAH.

In addition, AHS asked the College of Physician & Surgeons of Alberta (CPSA) to conduct an immediate inspection of anatomical pathology processes at the RGH and DSC. The results of these inspections in December 2011 and the most recent accreditation by the CPSA of anatomical pathology processes at the DSC and RGH completed in June 2009 would be considered as part of this review.

Although this review concerns anatomical pathology, the focus is on 'surgical pathology' or the examination of tissues and organs removed during surgery or biopsy. This review excludes other areas of anatomical pathology, such as post-mortem studies or forensic pathology.

Purpose

Pursuant to Section 14 of the *Health Quality Council of Alberta Regulation 130/2006*, Alberta Health Services (AHS) requested that the HQCA conduct an independent review of the quality of the preparation and interpretation of anatomical pathology specimens prepared and/or interpreted at the:

[i] The use of DSC and CLS DSC refer to the Calgary Laboratory Services Diagnostic and Scientific Centre.
[ii] Both the terms 'anatomical pathology' and 'anatomic pathology' are used in this report and mean the same thing: the branch of medicine concerned with the study of the cellular and tissue aspects of disease.

- Rockyview General Hospital (RGH) and Calgary Laboratory Services (CLS) Diagnostic and Scientific Centre (DSC) from January 2010 to December 2011, and
- Royal Alexandra Hospital (RAH) from July 2011 through October 2011.

Objectives

The HQCA, through a quality assurance committee (QAC) under Section 9 of the *Alberta Evidence Act*, was to conduct a thorough review of and determine any contributing factors related to:

- Anatomical pathology specimens prepared and/or interpreted at the RGH and the CLS DSC, including the 31 specimens already identified, for the period from January 2010 to December 2011, and
- Anatomical pathology specimens prepared and/or interpreted at the RAH from July 2011 to October 2011, including the 159 prostate biopsy specimens already identified for that period.

The review was also to consider any matter pertaining to the quality of the preparation and interpretation of anatomical pathology specimens.

To ensure the quality of pathology procedures, and based on the findings and analysis of the investigation and a review of current practices, the HQCA was to make recommendations about the quality of anatomical pathology specimen preparation and/or interpretation at the RGH, DSC, and the RAH.

Scope

Inclusion

- Whether appropriate standards, guidelines, and procedures (including best practices and necessary safeguards) were in place regarding the quality of the preparation and interpretation of anatomical pathology specimens, and
- The engagement and organization of health professionals who prepare and/or interpret anatomical pathology specimens.

Exclusion

- The collection, labelling, and transportation of specimens in and from operating rooms or other sites where biopsies are taken to the laboratory.
- Hospitals or clinics (public or private) in AHS other than the RGH, DSC, and RAH.

REVIEW GOVERNANCE

The HQCA was requested by Dr. Chris Eagle, President and Chief Executive Officer, Alberta Health Services, to conduct this review. Responsibility for this review lies with Dr. John Cowell, Chief Executive Officer and review sponsor, HQCA.

Review team

- Jan Davies MSc MD FRCPC, Quality and Safety Expert Consultant, Review Lead
- Donna MacFarlane RN, HQCA Administrative and Patient Safety Lead
- Carmella Duchscherer RRT BHS(RT) MPA, Quality and Safety Consultant
- Dennis Kendel MD FRCPC, Executive Physician Consultant, former Registrar of The College of Physicians and Surgeons of Saskatchewan
- Arlene Weidner RN MSc CHE, Senior Executive Nurse Consultant
- Eva Raik AM FRCPA FRACP, Pathology Quality Consultant
- Ward Flemons MD FRCPC, Quality Assurance/Quality Improvement Expert Consultant
- Charlene Blair BScPharm RPh, PGDM, HQCA Patient Safety Lead
- Rinda LaBranche RN BEd MEd, HQCA Patient Safety Lead
- Charlene McBrien-Morrison RT (CSLT) MBA, HQCA Executive Director
- Anette Mikkelsen BSc PT MBA, HQCA Quality and Patient Safety Initiatives Lead
- Kim Trufyn HQCA Administrative Assistant

APPROACH and METHODOLOGY

This review was carried out by an appointed quality assurance committee (QAC) of the HQCA and in accordance with Section 9 of the *Alberta Evidence Act*.[1] The HQCA will keep confidential the list of people whom it did or intended to call before the QAC and keep confidential whether an individual chose to appear or not appear before the QAC. No patient names or identifiers are disclosed.

The aim of the review is to report on findings and recommendations for system-level improvements for the delivery of healthcare in Alberta.

Methodology

This review was conducted according to the methodology outlined in *The Guide to Systematic Systems Analysis: A Practical Approach to Patient Safety Reviews*.[2] This methodology was "developed specifically for healthcare reviews and draws from aviation and human factors investigation techniques"[2]. The methodology encourages a systemic view of the healthcare system; that is, "how all parts of the healthcare system play a role", rather than a focus on "only one particular factor in isolation".[2]

Using this methodology, a three-phase, systematic approach was used for the review:

1. collection of information
2. analysis of information
3. development of recommendations

Collection of information

Information was gathered from a number of sources, including:

- patient health records
- documents and files from AHS and participating laboratories
- interviews
- site tours and observations of anatomical pathology laboratories
- review of literature
- review of other Canadian inquiries into anatomical pathology
- review of other laboratory accreditation programs
- discussions with experts

Analysis of information

A model of the healthcare system was used to ensure the entire system was taken into consideration. The model is made up of the five major components of the health system: patients, personnel, equipment/environment, organization(s), and regulatory agencies.

In the analysis phase each piece of information was organized according to which part of the healthcare system it came from. Then, all the information for each of the five major system components was

analyzed to identify system problems. Finally, the findings of the analysis were reviewed and examined to ensure that the perspective of the review team focused on the entire system, not individuals. The focus was not to find fault with individuals but to identify factors in the system that may contribute to patient safety problems.

Development of recommendations

Recommendations were developed to mitigate the quality and patient safety issues identified in the processing and interpretation of anatomical pathology samples and in the engagement and organization of health professionals.

Presentation of the findings

For the events at the RGH, DSC, and at the RAH, the investigation's findings are presented under the following sections: What happened to the patients?, Sequence of events, and Analysis.

This report also contains appendices related to a history of and further developments in anatomical pathology, accreditation of anatomical pathology services in Canada and internationally, and other inquiries into anatomical pathology that have been conducted elsewhere in Canada.

INTRODUCTION TO PATHOLOGY

To understand what happened to the patients and their specimens at the Rockyview General Hospital (RGH), Calgary Laboratory Services Diagnostic Scientific Centre (CLS DSC), and the Royal Alexandra Hospital (RAH), readers of this report may appreciate a brief introduction to the medical specialty of anatomical pathology.

Pathology is a branch of medicine concerned with the study of disease. The word 'pathology' comes from two other words meaning the 'study' of 'suffering'.[3] Pathology represents the "clinical diagnostic science that underpins patient care"[4] and can be considered to be the basis of clinical medicine, involving the "study of the patterns, causes, mechanisms and effects of illness (disease)".[5] (See Appendix II for a brief history of anatomical pathology.)

Health professionals who prepare and interpret tissue specimens

Pathologists

Pathologists are medical doctors who complete between four and seven years of specialized postgraduate study as residents, similar to other medical and surgical specialties. In Canada, this training is overseen by the Royal College of Physicians and Surgeons of Canada.[6]

Some trainee pathologists may choose to become anatomical pathologists and then subspecialize in surgical pathology, which is the focus of this review. This area of subspecialization involves the examination of tissues and organs removed during surgery or biopsy. Other anatomical pathologists focus on cytopathology, which is the study of abnormalities purely at the cellular level; molecular pathology, which is the study of abnormalities purely at the molecular level; or forensic pathology, which includes post-mortem examinations or autopsies to help determine cause of death, injury, or disease.

During their training, residents in anatomical pathology study every organ and tissue of the body, both macroscopically (with the naked eye) and microscopically, learning what every part looks like in the normal state and after changes produced by aging, injuries, and diseases such as cancer.

At the end of residency training, residents take written and oral examinations. In Canada, successful candidates are said to be Fellows of the Royal College of Physicians of Canada.[7] Similar training programs exist in Australasia,[8] the United Kingdom,[9] and the United States.[10] In Alberta, pathologists, like other physicians and surgeons, are registered under the College of Physicians & Surgeons of Alberta (CPSA).[11]

No matter what their area of special interest, pathologists are dedicated to the diagnosis and monitoring of disease. They are assisted in this work by many other experts in anatomical pathology, and by a range of clinical, technical, and administrative professionals including pathologists' assistants and medical laboratory technologists and technicians.

Pathologists' assistants

A pathologists' assistant (PA) may have a Master of Science degree or have received additional on-the-job-training. A PA works under the supervision of one or more anatomical pathologists. This means that a PA performs highly standardized tasks for specific medical activities previously carried out by a

pathologist, delegated by the pathologist to the PA. These tasks include the "initial examination, dissection, and gross description of surgically removed tissues" and preparation of frozen sections for tissue examination during surgery. Delegating such tasks allows a pathologist to spend more time reviewing and interpreting slides.[12]

The QAC learned that the PA, unlike other medical laboratory technologists, is not regulated under the *Health Professions Act* (HPA).[13] PAs have direct performance accountability to the pathologists who supervise their work. Pathologists are accountable to the CPSA for ensuring they practise within their competency profile.

As of July 1, 2012, there is a new PA training program as a specialization within the Medical Sciences Graduate Program, Faculty of Medicine, at the University of Calgary.[12] The program has been approved by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS), an American agency that also offers international accreditation of training programs of allied health professionals who work in anatomical pathology or clinical pathology laboratories.[14] This program now brings to three the number of training centres for pathologists' assistants in Canada.

Medical laboratory technologists, technicians, and assistants

Medical laboratory *technologists* (MLTs) are trained at universities, such as the University of Alberta,[15] and technological institutes such as Southern Alberta Institute of Technology.[16] Medical laboratory *technicians* or medical laboratory *assistants* (MLAs) may receive training at technological institutes.[17] The specific roles of these non-medical staff include the preparation of specimens from the operating room and tissue biopsies ready for interpretation by the pathologist. This work involves multiple and detailed steps described below. MLTs are regulated under the HPA.[18] In the field of anatomical pathology these non-medical staff are known as pathology technologists, pathology technicians, and pathology assistants. The latter are not the same as 'pathologists' assistants'.

How anatomical pathology specimens are prepared and interpreted

The preparation and interpretation of anatomical pathology specimens is complex.

One way of describing each step in the process is according to the **'Pre-Analytical – Analytical – Post-Analytical'** process,[19] which describes what happens to a sample once it has been received by a laboratory. This three-phase process is used in some laboratories in Alberta and elsewhere in North America. Another way of showing what happens to specimens is with the **'Request – Test – Report'** pathway.[20] This pathway focuses on both the specimen and the patient, starting when a patient sees a doctor who decides a test is needed to help determine the nature and severity of the patient's problem. Because of its 'patient focus', the QAC chose to use the Request – Test – Report pathway as a framework for the following description.

One of the events at the RGH and some of the cases from the RAH involved prostate tissue samples. The Request – Test – Report pathway is therefore used to follow a sample of prostate tissue from when a patient undergoes biopsy testing for possible prostate cancer.

Prostate cancer starts in cells of the prostate gland, part of the male reproductive system. The prostate's main function is to make some of the liquid (seminal fluid) that mixes with sperm from the testicles to make semen, which is then ejaculated during sexual intercourse. About the size of a large walnut, the

prostate is located just below the bladder, at the base of the penis and close to the rectum. The prostate gland wraps the urethra, the tube that carries urine and semen through the penis.[21]

In the early stages, men may not have any signs or symptoms of prostate cancer but symptoms may appear if the tumour grows, swelling the prostate so that it starts to press on the urethra. Passing urine may become more difficult or painful or there may be an urge to pass urine more often than normal. However, the same symptoms can occur simply through aging, because as men grow older, the prostate tends to enlarge and block the urethra or bladder. This non-cancerous enlargement of the prostate is known as BPH or benign prostatic hypertrophy. BPH is very common in older men.[22]

Prostate cancer, with its similar symptoms, is also common and will account for about one-quarter of all new diagnoses of cancer in Canadian men in 2012.[23] Except in a smaller number of men,[24] however, prostate cancer usually grows slowly and can often be managed conservatively. Indeed, prostate cancer is sometimes described as the cancer that men die *with* and not *from*: one in seven men will develop prostate cancer during his lifetime but only one in 28 men will die of prostate cancer.[23]

Because most prostate cancer is 'indolent' (slow growing) rather than 'aggressive' (fast growing), some delay in getting a diagnosis and/or treatment does not generally change what could happen to a patient. Indeed, some centres offer the 'conservative management of prostate cancer' or 'watchful waiting', with observation and prostate-specific antigen (PSA) testing until symptoms develop, followed by symptomatic or palliative treatment.[25] Because of the positive results from these centres and recent controversy about the role of PSA screening,[26] some centres are now providing 'active surveillance'. Patients with 'low-risk localized prostate cancer' are offered regular clinic visits, PSA testing, and prostate biopsies at set times.[27] Personalized treatment, including a consideration of the patient's "personal values",[28,29] is deferred until the disease progresses.[30] The aim is now "to trigger delayed treatment in those men who need it" but to avoid "triggering treatment in those who do not".[28] This approach is supported by the recently released results of the Prostate cancer Intervention Versus Observation Trial (PIVOT).[31]

Request phase

The process may start when a patient has symptoms such as frequent or difficult passage of urine. The patient sees a physician, such as his family doctor, to start the process to identify the problem. After talking with and examining the patient (including performing a digital rectal examination or DRE), the family doctor will usually order a blood test known as the serum PSA. If the family doctor determines that the prostate feels abnormal on DRE and/or the PSA result is elevated, then the patient may be referred to a urologist, a surgeon who specializes in the surgical treatment of conditions and diseases of the urinary tract (kidneys, ureters, bladder, urethra, prostate gland, testes, and penis). If the urologist determines that a patient might have prostate cancer, the urologist will discuss diagnostic and treatment options with the patient.

If the patient continues with more diagnostic procedures, the urologist will take several biopsies of the prostate. In this procedure, the urologist performs a transrectal ultrasound (TRUS) examination by passing a small probe into the rectum. TRUS uses sound waves to give an image of the prostate, which may show "dark or dense areas on the image that may represent cancer". At the same time, the urologist uses a needle to take several samples (or biopsies) of prostate cells. This test may be uncomfortable but does not last long and "local anesthetic (freezing) can be used to lessen the discomfort".[32]

Samples are usually taken in a systematic way with, for example, sampling from the left and right of the top (or apex), the middle, and the base of the prostate. Occasionally a urologist may take additional samples, such as from a nodule or lump in the prostate that is suspected of being cancerous. Each insertion of the needle removes a cylinder or 'needle core' of prostate tissue, measuring about one-half an inch long by one-sixteenth of an inch wide. Typically a urologist will remove six needle cores, or biopsies.

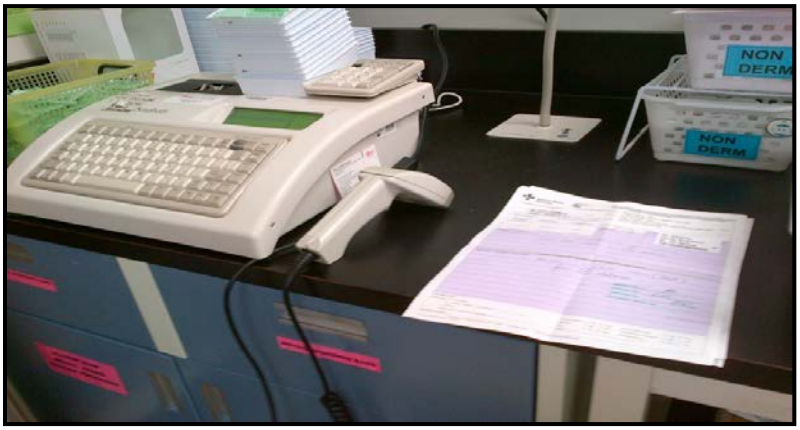
The prostate biopsies are then placed in small containers of special liquid that starts to 'fix' (preserve) the tissue and the urologist fills out a requisition form that accompanies the biopsies.

A: On the left are containers of liquid that start to 'fix' the tissue samples. Circled on the right are prostate needle biopsy tissue samples.

The biopsies must be identified so that they match the patient from whom they were taken. This may be done using the patient's name, date of birth, age, address, and the name of the physician ordering the analysis of the biopsies. Ideally, the requisition also provides some clinical details, such as any signs or symptoms in the patient. The form needs to be correct and complete. (In fact, the largest source of problems in anatomical pathology is incomplete or incorrect requisitions, particularly with respect to patient identification.) The biopsy specimens are then transported to the laboratory.

Test phase

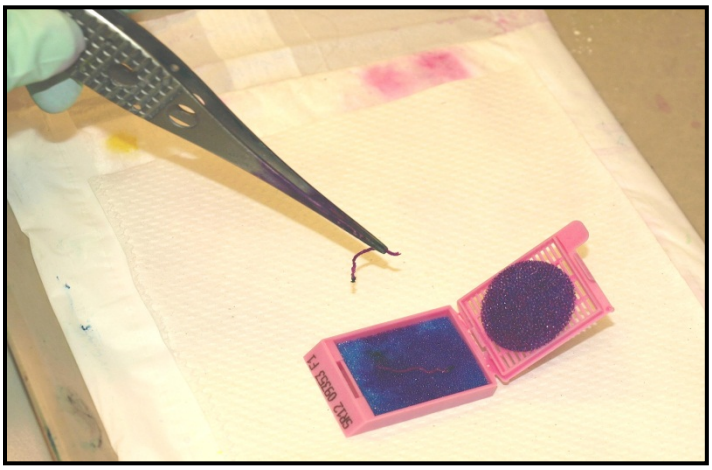
At the laboratory, the prostate biopsy specimens are received by a clerk who enters the patient's name and provincial healthcare number and/or hospital identification number, and the surgeon's/clinician's name, into the Laboratory Information System (LIS). The laboratory requisition information is verified and must correspond to the specimen information. This process is known as 'accessioning'.[33]



B: 'Accessioning': patient information is entered into the Laboratory Information System

The LIS generates a unique patient identification number and prints bar-code labels, which are then attached to the matching requisition and specimen containers.

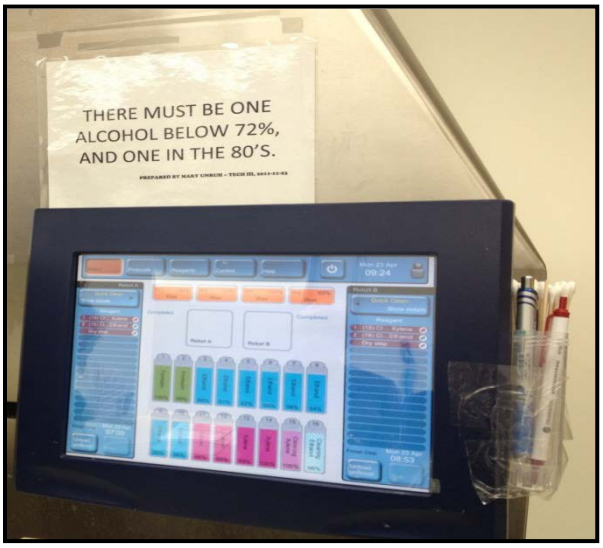
The sample is then passed to a pathologists' assistant (PA) or a pathology technologist (PT) for initial preparation. The PA or PT removes the prostate needle cores from the containers and begins a process known as 'grossing'. This involves placing the prostate needle cores into small, perforated plastic containers called 'cassettes'. Care is needed to ensure that each core is carefully positioned in the cassette and that each cassette is identifiable as belonging to that patient.



C: Needle core biopsies are placed into a cassette

The needle core biopsies in their cassettes are then put into a tissue processing machine that exposes the tissue samples to a sequence of various liquids.

D: A tissue processing machine



E: Tissue processing machine control panel

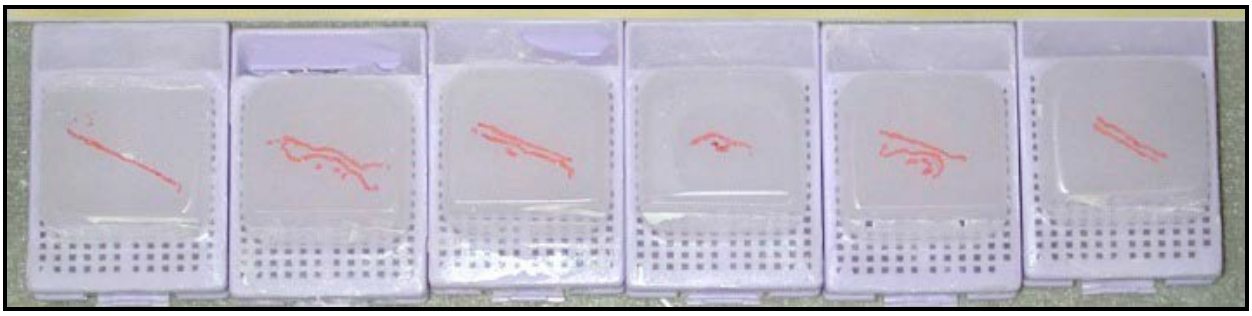
These liquids are specially formulated to first 'fix' the tissues and prevent them from decomposing. This fixation takes about two hours for prostate needle core biopsy samples, while larger tissue samples are left to fix for nine to 12 hours. (Fixation also helps preserve tissue "as near to its original form as possible",[34] makes the tissue easier to slice, and renders the tissue more sensitive to special stains.) Second, the

cassettes are immersed in a series of liquids that will remove water from the tissues (i.e., dehydrate them). The third liquid is intended to 'clear' the tissue, that is, to replace the dehydrating liquids present in the tissue specimens with a substance that will be compatible with the paraffin wax into which the tissues will be embedded. Lastly, the tissues are infiltrated with wax. At the end of the tissue processing machine's cycle, the cassettes are removed from the machine and moved to another work station.

The next stage of tissue processing involves removing the now-fixed and wax-infiltrated tissues and placing them in molds. Melted wax is poured into the molds and allowed to harden. This produces specimens 'embedded' in a small block of wax.

F: Melted wax is poured into a mold holding processed tissue

Once the wax has hardened and cooled, the wax blocks are kept on ice until needed, because cooling the blocks makes them easier to cut.

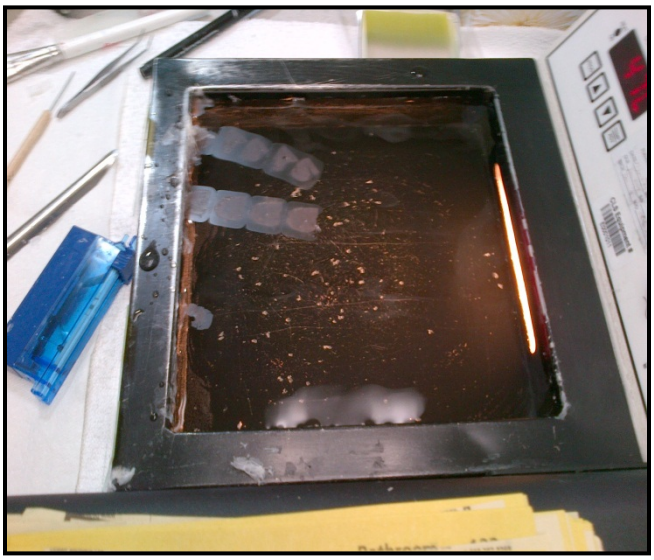


G: Needle core biopsies embedded in wax

In turn, each block is then popped out of its mold and placed on a special cutting tool known as a microtome. Using the microtome, a PT cuts extremely thin slices (three to four microns) of the prostate tissue and surrounding wax 'casing'. (One micron is equal to 0.00003937007 inches; a human hair has an average diameter of 40 to 50 microns.)[35]

These slices, or sections, come off the microtome as 'ribbons of tissue', which are gently placed in a water bath where they float on the surface.

H: 'Ribbon of tissue' on a microtome



I: Water bath with ribbons of tissue

Using a thin glass slide, the PT chooses between one and four serial sections from the ribbon of prostate tissue and then lifts the sections up onto the slide, taking care not to distort each section with wrinkles or folds in the tissue. (Imagine using tweezers to lift a one-inch square of wet, single-thickness paper tissue and slide it onto a glass plate without wrinkling or tearing the wet paper.)

J: Pathology technologist lifts a section onto a glass slide

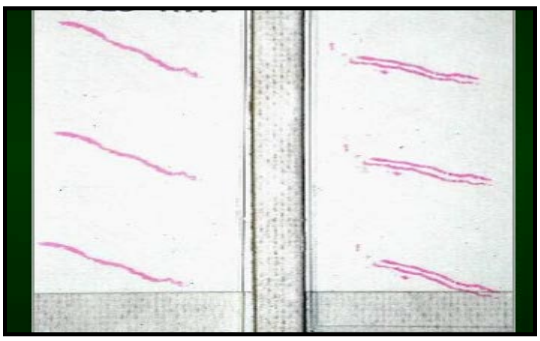
It is crucial the slices not be distorted because the pathologist who views the slide will want to look at specific parts of the cells and these become obscured if the tissue has been doubled-over. Wrinkles or folds (or other tissue 'artifacts') can also interfere with automated image analysis.[36]

The ribbon, with its one to four serial sections, represents one level of a prostate tissue biopsy block. In general, laboratories cut between two and three levels from each biopsy block.

An experienced PT takes about a minute and a half to cut and trim one block and can cut about 100–120 tissue blocks per day. From these blocks the PT will make up to 16 slides per block. To give an idea of

the volume of work that this entails, approximately 5,000 men undergo prostate biopsy testing in the Calgary and Edmonton Zones of AHS in a year. In these two centres about 100,000 to 150,000 slides of prostate biopsy tissue are produced annually. If other specialized testing is required for a given patient then more slides will be produced.

The glass slides with the prostate slices on them are allowed to dry, are gently heat fixed, and are then placed into wire racks. These racks are loaded into another machine that dips the slides into a special stain known as H&E (or Hematoxylin & Eosin). This stain differentiates the various cells within the prostate gland. Once the slides are dried, a very thin layer of plastic tape or glass (known as a 'cover slip') is positioned, taking care to avoid any air bubbles between the tissue and the glass.



K: Stained slide

Another test that may be done on prostate needle core biopsies is 'immunohistochemical analysis'. With this test, additional slices of prostate tissue are cut and the glass slides are exposed to chemical reagents that may help the pathologist to better identify cancerous cells.

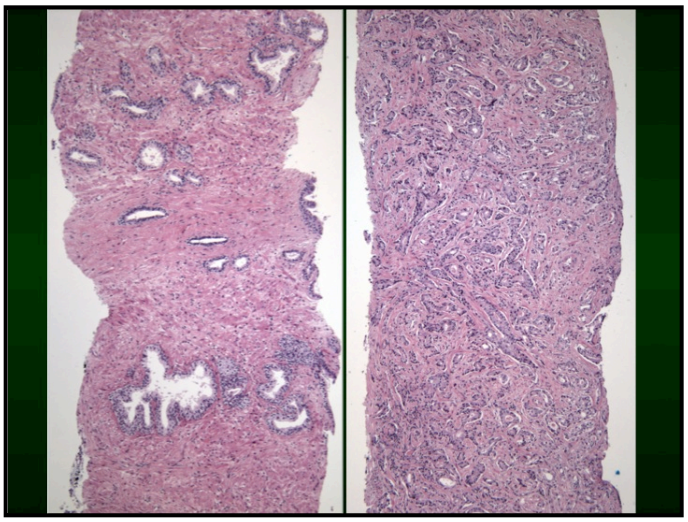
The prepared specimens, in the form of microscopic slides that are stained and cover-slipped, are placed in a cardboard tray and transported or passed along to the pathologist.

L: Cardboard tray holding microscopic slides ready for the pathologist

When a pathologist is ready to interpret a set of slides belonging to a patient, he or she is said to have 'signed out' the patient's case. Pathologists understand that the tissue biopsy or a surgical specimen actually represents a 'piece of a patient' and that when they are asked to look at a slide they are providing

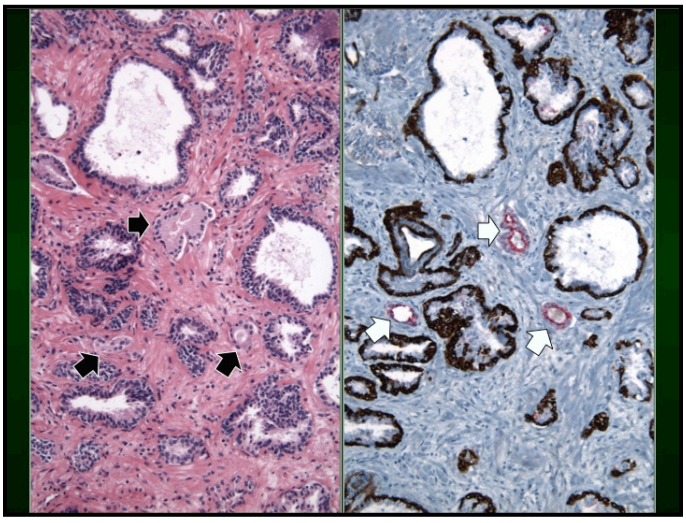
a consultation. This process is, at one level, no different from consultations provided by other medical specialists, such as heart or lung specialists.

After reading the requisition from the referring doctor (in this case a urologist), the pathologist then looks at each slide through the microscope and interprets the findings. Interpretation of that piece of tissue is in part a series of highly skilled tasks and in part the judgment and experience of the practitioner. It should be understood that the result is an interpretation of the sizes, shapes, and colours of pieces of tissue when seen through the microscope.



M: Prostate tissue samples as they appear under a microscope. The sample on the left is of normal prostate tissue; the sample on the right is of prostate cancer.

The pathologist provides an expert opinion of what he or she sees through the microscope. The pathologist also uses whatever information is provided in the requisition and that may be available from other sources, such as previous biopsies.



N: Differently stained prostate needle core biopsies as seen through the microscope. The arrows point to cancer cells.

Report phase

Generally one pathologist alone will report the results of the microscopic examination. At other times the pathologist may ask a colleague to take a look at the specimen. Sometimes this is done on an informal basis; at other times, a formal request for this additional review is made.

The pathologist then produces a report, which provides the tissue diagnosis of the patient's condition. Increasingly, pathologists use an electronic structured format known as 'synoptic reporting'. This type of standardized report has been shown to be more complete, containing relevant information using drop-down menus, standardized language, and discrete data fields. The pathologist signs the report to be sent to the consulting urologist. At this point the pathologist is said to have 'signed off' the case.

The urologist discusses the results with the patient. In effect, the urologist is passing on the opinion of the pathologist to the patient. The urologist, like other surgical and medical specialists, may choose to agree with the pathologist or to seek a second opinion or consultation from another pathologist.

FINDINGS

The events are described chronologically and then discussed at a system level according to all five components of the health system (patients, personnel, environment/equipment, organization, and regulatory agencies).

Cases at the Rockyview General Hospital (RGH) and Calgary Laboratory Services Diagnostic and Scientific Centre (CLS DSC)

What happened to the patients?

The prostate biopsy specimens of nine patients were misprocessed in December 2010 at the DSC. The processing problems made it difficult to interpret the slides made from these specimens but opinions were eventually offered about all the slides. The patients were seen in follow-up by their urologists to discuss their biopsy results. No patient received an incorrect diagnosis. Some patients had repeat biopsies as part of normal clinical care.

The tissue samples of 16 patients who had undergone a variety of biopsies and procedures at the RGH were misprocessed at the DSC in January 2011. There were no adverse outcomes for any of the patients. Similarly, none of a separate group of six patients was harmed after processing problems were identified with their tissue samples at the RGH in early March 2011. In both instances, pathologists were able to provide timely interpretation of all the samples.

The CLS Chief Operating Officer (COO) or a CLS executive pathologist contacted (or attempted to contact) all 31 patients to disclose the problems with processing their tissue samples. The first nine patients were contacted in late December 2010 while the patients from the January and March 2011 events were not contacted until early November 2011.

The QAC was unable to determine the degree of psychological distress suffered by any of the 31 patients but the possibility is acknowledged. Psychological distress would include the anxiety experienced by the patients and their families upon learning that a repeat prostate biopsy might be necessary or that there had been a problem with the processing of their biopsy and operative samples.

Sequence of events

The following table identifies the sequence of key organizational changes and events that took place in, or have directly impacted CLS, since 2008. The three misprocessing events that affected the 31 patients and that are the focus of this review are also identified in this table (shaded grey). The events are then discussed at a system level according to all five components of the health system (patients, personnel, environment/equipment, organization, and regulatory agencies).

It is important to emphasize that just because one event precedes another does not mean that one event caused the other or even that the two events are related.

Table 1: Chronology of key events at the RGH and DSC

Date	Key event
April 2008	▪ Changes were considered to the anatomical pathology service delivery model at Calgary hospitals. The CLS Executive sponsored a review of options.
April 2009	▪ CLS became a wholly owned subsidiary of AHS.
October 2009	▪ CLS Executive decided to centralize Calgary AP tissue processing services from the four hospitals to the DSC. ▪ Senior management changes occurred at CLS.
January to May 2010	▪ More management changes occurred at CLS. ▪ The CEO of AHS gave final approval to centralize AP services at the DSC.
Summer 2010	▪ Centralization began with three of the four sites (all but FMC) relocating, and problems with tissue processing started to emerge at the DSC site. ▪ Incorrect liquid was thought to have been used to fill an internal reservoir of a tissue processor affecting various specimens from 73 patients. Another and ultimately successful attempt was made to reprocess the tissues.
Late summer 2010	▪ Problems were found with the DSC facility and the plan to complete centralization was suspended until issues with space, ventilation, and various processes were resolved.
Fall 2010	▪ Because of complaints about the processing of prostate samples at the DSC, RGH pathologists requested services from former RGH staff only and proposed returning prostate tissue processing to the RGH.
Mid December 2010	▪ Misprocessing of prostate tissues occurred at the DSC, affecting the biopsy samples of nine patients. The biopsy samples were subsequently reprocessed. The processing problems made it difficult to interpret the slides and there were differences of opinion between RGH pathologists.
Late December 2010	▪ A decision was made to contact the nine patients to explain that there were problems with processing the tissue specimens and to let them know of the possible need for a repeat biopsy. Patients were called on December 23 and 24. Some of those contacted did not completely understand what they were being told and two of the patients were described as being extremely upset. ▪ Relationships between RGH pathologists and staff at the DSC became further strained. ▪ Meetings were held with pathologists to discuss complaints about disruptive interpersonal behaviours.
Early January 2011	▪ CLS initiated an internal quality review of AP centralization and attempts were made to improve relationships. ▪ Prostate tissue processing was moved back to the RGH on a trial basis.
Mid January 2011	▪ Misprocessing of various tissues occurred at the DSC, affecting the specimens from 16 patients. Pathologists were able to read the slides. It was felt there were no implications for the diagnosis or treatment of any of the 16 patients.
Late January 2011	▪ Opinions were eventually offered about all of the nine prostate slides (from the December event) after a prostate biopsy expert in the United States was consulted.
March 2011	▪ Misprocessing of various tissues occurred at the RGH, affecting the specimens from six patients. The specimens were reprocessed and pathologists were able to provide a diagnosis. There were no clinical implications to the six patients.
November 2011	▪ A decision was made to provide disclosure to patients connected to the January and March 2011 events, to let each patient know that there had been problems with tissue processing because of equipment malfunction. ▪ The HQCA review into anatomical pathology at RGH and the DSC in Calgary was announced. ▪ A tissue processor was loaded with three baskets instead of two, affecting various specimens from 25 surgical cases and an autopsy case. At the end of the processing cycle, problems with the tissues were discovered and the tissues were reprocessed satisfactorily. Pathologists were able to interpret all the slides.

Historical context

Although problems with the specimens from the 31 patients occurred in late 2010 and early 2011, the QAC looked back almost two decades for historical context. Until the **1990s**, anatomical pathology (AP) in Alberta was carried out in a number of independent hospital-based and private organizations. Starting in **1993**, the Alberta government began to decrease funding to laboratories by five to 10 per cent on a quarterly or biannual basis. In southern Alberta, most of the independent medical laboratories were run by two separate organizations, MDS Inc. and Kasper Medical Laboratories Inc. In **1994**, cuts to the provincial healthcare budget were announced, with reductions in healthcare workers' pay and planned closure of the Grace and Holy Cross hospitals in Calgary.[37] That same year the province was divided into 17 healthcare regions.

In **1995** MDS Inc. and Kasper Medical Laboratories Inc. merged their Calgary laboratory operations to form the MDS Kasper Medical Laboratories Partnership. The government withdrew fee-for-service billing by privately run laboratories and started to cut back laboratory funding by about 30 per cent, while also decreasing funding to other areas of healthcare by 20 per cent. Faced with a budget deficit, Calgary Regional Health Authority (CRHA) senior administrators determined that a new laboratory service delivery model was required. Consultants hired by the CRHA proposed and submitted a business solution to the government early in **1996**. Various service delivery models were considered before a choice was made to incorporate all the Calgary and area laboratories (with the exception of the Southern Alberta Provincial Laboratory of Public Health and Canadian Blood Services).[38] A single public-private partnership was formed between MDS Kasper Medical Laboratories and the CRHA, to form Calgary Laboratory Services (CLS). Ownership was split between MDS Kasper Medical Laboratories and the CRHA, with the CRHA agreeing to "manage all laboratory services in the Calgary region, including laboratory services provided within hospitals".[39] By the end of **1999**, a three-year process of centralization of the CRHA clinical microbiology service was completed, moving most (non-urgent) tests to an out-of-hospital, high-volume laboratory.[38]

In **2002** the University of Calgary began the purchase of a building near the northern end of the campus. Previously owned by Imperial Oil, the Imperial Oil Research Centre would provide the university with a high-quality facility with additional and necessary space. Imperial Oil would continue to occupy part of the 235,000 square foot facility, leasing space for ongoing research. The University planned to provide space for applied energy and science-based research.

In **April 2003** the 17 provincial healthcare regions were consolidated into nine regions and three boards. The former CRHA became the Calgary Health Region.[40] By the next month the University of Calgary had completed the purchase of the former Imperial Oil building.

In **2004** CLS relocated its central laboratory, now known as the Diagnostic and Scientific Centre (DSC), to the Imperial Oil Research Centre.

Having previously sold a 25 per cent share to the Calgary Health Region, MDS Kasper Medical Laboratories sold its remaining 25 per cent share to the Region on **April 4, 2006**. CLS became a wholly owned subsidiary of the Calgary Health Region.

In **February 2007** problems were encountered with the ventilation system at the RGH. In **November 2007** ventilation in the laboratories became inadequate, and processing for AP at the RGH was moved to the DSC.

Changes to the AP service delivery model are considered – April 2008

In **April 2008** the CLS Executive sponsored a review of options to improve the delivery of AP services because of limited capital funding, limited facility space, difficulties in staffing, and increasing work volumes.[41]

On **May 15** the then Health Minister announced the dissolution of the nine separate health regions and three health boards (Alberta Mental Health Board, Alberta Cancer Board, and the Alberta Alcohol and Drug Abuse Commission). These entities were to be replaced by a single health service provider for the province: Alberta Health Services (AHS).

In **June** AP processing services were moved back to the RGH after improvements were made to the ventilation there.

On **January 21, 2009** a draft version of the Anatomic Pathology Service Delivery Model was released.[42] A range of service delivery models was described, from one model in which AP services were distributed among the four Calgary hospitals (as existed at the time) to another model with all AP services centralized at the DSC.

In early **February**, as part of a plan aimed at ensuring the "highest levels of safety and quality in their anatomic pathology practice", CLS leadership had two American consultants undertake an external review of quality and safety in anatomical pathology "at an enterprise level" and with a "focus on the processes and systems that support quality assurance".[42]

On **March 23** a new CEO of AHS was appointed.

In **April 2009** the College of Physicians & Surgeons of Alberta (CPSA) conducted a regularly scheduled on-site accreditation inspection of CLS.

On **April 1** CLS became a wholly owned subsidiary of AHS. CLS retained its board and executive members, as well as its own vision, mission, and values statements. On **April 14** an initial version of a "Business Case for the Centralization of AP Technical Processing" was created.[43] The next day the Draft AP Service Delivery Model report was updated to include the changes in the organizational chart.

Between **May 5** and **October 1** the Business Case was revised, with some updates based on feedback.[43]

The decision is made to centralize AP Calgary services – October 2009

In **October** the Chief Operating Officer (COO) left CLS and an internal replacement was appointed. Other internal appointments included a new Vice-President (VP) of Operations.

On **October 7** the first draft of a "Communication Plan: AP Centralization – Technical Processing" was developed,[44] as well as the first draft of a Change Management Plan.[45] The latter was intended to "address the people side of change".[46] On **October 7 and 8** the financial and human resources effects of the business case for AP service centralization were approved by the CLS Executive.[43]

On **October 15** the final version of the Anatomic Pathology Service Delivery Model was produced. The report recommended centralization of AP to the DSC from the four acute care hospitals in Calgary (the Alberta Children's Hospital, the Foothills Medical Centre, the Peter Lougheed Centre, and the RGH).[41]

The next day a "Risk Management Plan: AP Centralization – Technical processing" was developed. Labelled "CLS Confidential", the plan included 23 "identified risks", including "negative employee perceptions" and "allocated space may not be adequate without major renovations".[47]

On **October 20** the first draft of an Implementation Plan was developed. The project was expected to last "180 days from formal approval date".[46] The same day the Communication Plan was updated, with the addition of a "communication rollout plan".[44] The first (and only) draft of a Resource Plan was also produced, which was to provide a record of all planning of AP centralization.[48]

On **December 17** the financial implications of the business case for centralization of AP technical processing were approved by AHS Capital Planning – Finance and by AHS Capital Planning on **December 22**.[49]

More management changes occur at CLS – January to May 2010

By **January 1, 2010** further reorganization occurred within CLS, with the new COO leaving. The position was filled internally on an acting basis by the then VP of Operations. A replacement VP of Operations was hired.

On **January 7** the "human resources impact" of the business case for AP centralization was approved by AHS Communications and CLS Executive.[49]

On **January 27** the then CEO of AHS gave final approval of the business case for centralization, which was to entail moving some of the non-medical staff and equipment from each of the acute care hospitals to the DSC. In addition, centralization would result in "layoffs of some laboratory technologists and assistants".[49]

On **February 26** the final version of the Implementation Plan was developed.

On **March 2** the final version of the Communication Plan was prepared. The purpose of the plan was to "mitigate communication breakdown among project participants and management by articulating how, what, when and to whom individuals will communicate and where the information will be maintained".[44]

On **April 12** the acting COO of CLS reported to the Medical Advisory Council (MAC) of CLS that AP still was to be centralized, although there might be some delays because of renovations at the DSC site. On **April 21** CLS conducted a Failure Mode and Effects Analysis (FMEA).[50] The intent of this FMEA exercise was to consider various ways in which problems might occur after centralization with AP processing and if there were current warnings or controls in place to mitigate those problems.

The CEO of AHS gave the signal to proceed with centralization of AP services in **May**. A start date of the summer of 2010 was assigned, which would coincide with the traditional peak of scheduled summer vacations. On **May 28**, the manager involved in the planning of AP centralization retired. One month later the acting COO became the COO.

Centralization begins and problems with tissue processing start to emerge at the new site – summer 2010

At the beginning of **June**, AP services from the Alberta Children's Hospital (ACH) were centralized at the DSC. This was followed one week later by centralization of AP from the Peter Lougheed Centre (PLC).

On **July 7** centralization of specimens from the RGH started. At the same time, the technical staff at the DSC was reduced. By **July 13**, the DSC extended its hours to improve turnaround times and rescheduled some technologists to an evening shift.

On **July 27** a problem was discovered with the processing of tissue samples at the DSC. The samples came from 73 patients who had had various types of biopsies. The tissues, in 105 cassettes, were then reprocessed but there were still problems. Pathologists at the DSC were informed. Another and ultimately successful attempt was made to reprocess the tissues. An internal process review of the July 27 problem was carried out. In addition, an overall quality assurance review of 'processing errors' at the DSC was undertaken by CLS.

Problems are found with the new facility and the plan to complete centralization is suspended – late summer 2010

The QAC learned that on **August 27** the COO asked people to identify any concerns about the centralization of FMC AP services to the DSC. The QAC also learned that on **September 2**, a safety learning report was submitted about issues in AP at the DSC. On that same day, a 'go forward' plan was identified to complete centralization of AP (i.e., bringing in the FMC site).

On **September 10** the COO of CLS met with the pathologists at the RGH to discuss issues raised about centralization. Five days later, the CLS MAC met and discussed the same issues. The plan to continue with the centralization of specimens from the FMC to the DSC was put on hold until problems with space, ventilation, and various processes were resolved. In addition, six technical staff were to be added to the DSC.

Problems with tissue processing continued at the DSC, especially those related to prostate needle biopsy specimens. There were problems with variable embedding, staining, and cutting of the sections.

On **September 24** a report was given by the VP of Operations to the Board of the CLS about the difficulties with AP consolidation. These problems, which had been identified by both the technical and medical staff, included space capacity and safety and quality issues. The Board was also told about the decision to postpone the move of FMC tissue processing to the DSC.

RGH pathologists request services from former RGH technologists only and propose returning prostate tissue processing to the RGH – fall 2010

Because of complaints about the processing of prostate samples at DSC, the RGH pathologists requested that only experienced RGH technologists cut the sections. From **October 1** onwards, prostate biopsy specimens were to be cut by former RGH technologists only.

On **October 5** an automated tissue processor at the DSC was taken out of use because of recurrent problems.

On **October 12** a senior technologist reported to the Planning and Operations Committee, Division of AP and Cytology, that there were problems with one specific brand of tissue processor. CLS was working with the vendor to attempt to resolve the problems.

The CLS MAC met again on **October 20**. There was general acceptance that centralization was not working as envisioned. There was still a desire to centralize – but not if patient care might be

compromised. Three days later, a meeting was held with various AP technical and medical staff. A decision was made to proceed with centralization but to address the issues first.

On **October 31** AHS approved an emergency equipment purchase for a new tissue processor.

On **November 3** a report was given by Operations to the Board of CLS again outlining the significant issues identified at the DSC, including a lack of space in the tissue processor area, issues with capacity, safety with respect to the lack of space, and quality of sample preparations. The transfer of work from the FMC remained on hold. On **November 4** CLS received a tissue processor on loan from Red Deer.

On **November 16** a senior pathologist and a senior technologist at the DSC wrote a briefing report about the potential relocation of the processing of prostate needle biopsies back to the RGH. This was followed two days later by a letter from a pathologist at the RGH asking that these services be returned to the RGH.

The tissue processing machine on loan from Red Deer underwent 'validation' at the DSC, with completion of this process on **November 22**, meaning that the machine could then be put into service.

On **November 24** the CEO of AHS was released from his contract. An acting CEO was appointed.

On **November 25** the RGH pathologists presented their own proposal to decentralize the prostate tissue processing back to the RGH.

Events concerning the first nine patients affected begin to unfold – mid December 2010

On **November 30, 2010** nine men underwent prostate needle biopsies at an outpatient clinic in Calgary. The specimens were transported to the DSC and received (or 'accessioned') the same day.

On **December 3** the nine specimens were being processed in a new tissue processor at the DSC when a malfunction occurred with the machine. The technician who discovered the error then sought advice from other technical staff at the DSC and over the weekend (**December 4–5**) the tissue underwent reprocessing. Because of strained relationships related to centralization problems, the technologist did not telephone any of the pathologists at the RGH about the reprocessing. It was the working practice, but not policy, to phone in such instances.

The specimens then underwent the standard protocols for embedding on **December 6**. The blocks of tissue were cut to produce slides over the course of the week by one RGH technologist. At that time, there was a priority list for the order in which various samples were processed, with prostate needle biopsy specimens designated as a 'lower priority' than 'rush' samples. The technologist simply affixed a yellow sticky note, stating "Reprocessed", onto each of the nine trays of slides as a way of notifying the RGH pathologists.

Meanwhile, on **December 12** a new policy about 'improperly processed tissue' was put into effect. This policy required that the technical staff contact a pathologist if there were problems with the processing of one or more tissue samples.

The majority of the slides from the nine patients were logged as having been received at the RGH on **December 13** and the balance on **December 14**. Once received, the trays of slides were placed on a shelf to await reading by a pathologist.

On **December 15** the COO reported to the MAC that a meeting was planned for the following week with the AP technicians from DSC to discuss their increasing frustration with AP centralization. It was expected there would be a request for additional staff to address the increased workload. The COO emphasized the importance of involving the frontline workers and the pathologists when planning future changes – so as not to repeat the problems with centralization.

That same day, a report from a technical working group was given by Operations to the CLS Board recommending that consolidation of FMC tissue processing remain on hold while issues with quality, space, and safety were investigated. Additional technical staff were now working to address quality concerns raised by pathologists. A pathologist member of the Executive reported to the Board that the RGH had expressed considerable frustration about the turnaround times for prostate biopsies and the quality of the slides. Partial decentralization was being considered in response to the issues. CLS was also looking at further renovations at the DSC to improve tissue processing there.

On **December 20** a pathologist in a leadership position at the RGH (Pathologist 1) received a phone call from a urologist wanting to know where the reports of some prostate needle biopsies were for some of his patients. The normal practice of the urologists at the outpatient clinic was to see each patient in follow-up two weeks after performing the needle biopsy to review the pathologist's interpretation of the needle biopsy specimen and discuss a treatment plan with the patient. The results were now a week overdue. The urologist expressed concern.

Pathologist 1 retrieved the tray of slides for one patient from the trays on the shelf on which they had been placed. At that time, the distribution of prostate cases among the anatomical pathologists at the RGH involved 'signing out' the prostate specimens randomly, meaning that there was no system for assigning specimens to a particular pathologist on any given day. When a pathologist finished other cases, he or she would check the shelf for prostate biopsy cases and then interpret one or more cases as time allowed that day.

Pathologist 1 then started to interpret the slides and noted they had been reprocessed. The pathologist then advised the other pathologists who had signed out the other cases (Pathologists 2 and 3) to report them as "no diagnosis due to technical processing failure".

Pathologist 1 then contacted a CLS Executive pathologist about the fact that the reprocessing appeared to compromise specimen quality. Pathologist 1 suggested that the CLS Executive pathologist contact the urologists and patients involved to explain the problem. The slides were returned from the RGH to the DSC.

On the same day, two RGH pathologists, including Pathologist 1, were asked individually to attend a meeting on December 22, 2010 to discuss some "HR-related issues" at the RGH.

On **December 21** the CLS Executive pathologist telephoned the urologists of all nine patients to explain what had occurred and faxed letters to the urologists. Not only were the results of the slides late but the slides themselves were apparently considered 'unreadable'. The fact that the slides were deemed unreadable meant that the nine patients might be faced with a decision about whether to undergo a repeat needle biopsy of the prostate. One of the urologists then strongly suggested that the CLS Executive pathologist should personally telephone each of the nine patients to inform them of the situation.

On **December 22** attempts were made at the DSC by senior technical staff, the CLS Executive pathologist, and a DSC senior pathologist to determine if any of the slides could be re-stained so as to improve their quality (especially that of the immunochemistry testing). The CLS Executive pathologist and the DSC senior pathologist reviewed the re-stained slides and thought that they were able to interpret them. They also asked the RGH pathologists to review the slides and make their best attempts to interpret them.

Pathologist 2 at the RGH sent suggestions to the CLS Executive pathologist about a new process for assigning prostate biopsies to specific pathologists.

A decision is made to contact the nine patients – late December 2010

That same day, an 'Emerging Issues Notification' and other supporting documents were sent from CLS to AHS about the reprocessing of the prostate biopsy specimens of the nine patients. The CLS Executive pathologist notified the local (Calgary Zone) and senior AHS administrators and a decision was made to speak with all nine patients.

The CLS Executive pathologist then started to contact the patients, trying, but not being able, to reach all nine over the next two days (December 23–24). The purpose of the calls was to explain that the results of the biopsies were late and to let the patients know of the possible need for a repeat biopsy. The HQCA's QAC learned from interviews held during this review that some of those contacted at the time did not completely understand what they were being told. Two of the patients were described as being extremely upset.

A decision was made by the CLS Executive pathologist and the DSC senior pathologist to send the specimens to an expert in prostate pathology elsewhere in Canada or the United States to provide an additional opinion. Pathologists in Toronto and Vancouver were not available. An international expert in prostate cancer in the United States agreed to review the slides.

Relationships become further strained – late December 2010

At the same time, individuals in leadership positions at CLS met separately with each of two pathologists from RGH about the "HR-related issues" at the RGH site. The purpose of both meetings on December 22 was to discuss complaints about unacceptable disruptive interpersonal behaviours attributed to the two pathologists.

Later that day, a memo was sent to all RGH pathologists, asking them to attend a meeting on December 23.

Two members of the CLS Executive attended the meeting on **December 23**, along with the RGH pathologists. Two versions of the purpose of the meeting were presented to the QAC during interviews. Version one was that the meeting was to discuss stress in the AP workplace and the intention of CLS to carry out a workplace review, using an external consultant. This individual was to conduct an 'environmental scan' throughout CLS, not just at RGH. CLS had used the consultant in the past, with reported success. Version two was that the meeting was to focus on several complaints of highly unprofessional behaviour by some of the pathologists.

Responses from the pathologists at the meeting were mixed. They ranged from vocal protestations to silent shock, with concerns raised about the alleged actions of individuals being discussed with the entire

group or that these behaviours were considered part of group behaviour. The meeting ended without a decision from CLS to carry out the workplace review.

Immediately after the meeting, a pathologist in a leadership position at CLS asked Pathologists 2 and 3 if they could try to read any of the prostate biopsy slides of the nine patients. They were asked to consider each needle core biopsy, rather than make an overall determination that all portions of all slides were 'unreadable'. If they were indeed able to interpret one or more cores, the two pathologists were also asked to write an addendum (or addition) to their initial "Unreadable" reports. Also just after the meeting, Pathologist 1 told colleagues that he/she was going to phone the Canadian Medical Protective Association (CMPA)[51] and suggested they do so as well. Legal assistance for pathologists who requested it was obtained from the CMPA on **December 29**. That day the slides of the nine patients were sent to the prostate biopsy expert in the United States.

On **December 30** a letter was sent in follow-up to each of the nine patients contacted on December 23 and 24. Each patient was told that he was one of nine patients whose prostate biopsy specimen was subject to a chemical processing error in the laboratory but that there was no question of any mix-up among patients and their specimens. An opinion was expressed that a "repeat biopsy will be necessary to safely and completely address" the patients' care.

Between **January 4 and 5, 2011** the American expert issued reports on the slides for all nine patients, commenting that the slides were generally 'readable'. That same day, the CLS Executive learned that the CMPA had contacted AHS legal counsel.

On **January 5** Pathologist 2 at the RGH indicated a preference not to issue an addendum report until the slides were returned by the expert. Because the American expert was not a pathologist registered to practise in Alberta, the expert's report could not legally be considered. CLS management deemed it important for the RGH pathologists to write addendum reports and to include the interpretations made by the expert. Each addendum would then help the urologists decide what was best for each of the nine patients.

Later that day a member of the CLS Executive met with the RGH pathologists to explain the rationale behind the workplace review that had previously been discussed, to understand the pathologists' point of view, and to agree on next steps.

Also that day, an announcement was made at the medical staff business meeting that a pilot project for the decentralization of prostate biopsies was being undertaken. This was because of the continued frustration expressed by the RGH urologists about turnaround times and by the RGH pathologists about the quality and turnaround times of the specimens.

CLS initiates an internal quality review of AP centralization and attempts are made to improve relationships – January 2011

On **January 6** an internal review at the DSC of the problem from December 3 determined that a member of the technical staff had not entered a change in alcohol concentration on the control panel of a tissue processor. Further training for all staff was provided. The CLS COO requested an internal quality review of AP centralization to be completed by the CLS quality department.

On **January 7** prostate tissue processing and cutting was moved back to the RGH on a trial basis. Two technologists were relocated from the DSC to the RGH to assist with the work.

On **January 17** the COO wrote to the RGH pathologists, responding to their concerns about the meeting on December 23 and committing to rebuilding trust with the group.

On **January 19** tissue samples of various types from 16 patients at the RGH underwent processing in a tissue processor at the DSC.

On **January 21** the RGH pathologists replied to the COO's letter of January 17. The pathologists indicated that the letter did not address the real issue, which was that of the December 23, 2010 meeting to discuss allegations of highly unprofessional behaviour.

Misprocessing of tissues occurs at the DSC – January 2011

On **January 26,** Pathologist 1 notified the VP of Operations of CLS that tissue samples that had undergone processing on January 19 appeared to have been misprocessed. Concern was expressed that the pathologists had not been advised of the processing problem. Despite the presence of some processing 'artifacts' (or irregularities), however, the pathologists were able to read the slides and signed off the reports. It was felt there were no implications for the diagnosis or treatment of any of the patients.

A reply the same day from the VP of Operations of CLS acknowledged the likely processor malfunction/error and stated that an investigation (an internal process review) was underway. There was thought to have been mix-up with one or more different reagents. As a result there were some tissue processing artifacts. The mix-up of reagents was not detected by the technologists because no error codes were shown on the processor.

A letter was sent by the COO of CLS to the RGH pathologists indicating a wish to build a more collaborative working relationship.

On **January 27**, in response to the event of January 19 and the internal process review, a memo was sent from Operations at CLS. The technologists at the DSC were advised that a 'buddy' process would be instituted when they were filling the processors with reagents, meaning a technologist would not do this work alone.

That same day the American expert returned the slides of the needle core biopsy specimens for the nine patients. His final opinion was that he was in fact able to read all the slides and to provide an opinion for each patient.

The slides were then returned to the three pathologists. Pathologists 2 and 3 issued addendum reports indicating they were able to read their seven of the nine cases. Pathologist 1 did not write an addendum report but reported the slides of the other two patients as "No diagnosis due to technical processing failure". The reports from the expert pathologist, with the addendum reports for seven of the patients, were then forwarded to the urologists of all nine patients.

The QAC learned that by **February 1** the concerns about highly unprofessional behaviour had effectively been dropped.

By **February 13** a new automated tissue processor had been installed at the RGH and validation had been completed.

The Executive team's newsletter for CLS staff was issued on **February 18**. It stated that a request had been made to AHS for bar-coding technology, that processing of prostate biopsies from RGH had been decentralized from DSC back to RGH as a temporary trial, and that centralization of specimens from the FMC to the DSC was permanently on hold.[52] That same day the COO reported to the MAC that CLS had yet to receive the quotations for the renovations at the DSC. Demand had exceeded the ventilation capacity of the DSC, meaning that the conditions in the laboratory there were unsuitable for the workers dealing with toxic chemicals.

Misprocessing of tissues occurs at the RGH – March 2011

On **March 2** a tissue processing error occurred at the RGH, affecting the specimens of six patients. The specimens were reprocessed and prepared according to the standard protocols. Because pathologists at the RGH were able to provide a diagnosis and to sign off on all six cases, there were no clinical implications and none of the six patients were told that there had been any problems with their slides.

On **March 23** an Internal Process Review of the events of December 3, January 19, and March 2 was conducted at CLS. A report was issued on **April 12** and contained 35 recommendations.

On **April 14** the acting CEO of AHS was named President and CEO.

The QAC heard that sometime in mid 2011 the 'trial' of returning prostate tissue processing to the RGH never officially ended. Rather, no further changes were made. The QAC also heard that while the workload for pathologists remained constant, the PTs were less than fully occupied and the automated tissue processing machine was not being used to its full capacity.

A decision is made to provide disclosure to patients connected to the January and March events – October 2011

In late **October 2011** a discussion was held between the executives of CLS and AHS. A decision was made by a member of the AHS Executive that the CLS Executive should undertake disclosure for the 16 patients whose biopsy samples had been misprocessed on January 19, 2011 and the six patients whose biopsies had been misprocessed on March 2, 2011. Over two days in early November 2011, all patients except one were telephoned by either the COO or a CLS Executive pathologist. (A letter was mailed to the one patient who could not be reached by phone.) The purpose of the call was to let each patient know that there had been problems with tissue processing because of equipment malfunction. However, all the pathologists were satisfied that they had been able to provide an interpretation of each specimen and there were no doubts about any of the patients' diagnoses. In addition, because of the impending HQCA review, the patients were told that there could be possible discussion in the media of misprocessed samples from 2010 and 2011. Interviewees told the QAC that some of the patients, because of a language barrier, could not understand why they were being telephoned. Others were apparently confused by the call.

On **November 2** the HQCA review into AP at RGH and the DSC in Calgary was announced.

On **November 7** a problem with processing occurred at the DSC. A processor was loaded incorrectly with three baskets of cassettes instead of two. At the end of the processing cycle, problems with the tissues were discovered and the tissues were reprocessed satisfactorily.

On **December 7 and 8, 2011** the CPSA conducted an on-site focused surgical pathology assessment of the DSC. This assessment was carried out at the request of the CEO of AHS. The outcome of this assessment is discussed later in this report.

Analysis

This section reviews the events that occurred and the factors that may have contributed to them, based on the five major components of the health system – patients, personnel, equipment/environment, organization(s), and regulatory agencies.

Patients

No specific patient factors can be said to have contributed to these events; however, there are significant patient-related factors in this review.

Shortly after the first event in December 2010, telephone calls were made on December 23 and 24 by a pathologist member of the CLS Executive to at least seven of the nine patients whose biopsy specimens had been misprocessed. In each call the patient was told that there had been a problem with processing the tissues and that he might need to undergo a repeat biopsy of the prostate. Some of the patients had difficulty understanding the concepts being explained on the telephone and at least two patients were described as "extremely upset".

In the second event in January 2011 and the third event in March 2011, although there had been processing problems with the tissue samples, pathologists had been able to provide a diagnosis for all of the patients. In early November 2011, all 22 patients received either a telephone call or a letter. The patients were told that there had been a problem with processing of the slides but not with the analysis or diagnosis by the pathologists.

In December 2010, all the telephone calls to the patients were made by a pathologist, who would have been able to provide and explain the technical and medical details as well as the implications of 'unreadable' slides. In November 2011 the telephone calls were made by either the same pathologist (who had made the phone calls in December 2010) or by the CLS COO. A decision was made that the pathologist would telephone all the patients with a diagnosis of cancer and the COO would telephone the others, all of whom had a procedure for a non-cancerous condition, such as gall bladder disease. In the December 2010 cases, all patients received a letter in follow-up, whereas in the November 2011 cases only one patient who could not be contacted by telephone was sent a letter.

Examining these two instances of disclosure – telling patients that something has gone wrong – and the reactions of some of the patients are useful to those who undertake disclosure.[53] First, the purpose of disclosure should always be clear. Disclosure most often involves providing a patient and/or family with a description of the events that led to a patient being harmed or nearly harmed. As stated earlier, none of the 31 patients suffered physical harm; rather, tissue samples were misprocessed. Disclosure on December 23 and 24 seemed premature: there were still questions about whether the slides were truly 'unreadable'. Indeed, two senior pathologists thought that they could make a diagnosis for the patients and plans were being made for an international expert to read the slides. None of the nine patients in December 2010 received a diagnosis that was then changed after the expert had reviewed the slides. The 22 patients who were contacted in November 2011 were told there had been a technical problem with their tissue samples

and that there had been no problem with the part of the testing that is the most important for them: the diagnosis or result.

With respect to timing, the dates when some of the patients were informed – December 23 and 24 – may have added to some patients' distress. While 'bad news' cannot always wait, consideration of the timing is important, including month, date, and time of day. The disclosure made to the nine patients in late December 2010 occurred some three weeks after each had undergone a prostate biopsy. In contrast, disclosure to the 22 patients in early November 2011 occurred either eight or 10 months after the date of an operation or biopsy. Again, the timing of the disclosure is questionable.

The method of disclosure is always critical. Not all patients can grasp specific technical details of their care when related by a stranger over the telephone and not all patients understand English. In addition, the two instances of disclosure were managed very differently. While every patient and family is unique, and every case of disclosure is also unique to the situation, a consistent approach is beneficial.

A key part of disclosure is planning.[54] Disclosure is ideally best carried out by a team of one or more physicians with an understanding of the issues and one or more individuals from the organization who have 'operational responsibility'. Factors to consider include knowledge of the patient(s) being called, whether or not a telephone call is the best way to give information, which team member(s) should make the call(s), and what should be said. The latter should include an apology, some details of what went wrong, what steps are being taken on behalf of the patient's well-being (if possible and necessary), and what is being done to investigate and attempt to fix the problems leading to the event(s).[53]

The disclosure made to the nine patients in late December 2010 occurred some three weeks after each had undergone a prostate biopsy. In contrast, disclosure to the 22 patients in early November 2011 occurred either eight or 10 months after the date of an operation or biopsy.

Finally, while the decision to undertake disclosure in December 2010 was made with the best of intentions for the nine patients and their families, the reported reactions of some of the patients suggests that it may not have helped as intended. The decision to undertake disclosure in November 2011 for the 22 patients is somewhat more problematic coming as it did between eight and 10 months after the problems with tissue processing occurred.

Personnel

While it might be tempting to focus on the decisions and actions of individuals, doing so would take too narrow a view of what went wrong, what can be learned, and, as a result, what can be improved. This is a systems review, with a focus on a system level rather than on a review of individuals and their behaviours.

The non-medical/technical staff

As centralization progressed over the summer of 2010, the technical staff at the DSC struggled to improve processes in an unfamiliar environment, where everyday working conditions had been changed without sufficient consultation. Some staff were now commuting long distances from their homes, which they had previously chosen because they were close to the particular hospital at which they worked. While it is true that any reorganization may require workers to adapt to new locations, in this case the workers were given

little notice about the changes they would have to make, nor were they given much information or opportunity to discuss the changes. During the interviews, this lack of communication was mentioned as contributing to the overall disruption brought about by centralization. In addition, as tissue processing services from each hospital were centralized to the DSC, space became increasingly limited, constraining work processes. Work schedules were also changed, with some staff now working day and evening shifts, as well as six days a week instead of the previous five.

As previously mentioned, problems with tissue processing occurred between July 2010 and November 2011. These misprocessing events were due to various actions performed by the technical staff in operating the tissue processing machines. These included filling a reservoir with the wrong reagent, not entering a change in the control panel, filling a reservoir with an incorrect percentage of alcohol, not filling a wax container, and loading the wrong number of baskets. In all of these events pathologists were able to interpret the slides.

As tissue processing services from each hospital were centralized to the DSC, space became increasingly limited, constraining work processes.

One might ask how it is that knowledgeable, experienced, and diligent technical staff could make errors with a tissue processing machine. The answer to this question lies in an understanding of human error. A simple definition of an error is a "divergence between the action actually performed and the action that should have been performed".[55] There are three kinds of errors: mistakes, lapses, and slips.

Mistakes are made when an individual plans to carry out an action but fails to assess the available information in determining options, making a choice between options, and judging the likely consequences of the planned actions.[56] Mistakes may also result when an individual tries to solve a new problem. These kinds of errors therefore come from misapplying information or having insufficient information.

In contrast, slips and lapses are made when the action was not carried out as planned. Slips may be verbal (e.g., stating "Please pass the salt" instead of "sugar") or active (e.g., filling the container with the incorrect tissue processing liquid). Lapses are due to simple, 'short-term' memory failures, like forgetting planned intentions,[56] such as forgetting to enter the change of processing agents on the machine's control panel.

Even the most highly specialized and most vigilant workers will make errors. Errors are also without 'human intention' in terms of motivation; no one ever plans to make an error. That is because errors occur as a result of "built-in deficiencies"[55] in such things as design of the workplace, equipment, and training manuals, to name just a few. Errors also occur because of environmental factors such as distractions caused by random noises, telephone calls, and requests for help from colleagues.

Note should also be made of the fact that the processing problems were the result of 'errors' and not of any type of non-compliance or "deviations from safe operating conditions, standards or rules". Laboratory staff are trained to be highly compliant with standard operating procedures and protocols. It was reported that some of the technical staff were demoralized by the problems with tissue processing. These reactions are not surprising. Despite their apparent best efforts, the products of their efforts – the slides – were less than perfect. Nevertheless, the QAC heard that technical staff continued to demonstrate their professionalism as they worked to resolve the tissue processing issues.

As in these cases, it is important to note that no single error can 'cause' harm on its own. In any event there are always multiple errors and factors that contribute to the final outcome. Similarly, errors should not be judged on the severity of any apparent results or outcome.

The pathologists

Some of the RGH pathologists had expressed concerns about problems with tissue processing since it had been centralized from the RGH to the DSC. These concerns included variability in the embedding, staining, and cutting of prostate needle biopsy specimens, as well as slower turnaround in providing reports to the urologists.

The RGH pathologists were accustomed to having dedicated technical staff prepare slides for them. Initially in the DSC, tissue processing was done by the 'next available' technical staff person. After the complaints by the pathologists about the slide quality, every member of the technical staff who processed tissues underwent a competency test, which was signed off by an RGH pathologist. However, by September 2010, 80 per cent of all prostate needle biopsies were still being cut by designated RGH staff members at the insistence of some of the RGH pathologists. But problems with tissue processing were ongoing, would seem to be solved, and would then recur. Pathologists complained both verbally and in writing. There were episodes of verbal abuse directed at some of the non-medical staff by a few pathologists.

Investigating specific episodes of verbal abuse, or the decisions or actions of specific individuals, is outside the scope of this review. However, disrespectful communication, such as yelling or abusive or demeaning language, negatively affects the workplace and damages relationships between healthcare providers. Impaired communication and professional relationships affects collaboration and the ability to effectively transfer vital information, which can affect patient care.

The effects of misprocessed tissues, together with requiring dedicated staff for prostate tissues, and escalating disruptive behaviours were demonstrated when a call was received on December 20 from a urologist about overdue reports of some prostate needle biopsy specimens. The delays in getting the slides to the pathologists was most likely due to the extra time needed to reprocess the slides and the fact that the pathologists were not immediately alerted to the reprocessing delay due to the technical staff's hesitancy to contact them directly. However, another contributor was the lack of a system for distribution of prostate cases among the RGH pathologists: cases were reviewed as time became available.

The normal practice of the urologists at the outpatient clinic was to see each patient in follow-up two weeks after performing the needle biopsy. In this instance the nine biopsies were performed on November 30 and the tissues sent to the DSC the same day. They were subsequently processed on December 3 when a malfunction occurred with the tissue processor. The tissues underwent reprocessing on the weekend of December 4–5. The tissues were then embedded, cut, and stained over the course of the week by one dedicated technologist. The slides were transported to the RGH on December 13 and 14. At this point, two weeks had passed since the biopsies were performed. A week later, on December 20, Pathologist 1 received the phone call from a urologist about overdue reports for the biopsies performed on November 30.

Pathologist 1 then viewed two sets of slides (that were part of the nine that had been 'reprocessed') and made a decision that the slides were 'unreadable'. This is the right of every pathologist – to say "I am not

able to provide a diagnosis" – even while other pathologists might determine that an opinion could be provided. The QAC heard that the preparation of slides that are deemed 'unreadable' is considered to be an extremely rare event, however no documented reports that provided or estimated the frequency of this event in healthcare could be found.

Pathologist 1 suggested to two, less senior, colleagues that the seven other sets of prostate needle biopsy slides were also unreadable. Had Pathologist 1's colleagues agreed, it could have meant that all nine patients might have had to undergo repeat prostate biopsy testing. Indeed, that is what the patients were told might happen when a CLS Executive pathologist telephoned them on December 23 and 24.

On December 22, administrative leaders held meetings with each of two pathologists, prompted by several specific complaints about their disruptive interpersonal behaviours. The following day, the administration of CLS called a meeting of all RGH pathologists to introduce the idea of CLS undertaking a workplace review with an external consultant. The QAC heard there were several different accounts of the purpose of the meetings, which contributed to misunderstandings between the RGH pathologists and those in leadership positions.

Environment and equipment

Environment

Limited space and ventilation were significant issues in the operation of the DSC.

The DSC is located in a building leased from the University of Calgary and occupies the greater part of the building's 235,000 square feet. The Business Case for AP tissue processing centralization developed in 2009 had noted that the space at the DSC was "limited".[43] Similarly, the Risk Management Plan identified that "allocated space may not be adequate without major renovation". The probability of occurrence of this 'risk' was rated as "2" (on a scale with a high of 5) and the estimated "project impact was also "2". The Steering Committee's response was "Accept: Renovations will be restricted to budget available".[47]

As each phase of AP centralization was undertaken, it became increasingly clear that the space designated for AP at the DSC was inadequate. Space had also been allocated to other CLS functions such as the hematology, clinical chemistry, and microbiology laboratories, as well as administration so the options to expand were limited. Available work space was affecting work flow, as well as storage space for processing liquids and containers of used liquids.

> As each phase of centralization was undertaken, it became increasingly clear that the space designated for anatomical pathology at the DSC was inadequate.

Coupled with the space limitations at the DSC was the site's insufficient ventilation capacity. Ventilation moves air from outside into the building, circulates the air inside the building, and moves the air back outside. This air exchange is critical for three major purposes: sufficient fresh air must be provided in the building to ensure the safe concentrations of oxygen and carbon dioxide, the air must be kept at an appropriate temperature (for people and equipment), and any potentially noxious chemicals in the air must be safely vented to the outside.

Some renovations were undertaken when CLS moved into the building to accommodate the increasing number of specialized machines used in the various areas of the laboratory. These machines all give off heat and require sufficient ventilation to maintain the optimal temperature in the laboratory. Some machines, such as those used in tissue processing in AP, use chemicals that may be considered toxic, depending on the concentration and the duration of exposure. Fumes from chemicals such as formalin and xylene must be vented outside for the protection of everyone in the area.

In June 2010 the volume of tissue processing increased as workload from the ACH and the PLC moved to the DSC, placing additional ventilation requirements on the DSC system. The demand on the ventilation system further increased when the RGH workload was added in early July. Installing special ventilation (slots) for the areas where tissues were 'grossed' (grossing stations) had resulted in a demand that had exceeded the ventilation capacity of the building. Two strategies were implemented to attempt to manage the peak ventilation demand. One partial workaround was the addition of an evening shift of technical staff members, to decrease the use of the grossing stations during the day and therefore the demand on ventilation. Another strategy was bringing in a machine to both stain and 'cover slip' the tissue slides. Unlike the new machine, the old machine (which is still in use) only stains the slides, which are then air dried before being 'cover-slipped'. As they dry, these slides give off xylene fumes, which must be vented.

It had become clear that there was insufficient capacity at the DSC to handle any additional volume, which caused the transfer of FMC workload to be put on hold.

Before centralization, the only mention of ventilation capacity in the 2009 Business Case was the cost of "minor renovations to centralize technical processing area at DSC", which included "ventilation for new equipment".[43] That cost was estimated at $50,000.

Once centralization had been halted, estimates were obtained for further renovations to help improve the ventilation capacity. The QAC heard that on October 19, 2011 the CLS MAC was told $200,000 had been approved by AHS for the heating, ventilation, and air conditioning design phase for improvements at the DSC. However, $2 million would be required for complete building upgrades and the work would take two years to finish.

Equipment

There is one specific piece of equipment central to this review: automated tissue processor machines.

Automated tissue processors are complex machines that partly replace human effort in many of the steps involved in AP processing. Through automation and increasing complexity, these machines expose small pieces of tissue to a range of special liquids over a controlled amount of time. The nature and sequence of use of these liquids are designed to fix the tissues, remove most of the water in the tissues, and then ready the tissues to be immersed in wax.

The complexity has brought its own issues. These can best be described in terms of 'usability', which describes the extent to which a piece of equipment is "easy to use or 'user friendly'".[57] The term 'usability' comes from a specialized area of study known as human factors, which is about the abilities and limitations of individuals, the environments in which they work, the equipment with which they work, and the people with whom they interact.

The five tissue processing events described to the QAC (see Table 2**)** relate to usability problems. The grey shaded areas represent the three events that are the focus of this review.

Table 2: The five processing events at CLS

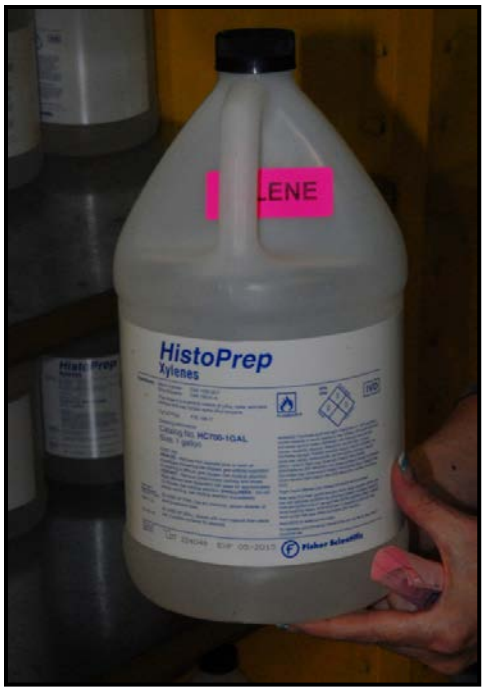
Date	Processing problem	# Patients affected
July 27, 2010	▪ Incorrect liquid was thought to have been used to fill an internal reservoir of a Brand X processor.	73 (various biopsies in 105 cassettes)
December 3, 2010	▪ Correct percentage of alcohol (70%) **not** entered when chemicals were changed on a Brand X processor. Machine setting automatically defaulted to 100% alcohol.	9 (prostate biopsies)
January 19, 2011	▪ Incorrect liquid used to fill an internal reservoir of a Brand X processor.	16 (mixed samples)
March 2, 2011	▪ A Brand Z processor was cycled without the wax reservoirs being filled.	6 (mixed samples)
November 7, 2011	▪ A Brand Z processor was loaded with three baskets instead of two, as was required for the Brand X processor next to the Brand Z machine. The Brand X processor can hold three baskets of 100 cassettes in each basket. Brand Z has a capacity of two baskets of 150 cassettes.	25 surgical cases and 1 autopsy case (in 94 cassettes)

CLS investigated these events and therefore the QAC did not reinvestigate them in detail. Rather, the QAC reviewed the recommendations generated after the investigations.

After an investigation into the January 19, 2011 incident of a machine reservoir being filled with the wrong liquid, steps were taken to minimize the possibility of a recurrence. These included a new 'buddy system' when staff changed reagents on machines. Both individuals were to initial the quality control chart. While adding a second set of eyes may help reduce problems, the practice does not provide a guarantee of 'no error'. "Double checking requires that one fallible person monitor the work of another imperfect person. Because people tend to hear what they expect to hear and see what they expect to see, effectiveness is reduced."[58] The buddy system can also be viewed as an inefficient use of a technical worker's time because one worker is pulled away from one task to watch another worker do something else.

A new 'buddy' system was introduced when staff changed reagents on machines. While adding a second set of eyes may help reduce problems, the practice does not provide a guarantee of 'no error'.

Another recommendation was that of adding colour-coded labels to the necks of the reagent bottles holding the clear, colourless processing liquids and to add the same colour-coded labels to the corresponding machine reservoirs.



O: Colour-coded labels to help differentiate bottles

P: Corresponding colour-coded labels on the tissue processing machine reservoirs

From a usability perspective, this is a stronger recommendation than that of the buddy system and comes closer to improving usability of the machines, but it is not a perfect answer. Labelling adds to the workload in the laboratory and there is still potential for error in mislabelling the bottles or the reservoirs.

At least one review described a tissue processing problem as the result of "human error". While it is true that the people who were working made errors, to say they were the 'cause' of the problem is to miss the opportunity to seek out some of the many factors that contributed to the problem. To simply ascribe a problem "to 'human error' can be seriously misleading if it implies 'operator error' when the true origin is poor design".[55]

Organization

Communication

The QAC heard that the plan for centralization had been treated as confidential because of the planned layoffs. Input was therefore not sought from frontline workers or many of the pathologists about how aspects of centralization should be undertaken and achieved. One way of thinking about organizations is the way they handle information. Three types of organizations have been described: those in which information is "actively sought", those in which information may be "ignored", and those in which information is "hidden".[59] The absence of transparency and the lack of adequate consultation and communication were factors in these events. Perhaps most significant about the 2010 centralization was the desire to keep certain organizational information contained and the reluctance to discuss the situation openly.

> The absence of transparency and the lack of adequate consultation and communication were factors in the events that unfolded.

Another aspect of information handling relates to the fact that the technical staff at the DSC did not communicate directly with the pathologists at the RGH about the processing errors in December 2010 but instead wrote "Reprocessed" on a yellow sticky note attached to the slides. The explanation for this was that some technical staff could no longer tolerate the comments and shouting of some of the RGH pathologists and were afraid to speak with some of the pathologists, demonstrating a deterioration in relationships between the technicians and those pathologists during the first six months of centralization. Disrespectful behaviour by physicians can impair communication and reduce collaboration.

The lack of communication with the pathologists also suggests an organization that had perhaps become less safety oriented than it had been in the past. Many times, an organization cannot know that a problem exists unless the workers provide this information. To do so, workers must not only feel free to reveal a problem and admit that errors had been made, but to "consider it their duty" to inform others of potential dangers (or potential improvements). The reluctance of some of the technical staff to speak with some of the RGH pathologists is therefore an example of an "organization's pattern of response to the problems and opportunities it encounters", particularly with respect to safety problems.[60] Organizations that are higher up the safety ladder, so to speak, are not only receptive of information but welcome and encourage it – at and from every level of the organization.

Reporting

In most healthcare organizations, the gathering of safety-related information is known as 'reporting'. Organizations that value information about problems will train individuals to seek them out, so that failures, such as improperly processed slides, should lead to some form of reporting and internal

investigation. Thus, organizations will be able to "make use of information, observation, or ideas wherever they exist within the system, without regard for the location or status of the person or group having such information, observations, or ideas".[59] The expected benefits will be an organization with better use of people and resources and improved morale, productivity, and, above all, safety for both patients and staff.

Reporting may be mandatory or voluntary. Before April 2011, the reporting policy at CLS was for *mandatory* reporting into the AHS Reporting and Learning System (RLS) only if a problem was detected when it had 'reached' the patient. An AHS 'Quality Assurance Review' would then be held, often jointly with the appropriate department providing care to the patient. In contrast, if a problem with tissue processing was caught and/or corrected before any slides were sent to a pathologist, then the technical staff could *voluntarily* submit a report to the RLS. The QAC heard that for some processing problems, no reporting was then – or is now – undertaken. But if a problem occurred, such as the need to reprocess tissues, then that problem would be subject to an 'internal process review'. This is the type of review that was carried out by CLS at the DSC and RGH for the three tissue processing problems central to this HQCA review.

If problems were encountered with tissue processing, then the technical staff would consult with one of the managers as to what to do next, such as whether to try to reprocess the tissues. They would notify the pathologists that there had been a problem with processing and identify any slides that had been reprocessed.

There is now a policy that requires a member of the technical staff to contact the AP site leader or one of the pathologists if there is a problem with processing. This is because sometimes reprocessing may actually make other tests, such as those for histochemistry, impossible to carry out. The pathologist determines what should be done next: proceed with the normal processing, salvage the tissue through reprocessing, or contact the doctor who sent the biopsy or tissue specimen to discuss the problem.

On May 16, 2011 the CLS Executive requested an overall internal quality review of AP consolidation, because of a perceived increase in processing errors. The results of the review stated that the steps taken by the CLS Quality Department to address the problems were sufficient. Further, it stated there had been no significant increase, as originally perceived, in the number of errors reported since AP centralization, in comparison to the pre-centralization period. These results were reported to the CLS Board on June 1, 2011. The HQCA's quality assurance committee questioned how these results could be known if reporting of problems was voluntary. Nor could the QAC determine how often in a year specimens require some form of reprocessing at CLS.

Leadership

The QAC heard concerns expressed about leadership at various levels of CLS including examples of poor communication, limited understanding of role and responsibility, and the manner in which highly charged situations were handled. The QAC also heard that some were 'reluctant leaders' and that taking a leadership role was not always valued by people in the organization.

Leaders should have clearly defined roles, responsibilities, and authority – as well as appropriate accountability. Although leadership training may help some, it may be less effective for an individual who does not want a leadership role but may have been convinced or coerced into accepting one.

Relationship with AHS

In February 2012 the Board of CLS, of which three members were senior AHS employees, was almost entirely removed by AHS. Only one board member was left, who was also a senior executive within AHS. The QAC learned that this change apparently occurred after the CLS Board had approved its strategic plan to be the top-performing laboratory in Canada. In addition, the most senior member of the Executive of CLS, the COO, instead of reporting directly to the CLS Board, now reports to the Vice-President of Laboratory Services in AHS and informs the sole board member of emerging issues.

This potential "role conflict" is recognized in mergers, which disrupt "existing roles and reporting structures" and create "new role profiles and structures".[61] The QAC was told that these governance changes have resulted in the need for clarification – not only of the expectations for individuals but of the 'status' of CLS itself. Some interviewees questioned if CLS had essentially become a department within AHS, as there was now limited ability for any independent decision-making by CLS leaders. Indeed, the QAC heard that there is no apparent independent decision-making by some CLS leaders. Some of this questioning, of course, may be the natural result of the loss of the "social identity" of CLS as an independent organization.[61]

Regulatory

Accreditation

The College of Physicians & Surgeons of Alberta (CPSA or the College) is the agency that currently accredits public and private laboratories in Alberta. Accreditation is the process of providing an external review of an organization or service, such as a laboratory, to see if the laboratory meets a set of standards. Previously under the *Medical Professions Act* and now under Schedule 21, Section 8 of the *Health Professions Act*[62] the CPSA has the statutory authority to accredit and regulate all privately run medical diagnostic facilities in Alberta, such as DynaLIFE Dx laboratories.[63] In contrast, "services provided in facilities owned or operated by a federal or provincial government or Alberta Health Services are not subject to accreditation by the College except where included under contract".[64] Thus, the CPSA is able to provide accreditation of CLS and other AHS laboratories because of a four-year contract (2011-14) with AHS to provide this service.

In December 2011 the CEO of AHS asked the CPSA to undertake an immediate inspection of the AP laboratories in Calgary to ensure the protection of the public.

Steps in the CPSA's program of laboratory accreditation

The CPSA accredits laboratories through a number of steps, including the development and maintenance of evidence-based standards/guidelines for laboratory practice. (There are no national standards for accreditation of diagnostic medical laboratories in Canada.) Monitoring compliance with these College-approved standards is achieved through on-site inspections of each laboratory every four years. Before each inspection, the laboratory completes several questionnaires about such aspects as personnel, training, procedures performed, equipment used, and safety issues. The on-site inspection is done on a regular working day by a team of experts from varied home bases in Alberta (that are usually geographically distinct) and different laboratory organizations (public or private).

A site's overall proficiency in laboratory testing is monitored through the Alberta Laboratory Quality Enhancement Program (ALQEP).[65] The ALQEP is a reference body for quality management of laboratories in the province. The program monitors the proficiency of each laboratory through review of a laboratory's performance on various tests.

Laboratories offering AP services are required by ALQEP to participate in the proficiency testing programs offered by the College of American Pathologists (CAP).[66] For example, AP laboratories must enroll in a technical test program that offers either simple staining or special staining of slides.[67] Laboratories submit slides from different cases, and technical staff and pathologists use criteria to grade the laboratory's technique of fixation/processing, cutting, and staining. Testing is focused on education to improve how AP slides are prepared. Following each survey, participating laboratories receive their own results and those of others (anonymized) to allow comparison against other laboratories, information about best practices for procedures and techniques, as well as data to help the laboratory improve the preparation of its slides. If there is evidence of substandard or unacceptable performance, then the ALQEP follows up.[68] Although the ALQEP monitors the performance of facilities, it does not assess the professional performance of individual pathologists.

For all other AP testing, where a proficiency testing program is not mandated, all laboratories and their pathologists are expected to participate in a formal External Quality Assurance (EQA) program. If no such program is available the lab participates in an informal inter-laboratory comparison program. EQA results are reviewed during the on-site inspections that occur every four years.

> A site's overall proficiency in laboratory testing is monitored through the Alberta Laboratory Quality Enhancement Program (ALQEP). The program monitors proficiency through review of a laboratory's performance on various tests.

Evaluation of the CPSA Laboratory Program

The CPSA Laboratory Program was compared with four other provincial laboratory accreditation programs in Canada, Accreditation Canada, and laboratory accreditation programs outside Canada.

The QAC considers that the CPSA program for accreditation of medical diagnostic facilities is a strong one by any measure. Over the past four decades the laboratory accreditation program operated by the CPSA has evolved with changes in the local environment and international standards. The CPSA has shown a commitment to continuous improvement of its laboratory accreditation program by benchmarking its standards against the current international standards.

The CPSA is nearing the completion of a three-year project in which it has revised of all of its laboratory accreditation standards and related accreditation processes. The new standards, which are currently undergoing stakeholder review, are fully compliant with recognized general and laboratory discipline-specific international standards. These standards include the accreditation checklists from the College of American Pathologists (CAP),[69] the Clinical and Laboratory Standards Institute (CLSI),[70] and the International Standards Association or ISO (specifically ISO 15189, ISO 15190, and ISO 22870).[71]

Once the stakeholder review is done, the CPSA plans to implement the new standards in 2013. The CPSA then intends to seek international accreditation of its documents, training programs, and accreditation processes through the International Society for Quality Assurance.[72] When the revised standards are

implemented in 2013, all CPSA-accredited laboratories in Alberta will be held to standards equal to those expected of high-performing laboratories globally.

The QAC heard concerns about the CPSA and its service contract with AHS as AHS is the CPSA's only client for accreditation of public laboratories. The CPSA is dependent on AHS for funding its contract to perform the accreditation and consequently, this relationship raises questions about the CPSA's independence from AHS and its ability to make objective recommendations. The QAC also heard suggestions that concerns about the service contract could be alleviated by having the government provide funding directly to the CPSA for the AHS accreditation (as it had done previously), thus creating greater distance between AHS and CPSA.

In addition, the QAC heard that the assessors who are used to accredit AHS laboratories are most often also employed by or contracted by AHS to provide laboratory services, given that the CPSA does not use experts from outside the province to conduct the accreditation. The QAC did note, that the College uses an external consultant to observe and report to AHS on the objectivity of the College's entire laboratory accreditation process. The consultant reviews the CPSA's processes and documentation related to the inspections of public diagnostic medical laboratories, provides global impressions of the strengths and weaknesses of the accreditation program including the accreditation standards and reports and provides recommendations. The consultant does not participate in the on-site inspection.

In Alberta, the CPSA is not only the accreditor of the laboratories but also regulates the pathologists who work in those laboratories. AHS, the sole public client of the CPSA for this program, in turn grants privileges to the pathologists who practise in the laboratories.

The QAC considered that these various processes (i.e., service contract, accreditation, regulation, and the granting of privileges) need to have sufficient degrees of separation to avoid the potential for conflict of interest.

CLS accreditation by the CPSA

In June 2009 CLS and the associated hospital laboratories underwent a regularly scheduled inspection by the CPSA. Some minor problems were found. The inspection report stated the "number of deficiencies does not necessarily reflect the quality of laboratory performance and deficiencies identified in reports are commonly seen across the province".[73]

Among the deficiencies noted was the fact that not all annual staff performance evaluations were up-to-date and that there was sometimes no documentation of investigation and corrective action of problems. Nothing in the inspection report revealed problems that might have predicted what would occur in late 2010 at the DSC and RGH.

Following the events that are the subject of this report, in December 2011, at the request of the CEO of AHS, the CPSA carried out another inspection of CLS, which included the DSC, RGH, and the FMC. The report contained the statement that "centralization of all processing and staining at the DSC from the PLC, RGH, and ACH (was) identified by all stakeholders as being a significant concern and root cause of (the) prostate biopsy issue at RGH".[74] In addition, a finding similar to one made in 2009 was again made in 2011: "A process is not in place for the periodic ongoing assessment of technical staff competency".[74] After the 2011 inspection, CLS was required to develop and implement such a process and had 90 days to do so. CLS also developed a competency assessment program for the most-senior pathology technicians

(Level 5/6) in April 2012. Whereas recommendations in the June 2009 inspection included a requirement to make changes, the report for December 2011 explicitly stated which changes were to be made within 90 days. This 90-day requirement is evidence of the CPSA's evolving program.

The results of the CAP Histology Proficiency Testing Program in 2010–11 for slides (fixation/cutting/staining) "indicated a trend of suboptimal performance with a number of scores below the program average cumulative score. There was documented evidence of management review (i.e., signatures) but no indication of investigation of the trend (of) below average scores."[74] Although CLS had no requirement from the CPSA to improve on the CAP finding, CLS nevertheless reinstated a microtomy competency assessment program in March 2012.

In Alberta, the CPSA is not only the accreditor of the laboratories but also regulates the pathologists who work in those laboratories. AHS, the sole public client of the CPSA for this program, in turn grants privileges to the pathologists who practise in the laboratories. The QAC considered that these various processes (i.e., accreditation, regulation, and the granting of privileges) need to have sufficient degrees of separation to avoid the potential for conflict of interest. (See Appendix III for Accreditation of Anatomical Pathology Services in Canada and Internationally.)

Cases at the Royal Alexandra Hospital in Edmonton

What happened to the patients?

In October 2011, 159 anatomical pathology cases were found to have been misinterpreted at the Royal Alexandra Hospital (RAH).

Of 1,727 patients whose slides were read by a locum (temporary) pathologist between July and October 2011, 159 had undergone prostate core biopsies. Of these, 34 were found to have major discrepancies between the opinion of the locum pathologist and the opinions of other pathologists. These major discrepancies had the potential to change treatment. The 34 patients were contacted directly by their urologists and are receiving appropriate care and follow-up. Of the remaining 125 patients, 62 were found to have minor discrepancies on review. Minor discrepancies are those that have no effect on overall diagnosis and that will not likely alter treatment. Whether these minor discrepancies resulted in any change of treatment for any patient is uncertain. Each urologist would have discussed the results with each patient case by case. To the best of the QAC's knowledge, after secondary review of the slides, no patient wrongly received a diagnosis of cancer and no patient underwent an operation that was unwarranted.

After the 159 cases of prostate core biopsies, the reports of the remaining 1,568 patients that were read by the locum pathologist were classified on the basis of the type of specimen and the diagnosis as high, moderate, or low probability of the patients suffering harm as a result of the pathology report. Of the 155 in the high-probability group, 14 had major discrepancies. (Two reports belonged to one patient.) Again, to the best of the QAC's knowledge, no patient underwent an operation that was unwarranted after secondary review of the slides. Of the 191 patients thought to have a moderate probability of harm, only one was found to have a major discrepancy. Some patients underwent additional biopsies to confirm the clinical impression, which could be part of normal clinical practice and cannot be directly attributed to the initial interpretation by the locum pathologist.

Of the remaining 1,222 patients classified as having a low probability of suffering harm, no major discrepancies were found for the first 290 reviewed up to August 28, 2012. There is a low probability that any of the remaining 932 patients will have suffered harm.

The QAC was not able to determine the degree of psychological distress suffered by any of the affected patients but this possibility is acknowledged. Psychological distress would include the anxiety experienced by the patients and their families during the course of having the previous tissue diagnoses reviewed and then possibly reversed.

Sequence of events

Between July and October 2011, 1,727 patients underwent an operation or a biopsy procedure and their tissue specimens were interpreted at the RAH by a pathologist (Pathologist A). This pathologist, newly retired from a hospital elsewhere in Alberta, had agreed to provide summer locum coverage in anatomical pathology at the RAH. During the four months, Pathologist A signed out a variety of cases as would be found in a general surgical pathology practice. These specimens included prostate needle core biopsies, and biopsies of the intestines, cervix, gallbladder, and appendix.

Prostate biopsy specimens

A problem was discovered in **October 2011** after a patient who had undergone a prostate biopsy in Edmonton, with interpretation of the biopsy by Pathologist A, then chose for personal reasons to undergo treatment of prostate cancer in another province. As part of the normal treatment plan there, the biopsy specimen was reviewed by a cancer pathologist in the other province (at the provincial tumour board) who disagreed with the grading of the severity of the cancer given by Pathologist A. The cancer pathologist contacted the Department of Pathology at the RAH. At about the same time, a local urologist thought that the interpretation given by Pathologist A of another specimen did not fit with the results expected from a patient's clinical presentation, examination, and anticipated diagnosis.

As a result, in the first week of **November 2011**, a senior AHS pathologist arranged for the prostate biopsy specimens of 18 patients previously signed off by Pathologist A to be randomly selected and undergo peer review by RAH departmental pathologists. A quantity of 18 was thought to be enough to determine if there were further diagnostic discrepancies. With this 'secondary review', there was disagreement about the diagnoses of the specimens of 12 patients. The 12 'discordant' reports were those in which Pathologist A missed the diagnosis of cancer or under-graded the malignancy and stage of the cancer. Administrative and physician leaders at AHS were alerted as to these discrepancies on **November 15**. At the same time, a senior urologist was asked to inform all the other RAH urologists that their patients' biopsies were to be re-read and to defer all decisions about treatment until the new reports were issued and diagnoses confirmed.

The senior AHS pathologist then arranged to send the 12 sets of prostate slides for further review to another pathologist in Alberta with expertise in prostate cancer (Pathologist B). On **November 30** Pathologist B reported major discrepancies with the interpretations of the specimens made by Pathologist A. Of the 12, three had originally been diagnosed as not having cancer when it was actually present. While Pathologist A had reported cancer in only one of four specimens from one patient, Pathologist B was able to detect cancer in three of the four specimens. In the specimens of two patients, Pathologist A also failed to report the fact that the cancer had extended, or invaded, into the tissue outside the prostate.

Further, Pathologist B found that Pathologist A's interpretations of specimens from eight patients had problems with what is known as the Gleason grade.[75] This is a classification of the grade of a prostate cancer. A low grade (of 1) represents cells that look quite normal or 'well differentiated'. A biopsy with a Gleason grade of 5 has only cells that are 'poorly differentiated' or abnormal. A pathologist determines two grades in a prostate biopsy and adding the two gives the Gleason sum or score. This score is then used to help determine the stage of the cancer.[76,77] In turn, staging contributes to predicting the prognosis of the cancer and guides choices for treatment.

As a result of this report, the senior AHS pathologist then arranged peer review of all the 159 prostate biopsy specimens that Pathologist A had interpreted between July and October of 2011. The review was conducted by three other pathologists from elsewhere in Alberta, who did not know the results of the interpretations by Pathologist A. This was done on the advice of another expert pathologist and is known technically as 'blinding' the reviewers to the original interpretation. Of the 159 specimens, Pathologists C, D, and E considered 96 to be 'discordant' on peer review; that is, they disagreed with Pathologist A. In 62 specimens the discordance represented minor discrepancies. As mentioned above, whether these minor discrepancies resulted in any change of treatment for any patient is unknown because each patient would

have had this discussion privately with his urologist. Clinical and second review of the slides confirmed that no patients were wrongly given a diagnosis of cancer. Some patients underwent additional biopsies to confirm their doctor's clinical impression.

Major discrepancies were found in 34 specimens. These discrepancies were thought likely to result in a change in the plans for the patients' care, such as when no cancer was reported by Pathologist A but Pathologists C, D, and E found cancerous cells to be present. The senior AHS pathologist then re-reviewed all 34 prostate biopsy specimens and dictated amended reports for Pathologist A's reports, to show the revised opinions.

After discussion with three senior physicians at RAH and AHS, a decision was made to ask a fifth pathologist, elsewhere in Canada, to peer review the 34 specimens for which there were major disagreements of clinical significance in the interpretations between Pathologist A and Pathologists B, C, D, and E.

Between **December 16, 2011** and **January 11, 2012** Pathologist F then reviewed 33 of 34 prostate biopsy specimens. Pathologist F did not review the slides of the patient who chose to seek treatment in another province because his case had already undergone separate review there, leading to the discovery of the misinterpretation of his and other biopsy specimens.

Pathologist F reviewed all the prostate tissue slides, the reports from Pathologist A, and the amended reports from the senior AHS pathologist. Pathologist F also reviewed the immunohistochemical slides for most of the tissue specimens. These slides are treated with special chemicals or immune system antibodies and help pathologists to distinguish between benign lesions of the prostate and prostate cancer, especially when dealing with very small biopsy specimens. The tests also help to distinguish between high-grade prostate cancer and other non-prostate malignancies.[78]

By **January 20** Pathologist F had found that all 33 specimens showed the presence of cancer of the prostate. Pathologist F was able to determine, as had Pathologist B, that Pathologist A had misinterpreted the specimens in several ways.

As part of the disclosure process, attempts were then made by a senior RAH/AHS urologist to personally contact all 96 patients for whose tissue sample reports there was some degree of discrepancy or discordance between the opinion of Pathologist A and the expert reviewers. The process of disclosure involved the senior RAH/AHS urologist phoning each of the patients to explain what had happened. In addition, the senior RAH/AHS urologist also wrote to each patient's urologist and family physician, indicating if contact had been made. (Some patients were away.) The purpose of the letter was also to make appointment time available for the patient to be able to go over the amended pathology report with his urologist and/or family doctors and to begin receiving appropriate care and follow-up. To expedite any required treatment, AHS arranged to have extra operating room and radiation therapy time made available for any of these patients who chose to undergo the treatment offered.

Specimen review process

A decision was made to review all of the work completed by Pathologist A. The review was developed, initiated, and organized by the senior AHS pathologist who determined that, between July and October 2011, Pathologist A had interpreted the tissue specimens of 1,727 patients in total, including the 159 patients whose prostate biopsy specimens were first reviewed. As well as examining the medical

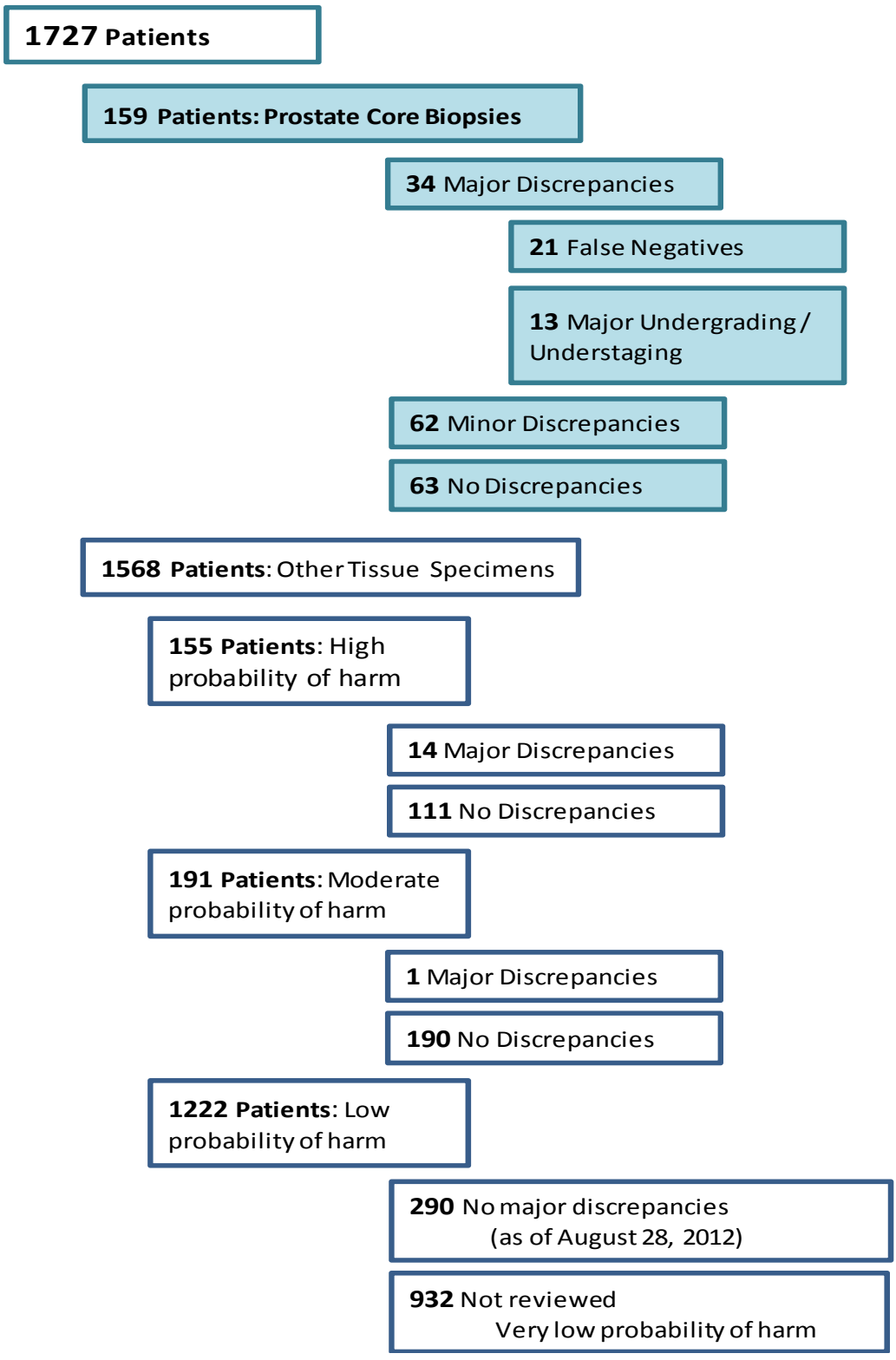
literature, the senior AHS pathologist contacted expert bodies in Canada, the United States, and the United Kingdom to obtain advice as to how to proceed with a review of this magnitude. The senior AHS pathologist was not able to find any relevant guidelines or protocols in the literature or in any of the specialty training bodies or organizations for pathologists, including those for Canada.

First, the senior AHS pathologist went through each of the reports for the 1,568 patients (1,727 in total, minus the 159 prostate biopsies) whose non-prostate specimens had been interpreted by Pathologist A. The senior AHS pathologist also considered relevant patient details, where available, such as history of the symptoms, condition, or disease. The reports were then coded as high, moderate, or low priority for review, based on the possibility that the patient was at a high, moderate, or low probability for harm if the diagnosis provided by Pathologist A was incorrect. Of the 1,568 patients, 155 were considered to be those with 'high' probability.

Eleven other RAH pathologists then reviewed these 155 sets of slides, according to the normal RAH peer review process. This was done to get an estimate of the degree of possible 'discordance' between the interpretations of Pathologist A and the RAH peer pathologists. Of the 155, major discrepancies were found in 14 sets of specimens for 13 patients. The senior AHS pathologist then reviewed each case. For each of the 13 patients, this further assessment determined that none of the patients had suffered harm: the correct diagnosis had been established and there were no false negatives.

Ten pathologists at DynaLIFE Edmonton then reviewed 191 sets of slides rated as 'moderate' probability. Major discrepancies were found with the slides of one patient. As of August 28, 2012, 290 of the 1,222 'low' probability specimens had been reviewed by two pathologists at the Grey Nun's Hospital in Edmonton and no major discrepancies were found. The QAC learned that AHS decided to stop the review of these low-risk cases because there is a very low probability that any of these patients will have suffered harm.

Table 3: Results for the 1,727 patients whose slides were read by a locum pathologist between July and October 2011 at the Royal Alexandra Hospital (blue shading defines patients whose prostate core biopsies were reviewed.)



Analysis

Patients

No specific patient factors can be said to have contributed to these events; however, the process of disclosure is an important patient-related factor in this review.

Once the misinterpretation of slides was discovered and reviews of the prostate specimens were underway, after discussions with senior pathologists, a senior urologist undertook disclosure for all the patients. The patients received their explanations from a clinician with a complete understanding of all the issues, including the effects that delay in diagnosis might have on prognosis and treatment options. Having the same individual conduct the disclosure for all patients may have reduced the variability and confusion that can result from having different people provide disclosure. The QAC learned that the initial planning for disclosure did not follow any specified organizational model but was, however, based on the 'first principles of good care'.

Personnel

Pathologist A was newly retired from another institution in Alberta and had been hired as a summer locum to help the pathologists at the RAH with their heavy workload in 2011. During that period, Pathologist A did not appear to have any difficulties with the work or the workload. It was not apparent until near the end of the locum period that Pathologist A had misinterpreted some slides.

When determining the appropriate qualifications and experience required for a particular position a human factors view of work is important. These work-related factors include workload,[79] complexity of cases, and remaining current.

Increasing workload (and complexity of work) is described as a problem in pathology worldwide. However, it is difficult to determine what an appropriate workload is for pathologists. This question is important because there is case-to-case variability in difficulty and, as a result, variability in the amount of time a pathologist spends with each case. Over the past two decades, the subspecialty of anatomical pathology has "evolved from providing just a diagnosis" to providing "additional information related to prognosis and therapy".[80] The work is becoming increasingly complex, with greater diagnostic detail now available from advances in knowledge, as well as from special immunohistochemical stains.[81] This is true for certain kinds of tissue specimens, including prostate needle biopsies, further increasing the workload.

Anatomical pathology experts perform a 'holistic' scan of the slide to detect what the diagnosis is and then search for anything else, whereas non-experts cannot distinguish important from less-important features of the slide and must search until they detect something.[82] An expert in this case would be considered as someone who is experienced and a non-expert someone with less experience. Non-experts take more time to 'search and detect'. If workload is increased to the point where a pathologist feels that scanning time must be reduced in order to get through all the work, then simply on a 'time-available basis', the non-expert could be more likely to misinterpret slides than would the expert.

Another work-related factor is that of remaining current with specific types of tasks. During the locum, Pathologist A signed out the prostate biopsy slides of more than 150 patients in four months. In contrast, in the previous two years Pathologist A had signed out the slides of fewer than 20 patients suspected of having prostate cancer. These differing numbers suggest more questions that could be asked of any

pathologist, or indeed, of any physician: how many cases of one specific type are enough to maintain competence? Are case numbers enough or are there other requirements, such as ensuring more-than-adequate knowledge of a specific subject? It is possible that a pathologist who has chosen to specialize in another area, such as breast or lymph cell cancer, might not have read an update about prostate cancer. The focusing of professional practice, or subspecialization,[83] is a concept that applies not only to pathology but to other medical and surgical specialties.

Organization and regulatory

The QAC heard that when interviewing Pathologist A for the locum position, a physician administrator at AHS had discussed recent work history with Pathologist A and Pathologist A's ability to interpret various types of tissues. No formal background checks were completed as to the amount or type of work the pathologist had carried out over the previous few years or how well qualified the individual was to complete the tasks required of the locum position. AHS has since reviewed procedures for the hiring of locums and will be adopting a more systematic approach. The QAC heard that for locums in anatomical pathology, this approach will apparently include having a pre-determined number of specimens undergo a mandatory second reading by another pathologist.

The question of who should conduct detailed performance reviews of physicians in Alberta is important. Two distinct yet parallel systems exist in the province related to physician performance. One regulates the practice of medicine in Alberta (which is governed by the CPSA), and one grants privileges and assesses the performance of physicians who practise medicine within AHS's jurisdiction. The challenge is that these systems, which share a common purpose – determining and assuring the ongoing competence of physicians – are not integrated and consequently do not share vital information relevant to the assessment of physician performance and competence.

At the time of these events there was no systematic approach to physician performance review by AHS. Since approval of the AHS Medical Staff Bylaws in 2011 all physicians who work in or for AHS will undergo performance review every three years.

In addition, every year when a physician applies for registration with the CPSA for a licence to practise medicine the physician is required to complete an online questionnaire. Questions include self-reporting of 'fitness to work' as well as participation in some form of educational program to maintain competence.

For new physicians the process is more detailed and includes background checks of education, training, and the possible existence of a criminal record. However, if a physician, who is already licenced in Alberta and in good standing with the CPSA, applies for a locum position then the CPSA may not become involved. As the regulator of physicians in Alberta, the CPSA would only become involved if a physician wished to work in a different area of practice or had been out of active practice for more than three years. In the case of Pathologist A this did not apply.

ISSUES, ANALYSES, AND RECOMMENDATIONS

Automated tissue processing machines

Issue

The automated tissue processing machines at the Calgary Laboratory Services Diagnostic and Scientific Centre (DSC) and Rockyview General Hospital (RGH) anatomical pathology (AP) laboratories are not optimally designed to avoid errors.

Analysis

In the time period under review (January 2010 to December 2011), it was learned that five separate instances of tissue processing errors occurred. Three of these occurrences involved the misprocessing of the 31 specimens that prompted this review. While the tissue processing machines are well designed to process tissues, the problems that occurred with the machines are best described as 'usability' issues. Design improvements in the tissue processing machines would reduce the opportunity for these errors to occur.

Calgary Laboratory Services has implemented corrective actions to address some of these issues; however, there is still opportunity to further reduce the potential for error.

1. RECOMMENDATION

Alberta Health Services (AHS) apply 'human factors' science to further mitigate usability issues associated with the use of AP automated tissue processing machines.

REQUIRED ACTIONS

- Undertake a formal human factors evaluation of the automated tissue processors at the DSC and RGH and other automated tissue processors throughout the province, including those of contracted laboratory service providers, and implement the required recommendations. These recommendations should, where possible, incorporate forcing functions, if re-engineering of the tissue processing machines cannot be undertaken.
- Set human factors standards for future purchasing of tissue processing liquids and automated tissue processing machines.
- In the long-term, advocate with the manufacturers for redesign of the automated tissue processing machines and tissue processing liquids (e.g., formalin and alcohol) to improve usability and lessen the probability of human error.

Calgary Laboratory Services (CLS) organizational structure

Issue

There continues to be lack of clarity related to CLS as a wholly owned subsidiary of AHS and the obligations of both organizations in that relationship. Recent changes in the CLS board structure and in

the reporting relationship for the CLS Chief Operating Officer (COO) to AHS have caused more uncertainty for CLS.

Analysis

In April 2006, CLS became a wholly owned subsidiary of the former Calgary Health Region. With the formation of AHS in 2009, CLS then became a wholly owned subsidiary of AHS. Early in 2012 the CLS Board was reduced to one member, who is also a member of the AHS Executive. This change has affected the reporting relationships of the CLS COO and physician leaders; the COO of CLS now reports directly to a vice-president of AHS and informs the CLS Board. These governance changes have resulted in a need for clarification of the expectations for individuals and the status of CLS itself, that is, if CLS is a 'department' within AHS. Clarity in all aspects of this structural change is critical, not only for the internal CLS leadership and staff, but also at a zone and provincial level.

In addition, concerns were expressed or noted about leadership at various levels of CLS including examples of poor communication, limited understanding of roles and responsibilities, and the manner in which highly charged situations were handled.

2. RECOMMENDATION

Alberta Health Services undertake an organizational review of all aspects of CLS to provide clear reporting and accountability structures within CLS and between AHS and CLS.

REQUIRED ACTIONS

- The organizational review include CLS governance; organizational structure; the leadership/executive requirements; reporting relationships, accountabilities, and authority; and the alignment of goals/priorities, funding/budget, communication channels, and human resources with those of AHS.
- Provide educational and mentoring support to individuals (both medical and non-medical) in leadership roles in CLS and in AHS Laboratory Services. This support should be aimed at helping individuals determine if they wish to remain in leadership roles and, if so, to enhance the knowledge, skills, and experience with various aspects of leadership, including setting priorities, responding to crises, and conflict resolution.

Centralization of AP services in CLS

Issue

The decision to centralize AP services in CLS remains unresolved.

Analysis

A decision was made in 2009 to centralize AP services in CLS. Despite considerable planning, including the development of a business case and plans for risk management, change management, communication, implementation, and resources, the completion of the centralization of AP services was put on hold in September 2010. Centralization was halted due to limitations with space and ventilation and various

problems with tissue processing, especially those related to prostate needle biopsy specimens. It was determined that centralization should proceed at a later date but not if patient care might be compromised and not until these specific issues had been addressed.

The QAC heard that the plan for centralization had been treated as confidential because of the planned layoffs. Input was therefore not sought from frontline workers or many of the pathologists about how aspects of centralization should be undertaken and achieved. A significant issue related to the centralization was the reluctance to discuss the situation openly and the desire to keep certain organizational information contained.

A Laboratory Assessment Report of CLS from the College of Physicians & Surgeons of Alberta (CPSA) in December 2011 noted that all CLS sites had problems with ventilation that would restrict any increase in workload capacity without significant renovation.

3. RECOMMENDATION

Alberta Health Services determine if centralization of all AP services in CLS should proceed from the perspective of patient care, the clinicians using the service, and the larger AHS AP laboratory strategy.

- Consider undertaking an operational review to examine service delivery models, type and volume of work, workload, current and future space and ventilation requirements, and equipment utilization for AP tissue processing and interpretation to assist in determining if centralization should proceed. The operational review would include effective staff and clinician engagement and communication strategies.

Disclosure of harm

Issue

The disclosure process following the events that occurred at the DSC, RGH, and Royal Alexandra Hospital (RAH) was inconsistent and did not appear to follow a specific organizational model.

Analysis

In the Rockyview General Hospital/Calgary Laboratory Services Diagnostic Scientific Centre events, disclosure was undertaken twice, once in December 2010 and once in early November 2011. There was no consistency in CLS's organizational approach to disclosure with respect to determining the necessity (no patients suffered harm or were nearly harmed), timing (either December 23–24 or several months after the events), or process of disclosure (including makeup of the disclosure team). The process resulted in confusion for some patients and the information provided was difficult for others to understand.

At the RAH, disclosure was undertaken and although no specific 'organizational' approach was followed, disclosure was completed on the basis of 'first principles of good care'.

4. RECOMMENDATION

Alberta Health Services ensure Laboratory Services staff and clinicians follow AHS disclosure policies and procedures.

REQUIRED ACTION

- Leadership and physicians in AHS Laboratory Services (including CLS) receive disclosure training, and evaluation of future episodes of disclosure is undertaken to ensure consistency with AHS guidelines.

Process for recruitment of locum pathologists

Issue

A thorough process for the hiring of the locum pathologist to fill a temporary vacant position at the Royal Alexandra Hospital (RAH) was absent.

Analysis

The pathologist who filled a locum position at the RAH was hired after a discussion with a senior individual at AHS. In part, because the pathologist had recently retired from another AHS hospital, no formal background checks were completed as to the amount or type of work the pathologist had carried out over the previous few years or how well qualified the individual was to complete the tasks required of the locum position.

A systematic review should be completed before a physician is granted a change in privileges, for example filling a locum position, to ensure the physician is capable of fulfilling the job requirements. Assumptions should not be made as to a physician's general and specific competence based on where a physician has trained or worked previously.

5. RECOMMENDATION

Alberta Health Services improve the process for the hiring of locum pathologists.

REQUIRED ACTIONS

- Develop a comprehensive approach to the granting of privileges, which should include checking the working background of the individual and the amount and type of work completed in a predetermined period.
- Develop and apply a systematic approach to the orientation/induction period of all newly hired pathologists, which would include review by another pathologist of all tissue specimen interpretations for a period sufficient to ensure that all types of tissues and an appropriate number of specimens are reviewed.

College of Physicians & Surgeons of Alberta (CPSA) accreditation

Issue

The current accreditation processes for AHS-owned, -operated, or -contracted medical diagnostic laboratories lacks sufficient separation between the organization conducting the accreditation and the laboratory being accredited.

Analysis

An important aspect of any accreditation process is that it is conducted by an external and fully independent organization. Currently, accreditation of AHS-owned, -operated, or -contracted medical diagnostic laboratories is conducted by the CPSA. Over the past four decades the laboratory accreditation program operated by the CPSA has evolved with changes in the local environment and international standards. The CPSA has shown a commitment to continuous improvement of its laboratory accreditation program by benchmarking its standards against the current international standards. The QAC considers that the CPSA program for accreditation of medical diagnostic facilities is a strong one by any measure and is fully compliant with recognized general and laboratory discipline-specific international standards.

AHS is the CPSA's only client for accreditation of public laboratories. The CPSA is dependent on AHS for funding its contract to perform the accreditation and consequently, this relationship raises questions about the CPSA's independence from AHS and its ability to make objective recommendations.

One of the difficulties for the CPSA is that the assessors who are used to accredit AHS laboratories are most often employed by or contracted by AHS to provide laboratory services. Although assessors come from different geographical areas of the province, they are still part of the organization being accredited. In addition, having the same individuals make repeated visits to the same site suggests the possibility that problems may not be noted because of 'familiarity' with a particular laboratory. The CPSA has contracted with a pathologist consultant from out-of-province to observe and report to AHS on the objectivity and thoroughness of the CPSA's laboratory accreditation process.

In Alberta, the CPSA is not only the accreditor of the laboratories but also regulates the pathologists who work in those laboratories. AHS, the sole public client of the CPSA for this program, in turn grants privileges to the pathologists who practise in the laboratories.

These various processes (i.e., accreditation, regulation of physicians, and the granting of privileges) need to have sufficient degrees of separation to avoid the potential for conflict of interest.

6. RECOMMENDATION

The CPSA, AHS and AH collaborate to implement an accreditation process for public medical diagnostic laboratories that mitigates the potential for conflict of interest.

REQUIRED ACTIONS

- Alberta Health assume responsibility for the signing and funding of the contract for accreditation of public diagnostic medical laboratories with the CPSA.
- The CPSA, as part of the accreditation contract and in addition to the external pathologist consultant, use assessors from other provinces and ensure that no assessor reviews a laboratory twice in succession.

Performance/assurance of competence of pathologists

Issue

The processes that support the regulation and assessment of the performance of individual pathologists that are conducted by the CPSA and AHS, respectively, need to be more closely integrated to fully support performance management and the assurance of competence of pathologists.

Analysis

Issues arose regarding the performance of Pathologist A at the Royal Alexandra Hospital and from this arose questions about how the performance of individual pathologists is determined.

Two distinct yet parallel systems exist in the province related to physician performance. One regulates the practice of medicine in Alberta (which is governed by the CPSA), and one grants privileges and assesses the performance of physicians who practise medicine within AHS's jurisdiction. The challenge is that these systems, which share a common purpose – determining and assuring the ongoing competence of physicians – are not integrated and consequently do not share vital information relevant to the assessment of physician performance and competence.

To strengthen the processes of regulation by the CPSA and privileging and performance management by AHS the ideal model is one developed jointly by AHS and the CPSA. This would not be a divesting of responsibility by the CPSA but an example of a shared model of responsibility. This model would coordinate the activities unique to AHS and to the CPSA as well as include the personal responsibility of each individual practitioner.

7. RECOMMENDATION

The College of Physicians & Surgeons of Alberta and Alberta Health Services create and implement a coordinated approach to assessing pathologists' competence and performance.

REQUIRED ACTION

- A provincial working group with representation from the CPSA, AHS leadership, and pathologists be tasked with the creation of a coordinated approach to the performance/assurance of competence of individual pathologists.

APPENDICES

Appendix I: Terms of Reference

HQCA
Health Quality Council of Alberta

Promoting and improving patient safety and health service quality across Alberta

Rockyview General Hospital and Calgary Laboratory Services Diagnostic and Scientific Centre and Royal Alexandra Hospital: Review of the Quality of Anatomical Pathology Specimen Preparation and Interpretation 2010-2011

Terms of Reference

Purpose

Pursuant to section 14 of the *Health Quality Council of Alberta Regulation* 130/2006, Alberta Health Services (AHS) requests that the HQCA conduct an independent review of the quality of the preparation and interpretation of anatomical pathology specimens prepared and/or interpreted at the:

- Rockyview General Hospital (RGH) and Calgary Laboratory Services (CLS) Diagnostic and Scientific Centre (DSC) from January 2010 to December 2011, and
- Royal Alexandra Hospital (RAH) from July 2011 through October 2011.

Objectives

The HQCA will, through a quality assurance committee under section 9 of the *Alberta Evidence Act*, conduct a full and thorough review of and determine any contributing factors related to:

- Anatomical pathology specimens prepared and/or interpreted at the RGH and the CLS DSC, including the 31 specimens already identified, for the period from January 2010 to December 2011, and
- Anatomical pathology specimens prepared and/or interpreted at the RAH from July 2011 to October 2011, including the 159 prostate biopsy specimens already identified for that period.

This review will include but not be limited to:

- Whether or not appropriate standards, guidelines and procedures (including best practices and necessary safe guards) are in place regarding the quality of the preparation and interpretation of anatomical pathology specimens, and
- The engagement and organization of health professionals who prepare and/or interpret anatomical pathology specimens.

The review may also consider any matter that pertains to the quality of the preparation and interpretation of anatomical pathology specimens.

The most recent accreditation by the College of Physicians and Surgeons of Alberta (CPSA) of anatomical pathology processes at the RGH / CLS DSC and the RAH, as well as the inspection to be conducted immediately by the CPSA at these sites as requested by Alberta Health Services, will be considered as part of this review.

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In order to ensure the quality of pathology procedures and based on the findings and analysis of the investigation and a review of current practices, the HQCA will make recommendations about the quality of anatomical pathology specimen preparation and/or interpretation at the RGH / CLS DSC and the RAH.

Stakeholders

Stakeholders that may be engaged in the review process include:

- Alberta Health Services
- Calgary Laboratory Services
- DynaLIFE$_{Dx}$ (Diagnostic Laboratory Services)
- College of Physicians and Surgeons of Alberta
- Alberta Health and Wellness

Project Management

John W. F. Cowell M.Sc., MD, CCFP, FRCP, CEO of the HQCA

Jan M. Davies M.Sc., MD, FRCPC, Professor, Faculty of Medicine, University of Calgary

Deliverables and Timeline

- Prompt reporting of any factual irregularities that may immediately affect patient safety will be provided to Dr. Chris Eagle, President and Chief Executive Officer, AHS, the Minister and the Deputy Minister of Health and Wellness.

- Regular updates on the progress of the review will be provided to Dr. Chris Eagle, President and Chief Executive Officer, AHS, the Minister and the Deputy Minister of Health and Wellness.

- A full report of the findings and recommendations will be made public by July 31, 2012.

Approved by:

Dr. John Cowell
Chief Executive Officer
Health Quality Council of Alberta

Dec 9, 2011
Date

Dr. Chris Eagle
President and Chief Executive Officer
Alberta Health Services

Dec 9th, 2011
Date

210, 811 - 14 Street NW Calgary, Alberta T2N 2A4 Ph: 403.297.8162 Fx: 403.297.8258 Website: www.hqca.ca

Appendix II: History and Further Developments in Anatomical Pathology

History

The earliest recorded studies in pathology date from the third century BCE, with descriptions of wound healing, infections, and breast tumours. These first records linked descriptions of the types of injuries suffered by soldiers in battle with examination of the patient, diagnosis, estimation of the likely outcome for the patient (prognosis), and treatments.[84] These records represent the first descriptions of decision-making in medicine and surgery,[85] with the physician deciding that the patient had "an ailment I will handle", "an ailment I will fight with", or "an ailment for which nothing is done".[84]

The next advances in pathology came through the study of patients' bodies after death (autopsy or post-mortem dissection), first performed in 1315. Over the next 200 years, these early 'pathologists' were able to demonstrate how post-mortem dissection could help determine cause of death.[86]

With the invention of the compound microscope in 1590[87] doctors and scientists could look at the individual cells that made up tissues and organs. Techniques were developed to 'fix' tissue specimens to stop them from deteriorating. Very thin slices of tissue were cut, placed on a piece of glass (a slide), and stained with special chemicals that differentially coloured different tissues and different parts of a tissue.[87] The slices of tissue were thin enough so that light could pass through them, which enabled pathologists to look through a microscope at the coloured tissue on the glass slide to judge if the tissue was normal or abnormal.

The use of a very cold knife to cut extremely thin slices of tissue provided the next advance in pathology in 1905 and greatly improved the treatment of patients undergoing operations for cancer. With this technique, the frozen slice (or 'frozen section')[88] could be quickly stained with one or more special dyes to highlight certain characteristics. Frozen sections take less time to produce than do 'fixed' specimens and are often used by pathologists to help guide surgeons during operations. Previously, patients would undergo operations to remove a cancer but then might need to have a second procedure some days or weeks later, once the results of the 'fixed' pathology specimens were available. With frozen sections, pathologists are usually able to determine if the surgeon has completely removed a tumour or if more tissue should be removed – while the patient is still in the operating room. This decision is based in part on looking at the distance or 'margin' between the cancer and the healthy tissue, hence the term 'good margins'.

Further developments

Although the specialty of pathology has benefitted immeasurably from the advances described above, new developments in digital pathology can help pathologists with ongoing continuing medical education and maintenance of competence.

The use of computers has enabled developments in pathology, including that of "whole slide imaging".[36] This process (or 'digitization') involves a specially programmed computer scanning the tissue on a traditional glass slide, which is photographed to produce a 'digital slide'. These digital slides can then be viewed by one or more pathologists in different locations in a process known as 'virtual microscopy', because the traditional light microscope is not used but is simulated.[36] Another development in 'virtual

microscopy' is "automated image analysis", which involves using computers to 'interpret' the digital slides.[89]

'Virtual pathology' is not intended to replace pathologists. Rather, digital imaging is being combined with broadband (Internet) transmission of images to provide "telepathology".[90] This web-based technology gives a pathologist practising alone access to another pathologist who can provide a 'second opinion' of the digital slides. Increasingly, digital pathology is also used in the education and training of medical students, residents, and pathologists;[91] in ongoing testing for individual proficiency;[92,93,94] and in multi-centre research.[36,92]

Although digital imaging has been under development for more than a decade, there are still issues to be resolved before the technology can be implemented broadly. These issues include:

- Regulatory – approval by federal and provincial or territorial health regulators.[36]
- Organizational – requirements for integration with hospital/laboratory information systems.[36]
- Equipment – the cost of high-quality scanners and high-resolution monitors,[92] massive computer storage capacity, and high bandwidth connectivity.[36]
- Personnel – an understanding of how pathologists look at real versus virtual slides,[93] the gaining of experience,[36] and availability of "well-trained support personnel".[94]
- Patient-related – validity of the technology in comparison to the 'gold standard' of light microscopy.[36]

More information can be found in the article by Cornish et al, 2012,[94] for a description of the advantages and disadvantages of digital pathology; the article by Pantanowitz et al, 2011,[36] which includes a description of the experience with digital pathology at the University Health Network in Toronto since 2004; and the article by Camparo and colleagues, 2012,[92] which provides an international perspective on the use of whole slide imaging and virtual microscopy in prostate pathology. (Please refer to References.)

Appendix III: Accreditation of Anatomical Pathology Services in Canada and Internationally

United States

Accreditation programs focused specifically on diagnostic medical laboratories have their origins in the United States. The American Society of Clinical Pathologists (ASCP) was established in **1922** and the American Board of Pathology in **1936**. However, the American Medical Association (AMA) did not actually recognize pathology as "the practice of medicine" until **1943**. Once pathology was formally recognized by the AMA the College of Pathology was established in **1946**.[95]

Very early on, the members of CAP demonstrated an interest in assuring high-quality and reliable laboratory testing in the United States. In **1949** CAP conducted the first chemistry survey and collaborated with the AMA on a blood-bank survey. The next year CAP issued a policy statement on cytology (the microscopic study of cells). In **1955** CAP adopted a surgical pathology policy, which was really a precursor to what today would be considered a 'practice guideline'.[96] (A guideline is a systematically developed statement designed to "assist practitioners and patient decisions about appropriate health care for specific circumstances".[97]) In **1959** CAP issued a comprehensive set of Laboratory Standards.

At the same time, by the late 1950s, the Joint Commission on Accreditation of Hospitals (JCAH) had become well established, with the program of accreditation offered by JCAH touching upon all aspects of hospital operations, including diagnostic laboratories. However, there was a growing sense in the medical laboratory community that the general program of accreditation offered by the JCAH did not adequately match the increasing complexity of laboratory operations.

As a result, the CAP decided to launch its own laboratory accreditation program. The flagship program operated by the College of American Pathologists (CAP) was approved by the CAP Board of Governors in **1962** and the first CAP accreditation was awarded to a laboratory in **1964**.[98]

In **1967** the *Clinical Laboratories Improvement Act* (CLIA) was passed in the United States, which required laboratories to meet certain standards. In **1968** the CAP basic survey was accorded 'CLIA-67 equivalency' and in **1969** CAP's entire lab inspection and accreditation program was declared "equivalent to CLIA-67 standards".[95]

Since then, CAP has emerged as the dominant medical lab accreditation agency in the United States. There are currently more than 7,000 CAP-accredited laboratories and 22,000 laboratories enrolled in CAP's proficiency testing programs.[98] In contrast, the Joint Commission accredits about 2,000 organizations providing laboratory services, which would include about 3,000 individual laboratories.[99]

Canada

The history of medical laboratory accreditation in Canada has unfolded very differently. While many individual Canadian pathologists have certainly made important contributions toward medical laboratory accreditation in Canada, the national specialist society for pathologists in Canada has not shown leadership like that of the CAP in the United States.

In Canada, most physicians who are certified specialists in the specialty disciplines recognized by the Royal College of Physicians and Surgeons (RCPSC)[100] organize themselves through national specialist societies. These societies have some linkage with the RCPSC, which provides varying amounts of logistical support to these national specialist societies. Legally, however, these societies are not part of the RCPSC. The specialty society for pathologists in Canada is the Canadian Association of Pathologists – Association canadienne des pathologistes (CAP-ACP).[101]

As early as September 1907 (and well before the American Society of Clinical Pathologists was established in 1922), there was an initial attempt by a group of Canadian pathologists to create a national organization within the Canadian Medical Association (CMA). This "Laboratory Section" remained separate until 1932 when it joined the CMA's Section of Medicine. In 1937 the Ontario Association of Pathologists (OAP) was founded, followed by the Association des pathologistes du Québec in 1946. Other provincial pathologists' organizations followed and in 1949 the first meeting of the Canadian Association of Pathologists (CAP-ACP) was held.[102]

The CAP-ACP has no accreditation program for medical diagnostic laboratories and, to date, no comprehensive set of standards for Canadian laboratories. In the wake of the problems with unreliable hormone receptor testing for breast cancer patients in Newfoundland, the CAP-APC produced guidelines for immunohistochemistry testing,[103] but little else in the way of national guidelines.

For this review, the QAC requested the opinion of the CAP-ACP on national standards for anatomical pathology in Canada. The QAC was told that currently the CAP-ACP, through its Patient Safety and Quality Assurance Committee, is working on a draft document for quality assurance in anatomical pathology. This document is not ready for release but the QAC was given some of the guiding principles on which the work to develop such national standards is being based. These principles include:

- "All patients should have access to the same high level of pathology diagnostic quality no matter where they live
- "Pathology reports should be standardized, timely, accurate, evidence-based, clinically relevant, and cost effective
- "Diagnostic standards should be based on the most current international consensus guidelines and classification systems
- "Continuous quality improvement promotes patient safety and improves outcomes
- "While no test or interpretive criterion can be 100% accurate due to inherent variables that lead to discrepancies, variation can be reduced by standardization of technical and interpretive processes
- "Pathologists must have access to relevant continuing education, self assessment, constructive peer review and competency testing designed to continuously improve individual skills
- "A quality management system must be in place in all clinical laboratories."[104]

In addition the QAC was informed that the CAP-ACP considered that "managing the quality of laboratory services is an institution-wide responsibility as pathology is a medical discipline. Clinical laboratories are integral to good patient care and do not operate in isolation from other clinical programs. Inherent in this principle is the assumption that clinical laboratories are provided with necessary and ongoing operating and capital resources to meet the standards enunciated in this document."[104]

While the medical profession in Canada has failed to develop a pan-Canadian laboratory accreditation program comparable to the CAP program in the United States, the impetus for the provincial programs now in place came largely from individual and groups of medical laboratory physicians who sought to ensure the safety and quality of the diagnostic services they provided. These commendable strategies initiated at the provincial level were eventually supported and reinforced by provincial governments, because of their desire to ensure consistently safe and high-quality services to all citizens, regardless of where citizens gained access to those services.

Some of the provincial programs were first developed as Quality Assurance activities and not as accreditation but then evolved into a more formal, government-supported accreditation program. An example of this evolution occurred in Ontario. In the **1960s** pathologist members of the Ontario Medical Association (OMA) Section on Laboratory Medicine started a voluntary proficiency testing program in hematology and chemistry. In **1972** the Ontario government passed legislation requiring licensing of medical laboratories and quality oversight. In **1974**, with funding support from the Ontario government, the OMA launched the Laboratory Proficiency Testing Program (LPTP). In **1992** the Ontario government initiated a Laboratory Services Review. One of the five recommendations from that two-year review was a need to implement a province-wide quality management system for all laboratories in Ontario. That recommendation prompted the OMA in **2000** to launch Quality Management Program – Laboratory Services (QMP-LS), which operates Ontario Laboratory Accreditation (OLA).[105]

Accreditation by OLA of medical laboratories is now mandated by the Ontario government for all medical diagnostic laboratories in that province. The provincial governments of New Brunswick and Newfoundland and Labrador have also mandated laboratory accreditation in their respective provinces and have contracted with OLA to operate the programs.[106]

In the four provinces west of Ontario, provincial governments turned to their respective Colleges of Physicians and Surgeons to establish and operate programs for diagnostic medical laboratories. The Colleges were perceived by governments as agencies that could tap into and mobilize the medical expertise from physicians that is essential to the operation of such programs. The Colleges also saw the operation of programs designed to assure the safety and quality of all services for all citizens as being well aligned with the mandate of the Colleges to protect the public.

The QAC questioned why the medical profession and provincial governments did not lobby the Canadian Council on Health Facilities Accreditation (CCHFA) to create a more 'fit for purpose' laboratory accreditation program if the 'generic' program, first offered by the CCHFA, did not meet their needs. This question remains unanswered but there are at least two plausible explanations. First, although the Canadian Medical Association (CMA) played an instrumental role in the founding of the initial CCHA, most doctors in Canada have little sense of connection with an organization that began as the CCHA and is now Accreditation Canada. It is therefore unlikely that laboratory medicine doctors would have turned to that organization to meet their wishes to have an accreditation program that was actually focused on the laboratory. Second, the CCHA (and its successive versions) took considerable pride in remaining independent of all levels of government. It is possible that requests for cooperation from governments would not have been well received by the CCHA.

Throughout its history, the CCHA/CCHFA/CCHSA/AC has demonstrated a somewhat uneven interest in and focus on medical laboratory services. At one time the accreditation site visits did have a significant focus on laboratories. The organization then retreated significantly from this.

In **2006** CCHSA introduced a new Biomedical Lab services accreditation unit to meet a demand in Quebec, which had never had a provincial accreditation system for laboratories. Also, because the Atlantic provinces all lacked provincial medical laboratory accreditation programs, Accreditation Canada had hoped to expand the reach of this unit into those four provinces. However, as noted earlier, the governments of New Brunswick and Newfoundland and Labrador opted to contract with Ontario Laboratory Accreditation (OLA). Currently, Accreditation Canada only administers its laboratory unit during accreditation site visits to Quebec, Nova Scotia, Prince Edward Island, and the territories.

Other countries

The QAC examined the national medical laboratory accreditation systems of three different countries: Australia, France, and the United Kingdom. One common theme was found: all three have national medical laboratory accreditation systems that exist in addition to their more general health service accreditation systems.

Australia

In the 1950's, the Australian Council on Healthcare Standards (ACHS)[107] started to accredit laboratories in hospitals – as part of the entire hospital accreditation – as in the United States and Canada. Then, in the 1970s the Commonwealth (federal) Government of Australia as well as the Royal College of Pathologists of Australasia (RCPA)[108] were concerned about the rise in costs and apparent fraudulent practices in the provision of pathology services. The RCPA advised the Commonwealth that standards needed to be established and enforced by some system of accreditation. In 1979 the National Accreditation Advisory Council (NPAAC)[109] was established under a (Commonwealth) Order in Council.

NPAAC proceeded to establish basic standards, which were to be used by pathology laboratories. However, these standards proved to be insufficient to deter some service providers from operating laboratories. The RCPA continued to agitate about those laboratories that were harming both the patients they served and the good name of the profession.

In 1982 the RCPA approached the National Association of Testing Authorities (NATA)[110] to propose a *voluntary* registration program for laboratories maintaining the NPAAC standards. This was willingly accepted by the good laboratories but did nothing to stop the so-called 'shonky' laboratories, which continued to provide both unnecessary testing of patients and questionable test results. These problems led in turn to increasing costs of the Commonwealth system of payment, the Medicare rebate.

It was not until 1985 when further action spurred the Parliamentary Public Accounts Committee to address the problem of medical fraud and over servicing. The RCPA urged the Commonwealth to make laboratory accreditation mandatory.

Although accreditation was supposed to be a State issue, the Commonwealth used its powers under the Health Insurance Act to limit payment of (Medicare) benefits only to those laboratories that were registered/accredited under the NATA/RCPA Scheme. This helped ensure uniform, minimally acceptable standards throughout Australia. Inspections were to be carried out by the NATA, in conjunction with the RCPA.

Under the Health Legislation Amendment Bill from 1986 onwards, laboratories not complying with the NPAAC standards could not obtain NATA/RCPA Accreditation. The consequent loss of revenue forced most of them either to comply or to close.

NATA has formal agreements with the RCPA and with Medicare, Australia.[111] Assessments are performed usually on a three-year cycle, however, if problems are perceived then follow-up visits ensure eventual compliance. The assessors are voluntary, unpaid pathologists and senior scientists supported by NATA staff. The assessments are conducted using the NPAAC Standards (now called Requirements) and the Australian Standard ISO 15189-2009 Standard.

The objectives of the NATA/RCPA Scheme are to:

- improve laboratory standards
- recognise those laboratories which achieve acceptable standards
- heighten awareness of the importance of education and training
- encourage debate and discussion regarding various standards
- ensure public protection by the enforcement of appropriate standards.

These objectives have largely been achieved. Whilst accreditation is costly, the process has brought considerable improvements. The number of 'problem' laboratories has decreased quite dramatically and fewer follow-up assessments are now required.

United Kingdom

In the United Kingdom (UK), national medical laboratory accreditation is achieved through a partnership between two agencies: the United Kingdom Accreditation Services (UKAS)[112] and Clinical Pathology Accreditation (CPA).[113] The UKAS is recognized by government as the national accreditation body and is the signatory to international recognition agreements on behalf of the UK.

In 2008 an independent review of National Health Service (NHS) Pathology Services in England recommended that all pathology service providers should be subject to mandatory accreditation by an organization independent of the providers and the professions. Another recommendation was that all providers of pathology services (including point-of-care testing) should be "required to participate in clinical audit and other clinical governance activities".[114]

France

In France COFRAC[115] is an overarching national agency that operates in compliance with an international standard, ISO/IEC 1700, which is intended to offer a framework for accreditation standards.[116] COFRAC assures compliance with laboratory testing standards (ISO 15189),[117] as well as with standards defined by the International Laboratory Accreditation Cooperation (ILAC)[118] and the International Accreditation Forum (IAF).[119] Accreditation is mandatory in France for all health service organizations, including medical diagnostic laboratories.

Appendix IV: Other Inquiries into Anatomical Pathology Elsewhere in Canada

Between 2008 and 2010 there have been three major inquiries into pathology services in Canadian healthcare systems. One was based in Newfoundland, one in New Brunswick, and one in Ontario. Two of the three inquiries were formal judicial inquiries; the third was a multi-physician-led review of pathology and surgical services in a southern Ontario healthcare system.

The QAC considered that information about these inquiries would be of use to the HQCA review. Accordingly, the three inquiries are presented sequentially, with a brief summary given of the circumstances that led to each inquiry, followed by the major issues identified. Many of the issues were specific to the healthcare system and/or province where the inquiry took place and these were not included. In addition, the QAC considered the recommendations generated in the three reviews, selected only those potentially relevant to the provision of anatomical pathology services in Alberta, and summarized them as to common themes.

Newfoundland and Labrador: Commission of Inquiry on Hormone Receptor Testing[120]

Background

In 2009, a public inquiry headed by the Honourable Justice Margaret Cameron in Newfoundland and Labrador on hormone receptor testing was completed.[120] (That Inquiry is referred to here as the Newfoundland Inquiry.) The inquiry looked into estrogen and progesterone receptor (ER/PR) tests that were carried out on breast cancer tissues from 1997 to 2005. These tests tell a patient if the cancer could be treated with certain drug therapies. The problem of erroneous hormone receptor tests in Newfoundland and Labrador was first recognized because of a patient in her 40's with metastatic breast cancer. The patient's ER/PR results were questioned three years after her diagnosis of cancer and were found to be different with re-testing. With her hormone receptor results now positive, additional treatments were an option. When other patients who had the same type of breast cancer (invasive lobular carcinoma) and hormone receptor results that 'converted' from negative to positive were discovered around the same time, suspicion arose that there could be a problem with the ER/PR testing. As a result, more than 1,000 other patients had their hormone receptor testing repeated.

Major issues

The inquiry concluded that the problem with inaccurate hormone receptor testing was related to poor fixation and processing of the samples of breast tissue, failure to follow proper testing procedures, and inadequate or improper antigen retrieval (or demonstration of the presence of the special proteins or antigens used in the tests). However, underlying these problems were a number of contributing factors and other important issues, including:

1. **A lack of quality assurance, quality control, and quality management:** Commissioner Cameron wrote that if measurements, such as ER/PR positivity rates, were collected and regularly reviewed, then the problems could have been identified, investigated, and fixed much sooner, thus reducing the number of patients affected.

2. **Inadequate management of affected patients:** The inquiry concluded that the follow-up and communication with patients was delayed because of issues with communication between members of the healthcare team and the patients, as well as problematic information management.
3. **Inadequate communication with key stakeholders:** The inquiry found fault with the health authority for its failure to be forthright with government. The health authority was found to have withheld relevant information as to the extent and the cause of the problem and in some instances, provided inaccurate information that minimized the seriousness and scope of the problem. Concern was also raised about the lack of timely communication with other health authorities, the media, and the public.

New Brunswick: Commission of Inquiry into Pathology Services at the Miramichi Regional Health Authority[121]

Background

The Honourable Justice Paul Creaghan led a public inquiry into pathology services at Miramichi Regional Health Authority.[121] (That Inquiry is referred to here as the New Brunswick Inquiry.) The Inquiry was called in response to a review of 227 breast and prostate samples that had been read by a general pathologist in 2004 and 2005, of which 18 per cent were found to be incomplete and three per cent to be incorrect. While the impetus for the inquiry was the performance of a single pathologist, the inquiry looked beyond the individual physician at the health system, including parties outside the health authority such as the provincial Department of Health, the College of Physicians and Surgeons of New Brunswick, the Canadian Medical Protective Association, and the Canadian Cancer Society.

Major issues

The inquiry found a number of system-level problems. Numerous problems with the human resource management of physicians were identified, including rushed recruitment processes, inadequate pre-employment reference checks, inadequate performance management, an informal physician privileging process, and a flawed disciplinary action process. Quality assurance (including peer review) and quality control were found to be absent or seriously lacking. As well, roles and responsibilities for important quality assurance and performance management activities were unclear. The College of Physicians and Surgeons of New Brunswick lacked the funding and resources to adequately perform its function. The inquiry also found that communication between the health authority and the Department of Health was delayed, resulting in ‘crisis management’, and that the Department of Health had failed in its oversight role to ensure adequate quality assurance and quality control processes were in place.

Ontario: Report of the Investigators of Surgical and Pathology Issues at Three Essex County Hospitals: Hôtel-Dieu Grace Hospital, Leamington District Memorial Hospital, and Windsor Regional Hospital[122]

Background

A patient underwent a mastectomy for what she and her surgeon thought was a malignant breast lump. Following surgery, however, pathological examination of the lump revealed that it was benign. It was then learned that the preoperative surgical biopsy was also benign and the report had been misread by the

surgeon. The hospital system believed there were issues regarding its anatomical pathology services in addition to the patient having undergone an unnecessary mastectomy. The Health Minister requested a review be conducted by three senior Ontario physicians. Part of their mandate was to review the surgical and pathology services at three Essex County Hospitals: Hôtel-Dieu Grace Hospital; Leamington District Memorial Hospital; and Windsor Regional Hospital.[122] (That review is referred to here as the Essex County review.)

The review focused most extensively on the practice of a single pathologist who was involved with the case in question (in 2010). All of the pathologist's cases from 2008 and 2009 were examined. A targeted review of cases dating back to 2003 was also carried out. In all, a total of 12,500 pathology reports issued by the pathologist were reviewed, with examination of 4,623 general cases and 53 neuropathology cases from 2008–09 and 1,551 cases from 2003–07. The pathology review also looked at a sample of 476 cases from the other four pathologists at Hôtel-Dieu Grace Hospital. A number of concerns came to light as a result of the review.

Major issues

Several issues were identified about the practice of anatomical pathology at the three hospitals in Essex County.

1. **Pathology reporting:** There was a need for Hôtel-Dieu to improve its pathology reporting process. Problems with reporting were made worse by the lack of effective communications between Hôtel-Dieu pathologists and surgeons. It was suspected that the lack of communication lead to asking for more second opinions than may have been necessary.

2. **Professional development**: Several cases were identified with insufficient clinical-pathological correlation, insufficient or inappropriate workup, inconsistent terminology and confusing terms, dated terminology, lack of standard reports, and insufficient use of current classification systems and grading and staging schemes.

3. **Quality assurance program:** The Chief of Pathology had been leading the development of a quality assurance program in pathology but had been faced with challenges in implementing it without full physician participation and the supporting resources to help the program succeed.

4. **Centralizing services:** There were differences in the working environments of the pathology practices at two hospitals. At one the pathologists took a team approach and frequently consulted with their colleagues. At the other hospital the working environment appeared quite different, with the pathologists in individual offices along a corridor that impeded easy interaction. There was less sharing of cases among pathologists and less than optimal communication.

5. **Relationships between medical leaders, senior management, and the Board:** There was a lack of respect between medical leaders, senior management, and the Board of Directors, with many unhealthy relationships appearing to have existed for more than a decade. It was also heard there were poor relationships between leaders at various levels of the organization, which wasted significant time and energy and fostered an unhealthy culture at times, characterized by distrust and disrespect.

   Medical and hospital leadership did not feel well supported by each other. Some physician leaders felt they were excluded from decision-making, and that hospital leadership was inclined to make

unilateral decisions about issues affecting medical staff without consulting them. Concerns were also expressed by physician leaders about the lack of following agreed-upon due process.

6. **Reporting safety issues:** Many physicians did not know about the policy or the process for reporting cases when a patient was harmed or nearly harmed. Many physicians expressed concerns that they would be criticized or blamed if they brought forward such information.

7. **Medical leadership roles and responsibilities:** The roles and responsibilities for a number of the medical leadership positions were out-of-date (some were almost a decade old). Performance reviews had not been carried out consistently in recent years.

Recommendations from these inquiries

The **Newfoundland Inquiry** generated a total of 60 recommendations. Fifty-two recommendations were made in the **New Brunswick Inquiry** to address the deficiencies identified and to restore the public's confidence in pathology services at Miramichi Regional Hospital. Nineteen recommendations were made to address the deficiencies identified in the **Essex County** review.

These 131 recommendations in total covered a range of issues, including 'best practices', quality assurance, roles and responsibilities, and review of the recommendations. The QAC recognized that these recommendations were generated in response to the specific problems identified in the three inquiries and therefore determined that it would be most helpful to readers of this report if the recommendations were consolidated. While each recommendation in its original wording was specific to an inquiry, in the process of consolidating the recommendations, the QAC removed all references to the inquiry of origin, so as to present 'generic lessons', as well as to ensure that the terminology used was congruent with that used in Alberta. The QAC also made a decision not to include recommendations where the topic of the recommendation was already in place or work was underway in Alberta.

These generic lessons relevant to the HQCA anatomical pathology in Alberta are:

- the need to provide adequate funding for laboratory information management systems
- the need for technical resources such as digital pathology, and
- the posting of policies and procedures relevant to disclosure and patient safety on their respective external websites so as to make them available to the public.

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LIST OF TABLES

ACRONYMS

ACH	Alberta Children's Hospital
AHS	Alberta Health Services
ALQEP	Alberta Laboratory Quality Enhancement Program
AMA	American Medical Association
AP	Anatomical (Anatomic) Pathology
ASCP	American Society of Clinical Pathologists
BPH	Benign Prostatic Hypertrophy
CAP	College of American Pathologists
CAP-ACP	Canadian Association of Pathologists - Association canadienne des pathologistes
CCHA	Canadian Council on Hospital Accreditation
CCHFA	Canadian Council on Health Facilities Accreditation
CCHSA	Canadian Council on Health Services Accreditation
CEO	Chief Executive Officer
CLIA	*Clinical Laboratories Improvement Act*
CLS	Calgary Laboratory Services
CLSI	Clinical and Laboratory Standards Institute
CMA	Canadian Medical Association
CMPA	Canadian Medical Protective Association
COO	Chief Operating Officer
CPSA	College of Physicians & Surgeons of Alberta
CRHA	Calgary Regional Health Authority
DRE	Digital Rectal Examination
DSC	Diagnostic Scientific Centre
ER/PR	Estrogen and Progesterone Receptor
EQA	External Quality Assurance
FMEA	Failure Mode and Effects Analysis
FMC	Foothills Medical Centre
H&E	Hematoxylin & Eosin
HPA	*Health Professions Act*
HQCA	Health Quality Council of Alberta
HR	Human Resources
IAF	International Accreditation Forum
ILAC	International Laboratory Accreditation Cooperation
ISO	International Standards Association
IT	Information Technology
JCAH	Joint Commission on Accreditation of Hospitals
LIS	Laboratory Information System

LPTP	Laboratory Proficiency Testing Program
MAC	Medical Advisory Committee
MLA	Medical Laboratory Assistant
MLT	Medical Laboratory Technologist/Technician
NAACLS	National Accrediting Agency for Clinical Laboratory Services
NATA	National Association of Testing Authorities
NHS	National Health Service
NPAAC	National Pathology Accreditation Advisory Council
OAP	Ontario Association of Pathologists
OLA	Ontario Laboratory Accreditation
OMA	Ontario Medical Association
PA	Pathologists' Assistant
PIVOT	Prostate cancer Intervention Versus Observation Trial
PLC	Peter Lougheed Hospital
PSA	Prostate Specific Antigen
PT	Pathology Technologist
QAC	Quality Assurance Committee
QMP	Quality Management Program – Laboratory Services
RAH	Royal Alexandra Hospital
RCPA	Royal College of Pathologists of Australasia
RCPSC	Royal College of Physicians and Surgeons of Canada
RGH	Rockyview General Hospital
TAT	Turn Around Times
TRUS	Trans Rectal Ultra Sound
VP	Vice-President

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