Niagara Health System
Système De Santé De Niagara

Final Report

To the Niagara Health System

On Radiology Quality Review

Dr. B. Yemen

Radiology Lead

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Introduction

Effective May 27, 2015, I began providing oversight and leadership to the external review of 4,189 CT, MRI, and Mammograms read by a Niagara Health System radiologist between May 4, 2014 and May 3, 2015. The purpose of the review was to identify and address potential patient impact arising from the radiologist's performance.

Under my direction, the Real Time Medical (RTM) external team, consisting of 15 radiologists, conducted a rigorous process that involved:

- Review of the CT, MRI and Mammograms images and associated reports using a common scoring methodology (modified RADPEER);
- Transcription of an addendum to the original report where changes to the original interpretation were required;
- The RADPEER score and revised addenda were provided by Real Time Medical to the hospital for appropriate follow-up actions;
- Where interpretation errors were identified, a clinical review team comprised of NHS physicians and nurses conducted comprehensive chart reviews;
- Where required, the NHS clinical review team made contact with Family Physicians/ Specialists to:
    - Determine whether follow-up treatment and care had already occurred through existing quality assurance processes
    - Facilitate further treatment and follow-up where necessary
- Significant findings were communicated to me by the NHS Operations Manager;
- Quality assurance activities were undertaken to ensure the integrity of the review process.

<u>Key Findings</u>

With this report I am forwarding the overall review findings for the reviewed CT, MRI and Mammograms. I would like to highlight the following:

- The clinically significant impact to patient care has been identified at 0.07% for CT and 0.04% for MRI. This represents three patients in total – two in the CT group and one in the MRI
- There was no clinically significant impact to patient care in the Mammogram group

I am confident in my conclusions and that the review can be completed at this time and no further action is required. I believe the review has achieved its purpose and it is unlikely that further investigation would provide a significant improvement to patient care.

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Dr. Brian Yemen
Diagnostic Imaging Department
Juravinski Hospital and Cancer Centre

Review Initiation

In April 2015, concerns were raised by a patient and family about the interpretation of a MRI- Head scan by a NHS radiologist. The NHS took immediate steps to investigate these concerns including the initiation of an internal review of the radiologist's clinical practice. The radiologist agreed to step aside from their clinical responsibilities pending the results of the internal review.

A review of 150 randomly selected CTs interpreted by the radiologist between November 2014 and April 2015 was initiated. For comparison purposes, 50 random CT scans from across the NHS were also identified for review. The 200 CT scans were randomly assigned and reviewed by radiologists at the St. Catharines Site (SCS) using the American College of Radiology (ACR) scoring system (Appendix 1).

Based on the internal review findings and in consultation with Dr. Brian Yemen who oversaw a similar external review at Trillium Health Partners in 2013, the decision was made to undertake a comprehensive review of scans interpreted by the radiologist over a one year period between May 4, 2014 and May 3, 2015. The radiologist continued to be off work during the external review. The following scans were included in the Radiology Quality Review (RQR) 2015:

- CT – 2739
- MRI – 1440
- Mammography – 10

Exams performed as part of the Ontario Breast Screening Program (OBSP) were **not** part of the review.

Description of Team Components

Overview of Team Process

An incident management structure (Appendix 2) was implemented for the Review that identifies and clearly defines the organizational structure including reporting relationships and the resources required for a comprehensive quality review process. The RQR 2015 team met regularly throughout the Review with designated leads providing status updates related to their respective area of responsibility at each meeting:

- Radiology Review
- Clinical Review Team
- Communications
- Planning
- Human Resources

- Finance/Administration
- Information Communications Technology
- Risk and Legal

At the end of each business day, an Incident Action Plan (Appendix 3) was completed by the Operations Manager to detail status updates and to articulate goals and related actions for the next 24-hour period. This prospective planning was essential for ensuring accountability at all levels of the organizational structure throughout the Review.

Accountabilities

Executive Team

A review of this magnitude requires many different components to come together and work seamlessly and efficiently in order to ensure timely and effective turnaround. First and foremost, Executive Team commitment to the Review as an organizational quality improvement initiative was imperative. This was essential in ensuring that the Review was not considered to be only Diagnostic Imaging focused but rather viewed as an organizational initiative requiring the cooperation of many different departments and staff. Secondly, Executive Team support was required to ensure the timely allocation of the resources required for the Review. The Executive Team met three times weekly throughout the duration of the radiology review in order to provide ongoing support and direction as required.

Radiology Lead

The Radiology Lead, Dr. Brian Yemen, directed the work of the external radiology team to ensure that a rigorous review process was followed that included:

- Review of identified CT, MRI and Mammogram images, including associated priors and reports using a common scoring methodology (modified RADPEER);
- Transcribing an addendum to the original report in instances where changes to the original interpretation were required;
- Ensuring that the RADPEER score and revised addenda were provided to the NHS for appropriate follow-up.

Additionally, the Radiology Lead participated in:

- The selection process for the Real Time Medical external radiologist team;
- Executive Reviews where potentially moderate harm or higher was identified related to interpretation discrepancies; and,
- Regular quality assurance activities.

Operations Manager

The Operations Manager provided oversight for all operational components of the review to ensure smooth and consistent work flow. The Operations Manager:

- Provided regular status updates to the Radiology Review Lead;
- Participated in case presentations to the Executive Review Team;
- Participated in patient/family disclosure meetings;
- Acted as the point-person for communications with the project manager at Real Time Medical;
- Completed daily incident action plan reports.

Communications Team

The Communications Team consisted of several different components that were integral to the Review process. All internal and external communications including media events were managed by the Communications Team Manager.

The need for a Call Centre to manage communication with the public, both patients and physicians, was identified as a priority. A core group of five staff were selected to work in the Call Centre Monday to Friday 0830-1630 hours - staffing was flexible based on the number of calls coming into the NHS. Scripting was developed specific to calls from patients, families, and physicians to ensure consistent and accurate communication of information. An automated voice message was available outside of regular business hours with the ability to leave a message and the Call Centre team returned all voicemail messages on the next business day. The Patient/Public Lead was present and accessible in the Call Centre when it went live on June 22, 2015 and on an ongoing basis to ensure that support was available to address any issues and ensure their timely resolution. All calls were documented on a hardcopy form and then entered into the RQR 2015 database. Any concerns identified by the Call Centre staff that required further investigation and follow-up were referred to a Patient Relations Specialist.

The Call Centre staff took on additional responsibility once the Review was underway. In instances where the NHS physician reviewer identified the need for follow-up communication with the most responsible physician for clinical correlation of review findings or to determine if further imaging was required, the Call Centre staff sent out a form letter by fax. They made follow-up phone calls to the physician offices and tracked and monitored the return of the letter with the physician signature and indication of further action to be taken if any.

A Patient Navigator was assigned to coordinate follow-up testing when ordered by the most responsible physician. The Patient Navigator contacted each patient and expedited exam bookings based on the individual's preference. Arrangements were made to meet each patient at the front

entrance of the hospital and escort them to the Diagnostic Imaging Department. A warm hand-off was completed with the staff performing the exam. Once complete, the Patient Navigator accompanied the patient back to the front entrance of the hospital and ensured that a voucher was provided to pay for parking.

Data Management

A purpose-built database was developed for the Radiology Quality Review by an Information and Communications Technology specialist at the NHS. The database consists of two main components - the Call Centre section, which had pre-determined fields for documentation of patient, physician, and general public calls. All individuals calling to determine if they were part of the review were asked to provide their health card information to ensure accurate identification prior to any details being provided.

The second component of the database was related to the documentation of the various stages of clinical review and follow-up care coordination with physicians and patients. Nurse and physician reviewers had designated areas for documentation related to the chart review process. Additionally, there were specific documentation requirements for the Call Centre staff to detail interactions with physician offices and patient follow-up activities.

Clinical Review Team

The Clinical Review Team (CRT) was comprised of nine NHS Registered Nursing staff and eight NHS physicians representing different specialty areas of practice including general medicine, oncology, emergency, neurology, orthopedics, and gynecology. The CRT was overseen by Dr. J. Viljoen who coordinated the clinical review process. Daily reports were received from RTM and all exams that were not in full agreement with the original interpretation underwent a comprehensive clinical chart review.

Nurse Review

The nurse reviewers were responsible for providing the first level of chart review to gather clinical information in the following areas:

- Documentation of the discrepancy between the original NHS exam report and the revised RTM report including any recommendations for follow-up;
- Noting any pre and/or post diagnostic imaging exams relevant to the care of the patient;
- Past medical history;
- Clinical course post review exam with details regarding hospital visits, emergency contacts and other information related to subsequent episodes of care.

Physician Review

The physician reviewers were responsible for indicating:

- Whether appropriate care and follow-up occurred related to the identified radiology discrepancy;
- The clinical significance of the discrepancy;
- Whether potentially moderate harm or higher had occurred with escalation of these cases for executive review.

Health Information Management

A process was established with the Health Information Management (HIM) to ensure that individuals coming into the hospital and requiring assistance regarding the review would be assisted in an efficient and timely manner. HIM staff received instruction regarding consistent communication with the patients and a quiet area with a phone was designated so that patients could contact the Access Line to identify if they were part of the review or not.

A transcriptionist from HIM was assigned to work with the RQR 2015 team. Dr. Viljoen dictated a progress note on each patient who had a comprehensive chart review completed by the Clinical Review Team. The transcriptionist transcribed the progress notes and these went out electronically to the exam ordering physician and/or the family physician. A process was also established in HIM to track the number of patients requiring transfer of medical records or copies of diagnostic imaging exams related to the radiology review.

Real Time Medical

Radiologist Selection Process

Real Time Medical (RTM) submitted a proposed roster of radiologists for participation in the radiology review. The Curriculum Vitae (CV) of all of the proposed candidates were reviewed by Dr. B. Yemen and Dr. A. Mehta, Chief of Diagnostic Imaging at NHS, to ensure that they had a minimum of five years of radiology clinical practice and prior participation in at least one large radiology review. Additionally, each of the radiologists was required to sign a conflict of interest waiver prior to being considered for the review. A final list of 15 RTM radiologists was submitted for credentialing and approved for temporary NHS privileges.

American College of Radiology Process

The RADPEER scoring system was originally designed by an American College of Radiology (ACR) safety task force in 2000 as an educational tool involving a 4-point rating scale for use in the peer review process. Revisions to the original scale were made in 2009 to provide the peer reviewer with

the option of evaluating clinical significance and to ensure that the RADPEER categories are clearly defined and understood to increase rater consistency.

The modified RADPEER (Table 1) methodology was used for the assessment of the CT, MRI, and Mammography exams. Modifications to the RADPEER system include the addition of 1b, 1c and 5 scores (Real Time Medical, 2015). The 1b classification is used when the reviewer agrees with the original report conclusion and also identifies opportunity for improved report structure and description (including grammatical improvements). The 1c classification is used when the reviewer agrees with the original report but identifies that no recommendation for follow-up was made. A score of 5 is applied in situations when the original image quality is poor, which impacts the reviewer's ability to complete the review process.

Table 1: RADPEER Scoring

Score	Clinical Significance	
1. **Concur with interpretation**	1a 1b 1c	Full concurrence Concur with comment/concern Concur/follow up recommended
2. **Discrepancy in Interpretation/ not ordinarily expected to be caught/made (understandable miss)**	2a 2b	Unlikely to be clinically significant Likely to be clinically significant
3. **Discrepancy in Interpretation/ should be caught/made most of the time**	3a 3b	Unlikely to be clinically significant Likely to be clinically significant
4. **Discrepancy in Interpretation/ should be caught/made almost every time (misinterpretation of findings)**	4a 4b	Unlikely to be clinically significant Likely to be clinically significant
5. **Non-Diagnostic**	Cannot review due to image quality	

Quality Assurance Measures

From a quality assurance perspective, regular quality control activities were undertaken throughout the review to ensure the quality and integrity of the process. An audit was performed at the mid-way point of the review to ensure confidence in the results obtained from Real Time Medical. Dr. B. Yemen also participated in several quality assurance meetings with Real Time Medical to discuss and review quality topics associated with the review.

Executive Review Process

In instances where the clinical chart review team determined that a patient may have been negatively impacted by the original radiology interpretation, the individual case and circumstances were escalated for an executive review with a team comprised of executive leads from the NHS, the Clinical Review Team Lead, the Operations Manager, and Dr. B. Yemen. The executive process provided a second review of each case to determine whether harm had occurred and if disclosure was required.

Disclosure Process

A formal disclosure process was undertaken in instances where quality of care was impacted. In these situations, the Clinical Review Team Lead, the Review Operations Manager, and a Patient Relations Specialist organized a meeting with the patient/family to inform them about the quality of care issue so that they could make informed decisions regarding their future care. Communication with the most responsible physician was maintained throughout the disclosure process to ensure ongoing support and follow-up.

Results

The RQR 2015 results are as follows:

- The clinically significant impact to patient care has been identified at 0.07% for CT and 0.04% for MRI. This represents three patients in total – two in the CT group and one in the MRI
- There was no clinically significant impact to patient care in the Mammogram group

Next Steps

NHS has a number of quality assurance processes built into all aspects of its programs and services including within the Diagnostic Imaging Department. At the time of initiation of the RQR 2015 review, preparations were already underway in the Diagnostic Imaging Department to implement a peer review program. The peer review program was launched in July 2015 and brings an added level of rigor to quality assurance processes within the department. The peer review program will identify ongoing areas of focus for quality improvement efforts within the Diagnostic Imaging Department.

Appendix 1

American College of Radiology Rating Scale

1 Concur with interpretation

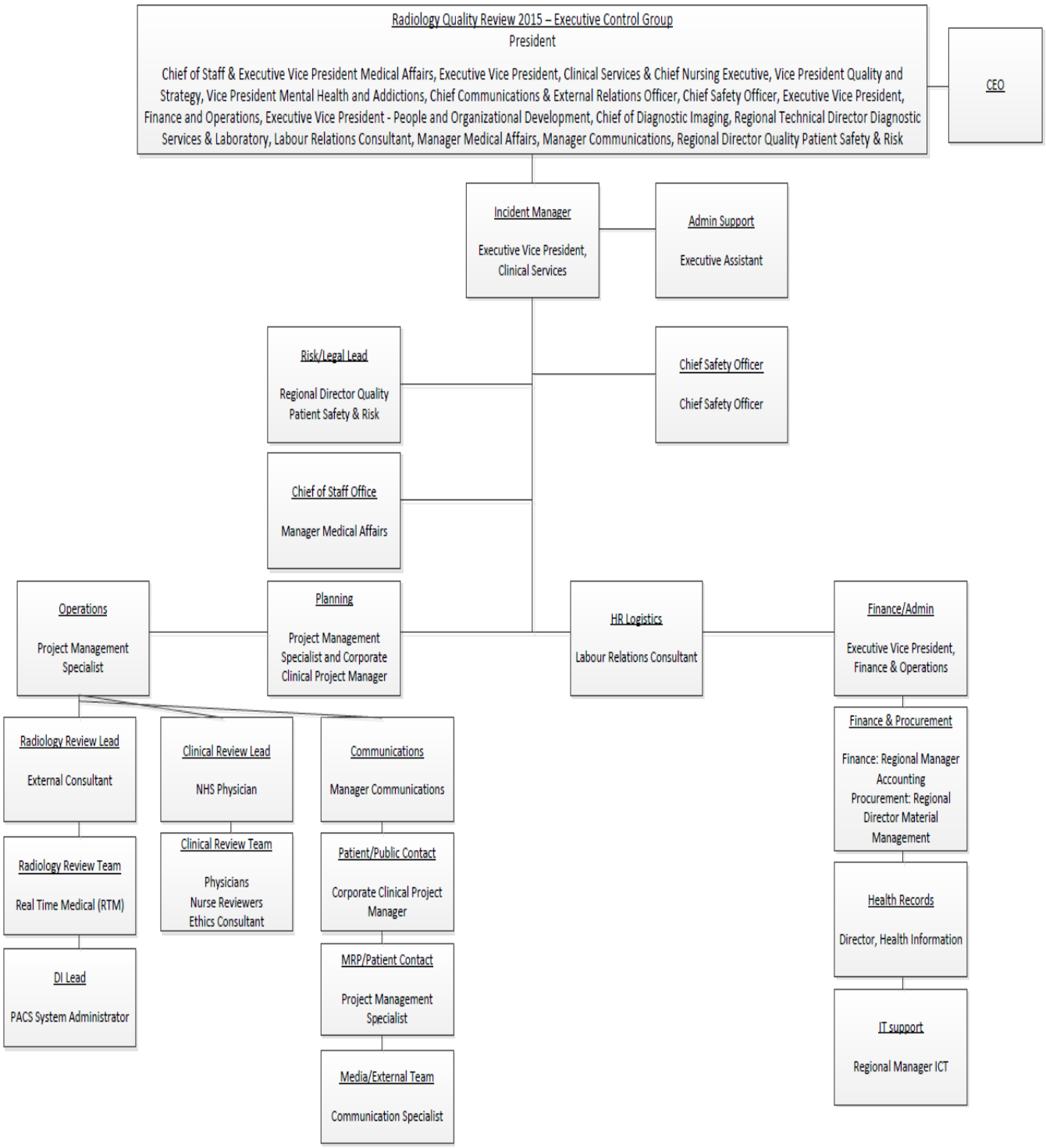
2 Discrepancy in interpretation/not ordinarily expected to be made (understandable miss)
- a. Unlikely to be clinically significant
- b. Likely to be clinically significant

3 Discrepancy in interpretation/should be made most of the time
- a. Unlikely to be clinically significant
- b. Likely to be clinically significant

4 Discrepancy in interpretation/should be made almost every time—misinterpretation of finding
- a. Unlikely to be clinically significant
- b. Likely to be clinically significant

Appendix 2

Incident Management Structure



Appendix 3

Radiology Quality Review 2015
Incident Action Plan

Date Submitted: _____ **For Period:**_____

1.0 SITUATIONAL REPORT

Operational General Update:

Radiology Review Team:

Status of Study Review:

Number of scans to be reviewed:

CT	MRI	Mammography

Number completed:

CT	MRI	Mammography

Results:

Table 1.0 – Standard Classification Grid

Score		Clinical Significance
1. Concur with interpretation	1a	Full concurrence
	1b	Concur with comment/concern
	1c	Concur/follow up recommended
2. Discrepancy in Interpretation/ not ordinarily expected to be caught/made (understandable miss)	2a	Unlikely to be clinically significant
	2b	Likely to be clinically significant
3. Discrepancy in Interpretation/ should be caught/made most of the time	3a	Unlikely to be clinically significant
	3b	Likely to be clinically significant
4. Discrepancy in Interpretation/ should be caught/made almost every time (misinterpretation of findings)	4a	Unlikely to be clinically significant
	4b	Likely to be clinically significant
5. Non-Diagnostic		Cannot review due to image quality

1a	2a	3a	4a
1b	2b	3b	4b
1c	Pending Arbitration:		Total:

Status of Addendums

Completed:	To be completed:

Comments:

Clinical Review Team:

Status of Review:

Number of Cases to be Reviewed Initial Entry (Nurse Review)

CT	MRI	Mammography

Number of Cases Waiting for Physician Assignment

CT	MRI	Mammography

Closed Cases	Remaining in Clinical Review

Status of Final Dictations

Completed:

Comments:

Communications:

Patient Access Line:

AS OF:

Total Number of Calls Received to date: Total Number of Calls Received Today:		
Patient Access Line: To Date: Today:	**Physician Access Line:** To Date: Today:	**General Inquires:** To date: Today:

Call Status:

Number Resolved: To Date: Today:	**Number Open:**	**Number Escalated:** Patient Relations: CRT:
Part of Review: To Date: Today:	**NOT part of Review:** To Date: Today:	

Comments:

Human Resources/ Logistics:

-N/A

ICT:

- N/A

Finance/Admin

Total Number of FOI Requests:	
Chart Requests:	Film Requests:

Comments:

2.0 OBJECTIVES

Next 24hrs

Radiology Review Team:

Clinical Review Team:

	Communications:
	Human Resources:
	ICT:
	Admin/Other:
3.0 EXECUTION	
Resources	**Current:** Summary to date: Total Staff: / Total Hours: / Total Cost:
	Required:

Business Cycle for next period: _____

Time	*Activity*

Submitted: _____ by: _____
(Date) Operations Manager

Approved by: _____ on: _____
Incident Manager (Date)