

Investigation into
Medical Imaging, Credentialing and Quality Assurance

Phase 2 Report

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EXECUTIVE SUMMARY

Since the creation of the health authorities in British Columbia there have been many changes that affect the delivery of services to those in need. Medical care is more complex, new technologies offer improved diagnosis and treatment, patients are living healthy lives while managing multiple chronic conditions and the knowledge explosion challenges practitioners to remain current. This complexity has increased the expectation of the public and patients regarding the quality of care that they can expect from the health system and from health care professionals. To meet these challenges and expectations, the health authorities must apply the same intense effort to assessing the quality of services and their medical staff as they do to operational and fiscal management.

So too has the bar been raised for the College of Physicians and Surgeons of British Columbia (the College) as the public expects it to “establish, monitor and enforce high standards of qualification and medical practice across the province”[1]. As the health care landscape is changing, it is expected that the College’s assessments of medical practitioners will be current and that it will work collaboratively with the health system.

It is the College’s role to manage the assessment of medical professionals who have been educated outside of Canada and who wish to practice medicine in BC. It is the assumption of the public that the quality of all providers is assessed and that where skills, knowledge or performance are lacking that the College will take steps to protect the public and require remediation if appropriate.

On February 11, 2011, the Honourable Colin Hansen, then Minister of Health Services, requested an independent two-part investigation into the quality of diagnostic imaging in BC after a series of events called into question the quality of diagnostic imaging in four health authorities. Dr. Doug Cochrane, Provincial Patient Safety and Quality Officer and Chair of the BC Patient Safety & Quality Council was asked to lead the review. The first report, submitted to the Minister on March 9, 2011, focused on the credentials and experience of the individual radiologists. This report represents the second part of the investigation and provides: 1) a detailed description of the events, including the responses of the health authority, their relationship with the College and the impact the events had on the communities involved; 2) a review of quality assurance and peer review of medical imaging; and 3) a review of physician licensing, credentialing and privileges and the roles played by the College and BC’s health authorities.

To undertake this investigation, the Provincial Patient Safety & Quality Officer established a review team to conduct the review and develop recommendations for the Minister’s consideration. The members of the review team included Dr. Cochrane MD FRCSC, Dr. David Matheson MD FRCPC, Ms. Anna Needs BSocSci MIR, and Mr. Andrew Wray BSc. During the review, the expertise of the BC Radiological Society (BCRS), the health authority Vice-Presidents responsible for medical affairs, quality and safety and the College of Physician and Surgeons of British Columbia was also called upon. The patients and family members affected by these events, as well as health authority administrative and technical staff, were interviewed to gain an understanding of the impact on patient and public confidence, event chronology and context. The health authority medical staff bylaws and rules and the Lower Mainland Medical Imaging (LMMI) agreements with the health authorities were also reviewed. Systematic reviews of the literature on: 1) imaging quality, interpretive error and peer review in diagnostic imaging; 2) clinical

governance; and 3) credentialing for the purposes of licensure and privileging were used to inform the investigation plan and resulting recommendations.

The review team found that the individual events each had their unique context, genesis and impact. They include: a practitioner providing services in areas outside of his licensed scope of practice; providers who did not realize that they were not providing quality interpretations, and who never had the benefit of formal feedback and review; and, a provider whose experience proved inadequate for the practice that he was asked to perform. These events had in common the failure of the credentials review processes, and the privileging and medical review processes of the College and the health authorities. In no case were there credible monitoring or processes in place that would have detected these deficiencies and addressed them.

The Phase 1 review [2] provided reassurance that the other radiologists practicing in the Province are appropriately qualified and are responsibly maintaining their continuing education in the manner specified by the College and the Royal College of Physicians and Surgeons of Canada. The scope of this review did not allow the review team to assess other disciplines and it is expected that they too are performing to acceptable standards. However, this review points out that similar events could occur unless steps are taken to address the system gaps revealed by these failures. These events provide the health authorities and the College with the opportunity to review their own processes and to make changes as needed to assure themselves and the public that events such as these are less likely to happen in the future.

A key aspect of these events was the impact they had on the communities in which they occurred. The public's confidence in the health system was shaken by the recognition that the quality monitoring that they thought existed, did not. They wondered where else there were quality gaps. All individuals interviewed wished to know of events that would affect their own care and the health care system, even before all of the information is known. Many patients commented favourably on the direct personal communication that the some health authorities had with them.

The review team was reassured that of the many patients exposed to risk resulting from interpretive errors, very few sustained direct harm. Imaging was one element of the information used to define the care for individual patients. When an interpretation was at variance to what was expected or was incomplete, the treating physicians sought other opinions. This diligence was critical in minimizing patient harm.

To date, 7924 studies have been reviewed. Interpretive discrepancy rates varied with the imaging modality and the individual radiologist. Computed tomography (CT) studies triggered the initial clinical concern and proved to be the studies at highest risk for interpretive differences. Radiographs, ultrasound and mammography (diagnostic and screening) interpretations were reviewed and found to be within accepted ranges. Magnetic resonance (MR) interpretations were not reviewed as none of the radiologists involved read MR studies.

The health authorities acted promptly in order to overcome numerous impediments to undertake detailed and thorough reviews once they were aware of the events.

The number of studies reviewed and the prevalence of clinically important discrepancies.

Imaging Modality	Studies Reviewed	Clinically Important Discrepancies (%)
CT	4208	1.4 - 17
Radiographs	1500	<1%
Diagnostic and screening mammograms	1927	Within BC Cancer Agency standards
Other studies (cardiac and non-cardiac ultrasound)	289	0

CONCLUSION

The frequency of events like those addressed by this investigation is unknown. Structured quality surveillance systems for diagnostic imaging or other disciplines are in the early phases of development in BC. These events came to attention when the frequency of error triggered concerns from those physicians who were receiving reports. In one event, the performance went undetected until another health authority raised concern. In others, the medical community held concerns regarding physician performance for some time prior to any action being taken. With such systems in place, the ability for the health authority to identify and act promptly will be improved.

Each of the five events reviewed in this Phase 2 report has its own chronology and context. Each unfolded as it did as a result of a unique combination of causal and contributing factors. These factors, in combination, represent failures on multiple levels: of the physician and health care community to make competence issues known, of medical administration to provide supervision and remediation as necessary, of the health system's credential review process to be sufficiently specific to ensure that credentials are appropriate for a practice in BC, and of the health authorities and the College to recognize their mutual responsibilities to monitor clinical quality and take action when needed as they work together in the interest of quality care for patients.

Each of these factors can be improved so that a robust quality assessment system is created to support care for patients. Since February 11, health authorities are already working to address many of them. The recommendations are intended to address the specific issues seen in diagnostic imaging and to improve the quality of medical services generally by aligning the interdependent mandates of the College and the health authorities so that they can ensure the best services and outcomes for all patients.

These events have shaken the confidence of patients in many communities. Based on patient input, the health system is now building systems that will monitor competence, allowing it to justly address performance issues and to communicate with patients and families in ways that are timely and respectful. Such systems will ensure the best quality of medical services for British Columbians.

RECOMMENDATIONS

Recommendation 1: That Lower Mainland Medical Imaging require the presence of an ultrasound technician during non-emergency hours so that a structured ultrasound examination is performed and relevant images and parameters are recorded in addition to the study interpretation.

Recommendation 2: That VCH develop health authority departments to provide support to the medical leadership working in all facilities. The responsibilities of such departments should include quality monitoring and improvement of services, peer review, performance monitoring for professional staff, coverage for vacancies and professional back up in emergencies.

Recommendation 3: That Lower Mainland Medical Imaging move promptly to review the management of the department including the working relationships of the staff and address deficiencies that may exist so that the work environment is improved and recruitment efforts are more likely to succeed.

Recommendation 4: That SJGH develop relationships with VIHA or a denominational partner that ensure that department heads have access to support in carrying out the duties required of their position.

Recommendation 5: That SJGH department heads not engage in administrative responsibilities in practice groups that might create, or be seen to create a conflict of interest for him or herself or SJGH.

Recommendation 6: That SJGH participate in the province-wide credentialing, privileging and medical staff review process described elsewhere in the report.

Recommendation 7: That FHA review its practice of delegating to practice groups health authority responsibilities including medical staff recruitment, hiring, staffing in health authority facilities and service quality assessment.

Recommendation 8: That the relationship of a Local or Regional Department Head with a practice group should be reviewed to ensure that there is no real or perceived conflict of interest between the role as department head and any administrative or business responsibilities to the group. Where such conflicts are found, the Local or Regional Department Head should resign from practice group administrative responsibilities while in the health authority Department Head role.

Recommendation 9: That FHA clarify the use of temporary and locum appointment categories when applications for medical staff membership are being evaluated.

Recommendation 10: That FHA finalize the section in its Medical Staff Rules describing in-depth review.

Recommendation 11: That FHA review its Medical Staff Rules to ensure that the authority and responsibilities of the Regional Department Head and Local Department Head are clearly described.

Recommendation **12**: That FHA provide further communications to the public regarding the status of the review and changes made as a result of the review. In the development of communications to the public, the language used should be appropriate for patients and family members.

Recommendation 13: That the FHA Medical Imaging Regional Department collect detailed practice experience information for all applicants for appointment and all members and locums working in the department. The information will be reviewed by the Local Department Head and the Regional Department Head as part of the appointment and reappointment processes and prior to the individual commencing service in the health authority.

Recommendation 14: That Fraser Health ensure that all medical staff providing speciality services that require special qualification or certification, have these qualifications before privilege is granted or that the board knowingly appoints and privileges with conditions.

Recommendation 15: That the health authorities and College develop a comprehensive retrospective review process that can be used in the health system or the private sector should the need arise.

Recommendation 16: That the College and the health authorities develop a standardized retrospective peer review process designed for quality improvement in the health authorities and private facilities.

Recommendation 17: That the Provincial Medical Imaging Advisory Committee (MIAC) establish a provincial management system for diagnostic imaging peer review in BC and that this system manage both concurrent and comprehensive retrospective peer review processes. The boards of the health authorities and the College retain the responsibility to commission reviews and to act on performance issues that become apparent.

Recommendation 18: That each health authority establishes a Diagnostic Imaging Quality Assurance Committee with authority vested by the board, to provide oversight for diagnostic imaging services provided by the health authority.

Recommendation 19: That the BC Radiological Society (BCRS), in conjunction with the MIAC and the

College establish a library of images that reflect difficult interpretations and common errors that can be used for teaching purposes (resident and continuing professional education) and for proficiency testing.

Recommendation 20: That the BCRS, the Canadian Association of Radiologists and the Royal College establish modality specific performance benchmarks for diagnostic radiologists that can be used in concurrent peer review monitoring.

Recommendation 21: That the health authorities develop a program whereby short-term vacancies in the radiology technical and professional staff can be filled by using staff from other facilities, as permitted by collective agreements. When such services are needed, expenses incurred by the technician or radiologist should be reimbursed.

Recommendation 22: That the health authorities in conjunction with the Provincial Ethics Committee, the public, represented by two members of the health authority boards, the Office of the Provincial Health Officer and other stakeholders should develop a guideline for the management of adverse events that affect many patients or when there is a threat to public safety. Issues to be addressed by this group include communication planning for patients and providers, technical assessments, review logistics, implementation management and appropriate payment for those harmed and those doing the reviews.

Recommendation 23: That the health authorities undertake a risk assessment of their preparedness to deal with a retrospective review in a clinical area, taking into consideration the provincial guideline on adverse event management involving many patients and the difficulties encountered by VCH and FHA in executing their diagnostic imaging reviews. These assessments should be presented to the health authority boards and shared amongst the health authorities.

Recommendation 24: That the health authorities and affiliates create a single medical staff administration that will be governed by and serve all of the health authorities and affiliated organizations. This organization should have information sharing agreements with the College so that the results of licensing, credential review and privileging are available to all parties.

Recommendation 25: That the health authorities and affiliates standardize their processes for medical staff appointment, credential review and privileging and physician review. Included would be common definitions for core and speciality privileges, common reporting formats for medical advisory committees and health authority and affiliate boards. These activities should be supported by a single information system.

Recommendation 26: That the health authorities, affiliates and the College develop a performance

assessment and review process for all physicians. The health authority medical staff rules provide a foundation for this work. Health authority boards should approve the review process and how it is applied so that they are assured that the process provides a suitable foundation for the recommendations being brought to them for decision.

Recommendation 27: That the health authorities and affiliate boards agree that if an application for specialty privileges is beyond the ability of the available medical administrative officers to evaluate, the application would be assessed by an appropriately qualified administrative officer (for example, the relevant regional or health authority department head from the health authority or another health authority if required).

Recommendation 28: The College augment their support for the integration of provisional registrants and international medical graduates (IMG) into practice by clearly specifying the expectations of IMGs and the requirements, roles and responsibilities of a sponsoring organization and the supervisor.

Recommendation 29: That the College, in conjunction with other provincial regulatory bodies, develop methods for clear communication of credentials and license information when individuals apply for a licence in another jurisdiction. This would include a consistent taxonomy for describing and communicating information now implied in a certificate of standing and a standardized process to share other relevant information.

Recommendation 30: That the Lower Mainland Medical Imaging complete the development of the quality plan for services that is alluded to in Services Standards and Performance Section 5.1 and 11 of the Master Services Agreement and in Appendix 2, section 2.2.

Recommendation 31: The boards of the member health authorities and Providence Health Care review Section 11 of the Lower Mainland Medical Imaging Master Services Agreement in light of the learnings from these reviews and that the boards review and approve the final Lower Mainland Medical Imaging quality plan.

Recommendation 32: That the BC Perinatal Program develop or adopt and promulgate standards for obstetrical ultrasound assessments in the first, second and third trimesters that are performed in community and tertiary facilities.

Recommendation 33: That the Ministry respond to the College with its assessment of the College's proposed bylaw changes as they pertain to the management of IMGs.

Recommendation 34: That the Ministry develop funding models to support quality improvement including comprehensive retrospective reviews and performance and in-depth reviews of medical professionals. The Ministry complete the revisions of the payment schedule for medical administration positions in the health authorities.

Recommendation 35: The Ministry of Health or delegate review the implementation of these recommendations and report to the public in September 2012.

PROJECT OVERVIEW

INTRODUCTION

Prompted by concerns regarding the quality of radiology image interpretation, the Honourable Colin Hansen, Minister of Health Services, requested an independent investigation into the credentialing of radiologists and medical imaging quality assurance in BC on February 11, 2011. This investigation, to be led by Dr. Douglas Cochrane, Provincial Patient Safety and Quality Officer and Chair of the BC Patient Safety & Quality Council, was to examine all aspects of the licensing and credentialing of radiologists in two phases. The first phase report was submitted to the Minister on March 8, 2011 [2]. The second phase of the investigation, presented in this report, examined the specific instances where medical imaging quality has been called into question and the health authority response to these events. It reviews the existing structure for the licensing and credentialing of physicians in BC's health authorities including the processes for quality assurance and peer-review. Recommendations are made specific to the events where applicable, and to the health system so that events such as these can be prevented in the future.

BACKGROUND

In October 2010, concerns were raised to Vancouver Coastal Health (VCH) administration about the quality of a radiologist's interpretation of CT scans. The health authority investigated these concerns by consulting the College of Physicians and Surgeons of British Columbia (the College) and reviewing the medical imaging reports. The review by VCH identified the breach of a voluntary undertaking not to interpret CT scans or obstetrical ultrasounds and the failure to report personal skill upgrading done in CT and ultrasound imaging to the College. As a result, a formal review of this individual's CT interpretations was performed by VCH. Significant discrepancies between the individual's reports and those reports provided by peer reviewers assessing the same images were found.

In December of 2010, Fraser Health (FHA) was informed by the College of concerns regarding the interpretation of CT scans by a locum radiologist. This individual had provided locum services in Interior Health (IHA) and had been the subject of a quality review prompted by physician concern. IHA had notified the College, and they in turn informed Fraser Health who then undertook a review of the CT interpretations reported by the locum during the month he/she practiced in the region. The results of this review were consistent with the findings of Interior Health; the radiologist in question was found to have insufficient knowledge and skill to interpret CT scans.

In January 2011, concerns were expressed by referring physicians at St. Joseph's General Hospital in Comox (SJGH) about the interpretation of CT scans by a local radiologist. A formal and comprehensive third party review was undertaken to ascertain the merit of these concerns.

In February 2011, FHA became aware of concerns regarding the quality of imaging interpretations by a member of the FHA Medical Staff. This individual had been recruited to British Columbia to fill a vacancy

and had received a provisional license from the College under the conditions required of international medical graduates. He was sponsored by FHA and his practice was under supervision by a qualified member of the College. As a result, a comprehensive review of his interpretations is currently underway.

In all cases, the privileges of the radiologists were suspended, either voluntarily or by the health authority, and third party reviews were undertaken to assess the quality of the original diagnostic imaging interpretations and reports. Where discrepancies were identified, follow up with patients and the referring physicians was provided and any necessary treatment plan changes were implemented. This Phase 2 report describes the events, the responses of the health system and the impact upon patients, families and the communities. It also provides an analysis of the fundamental and contributory causes.

MANDATE

The investigation requested by Minister Hansen is described in the Terms of Reference (see Appendix I).

The objective of the second phase of the investigation is to provide recommendations to the Minister of Health Services on how the credentialing and quality assurance processes within health authorities can be improved.

The scope of this phase of the review includes a description of the incidents, an analysis of causes, the response by the health authority to the event and the role of the College. Comments are provided on the relationship of the College with regulatory bodies in other provinces with respect to the transfer of licensing information when individuals change jurisdictions.

A critique of health authority physician credentialing and privileging as they apply to the genesis of these events is provided.

Based on the input of patients, members of the public and health care workers, the review team has chosen to comment upon the impact of these events on the communities as they have affected the public trust and the confidence in medical professionals.

METHODOLOGY

The event descriptions are based on interviews with patients, family members, and administrators (Appendix II) and reports and updates from the health authorities including the medical administrators, corporate officers and staff working in the health authority medical staff offices. John Mathieson was of particular assistance in detailing the review methods for Powell River and Comox.

Dr. Cochrane met with and received communication from the College Registrar and the Senior Deputy Registrar. The health authorities and the College had established a joint working group by to address issues regarding licensing, credentialing and privileging prior to the call for the review; the review team was updated on their work. Dr. Cochrane was also made aware of work being supervised by the health authority vice presidents responsible for medical administration and the CIO Council on the selection and implementation of an information system to support medical credentialing, privileging and review.

Dr. Cochrane met with the BC Radiological Society, Emil Lee, President, Bob Rauscher and Andrew Mason on several occasions to review the progress being made on peer review and imaging quality.

The review team consulted with the Registrars of other provincial Colleges of Physician and Surgeons and ministry and health authority officials from other provinces who have or are undertaking reviews of imaging interpretations.

The provincial ethics directors and patients have provided valuable input to Appendix VIII entitled "Principles and Framework to Support the Management of Adverse Events and Disclosure that Affect Many". Ms. P. Washington was asked to review the legislation governing the College and the health authorities with respect to limitations and barriers that might be faced if the College and the health authorities were to share physician performance information.

BC Patient Safety & Quality Council staff provided technical advice regarding sampling strategies and CUSUM analyses. Literature reviews were greatly assisted by Dr. Vicki Foerster.

FINDINGS AND ANALYSIS

The following section of the report provides a chronology and analysis of the events that precipitated this review. It examines each of the events independently and provides recommendations specific to that event should there be any. Recommendations with provincial scope are reserved for subsequent sections of the report but are informed by the events described here.

VANCOUVER COASTAL HEALTH - POWELL RIVER GENERAL HOSPITAL

SUMMARY OF THE FACTS

The radiologist was practicing radiology and providing services using modalities (computed tomography and obstetrical ultrasound imaging) that were beyond the scope defined by his license to practice medicine in British Columbia. The review determined unacceptable error rates for computed tomography interpretation. A review of obstetrical imaging studies was not possible due to incomplete documentation.

CHRONOLOGY

July 2002

Powell River General Hospital (PRGH) had been searching for a radiologist to replace the incumbent who had retired. Efforts had not been successful until July 2002 when the radiologist was recruited having been in practice in Fort McMurray, Alberta.

During the credentials review, PRGH was made aware of voluntary undertakings placed on the radiologist's license by the College of Physicians and Surgeons of Alberta. The undertakings restricted the radiologist from reading CT or obstetrical ultrasound scans until additional training had been taken at an accredited facility and the College had approved that training. The BC College imposed the same restrictions upon his license.

The radiologist was credentialed and granted privileges to provide services that were within his licensed scope of practice.

August 1, 2002

The radiologist started his practice at PRGH.

November/December 2003

The radiologist undertook 2 weeks of training in obstetrical ultrasound at BC Women's Hospital (BCWH) in December 2003. He did not inform the College of this training. Subsequently, he began reading obstetrical ultrasounds at PRGH. No certification of training was provided by BCWH at that time. No records exist of a formal recommendation for privileges in obstetrical ultrasound reading by the PRGH Medical Advisory Committee (MAC), the body responsible for making recommendations to the board. A letter dated November 2010 from BCWH noting the dates of the radiologist's training was received by VCH in February 2011.

March 2010

A new CT scanner was installed at PRGH and began acceptance testing for the Diagnostic Accreditation Program (DAP). Experienced CT technicians were hired to assist in the set-up of the scanner, and its subsequent operation.

April 2010

April 6 the radiologist informed the Powell River MAC that he had completed a two week CT training session at Royal Jubilee Hospital in Victoria (RJH). He presented his certificate of attendance to PRGH administration. The Rural Education Action Plan supported him financially.

The radiologist completed a PRGH "Additional Privileges Request" form so that he could begin reading CT scans. Privileges were granted as the PRGH administration believed that the Royal Jubilee program satisfied the conditions of the radiologist's voluntary undertaking. PRGH did not confirm this understanding with the College. The radiologist did not inform the College of this educational experience nor did he request a College review of the undertakings attached to his license to practice.

The radiologist was appointed as Medical Director of the CT Facility by the College for the DAP program.

April 19 - Patients began receiving their CT scans locally and the radiologist began interpreting the scans.

Diagnostic imaging technologists expressed concerns regarding CT imaging protocols, study areas and interpretations of CT scans. The PRGH Radiology Site Coordinator was informed of these concerns.

September 2010

Concerns regarding the interpretation of CT studies and completeness of reports of five patients were brought to the attention of the Medical Director PRGH and the Co-Senior Medical Directors, Coastal Health Service Delivery Area (HSDA) by medical staff members.

October 2010

The Medical Director PRGH advised the Rural Medical Advisory Committee of the medical staff's concerns and a motion was sent to the Health Authority Medical Advisory Committee (HAMAC) regarding the

radiologist's CT reporting quality. The VCH Regional Medical Imaging Director was asked to investigate the concerns of the medical staff.

On October 8, the VCH Regional Medical Imaging Director learned, from the College Deputy Registrar of the radiologist's voluntary undertakings and the fact that the College had not been updated on, nor approved any training in obstetrical ultrasound or CT scanning for the radiologist. The radiologist was therefore practicing medicine beyond the scope allowed by his medical license. The VCH VP Medicine, Quality and Safety suspended the radiologist's privileges to read CT and obstetrical ultrasound on October 8, 2010.

Arrangements were made for all CT scans and obstetrical ultrasound scans to be read by the medical staff at Lions Gate Hospital and St. Joseph's General Hospital in Comox, respectively. The DAP and Medical Services Plan were notified that the radiologist was no longer the Medical Director of the Powell River Hospital CT facility and was replaced by Medical Director of Radiology LGH.

October 19 - The College was informed that VCH would review the work of the radiologist. The VCH VP Medicine, Quality and Safety requested that VCH Medical Imaging Regional Director undertake a review of the radiologist's work. Informal notification was provided to the Ministry of Health.

October – November 2010

A plan to re-read all 894 CT examinations read by the radiologist between April and October 2010 was developed. Radiologists from three VCH community hospitals would re-read all the scans of these patients and would have access to the clinical history, prior imaging studies, and requisition information, but not to the radiologist's reports.

Technical issues that needed to be addressed prior to the review proceeding included:

- Transfer of scans from PRGH and from VIHA (prior studies) to reviewers at LGH, Richmond General and UBCH.
- Preparation of the transcription services to transcribe the review reports.

These issues took almost two months to be addressed and are in part responsible for the delay in informing patients of their review results.

December – January 2011

December 6 – January 7, 2011 - Image review and report generation.

December 23 – January 2, 2011 - Report discrepancy analysis and draft report is processed.

January 16, 2011 – VCH received information about category 3 discrepancies.

January 27, 2011 – The Ministry of Health was formally notified.

February 2011

February 4 - The final discrepancy analysis and report was available to VCH.

February 6-10 –Medical Director of Radiology LGH reviews the images of all 3b and 3a discrepancies (see page 30 for full description of clinical discrepancy categories) to determine the findings of clinical concern in preparation for discussion with the patients’ physicians.

February 7 –The initial and official addendum of all reviewed reports were faxed to the attending/ordering physician for all of their patients (not known to be deceased) with category 3a and 3b discrepancies, along with letters for their charts (including a copy of the letter to be sent to the patient).

February 7 – Patient Care Quality Office phone and email access were opened to the public and a Patient Care Coordinator was charged to assist with coordinating patient care issues.

February 8 through 15 – Physician/patient contact begins.

February 10 – The radiologist was advised of the preliminary findings of the CT review. He was notified that due to persistent errors of detection, integration and development of appropriate differential diagnosis in the CT review, additional reviews of other modalities would be done. The radiologist was advised that he was obligated to cooperate with the review, and that he was to withdraw from all practice. The radiologist agreed to step down on February 10. He agreed to cooperate fully with both the VCH internal and the Cochrane Review, announced February 11.

February - May 2011

February to May 9 - Plain film review was planned and conducted.

June 2011

June 15 - The radiologist resigned his medical staff membership and privileges.

The radiologist declined the opportunity to be interviewed by Dr. Cochrane.

REVIEW METHODOLOGY AND RESULTS

CT REVIEW

The review undertaken was a three-phase process starting with image re-reading and second report generation (Phase 1). The two reports were compared by a third party and discrepancies classified according to the report discrepancy grading system described in **Appendix V**. The Medical Director of Radiology LGH reviewed the images of all 3b and 3a discrepancies to determine the findings of clinical concern (Phase 3).

Review of 891 scans in 774 patients was performed.

Discrepancy Code	Total Patients	Total Exams	% Discrepancy
0	237	238	27%
1	287	301	34%
2	193	200	22%
3a	109	115	13%
3b	35	37	4%
Not Applicable	3	3	
Total	891	894	

Follow-up with the attending physician and chart review were performed in all cases where compromise in care might have been possible because of interpretive error. Nine patients in total were deemed to have had their care compromised because of the error in scan interpretation.

RADIOGRAPH REVIEW

The three-phase review methodology used in the CT review was applied to the radiograph review.

Five hundred and ninety-four (594) radiographs were reviewed.

Discrepancy Category	Total	%
0	487	81.99%
1	88	14.81%
2	15	2.53%
3a	4	0.67%
3b	0	0%
Total	594	

Nineteen (19) (3.20%) studies were found to have category 2 or 3a discrepancies. No patients experienced compromise in care arising from the discrepancy.

OBSTETRICAL ULTRASOUND REVIEW

It was impossible to review obstetrical ultrasound studies retrospectively because a standardized approach for image recording and reporting was not taken for each examination. As a result, the focus of the look-back was on those pregnancies that ended in a mortality or morbidity and to review the scan data as it had been recorded.

The studies of nine hundred and seven patients (who had undergone 2295 examinations) were matched to perinatal mortalities and morbidities. No perinatal deaths were related to ultrasound reporting. Concerns about three infants with congenital anomalies were reviewed and it was determined that these anomalies would not have been detected on prenatal ultrasound imaging.

Because of the limitations in the reporting and in the recording of image data, VCH was not able to determine whether any patients experienced compromise in care.

NOTIFICATION OF PATIENTS AND COMMUNICATION WITH THE PUBLIC

CT SCAN REVIEW

PHYSICIANS

Physicians whose patients were found to have a Category 3a or 3b discrepancy received a fax on February 7 containing the original report and the addendum. This was followed by a phone call placed between February 8 and February 15 from the Senior Medical Director, Coastal HSDA and the Medical Director of Radiology LGH in which there was discussion about:

- The patient's current needs
- The need for expedited access to follow-up exams and care,
- Whether the interval between initial and final reports would have compromised the care of the patient.

A subsequent request was sent by fax to all physicians with patients having a Category 2, 3a, or 3b discrepancy for which follow-up was not confirmed. VCH is unable to make contact with the current physician of 65 patients, all of whom had Category 2 discrepancies. The details of the efforts for follow-up are provided in the VCH Radiology Review – Final Reports P 2.

February 9 – 11

A fax was sent to physicians of patients with category 0, 1 and 2 review results, indicating the discrepancy code, along with an issue description and notice that patient specific documentation and report pairs would follow. February 10 -11, paired reports for all of the patients (not known to be deceased) with Category 0-2 discrepancies were couriered to the physicians, along with documentation for their charts.

PATIENTS

Letters were mailed February 10 for delivery February 11 to all living patients who had had a CT scan that was reviewed.

Personal phone calls to the nearest relative identified on hospital records for deceased patients who had had a CT were made from February 10 -14. Letters were then sent following the phone calls unless the relative stated that they did not want a letter.

Families of deceased unable to be contacted by phone were sent registered letters (mailed on February 15).

ULTRASOUND REVIEW

PHYSICIANS

On February 9, a fax was sent to physicians of their obstetrical ultrasound patients whose studies were undergoing review indicating the discrepancy code, the issue overview and notice that patient specific documentation would follow. February 10-11, copies of obstetrical ultrasound reports were sent by courier to physicians for all of their patients not known to be deceased, along with letters for their charts.

PATIENTS

Letters were mailed February 10 for delivery February 11 onward to all obstetrical ultrasound patients not known to be deceased or to have had a perinatal death.

Obstetrical ultrasound patients known to be deceased or who had a perinatal infant death were notified by personal telephone call to the nearest relative on record (deceased) or mother (perinatal death) following chart review starting February 15.

RADIOGRAPH REVIEW

PHYSICIANS

VCH decided to release amended reports to the physicians of those patients having category 2 and 3a discrepancies. All other original interpretations reported by the radiologist stood unchanged. Between May 16 and 20, Medical Director of Radiology LGH or Senior Medical Director, Coastal HSDA contacted all physicians to inform them of the discrepancies and to determine the patient's current clinical situation. Letters outlining the discrepancy with a copy of the original report and the addendum were issued on May 24.

PATIENTS

Patients were not notified directly by VCH.

OBSERVATIONS

REGARDING THE REVIEW

The review process was comprehensive and complete. It addressed the obligation to correct issues of patient care.

REGARDING PUBLIC COMMUNICATION

VCH decided to delay patient notification and public communication until the review was completed. Communication with the public occurred on February 11 as part of the public announcement with the Ministry and FHA. Physician and patient notification began shortly before. Although many issues were beyond the control of VCH and delayed the analysis, there was almost a four-month interval from the time the decision was taken to do the review and when patients were notified. Once VCH was made aware of category 3 discrepancies on January 16, it acted promptly to inform patients.

The physician communication process engaged the primary care physicians for patients successfully. The plan was comprehensive providing the physician with background information and the outcomes of the review as they applied to his/her patients. It detailed VCH expectations of them in the patient notification and disclosure process and follow-up. Patient specific communication provided the individualized results and the actions to be taken, including expedited access to follow-up exams and care and an assessment of the impact of the incorrect diagnosis.

The plan for patient communication was comprehensive and well executed. All patients with serious discrepancies were notified and all obstetrical patients where a concern lay because of a foetal demise or malformation were reviewed.

Patients reported that the written communication with them seemed cumbersome and the language used in letters was confusing or not clear.

Patients affected by the event directly and who VCH administration contacted were appreciative of the direct communication and disclosure provided to them. The toll-free line and the support of the Patient Care Quality Office worked well for both the patients and the public and for VCH by providing access to information and problem solving.

PROFESSIONAL ISSUES

It would appear that the radiologist may not have been aware of the meaning of the voluntary undertakings and the requirements to address them. He did not notify the College of his efforts to upgrade. This deprived the College of an opportunity to evaluate the remediation work that he had done and to provide their final determination as to its adequacy.

Staff reported that when the ultrasound technologist left PRGH, the radiologist assumed the technician job as well as his own. Members of the technical staff (many of whom had ultrasound exposure during their training) recognized the radiologist's technical deficiencies. He was reported to have been too fast, seemed incomplete, and did not always store representative images. Because there were no images recorded in a standardized fashion, no valid review of obstetrical ultrasound studies was possible.

The radiologist's interactions with a number of the technical staff were reported as non-collegial. They perceived him as being abrupt and non-responsive to questions and requests for advice. They reported that the radiologist was not willing to interact with the staff or discuss issues or errors. Non-medical staff

members stated that they were fearful of retaliation from the department.

Recommendation 1: That Lower Mainland Medical Imaging require the presence of an ultrasound technician during non-emergency hours so that a structured ultrasound examination is performed and relevant images and parameters are recorded in addition to the study interpretation.

ORGANIZATIONAL ISSUES

The retention of credentialing and privileging at the level of facilities does not take advantage of a health authority structure that can provide greater support to and rigor for these processes. Department quality activities and performance management of medical staff suffer in facilities with small groups of providers, as they are often inter-dependent with regard to business practices, on-call schedules and social interactions. These relationships may preclude effective management and peer review. Credentialing and privileging at the facility level undermines the ability of the health authority to support its medical staff and to assure provider quality to the patients for which it is responsible.

VCH had attempted to consolidate the medical administration structures supporting credentialing, privileging and review in all of its facilities. To date this has not been successful, reportedly because of the desire of these organizations to preserve independence and identity. The creation of the Rural Medical Advisory Committee was done to honour the unique practice environments of rural facilities. The RMAC has a seat on the HAMAC and has direct representation to administration at the HSDA and health authority levels.

VCH is now in the process of planning and implementing health authority wide departments. Establishment of such an organization should assist smaller facilities to address their manpower needs, and will relieve them of the conflicts that impede peer management in small and very small departments.

Recommendation 2: That VCH develop health authority departments¹ to provide support to the medical leadership working in all facilities. The responsibilities of such departments should include quality monitoring and improvement of services, peer review, performance monitoring for professional staff, coverage for vacancies and professional back up in emergencies.

THE PRGH MAC AND MEDICAL STAFF

The reaction of the medical staff to the public recognition that there was a problem in CT reporting was reported as a combination of relief and guilt. Medical staff members had been aware of deficiencies and had been asking for revised reports for some time. Some assumed the responsibility lay with VCH.

CULTURE IN THE RADIOLOGY DEPARTMENT AT PRGH

The PRGH imaging staff and management knew that problems existed in report accuracy from the time the scanner was commissioned. Reports were being sent back for revision from ordering physicians and the technical staff was aware of deficiencies in scanning processes and interpretation. These concerns were made known to the Site Coordinator, Diagnostic Imaging and no actions were evident. Some staff felt that they were left without support and were fearful of reprisal if issues and concerns were voiced.

Interviewees report there was minimal HSDA level supervision of technical and administrative site staff. This may have been due to turnover in administrative positions due to retirement, disability leave and an interim appointment. As a result, there was insufficient attention to staff assessment, organizational culture, and quality structure; PGRH was left on its own.

As a result, there was insufficient attention to staff assessment, organizational culture, and quality structure; PGRH was left on its own.

Recommendation 3: That Lower Mainland Medical Imaging move promptly to review the management of the department including the working relationships of the staff and address deficiencies that may exist so that the work environment is improved and recruitment efforts are more likely to succeed.

WHAT WAS LEARNED FROM PATIENTS AND THE COMMUNITY

The patients in Powell River made the following observations and comments in the aftermath of the event:

- Confidence in the medical care system was lost.
- “Why do we always have to put up with “second best” medical professionals? This situation would never have been acceptable anywhere else”.
- It is a small town, we know each other personally and word travels quickly.
- Imaging is only one issue that affects patient care.
- Critical review into the care of patients who have suffered adverse events is lacking.
- Commitments to implement change by administration are not carried out.

With regard to the notification process, patients indicated that the written communications to them could be improved by:

- Using language that they could understand.
- Reporting all of a patient’s issues in one letter rather than sending multiple letters about individual studies.

VCH created a special intake centre through the Patient Care Quality Office (PCQO), relying on the existing toll-free line, and staffed with experienced PCQO staff. Calls were received concerning 77 patients. Of these 77 contacts, 45 were related to CT studies, 12 to obstetrical ultrasound. Fifty-seven related to the issues of primary concern with the radiologist. Nineteen (19) related to concerns about practice in other modalities (16 ultrasound, 3 plain film imaging), and one complaint was not about the radiologist’s

practice, but rather a complaint that VCH could allow this to have occurred at all.

A number of calls were requests for clarification or reassurance or repeat scanning. Other patients offered their cases for inclusion in further 'other modalities' review, as they felt there might have been other deficits in practice quality.

THE VCH RESPONSE

Upon notification of the breach in license restriction, VCH acted swiftly and appropriately to address the situation, and to provide professional services to replace the radiologist.

A comprehensive and rigorous review was planned and eventually undertaken, using appropriate methodology and controls. For a variety of technical reasons, not known to VCH at the time the review was to commence, image review was delayed because electronic interfaces had to be built to allow image transfer to reviewing radiologists and transcriptions systems required modification to handle the specifics of the review process. As a result, the time interval from knowing of the breach in credentialing until the patients were notified was lengthy. During this time, no patients with category 2 or 3 discrepancies were informed and the review was not publically announced.

Patients from Powell River and members of the public felt that notification was delayed unduly. They felt as patients and as a community that they were entitled to have known of the issues and concerns that affected their health care earlier. Considered in the decision to defer public notification until the review was completed, priority was given to knowing the risk of individuals and to have specific details relevant to the care of individual patients. In addition, there was concern that partial information would not be useful and would raise public concern. Other factors were not mentioned in the decision to defer public notification. In retrospect, the diagnostic imaging staff had made quality issues known to PRGH administration as early as the spring of 2010 and deficiencies were known amongst the hospital community. Based on this community "awareness", the public should have been informed when it was determined that a review was necessary. The public should have been informed that the process was going to be prolonged for technical and logistic reasons. The interviewees indicated that such communication would have been respectful of them and of the patients who were affected by the event.

The patients did not support the decision to delay notification of patients whose studies fall in the category 3a and 3b, until the review was completed. Delay did not respect the need for patients and their physicians to know of changes in diagnosis and therefore perpetuated, for a time, incorrect working diagnoses and possibly inappropriate treatment. Neither the patient nor the physician was "empowered" to consider other working diagnoses because they were unaware that the imaging diagnoses were in question.

RELATIONSHIP OF VCH AND THE COLLEGE OF PHYSICIANS & SURGEONS

While the health authorities came into existence in December of 2001, facilities retained and continue to

hold authority for medical staff credentialing and privileging. As a result, the College communicated with PRGH rather than with Vancouver Coastal Health Authority. The failure to consolidate these functions at the health authority level set the stage for the subsequent communication breakdown.

The PRGH administration erred in granting the radiologist privileges to read CT scans based on his application for additional privileges and his certificate of attendance from Royal Jubilee Hospital. It is not apparent that a qualified radiologist reviewed this application and therefore any review lacked professional critique. The administration did not confirm with the College that the time spent by the radiologist with VIHA, to upgrade his CT reading skills, would address the undertakings on his license.

The College, responsible for the Diagnostic Accreditation Program, should have been aware of the undertakings placed on the radiologist's license. It failed to recognize these and appointed the radiologist as Medical Director of the CT facility under the DAP program.

ANALYSIS AND CONTRIBUTING FACTORS

WHAT HAPPENED AND WHY

The radiologist was practicing medicine in areas restricted by his BC medical license (the undertakings). He failed to limit his practice to the scope of his license. He failed to communicate his upgrading in CT and obstetrical ultrasound to the College. The College had no knowledge of upgrading, was not able to evaluate his training and was therefore not in a position to remove the undertakings.

PRGH did not understand the meaning of the undertakings nor did the facility recognize its responsibilities to the College. PRGH privileged the radiologist without considering the undertakings and without informing the College.

The quality of the radiologist's CT interpretation did not meet the expectations of the ordering clinicians as evidenced by the requests for report revisions. The hospital community, including the medical staff, knew this. Despite the department management being apprised of the concerns, these concerns were not made known to the health authority supervisors. The medical staff did not act expeditiously on the information known to them.

The failure of the College to check the radiologist's license prior to his appointment as the Medical Director of the CT facility for the DAP program.

Failure of the College to include VCH in the communications about the radiologist.

CONTRIBUTING FACTORS

1. Failure of the PRGH administration to review the radiologist's application for additional privileges with the College when they knew of the undertakings on his license to practice.
2. The decentralized credential and privileging review process, allowed a superficial review of the

- radiologist's application for additional privileges when the CT scanner was commissioned.
3. Failure of the PRGH and LMMI administration to be aware of and address the staff culture in the radiology department.
 4. The belief by the general community that "any doctor is better than no doctor".
 5. The desire for PRGH medical staff and facility autonomy that has interfered with the efforts to consolidate medical staff credential review, appointment, privileging and review process at the health authority level and has stood in opposition to health authority departments.
 6. A department of only one medical member.
 7. Departures of technical staff and lack of their replacement.
 8. Vastly dissimilar information system infrastructures amongst the imaging departments in VCH (and other health authorities).

VANCOUVER ISLAND HEALTH AUTHORITY - ST. JOSEPH'S GENERAL HOSPITAL COMOX

SUMMARY OF THE FACTS

The radiologist had been practicing in Comox for many years. In August of 2009, after much effort by the community on behalf of the hospital, a new 64-slice CT scanner was acquired. Previously, the hospital had a 4-slice scanner. The radiologist had planned to do additional formal training when the first scanner was commissioned; however, this training was not done. The radiologist subsequently learned the new technology informally.

In 2010, with the arrival of new surgical specialists on staff, it was apparent that the radiologist's CT interpretations did not meet the expectations of his colleagues and did not reflect contemporary interpretation of abdominal and chest anatomy and pathology. Other radiologists practicing at St Joseph's General Hospital (SJGH) were able to meet this expectation. As a result of concerns raised by clinical colleagues, the radiologist interpretations were reviewed. The lack of formal training in the use of new technology is fundamental to the cause of this event.

CHRONOLOGY

June 2001

A 4-slice CT was acquired at SJGH. The radiologist intended to take a CT reading course but personal matters arose that made the planned retraining program impossible.

2002

The radiologist applied to SJGH for CT privileges indicating that he was comfortable reading CT scans based on his experience using the scanner at SJGH. Privileges were granted by the SJGH Board.

August 2009

A 64-slice CT scanner was installed in Comox. The radiologist felt he was comfortable reporting CT studies. No additional training was recommended or taken.

Summer 2010

The Department Head of Radiology SJGH discussed imaging modality credentialing with the Department Head of Radiology VIHA.

October 2010

The Department Head of Radiology SJGH discussed plans, retirement and on-call commitment with the radiologist. CT interpretation was a large part of the work done on-call. If the radiologist was not to read CT scans, effectively he could not be on call. Other members of the practice group did not support an arrangement that would increase their on-call commitment.

November 2010

Surgeon(s) informally brought concerns to the Department Head of Radiology SJGH regarding the radiologist's CT interpretation. The Department Head and another radiologist (past Department Head, Radiology SJGH) met with the radiologist to discuss these anomalies. The Department Head of Radiology SJGH suggested a voluntary audit, retraining or retirement. The radiologist did not agree. The Department Head of Radiology SJGH requested that the surgeons put their complaints/concerns regarding the radiologist in writing.

December 2010 – January 2011

The Department Head of Radiology SJGH did an informal review of cases reported by the radiologist. The results of the informal review led to the determination that a comprehensive review was needed.

January 18, 2011

The Department Head of Radiology SJGH advised the Medical Director SJGH of interpretive discrepancies in seven cases. The Medical Director suspended the radiologist's CT privileges. He subsequently discussed the issue with the Department Head of Radiology VIHA.

January 20, 2011

The radiologist was advised of the results of the preliminary review and his error rate in CT interpretation.

Late January / early February 2011

Arising from informal communications amongst the health authority CEOs, the Ministry of Health enquired of all health authorities whether issues existed in their radiology services. The VIHA CEO indicated that there were no issues of which he was aware.

February 11, 2011

The Medical Director SJGH advised the Chief Medical Officer VIHA of the concerns regarding CT interpretation by the radiologist. The radiologist voluntarily suspended his work. The Chief Medical Officer VIHA advised the VIHA Acting CEO and COO who then communicated with the SJGH CEO and the Ministry.

The SJGH CEO advised the Assistant Deputy Minister (MOH).

VCH and FHA announce the reviews in diagnostic imaging being done in their health authorities. Later that day, VIHA announces a review of the radiologist's work.

February and March 2011

The radiologist took a leave of absence beginning February 14 pending a full assessment of his work.

Members of the public raised concerns regarding the interpretation of other imaging modalities, screening mammography, and mammography. Reviews of these modalities were started.

April 7, 2011

The reviews were completed.

June 2011

The SJGH Board reinstated privileges permitting the radiologist to provide radiology services exclusive of CT scan interpretation.

METHODOLOGY AND RESULTS

CT REVIEW

A three-phase review was performed to detect differences on image interpretation, based on reports and to determine the impact of discrepancies on the management of patients. All imaging studies were re-read by a reviewing radiologist who had access to the patient's imaging that had been done prior to the study under review and the clinical history provided on the original requisition. The reviewer did not have access to the radiologist's original report, or to any studies performed after the date of the study under review (Phase 1).

In the second phase, a team of five adjudicators compared the original reports with the review reports. The reports were compared for discrepancies, and grades were assigned based on the level of agreement or discrepancy. The names of the reporting physicians were not visible to the adjudicators until after their initial adjudication. The adjudicators were qualified in reading CT studies.

The adjudicators categorized the differences in the reports based on the modified Radpeer categorization scheme similar to that used for the Powell River and Abbotsford reviews and attempted to judge the clinical importance of the discrepancy (Clinical Category). The re-read findings were also classified based on the clinical report discrepancy score (Appendix V).

If the two reports were in agreement, or near-agreement, no further image review was undertaken. Near-agreement included clinically unimportant discrepancies. If a discrepancy of potentially clinical significance

was found, the adjudicator(s) reviewed the images, and attempted to come to a decision about which report was correct. If the adjudicator felt there was a discrepancy that had the potential of being of clinical importance to the patient, a grading of 2 (possibly important) or 3 (likely important) was assigned. Sub-grading was provided for grade 3 discrepancies, with 3a being used for non-acute discrepancies and 3b used for discrepancies thought to be of acute clinical importance.

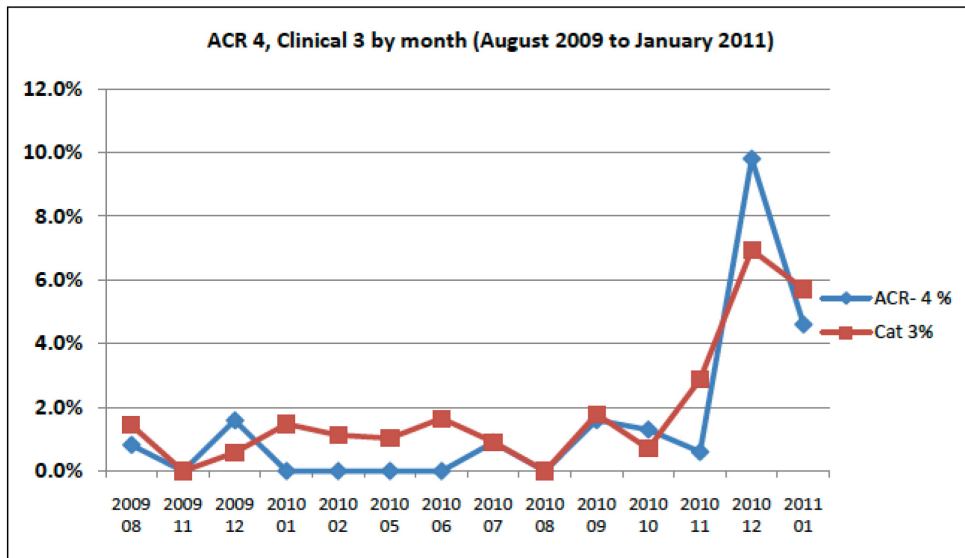
Phase 3 of the process consisted of a consensus meeting of adjudicators to review all studies graded 2 or 3. At least 3 of the 5 adjudicators met, and reviewed the reasons for their decisions. This was done to ensure consistency amongst the adjudicators. In cases where the adjudicators were unsure of a final rating, additional subspecialist radiologists were consulted.

The review included 2,721 scans on 2312 patients that had been reported between August 1, 2009 and January 16, 2011.

Clinical Discrepancy Category	Number	Percentage
0	1185	46%
1	1207	47%
2	137	5%
3a	34	1%
3b	10	0.4%
+ body parts included in other exams	148	0%

ACR Score	Number	Percentage
1	2521	93%
2	49	2%
3	116	4%
4	32	1%

Review of the data over time showed an increase in the clinical discrepancy rate towards the end of the study period (see Figure below).



The reviewers made the following observations and recommendation:

- 1) The percentage of discrepancies was much higher during the final months than it had been during most of the review period. It was during this time that the clinical concerns arose that resulted in the generation of this review.
- 2) The reviewers acknowledged that there is no accepted data for judging the minimum level of competence of a radiologist reading CT scans. They did however recommend that if this radiologist wished to return to the practice of CT scan reporting, a period of in-residence training of two months or more would be advisable, along with relevant refresher courses and initial monitoring of reports by colleagues.

SCREENING MAMMOGRAPHY REVIEWS

Stimulated by the media reports regarding radiology services at SJGH in Comox, the Screening Mammography Program of British Columbia (SMPBC) reviewed the radiologist's most recent performance benchmarks reported in November 2010 for the period of 2009. His performance was within the program standards in 2009.

In addition, all studies performed by the radiologist in the interval of August 1, 2010 to the radiologist's last report on February 11, 2011 were reviewed. The review re-read 1875 digital screening mammograms. One study in this time interval was not available and one patient, whose study fell outside of the study interval, requested that her images be reviewed.

Two qualified and credentialed screening radiologists experienced in reporting digital mammograms performed the review. The digital images and reports were forwarded to the SMPBC central office where the review occurred. The radiologists had the history as set out on the requisition and previous films but were blinded to the previous interpretation.

The mammograms were reviewed and reported using standard SMPBC reporting methods and criteria.

Of the 1875 cases reviewed 1751 showed no abnormality and 124 required further follow up. Of those flagged for follow-up, no abnormality was found on diagnostic testing in 104 patients, while further diagnostic assessment was needed for 20 patients and no patient has had a positive biopsy(to July 2011). These results indicate acceptable performance of a screening radiologist

Due to concerns expressed by the public, the SMPBC performance records of another radiologist were reviewed. This individual's performance was within the standards of the program including the number of post-screen cancers diagnosed.

OTHER MODALITIES

Given the performance pattern change noted in the CT review, it was decided to review other modalities in an attempt to clarify underlying causes. Studies originally reported by the radiologist in November 2010 (a sample of two days of work) and all studies performed in January and February 2011 (cardiac ultrasound studies were performed in the interval of October 2010 to February 2011) were re-read and reported.

Imaging Modality	Number of Studies Reviewed
Radiographs	905
Fluoroscopes	42
Mammograms	52
Cardiac Ultrasound	60
Non-cardiac Ultrasound	229

The same methodology as used in the CT review was applied to these reviews with the addition of additional reviewers to ensure that expertise was provided. In addition to the scoring tools used for CT, the reviewers were asked to determine whether or not the study required further review, or not.

In all cases, the clinical grade was either 0 or 1 and the ACR grade was 1 or 2. In no case was a finding of clinical significance missed or misinterpreted. The ultrasound studies were reported with an appropriate synthesis of information, and in a clinically useful report structure. Relevant images were recorded. Fluoroscopy studies with recorded images, needle trajectory and use of contrast were appropriate. The reviewers agreed "the report quality and methods were well within the range expected of a qualified radiologist."

OBSERVATIONS

ORGANIZATIONAL ISSUES

In 1913, Comox Logging and the Sisters of St. Joseph's created a hospital for the care of individuals working in the Comox Valley logging industry. Currently, St Joseph's and its facilities are the responsibility of the Diocese of Victoria.

SJGH is an independent denominational facility, is a member of the Denominational Health Association and manages a laundry and the Glacier View Lodge in addition to the hospital.

In BC, each denominational facility has an affiliation agreement with the regional health authority in which it resides. SJGH has such a relationship with the Vancouver Island Health Authority (VIHA). VIHA has responsibility for planning, funding, monitoring and "a degree of" (sic) operational overview. SJGH has its own board, operates its facilities and has its own medical staff bylaws and rules. The medical structure is based on departments.

Credentialing, privileging and medical staff review are SJGH's responsibility. There is no shared responsibility with other denominational organizations or VIHA with regard to medical administration, patient safety or clinical quality programs. Support can be requested from VIHA as was done by the Department Head Radiology SJGH in the summer of 2010 when she spoke with the Department Head Radiology VIHA regarding credentialing.

The relationship of SJGH to VIHA remains unclear. This issue may be solved with the closure of the SJGH acute facility and the development of a new hospital under VIHA's jurisdiction; in the interim, a solution is required to support SJGH Department Heads and to provide rigor to the appointment, reappointment and evaluation process for the medical staff. The interaction of SJGH and VIHA during this review shows that closer relationships can be functional. Relationships made with other denominational partners could also serve this purpose

MEDICAL STAFF AND DEPARTMENTAL ARRANGEMENTS AT SJGH

Groups or individuals who are members of the medical staff provide services in the Hospital. Under this structure, the Department Head, who may be a member of the practice group, may find him or herself in conflict when exercising the Department Head responsibilities. In particular, this conflict may surface when the Head must evaluate his/her department members, who are also on-call or business partners. Like department heads in some other health authorities and facilities, the department heads at SJGH have no robust processes for monitoring member performance and therefore are not (always) aware of department member strengths and weaknesses. Informal communication from other medical staff members is usual.

The SJGH Medical Advisory Committee (MAC) relies on the department head to adjudicate the quality of individuals who are privileged. As there is no process for such evaluation, the credentialing process and

the subsequent MAC approval seem functionary and add no critical review. This process does not protect the organization and the public.

The MAC and medical staff leadership roles are tightly integrated; the President of the Medical Staff is MAC Chair and the Vice Chair of the Medical Staff is the Chair of the Credentials Committee of the MAC. This mixes elected and appointed roles and can lead to confusion in the MAC regarding its responsibility to ensure quality versus medical staff advocacy.

SJGH does not have a fulsome process to review and affirm a medical staff member's credentials and competence when he or she is expected (or requests) to use new technology.

The medical administration is aware of these weaknesses. The Department Head of Radiology and the Medical Director offered the following suggestions for improvement (paraphrased):

- From a quality perspective, credentialing should not be a hospital responsibility because the department heads do not have the tools to do it properly. An agreement with VIHA or another body, allowing SJGH medical department heads and MAC committees to participate in the health authority processes would be valued.
- Guidance regarding competence assessment is needed. This should come from professional bodies.
- There needs to be an appropriate and rigorous process for audit and reviews of clinical services. This is a particularly difficult problem for small departments because of the interdependencies of the members. Such reviews should be undertaken in conjunction with the health authority or other multi-institutional organization.
- There need to be clear standards and guidance for the training of rural specialists. A formalized re-training and upgrading system should be established for medical professionals. Mandatory re-certification is supported.

Recommendation 4: That SJGH develop relationships with VIHA or a denominational partner that ensure that department heads have access to support in carrying out the duties required of their position.

Recommendation 5: That SJGH department heads not engage in administrative responsibilities in practice groups that might create, or be seen to create a conflict of interest for him or herself or SJGH.

Recommendation 6: That SJGH participate in the province-wide credentialing, privileging and medical staff review process described elsewhere in the report.

PROFESSIONAL ISSUES

The radiologist's personal concerns coinciding with the introduction of the 4-slice CT scanner precluded him from taking additional training as he had originally planned. Unfortunately, such training was not subsequently pursued. The radiologist relied on self-directed literature review and on-the-job exposure to provide him with the "experience" to read CT scans.

The radiologist's reaction to the input from his colleagues and the Department Head was that he would need to work harder. He was not aware of any factors that might account for the change in error rate detected by the review in late 2010.

WHAT WAS LEARNED FROM PATIENTS AND THE COMMUNITY

It is clear that the confidence in the health system was shaken by this event. The members of the public were disappointed. Hope and trust had been undermined and for some, lost. They felt, as did patients in Powell River, that professionals would keep "up-to-date" in their training and that checks would be in place to assure this. Their confidence in the health system had been undermined and yet many who had services provided by the radiologist were supportive of him and thought him ill-treated in the press and in the community. He was recognized publically as a very active health advocate for the community.

The release of information that allowed the radiologist to be identified was seen as inappropriate.

The issue seemed to "get to the paper before anyone knew". The public communication was seen to be too political, too fast, and seemed designed to "make the problem go away". The impact on hospital staff was overwhelming.

Regarding communication with the public, patients felt that direct personal contact and communication was required when errors affect their care. In the situation where it was not possible to contact individuals personally at the outset, public communication through press releases was appropriate. With a public announcement, however, should come a commitment for on-going communication and dialogue regarding the review process with updates on a regular basis. The follow-up, to date, has not been adequate according to several patients interviewed.

The communication to patients and family were felt to be most important. The patients interviewed felt that those directly impacted should have had direct personal communication in the form of a home visit or, at least, an arranged office visit to begin the disclosure. Because the patient communication was based on studies, rather than the individual, patients found the multiple letters to be confusing and not helpful as they were worded in a way that was difficult to understand.

Patients pointed out that some primary care physicians were not well prepared for their role in communication and disclosure. Inter-physician communication was poor for some patients with respect to changes needed in care plans.

Patients impacted financially because of changes in their care, felt that these costs should be recognized and addressed expeditiously.

THE VIHA RESPONSE

Communication between VIHA and SJGH regarding the concerns about the radiologist's CT interpretations failed. The informal communication regarding credentialing that occurred between the Department

Heads SJGH and VIHA proved to be timely but it exposed the vulnerabilities created by the lack of formal communication and support structures for the department heads at SJGH, and perhaps those serving in other small isolated facilities.

Timely communications from SJGH to VIHA regarding the perceived radiology quality issues did not occur, perhaps due to the sense of independence held by SJGH. Unfortunately, public communications unintentionally allowed the radiologist to be identified. This undermined confidence in the process amongst the health care community and diverted the focus from the quality of care for patients to a personal attack on the radiologist.

Following the recognition that a review was required, VIHA acted promptly to coordinate and support the review process. In contrast to other reviews that were delayed by technical difficulties, the VIHA implementation of interfaced radiology information and archiving systems facilitated a timely review. Radiologist recruitment and payment issues were addressed and did not impede the review.

ANALYSIS AND CONTRIBUTING FACTORS

WHAT HAPPENED AND WHY

The radiologist did not recognize his limitations with respect to CT scan interpretation. He did not undertake the upgrading that he had planned to do when the scanner was commissioned or subsequently.

The departmental quality review process was not well established and therefore was not able to detect deficiencies until colleagues expressed concerns. Neither the SJGH administration nor the MAC took steps to ensure departmental quality.

The department did not have the tools to support or measure performance. This included:

- The lack of a structured evaluation process to assess medical staff performance; and
- The lack of support for department heads in small facilities to execute their responsibilities.

The complexity of interpersonal relationships amongst members of small departments may have interfered with the ability of department head(s) to detect and therefore address issues earlier.

There was no post-CT implementation review of interpretive quality in either 2001 or 2009.

CONTRIBUTING FACTORS

1. The inability of small organizations to maintain quality assessment processes of sufficient rigor to detect quality issues in a timely fashion.
2. Confusion regarding the affiliation between SJGH and VIHA fostered by SJGH's culture of autonomy with respect to medical quality and performance evaluations.
3. The failure of the medical staff to support each other and SJGH when quality and performance issues are apparent.

FRASER HEALTH AUTHORITY - ABBOTSFORD REGIONAL HOSPITAL AND CANCER CENTRE, CHILLIWACK GENERAL HOSPITAL, FRASER CANYON HOSPITAL AND RIDGE MEADOWS HOSPITAL

FHA1 RADIOLOGIST ²

SUMMARY OF THE FACTS

The radiologist, not previously known to FHA, an international medical graduate without Royal College certification, was recruited through Health Match BC to join Valley Medical Imaging (VMI) as a radiologist in the Fraser Valley. The Fraser Health Authority (FHA) sponsored him and his supervisor was a VMI radiologist. The College granted him a provisional license for the period October 2008 through October 2009 and FHA appointed and privileged him. Under the direction of VMI, the radiologist provided diagnostic imaging services at Fraser Canyon, Chilliwack, Abbotsford, Mission and Langley hospitals. During this time, the radiologist's performance was monitored. Due to concerns regarding competence, the radiologist's supervisor withdrew from his role as supervisor in October 2009. Under the College bylaws, the withdrawal of the supervisor resulted in termination of the radiologist's provisional license.

The radiologist was re-licensed by the College and re-privileged by FHA in 2010. Under the terms of his license, quality reviews were done and revealed error rates higher than deemed acceptable. As a result, an extensive review of his work is underway.

CHRONOLOGY

October 2008 – October 2009

The radiologist was recruited to VMI through Health Match BC.

As an international medical graduate (IMG), the radiologist was sponsored by FHA, supervised by VMI, licensed by the College, credentialed, and privileged by FHA.

Throughout 2008-2009, the radiologist provided diagnostic imaging services at Fraser Canyon, Chilliwack, Abbotsford, Mission and Langley hospitals under a schedule controlled by VMI.

During this year, the College required updates from the supervisor on the radiologist's performance. These reports were submitted by the first supervisor but were not provided to the radiologist. VMI members also provided input on the radiologist's performance and based upon that input and a missed diagnosis, the supervisor reviewed a sample of the radiologist's mammogram and radiograph interpretations. This review was done prior to October 2009. Concerns arising from this review and the VMI input were not communicated to the radiologist until the end of October.

At the end of October 2009, immediately prior to the termination date of the radiologist's provisional

license, the radiologist was informed by VMI that his performance did not meet expectations and that he would not be accepted as a member of the group; the first supervisor withdrew. Because of the withdrawal of the supervisor, the radiologist's provisional license was terminated, as required by the College bylaws. The first supervisor informed the College of his concerns regarding the radiologist, and in conversation with the College Registrar it was decided that a formal review was not required.

November 2009 – 2010

The radiologist moved to Ireland where he provided diagnostic imaging services and upgraded his mammography skills.

November 2010

In 2010, the radiologist, wishing to stay in Canada and practice radiology, returned from Ireland and applied to the College for a provisional license and to FHA to practice at Ridge Meadows Hospital under the supervision of the second supervisor.

The College required the radiologist to complete a mammography review course prior to starting work, and issued a provisional license. The second supervisor was to provide quarterly updates on the radiologist's performance. The radiologist was credentialed and appointed to the Locum Medical Staff category in FHA in November 2010. It was felt that the patients that were imaged at Ridge Meadows Hospital (compared to the other facilities in which the radiologist had practiced in 2008-09) would provide a practice environment where it would be unlikely that he would encounter difficulties.

February 14, 2011

Following the public announcement of the radiology reviews in the province, the second supervisor disclosed the circumstances of the radiologist's appointment and upcoming quarterly review of his practice to the Regional Department Head, Radiology and FHA.

March 2011

The initial quarterly review of the radiologist was completed on March 3, 2011. The initial review consisted of a sample of mammograms (12 of 184 read), radiographs (120 of 2,969 radiographs) and computed tomographic scans (197 of 402 CT scans).

On March 3, 2011, the Fraser Health Medical Imaging Regional Department Quality Committee received the results of this quarterly review. It was decided to expand the review to all CT scans interpreted by the radiologist in 2008/2009 (in total 1,933 examinations) and review his work performed in 2010-2011 (in total 402 CT scans, 184 mammograms, and 2,969 radiographs).

The College was notified of the decision to undertake an expanded review March 8, 2011.

The radiologist did not provide services in Fraser Health facilities after March 2011. His appointment to

the Fraser Health Authority Medical Staff expired on July 31, 2011.

April 2011

College was updated on the FHA reviews.

July 2011

The review of the radiologist's work is still underway in FHA and due to be completed in September, 2011.

REVIEW METHODOLOGIES AND RESULTS

The first review of mammography was a single person retrospective review performed by the first supervisor.

The College quarterly review was intended to evaluate the quality of the radiologist's work and to provide direction to quality improvement efforts if necessary. The process entailed a review by a peer with comparison of the radiologist's results with those of the peer.

MAMMOGRAPHY REVIEW

On March 31, 2011, reporting on the quarterly review, the second supervisor found no significant discrepancies in mammography or radiographs; however, nine major discrepancies were noted in the CT reports (from a total of 197 scans). Based on clinical follow-up, none of the nine patients came to harm because of actions taken based on the radiologist's interpretations. All patients for whom there was a discrepancy revealed by the review were notified in writing of the discrepancy by the Regional Department Head.

The mammography review of interpretations done by the radiologist in 2008/2009 and in 2010 has followed a modification of the report comparison process and discrepancy analysis used in Comox and Powell River. When the reviewer recommended biopsy or immediate action, he/she reviewed the original report, with notification of the referring physician should a significant discrepancy in report recommendations exist. In the second phase, the reports were assessed by an adjudicator to score the degree of discrepancy; and in phase 3, significant discrepancies were referred to a panel of radiologists, who reviewed the reports and the images. The panel determined the preferred report.

In total 184 mammograms are being reviewed. The results of the mammography review are not yet available. Referring physicians will be notified of the discrepancies in interpretation during the course of the review.

CT REVIEW

The review of CT and radiograph interpretation began on July 12, 2011; it was delayed because of IT issues, reviewer manpower and compensation issues. To date, 25% of studies have been reviewed. The completion target is the end of September.

The same process used for the mammography review will be applied for CT except that the reviewer will read the films and then refer to the radiologist's report to determine discrepancies. The reviewer will not dictate a report. The discrepancies will be classified using report discrepancy grades. Patients whose imaging revealed discrepancies of clinical import will be notified as these discrepancies are found. It is expected that the reviews will be completed by the end of September.

The analysis of the 197 CT investigations done to date has revealed a consistent problem in the interpretations of one anatomical region. Based on this finding, the computed tomography studies to be re-read will focus on these studies (800 in total of 1900+).

OBSERVATIONS

REGARDING THE REVIEW

The College's quarterly reviews were intended to evaluate the quality of the radiologist's work and to provide focus for quality improvement if necessary. The process involved review by a peer with comparison of the radiologist's results with those of the peer. This is an acceptable methodology when reviews are undertaken for quality assurance purposes.

The reviews of the other modalities have yet to be completed so no comment can be made on the processes used, however, the planned approach will mirror that used for the mammography review and will provide the rigor necessary for a comprehensive retrospective review.

REGARDING PUBLIC COMMUNICATION

Communication with the public regarding the review of the radiologist's work has only occurred in the context of the public announcement of the Phase 1 report[2]. The prior reviews were part of the College's assessment program. In this circumstance, public communication is neither required nor appropriate.

The physicians responsible for patients whose reviews showed discrepancies received amended reports, and where those discrepancies were clinically important, direct communication from the reviewing radiologist was received. This was a suitable approach given the knowledge of the issues at the time. A more fulsome communication strategy will be required when the final review results are known.

PROFESSIONAL ISSUES

By his own acknowledgement, the radiologist lacked experience working in a digital world. One of the principal causes for his interpretation errors was his lack of familiarity with digital tools that facilitate interpretation. These skills were not learned prior to coming to Canada. The radiologist should have recognized this fundamental deficiency in experience when he arrived and he should have requested help to address this deficiency.

The College was not aware of the deficiency in the radiologist's basic education/experience. Neither the VMI nor the FHA credential review and privileging process were aware of this skill deficiency and its implications.

The results of the supervisory reviews during the radiologist's first appointment were not provided to the radiologist in a timely fashion nor were they communicated effectively within FHA.

The results of the quarterly reviews of the radiologist by the first supervisor appear not to have been communicated to the radiologist. No formal remediation was provided during the radiologist's first appointment.

ORGANIZATIONAL ISSUES

RELATIONSHIP OF FHA WITH PROVIDER GROUPS

Historically, the involvement of FHA in the appointment of staff under temporary and locum categories has been minimal. In the case of diagnostic imaging, the practice groups who were responsible for scheduling in health authority facilities would declare a need, decide upon a candidate and would request an application for appointment from the health authority medical staff office. When such an application was received, it was checked for completeness and the supplied references read. If the application was complete and the qualifications were in keeping with the general requirements of the appointment, no further scrutiny was taken and the application approved by the RDH, HAMAC and the FHA Board.

The initial recruitment of the radiologist was undertaken to meet the needs of a practice group and the support for his success lay with his supervisor from the practice group. Although FHA acted as the radiologist's sponsor on two occasions, it is not clear that the radiologist's recruitment was intended to meet a declared FHA need or that FHA understood its responsibilities as a sponsor. The due diligence expected of FHA for credentialing and review prior to privileging was not performed but was delegated to the practice group and their business manager.

Given that there are different practice groups in FHA providing imaging services, a centralized credential review and privileging process is necessary. In addition, as the department heads may be members of the practice groups, they are in a perceived or real conflict of interest with respect to their health authority duties. It is probable that there will be times when the interests of the health authority differ from the interests of the practice group. Such differences may surface with respect to human resource planning and management, program delivery, technology acquisitions and competence assessments.

Recommendation 7: That FHA review its practice of delegating to practice groups health authority responsibilities including medical staff recruitment, hiring, staffing in health authority facilities and service quality assessment.

Recommendation 8: That the relationship of a Local or Regional Department Head with a practice group should be reviewed to ensure that there is no real or perceived conflict of interest between the role as department head and any administrative or business responsibilities to the group. Where such conflicts are found, the Local or Regional Department Head should resign from practice group administrative responsibilities while in the health authority Department Head role.

Communication within the Diagnostic Imaging Department and the medical administration of Fraser Health was ineffective (the second supervisor was not made aware of the issues that the first supervisor had recognized except through conversations with the College Deputy Registrar at the time the radiologist reapplied for privileges in 2010).

The request for licensure and appointment from the radiologist received a detailed review by the second supervisor and the Deputy Registrar. A plan, as mandated by the College bylaws, was put in place and acted upon. It is not clear that FHA performed its own risk assessment or that the board was aware of the risks and history of this appointment.

COLLEGE MANDATED PERFORMANCE REVIEWS

The performance review methodology used by the first supervisor, and required for the College quarterly reviews, is less formal than that used for comprehensive retrospective reviews. Instructions from the College to supervisors do not specify the purpose and the methods to be used for such reviews. The instructions to supervisors are not specific to the type of practice being evaluated. Supervisors are not trained to evaluate the qualitative and quantitative performance of the provisional registrant. Supervisors are not formally evaluated.

Bodies sponsoring IMGs including the health authorities, individual facilities and UBC, must understand their responsibilities to the College and the IMG.

Proposed revisions to the College bylaws that would address some of these issues have not received a reply from the Ministry of Health.

Health authorities should provide support and mentoring to other provisional, temporary and locum appointees entering practice in their facilities.

Establishing and completing the comprehensive retrospective reviews have been problematic for FHA for the following reasons:

- Inability to gather the necessary information (defining the population of studies to be reviewed, reports, image data) so that the review can be done in a timely fashion;
- The lack of qualified radiologists willing to do these reviews, including the lack of locum radiologists to “back fill” those doing the reviews; and
- The lack of a compensation policy and schedule for the reviewers.

These same issues were important causes for delay in starting the review in Powell River.

MEDICAL STAFF ORGANIZATION

Medical staff membership categories for temporary and locum staff as defined in the FHA Medical Staff Bylaws, create confusion. In both situations, the appointment is of an appropriately qualified practitioner for a specific purpose (temporary service need or in the case of a locum, replacing an absent member of the active, provisional, or consulting staff or for the purpose of replacing the duties of a vacant medical staff position) for a specific time not to exceed 12 months. In neither category is it implied that an active staff appointment will follow.

For both categories, it is assumed that the privileges provided will address the service needed. The wording of the locum category (Article 7.56) suggests that privileges will be defined by the vacancy and not the capabilities of the individual. Further the rules (Article 3.3.5) state: “Where a Member of the Locum Tenens Staff is replacing a Member on temporary leave, the *replaced Member is responsible* to determine what aspects of his/her practice that the Locum Tenens Staff Member is prepared and qualified to cover” (emphasis added). While not the intent, this clause appears to transfer the responsibility to define the privileges to the “replaced member”. It is expected that the FHA appointment process (credential review and privileging) would be the same regardless of the appointment category.

Both temporary and locum categories allow for reappointment in the same category “upon review” (Articles 6.6.3, 6.7.3). These clauses provide for the situation where an individual is a “never ending” temporary or locum member of staff. These provisions should be limited to two terms, after which the member must apply for active staff status and the health authority must make a decision to recommend to the Board his/her active membership.

While the locum category may serve as a placeholder for future permanent staff recruitment, it provides no other value and allows practitioners to enter the health authority and provide services without the health authority exercising its responsibility for the services to be provided.

The temporary category can be applied to “special or urgent circumstances,” in which case the RDH may grant temporary appointment and privileges (FHA MS Bylaws 4.1.4). The intent of this clause is to allow appointment to address an emergency workforce issue. It is known that absences in the practice group prompted the appointment of this FHA2 radiologist but the nature and type of absences is not known. It is not clear that they would justify the use of this appointment category. Using this category to address last minute scheduling is not appropriate. Vacation, meeting and other forms of leave should be defined in advance and in sufficient time that last minute recruitment of temporary or locum staff is minimized. It is noted that temporary appointments granted by the RDH are to be ratified by the board at its next meeting.

Recommendation 9: That FHA clarify the use of temporary and locum appointment categories when applications for medical staff membership are being evaluated.

Recommendation 10: That FHA finalize the section in its Medical Staff Rules describing in-depth review.

RESPONSIBILITIES OF THE HEALTH AUTHORITY (REGIONAL) AND LOCAL DEPARTMENT HEADS

Responsibilities of the Regional Department Head (RDH), as defined in the Medical Staff Rules are comprehensive and define the role's authority with respect to medical staff appointments, standards of clinical practice for the department, and the performance of members of the Department. The local department heads (LDH) appear to function as a channel for communication, investigate complaints, review human resource requirements and participate in the selection of applicants to fill vacancies. It is not clear how these roles interact and where the lines of authority lie.

The health authority, through the RDH, has the responsibility to develop the human resources plan and to make the final recommendation for recruitment. It cannot delegate these responsibilities to practice groups or the local department head. The rules are specific that the RDH is responsible for the biannual review of appointments and privileges. There is no mention in the rules of the qualifications and training needed for appointees to these positions. The RDH should be responsible for developing the position description for the LDH.

Recommendation 11: That FHA review its Medical Staff Rules to ensure that the authority and responsibilities of the Regional Department Head and Local Department Head are clearly described.

WHAT WAS LEARNED FROM PATIENTS

The review has not been completed so no patients have been interviewed.

THE FHA RESPONSE

The review will not be completed until the end of September. This is six months after the decision was made to do a review. The start of the review has been delayed because FHA faces issues similar to those faced by VCH-Powell River with respect to image transfer, transcription and the recruitment of reviewers. Discussions between FHA and the Ministry of Health were required to address the issue of funding for review services.

It is FHA's plan to notify all patients, and their primary care physicians, when imaging results are modified by the review as soon as this information is available from the adjudicators. This should allow the health authority to interact with primary care physicians and with patients (where necessary) to ensure they receive the appropriate care necessitated by the change in imaging interpretation as soon as possible. Based on input from patients affected by other events, the language used in these communications needs to be appropriate for patients and family members.

Recommendation 12: That FHA provide further communications to the public regarding the status of the review and changes made as a result of the review. In the development of communications to the public, the language used should be appropriate for patients and family members.

RELATIONSHIP OF FRASER HEALTH TO THE COLLEGE OF PHYSICIANS & SURGEONS

As an IMG, the radiologist required a sponsoring organization (Fraser Health) and a supervisor acting on behalf of the College. At the time of his being granted a provisional license, the College's instruction to the radiologist's supervisors did not describe the components and competencies to be included in a robust quarterly review when the individual undergoing evaluation is a specialist. The instructions and training for supervisors are voluntary. FHA did not assume a role in the supervision of the radiologist during his first tenure. As a result, deficiencies were not recognized in a timely fashion so that remediation might have been undertaken. Feedback to the radiologist was delayed until the termination of his contract which then resulted in a non-renewal of license.

The radiologist came to BC with deficient skills relative to what was expected. The fact that he came with these deficiencies suggests that:

- He himself was not aware of the nature of the practice he was coming into, and therefore, did not recognize nor take remedial action.
- The College of Physicians & Surgeons did not recognize that he did not have the skills necessary to practice in the B.C. environment.
- The practice group and FHA did not recognize that he was not prepared to provide the services for which he was recruited.
- FHA did not request a Certificate of Professional Conduct from the College at the time of reappointment

The FHA did not have a standard process for direct communication with the College(s) or referees for new or repeat applicants.

ANALYSIS AND CONTRIBUTING FACTORS

WHAT HAPPENED AND WHY

The training and experience that the radiologist had in using digital tools and assessing studies that contain large volumes of data was not adequate for the tasks he was asked to perform in the work environment. The College, VMI and FHA did not recognize these deficiencies because they assumed his training and experience was equivalent to that of graduates of Canadian programs who would have been exposed to these tools and studies. The College, VMI and FHA did not know to inquire into the details of the radiologist's training environment relating to differences involving film versus digital technologies.

At the time of the reapplication (2010), communications within FHA failed and the results of the radiologist's reviews in 2008-2009 were not made known to the new supervisor. The radiologist did not provide a FHA reference from his prior appointment and the FHA appointment process did not enquire of the Abbotsford LDH or the first supervisor prior to his reappointment. It appears that this is due to the practice of local privileging and interactions of the College with the facility without engagement of the health authority or the RDH.

CONTRIBUTING FACTORS

1. The failure of the radiologist to recognize and act upon his limitations with respect to imaging modalities and digital tools.
2. The effective delegation by FHA of the radiologist's performance assessment and review process to VMI.
3. The failure of the College and FHA to perform their own detailed risk assessment at the time of reapplication at a different FHA site for license and medical staff membership.
4. Delegation of recruitment, "hiring" and evaluation by FHA to VMI (as the IMG sponsor).
5. Failure to provide timely feedback to the radiologist so that remediation could have been provided during the first appointment.

FRASER HEALTH AUTHORITY - ABBOTSFORD REGIONAL HOSPITAL

FHA2 RADIOLOGIST³

SUMMARY OF THE FACTS

The radiologist, previously not known to FHA, was recruited by Valley Medical Imaging to provide temporary coverage for the practice group at Abbotsford Regional Hospital and Cancer Centre and Chilliwack General Hospital. VMI's business manager had interviewed the radiologist prior to the commencement of this appointment. Neither the LDH nor the RDH was involved in the recruitment process. FHA managed the credentialing and appointment process to the medical staff.

Discrepancies in the radiologist's interpretations of CT scans were not recognized during his period of service (from August 18 to September 17, 2010).

CHRONOLOGY

August 16, 2010

The radiologist applied for and received a temporary appointment to the FHA Medical Staff. He was to provide services at Abbotsford Regional Hospital and the Cancer Centre and Chilliwack General Hospital as defined by the VMI.

The radiologist had an unrestricted license in good standing in British Columbia at the time of application to FHA. Three written references were reviewed and no issues were identified. No personal contact was made with the referees by the credentialing staff, the Regional Department Head (RDH) or the Local Department Head (LDH) in Abbotsford.

The radiologist indicated that he possessed the necessary skills to perform and interpret CT scans and while he did not have advanced training in CT colonography, he intended to take the certification course offered by the College.

September 8, 2010

The Health Authority Medical Advisory Committee approved the radiologist's appointment to the Temporary Medical Staff category. The recommendation was approved at the FHA board on November 1.

August 18 to September 17, 2010

The radiologist was scheduled by VMI, with approval from Abbotsford Regional Hospital's Department of Radiology, to provide imaging services including CT at Abbotsford Regional Hospital and Cancer Centre

and Chilliwack General Hospital. The radiologist interpreted CT scans, ultrasound images, radiographs and mammograms.

December 9, 2010

The LDH at Abbotsford Regional Hospital received a call from the Deputy Registrar of the College, regarding the radiologist's license and the fact that a restriction had been placed upon it regarding CT scan interpretations. The LDH received a letter, dated December 17, from the Deputy Registrar in follow up to their conversation on December 9th.

December 14, 2010

The LDH initiated a review.

December 2010 – February 2011

The VP Medicine FHA was notified of the concerns, and that a letter was being sent to the College on December 20. The plan for a CT scan review was discussed with the RDH and the LDH. The review process was finalized on December 20 and commenced December 21. It was planned that when reviewers encountered major errors and felt it was prudent to do so, direct verbal communication with the ordering physician would be initiated and documented. All CT scans (174 scans on 170 patients) were re-read and discrepancies recognized described by February 5.

The Regional Department Medical Quality Committee reported to the Health Authority Medical Advisory Committee on February 9. The FHA Board Quality Performance Committee was informed on February 10.

Stimulated by the knowledge of the events unfolding in Powell River and that a public disclosure was planned, on February 10, the RDH reviewed the reviewer's reports and categorized them for analysis and presentation. The RDH identified ten major errors of interpretation with numerous errors of lesser significance. The results of this preliminary review were used to inform the initial disclosure process, communication to the public and correspondence with the College. The LDH notified the College that in his view, the radiologist did not possess the requisite skills and knowledge to interpret CT examinations and that his practice should be restricted in that regard.

On February 11, FHA disclosed the review to the public.

REVIEW METHODOLOGY AND RESULTS

The methodology used by the RDH in reviewing scans performed on the 170 patients incorporated image re-read and report comparison. Studies were re-read by qualified reviewers and reports and/or addendums issued as needed. The RDH then adjudicated the reviewers' interpretations and categorized the errors as: "no error", "minor or moderate" and "major error" referring to images where necessary.

The rate of major errors was 6%, with minor and moderate errors totalling 45%. The majority of interpretive differences were missed features.

NOTIFICATION OF PATIENTS AND COMMUNICATION WITH THE PUBLIC

Between February 11 and 13, 2011, the RDH contacted all patients and families whose CT reports contained major errors. He informed all seven living patients of the error, apologizing on behalf of FHA. He answered questions and offered assistance to facilitate follow up testing or appointments that might be required. Families of the 3 deceased persons were contacted directly between February 14 and 17, and informed of the error and offered an apology on behalf of FHA.

On February 14, 2011, a letter was couriered to all patients who had a CT scan reported by the radiologist where the review found no discrepancy or a minor/moderate discrepancy.

OBSERVATIONS

REGARDING THE REVIEW

The review process, while differing in final categorization of the discrepancies, was based on the ACR Peer Review White Paper [3]. Given the urgency to provide information for the February 11 public communication, the discrepancy categorization was simplified and a single individual performed a combined phase 2 and 3 review. Neither of these variances from the approach used for other reviews detracts from the validity of this review's conclusions.

REGARDING THE NOTIFICATION OF PATIENTS OF DISCREPANCIES IN INTERPRETATIONS

- The notification of patients whose scans interpretation showed significant error by the RDH was timely. The follow-up letter was appropriate. Appropriate supports were offered to patients to ensure that their care needs were addressed. Apology was given.
- Patients who were interviewed appreciated the direct personal contact by the RDH. Several patients expressed their gratitude for the sensitivity and timeliness he showed in the disclosures. The communication to those patients whose studies showed no error was timely and the method, by couriered letter, appropriate.

REGARDING PUBLIC COMMUNICATION

Public communication was part of the February 11 public announcement with the Ministry of Health and VCH. The public information hot line was available on February 11 and thereafter to address patient and

public concerns.

ORGANIZATIONAL ISSUES

FRASER HEALTH CREDENTIALING AND PRIVILEGING PROCESSES

The recruitment process was managed by VMI without participation from FHA. The radiologist was interviewed by the VMI business manager and not by partners of the firm or the local department head (Abbotsford). The radiologist may not have been comfortable indicating competence concerns regarding his professional skills to a non-radiologist during this interview process.

The FHA credential review and privileging process was not sufficiently rigorous to detect that the radiologist may have lacked the skills to safely perform the duties required of him in the role he was being privileged to perform. His supporting references were from non-radiologist colleagues, who were not contacted to provide confirmation of their recommendations.

VMI did not provide formal supervision of the radiologist during his locum. He was free to consult with colleagues when he had questions or needed an additional opinion. FHA did not provide supervision during his locum.

This event brings to attention the issue of the relationship of the FHA medical imaging service to radiology business groups who provide services using health authority facilities. A similar theme arose from the event surrounding the FHA1 radiologist.

Recommendation 13: That the FHA Medical Imaging Regional Department collect detailed practice experience information for all applicants for appointment and all members and locums working in the department. The information will be reviewed by the Local Department Head and the Regional Department Head as part of the appointment and reappointment processes and prior to the individual commencing service in the health authority.

Recommendation 14: That Fraser Health ensure that all medical staff providing speciality services that require special qualification or certification, have these qualifications before privilege is granted or that the board knowingly appoints and privileges with conditions.

WHAT WAS LEARNED FROM PATIENTS

Patients and family members articulated clearly that they expect health care providers to be competent and up-to-date with the technologies they use in their day-to-day work. Patients and the public expect that individuals who are not up to date and competent would be required to upgrade their skills so that they can provide a level of performance consistent with currently trained colleagues, or that they are not allowed to provide services that use these imaging modalities. Patients recognize that upgrading is

needed as technologies and personal capabilities change and that this is an on-going activity throughout the course of a professional's lifetime. The patients and public clearly stated that the responsibility to ensure competence was shared equally by the individual and the system in which they were working.

Individual patients described the impact of diagnostic and interpretative errors on their care and their quality of life. The imaging was only one part of the complete medical management for these patients. FHA has the opportunity to review the care provided to individuals and to make changes that will improve the quality of care to be provided to these patients and others, in the future.

Most patients spoke passionately to their belief that they trust the system and that trust is easily lost. They all felt that providers of any specialty, who lack qualifications, should not be allowed to slip through the cracks. There is little tolerance for what is seen as lack of due diligence on the part of the College and the health authority.

Communication from the FHA to patients was an issue for several patients. There are sensitive issues such as pre-existing medical illnesses (cancer, in particular) where messaging regarding diagnostic error requires special sensitivity and timeliness. Patients recognize that few health care professionals have a complete view of any one patient's care, and spoke to the importance of their primary care physician being "on the ball" and able to provide follow-up for imaging results.

The patients indicated that, when needed, a phased communication and disclosure process would be acceptable. In the circumstance where a review is thought to be necessary, all patients interviewed felt that they should have been made aware of this at the time the decision was made to do a review. Patients felt that direct communication by phone or home visit by a knowledgeable physician was the most desirable form of notification. When asked, if it was not possible to receive personal communication (because of the number of patients to contact), they agreed that public notification would be acceptable if it included a clear timeline as to when their individual risk would be known and the actions that they and their doctor should take.

All patients felt that FHA needed to be more proactive in their communications by providing information on required additional or follow-up imaging, testing and care when this was known. They also felt that communication regarding the status of the review and changes made as a result were critically important.

THE FHA RESPONSE

When it was recognized that the radiologist did not possess the skills to interpret CT scans (based on the letter from the College to the LDH), FHA responded promptly to undertake the review. This investigation involved CT scans; no other imaging modalities were reviewed. This review was completed in a timely fashion.

Sensitized by knowledge of events in Powell River and a date of public announcement on February 11, it was decided by FHA to join the public announcement with the Ministry of Health and with VCH.

The time taken to do the review and to define the risk for individual patients was one month and communication plans for patients were finalized and implemented in the next month. There are no

patients who suffered physical harm because of scan misinterpretation.

The process for disclosure, support and apology are to be commended. It is expected that patients will be notified when the major errors were recognized as the current review progresses.

THE IMPACT OF THIS EVENT ON THE COMMUNITY

FHA received 205 calls in total to their hotline and addressed questions and provided clarification and answers where possible.

ANALYSIS AND CONTRIBUTING FACTORS

WHAT HAPPENED AND WHY

The radiologist did not have the experience and skill to read CT studies with acceptable accuracy. He was not aware of his limitations having performed such interpretations previously. The credentialing and privileging process was not designed to assess the fit of the radiologist's "education/experience" with the tasks he was asked to, and agreed to perform. Neither VMI nor the FHA credential review process asked for a detailed description of the radiologist's competencies with respect to his skills and experience with imaging modalities (in particular CT).

CONTRIBUTING FACTORS

1. Delegation of the recruitment, "hiring" and evaluation process to VMI.
2. The failure to request that the radiologist provide references from peer radiologists who could attest to his professional abilities.

INTERIOR HEALTH AUTHORITY - EAST KOOTENAY REGIONAL HOSPITAL CRANBROOK

SUMMARY OF THE FACTS

The radiologist was retained to provide locum services for a Department of Radiology member's practice at East Kootenay Regional Hospital (EKRH) from September 20 to October 12, 2010. He had been recruited through Health Match BC. The radiologist found himself in a situation in which he did not have the skills needed for the practice that he was asked to assume. This deficiency resulted in misinterpretations of CT scans.

CHRONOLOGY

October 2010

Towards the end of the radiologist's term of service, the Chief of Staff identified two studies involving his own patients with which he disagreed with the radiologist's interpretation. The Department Head Radiology EKRH initiated a review of all computed tomographic studies read by the radiologist during his locum. As no complaints were raised regarding his competence in other imaging modalities, no other reviews were performed.

November 2010

Following the radiologist's term of service, the Department Head Radiology EKRH, wrote to the College on November 17, describing the results of his review and a recommendation that the radiologist's license be restricted to diagnostic imaging excluding computed tomography. The College responded with agreement to this recommendation and precluded the radiologist from reporting CT in BC until he obtained further training and provided confirmation that he was qualified to do so.

REVIEW METHODOLOGY AND RESULTS

The methodology used was a single observer re-read with analysis of reports. The clinical categorization of report discrepancies was applied.

The review addressed only computed tomography. Every case was re-read by a permanent member of the Radiology Department at EKGH. Addendums were issued where discrepancies existed and further discussions were held with ordering physicians regarding the clinical significance of the discrepancies. The review was completed within three weeks of the radiologist's completion of the locum.

In the 222 studies in 205 patients, category 2 discrepancies were found in 7%, and category 3a,

discrepancies in 4%. There were no category 3b studies. The 3a discrepancies were individually reviewed. The discrepancies resulted from missed features, the failure to make recommendations on reports and misinterpretation of imaging features.

No patient was injured because of the discrepancies in interpretation.

OBSERVATIONS

REGARDING THE REVIEW

- An acceptable methodology and discrepancy classification was used.
- The review was undertaken in an expeditious fashion.
- The College was notified in a timely fashion.

REGARDING NOTIFICATION OF PATIENTS OF DISCREPANCIES IN INTERPRETATION

- Patients and practitioners were notified as the review progressed.
- If no discrepancy or no clinically significance discrepancy (Category 0 or 1) was found on review, a letter from the medical director was sent to patients and ordering physicians.
- When the discrepancy might be clinically significant, a letter was sent from the Senior Medical Director, and phone call made to the attending and family physicians when the discrepancy was recognized.
- When the discrepancy was likely to be clinically significant, a letter was sent from the Senior Medical Director, and phone call made to the attending and family physicians when the discrepancy was recognized.

REGARDING PUBLIC COMMUNICATION

There was no formal public communication.

ORGANIZATIONAL ISSUES

IHA CREDENTIAL AND PRIVILEGING

The credentials review by the College and the credentialing and the privileging processes performed by IHA did not reveal the radiologist's competency deficiency in reading CT studies. The credential review process was performed by the EKRH Chief of Staff's office and temporary privileges approved by the Senior Medical Director, Acute Services East and by the VP Medicine IHA. There was not time for the application to progress through the MAC to the board.

The reference checking entailed reading the letters and a conversation with one referee who commented

that, “the radiologist is doing a locum at the ARHCC, CGH and the VMI clinics in the Fraser Valley. I have had limited personal contact but I know of NO personal or professional issues which would preclude his working as a Locum in your facility.” There was no indication of concern in the written responses from the other references.

In the IHA application to join the medical staff, the request of the applicant for a confidential reference does not require the referee to speak to the technical capabilities and competences of the applicant with respect to the specific skills of the job to be done. The format and the questions are general and would not reveal deficiencies unless the respondent answered yes to questions 12 and 13⁴. This would be unlikely given that the candidate selects these referees.

THE IHA RESPONSE

IHA’s response with respect to the review was timely. It used accepted methodologies and the communication with attending physicians was prompt. The health authority indicates that they assured appropriate follow-up for individual patients.

These issues served to stimulate further investigations elsewhere in the Province.

THE IMPACT OF THIS EVENT ON THE COMMUNITY

To the review team’s knowledge, this review did not become an issue in the community.

ANALYSIS AND CONTRIBUTING FACTORS

WHAT HAPPENED AND WHY

The radiologist did not have the experience and skill to read CT studies with acceptable accuracy. He was not aware of his limitations, having been performing such interpretations previously. The credentialing and privileging process was not designed to assess the fit of the radiologist’s “education/experience” with the tasks he was asked to, and agreed to perform. The credential review process did not require a detailed description of the radiologist’s competencies with respect to his skills and experience with imaging modalities (in particular CT).

CONTRIBUTING FACTORS

1. The failure to request that the radiologist provide references from peer radiologists who could attest to his professional abilities in detail.
2. Other than the facility department head, medical administrative officers who were required to sign off on the application did not have the information or knowledge of the technical competencies required of the position based on the details provided in the application.

QUALITY ASSURANCE AND PEER REVIEW IN DIAGNOSTIC IMAGING

The health authorities have established medical quality and safety committees (or equivalent) under the authority of the HAMAC and all health authority boards have created committees to evaluate the quality of clinical services and providers. In the case of diagnostic imaging, boards have also had the benefit of the DAP peer review of the department's performance against established standards. Despite these structures, the oversight of diagnostic imaging clinical quality can be improved as demonstrated by these events.

The phase one report provided the following recommendations to address some of the gaps initially identified in radiology peer review:

1. It is recommended that the Ministry of Health Services, the College of Physicians and Surgeons and the health authorities create a province-wide concurrent peer review system for diagnostic imaging for quality review and monitoring of image interpretation and technical image quality.
2. Until province-wide prospective concurrent peer review is fully implemented, it is recommended that the College through its Diagnostic Imaging Quality Assurance Committee undertake retrospective screening reviews of imaging services in selected facilities beginning immediately. Determination of the facilities to be reviewed is seen as a joint responsibility of the health authority and the College. Criteria for a screening review might include facilities whose radiologists request such a review and those where the peer support has been limited or absent.
3. It is recommended that the Diagnostic Accreditation Program immediately undertake the medical review for any facility that has not yet had this completed as part of the last DAP diagnostic imaging review. The program should use the published 2010 standards for these assessments, the results should be made known to the responsible health authority.
4. It is recommended that health authority boards instruct their Medical Advisory Committees or equivalent to implement clinical audit and peer review programs for all medical staff members, including regular in-depth performance reviews as described in their medical staff rules. The results of these reviews should be reported as part of the regular appointment and re-appointment process or as necessary when performance concerns and remedial actions are necessary. Medical staff member participation in these reviews should be reported to the Board quarterly.

To supplement these recommendations, additional structures are needed to further the establishment of a robust and reliable quality system. Given the interplay between the health authority and private sectors, and the fact that many radiologists work in both, quality assurance processes of a similar standard are needed for both sectors. The recommendations address the following issues:

1. The definition of a comprehensive retrospective review process for diagnostic imaging that can be used by the health system and the College should be needed.
2. The development of a retrospective peer review process focused on quality improvement for use by the health authorities and the College.
3. The establishment of a management system to provide oversight for the peer review processes used in the health authorities and by the College.
4. The establishment by each health authority board, of a Diagnostic Imaging Quality Assurance Committee mandated to provide oversight of imaging quality and practitioner competence for the health authority.

Recommendation 15: That the health authorities and College develop a comprehensive retrospective review process that can be used in the health system or the private sector should the need arise.

During the course of the individual reviews, it was apparent that each health authority was adopting and adapting their review process and communication plans. The reviews used the ACR Radpeer categorization scheme (or modifications) but other aspects of the process were inconsistent. The review team is indebted to Dr. Mathieson and his staff for the standardization provided to two of the reviews, allowing interpretability. Given the overall variation in process and therefore the generalizability of conclusions, the collective learning from these events should be harnessed into a guideline for the future use. This would include guidance for the technical issues, review methodology and discrepancy categorization as well as processes for the communication to patients and with the public. This work should address the impediments that were faced by the health authorities in undertaking their reviews including issues related to image transfer, report generation and transfer, compensation for reviewers, adjudicators and radiology and support staff, and back fill radiologists. Appendix V provides suggestions based on components that VIHA and VCHA incorporated into their reviews and that the review team considered leading practices.

Recommendation 16: That the College and the health authorities develop a standardized retrospective peer review process designed for quality improvement in the health authorities and private facilities.

To address the Phase 1 report[2]“Retrospective Screening”, the College and the health authorities should formalize a retrospective review process designed for quality improvement. Such a review would be intended to assure the quality of image interpretation and to provide support for additional training and supervised experience if needed. Health authority boards or the College can commission this type of review. An individual medical staff member may request such a review. The results of the review would be reported to the Department Head and the health authority or College Diagnostic Imaging Quality Assurance Committee. The Department Head will provide the results to the medical staff member and will develop, with the staff member an improvement plan. Suggestions for the methodology are described in Appendix.

Recommendation 17: That the Provincial Medical Imaging Advisory Committee (MIAC) establish a provincial management system for diagnostic imaging peer review in BC and that this system oversees both concurrent and comprehensive retrospective peer review processes. The boards of the health authorities and the College retain the responsibility to commission reviews and to act on performance issues that become apparent.

The management system could address the following responsibilities:

1. To review and revise as necessary the province-wide concurrent peer review process for diagnostic imaging and procedural services for use by the health authorities and the College in BC. Components of this process would include:
 - a. Review methodology;
 - b. Sampling strategy;

- c. Reporting standards and frequency;
 - d. Education program for reviewers and adjudicators; and
 - e. Formal review of the performance of the reviewers and adjudicators.
2. To oversee comprehensive retrospective peer review process (Recommendation 1 above) for diagnostic imaging and procedural services in BC. The components could include:
 - a. Recommendation of sites to be reviewed:
 - i. based on compliance with Diagnostic Accreditation Program standards;
 - ii. quality issues raised through internal health authority processes; and
 - iii. at the time of introduction of new technology to the health authority facility.
 - b. Development of a library of images for proficiency testing.
 - c. Reporting standards for health authorities and the College.
 - d. Education and evaluation of reviewers.
 3. To oversee and evaluate the quality of the peer review processes.
 4. To act as a resource for the health authorities and College regarding upgrading programs available to practitioners in BC.
 5. To serve as a resource in communication with other jurisdictions.

Recommendation 18: That each health authority establish a Diagnostic Imaging Quality Assurance Committee with authority vested by the board, to provide oversight for diagnostic imaging services provided by the health authority.

The Diagnostic Imaging Quality Assurance Committee (DIQAC), if none already exists, would be designated by the health authority board to monitor and report upon the quality of care provided by the diagnostic and interventional imaging services of the organization. The DIQAC would supervise all aspects of diagnostic imaging quality assurance including those aspects related to equipment, radiation and magnetic field safety, technical performance of imaging and interventional studies and procedures and image interpretation and communication.

Suggested terms of reference for this committee are provided in Appendix VI. The College has established a DIQAC with similar authority to address its responsibilities to monitor and assure quality in diagnostic imaging in the private sector.

Recommendation 19: That the BC Radiological Society (BCRS), in conjunction with the MIAC and the College establish a library of images that reflect difficult interpretations and common errors that can be used for teaching purposes (resident and continuing professional education) and for proficiency testing.

The cases could be derived from the concurrent and retrospective peer reviews performed in BC and elsewhere.

Recommendation 20: That the BCRS, the Canadian Association of Radiologists and the Royal College establish modality specific performance benchmarks for diagnostic radiologists that can be used in concurrent peer review monitoring.

The results of the concurrent peer review could provide data upon which such benchmarks could be adjusted over time.

Recommendation 21: That the health authorities develop a program whereby short-term vacancies in the radiology technical and professional staff can be filled by using staff from other facilities, as permitted by collective agreements. When such services are needed, expenses incurred by the technician or radiologist should be reimbursed.

ADVERSE EVENT MANAGEMENT IN THE HEALTH AUTHORITIES

Recommendation 22: That the health authorities in conjunction with the Provincial Ethics Committee, the public, represented by two members of the health authority boards, the Office of the Provincial Health Officer and other stakeholders should develop a guideline for the management of adverse events that affect many patients or when there is a threat to public safety. Issues to be addressed by this group include communication planning for patients and providers, technical assessments, review logistics, implementation management and appropriate payment for those harmed and those doing the reviews.

A guideline should include details describing:

1. The multidisciplinary assessment and management team composed of clinical, epidemiological, ethical, administrative, communications, legal and other experts, including a patient experience expert, to consider disclosure in a structured way and to manage the complex processes of communication to all parties;
2. The situational assessment of the event needed to determine its extent and the required look-back and case identification process(es);
3. The roles to be played by other provincial resources organizations and bodies;
4. The structure and timing of communication with the public, the care providers who are assumed to have a role in communicating with patients, for patients and family members including those in special situations (deceased patients, minors, specific sensitive diagnoses) and other responsible parties (regulators, insurers and others). A communication plan should be based on known facts, and would respect the confidentiality of individuals while based on the goal of achieving the best possible quality care of individual patients;
5. Assessment of the risk of the event to individuals and the likelihood of the event happening to an individual if this is not known. This would include an assessment of scientific knowledge as well as qualitative data that may be relevant to the assessment;
6. Revisions of care plans needed to protect patients, to assess new medical needs including additional investigations and treatments and to provide follow-up as needed to ensure that the appropriate management is enacted;
7. Definition of a formal investigation including the process for selecting an external reviewer and timeline to determine causes and to make recommendations to prevent similar events in the future;
8. The processes to be used to follow up with patients, families, the health authorities and the public regarding actions taken and changes implemented;
9. The effects of the event on third parties including health care staff and providers;
10. The payment for external investigation, professional review and case identification expertise, disclosure and notification support and other incurred costs; and
11. The appropriate payment to those harmed.

Additional details can be found in Appendix VIII.

Recommendation 23: That the health authorities undertake a risk assessment of their preparedness to deal with a retrospective review in a clinical area, taking into consideration the provincial guideline on adverse event management involving many patients and the difficulties encountered by VCH and FHA in executing their diagnostic imaging reviews. These assessments should be presented to the health

authority boards and shared amongst the health authorities.

These events revealed a number of challenges and impediments to undertaking this type of review in a way that could meet the needs of the health system, patients and the public. Similar challenges have arisen in the past in other public profile events in other health authorities. How each of these events may impact a health authority will differ and therefore an assessment of the preparedness of the health authority for such events will be informative for the Board and the executive.

PHYSICIAN CREDENTIALING, PRIVILEGING AND REVIEW

This review of diagnostic imaging has exposed weaknesses in medical administration that extend beyond image interpretation. These include the communication between the College and the health authorities, the College assessment and support of international medical graduates, and the health authority credentialing, privileging and review processes for physicians. The review revealed several factors that contribute to the weaknesses of these processes. These include:

1. The separation of licensing, a College responsibility, and credentialing and privileging, a health authority responsibility (or in the case of SJGH, a facility's responsibility). Licensing and credential review are one-time processes that apply to the provider. In today's health system, the services needed and provided by individuals change over time. Some of these changes require new qualifications. Privileging and annual review are intended to address these changing needs but are applied unevenly across the health system.
2. Differing legislative foundations (Health Professions Act for the College and the Hospital Act for the health authorities) that may limit the exchange of physician performance information between the College and the health authorities.
3. Credential review⁵ and privileging⁶ remain delegated to facilities in some health authorities rather than being administered regionally, a reminiscence of the days where hospitals were legislatively and organizationally independent.
4. The capability of the health system to evaluate provider performance is limited in large part because clear post-qualification standards are not available, satisfactory professional performance is assumed and efforts to assess performance are only undertaken when performance is questioned;
5. The ability to provide quality care may vary over the career of a professional due to personal health, changing interests and opportunities for learning.
6. Providers move within and between health authorities and sectors. As has been seen, communications between and within health authorities and with the College may not be reliable.
7. Public expectation that provider quality is being evaluated so that quality can be assured.

Recommendation 24: That the health authorities and affiliates create a single medical staff administration that will be governed by and serve all of the health authorities and affiliated organizations. This organization should have information sharing agreements with the College so that the results of licensing, credential review and privileging are available to all parties.

Health care services are complex and require highly educated, skilled, and experienced practitioners. The evaluation of an individual's qualifications and competence requires an understanding of current standards of care, assessed against the individual's education as well as evaluation of their non-technical and interpersonal skills.

During the course of this review, it was apparent that the health authorities remain autonomous with respect to medical administration. These events reveal variability in the due diligence applied to recruitments and performance reviews in health authorities. The discipline specific standards against which individuals should be evaluated are not described with the result that it is left to the judgement of those responsible in medical administration. Performance reviews as described in the medical staff rules

of the health authorities and affiliates have not been done consistently. This may be in part due to the lack of appreciation for the importance of this work in ensuring the quality of health authority services and assuring the public of the quality of providers. It was also evident that this is due to the lack of tools, experience and training for department heads and other responsible administrators.

To assist the health authorities and the College to address this fundamental quality issue, a central administration is recommended. A more distributed organization will perpetuate the inconsistencies of standard interpretation for speciality privileging and for performance review. A centralized service, through its joint health authority management structure, will assist in relationship development between the health authorities so that “cross coverage” and experience-sharing can begin, for example within medical administration for reviews and evaluation, to address vacancies and emergency absences. Perhaps most importantly, it provides providers and the public with the knowledge that the interpretation of standards, the requirements for specialty competencies and the process of reviews will be consistently applied. The quality created by such a body will ensure the health authority boards that the appointment, review and reappointment process is rigorous and reliable and that the recommendations made for their approval include all relevant factors. It will also bring the health authorities and the College together to set or adopt competency standards and regularly review licensees to ensure that qualifications are in keeping with the scope of services being provided.

The differing legislation under which the health authorities and the College act should be reviewed and amended as necessary to ensure that there is no impediment to the free exchange of information as described in Appendix IV.

Additional details can be found in Appendix.

Recommendation 25: That the health authorities and affiliates standardize their processes for medical staff appointment, credential review and privileging and physician review. Included would be common definitions for core and speciality privileges⁷, common reporting formats for medical advisory committees and health authority and affiliate boards. These activities should be supported by a single information system.

Aspects of these processes that would be suitable for standardization include:

- Common application processes (forms, timeline, referee requirements⁸, review processes) at the time of initial application and at reappointment if applicable.
- An application for privileges should specify the areas of practice, technology and procedures in which the applicant has skills. Credential review should ensure that the necessary qualifications (or upgrading) have been completed in a manner satisfactory to the College and health authority.
- Maintain an up-to-date repository of individual skills and qualifications available to the health authorities to be used in dealing with urgent medical service requirements.

Additional guidance is found in Appendix.

Recommendation 26: That the health authorities, affiliates and the College develop a performance

assessment and review process for all physicians. The health authority medical staff rules provide a foundation for this work. Health authority boards should approve the review process and how it is applied so that they are assured that the process provides a suitable foundation for the recommendations being brought to them for decision.

The College and the health authority and affiliate boards share the responsibility to ensure that professionalism and appropriate standards and patterns of medical care are observed and provided in the services to patients and clients. They also share the responsibility to ensure that properly qualified individuals are licensed when permitted to practice in their facilities. Performance review as described in the medical staff rules of the health authorities is one method by which both the College and the boards can be apprised of clinical competence. The events under review suggest health authorities do reviews infrequently, if at all, and when they are done, they vary in stated purpose, approach, components and follow-up of outcomes.

Building on the foundation described in the medical staff rules, the following are aspects to be considered in the development of the review process so that it is valuable to all parties and so that the public is assured of the competence and skill of the providers in the health system:

- The intent of the review is to support quality improvement and career development. It is not a disciplinary process. The process and outcomes of the review process must be, and be seen to be, fair and equitable.
- The review process should be structured and consistent across all health authorities. A list of elements and tools found useful in other jurisdictions are found in Appendix IX.
- Medical administrators who are charged with conducting reviews should be provided with training in the process of the review and providing feedback.
- Health authorities should have the necessary data monitoring systems so that medical administrators have the content needed for meaningful reviews.

Recommendation 27: That the health authorities and affiliate boards agree that when an application for specialty privileges is beyond the ability of the available medical administrative officers to evaluate, the application would be assessed by an appropriately qualified administrative officer (for example, the relevant regional or health authority department head from the health authority or another health authority if required).

Recommendation 28: That the College augment their support for the integration of provisional registrants and international medical graduates (IMG) into practice by clearly specifying the expectations of IMGs and the requirements, roles and responsibilities of a sponsoring organization and the supervisor.

BC has been and will remain dependent upon international medical graduates to provide care. The integration of these individuals into the health system must be planned and designed to allow them to achieve success in this professional transition.

One of the reviews revealed that an IMG was unaware of these expectations that the College had of him. Expectations should include:

- Awareness of the standards of the specialty to which she/he has applied.
- A determination of whether his/her training (both content and technical) is adequate for the role to be assumed.
- Willingness to take additional training and upgrade in a form satisfactory to the College and the health authority.
- Clear understanding of the evaluation process and the implications of the reviews.

The College requires a sponsor for each IMG and a clinical supervisor, usually a clinician knowledgeable in the field, who is working on behalf of the College to determine the suitability of the IMG for practice in BC. IMG's are required to attend an orientation session prior to providing services in BC. Supervisors are offered a training session that describes their role and responsibilities to the College and to the IMG. There is no obligation on their part to attend and there is no on-going supervision by the College of the supervisors' performance.

Supervision at this time is a voluntarily responsibility. Neither the College nor the health authorities provide compensation to the supervisors for their management and evaluation of the IMG.

To better support the provisional registrant and the IMG, the following suggestions are made to the College:

1. Require an orientation program for potential and current supervisors.
2. Remunerate supervisors for their work on behalf of the health system.
3. When a competency assessment is needed, base it upon the foundation put in place for credentialing and specialty privileging, and specify the details of the review and assessment of skill, knowledge and competency, including where this assessment can be performed, the criteria for successful completion and the required evidence of successful completion.
4. The IMG should have a clear understanding that s/he will receive feedback from the supervisor and that s/he has the responsibility to ask for the feedback if it is not forthcoming and to see evaluation reports that are submitted to the college.

Recommendation 29: That the College, in conjunction with other provincial regulatory bodies, develop methods for clear communication of credentials and license information when individuals apply for a licence in another jurisdiction. This would include a consistent taxonomy for describing and communicating information now implied in a certificate of standing and a standardized process to share other relevant information.

Communication of a licensee's standing when she or he transfers to another jurisdiction is generally a reliable process; however, the terms used in describing qualifications on statements of standing vary between jurisdictions. In light of new interprovincial trade agreements that may modify the degree of control the College will have over licensing individuals coming from other jurisdictions, it is particularly important that the provincial Colleges of Physicians and Surgeons use a common language to describe and share the type of license, and other relevant information. Such information could include specialty

qualifications and upgrading, limitations or undertakings, data on clinical quality, complaints, and disciplinary actions.

RECOMMENDATIONS FOR OTHER ORGANIZATIONS

Recommendation 30: That the Lower Mainland Medical Imaging complete the development of the quality plan for services that is alluded to in Services Standards and Performance Section 5.1 and 11 of the Master Services Agreement and in Appendix 2, section 2.2.

Recommendation 31: The boards of the member health authorities and Providence Health Care review Section 11 of the Lower Mainland Medical Imaging Master Services Agreement in light of the learnings from these reviews and that the boards review and approve the final Lower Mainland Medical Imaging quality plan.

Recommendation 32: That the BC Perinatal Program develop or adopt and promulgate standards for obstetrical ultrasound assessments in the first, second and third trimesters that are performed in community and tertiary facilities.

Recommendation 33: That the Ministry respond to the College with its assessment of the College's proposed bylaw changes as they pertain to the management of IMGs.

The College Bylaws describe the requirements for supervision and performance evaluation of provisional registrants and those returning to practice, however the bylaws are known to be inadequate with respect to detailing the roles and responsibilities of the sponsor and the supervisor. The Federation of Medical Regulatory Agencies of Canada (of which the College is a member) is currently working on national standards for sponsorship and supervision of IMG. When these standards are defined, they will be adopted nationally. In the interim, revised bylaws, including revision to the section managing provisional registrants, have been submitted to the Ministry for review.

Recommendation 34: That the Ministry develop funding models to support quality improvement including comprehensive retrospective reviews and performance and in-depth reviews of medical professionals. The Ministry complete the revisions of the payment schedule for medical administration positions in the health authorities.

Recommendation 35: That the Ministry of Health or delegate review the implementation of these recommendations and report to the public in September 2012.

ACKNOWLEDGEMENTS

The Patient Safety and Quality Officer for British Columbia and the review team wish to thank the individuals who were interviewed, provided documents and patiently answered our many questions. Their contribution has helped the review team understand the issues and the impact that these events have had on communities and the health system. Their input has been fundamental in helping the reviewers reach their conclusions and recommendations.

In particular, Dr. Cochrane thanks the patients and the families who took time to meet with the review teams, who shared openly their experiences and who provided clear and detailed advice on the expectations for competence of the professionals working our health system. They were forthright in their expectations of the process to be used in communications with them and with the public should events of this scale happen in the future.

ABBREVIATIONS

BCRS	BC Radiological Society
BCPSQC	BC Patient Safety and Quality Council
CPSBC	College of Physicians and Surgeons of BC
CRR	Comprehensive Retrospective Reviews
DAP	Diagnostic Accreditation Program
DIQAC	Diagnostic Imaging Quality Assurance Committee
FHA	Fraser Health Authority
HAMAC	Health Authority Medical Advisory Committee
HAMSA	Health Authority Medical Staff Administration Office
IIG	Image Interpretation Grading
IHA	Interior Health Authority
IMG	International Medical Graduate
LMMI	Lower Mainland Medical Imaging
MIAC	Medical Imaging Advisory Committee
PHC	Providence Health Care
PHSA	Provincial Health Services Authority
PRGH	Powell River General Hospital
RDG	Report Discrepancy Grade
SJGH	St Joseph's General Hospital
VCH	Vancouver Coastal Health
VIHA	Vancouver Island Health Authority

APPENDIX I

TERMS OF REFERENCE FOR THE REVIEW

Dr. Doug Cochrane Investigation into Medical Imaging Credentialing and Quality Assurance

Phase 1

Objective:

The objective of Phase 1 of the investigation is to ensure that radiologists currently practicing in BC are appropriately credentialed and experienced to interpret images generated by medical imaging modalities.

Scope:

Radiologists that read and interpret images from all medical imaging modalities are within scope of Phase 1, but the focus of Phase 1 is on:

- ultrasound,
- computed tomography (CT),
- magnetic resonance imaging (MRI), and
- interventional radiology procedures.

The scope includes images generated by health authority owned and operated sites, as well as images that may have been produced elsewhere and referred to a health authority for diagnostic interpretation.

Radiologists that work solely in Community Imaging Clinics and do not provide publicly-funded medical imaging services are not within scope.

Process:

Dr. Cochrane will gather information from each health authority, the BC College of Physicians and Surgeons, and other sources as required, about the individual radiologists including their appointment history, educational background, medical credentials/privileges, and license status.

Deliverables and Timing:

Dr. Cochrane will deliver a report on his findings by March 14, 2011, for public release.

Phase 2

Objective:

The objective of Phase 2 of the investigation is to provide recommendations to the Minister of Health Services on how the credentialing and quality assurance processes within health authorities can be improved.

Scope:

The following is within scope of Phase 2:

- A full description of the incidents where physicians lacked either the appropriate credentials or experience to interpret images, including analysis of the response by health authorities when they learned of problems, the relationship between the BC College of Physicians and Surgeons and health authorities, and the relationship between the BC College of Physicians and Surgeons and other professional and regulatory bodies in BC and other provinces.
- A review of all processes related to physician credentialing and privileges within health authorities, including the role played by the BC College of Physicians and Surgeons.
- A review of all processes related to quality assurance and peer review of medical imaging reports.
- Further issues that arise during the course of the review.

Process:

Dr. Cochrane will gather information for fact finding and analysis by working with representatives from each health authority, the BC College of Physicians and Surgeons, the BC Radiological Society, the Ministry of Health Services and other organizations as required.

Deliverables and Timing:

Dr. Cochrane will deliver a report with recommendations for the Minister of Health Services by August 31, 2011.

APPENDIX II

ADVISORS AND INTERVIEWEES

Dr. J. Mathieson

BC Radiological Society

BC Provincial Ethics Committee

BC Perinatal Care Program

Ms. P. Washington

Dr. T. Taylor

Dr. T.Theman

HEALTH AUTHORITY STAFF AND PATIENTS

ABBOTSFORD REGIONAL HOSPITAL

May 26, 2011

Three patients and family members

Dr. Spencer Lister, Chief Radiologist, Medical Imaging
Dr. Chung Ko, Program Medical Director, Medical Imaging
Dr. Andrew Webb
Dr. Nigel Murray

ST. JOSEPH'S GENERAL HOSPITAL, COMOX

May 12, 2011

Four patients and family members

M. Pontus, President and CEO
Dr. Astrope, Chair Dept. of Radiology
Dr. Wiens, Vice Chair Credentials
Dr. Fockler, Medical Director
Radiologist
Dr. R. Crow Executive VP and Chief Medical Officer
Ms. C. Mackay Executive VP and COO VIHA

POWELL RIVER

VCH – COASTAL HSDA

May 24, 2011

Dr. Dick Lupton Co-Sr. Medical Director, VCH
Dr. John Maynard Co-Sr. Medical Director & Director Risk Management, VCH
Dennis Hummerston, Operation Director, Coastal & Lower Mainland Medical Imaging

Darren Kopetsky,	Regional Director, Client Relations & Risk Management
Dr. Simon Bicknell	Director, Department of Diagnostic Imaging
Egidio Pasin,	Site Coordinator, Diagnostic Imaging
Dr. Kellé Payne,	Director, Clinical Quality & Patient Safety
Wendy Hansson	Chief Operating Officer, Coastal Community of Care

POWELL RIVER

June 3, 2011

Three families and two patients

Kevin Caul	Site Coordinator, Diagnostic Imaging
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Medical Staff

Diagnostic Staff Meeting

Lu Wuthrich	Manager, Acute Services
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Dr. Sneetab Takhar,	Internal Medicine
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Jacqueline Behan,	X-ray Technician
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Susan Dawkins,	CT Scan Technologist
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Dr. Pawel Makarewicz,	Medical Director
-----------------------	------------------

Other staff member

VANCOUVER COASTAL HEALTH

Monday, June 20, 2011

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APPENDIX III

DETERMINATION OF BENCHMARKS FOR PEER REVIEW IN DIAGNOSTIC IMAGING

COMPREHENSIVE RETROSPECTIVE REVIEW

Comprehensive retrospective reviews (CRR) have two purposes: 1) the determination of risk or danger to the health of individuals so that the risk can be mitigated and 2) the evaluation of the quality of imaging interpretations of an individual or group. CRR are risk-based reviews that focus on imaging modalities for which concerns were raised and/or when the practitioner does not have specialty qualifications or recognized competence. These reviews may involve a focused retrospective review of a sample of studies read by the individual under review to help determine the level of risk. CRR will always include a retrospective review of all studies read during a specific period.

To date, CRR results have not been published in the medical literature. Published work describing peer review processes have been developed for quality improvement and monitoring purposes and not for performance evaluation as required by the events in BC (see below). It is therefore not possible to adopt literature reported error rates and to use as a threshold for evaluation purposes.

In Canada there have been reviews of the quality of services provided by radiologists in PEI, New Brunswick, Saskatchewan and BC. These reviews have used somewhat different methodologies by all were focused on determining the interpretive discrepancy rate and whether differences resulted in patient impact. All have used some variation of the American College of Radiology categorization of discrepancies detected by a re-read of images. Adjudication of discrepancies was done when necessary.

The available discrepancy rates determined by reviews in Canada are listed in the accompanying table. The rates appear to vary with the imaging modality. The highest discrepancy rates are seen with CT scanning. There are several reasons for this: 1) CT examinations are complex examinations with large volumes of data that can be viewed in multiple ways using digital tools, 2) it is a technology that is best learned with structured training rather than through on-the-job approaches. A CRR exposes the reviewer to a strong attribution bias, which must be considered in the setting of benchmarks. This report proposes that the provinces that have done these reviews share the final discrepancy rates and that these results be used as the modality specific benchmarks for reviews in the future. Until this data is available, it is proposed that the revised ACR categorization be used and the following discrepancy benchmarks (Category 3 and 4) be used to trigger further investigation: 5% for all modalities, CT and MRI (all body anatomies) 7%.

SUMMARY OF DISCREPANCY RATES FROM BC AND OTHER JURISDICTIONS

Province	Year of Review	Modality	Significant Interpretive Difference %(ACR Category 3 and 4) ^{ix}	
BC	2011	Rad1	CT	11 (7 / 4)
		Rad1	CT Phase 1	6
	Rad2	Mammography	Not yet completed	
		CT Phase 2	Not yet completed	
	Rad3	CT	6.4 (5 /1.4)	
		Screening Mammography	Within Standard	
		Radiographs	0	
		Fluoroscopy	0	
		Mammograms	0	
		Cardiac Ultrasound	0	
		Non-cardiac ultrasound	0	
	Rad4	CT	36 (22 / 14)	
		Radiographs	3.5 (2.53 / <1)	
		Obstetrical Ultrasound ^x	-	
NFLD			Not Available	
PEI	2008	Radiographs	11	
		Ultrasound	Not Available	
		CT	25	
		MRI	Not Available	
NB	2011	Radiographs		
		Ultrasound	5.2 % overall	
		Fluoroscopy		
SA	Cypress Hills		12	
		Yorkton		
	Yorkton	Radiographs	2	
		CT	8	
		Mammography	3	
	Ultrasound	3		

CONCURRENT PEER REVIEW

There are a number of individual institutional or practice studies where discrepancy rates have been determined in studies done for quality improvement purposes. There are no published and generally accepted benchmark data describing interpretation accuracy for either general or subspecialty radiologists.

The ACR reports combined category 2, 3 and 4 discrepancy rates totalling 3%. This is in the context of a re-read of priors at the time a new study is being read. This is a voluntary system. (category 2 - 2.51% ; category 3 - 0.32 % and category 4 - 0.07%)[3]. Using a process similar to that used in Comox and Powell River, Soffa et al [4] report discrepancy rates of 3-5 % depending on the modality. In the teaching environment, surveys indicate that a miss rate of 10% is an informal benchmark [5].

APPENDIX IV

RETROSPECTIVE QUALITY REVIEW

The retrospective quality review is intended to assure quality of image interpretation and to provide support for additional training and supervised experience if needed. A health authority board or the College can commission this type of review. An individual medical staff member may request such a review. The results of the review will be reported to the department head and the health authority or College DIQAC. The Department Head will provide the results to the medical staff member and will develop, with the staff member an improvement plan.

The total number of records to be reviewed will range from 10% of the studies read in the last 6 months (1/2 day work per week) for an individual who has been providing services for over 6 months, to 20% (1 day work per week) of studies read by those providing services for less than 6 months.

With access to the clinical history as written on the original requisition, relevant priors and without access to the original report, or to any studies performed after the date of the study under review, each case will be reviewed by one or more members of the review team, who will document his interpretation and then review the original report. The reviewer assigns the report discrepancy grade (RDG). All providers with either a significant change in the discrepancy rate or whose RDG 2 and 3 exceed x%^{xi} may be subject to additional review.

APPENDIX V

DEVELOPMENT OF A COMPREHENSIVE RETROSPECTIVE REVIEW PROCESS FOR DIAGNOSTIC IMAGING IN BC

PROCESS OF THE COMPREHENSIVE RETROSPECTIVE REVIEW

The comprehensive retrospective review should be designed to evaluate the quality of a health care provider's services and to expose errors that will have an impact on the care of patients by evaluating the quality of interpretation and reporting. The review process involves re-reading the study, the generation of a new report, comparison of the reports and where there is disagreement, adjudication of the image interpretation by an additional image reading. The process is completed by obtaining updates to determine the true clinical impact on patients whose studies revealed clinically significant disagreements on review (clinical scores 2 and 3)^{xii}.

Re-reading and Reporting

A team of radiologists qualified in the modality under review will serve as reviewers and adjudicators. All "at-risk" images will be reviewed in reverse chronological order, in 3-month blocks, from the date that the concern is recognized, and until a stable monthly error rate is established or a minimum of 6 months' work has been reviewed.

One or more members of the review team review each study. The reviewing radiologist(s) does not have access to the original report, or to any studies performed after the date of the study under review but does have access to the clinical history as written on the original requisition and prior studies. The radiologist under review is not identified. The reviewing radiologist documents his/her report.

Adjudication of Reports and Classification of Discrepancies

1. Determination of Clinical Impact

As the report of an interpretation is the principle way that radiologists convey their findings to colleagues, the quality of the report including the description of findings, the discussion of relevant features that are absent, the interpretation and recommendations need to be all assessed. An adjudicator compares the original and new report and applies a report discrepancy grade (RDG) using the scale below.

RDG 0	No discrepancy between the reports.
RDG 1	No clinically significant discrepancy between the reports.
RDG 2	Discrepancy between the two reports, which may potentially be significant depending on the patient's clinical situation.

RDG 3a	Discrepancy between the two reports, which almost certainly is clinically significant, and is likely to alter follow-up and/or treatment.
RDG 3b	Discrepancy between the two reports, which almost certainly is clinically significant, and is likely to alter short-term follow-up and/or immediate treatment.

Reports of studies showing concurrence (RDG 0, RDG 1) require no further action. Reports showing disagreement in image interpretation (RDG 2 and 3), require adjudication.

2. Image Interpretation

The quality of image interpretation is an important aspect as it points to areas of professional skill and competence. Deficiencies in feature recognition and interpretation can be described and used as the basis for an individual’s remediation and for the development of a library of difficult cases and common errors that can be used for teaching purposes. Image review is performed for all studies categorized as RDG 2 or 3 by adjudication team. When the adjudicators are unsure of a final rating, additional subspecialists are to be consulted and the images read by these experts. An image interpretation grading (IIG) is applied to the studies relative to the original interpretation, as follows:

IIG 1	Concur with interpretation
IIG 2	Difficult diagnosis, not ordinarily expected to be made
IG 3	Diagnosis should be made most of the time
IG 4	Diagnosis should be made almost every time—misinterpretation of findings

Determination of Clinical Impact

The primary care providers for all patients having a RDG of 2 or 3 will receive follow up by the review team and be asked to describe whether there had been a change in diagnosis or treatment as a result of the discrepancy and what specific actions were required. The primary care providers will also be asked to categorize the patient’s management as:

- No change.
- Diagnosis made by other means and patient is in treatment.
- Patient referred for further diagnosis and treatment.
- Patient demise - expected.
- Patient deceased due to consequences related to image interpretation.
- Patient’s condition unknown.
- Other.

Notification of Physicians

Notification that a review is underway should be issued when a comprehensive retrospective review is known to be required. Each ordering (and most responsible) physician should be notified for each study he or she ordered.

The notification will:

- Specify the study type (modality) that is being reviewed;
- Indicate whether the study should be repeated if the original is not of adequate technical quality;
- Provide an indication of when the review report will be available; and
- Recommend review of the patient’s care plan if (s)he is not following the expected clinical course.

Method of Notification of results to be sent as soon as the case review is completed:

Category RDG 0 and 1	Notification by fax or email indicating that the study has been reviewed and that the review and original interpretations agree.
Category RDG 2 and 3	Immediate notification by email and fax + registered letter, that 1) the study is undergoing further review and 2) the results of the review may be of clinical importance to the patient’s management. The notification will include an estimated date for issuing the review report.

When the category 2 and 3 results are known:

- Direct and immediate phone or personal communication of the results to ordering/most responsible physician followed by registered letter with the explanation of the review process and new report.
- Confirmation of receipt of information.
- Confirmation that the patient was contacted by the ordering physician.
- Confirmation that the patient has been contacted by a member of the review team.
- Feedback on clinical management changes due to change in interpretation of the study under review (see above - *Determination of Clinical Impact*).
- Direct disclosure discussion with patient/family for RDG 3.

ACTIONS TO BE TAKEN BASED ON THE IIG

IIG 1	No further image review was undertaken.
IIG 2	Potential clinical significance is judged based on the imaging findings and clinical information. If there is agreement between the original reporting radiologist and the adjudicator as to the findings, an addendum or new report is issued by the original reporting radiologist. If there is disagreement, the adjudicator issues a new report describing the image findings and includes a statement that this report is the result of an adjudicated review. The cases are added to the error count.
IIG 3	An addendum or new report is issued by the reviewers and case added to error count, as per IIG2.
IIG 4	An addendum or new report is issued by the reviewers and case added to error count, as per IIG2.

Following removal of identifying data, IIG 3 and 4 cases should be provided to professional bodies to form

a basis for their continuing professional education programs.

Notification of Patients

Ideally this is to be done by the primary /most responsible physician however in their absence, this responsibility falls to the health authority. The health authority also carries its own responsibility to disclose if harm has occurred

Notification to Public

The public should be informed that a review is underway and the expected time line for the completion of the review. Patients should be informed that their own studies are under review and the expected timeline for communication of their own review results and how and who will provide the results of the review for them. They should be asked to direct questions to their family physician and to the health authority (through a process defined for that purpose). The principles that should underpin the management of adverse events and disclosure that affect many are described in more detail in Appendix VIII.

Patient Notification

Category RDG 0	Notification by letter indicating that the review confirms the original report
Category RDG 1	Notification by letter indicating that the review confirms the original report
Category RDG 2 and 3	Direct and immediate communication of the results to patient by the physician and/or health authority. Options include visit by home care nurse or physician, request for visit in office; followed by registered letter with the explanation of the review process and new report. Disclosure discussion with patient/family as soon as can be arranged.

If the patient was deceased, the closest living relative or responsible person is to be notified using the same process. If there is no most responsible physician, the health authority assumes the role to notify.

APPENDIX VI

RELATIONSHIP OF THE HEALTH AUTHORITIES AND THE COLLEGE OF PHYSICIANS AND SURGEONS

These diagnostic imaging reviews have raised questions regarding the relationship of the health authorities and the College of Physicians and Surgeons of BC (the College). The health authorities and the College have unique mandates, are regulated by different legislation but share the responsibility to assure the quality of services provided by medical professionals practicing in the health authorities. Each organization has specific mechanisms by which they review the quality of services and affect change when services are unacceptable. These recent quality failures demonstrate the requirement that the health authorities and the College work in collaboration to assess physician competence and improve performance assessment.

This document describes a proposal whereby the College and the health authorities can share information on the quality of physician practices and performance so that both can ensure optimal care for patients and support for their members/providers while retaining the confidentiality of this information. This proposal assumes that the health authorities will establish, fund and jointly govern the BC Health Authority Medical Staff Administration Office (HAMSA Office). This office will house practitioner records and will be responsible to oversee and manage standardized processes for appointment and privileging for all health authorities, including Providence Health Care and other affiliated health care facilities. This “office” and its “information system” (Health Authority Medical Staff Administration System - HAMSAS) will serve as a single point of contact for the College(s) and the health authorities. The office will support each health authority with reports, analysis and documentation for their board credentialing processes, reviews, and other activities as approved. The health authorities retain control over their medical staff members and act as data stewards with respect to physician data. An example of such a system already in operation in British Columbia is the BC Patient Safety Learning System (PSLS).

The activities of joint interest to the College and the health authorities include:

1. Setting of credentialing and privileging standards, including the requirements for specialty privileging;
2. Granting of specialty privileges based on such standards;
3. Bilateral sharing of the results of reviews or audits undertaken to assess physician performance;
4. Sharing of recommendations arising from in-depth reviews performed by the health authority with the College where such recommendations reflect the quality of physician services;
5. Sharing of licensing information; and
6. Adequate mentoring and supervision of provisional licensees, those returning to practice, and any other members of the College requiring supervision of their clinical activities.

The following are components for consideration:

1. SETTING CREDENTIALING AND PRIVILEGING STANDARDS

The College define credentialing standards for BC physicians based on the competency standards established by the Royal College of Physicians and Surgeons of Canada (RCPSC), the Medical Council of Canada (MCC), the College of Family Physicians of Canada (CFPC) for postgraduate training and successful qualification. These competency-based standards are updated as they evolve.

The College and the health authorities will jointly define specialty qualifications (procedure, technique and services). Specialty qualifications are required by individuals if they are to provide services that have been deemed to require special competence through training and/or experience. These qualifications would be over and above the basic qualifications required of the College for licensure and the qualifications and credentials required by the health authorities for core privileges. Current examples of this specialty qualification include interpretation of colon CT, obstetrical ultrasound, and interventional radiologic procedures.

The specialty qualifications would be reviewed and revised by a joint College and health authority committee as the graduate competencies, as defined by the RCPSC or CFPC change, when new technology is introduced into the clinical practice environment, or when quality reviews suggest skill upgrading is necessary. The health authorities and the College will establish the standards by which specialty qualification can be obtained and maintained. The health authority can then use the specialty qualification requirement as the basis for their decision to grant specialty privileges to an individual physician. When privileges are granted, the College is notified of the core and specialty privileges granted to a licensee.

2. HEALTH AUTHORITY APPOINTMENT AND GRANTING OF PRIVILEGES

The College regularly provides the details of the individual's license, any specialty qualifications and any limitations or undertakings to the HAMSAs office. The health authority reconciles the College data with other factors it considers in the (re-)credentialing process including the in-depth review if applicable, service and human resource plans. If the individual does not hold the specialty qualifications required to provide services, the health authority must determine, based on their clinical needs, whether to refuse privileges or to grant temporary privileges subject to the individual meeting the requirements of specialty qualification within a defined time period[6]. This process would also apply to locum appointments to insure the locum has needed skill set as the individual he/she is replacing

3. INFORMATION SHARING

A concurrent and longitudinal record of competencies underlying the qualifications granted by the RCPSC, MCC and CFPC is to be maintained by the College. This record is updated as these competencies evolve. Such modification will trigger the College to review each member to whose practice the modifications may

apply. The information holds of the parties include:

THE COLLEGE RETAINS THE FOLLOWING INFORMATION FOR EACH PHYSICIAN MEMBER:

1. The information provided to the College at the time of the application and updated from time to time regarding business arrangements (for example corporation status).
2. Competencies based on qualifications present at the time of licensure.
3. Requirements for upgrading determined by review of changes in competency standards relevant to the member's practice domain.
4. Documentation from the health authority and the member as to whether the member's scope of practice (privileges) require this upgrading and if so, when and how the upgrading will occur.
5. Documentation suitable to the College and the health authority describing the content of the upgrading and confirmation that the upgrading has been completed.
6. The health authority provides the core and specialty privileges granted to a licensee.

INFORMATION PROVIDED TO HAMSA BY THE COLLEGE FOR EACH PHYSICIAN

The plan proposes that the following will be provided to the HAMSA by the College:

1. Current license with undertakings and limitations if any.
2. Current privileges (core and specialty) in all health authorities where the individual has privileges.
3. Reconciliation of competencies present at the time of licensure.
4. Requirement for upgrading when the competencies change.
5. Evidence of satisfactory upgrading where necessary.

INFORMATION HELD BY HAMSA ON BEHALF OF THE HEALTH AUTHORITY FOR PHYSICIANS

1. Information provided to the health authority at the time of application and updated as defined by the medical staff rules for annual reappointment, ad hoc or regular in-depth review.
2. Individual longitudinal record - annual reappointment – declarations, certification of completion of courses such as safe medication, hand hygiene, infection control, radiation safety, privileges (core and specialty), upgrading planned or completed.
3. Results of regular (annual) reviews by the Department Head, VP Medicine and Credentials Committee.
4. Documentation from the health authority board informing the provider of privileges including restrictions (type, location, service populations), upgrade requirements, planned reviews/actions.

INFORMATION PROVIDED ANNUALLY TO THE COLLEGE BY HAMSA FOR EACH PROVIDER

1. The core and specialty privileges granted to a licensee, updated when changed that are provided to the health authority.
2. The results of reviews or audits undertaken to assess individual clinical quality.
3. Recommendations arising from in-depth reviews performed by the health authority where such recommendations affect the quality of the physician services.
4. Individuals whose privileges exceed their credentials.

4. CONSENT TO SHARE PHYSICIAN DATA

Physician consent to share information between the College and the Health Authority Medical Staff Administration System will be obtained as part of the initial application to membership on the medical staff. This consent will be in effect, for a period of one year and renewed annually at the time of re-appointment. When personal information is exchanged between the College and the health authority, the physician will be notified and provided with a copy of this information.

In summary, as mentioned above, information that could be shared between the health authority and the College may include:

1. Qualifications – core and specialty competence based on the College credential review and license.
2. Limitations or undertakings with regard to the license and the scope of services the individual is authorized to provide in BC core and specialty privileges.
3. Date of last in-depth review and recommendations as they apply to the practice of medicine.

A preliminary review of the legislation governing the ability of the College and the health authorities to share information regarding quality of physician practice suggests that amendments may be need for the *Health Professions Act* (HPA), either of section 26.2 or 32. It is recognized that the College board can choose to release information under section 53(1)b if it is deemed the release of information to be in the public interest. Section 51 of the *Evidence Act*, which governs the health authorities, is not thought to be an impediment to information exchange so long as the appropriately constituted quality committee considers and agree that it is appropriate to make the disclosure.

The health authorities and the College must review their respective legislation that governs information sharing to ensure that there are no impediments to the bidirectional exchange of information regarding the quality of practitioner performance and if barriers exist, that the responsible body addresses them.

5. HAMSA OFFICE

The HAMSA Office would be responsible to the health authorities and therefore representatives from the health authorities will govern the HAMSA Office. The following committees are suggested to supervise

governance and operations:

- Steering Committee – health authority Chief Medical Administrators and College by invitation.
- Working Committees – health authority Medical Staff Directors.

These committees would be responsible for:

1. oversight for the operation of the HAMSA Office and its information system;
2. defining and updating standardized appointment and re-appointment processes for all health authorities;
3. providing reports to the department head, the HAMAC and to the credentials committees of the health authority boards;
4. providing reports to health authority boards;
5. providing direct support for senior medical administrators within the health authorities;
6. acting as a liaison with the College; and
7. helping the member health authorities implement effective performance assessment processes.

The HAMSA office will be led by a Provincial Director and staffed as needed to address the workload needs of the health authorities. The Director, who is responsible to the Steering / Governing committee, will manage the HAMSA Office. Staff of the office will be employees of one of the health authorities (to be determined by the steering committee). The HAMSAS will be developed for the purposes of the HAMSA Office. The health authorities will fund the operations of the office and the information system.

APPENDIX VII

HEALTH AUTHORITY DIAGNOSTIC IMAGING QUALITY ASSURANCE COMMITTEE

SUGGESTED TERMS OF REFERENCE

Where health authorities do not have a Diagnostic Imaging Quality Assurance Committee (DIQAC) in place, the following are suggested terms of reference to facilitate the committee's establishment.

PURPOSE

The Diagnostic Imaging Quality Assurance Committee (DIQAC) is designated by the health authority board to monitor and report upon the quality of care provided by the diagnostic and interventional imaging services of the health authority. As with all board-designated quality committees, the DIQAC's deliberations are subject to Section 51 of the *Evidence Act*.

The committee will raise awareness of quality of care issues within the organization.

The DIQAC provides support and participates in the creation of a safety culture by raising awareness of patient safety issues.

The DIQAC supervises all aspects of diagnostic imaging quality assurance including those aspects related to equipment, radiation and magnetic field safety, technical performance of imaging and interventional studies and procedures and image interpretation and communication.

The committee acts promptly to rectify clinically relevant interpretive discrepancies.

The committee initiates quality improvement projects in areas identified as having the need, using established tools and models for improvement.

The DIQAC reports to the medical advisory and administrative management structures in the health authority and to any inter-health authority governance structures that are in place (from time to time).

ORGANIZATION OF THE DIQAC

The Committee membership will be drawn from administrative, technical and professional staff of the department (program). Where applicable, the LMMI will join the membership. The health authority department responsible for quality and patient safety will provide administrative support. Guests are invited to provide clinical input regarding quality and timeliness of services provided. Individual case reviews (discrepancy reviews) should involve or seek input from the referring providers.

The committee is organized by subspecialty^{xiii} and reviews could happen within each subspecialty area.

DUTIES

1. To study, investigate, evaluate and report on the quality of diagnostic imaging and procedural services provided by the health authority.
2. To ensure that quality assurance, improvement, utilization, and risk management systems are in place and functional for the department (program) and integrated services.
3. To undertake formal review of quality issues (technical and interpretive) that are revealed through regular monitoring, quality control, complaints or other methods and to implement recommendations.
4. To regularly receive, review and monitor information, including quality assurance and surveillance reports related to:
 - a. equipment safety – radiation and magnetic;
 - b. patient safety and staff safety in the workplace;
 - c. technical performance of imaging and interventional studies and procedures;
 - d. image interpretation and communication including:
 - i. peer review – concurrent and retrospective, second opinion, that are in compliance with provincial standards (DAP and College). Where necessary to act or delicate adjudication responsibilities;
 - ii. discrepancy rounds; and
 - e. service utilization.
5. To identify priorities related to quality assurance and improvement, utilization and risk related initiatives and to sponsor on-going projects dedicated to improving identified processes and outcomes.
6. To refer concerns regarding the quality of profession performance to the department head and /or administrative officer.
7. To review all process and system failures. To review and trend the number and types of critical incidents as reported by staff, patients and others.
8. To define, supervise and act upon proactive risk assessments.
9. To undertake patient safety culture surveys and to improve in areas found to be deficient.
10. Supervise preparation for Diagnostic Accreditation Program reviews.
11. Supervising the remediation of deficiencies and acting upon recommendations from accreditation and other reviews.
12. To report regularly and make recommendations to the MAC regarding quality, utilization, risk system and the activities of the committee(s).
13. The chair of the committee will regularly liaise with the senior medical administrator.
14. Ensure that recommendations approved by MAC are acted upon in a timely and on-going fashion,

with regular reports to the MAC.

15. To receive reports from supervisors of new graduates, international medical graduates and locums including those that are supervised as required by the College.
16. Ensure the supervisor discharges her responsibilities as required by the health authority and the College.

APPENDIX VIII

PRINCIPLES AND FRAMEWORK TO SUPPORT THE MANAGEMENT OF ADVERSE EVENTS AND DISCLOSURE THAT AFFECT MANY

CONTEXT

In the recent past, many patients in every province in Canada and every health authority in BC have faced an event or series of events where injury or increased risk of injury has occurred because of medical error. The public's right to transparency, accountability and to safe care obligates providers and governors to disclose information to patients about events that have, or could, affect their health and risk of harm. Failure to disclose such information reflects upon the institution, providers and the health system as whole. Public confidence is undermined.

A profound shift has taken place in the last decade; patients' right and need to know now supersedes institutional or provider self-interest. Disclosure is the default position to be taken by the health system in BC when such events occur.

EXAMPLES OF AREAS AT RISK OF ADVERSE EVENTS THAT AFFECT MANY PEOPLE

Over the past several years, adverse events that affect many patients have occurred in Canada in each of these areas. Unfortunately, similar events have repeated in different jurisdictions and at different times.

- Diagnostic testing; laboratory or diagnostic imaging.
- Sterilization/decontamination breaches.
- Information system failures and security breaches.
- Epidemics, water quality system failures and other public health issues.
- Devices failure.
- Health care provider quality.

PRINCIPLES GUIDING DISCLOSURE

The sharing of information (disclosure) is justified, based on the professional, ethical and moral obligations of health care providers. It is further reinforced by the values that underpin our public health system: transparency, respect, accountability and a commitment to the principles of social justice. Methods for assessing the probability of occurrence, event severity and amenability to treatment are useful in risk assessment, defining investigations needed and for formulating communication plans. However, they should not determine whether individual and public disclosure should take place.

In principle, the patient and public's "need to know" trumps institutional self-interest. To disclose should be the default position taken when adverse events occur because of the provision of health care in BC

"Risks to the institution are associated with disclosure [but] they are outweighed by the institution's obligation to be transparent and to rectify unanticipated patient harm"[7].

"Institutions should proactively ... disclose all large-scale adverse events to affected patients unless a strong, ethically justified case can be made not to disclose"[7].

"Disclosure promotes a culture of safety where learning from adverse events and improvements to practice and the health care system are valued" [8].

"Clinicians and organizational leaders are to work together to ensure that appropriate disclosure to patients or their personal representatives is a routine part of the response to a harmful or potentially harmful adverse event" (Veterans Health Administration directive on disclosure of adverse events to patients)[9].

ETHICAL AND LEGAL FOUNDATION

The moral, ethical and legal requirements of informed consent form the basis for the social relationship (contract) between the provider and health authority and the patient or client. Disclosure is a part of this relationship. The public trust accorded health care professionals and institutions is dependent upon effective self-regulation and openness [10]. "Timely and effective disclosure can enhance patient and public trust" [7].

Communication between the provider, health authority and patient or client establishes a social contract between the parties that includes the sharing of information, in a form that the patient understands, about:

- The health issues facing the patient and their progression without treatment.
- Treatment options and their benefits and risks.
- Commitment to share new information including real and potential errors, mistakes, and complications, now or in the future.
- Commitment to honour the relationship until the patient or the condition requires that it be changed.

"Patients have the right to make their own decisions about health care. This is the basis for informed consent. The right to know about the care that has been provided and the outcome(s) of that care extends the process of informed consent to include disclosure of harm"[8].

When unexpected events occur, whether they are preventable or not, the obligation exists upon health care professionals to provide complete communication in a fashion that patients can understand. "The disclosure policy... is written from the perspective of what a patient would want and reasonably expect to learn when he or she experiences harm while receiving health care"[8].

When events affect many people, disclosure to the public in addition to disclosure to individual patients is required. Canadian law imposes a duty of care on providers to inform patients of errors that occur during

their care, if a reasonable person in the patient’s position would want to know about the mistake” [7, 11]. These events represent a breach of trust in the medical profession and in the health care system. They impact patients in different ways; the most important is that the error, particularly a missed diagnosis, may destroy hope.

“Canadian case law requires that healthcare facilities engage in timely review to identify patients who may be at risk and employ effective communication strategies to alert them” [11]. Although this is not yet the case in British Columbia, legislation in Manitoba and Quebec requires that patients be informed of “critical incidents” or “accidents” (respectively).

The Canadian Medical Association’s Code of Ethics (2004) requires disclosure to patients of harm [14]. BC’s *Apology Act* states that an apology does not constitute an expression or implied admission of fault or liability. Section 51 of the *Evidence Act* permits the facts of a patient’s care to be disclosed. The discussions of a section 51 committee cannot be disclosed.

“There is no consensus about the need to disclose near miss incidents” Because patients are not physically injured, they may not benefit from the disclosure and may in fact be psychologically harmed [7].

PRINCIPLES UNDERPINNING THE DISCLOSURE PROCESS

TIMELINESS OF DISCLOSURE

When unexpected events occur, whether they be preventable or not, the obligation is to provide complete communication to patients. For events that affect many patients, disclosure by the organization, to the public in addition to disclosure to the individual may be necessary.

Error or harm must be disclosed in a timely fashion, even before its’ full impact is not known [15].

Communication (disclosure) with the patient (or authorized substitute decision maker) must occur if:

- there has been harm;
- there is a risk of potential future harm (serious health consequence);
- there is a need to change the clinical care or monitoring plan for the patient (management);
or
- there is a change to the risk and understandings that were agreed upon as part of informed or implied consent.

NOTIFICATION OF PATIENTS

The method of communication with the patient must be informed by the severity of the event, the risk to the patient and the need to make treatment decision(s).

All patients whose care is (potentially) affected should be notified so that they are aware of the fact that their care/monitoring/treatment is under review. Although it is often thought that notification at this stage will be distressing, patients interviewed in follow-up to the diagnostic imaging review, indicated without reservation that they expected to be notified early, even before the details of the event and the risks for themselves were known. They further indicated that they expected that public notification would

be followed, within a timely interval (weeks), with details relevant to their individual risk including immediate risk mitigation strategies, the need for additional or repeat investigations and actions to be taken to protect themselves or others from risk of exposure to a similar event. They also wanted to be informed of future actions that will be taken to prevent a re-occurrence of the event.

Patients are clear that the disclosure to them individually must use language that is appropriate to their understanding and that written communications to them be comprehensive to all events relevant to them. For example if an individual has undergone multiple tests and they are all under investigation, the communication to the patient should include the results and implications for all tests.

Disclosure is provided to all patients including minors or deceased persons through those authorized to exercise the patient's rights under law. Personal communication is preferred over other methods of communication. Where it is not possible to communicate personally individual contact may include the following:

- Notification by phone followed by a registered letter.
- If no phone contact is established, then by letter.
- Mailing of letters should be timed to increase the likelihood that the maximum number of patients receives notification at the same time.

COMMUNICATION WITH THE PUBLIC

In the majority of circumstances, the disclosure process begins with a personal conversation with the patient when it is known that an individual is at risk as a result of the event. However, there are times when communication with the public may be necessary prior to individual patient communication, for example when:

- The impacted clients or patients cannot be identified and the public is asked to help the health system identify patients at risk.
- Incorrect information is circulating in the public domain that has potential to cause harm to patients or to the institute's or provider's reputation.
- The scale of the event is so large that timely communication with individual patients is not possible and rapid, mass communication is in the patients' and public's best interest.

The public is aware that investigations need time to be done correctly. Patients interviewed requested that the health authority communicate directly with the public and not leave communication and speculation to the media. They requested that the health authority publish regular updates describing the process of the review and the results found. This activity is expected to occur concurrently with disclosure to individual patients, as their risk is known.

The health authorities must provide mechanisms for individual members of the public to communicate to them. Web sites, hotlines, and primary care physicians serve this important role.

COMMUNICATION WITH THE PATIENTS' CARE PROVIDERS

When a patient or member of the public has been made aware of the event, it is likely that she/he will seek further information related to their care from their specialist or their general practitioner.

A formal communication plan is needed for care providers as they assume a critical role in communicating to patients on behalf of the health system. Prior to patients being notified, either individually or through the media, the patient's primary care provider should be informed. She/he requires information describing the event, the implications for patient care and the steps that they must take on behalf of their patients to facilitate diagnosis and treatment. They need to be aware of the follow-up information that they are required to provide to the health system. Clear communication with the patient's care provider is essential if a change is being recommended to the patient's care plan so that the needed care can be facilitated.

As with the public, regular updates as to the process and results needs to be provided to care providers who continue to interact with patients.

COMMUNICATION WITH THE MINISTRY OF HEALTH

The health authorities have a responsibility to communicate amongst themselves, with the Ministry of Health and with the public in the face of events that put patients at risk or have resulted in harm. At the present, there are several avenues for such communication with the Ministry, including the Offices of the Deputy and the Assistant Deputies, Clinical Care and Patient Safety Branch, the Divisions and Government Communications and Public Engagement. Each of these bodies has specific responsibilities and information needs. The Ministry would:

- ensure that patients are informed of the event and that they and their contacts are protected from further harm;
- ensure that patients receive the medical care required as a result of the event;
- ensure that risks known to be present in one health authority are made known to other authorities; and
- to assist a health authority, or if applicable to develop and execute coordinated plans for risk mitigation, investigation and communication to the public.

During the diagnostic imaging review, early informal communication between facilities, health authorities and the Ministry did not raise the awareness of the issue of diagnostic misinterpretation to a level necessary for earlier intervention. It is recommended that the public's interests and safety would best be served if health authority communication with the Ministry channelled through a single division. This division would be responsible for coordinating communication with other Ministry groups. In this way, the health authority focus of the on the investigation would not be deflected by multiple requests for information and updates from various internal bodies in the Ministry.

THE DISCLOSURE PROCESS –PROCESS GUIDANCE

Based on the recent experience in BC with adverse events affecting many people, and the principles noted previously reflecting a commitment to openness and transparency, it is recommended that the Ministry, the health authority quality/risk officers and the provincial ethics committee develop a policy document for dealing with such events in the future. Areas to be considered include:

1. The description of a multidisciplinary team composed of clinical, epidemiological, ethical, administrative, communications, legal and other experts, including a patient experience expert, to consider disclosure in a structured way and to manage the complex processes of the review and communication to all parties.
2. The situational assessment of the event to determine its extent and the required look-back and case identification process(es).
3. The roles to be played by other provincial resources organizations and bodies.
4. The structure and timing of the communication plan for the public, the care providers who are assumed to have role in communicating with patients, for patients and family members including those in special situations (deceased patients, minors, specific sensitive diagnoses) and other responsible parties (regulators, insurers and others). Such a plan should be based on known facts and not speculation and should respect the confidentiality of individuals and the process as required by legislation.
5. Assessment of the risk to individuals and the likelihood of the event happening to an individual if this is not known. This would include as assessment of scientific knowledge as well as qualitative data that may be relevant to the assessment.
6. Tactics needed to protect patients, to assess new medical needs including additional investigations and treatments and to provide follow-up as needed to ensure that the appropriate management is enacted.
7. Definition of a formal investigation including the process for selecting an external reviewer if required, and timeline to determine contributing factors and to make recommendations to prevent similar events in the future.
8. The processes to be used to follow up with patients, families, the health authorities and the public regarding actions taken and changes implemented.
9. The effects of the event on third parties including health care staff and providers.
10. The payment for external investigation, professional review and case identification expertise, disclosure and notification support and other incurred costs.

APPENDIX IX

PHYSICIAN PERFORMANCE ASSESSMENT

Physicians individually and the medical profession as a whole must be accountable for sustaining and enhancing physician knowledge, skills, attitudes and competencies over the lifetime of their practices. Reviews are a method to demonstrate this accountability and they provide confidence in the integrity of self-regulation within the profession.

Reviews of clinical quality foster organizational, individual, and team accountability for overall quality of professional practice. Where teams deliver services, reviews help individual professionals understand their roles in the success or failure of the delivery of the service.

Each of the health authority boards through their medical staff rules defines the components of the review process for medical staff members. Typically there is an annual review prior to the recommendation to the board for reappointment and an in-depth review less frequently. The intent of in-depth review is quality improvement and career development. The process involves an achievement review, which provides those being reviewed with feedback about their medical practice through the eyes of those they work with and serve. The review also includes a self-assessment and is designed to be educational and potentially corrective. In-depth review will be performed in accordance with disclosure safeguards found in Section 51 of the *Evidence Act*.

The degree of detail specified for these processes varies amongst the health authorities. For example, one health authority describes their review process at a high level (VCH):

Every 5 years all members of the Medical Staff will undergo an in-depth review. It will be completed by the respective department head with the assistance of the HAMAC Credentials Committee and senior medical administrators.

The in-depth review may consist of the following domains:

1. Interpersonal and Communications Skills
2. Professionalism
3. Psycho-Motor Skills
4. Cognitive Skills
5. Patient Outcomes

While another specifies the components of the review process in more detail including (PHSA):

Input from non-medical staff co-workers, medical colleagues, and members of clinical or academic teams,

who will assess attributes of the medical staff member's performance in relation to clinical knowledge and skills; communication skills; psychosocial management; office management; and collegiality.

The in-depth review may include any or all of the following:

1. Clinical documentation with an assessment of the quality, accuracy, and timeliness of reports.
2. Input from patients to determine their view of the medical staff member's professional attitude and communication skills (for those specialties where appropriate).
3. Review of current Curriculum Vitae and a personal statement from the medical staff member outlining goals and objectives, including successes challenges.
4. Complications and mortality review.
5. Review of incident reports and complaints.
6. Continuing education and additional competence training.
7. Procedural privilege evaluation, including frequency of procedures done.
8. Direct observation of procedural and assessment skills.
9. Interview or communication with members of affiliated organizations and regulatory bodies.
10. Utilization/quality assurance information.

In both of these examples, the components of a review are listed but not required.

The departmental/program structures within which these responsibilities are discharged vary across the health authorities. The education and training of medical leaders responsible for these reviews has usually been "on-the-job training" or self-taught.

In-depth reviews are in the medical staff member's interest if they are focused on the individual's clinical quality and career development. They are also in the interest of the health system as they create the opportunity to align medical providers with the strategic directions and clinical service needs of the health authority. Boards assume that the quality reviews are being completed and are the foundation of the recommendations made for reappointment and privileging. It is the expectation of the public that evaluations are being conducted and that they are designed to assure that providers have demonstrated the expected competencies to provide quality care.

The responsibility to perform reviews lies with the department/program head in a discipline area. Conducting a review is a learned skill, it is not an informal conversation and it is not a quasi-judicial procedure. To make these reviews valuable to all parties, those responsible for conducting the reviews must have the interpersonal, technical and social skills to do them properly. Such skill development has generally been informal and on-the-job. Department/program heads do not, in general, have the tools, content or standards upon which to base these discussions or made evaluations. In departments, with few members, other relationships can interfere with the department head executing and the member benefiting from the review

PURPOSE OF PHYSICIAN PERFORMANCE ASSESSMENTS

The assessment of physician performance is to provide the foundation for performance management and career development, and is required to:

1. Identify those physicians whose performance is consistently excellent.

2. Identify opportunities for any physician to improve their own competence in the delivery of patient care, where such is needed or is declared by the individual[12, 13].
3. Clarify diversion of physician's goals from those of the health authority.
4. Provide follow-up/initiation of improvement plans required of the professional to address evolving needs of the organization(s). Such plans may have been required by the College, the health authority or the faculty.
5. Create opportunity for discussion of individual needs and future plans and how these may affect the organization (department).
6. Review the organization's support of agreed to commitments.

BEST PRACTICES IN REVIEWS FOR PHYSICIANS

1. Develop a culture of accountability within the organization that is expected of all professionals, management and staff.
2. Align organizational priorities with physician / professional manpower plans (recruitment, retention and succession) and physician performance.
3. Use the opportunity afforded by the assessment to address needs of the organization and the physician.
4. Monitor for exceptional practices that will allow the organization to build its strength to provide services (clinical education and or research) in BC or world-wide.
5. Monitor for "sentinel events" and bring patterns of recurring or clustered problems to the Department Head's attention in a timely way.
6. Send the most sensitive peer review cases to an independent, often external, review organization.
7. Utilize a quality review or other committee/panel structure to make final recommendations based on the results of the assessment – either to recommend.
8. Opportunities for changes in the organizational strategic direction or for the imposition of limitations on privileges.

FORMAL IN-DEPTH REVIEW

In support of the direction provided by the medical staff rules in each health authority, the following is a listing of the components of a rigorous in-depth review.

A. Background Documents Provided by the Member

- Current employment agreement, contract or letter of appointment
- Current curriculum vitae
- Self-evaluation report based on actions arising from last review (goals and objectives), and overall perception of performance including successes & challenges (Personal development plan)
- Continuing Professional Development, including MOCOMP/MainPro hours & updates specific to departmental/program requirements
- Recertification examination results

B. Multisource Feedback on the Members Performance Provided by the Health Authority^{xiv}

- 360 degree reviews to include questions regarding transfer of care between physicians
- Peers

- Colleagues
- Patients
- Organization's leadership input - organizational requirements in the career plan and performance to date.
- Interview or communication with members of affiliated organizations and regulatory bodies as needed

C. Quality Monitoring and Improvement Provided by the Health Authority

- Peer review
- Complications & mortality review (discrepancy meetings)
- Review of incident reports & complaints
- Clinical audits of own and group practice regarding special outcomes
- Proficiency Reviews - direct observation of procedural and assessment skills,
- Utilization/quality assurance information

D. Performance to Organizational Strategies Provided by the Health Authority

- CCM group performance
- NSQIP individual performance if applicable

E. Compliance with Health Authority Policies and Procedures Provided by the Medical Staff Office

- Inpatient & outpatient clinical documentation with an assessment of the quality, accuracy, and timeliness of reports
- Compliance with policies / completing education modules
- Medical staff bylaws and rules
- Code of conduct policy
- Respectful workplace policy
- Disclosure and reporting policy
- Infection control
- Safe prescribing
- Hand hygiene
- Orientation manual
- Computer orientation
- PSLS orientation

PERFORMANCE INDICATORS PROVIDED BY THE HEALTH AUTHORITY

To inform the reviews discussion of clinical quality, the health system must provide evidence of both process and outcome evidence. NSQIP and CCM will form the basis of this as the data is being collected for quality improvement purposes. In areas where structured quality measurement programs are not in place, the following indicators have been found useful in other jurisdictions to improve clinical services,

For Cognitive Specialties

LOS based on the five most frequent disease entities or case mix groups (CMGs) for the division in which the member does the majority of his work
Infection rates; chest, blood stream, urinary tract
DVT/PE acquired after admission to an inpatient unit
Risk adjusted mortality (HSMR only available at the hospital level),
30 day mortality
Unexpected deaths defined as:
Unexpected inpatient deaths
Death during elective/invasive procedures
Deaths within 72 hours of procedure or discharge
All pediatric deaths
Deaths secondary to:
Medication reaction
Blood transfusions
Inpatient accident e.g. fall
Acquired hospital infection causing death
Procedure volumes
Admission for chronic conditions that could be managed in primary care
Rate of ambulatory sensitive conditions
Adverse events (through PSLs)
Patient satisfaction – Patient Care Quality Review Office, informal communications
Complaints/compliments (through Patient Care Quality Office)
Medical staff bylaw/rule compliance
Response to pages
Failure to provide adequate coverage
Failure to provide adequate handover and transfer of care
Failure to see patients in a 24 hour period
Completion of records
Other Bylaw issues
Discharge issues
Timeliness
Utilization data
Pathology testing
Radiology imaging requests
Rate of readmission within 30 days for same diagnosis
Admission for chronic conditions that could be managed in primary care
Waiting times for the next urgent and the third next elective consultation

Procedural Specialties Indicators

NSQIP data at department and individual level for surgical specialties
LOS based on five most frequent disease entities or case mix groups (CMGs) for the division in which the member does the majority of his work
Infection rates
DVT/PE acquired after admission to an inpatient unit
Risk adjusted mortality (HSMR only available at the hospital level),
30 day mortality,
Unexpected deaths
Unexpected inpatient deaths

Death during elective/invasive procedures
Deaths within 72 hours of procedure or discharge
All pediatric deaths
Deaths secondary to:
Medication reaction
Blood transfusions
Inpatient accident e.g. fall
Acquired hospital infection causing death
Procedural complication causing death
Procedure volumes - Ambulatory vs. inpatient procedures, ambulatory procedures performed as in-patient
Complication rates, including procedural complications causing unexpected temporary or permanent disability
Adverse events (through PSLs)
Readmit rates within 7 days and 28 days of discharge or procedure (unplanned readmission rates)
Wait list times and numbers
Complaints/compliments - Patient Care Quality Review Office, informal communications
Medical staff bylaw/rule compliance
Response to pages
Failure to provide adequate coverage
Failure to provide adequate handover and transfer of care
Failure to see patients in a 24 hour period
Completion of records
Other Bylaw issues
Discharge issues
Timeliness
Utilization data
Pathology testing
Radiology imaging requests
Rate of readmission within 30 days for same diagnosis
Waiting time for the next elective procedure
Waiting time performance to national (if available) or local standards

PROFICIENCY REVIEWS

Peer review (proficiency review) has received attention in the Phase 1 report[2]. Peer review is applicable to procedural and cognitive specialties. Standardized and consistently applied peer review has not been implemented in BC. The following provides suggestion on how this can be done at minimal cost. Such reviews would be assessed as part of the in-depth review and would supplement the informal peer review that is already in place.

PROCEDURAL SPECIALTIES – SURGERY, GASTROENTEROLOGY, INTERVENTIONAL RADIOLOGY AND CARDIOLOGY, ULTRASOUND

Procedural observation would be mandated annually during the period of provisional or temporary appointment and after 65 years. It would be done every three years in the interim. The peer observation would assess both technical and non-technical skills during two operative or procedural slates. If simulators of sufficient sophistication are available, time on the simulator could replace “in-the-OR” observation.

Results reported to the appropriate health authority quality committee and the department/program head.

COGNITIVE SPECIALTIES

1. DIAGNOSTIC IMAGING AND PATHOLOGY

Participation in concurrent peer review program for diagnostic imaging. Until this is in place and for pathology, the peer review would annually assess(TBD) studies, appropriate to the areas of practice. Results reported to the appropriate health authority quality committee and department/program head.

2. MEDICINE, PEDIATRICS, PSYCHIATRY

Observation of actual consultations annually during probation and after 65 years and triennially in the interim over two clinical office days. Technical and non-technical skills would be assessed.

Results would be reported to the appropriate health authority quality committee and department head.

USE OF TRIGGERS FOR MORBIDITY AND MORTALITY SURVEILLANCE

Triggers tools have been used extensively in VCH and Providence Health Care to create the foundation for an adverse event surveillance system. This work is based on classical studies of adverse events in adult care and paediatrics. Positive triggers can direct attention to morbidity and mortality that merit review at the individual and division/department levels.

Triggers that have been used in clinical studies include:

Medical M&M Rounds:

- unexpected deaths
- rapid response team cases
- educational/interesting cases
- transfusion or use of blood products
- drop in Hgb or Hct greater than 25%
- in-hospital code or respiratory arrest
- patient fall
- pressure ulcers
- readmission within 30 days
- use of restraints
- any procedural complications
- ventilator associated pneumonia
- readmission to ICU
- PTT greater than 100 seconds
- INR greater than 6
- glucose less than 2.5 mmol/l
- BUN or creatinine greater than 2x baseline
- Vitamin K administration
- use of benadryl, flumazenil, naloxone
- discharge against medical advice

Surgical M&M Rounds:

- return to surgery – planned or unplanned
- change in surgical procedure
- unplanned admission to ICU post operatively
- intubation/reintubation/BiPAP use in PACU
- intraoperative x-ray not routinely associated with the surgical procedure
- intraoperative or post operative death
- intraoperative administration of epinephrine, norepinephrine, naloxone, flumazenil
- PTT greater than 100 seconds
- INR greater than 6
- glucose less than 2.5 mmol/l
- BUN or creatinine greater than 2x baseline
- Vitamin K administration
- postoperative rise in troponin
- change of anesthetic during procedure
- PACU consults
- post operative complications
- unplanned arterial or central line insertion during operative procedure
- unplanned repair or removal of organs
- readmission within 30 days
- discharge against medical advice

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ENDNOTES

¹ Health authority departments should be structured so that they address the medical quality responsibilities of the VCH and PHC boards.

² FHA1 radiologist is called "the radiologist" in this section

³ FHA2 Radiologist is referred to as "the radiologist" in this document

⁴ Question 12. Do you have other information you would prefer to discuss verbally and confidentially with the Medical Director? Question 13. Is there any other information about the applicant that you feel Interior Health Authority should know in considering the applicant's appointment or privileges

⁵ Credentialing is the process of assessing a practitioner's qualifications for membership to medical staff.

⁶ Privileging is the process of requesting privileges, reviewing qualifications, approving and granting clinical privileges, i.e., determining what the practitioner can do at each facility for which privileges are requested.

⁷ Core privilege are those clinical processes or activities within a specialty or sub-specialty that any appropriately trained, actively practicing practitioner with good references would be competent to perform.

Specialty privileges are clinical processes or activities that generally relate to new advances in technology, high risk procedures, and issues that cross specialty lines and that require specific training and/or experience beyond those activities included in core privileging.

⁸The instructions to applicants should indicate that the referees should include two peers in the field in which they are applying and consent should be requested by the HA to communicate directly with past medical directors or VP Medicine in their previous place(s) of work.

¹⁰ Overall Percentage (Category 3 / category 4)

¹¹ Because there no structure for obstetrical ultrasound reports, a report review could not be performed.

¹² To be determined by the rates observed by the province-wide concurrent peer review process and many be specific to modality and anatomical area

¹³Based on the best practices from VIHA and VCH

¹⁴ Modality and subspecialty are used interchangeably

¹⁵ A standardized province-wide approach to multisource feedback including the 360 review, based on the Alberta College of Physicians and Surgeons, PAR (Physician Achievement Review Program) is already in place in some health authorities. This process has been automated but third party reporting has not been implemented