

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

Investigation Team

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July 23, 2010


The Honourable Deb Matthews
Minister of Health and Long-Term Care
Government of Ontario
Toronto, Ontario

Dear Minister Matthews,

We are pleased to submit this report on the Investigation of surgical and pathology issues at three Essex County Hospitals: Hôtel-Dieu Grace Hospital, Leamington District Memorial Hospital and Windsor Regional Hospital. The Investigation Team makes 19 recommendations in the areas of pathology, surgery, medical-hospital leadership at Hôtel-Dieu Grace Hospital, quality and safety for the benefit of patients in Essex County and the province as a whole, and next steps.

We look forward to your response to our recommendations.

Yours truly,



Barry McLellan, FRCPC
Team Lead



Robin McLeod, FRCSC
Lead, Surgery



John Srigley, FRCPC
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CONTENTS

ACKNOWLEDGEMENTS.....	I
EXECUTIVE SUMMARY	II
PART A: INTRODUCTION.....	1
A1. Background Leading Up to the Investigation, the Investigation Team and Terms of Reference	1
A2. Overview of the Report.....	2
PART B: BACKGROUND	4
B1. The Three Essex County Hospitals.....	4
<i>Hôtel-Dieu Grace Hospital.....</i>	<i>4</i>
<i>Leamington District Memorial Hospital.....</i>	<i>7</i>
<i>Windsor Regional Hospital.....</i>	<i>10</i>
B2. Understanding Pathology and Surgery Services, and the Inter-Relationship Between the Two	14
PART C: THE INVESTIGATION	16
C1. Overview of the Structure and Methods Used to Support the Investigation..	16
<i>Structure</i>	<i>16</i>
<i>Methods</i>	<i>16</i>
<i>Conducting Site Visits, Meetings and Interviews</i>	<i>16</i>
<i>Reviewing Background Documents and Reports</i>	<i>17</i>
<i>Conducting Pathology and Surgery Case Reviews</i>	<i>17</i>
<i>Developing a Fast Track Process to Determine an Appropriate Medical Response in the Event of Significant Discrepancies in the Pathology Reviews</i>	<i>17</i>
C2. The Pathology Review	18
<i>Methods to Investigate Pathology.....</i>	<i>18</i>
<i>Obtaining Input Through Interviews and Site Visits.....</i>	<i>18</i>
<i>Establishing a Team of Pathology Reviewers</i>	<i>19</i>
<i>Identifying Pathology Cases to be Reviewed and Conducting the Review</i>	<i>20</i>
<i>Investigation Team Findings and Recommendations About Pathology</i>	<i>22</i>
<i>Introduction.....</i>	<i>22</i>
<i>Pathology at Hôtel-Dieu Grace Hospital.....</i>	<i>22</i>
<i>Pathology at the Three Essex County Hospitals</i>	<i>32</i>
C3. The Surgery Review.....	35
<i>Introduction.....</i>	<i>35</i>
<i>Methods to Investigate Surgery</i>	<i>35</i>
<i>Obtaining Input Through Interviews and Site Visits.....</i>	<i>35</i>
<i>Establishing a Team of Surgery Reviewers.....</i>	<i>36</i>
<i>Identifying the Surgery Cases to be Reviewed and Conducting the Review</i>	<i>36</i>
<i>Investigation Team Findings and Recommendations About Surgery.....</i>	<i>37</i>
<i>Surgery at Hôtel-Dieu Grace Hospital</i>	<i>37</i>
C4. The Relationship Between Medical and Hospital Leadership at Hôtel-Dieu Grace Hospital.....	39

C5. Supporting a Quality and Safety Agenda for the Benefit of Patients.....	40
<i>Introduction.....</i>	<i>40</i>
<i>Quality and Safety at Hôtel-Dieu Grace Hospital</i>	<i>41</i>
<i>Quality and Safety at the Three Essex County Hospitals.....</i>	<i>43</i>
<i>Quality and Safety in Pathology Across Ontario.....</i>	<i>45</i>
C6. Next Steps.....	46
PART D: CONSOLIDATED LIST OF RECOMMENDATIONS	48
APPENDICES.....	53
Appendix A: Terms of Reference for the Investigation	53
Appendix B: Ontario Regulation 150/10 Made Under the <i>Personal Health</i>	
<i>Information Protection Act, 2004.....</i>	55
Appendix C: Site Visits, Meetings and Interviews	56
Appendix D: Documents and Reports	60
Appendix E: Standard Pathology Review Template.....	64
Appendix F: Distribution of Pathology Specimen Types.....	65

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- The executive and medical leaders at Hôtel-Dieu Grace Hospital, Windsor Regional Hospital and Leamington District Memorial Hospital for fully supporting the Investigation, sharing information freely and openly with the Investigation Team, and responding to requests for documents in a timely manner. The Team was provided with all the medical and pathology records and materials that were needed to conduct the Investigation. This information was provided even when doing so may have disrupted ongoing or planned internal investigations. Thanks are also extended to staff at Hôtel-Dieu Grace Hospital, especially the medical laboratory assistants, who worked diligently to compile case lists and pull slides and pathology reports, and to administrative staff for organising and scheduling meetings.
- The 14 external pathology reviewers and the three external surgery reviewers for assessing cases and providing their professional expertise.
- The leadership and staff of the Erie St. Clair Local Health Integration Network for supporting the Investigation and providing file and record management and inventory control.
- Ms. Dorothy Zwolakowski for serving as the full-time Project Coordinator and her employer, the Office of the Chief Coroner, for supporting her secondment to the Investigation.
- Dr. Joann Trypuc, PhD for working with the Investigation Team to develop its report.
- The Ontario Government for passing Ontario Regulation 150/10 made under the *Personal Health Information Protection Act, 2004 (Disclosure by and to Hospital Investigators)*. This temporary Regulation enabled the Investigation Team and the College of Physicians and Surgeons of Ontario to exchange appropriate personal health information related to the Investigation in the interest of advancing public safety.

EXECUTIVE SUMMARY

On March 1, 2010, Ontario's Minister of Health and Long-Term Care, Deb Matthews, appointed an Investigation Team to review and report on issues related to the quality of care and treatment of patients at three Essex County Hospitals: Hôtel-Dieu Grace Hospital, Windsor Regional Hospital and Leamington District Memorial Hospital. The Minister was responding to growing public concerns about reports of errors in surgery and pathology at Hôtel-Dieu and, more generally, in Essex County.

The Investigation Team – Dr. Barry McLellan (Team Lead), Dr. Robin McLeod (Surgery Lead) and Dr. John Srigley (Pathology Lead) – was asked to examine Hôtel-Dieu's quality of surgical care and pathology services, its treatment of patients and errors in surgery and pathology, and other issues. The Investigators were also asked to determine whether these issues needed to be examined at the other two hospitals. Soon after the Team launched an extensive and comprehensive process to conduct its work, it concluded that the major issues of public concern focused on pathology and surgery services at Hôtel-Dieu and the care provided, in particular, by a general surgeon (Dr. Barbara Heartwell) and a pathologist (Dr. Olive Williams). The Investigators also examined relevant issues, and assessed the Leamington District Memorial and Windsor Regional Hospitals for opportunities to improve patient safety and quality of care, and to maintain public confidence in the hospitals in Essex County.

The Investigators make 19 recommendations in five areas based on information gathered from 12 site visits to Windsor, meetings with over 75 individuals, an extensive document review, an analysis of 128 surgical records and 6,703 pathology cases, and a review of 19 additional cases of concern. In the interest of public safety, the Investigators worked with the hospital leadership to put a fast track process in place to contact patients if the review of pathology cases identified a case where there was a significant difference of opinion between the original pathologist and the reviewing pathologists. All of this work was made possible through the consistent cooperation of the administrative and medical leadership of the three Essex County Hospitals, the assistance of the Erie St. Clair Local Health Integration Network, and the support of the Ontario Government which passed a temporary Regulation that allowed the Investigators and the College of Physicians and Surgeons of Ontario to share appropriate personal health information related to their respective investigations.

1. Pathology

Pathology at Hôtel-Dieu

The Investigators established a Pathology Review Team led by Dr. John Srigley and made up of 14 pathologists working in five large community hospitals in Ontario. Two different reviewers conducted independent reviews of all of Dr. Williams' pathology cases in 2008 and 2009 (4,623 general and 53 neuropathology cases signed out by Dr. Williams), a targeted sample of Dr. Williams' pathology cases in 2003 to 2007 (1,551

cases), and a targeted sample of pathology cases from 2008 and 2009 of the four other Hôtel-Dieu pathologists (476 cases).

Although Hôtel-Dieu has made notable improvements in pathology reporting over the past few months, the Investigation Team supports a concerted improvement effort and recommends that pathology and surgery leadership at Hôtel-Dieu reach consensus on improved pathology reporting processes, and that all pathologists participate in continuing professional development activities under the guidance of the Department Chief.

After conducting a comprehensive retrospective review of 6,227 of Dr. Williams' cases, the Pathology Review Team expressed concerns about potential adverse clinical consequences of certain diagnoses made by Dr. Williams' and had significant concerns with the quality of a subset of her reports. Dr. Williams no longer practises in Ontario. The Investigation Team recommends that the College of Physicians and Surgeons of Ontario consider undertaking a clinical competency assessment of Dr. Williams if she decides to resume clinical practice in Ontario in future.

Pathology at the Three Essex County Hospitals

The Investigation Team makes a series of recommendations to improve pathology services across the three hospitals. It recommends that all pathologists adopt the Quality Assurance Program in pathology that has been evolving over the last six years, and that laboratory physician and administrative resources be appropriately allocated to support the Program. The Investigation Team observed and heard of significant differences in the working environments of the pathology practices at Hôtel-Dieu and Windsor Regional. To improve the quality of Windsor's pathology services and strengthen the working environment, the Team recommends that all pathologists be centralized at the Windsor Regional site. If this recommendation is acted upon a rotating pathologist should be available on the Hôtel-Dieu site daily. The Team also recommends that the three Hospitals improve their process of preparing cytological specimens through the use of contemporary liquid-based cytology systems, that they examine the role of digital scanning technology to facilitate second opinion consultations and improve timely diagnosis in specialized areas such as neuropathology, and that the current collaboration between the three hospitals and London Health Sciences Centre be enhanced, especially in specialized areas of pathology.

2. Surgery

The Investigators established a Surgical Review Team led by Dr. Robin McLeod and made up of three additional surgeons working in Toronto. The Team conducted a comprehensive review of 128 surgical cases performed by Dr. Barbara Heartwell from 2000 to 2010.

The Surgical Team was of the opinion that – notwithstanding specific cases of concern that were brought to their attention and were reviewed (including cases that received

public attention) – Dr. Heartwell generally performed safe surgery and provided safe care. The Surgical Team had some concerns that Dr. Heartwell may not be keeping up-to-date with certain advances in the surgical management of patients and has been slow to adopt new surgical techniques. In the Surgical Team’s opinion, this has not, however, had a significant impact on the quality of Dr. Heartwell’s surgery. The Investigation Team recommends that Hôtel-Dieu re-consider its current position that Dr. Heartwell’s practice be restricted given the findings of the review conducted by the Surgical Review Team. The Surgical Team did identify specific areas for ongoing improvement, and recommends that Dr. Heartwell be required to attend and participate in quality and continuing professional development initiatives that the Team identifies. Dr. Heartwell should also review all pre-operative diagnostic tests, including biopsy results, as part of the surgical checklist at the start of all of her surgeries.

3. Medical-Hospital Leadership

Over the course of its review, the Investigation Team heard about long-standing unproductive relationships at Hôtel-Dieu that were characterised by a concerning lack of respect between medical leaders, senior management and the Board of Directors. The Team recommends that Medical Leaders, Senior Management Staff, and the Board of Directors at Hôtel-Dieu foster mutually-supportive relationships based on trust and due process. The Team identifies mechanisms to help develop this environment.

4. Supporting a Quality and Safety Agenda for the Benefit of Patients

In light of Bill 46, the *Excellent Care for All Act* and the change to Regulation 965 under the *Public Hospitals Act* related to critical incident reporting, the Investigation Team makes a number of quality and safety recommendations in three areas.

Quality and Safety at Hôtel-Dieu

To ensure that Hôtel-Dieu continues its quality and safety efforts, the Investigation Team recommends that the hospital support ongoing leadership training and education in quality and safety for its Board, Senior Management Staff and Medical Leaders. Potential educational sessions are proposed. The Team also recommends that all medical staff at Hôtel-Dieu be educated about the hospital’s policy for reporting errors, and that the hospital continue developing a cultural environment that focuses on quality improvement, building on lessons learned and high performance.

Quality and Safety at the Three Essex County Hospitals

The Investigation Team identified three areas for joint quality and safety initiatives. One recommendation is for the three hospitals to continue collaborating to advance patient quality and safety at all levels. Opportunities include setting up formal communications about critical incidents and quality of care, sharing medical information to avoid duplication and reduce errors, developing protocols to support the smooth and safe transfer of patients from one organisation to another, common credentialing for medical

staff, and an integrated Human Resource Plan. The Erie St. Clair LHIN could play an important role facilitating these joint initiatives.

A second recommendation requires surgeons at Hôtel-Dieu who perform breast cancer surgery to attend the Breast Multidisciplinary Cancer Conferences (MCCs) held at Windsor Regional, and surgeons at Windsor Regional who perform gastrointestinal cancer surgery to attend Gastrointestinal MCCs held at Hôtel-Dieu. The three Essex County Hospitals should work towards developing joint MCCs.

A third recommendation is for the three Essex County Hospitals to review the current roles and responsibilities of medical leadership positions in the context of the new legislation. The terms of reference for these positions should have clear roles, responsibilities and term limits, be supported with quality and safety performance expectations, and include regular performance reviews.

Quality and Safety in Pathology Across Ontario

The Investigation highlighted the critical importance of quality and safety in pathology. Although individual hospitals can do a lot to improve their pathology processes, the Investigation Team supports a broader provincial approach to guide individual efforts. The Team recommends that the Ministry support the development and implementation of a provincial quality assurance system for pathology that includes standards and guidelines and considers similar plans for other areas of interpretive diagnostic medicine. The Team further recommends that the Ministry work with others to develop and, where appropriate, implement the provincial standards and guidelines. It is further recommended that the Ministry require – by March 31, 2011 – a recommended standard for a pathology quality assurance program in Ontario along with a plan to identify the requirements to support the standard.

5. Next Steps

In the opinion of the Investigation Team, a significant amount of time, attention and effort will be required to plan for and implement the recommendations, as appropriate. These requirements go beyond what can reasonably be expected of current hospital, medical and LHIN leadership. The Team, therefore, recommends that the Ministry consider appointing a facilitator to address the recommendations of the Investigators' Report.

PART A: INTRODUCTION

A1. BACKGROUND LEADING UP TO THE INVESTIGATION, THE INVESTIGATION TEAM AND TERMS OF REFERENCE

On March 1, 2010, Ontario's Minister of Health and Long-Term Care, Deb Matthews, appointed an Investigation Team to review and report on issues related to the quality of care and treatment of patients at three Essex County Hospitals: Hôtel-Dieu Grace Hospital, Windsor Regional Hospital and Leamington District Memorial Hospital. The Minister was responding to growing public concerns about reports of errors in surgery and pathology at Hôtel-Dieu and, more generally, in Essex County.

Minister Matthews appointed three members to the Investigation Team with experience and expertise in system reviews, surgery and pathology. The members of the team appointed through Order-in-Council included:

- Dr. Barry McLellan (FRCPC): President and Chief Executive Officer, Sunnybrook Health Sciences Centre, Toronto; former Chief Coroner of Ontario; Professor, Department of Surgery, University of Toronto. Dr. McLellan was the Team Leader and Coordinator.
- Dr. Robin McLeod (FRCSC): Surgical Lead, Quality Improvement and Knowledge Transfer, Surgical Oncology Program, Cancer Care Ontario; Angelo and Alfredo De Gasperis Families Chair in Colorectal Cancer and Inflammatory Bowel Disease Research, Mount Sinai Hospital; Professor, Departments of Surgery and Health Policy, Management and Evaluation, University of Toronto. Dr. McLeod was the Team Lead for Surgery
- Dr. John R. Srigley (FRCPC): Clinical Lead, Pathology and Laboratory Medicine Program and the Pathology Checklist and Stage Capture Project, Cancer Care Ontario; consultant pathologist The Credit Valley Hospital (Mississauga); Professor, Department of Pathology and Molecular Medicine at McMaster University. Dr. Srigley was the Team Lead for Pathology.

The Investigators were asked to:

1. Investigate and report on issues relating to the following at Hôtel-Dieu Grace Hospital (HDGH):
 - a) The quality of care and treatment of patients at HDGH, analysis of any errors with particular reference to pathology results and recent reports of any surgical errors over the last two years.
 - b) The processes and practices employed by HDGH to measure and improve the clinical appropriateness and quality of surgical care and the quality of pathology services.

- c) Review the surgical leadership structure, the process for previewing adverse events, the structure and culture of communication between pathologists and surgeons, and the recorded frequency of Multidisciplinary Case Conferences for cancer patients at HDGH.
 - d) The executive and board monitoring of patient care and professional staff conduct with specific reference to whether HDGH has appropriate patient care practices and procedures to protect the safety and security of their patients.
 - e) The role of the Hôtel-Dieu Medical Advisory Committee in fulfilling its responsibilities under the *Public Hospitals Act*.
2. Based on the findings on the issues above, determine whether similar or other issues should be reviewed at Leamington District Memorial Hospital and Windsor Regional Hospital.
 3. Investigate and report on issues relating to shared pathology services at the Hospitals.
 4. Review the status of recommendations from all relevant previous studies, strategies and reports regarding medical care quality, surgical services and pathology services at the Hospitals.
 5. Provide specific systemic recommendations to promote accountability among hospital boards for the quality of the pathology processes and surgical care (beyond the role of the Medical Advisory Committee).
 6. Make recommendations and identify next steps for the Hospitals and the Local Health Integration Network to respond to issues identified in the Investigation.

See Appendix A for the complete Terms of Reference for the Investigation.

The Investigators began working almost immediately by visiting Windsor to gather facts about the concerns and reports of surgical and pathology errors. After reviewing extensive documentation, and interviewing senior management and medical leaders at the three Essex County Hospitals and the leadership of the Local Health Integration Network, the Team concluded that the major issue of public concern surrounded pathology and surgery services at Hôtel-Dieu and the care provided, in particular, by a general surgeon (Dr. Barbara Heartwell) and a pathologist (Dr. Olive Williams). The Investigators focused significant attention on closely examining the issues that were identified. The Investigators also focused attention on Leamington District Memorial Hospital and Windsor Regional Hospital in so far as there were opportunities to improve patient safety and quality of care, and restore public confidence in the hospital system in Essex County.

A2. OVERVIEW OF THE REPORT

Part B presents background information which includes a summary of the three Essex County Hospitals and a brief description to enable the lay reader to understand pathology and surgery services, and the inter-relationship between the two (Chapters B1 and B2, respectively).

Part C presents the results of the Investigation beginning with an overview of the structure and methods used in the Investigation (Chapter C1). Chapter C2 presents the results of the pathology investigation and includes detailed information on the methods used to investigate pathology, and the Investigation Team's findings and recommendations about pathology services. Similarly, Chapter C3 presents the results of the surgery investigation and includes detailed information on the methods used to investigate surgery, and the Investigation Team's findings and recommendations about surgical services.

Chapter C4 presents the Investigation Team's observations and recommendations on the relationship between medical and hospital leadership at Hôtel-Dieu.

Chapter C5 focuses on the requirements to support a quality and safety agenda for the benefit of patients. Recommendations are targeted at Hôtel-Dieu, the three Essex County Hospitals, and the province. Finally, Chapter C6 presents next steps.

Part D presents the consolidated list of recommendations followed by supporting appendices.

PART B: BACKGROUND

B1. THE THREE ESSEX COUNTY HOSPITALS

The three Essex County hospitals were asked to provide information on their organisation's history, its services and priorities, detailed activities, organisational structure, and current quality and safety initiatives. This chapter summarises the highlights of this information.

HÔTEL-DIEU GRACE HOSPITAL¹

History and Overview of the Hôtel-Dieu Grace Hospital

Hôtel-Dieu Grace Hospital is made up of three founding organisations. The first – Hôtel-Dieu of St. Joseph's Hospital – was officially founded in 1888 by the Religious Hospitallers of St. Joseph who came from Montreal to Windsor at the invitation of Pastor Dean T. Wagner of St. Alphonsus Church. The Sisters had offered to help build a hospital if one was ever planned in Windsor. Construction of the hospital began October 10, 1888 with the official opening in February 1890. The second hospital – the Salvation Army Grace Hospital – was founded by the Salvation Army in 1918 to support the growing community's need for another hospital. The third organisation was the Villa Maria Home for the Aged.

In mid-1991, the Chief Executive Officers of the two hospitals began discussing the advantages of sharing services and eliminating duplication. On April 1, 1994, the two hospitals and Villa Maria signed a formal Alliance Agreement to operate one corporate structure, governed by one Board, managed by one Chief Executive Officer, staffed by one medical staff and with one Medical Advisory Committee, and financed with one budget.

Hôtel-Dieu Grace Hospital's vision is: *Inspired People, Extraordinary Care*. Its mission is: *Hôtel-Dieu Grace Hospital is a health care community that is inspired by Jesus Christ's healing ministry, respecting the sanctity of life. Our compassionate hearts and competent hands will care for the body, mind and spiritual wellbeing of our diverse community.*

Hôtel-Dieu is located on one site and provides advanced care in the areas of:

- Complex trauma
- Renal dialysis (including responsibility for regional renal program)
- Acute mental health
- Advanced cardiac care (including angioplasty)
- Diagnostic Imaging (including interventional radiology)
- Neuroscience (neurology, stroke and neurosurgical)

¹ Information submitted on June 3, 2010 by Pat Somers, Senior Vice President, Patient Services and Chief Nursing Executive, Hôtel-Dieu Grace Hospital.

- Surgery (including general, thoracic, vascular)
- Intensive Care

Hôtel-Dieu also supports the Schulich School of Medicine and Dentistry which is located at the University of Western Ontario and has expanded its undergraduate medical program to the University of Windsor. Hôtel-Dieu is one of the sites that delivers the program.

Services and Priorities at the Hôtel-Dieu Grace Hospital

In the Spring of 2009, Hôtel-Dieu's Board of Directors confirmed the following five strategic priorities:

1. Service Excellence: Quality and Patient Safety
2. Outstanding Performance: Ensure Value
3. Engaged People: Healthy People Place
4. Continuous Improvement: Leading Innovation
5. Integrated Services: Collaborative Spirit

Each Strategic Priority has annual corporate objectives, targets and performance metrics. Hôtel-Dieu's Strategic Planning Framework includes an Accountability Framework that identifies the roles the different levels of leadership will take for the five Strategic Priorities. The Accountability Framework also includes 90 Day Plans for those in leadership positions to work with their supervisory staff to develop strategies that will meet annual corporate objectives.

Hôtel-Dieu Grace Hospital Statistics

Hôtel-Dieu reported the following statistics on June 3, 2010:

- Total number of beds: 309
- Medical beds: 101 beds which include Neurology, General Medicine and Renal In-patients, the Clinical Teaching Unit, 4 Medical and Telemetry, and General Medicine
- Surgical beds: 84 beds which include Neurosurgery, General Surgery and Orthopaedics
- Intensive Care Unit: 20 beds
- Cardiac Care Unit: 9 beds
- Telemetry: 27 beds
- Mental Health Unit: 68 beds
- Total patients each year: 224,594
- In-patients each year: 11,582
- Emergency Room patients a year: 57,055
- Diagnostic exams a year: 167,525
- Nuclear medicine tests a year: 27,558
- Dialysis visits a year: 34,824
- Day surgeries a year: 20,531
- Cardiac catheterizations a year: 1,928

- Percutaneous Coronary Interventions (PCI) a year: 433
- Annual Budget: \$206 million
- Number of employees: 1,785 staff (691 registered nurses; 103 registered practical nurses; 991 allied health and support staff)
- Physicians: 413
- Volunteers: about 750 volunteers who gave 74,000 hours of service last year

Organisation Structure

Hôtel-Dieu is governed by a Board of Directors. A President and CEO manages the operations of the hospital and reports to the Board. Hôtel-Dieu recently reorganised its senior leadership team to enhance quality patient safety, continue to build physician leadership capacity and physician engagement, and drive organisational effectiveness and cultural transformation. Two new positions were created:

- Vice President Medical and Academic Affairs: this physician leadership role will support quality and patient safety and build physician leadership capacity. The medical and nursing leaders of Hôtel-Dieu's clinical programs will report jointly to this position and the Vice President Patient Services. This will enable better coordination of patient safety and quality initiatives in Hôtel-Dieu's core programs.
- Vice President People Services, Organisational Effectiveness and Corporate Strategy: this person will focus on improving organisational effectiveness and supporting cultural transformation.

Hôtel-Dieu's Medical Leadership includes the Chief of Staff who reports to the Board and oversees Chiefs of the following departments: Anaesthesia, Diagnostic Imaging, Emergency Medicine, General Practice, Laboratory Medicine, Medicine, Neurosciences, Psychiatry and Surgery.

Quality and Safety Initiatives

Hôtel-Dieu has identified quality and patient safety as its number one strategic priority. The hospital has numerous quality and safety initiatives some of which include the following:

- *Patient Safety Monitor*: This quarterly public newsletter includes an analysis of quality and safety indicators, and actions taken to make improvements. The report is widely disseminated and is discussed regularly in the Medical Advisory Committee, Professional Nursing Practice Team, the Patient Safety and Quality Committee of the Board, and at the Board.
- *Patient Safety and Quality Committee of the Board*: In addition to scheduled program quality presentations, the annual work plan of the Patient Safety and Quality Committee includes quarterly education sessions for the committee members. Education sessions in 2009/10 have included: Pain Management as a Patient Safety Issue; Medication Reconciliation "What is all the fuss about?"; Prospective Analysis – Renal Patient; and Care of the Geriatric Client in the Emergency Department. The

Patient Safety and Quality Committee of the Board hosted National Patient Safety Week activities in November 2009.

- The Surgical Safety Checklist was initiated in the spring of 2010.
- Hôtel-Dieu revised its Quality Assurance Program.
- Internal recommendations have been made to enhance pathology reports.
- Hôtel-Dieu has had significant and sustained improvement in a number of publicly-reported indicators such as hand washing compliance (92%).
- Hôtel-Dieu is planning an International Safety Symposium for the Fall of 2010 with an American hospital partner.
- The credentialing process has been enhanced and a comprehensive credentialing policy has been developed.
- Hôtel-Dieu has continued to evolve its Multidisciplinary Mortality and Morbidity Review Team.
- Quality initiatives have been introduced in laboratory services.
- A Sentinel Event reporting structure has been developed, and Safety Huddles and Reviews of the Quality of Care Information Protection Act have been introduced, all of which support the shift to a safety culture.

LEAMINGTON DISTRICT MEMORIAL HOSPITAL²

History and Overview of the Leamington District Memorial Hospital

Leamington District Memorial Hospital (LDMH) was originally built in 1948. It is located in the Municipality of Leamington, a suburban rural community on the north shores of Lake Erie in the western part of Essex County.

LDMH's vision is: *We will be a respected leader in an integrated health system.* The hospital's mission is: *LDMH is dedicated to improving the health of the people we serve; with compassion and in partnership with others we will provide excellence in quality, continuity of service and delivery of health care.*

LDMH's catchment population of about 75,000 includes the communities of Leamington, Kingsville, West Kent (Wheatley), Essex, Pelee Island and the surrounding county regions. The residents in the first three communities are LDMH's core communities, comprising over 80% of the total use of the hospital's major programs and services.

Services and Priorities at Leamington District Memorial Hospital

In the 1960s, LDMH operated over 140 beds with an Emergency Department and some out-patient services. In the early 1980s, budget constraints began impacting on the hospital to the point that today, the hospital operates 65 beds. LDMH has been classified as an efficient small community hospital providing primary and some secondary care services.

² Information submitted on June 4, 2010 by John P. Stenger, Chief Executive Officer, Leamington District Memorial Hospital.

The role of LDMH continues to evolve. In the mid-1990s, LDMH began developing partnerships with the Windsor hospitals and major long-term care and community organisations in Windsor/Essex. In 2009/10, faced with a lack of human and financial resources, LDMH decided to transform itself into an acute care hub or access point to the larger network of health care. LDMH will extend its reach toward larger secondary hospital services and increase integration with community-based services. LDMH adopted key strategic directions in 2009/10 to evolve in these directions:

- LDMH should look to all opportunities for integration and alignment with a larger hospital for all back office services, especially in areas where integration has not yet been initiated.
- LDMH should look to the integration of diagnostic imaging services as a key priority over the next two to three years. The goal of integration should be common referral and booking systems to improve the use and allocation of resources throughout the region (i.e., balancing volumes between the three hospitals' diagnostic imaging services to lower wait times and maximize resources).
- One of the most important levers in enabling integration of support and/or clinical services is the development of an Information Technology strategic vision and plan for the region.
- The development of an "alliance" or network in an integrated system with a larger hospital(s) is necessary to provide seamless access to primary, secondary, and tertiary care for residents and to ensure the future sustainability of services in LDMH.

LDMH also identified potential strategic directions for each of its program areas:

- *Medicine and Emergency Services*: Improve alignment and integration between LDMH's Medicine and Emergency services. The focus should be on developing "case management models" for high volume services (i.e., cardiology, pulmonary, gastro-hepatobiliary type cases) and ensuring continuity of care in how these programs are delivered.
- *Medicine*: Develop greater expertise and focus on the needs of seniors and geriatrics in the acute care medical program. In its Medicine Program, LDMH could begin focusing on the acute needs of its elderly medical patients and the continuum of care for the high volume cases.
- *Emergency Services*: Recognise that the ER is the "front door" for hospital and community services. It is essential to maintain a model of care for 24-hours-a-day, 7-days-a-week ER coverage, at least in the short term, until the healthcare access points are more fully developed.
- *Intensive Care Unit (ICU)*: LDMH's intensive care unit should begin specialising in advanced cardiac and respiratory services within the scope of the Medical Program. The unit could become a successful "cardiac care unit" within an integrated critical care strategy throughout the region. Access to medical expertise should be developed through an integration model with Hôtel-Dieu (the closest tertiary care centre).
- *Obstetrics and Gynecology*: LDMH has concerns about the future of this program. Currently, there is just enough work for about two obstetricians/gynaecologists. If the birth rate continues to decrease, the program may be jeopardized within five years. To sustain this program, LDMH will consider developing a regional/

integrated program with Windsor Regional Hospital. Alignment could include pre- and post-natal care at LDMH, and out-patient gynaecological procedures in the LDMH operating room.

- *Surgery*: LDMH is looking at possibly developing specialty expertise in out-patient General Surgery (including endoscopy, colonoscopy, etc.) and screening procedures. Other surgical services might include out-patient gynaecological services, urology and minor orthopaedic services.

Leamington District Memorial Hospital Statistics

Leamington District Memorial Hospital reported the following activity from April 1, 2009 to March 31, 2010:

- Total number of beds: 65 (+4 surge beds)
- Acute beds: 50 (+ 4 surge beds) accounting for 17,216 patient days and 2,603 acute separations
- Complex Continuing Care Beds: 15 beds accounting for 5,845 patient days and 78 separations
- Intensive Care Beds: 2 (+1 surge bed) accounting for 798 patient days
- Surgical Cases: 4,426 (3,785 day surgeries and 641 in-patient surgeries)
- Ambulatory Care Visits: 12,614
- Births: 246
- Emergency Visits: 26,406
- CT Scans: 5,267
- Ultrasounds, x-Rays, Mammograms: 40,932
- Annual Budget: \$36.4 million

Organisation Structure

LDMH is governed by a Board of Directors. A President and CEO manages the operations of the hospital and reports to the Board. Currently, the Chief of Staff is a surgeon. Medical Chiefs are designated for Obstetrics, Paediatrics, Surgery, Complex Continuing Care and Emergency. These chiefs, along with Clinical Directors, co-lead multidisciplinary care teams in their respective areas. The teams manage process, clinical improvements, budgets, accreditation and quality issues. Medical Chiefs are also designated for Anaesthesia, Diagnostic Imaging and Internal Medicine.

LDMH's Internal Medicine Department has an agreement with Hôtel-Dieu to support an Integrated Chief of Intensive Care for both hospitals. This agreement includes intensivist consultation for LDMH, referral and admission of Level 3 ICU patients to Hôtel-Dieu, and a repatriation agreement to return patients from Hôtel-Dieu back to LDMH.

LDMH also has an agreement with Chatham-Kent Health Alliance to provide out-patient mental health services in the ambulatory care setting, in-patient mental health service consultations, and video-conferencing of crisis services through the Emergency Department.

LDMH has visiting specialists from the Hôtel-Dieu Grace and Windsor Regional Hospitals in surgery (orthopaedics, plastic surgery, dental), urology and diagnostic imaging. LDMH has a contractual arrangement with Hôtel-Dieu to provide nuclear medicine interpretation.

LDMH shares its pathology service with the other two Essex County Hospitals through the Windsor Essex Pathology Associates and the Windsor Essex Integrated Laboratory Service.

Quality and Safety Initiatives

Within the last 12 months, LDMH has conducted the following quality and safety activities:

- Formal review and redesign of its case review process.
- The Risk Manager, Chief of Staff and Chief of Medical Quality of Care have attended all case reviews, and have reported themes and findings to the Medical Quality Care Committee.
- Policies on sentinel event reporting and disclosure have been reviewed and revised using Hôtel-Dieu's policies which were developed by a lawyer.
- The Risk Manager provided one-on-one education for all new medical staff during orientation.
- All risk reports and case reviews have been centralised through the office of the Risk Manager.
- Risk Monitor Pro, a computerized reporting tool for risk events, was implemented.
- Follow-up on case reviews are reported to the Board on a quarterly basis.
- The Erie St. Clair Local Health Integration Network and the Windsor hospitals were notified of sentinel events.
- Risk Management training on "Enterprise Risk" was provided in preparation for the Risk Management Program review. A review of the Risk Management Program and development of a training program for all staff and affiliates was established as a corporate priority.
- The decision was made to establish one central file for all risk files.

WINDSOR REGIONAL HOSPITAL³

History and Overview of the Windsor Regional Hospital

Windsor Regional Hospital (WRH) was established in 1994 as a result of the merger of two hospitals: Metropolitan General Hospital and the Windsor Western Hospital Centre Incorporated. The two founding hospitals brought over 182 years of combined history in healthcare. WRH's vision is: *Outstanding Care – No Exceptions!* Its mission is: *We provide outstanding care with compassion.*

³ Information submitted on June 4, 2010 by Gisele Sullens, Director of Public Affairs, Communications and Philanthropy, Windsor Regional Hospital.

WRH provides acute care, rehabilitation, mental health and continuing care services on two sites: Metropolitan Campus and Western Campus.

- The Metropolitan site provides acute medical and surgical services including emergency, the family birthing centre, neonatal intensive care, paediatric services, critical care, and regional cancer services (in-patient oncology, the cancer centre and the breast health centre).
- The Western site provides regional rehabilitation services, specialized tertiary mental health and complex continuing care.

WRH has a number of satellite locations throughout the region that provide services including the Windsor Regional Children's Centre, Windsor Regional Problem Gambling Services, Windsor Regional Withdrawal Management and Addictions Program, Windsor Regional Residential Treatment Centre, Ontario Breast Screening Program and Windsor Regional Help Link Services.

WRH is the largest hospital in the Erie St. Clair LHIN providing care to over 400,000 people in Windsor and Essex County. WRH also supports the Schulich School of Medicine and Dentistry which is located at the University of Western Ontario and has expanded its undergraduate medical program to the University of Windsor. WRH is one of the sites that delivers the program.

Services and Priorities at Windsor Regional Hospital

WRH provides the following programs and services:

- *Surgical Program:* The Emergency Department provides services to emergency, urgent and non-urgent patients. The pre-admission clinic assesses patients before they are admitted to surgery. The Day Surgery Unit includes surgical out-patients and patients undergoing cystoscopic and selected endoscopic procedures. The Operating Room provides services in general surgery; urology; gynaecology; orthopaedics; ear, nose and throat procedures; plastics; dental/oral/maxillofacial procedures; and cancer. Post-operative care is provided on two in-patient surgical units (gynaecology and obstetrics, and orthopaedics and major general surgery). Ambulatory Care provides follow-up services for burns, plastics, orthopaedic care, and urology with endoscopy including diagnostic procedures involving the colon and gastrointestinal tract.
- *Medicine Program:* Care is provided to patients 14 years and older. The Intensive Care Unit assesses, plans, monitors and treats acute medical and surgical patients with life-threatening illness or multiple system failures. The Cardiac Care Unit provides intensive cardiac care services including cardiac monitoring, ventilation support and monitoring. Cardiology services provide cardiac and medical care for patients "stepping down" from intensive or critical care. The Cardio-Pulmonary Department provides a variety of in- and out-patient diagnostic testing.
- *Women's and Children's Program:* This program provides a Labour Birthing Recovery Postpartum service including 24-hour mother and baby care. Screenings and assessments are conducted in the Antenatal Clinic and physicians on-call conduct their office hours on site. The Maternal Newborn Clinic provides follow-up

support, care and counselling for mothers and babies. The Neonatal Intensive Care Unit (NICU) provides intensive care to critically ill and premature infants at 26+ weeks. Out-patient programs include the NICU follow-up clinic and neurodevelopment clinic. The Paediatric program (newborn to youth 18 years of age) provides in-and out-patient care for many medical, surgical, cancer and mental health issues.

- *Integrated Cancer Program:* Specialised cancer care is provided to patients 14 years of age and older. The Acute Care In-patient Unit provides chemotherapy, radiation therapy, and acute pain and symptom management. The Palliative Unit provides care, pain and symptom management to patients needing end of life care. The Windsor Regional Cancer Centre provides radiation and chemotherapy treatment, systemic therapy and supportive care out-patient services.
- *Mental Health, Addictions and Geriatric Support Programs:* Many specialised mental health and addiction services are provided on the Western site as well as off-site. Services include: Mood and Anxiety Treatment Program, Concurrent Disorder Treatment Program, Residential Rehab and Treatment Program, Mental Health Program for Older Adults, Withdrawal Management, Problem Gambling Services, Dual Diagnosis Outreach Program, Acquired Brain Injury Consult Team, Geriatric Assessment Program, Adult Day Program, Addiction Assessment Referral and Service and Remedial Measures.
- *Regional Rehabilitation Program:* The in-patient unit on the Western site serves patients who need active rehabilitation. The current Western Redevelopment Project includes a total reconstruction of this facility.
- *Complex Continuing Care:* This program offers services to medically unstable adults with complex physical and cognitive challenges.
- *Family and Children Mental Health Services:* This facility serves children, adolescents and their families who are dealing with social, emotional and/or behavioural issues. The Ozad Institute for Neurodevelopmental Disorders is dedicated to research, education and training in developmental disabilities; Help Link Services connect parents seeking assistance for their children with Ministry-funded and voluntary sector supported services; the Sexual Assault Treatment Centre includes the Sexual Assault Program (for medical, evaluation, and evidence collection after an alleged sexual assault for women, men and children 13 years of age and older); SAFEKIDS Program (medical examination and evaluation for children under the age of 13 years after alleged sexual assault/abuse); and Domestic Violence Program (documentation and forensic photography for women who have been physically assaulted/abused by their past or present partner or significant other).
- *Professional Services:* Assistance and counselling services are provided to patients receiving care at WRH and those who work there.
- *Clinical Support Services:* These services include Diagnostic Imaging and Joint Pharmacy and Laboratory services at WRH, Hôtel-Dieu Grace Hospital and Leamington District Memorial Hospital.

Windsor Regional Hospital Statistics

Windsor Regional Hospital reported the following activity from April 1, 2009 to March 31, 2010:

- Beds: 669
- Admissions: 21,287
- Surgical Procedures: 15,209
- Out-patient Visits: 152,578
- Births: 3,923
- Emergency Visits: 68,667
- X-Ray, CT Scans, Ultrasounds: 139,693
- Laboratory Tests: 2,888,049
- Operating Rooms: 11
- Annual Budget: \$303.5 million
- Full-time and Part-time Employee Base: 2,934 employees (Nursing Staff: 1,191; Support Services: 976; Allied Health Professionals: 392)
- Physicians: 445
- Medical Students (Clerks and Residents): 33
- Board of Directors: 16
- Foundation Board of Directors: 15
- Volunteers: 513

Organisation Structure

Windsor Regional Hospital is governed by a Board of Directors. A President and CEO manages the operations of the hospital and reports to the Board. The Chief of Professional Staff also reports into the Board. The President and CEO and the Chief of Professional Staff are responsible for organising and supervising the care provided by all Professional Staff to ensure the quality of care meets the policies and standards set by the hospital.

Medical Leadership includes the Chief of Staff who oversees Chiefs of the following departments: Anaesthesia, Diagnostic Imaging, Emergency Medicine, Family Medicine, Laboratory Medicine, Medicine, Obstetrics and Gynaecology, Oncology, Oral and Maxillofacial Surgery and Dentistry, Paediatrics, Psychiatry and Surgery.

Quality and Safety Initiatives

Some of Windsor Regional Hospital's patient quality and safety initiatives include the following.

- *The Pulse of Quality – Monday Morning Huddles*: In August 2008, WRH began these weekly meetings to review the results of selected quality indicators using safety and quality data from the week before. The weekly huddles provide an opportunity to review the hospital's performance in patient safety and quality, for everyone to think about how they can personally contribute to making progress on an indicator, for leaders to have more influence and empower staff to respond weekly to

areas for improvement. The Vice Presidents and Directors of Clinical and Support Services report indicator results and weekly action plans. The Clinical Practice Leads for each program meet after the Monday Morning Huddle to discuss results and actions, which are then communicated to the direct care providers.

- *Patient Falls*: As part of the WRH's strategic direction for Patient Quality and Safety, one unit was chosen for targeted action on patient safety. The first patient safety indicator selected by the unit – which became known as the Patient Safety Unit – was reducing patient falls. All unit staff were involved in deciding how best to reduce falls. The success of this initiative (no falls on the unit since August 2009) is being shared with other WRH units.
- *Safer Healthcare Now*: WRH is focusing efforts to reduce complications due to hospitalization using the Safer Healthcare Now indicators. These include: reduce central line infections; reduce mortality associated with acute myocardial infarctions (AMI); reduce the incidence of surgical site infection; reduce the baseline rate of ventilator-associated pneumonia; reduce the incidence of venous thromboembolism (VTE) in the hip fracture population; reduce MRSA infections by implementing five evidence-based infection control interventions; and reduce discrepancies between the patient medication history and what is ordered and documented by the physician.

B2. UNDERSTANDING PATHOLOGY AND SURGERY SERVICES, AND THE INTER-RELATIONSHIP BETWEEN THE TWO

Pathology is the study of disease. A pathologist is a medical doctor who has specialty training in anatomical or general pathology. He or she has undergone a post-MD training program similar in length and complexity to surgeons and other medical specialists.

Surgeons – who undergo post-MD training in their area of specialty – perform surgery for cancerous and non-cancerous conditions (e.g., gall stones, hernias, appendicitis, etc.). Surgeries can be performed as emergencies or as scheduled procedures (elective). Usually before surgery is performed, patients undergo investigations that may include blood tests, x-rays, other imaging tests, and biopsies of the affected organ. This information is important to determine the diagnosis, to decide if surgery is warranted, to determine if further treatment is needed before surgery, and to plan what operation should be performed. For many conditions – especially where a cancer diagnosis is suspected – a biopsy is performed. A biopsy can be done by using a needle to obtain tissue, by performing an endoscopic procedure along with the biopsy,⁴ or by cutting out a small piece of tissue surgically. The tissue is sent to the pathologist who analyses the sample.

The process of analysing tissue is done in two phases. In the first phase, medical laboratory technologists prepare slides of the tissues. In the second phase, the pathologist analyses the slides to identify the diagnosis. Using a microscope, the pathologist

⁴ An endoscopic procedure uses a flexible optical instrument that is inserted through a natural opening of the body or a small incision and enables the physician to examine a part of the body's interior.

identifies patterns in the tissue and cells that correspond to different diseases. The pathologist then correlates the features of the pathology with a patient's clinical information to determine the *diagnosis*. At times, the pathologist can also obtain information on the *prognosis* (likely outcome of the disease), and provide *predictive information* that can determine whether a patient might benefit from additional therapies.

In addition to analysing tissue from biopsies obtained before surgery, pathologists also analyse tissue removed from patients during surgery. By law, this tissue must be sent to a pathologist for review. The pathologist assesses the tissue and provides additional diagnostic and prognostic information to the surgeon and other team members. Often, the pathology will confirm the clinical diagnosis. In some situations – most notably in cancer operations – the diagnosis will be confirmed and information from the pathology report will be used to determine how advanced the cancer is, the prognosis of the cancer, and whether and what kind of further treatment is required (e.g., radiation, chemotherapy). One of the most significant roles of the pathologist is in the area of cancer medicine and, in fact, the pathologist can be thought of as a “diagnostic oncologist” (cancer doctor). It is estimated that about two thirds of a pathologist's routine working time is devoted to cancer-related activities.

The working relationship between the pathologist and surgeon is crucial. The pathologist depends on the surgeon to provide an appropriate sample as well as relevant clinical information to assist the pathologist to make a diagnosis. By the same token, the surgeon depends on the pathologist for accurate pathological results of both the biopsy and final pathology reports to make treatment decisions. The pathologist must provide the surgeon with a pathology report that is timely, accurate, complete, and written in an acceptable and readable format.

The pathologist and surgeon should have strong mutual respect, and engage in effective and open communications when discussing patients. In many situations, the decision about diagnosis and optimal treatment is straightforward but in those situations where it is not, pathologists, surgeons and other physicians involved in treating patients must communicate effectively. When this process breaks down, there is a chance that patients may receive inappropriate care resulting in adverse outcomes.

Most hospitals that treat cancer patients have regular forums to discuss the diagnosis and treatment of individual patients especially if the case is complicated or challenging. These meetings – known as Multidisciplinary Cancer Conferences (MCCs) or Tumour Boards – are attended by multiple members of the care team including pathologists and surgeons. The primary function of MCCs is to ensure that a multidisciplinary group discusses all appropriate diagnostic tests, all suitable treatment options, and the most appropriate treatment recommendations for each cancer patient before treatment occurs.

PART C: THE INVESTIGATION

C1. OVERVIEW OF THE STRUCTURE AND METHODS USED TO SUPPORT THE INVESTIGATION

STRUCTURE

The Investigation Team used the following structure to conduct its work.

- A full-time Project Coordinator provided quality oversight for the complex and labour-intensive process of managing the review of pathology cases. In addition to supporting the processes that were used, the Coordinator also provided analytic support to the Team and helped coordinate the Team's activities on site in Windsor.
- The Erie St. Clair Local Health Integration Network managed files and records, and conducted inventory control.
- The Investigators relied on the consistent cooperation of the administrative and medical leadership of the three Essex County Hospitals to provide access to information and be available to meet, when required.

Although it was not a formal part of the structure supporting the Investigation, the Ontario Government enabled the exchange of important information between the Investigators and the College of Physicians and Surgeons of Ontario by passing Ontario Regulation 150/10 made under the *Personal Health Information Protection Act, 2004 – Disclosure by and to Hospital Investigators* (see Appendix B). This temporary regulation allowed the Investigators and the College to share appropriate personal health information about their respective investigations. This was particularly helpful when information needed to conduct investigations was only available to one of the parties.

METHODS

The Investigators used four key methods over the course of their work: 1) conducting site visits, meetings and interviews; 2) reviewing background documents and reports; 3) conducting pathology and surgery case reviews; and 4) developing a fast track process to determine an appropriate medical response in the event of significant discrepancies in the pathology reviews.

Conducting Site Visits, Meetings and Interviews

The investigators conducted site visits and consultations with numerous individuals and groups (see Appendix C). These consultations included:

- Interviews with surgeons, pathologists, and medical leaders at the three Essex County Hospitals, and especially at Hôtel-Dieu.
- Meetings with executive leaders at the three Essex County hospitals and the Chief Executive Officer of the Erie St. Clair LHIN.
- Meetings with various staff to gather facts and information related to the Investigation.

The Investigators made a total of 12 site visits to Windsor and met with over 75 individuals over the course of the Investigation.

Reviewing Background Documents and Reports

Numerous documents and reports were examined (see Appendix D). These included a wide range of policies and procedures at the three Essex County hospitals for credentialing physicians, managing risk, disclosing critical incidents, advancing quality of care, and reporting on and addressing safety issues.

Conducting Pathology and Surgery Case Reviews

An extensive review of pathology and surgery cases was conducted focusing on two physicians at Hôtel-Dieu (Dr. Olive Williams and Dr. Barbara Heartwell). In addition, to provide some context for the review of Dr. Williams' cases, a sample of pathology cases from the four other pathologists at Hôtel-Dieu were reviewed.

The same general approach was used to review pathology and surgery cases: input was obtained through site visits and consultations, teams of reviewers were established, and cases were identified and reviewed. A total of 6,703 pathology cases and 128 surgical cases were reviewed. See Chapter C2 for the detailed approach for the review of pathology cases, and Chapter C3 for the detailed approach for the review of surgery cases.

Dr. John Srigley (Team Lead for Pathology) and Dr. Robin McLeod (Team Lead for Surgery) reviewed 19 additional cases of concern that were brought to the attention of the Investigators through three sources. One source was Hôtel-Dieu which was conducting internal reviews of selected pathology and surgery cases; the second source was a small number of individuals who contacted the Investigation Team directly and requested a review of their cases; and the third source was *Hotline* cases. In January 2010, Hôtel-Dieu established a hotline number for the public to call with concerns about the hospital care they received. As of June 25, 2010, the hospital had received 327 calls. Hôtel-Dieu set up an internal process to address the issues raised by these callers. The hospital kept the Investigators informed of the calls and the issues raised, and provided more detailed information on calls that met certain criteria developed by the Investigators (e.g., cases where specific pathology and surgery concerns were identified during an internal review).

Developing a Fast Track Process to Determine an Appropriate Medical Response in the Event of Significant Discrepancies in the Pathology Reviews

The Investigators – along with the joint Chief of Pathology for the three Essex County hospitals and the Chiefs of Staff of the three hospitals – developed a fast track process to determine an appropriate medical response if the review of pathology materials identified a case where there was a significant difference of opinion between the original pathologist and the reviewing pathologists (working under the direction of the

Investigation Team). For example, the original pathologist may have given the surgeon an opinion that the patient had a specific condition whereas the reviewing pathologist thought the patient did not have the condition (false positive). Similarly, the original pathologist may have given the surgeon an opinion that the patient did not have a specific condition whereas the reviewing pathologist thought the patient had the condition (false negative). The fast track process included informing the Chief of Pathology of the results, and requiring the appropriate Chief of Staff to communicate with each patient's Most Responsible Physician. The patient's physician would then assess all of the patient's clinical information and determine the appropriate course of action.

C2. THE PATHOLOGY REVIEW

METHODS TO INVESTIGATE PATHOLOGY

A "pathology case" is made up of two parts: a patient's pathology slides and his or her pathology report which includes the pathologist's diagnosis based on a macroscopic inspection of the specimen and a microscopic examination of slides prepared by the laboratory. The pathology report may include other information such as the results of special studies, comments about the correlation between the pathological and clinical information, and sometimes a diagnosis by another pathologist who has consulted on the case.

Hôtel-Dieu's pathology reports before mid-2007 are paper reports that are bound as journals. The pathology reports are organised in the journals in consecutive order alphabetically by patient name. On average, there are about 35 pathology journals each year from 2003 to 2006. Paper pathology journals also exist for the first part of 2007. Hôtel-Dieu has electronic pathology reports from mid-2007 to the present.

Three methods were used to investigate pathology: 1) obtaining input through interviews and site visits; 2) establishing a team of pathology reviewers; and 3) identifying pathology cases to be reviewed and conducting the review.

Obtaining Input Through Interviews and Site Visits

Dr. John Srigley, the Team's Pathology Lead, made three site visits to Windsor, conducted 14 interviews and met with various staff to gather facts about the Investigation (Appendix C):

- On March 15, 2010, Dr. Srigley met Executive and Pathology Department staff at Hôtel-Dieu to gather facts and review a number of selected pathology cases.
- On April 13, 2010, Dr. Srigley met individually with nine staff pathologists working in Hôtel-Dieu Grace Hospital and Windsor Regional Hospital, and with laboratory administrators.
- On June 17, 2010, Dr. Srigley met with Dr. Olive Williams and one additional pathologist at Hôtel-Dieu who had been unavailable to meet in April.

Establishing a Team of Pathology Reviewers

The Investigation contracted the services of 14 external pathologists working in one of five large community hospitals in Ontario. Three teams of four pathologists each were established for the general review of pathology cases. Two teams were made up of four pathologists on staff at Grand River Hospital (Kitchener) and four on staff at Niagara Health System (Regional Municipality of Niagara). The third team was made up of three pathologists on staff at The Credit Valley Hospital (Mississauga) and one on staff at North York General Hospital. Community pathologists were chosen as reviewers because they practise in general hospitals that provide a range of services similar to those provided in Windsor. The review pathologists also practise general surgical pathology and cytopathology which is similar to the practices of Dr. Williams and her colleagues at Hôtel-Dieu.

In addition to the general review of pathology cases, the Investigation also assessed a small number of neuropathology cases. All primary brain tumours diagnosed at Hôtel-Dieu are routinely sent for consultation to the Neuropathology Service at London Health Sciences Centre. There was little concern about these cases; however, since Dr. Williams signed out cases with secondary cancers and other conditions, it was seen as important to review the neuropathology cases. Two pathologists who routinely practice neuropathology at Trillium Health Centre (Mississauga) reviewed these cases.

The role of the reviewers was to work with the Pathology Lead, Dr. John Srigley, to provide input into and reach consensus on the methods used to review the cases and to conduct independent expert assessments of the cases. Dr. John Srigley supervised the 15-member Pathology Review Team that included himself and 14 other pathologists:

- Dr. Adrian Batten (FRCPC), Pathologist, Grand River Hospital Corporation
- Dr. Satish Chawla (FRCPC), Pathologist, Niagara Health System
- Dr. Claire Coire (FRCPC), Pathologist, Trillium Health Centre
- Dr. Brian Cummings (FRCPC), Pathologist, Grand River Hospital Corporation
- Dr. Sanjeev Deodhare (FRCPC), Pathologist, Credit Valley Hospital
- Dr. Demo Divaris (FRCPC), Pathologist, Grand River Hospital Corporation
- Dr. Tim Feltis (FRCPC), Pathologist, Credit Valley Hospital
- Dr. Sangeeta Joshi (FRCPC), Pathologist, Niagara Health System
- Dr. Suhas Joshi (FRCPC), Pathologist, Niagara Health System
- Dr. Mona Kamel (FRCPC), Pathologist, Trillium Health Centre
- Dr. Linda Kapusta (FRCPC), Pathologist, Credit Valley Hospital
- Dr. C. S. Leung (FRCPC), Pathologist, North York General Hospital
- Dr. Franklin Ling (FRCPC), Pathologist, Grand River Hospital Corporation
- Dr. Subhash Patel (FRCPC), Pathologist, Niagara Health System

The review of pathology cases took 10 weeks from the beginning of April to mid-June, 2010.

Identifying Pathology Cases to be Reviewed and Conducting the Review

Four groups of pathology cases were reviewed as described below (Table 1).

Table 1: Pathology Cases Reviewed and Number of Cases

	Cases Reviewed	Number of Cases
1.	Review of All Dr. Williams' Pathology Cases in 2008 and 2009 (General Cases + Neuropathology Cases Signed Out by Dr. Williams)	4,623 (General) 53 (Neuropathology)
2.	Targeted Review of Dr. Williams' Pathology Cases in 2003 to 2007	1,551
3.	Targeted Sample of Pathology Cases from 2008 and 2009 of the Four Other Hôtel-Dieu Pathologists	476
4.	Additional Cases of Concern	19

1. Review of All Dr. Williams' Pathology Cases in 2008 and 2009 and Neuropathology Cases Signed Out by Dr. Williams

All of Dr. Williams' pathology cases in 2008 and 2009 were pulled for review. These 4,623 general cases included electronic pathology reports and slides that were directed to the general team of 12 reviewers. Each case was reviewed independently by two different reviewers working at two different hospitals. For the first review, the pathology cases were evenly distributed to the 12 reviewers at their base hospitals. Each reviewer assessed the pathology report and slides using a standard evaluation template developed for this Investigation (Appendix E). When all the cases were reviewed once and the evaluations submitted to the Project Coordinator, all the cases were distributed to a second reviewer at another hospital who, once again, evaluated the report and slides using the standard template. If the two independent assessments differed, the two reviewers consulted each other. Sometimes, this was accomplished by phone but in a number of instances, the reviewers met face-to-face to review the slides and written records. This process resulted in consensus in all cases.

A total of 53 neuropathology cases from 2008 and 2009 were independently reviewed by the two neuropathology reviewers.

The review of all of Dr. Williams' pathology cases and the neuropathology cases signed out by her resulted in two independent reviews of 4,623 general pathology cases and 53 neuropathology cases in 2008 and 2009.

2. Targeted Review of Dr. Williams' Pathology Cases in 2003 to 2007

Dr. Williams came on staff at Hôtel-Dieu in September 2003. Between 2003 and 2007, she completed about 2,500 pathology cases each year for a total of about 12,500 pathology cases. Dr. Williams' reports from 2003 to mid-2007 were identified manually in Hôtel-Dieu's pathology journals and copied. Her pathology records beginning in the latter part of 2007 were available in electronic format.

All of Dr. Williams' 12,500 pathology reports from 2003 to 2007 were evenly distributed among the 12 reviewers. Each reviewer was instructed to assess the reports and select those that met any of the following criteria:

- Breast, prostate, colon (including rectum), lung and endometrial biopsies diagnosed as cancer, suspicious or atypical. These cases were chosen to assess false positives (i.e., cases incorrectly diagnosed as cancer).
- Benign breast and prostate biopsies. These cases were chosen to assess false negatives (i.e., cases incorrectly diagnosed as benign).
- All other cases where the reviewer assessed the record and thought there were unusual findings or the report was ambiguous.

The reviewers provided the Project Coordinator with the case numbers of 1,551 pathology reports that met the above criteria. The Coordinator then forwarded the corresponding pathology slides to the reviewers to conduct the first review of the targeted pathology cases using the standard evaluation template. When all the cases were reviewed once and the evaluation submitted to the Project Coordinator, the cases were assigned to a second reviewer at the same hospital. If the two reviewers disagreed about a case, they consulted each other and reached final consensus. This review resulted in two independent reviews of 1,551 pathology cases assessed by Dr. Williams from 2003 to 2007.

3. Targeted Sample of Pathology Cases from 2008 and 2009 of the Four Other Hôtel-Dieu Pathologists

To provide some context for the review of Dr. Williams' cases, a selected sample of about 120 pathology cases signed out in 2008 and 2009 by each of the other four pathologists at Hôtel-Dieu were independently reviewed. The selection criteria for these cases included breast, prostate, colorectal, gastric and lung biopsies that led to benign, malignant or atypical diagnoses.

Of the pathology cases that met these criteria, 476 cases were selected, anonymized (i.e., the pathologists' names were removed), and the cases were evenly distributed to the 12 reviewers at their base hospitals. Each reviewer assessed cases using the standard evaluation template. When all the cases were reviewed once and the evaluation submitted to the Project Coordinator, the cases were given to a second reviewer at the same hospital. Pairs of reviewers consulted each other and reached consensus if their independent reviews differed. This review resulted in two independent assessments of 476 pathology cases from the four other Hôtel-Dieu pathologists in 2008 and 2009.

4. Additional Cases of Concern

As noted previously (Chapter C1), 19 additional cases of concern were brought to the attention of the Investigators through three sources: Hôtel-Dieu Grace Hospital, direct communication with the Investigation Team, and *Hotline* cases. Dr. Srigley, the Team's Pathology Lead, reviewed the pathology aspects of these cases.

INVESTIGATION TEAM FINDINGS AND RECOMMENDATIONS ABOUT PATHOLOGY

Introduction

Eleven pathologists were practising in Windsor at the end of 2009. The pathologists were members of the Windsor-Essex Pathology Associates, a business partnership that contracts with the Windsor Essex hospitals for professional and laboratory medicine services. Although all the pathologists belonged to one group, five were practising at Hôtel-Dieu Grace Hospital and five at the Windsor Regional Hospital in 2009. The 11th pathologist – Dr. David Shum, the Chief of Pathology – continued to rotate between both sites and do administrative work.

Although the pathologists practised on two sites, technical services were conducted at Windsor Regional. Before January 25, 2010, the macroscopic assessment of specimens was carried out in each of the two hospitals. On January 25th of this year, this function was consolidated at Windsor Regional Hospital. The two pathologist assistants who work with the pathologists doing gross examination of specimens are now located on the Windsor Regional site.

In the past, the Windsor pathologists were responsible for conducting the pathology tests of patients receiving care in the hospital where the pathologist was located. The pathologists at Hôtel-Dieu also reviewed the specimens coming from the Leamington District Memorial Hospital. On October 1, 2009, the Windsor Regional Histology laboratory began consolidating all the surgical pathology cases in Windsor and Leamington and distributing them to the pathologists at Hôtel-Dieu and Windsor Regional. Cases needing a second external review are usually sent to London or Toronto.

The following two sections address:

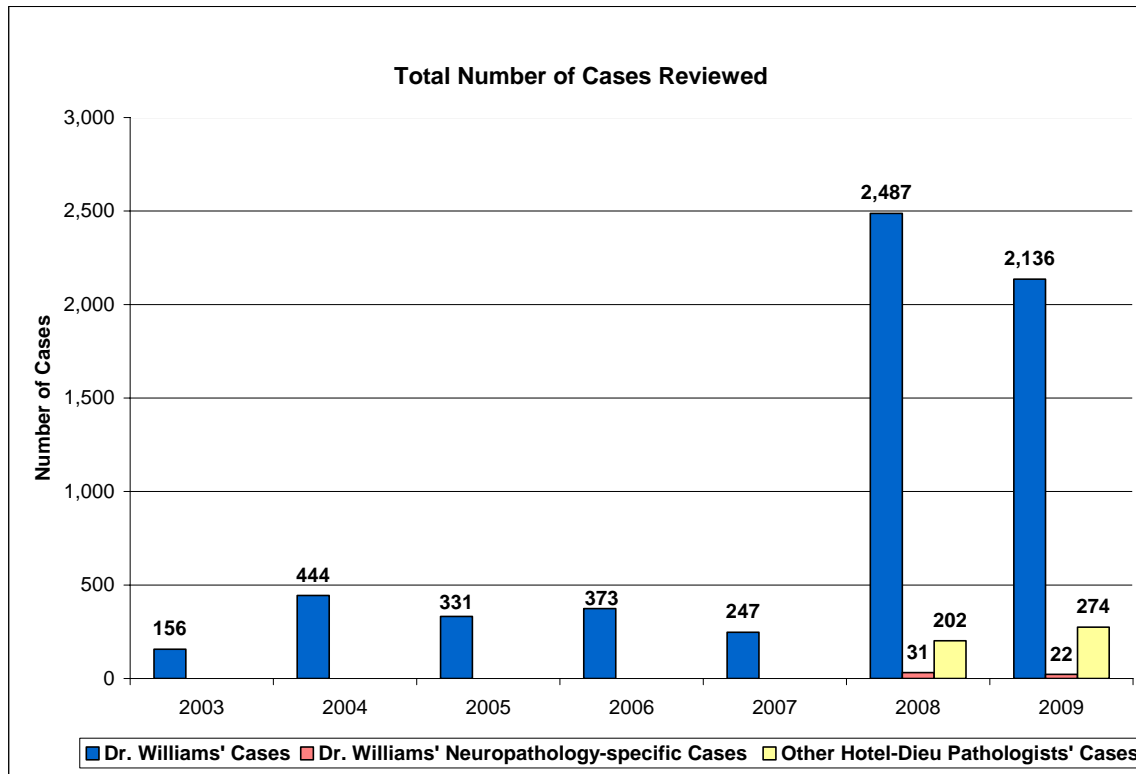
- Pathology at Hôtel-Dieu Grace Hospital which includes the analysis of pathology records, and issues arising from the pathology review.
- Pathology at the Three Essex County hospitals

Opportunities to improve the quality and safety of pathology across Ontario are presented in Chapter C5.

Pathology at Hôtel-Dieu Grace Hospital

Analysis of the Pathology Records

The Pathology Review Team conducted a comprehensive review of 6,227 pathology cases of Dr. Williams (6,174 general and 53 neuropathology cases). The Team also reviewed 476 cases performed by the other four pathologists. Figure 1 and Table 2 show the distribution of cases by year.

Figure 1: Total Number of Cases Reviewed**Table 2: Distribution of Pathology Cases**

Year	Dr. Williams' Cases	Dr. Williams' Neuropathology-specific Cases	Other Hôtel-Dieu Pathologists' Cases	Total
2003	156			156
2004	444			444
2005	331			331
2006	373			373
2007	247			247
2008	2,487	31	202	2,720
2009	2,136	22	274	2,432
Total	6,174	53	476	6,703

The pathology cases represented a wide range of specimen types (see Appendix F). Of the 6,703 cases, the most frequent specimen types were gastric (12%), colorectal (12%), breast (11.6%) and skin (9%). All other specimen types accounted for 7% or less of cases with one exception. The “other” category – which includes pancreas, kidney, thyroid, spleen and so on – accounted for 14% of all specimen types.

The Pathology Review Team assessed three main areas in its review of cases:

- Adequacy of the clinical diagnosis/information provided in the pathology cases

- Agreement or disagreement with the original diagnosis and the potential clinical significance of any disagreement
- The quality of the written report

It is important to note that data must be interpreted with caution when the number of cases is small. Since there were only a total of 53 neuropathology cases and they included pathology reviews by Dr. Williams and, in some cases, London-based pathologists, the Investigation Team analysed these cases separately. In the Team's opinion, there were no findings of significant concern in the neuropathology cases.

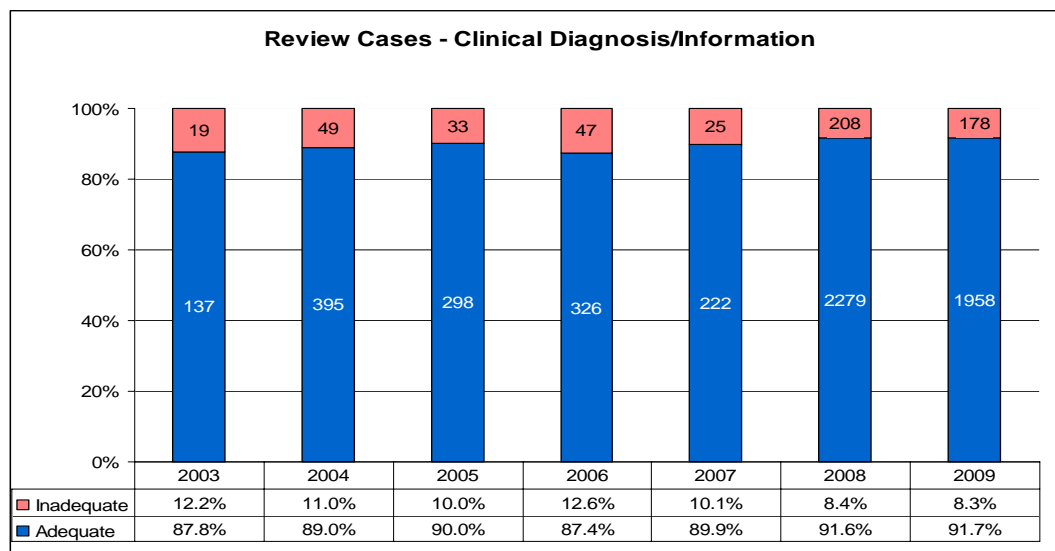
The analysis below presents the Pathology Review Team's findings for all the other cases reviewed.

Review Area 1: Adequacy of the Clinical Diagnosis/Information Provided in the Pathology Cases

A pathologist needs to have appropriate demographic and clinical information about a patient to do a quality evaluation of the pathology specimen. The submitting clinician is responsible for providing necessary information – such as the clinical presentation and the working diagnosis – to enable the pathologist do his or her job well.

The pathology reviewers assessed the adequacy of the clinical diagnosis and information found in the pathology cases. The review of Dr. Williams' cases found the following (Figure 2)

Figure 2: Adequacy of Clinical Diagnosis/Information Provided in the Review of Dr. Williams' Pathology Cases (Targeted Cases in 2003 to 2007; All Cases in 2008 and 2009)



- In their review of targeted cases from 2003 to 2007, the pathology reviewers concluded that there was inadequate clinical diagnosis/information in at least 10% of Dr. Williams' cases in each year (12.2% in 2003; 11.0% in 2004; 10% in 2005; 12.6% in 2006; 10.1% in 2007).
- In their review of all of Dr. Williams' pathology cases in 2008 and 2009, the pathology reviewers concluded that 8.4% of her cases in 2008 and 8.3% of cases in 2009 had inadequate clinical diagnosis/information.

The pathology reviewers did not find significantly different results when assessing the 2008 and 2009 targeted cases of the other four pathologists at Hôtel-Dieu).

The Investigation Team notes that, regrettably, it is not unusual for clinical diagnosis and other information to be missing on pathology requisition forms. A 1994 Q-Probes study of 1,004,115 pathology cases from 417 institutions found that failure to provide adequate clinical history accounted for 40.4% of all deficiencies identified in the study.⁵ Given that the definition of "adequate" may vary, the research literature is inconclusive about the actual prevalence of missing clinical information on pathology requisitions. In the experience of the Pathology Review Team, the proportion of cases missing clinical diagnoses or information in the case reviews of Dr. Williams and the other four Hôtel-Dieu pathologists is within the range commonly seen by colleagues in similar-sized organisations in Ontario.

Review Area 2: Agreement or Disagreement With the Original Diagnosis and the Potential Clinical Significance of any Disagreement

Figure 3 presents the reviewers' opinions on the original diagnosis found in Dr. Williams' pathology cases and the potential clinical significance of any disagreements or discrepancies. A disagreement or discrepancy means there was a difference between the original interpretation of the pathologist and the interpretation of the pathology reviewers.

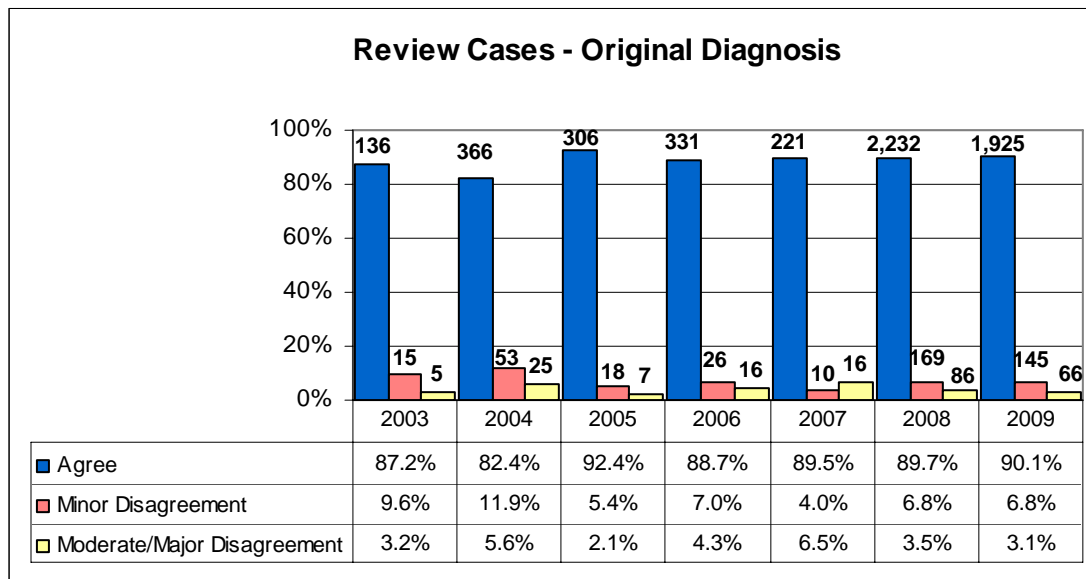
The review of Dr. Williams' cases found the following (Figure 3):

- In their review of targeted cases from 2003 to 2007, the pathology reviewers disagreed with Dr. Williams' original diagnosis – either minor or moderate/major disagreement – in 12.8% of cases in 2003; 17.5% of cases in 2004; 7.5% of cases in 2005; 11.3% of cases in 2006; and 10.5% of cases in 2007.
- In their review of all of Dr. Williams' pathology cases in 2008 and 2009, the pathology reviewers disagreed with Dr. Williams' original diagnosis – either minor or moderate/major disagreement – in 10.3% of cases in 2008 and 9.9% of cases in 2009.

⁵ Nakhleh, R.E. and R.J. Zarbo. 1996. "Surgical pathology specimen identification and accessioning: a College of American Pathologists Q-Probes study of 1,004,115 cases from 417 institutions" *Arch Pathol Lab Med* 120: 227-223. As cited in Nakhleh, R., P. Fitzgibbons (editors). 2005. *Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction*. Illinois: College of American Pathologists. Pg. 48.

When the pathology reviewers assessed the cases from the other four Hôtel-Dieu pathologists in 2008 and 2009, the reviewers disagreed with the original diagnosis – either minor or moderate/major disagreement – in 10.5% of cases.

Figure 3: Agreement or Disagreement With the Original Diagnosis in the Review of Dr. Williams' Pathology Cases (Targeted Cases in 2003 to 2007; All Cases in 2008 and 2009)



Legend	
	Agree: Including some cases where further testing recommended (Categories A and B as noted in Appendix E)
	Minor Disagreement: Including some cases where further testing recommended (Categories C and D as noted in Appendix E)
	Moderate/Major Disagreement: With or without clinical significance (Categories E and F as noted in Appendix E)

A significant amount of research has been conducted on discrepancy rates in diagnostic pathology. It is difficult to compare many of these studies since different research methods are used, different groups are studied, and “clinically significant discrepancy” is defined in various ways. Some studies examine individual pathologists whereas others examine general groups; some studies are retrospective whereas others are prospective; some studies are “blinded” where the reviewer does not know the original diagnosis whereas others are “non-blinded”; some studies use general surgical pathologists as reviewers whereas others use sub-specialists; and some studies target samples of cases whereas others look at the complete group of cases (known as “consecutive cases”).

A review of published studies showed total discrepancy rates ranging from 0.5% to 43%.⁶ One study of 3,000 consecutive cases found a total discrepancy rate of 7.8%.⁷

⁶ Renshaw, A. A. 2001. “Measuring and reporting errors in surgical pathology.” *Am J Clin Pathol* 115: 338-341.

⁷ Whitehead, M.E. et al. 1984. “Quality assurance in histopathologic diagnoses: a prospective audit of three thousand cases.” *Am J Clin Pathol* 81:487-491.

Another major study of discrepancies in anatomic pathology in 74 institutions (including Canadian institutions) which used a secondary pathologist review found a wide variation in discrepancy rates.⁸ The average discrepancy rate was 6.7% with a median discrepancy rate of 5.1%. The discrepancy rates in a quarter of the institutions below the median (25th percentile) to a quarter of the institutions above the median (75th percentile) ranged from 10% to 1%. A College of American Pathologists' review of published reports on targeted cases concluded that a reasonable threshold for overall discrepancy rates between original and outside review diagnosis is 10%.⁹

While there is no directly comparable research study to the one done for this Investigation, it is the opinion of the Investigation Team that an **overall discrepancy rate** of about 10% appears to be within the general discrepancy range reported in the literature for various practice groups.

- The overall discrepancy rate for Dr. Williams' consecutive cases in 2008 was 10.3% and 9.9% in 2009. These rates appear to be close to or within the accepted overall discrepancy threshold reported in the literature. It is not appropriate to compare the discrepancy rates of Dr. Williams' targeted cases reviewed in 2003 to 2007 to those in the medical literature as there are no directly comparable studies.
- The cases reviewed from the other four Hôtel-Dieu pathologists were a sample of targeted cases and, as such, are not directly comparable to the analysis of Dr. Williams' consecutive cases in 2008 and 2009. When assessing the targeted cases of the other four pathologists, the Pathology Review Team did not have concerns with the overall discrepancy rate of 10.5% for this group (2008 and 2009 cases)

The Investigation Team focused particular attention on cases where there was a potentially **significant clinical discrepancy** between the original pathology assessment and the assessment of the pathology reviewers.

As noted in Figure 3, the pathology reviewers had moderate or major disagreement with the original diagnosis in 221 of Dr. Williams' 6,174 cases. A more detailed analysis found that in 45 of these 221 cases, there was sufficient concern that the disagreement may have clinical significance that might need further investigation, treatment or patient follow-up. As noted in Chapter C1, the Investigators – along with the Chief of Pathology for the three Essex County hospitals and the three hospitals' Chiefs of Staff – developed a fast track process to determine an appropriate medical response in these cases.

When the 45 cases were reviewed through the fast track process, the Most Responsible Physicians determined that 8 out of the 45 patients needed further follow-up with some needing additional investigation and/or treatment. All of these patients (or their families) were contacted by or through their Most Responsible Physician as part of this Investigation.

⁸ Raab, S.S, R.E. Nakhleh and S. G. Ruby. 2005 (April). "Patient Safety in Anatomic Pathology: Measuring Discrepancy Frequencies and Causes." *Arch Pathol Lab Med* 129: 459-466. Pg. 461.

⁹ Nakhleh, R., P. Fitzgibbons (editors). 2005. *Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction*. Illinois: College of American Pathologists. Pg. 61.

The Pathology Review Team used these fast-track cases to calculate Dr. Williams' significant error rate. In order to compare this rate to those found in the medical literature, the analysis was limited to the consecutive cases of 2008 and 2009. Of the 4,623 pathology cases reviewed by Dr. Williams in 2008 and 2009, the Review Team identified 30 cases of sufficient concern to warrant fast tracking. As well, Dr. Srigley independently reviewed 19 additional cases of concern that were not part of the larger pathology review and which included some cases from Hôtel-Dieu pathologists other than Dr. Williams. Of these 19 cases, there were four cases of Dr. Williams in 2008 and 2009 that were of sufficient concern to warrant fast tracking. Thus, it was determined that Dr. Williams had 34 cases of significant clinical concern in 2008 and 2009. This results in a 0.73% clinically significant error rate (34/4,627).

A review of a limited number of available research studies concluded that a reasonable threshold for clinically significant errors detected by surgical pathology case review is less than 2%.¹⁰ Raab et al.'s study, noted above, found that 1.1% of all anatomic pathology cases that underwent secondary review were associated with a harmful significant event.¹¹

- Based on the cases reviewed for the Investigation, the discrepancy rate for significant disagreements for Dr. Williams of 0.7% is within the acceptable range quoted in the literature.
- As noted earlier, the cases reviewed from the other four Hôtel-Dieu pathologists were targeted cases and, as such, are not directly comparable to the analysis of all of Dr. Williams' consecutive cases (2008 and 2009). Two cases from the other Hôtel-Dieu pathologists were forwarded for a fast track review. The discrepancy rate for significant disagreements for the other four pathologists, based on this targeted review, are certainly within the acceptable range as quoted in the medical literature.

Review Area 3: Quality of the Written Report

The pathology report is the pathologist's record of the patient's specimen. The report includes macroscopic and microscopic observations, the recorded diagnosis, and sometimes a comment that correlates pathological and clinical information. Reviewers assessed the quality of reports according to whether they had no concerns, minor concerns or moderate/major concerns.

The review of Dr. William's cases found the following (Figure 4):

- In their review of targeted cases from 2003 to 2007, the reviewers had moderate or major concerns about the report quality in 2% or less of cases in each year (0.6% in 2003; 2.0% in 2004; 0.6% in 2005; 1.9% in 2006; 2.0% in 2007).

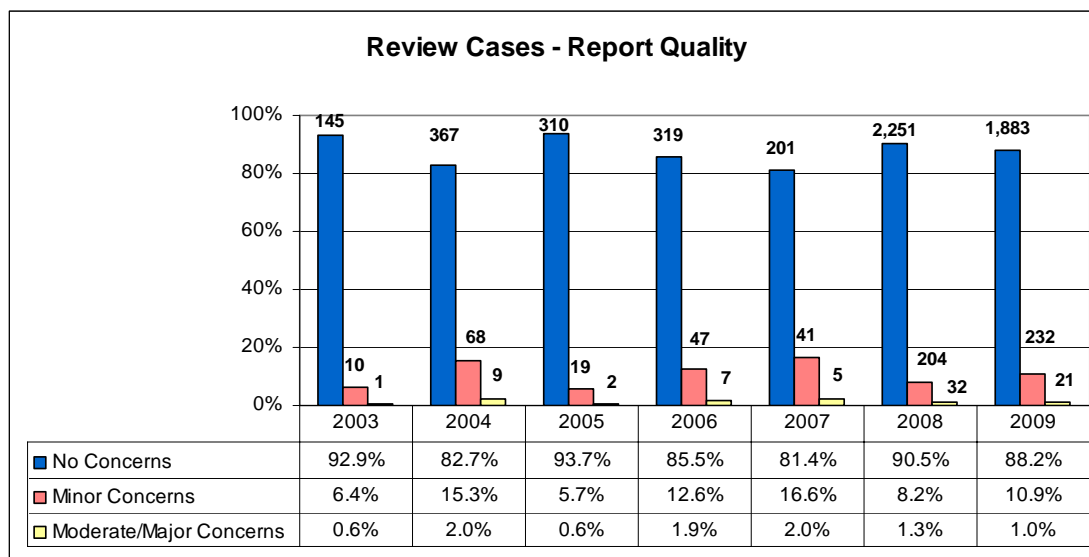
¹⁰ Nakhleh, R., P. Fitzgibbons (editors). 2005. *Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction.* Illinois: College of American Pathologists. Pg. 58.

¹¹ Raab, S.S, R.E. Nakhleh and S. G. Ruby. 2005 (April). "Patient Safety in Anatomic Pathology: Measuring Discrepancy Frequencies and Causes." *Arch Pathol Lab Med* Vol. 129, 459-466. Pg. 465.

- In their review of all of Dr. Williams' pathology cases in 2008 and 2009, the pathology reviewers had moderate or major concerns about report quality in 1.3% and 1.0% of cases, respectively.

The reviewers had moderate or major concerns about report quality 0.6% of the targeted cases reviewed from the other four Hôtel-Dieu pathologists in 2008 and 2009.

Figure 4: Concerns with Report Quality in the Review of Dr. Williams' Pathology Cases (Targeted Cases in 2003 to 2007; All Cases in 2008 and 2009)



Concerns about report quality are critically important. Reports need to be complete and readable. Inconsistencies, ambiguities or significant typographical errors can lead to misinterpretations by clinicians, treatment errors and miscommunication to patients.

Raab et al.'s multi-institutional study, noted earlier, found that .07% of reports in 6,186 specimens were deemed to be "markedly unclear" and 0.3% were "moderately unclear".¹² For this Investigation, the pathology reviewers had moderate/major concerns about the quality of Dr. Williams' reports in 1% of cases reviewed in 2009 and 1.3% of cases reviewed in 2008.

The review of Dr. Williams' cases from 2003 to 2007 was a targeted sample but it is noted that the pathology reviewers had moderate/major concerns about the quality of Dr. Williams' reports in 2% of the cases that were reviewed in 2004 and 2007, and in 1.9% of cases reviewed in 2006.

¹² Raab, S.S, R.E. Nakhleh and S. G. Ruby. 2005 (April). "Patient Safety in Anatomic Pathology: Measuring Discrepancy Frequencies and Causes." *Arch Pathol Lab Med* Vol. 129, 459-466. Pg. 463.

Issues Arising From the Pathology Review Specific to Hôtel-Dieu

The Investigation Team identified three issues arising from the pathology review specific to Hôtel-Dieu.

Pathology Reporting Process

The Pathology Review Team identified the need for Hôtel-Dieu to improve its pathology reporting process. Over the course of reviewing 6,703 pathology cases, the Team identified cases where:

- Two different diagnoses were noted (one from Hôtel-Dieu and one from an external review with no determination of the final diagnosis);
- It was unclear whether a second pathology review had been requested;
- The surgeon had proceeded to operate without waiting for the results of a second review;
- The post-operative pathology reports were not included in the patient's chart; and
- Results of special studies such as immunohistochemistry were not included in the original pathology report or in an addendum report.

Hôtel-Dieu has made improvements in pathology and pathology reporting over the past few months. One new pathologist has been recruited and communications are improving. The diagnosis is bolded on the pathology record and synoptic reports have been adopted. The Investigation Team believes that Hôtel-Dieu needs a sustained and concerted effort to improve pathology reporting processes. The College of American Pathologists has standard checklists for cancer resection specimens that have been accepted by Ontario's pathology community and are currently being used in Windsor. In addition, Path2Quality is developing best practice guidelines for internal quality assurance in pathology.¹³ The project is developing surgical pathology safety checklists which will be helpful to Hôtel-Dieu.

The Pathology Review Team observed that problems with reporting were made worse by the lack of effective communications between Hôtel-Dieu pathologists and surgeons. It is suspected that the lack of communications leads to asking for more second opinions than may be necessary. Pathologists and other clinicians need to consult with each other about patients, and work collaboratively to determine a correct diagnosis and proper treatment plan in cases that are less clear.

¹³ Path2Quality is a collaborative initiative of the Ontario Medical Association Section on Laboratory Medicine and the Ontario Association of Pathologists.

It is recommended that:

- R1 The current pathology reporting processes be reviewed by the leadership of pathology and surgery at Hôtel-Dieu Grace Hospital, and consensus be reached on a new standard report format, policies and processes for obtaining and recording a second review, standards for follow-up, and processes for effective communications and clarification.**

Professional Development

In its review of cases, the Pathology Review Team identified cases with insufficient clinical-pathological correlation, cases with insufficient or inappropriate workup, the use of inconsistent terminology and confusing terms, the use of dated terminology, the lack of standard reports, and insufficient use of current classification systems and grading and staging schemes. Although pathologists are encouraged to attend appropriate continuing medical education events and to follow the appropriate Royal College of Physicians and Surgeons guidelines for continued professional development, the Investigation Team believes that Hôtel-Dieu pathologists would benefit from targeted professional development opportunities.

It is recommended that:

- R2 All pathologists participate in continuing professional development under the guidance of the Department Chief. Training should focus on the use of: i) standardized, contemporary approaches to investigating disease; ii) current terminology; iii) current classification systems; and iv) current grading and staging schemes.**

Dr. Olive Williams

Dr. Olive Williams has been providing pathology services at Hôtel-Dieu Grace Hospital since September 2003. She is a Fellow of the Royal College of Physicians and Surgeons of Canada.

The comprehensive retrospective review of Dr. Williams' cases indicated that the proportion of discrepancies between her assessments and those of the reviewers appeared to be within the accepted range as generally found in the research literature. The *overall* discrepancy rate between Dr. Williams' diagnosis and those of the pathology reviewers appeared to be within the accepted overall discrepancy threshold. The discrepancy rate for *significant clinical concerns* for Dr. Williams was also within the acceptable range reported in the literature. Finally, concerns about the *quality* of Dr. Williams' reports are slightly higher than the acceptable threshold in 2009 and even higher in 2008 (and in three of five years in the review of a targeted sample of cases from 2003 to 2007).

Notwithstanding the fact that Dr. Williams' discrepancy rates were within accepted ranges as reported in published studies the Pathology Review Team was concerned about the potential serious adverse clinical consequences of certain discrepant diagnoses in Dr. Williams' cases. The Review Team also had particular concerns about the quality of her reports: there was inadequate workup in some cases, a failure to report certain special studies that had been carried out, the use of outdated terminology and classification systems, somewhat ambiguous or incorrect use of clinical terms, and the lack of clinical pathological correlation.

The Investigation Team understands that Dr. Williams is not practising in Ontario at this time. Given the concerns of the Team noted above,

It is recommended that:

- R3 The College of Physicians and Surgeons of Ontario consider undertaking a clinical competency assessment of Dr. Olive Williams if she decides to resume clinical practice in Ontario.**

Pathology at the Three Essex County Hospitals

Quality Assurance Program

Over the course of its review, the Investigation Team was struck many times by the importance of a quality assurance program for pathology. In his six years as Chief of Pathology for the three Essex County Hospitals, Dr. David Shum has been leading the development of a Quality Assurance Program in pathology. The program includes peer assessments, auditing and analyses of correlations. The investigators commend Dr. Shum's efforts to evolve the program over time. The Team also recognises the challenges of implementing such a program without full physician participation and the supporting resources to help the program succeed. Although the Investigators support the development of a provincial quality assurance program (see Recommendation 17), in the interim, the Essex County Hospitals need to continue developing and implementing their local pathology Quality Assurance Program. Documented peer assessments are a critical component of the program. This time intensive activity needs to be supported with appropriate laboratory physician and administrative resources.

It is recommended that:

- R4 All pathologists working in Windsor adopt the Quality Assurance Program for Pathology developed by the Chief of Pathology which includes peer assessments, auditing and correlational analysis. Appropriate laboratory physician and administrative resources should be allocated to support the Program.**

Centralising Services

Over the course of the site visits and interviews, the Investigators were able to observe and assess the pathology practices on the two sites (Hôtel-Dieu Grace Hospital and Windsor Regional Hospital). As noted earlier, five pathologists practised at Hôtel-Dieu and five at Windsor Regional in 2009. The 11th pathologist – the Chief of Pathology – rotated between both sites and performed clinical and administrative duties. The technical services and macroscopic assessment of specimens were conducted at Windsor Regional.

The Team observed and heard of differences in the working environments of the pathology practices at the two hospitals. Windsor Regional's five pathologists appeared to work well together in a shared space, they shared cases easily, and seemed to have strong collaborative working relationships with their clinical colleagues at the hospital and the Regional Cancer Program. These pathologists took a team approach and frequently consulted with their colleagues. In addition to doing general work, these pathologists have developed areas of specialisation. In contrast, Hôtel-Dieu's working environment appeared quite different. The pathologists have individual offices along a corridor which impacted on their ability to interact easily. As a result, there was less sharing of cases among pathologists and less than optimal communication. It is the view of the Investigators that the quality of Windsor's pathology services would be strengthened and the working environment improved if all the pathologists were centralized at the Windsor Regional site. Working together in an open, collegial and supportive environment would help advance quality, increase inter-professional consultations and communications, and promote professional development opportunities. It would also promote specialisation of pathologists which would benefit Essex County residents who might need specialised pathology services. A rotating pathologist should be available on the Hôtel-Dieu site daily for consultations. This pathologist would be expected to interact and communicate openly with the surgical staff (and other clinicians) when working at Hôtel-Dieu. The hospitals and Erie St. Clair LHIN would need to consider the space and resource requirements to support the move to a centralized pathology service.

It is recommended that:

- R5 The group of Windsor pathologists be centralized on one site – Windsor Regional Hospital – to support the successful development of the quality assurance plan, improve inter-professional communication, support increased specialisation in pathology, and enhance education opportunities (including multi-disciplinary cancer conferences and routine prospective multi-headed microscope slide conferences). To ensure optimal care at the Hôtel-Dieu Grace Hospital, a rotating pathologist should be available on this site daily. The pathologist should interact and communicate openly with the Hôtel-Dieu Grace Hospital clinicians and be readily available for consultations and rounds.**

Cytological Specimens

The Pathology reviewers noted that the preparation of cytology samples is generally of poor quality.¹⁴ Currently, the material is often preserved inadequately with thick preparations and poor quality staining which makes it difficult to interpret slides. At times, the material processed from blocks of cells was also poorly preserved and stained. The reviewers noted that using contemporary liquid-based cytopreparatory techniques is critical for the preparation of high quality slides. The Investigation Team is aware of and supports current plans to purchase new equipment and change the slide preparation process. It is important that this improvement occur in a timely fashion.

It is recommended that:

R6 The Essex County Hospitals improve the process of preparing cytological specimens through the use of contemporary liquid-based cytology systems.

Digital Scanning

The Investigators learned that it can take more than two weeks from the time a patient has a neurosurgical procedure in Windsor to the time the neurosurgeon receives the patient's pathology report (neuropathology is obtained at London Health Sciences Centre). A process is needed for more efficient reporting of neurosurgical pathology specimens. Improvements could include more efficient processing, movement and reporting of pathology specimens or the use of electronic images with remote reporting (in London or elsewhere). Digital scanning technology may also facilitate second opinion consultations for a wide variety of other cases, most notably cancer cases. It should be noted that digital scanning technology and remote review are also recommended as part of a provincial quality assurance system for pathology (Recommendation 17).

It is recommended that:

R7 The three Essex County Hospitals examine the role of digital scanning technology to facilitate second opinion consultations and improve timely diagnosis in specialized areas such as neuropathology.

Access to Specialised Pathology

The Essex County Hospitals and the London Health Sciences Centre are academic partners in a distributed medical school (i.e., medical students are trained at both sites). In addition, there is a natural link between these two centres since Windsor often refers patients to London for tertiary health care. In recent years, there have been fewer second opinion pathology consultations between the two organisations due, in part, to regulatory

¹⁴ Cytology samples are samples of individual cells and small clusters of cells that are used to help diagnose and screen for disease.

and financial issues. There is a need to support second opinion consultations, when needed, between Windsor and London in selected specialty areas. Digital scanning technologies as noted in Recommendation 7 would also help support this practice.

It is recommended that:

R8 The existing collaboration between the Essex County Hospitals and their academic health sciences partner, London Health Sciences Centre, be enhanced especially with respect to specialized areas of pathology including neuropathology, hematopathology and other areas.

C3. THE SURGERY REVIEW

INTRODUCTION

The Investigation Team conducted interviews and reviewed documents in the first month of its mandate to help assess the major directions for its work. Based on the results of its early work, the Team decided to focus on general surgery. Other surgical disciplines such as thoracic or orthopaedic surgery were not reviewed. After speaking with the Surgeons-in-Chief at the three Essex County hospitals and other leaders, the main focus of the investigation was the surgical cases of Dr. Barbara Heartwell at Hôtel-Dieu. The surgical services at the other two hospitals were not assessed in detail.

METHODS TO INVESTIGATE SURGERY

Three methods were used to investigate surgery: 1) obtaining input through interviews and site visits; 2) establishing a team of surgery reviewers; and 3) identifying the surgery cases to be reviewed and conducting the review.

Obtaining Input Through Interviews and Site Visits

Dr. Robin McLeod – the Team’s Surgical Lead – made four site visits to Windsor during which she conducted interviews with 23 individuals and met with various other staff (see Appendix C):

- On March 15, 2010, Dr. McLeod met various staff at Hôtel-Dieu to gather facts about the Investigation and review the surgical details of cases of concern that were identified by Hôtel-Dieu administration.
- On March 29, 2010, Dr. McLeod met with Dr. Barbara Heartwell, with a number of staff surgeons individually, and held a group meeting with two members of the Division of General Surgery.
- On April 12, 2010, Dr. McLeod conducted an audit of charts with the assistance of three other surgeons from outside of Windsor.
- On May 31, 2010, Dr. McLeod met with senior administration of Hôtel-Dieu and a number of individual physicians including the general surgeons who had not yet been interviewed. She also reviewed additional cases.

Establishing a Team of Surgery Reviewers

Dr. McLeod supervised a four-member Surgical Review Team that included herself and three additional surgeons, all of whom are fellows of the Royal College of Surgeons of Canada and associated with the University of Toronto: Dr. Brian Pinchuk (FRCSC), Dr. Sandra Demontbrun (FRCSC) and Dr. Shawn Forbes (FRCSC).

Identifying the Surgery Cases to be Reviewed and Conducting the Review

Two groups of surgery cases were reviewed as described below (Table 3).

Table 3: Surgery Cases Reviewed and Number of Cases

	Surgery Cases Reviewed	Number of Cases
1.	Random Sample of Dr. Heartwell's Surgery Cases by Type of Surgery From 2000 to 2010.	128
2.	Additional Cases of Concern	19

1. Review of a Random Stratified Sample of Dr. Heartwell's Surgery Cases from 2000 to 2010

The Investigators reviewed a random sample of Dr. Heartwell's cases from the last 10 years. During this time period (2000 to 2010), Dr. Heartwell had performed 4,892 surgical procedures at Hôtel-Dieu (692 breast cancer surgeries and 4,200 surgeries for a range of other conditions including head and neck ailments, gallbladders, hernias, etc.).

The complete list of Dr. Heartwell's cases were forwarded to the members of the Surgical Review Team who identified a random sample of cases. The four-member Team conducted a comprehensive review of 128 cases and concluded that these cases provided a very good overall assessment of the care provided by Dr. Heartwell. The Team had access to Hôtel-Dieu's electronic charts and Dr. Heartwell's office charts during its review.

The sample of 128 surgery cases that were reviewed included:

- 28 breast procedures
- 30 thyroidectomies and/or parathyroidectomies
- 20 procedures involving the gastrointestinal tract
- 19 hernia repairs (inguinal, incisional and umbilical)
- 9 cholecystectomies
- 2 appendectomies
- 20 other procedures

2. Review of Additional Cases of Concern

As noted previously (Chapter C1), 19 additional cases were brought to the attention of the Investigators through three sources: Hôtel-Dieu, direct communication with the Investigators, and *Hotline* cases. Dr. McLeod, the Team's Surgery Lead, reviewed the surgical components of all of these cases.

INVESTIGATION TEAM FINDINGS AND RECOMMENDATIONS ABOUT SURGERY

Surgery at Hôtel-Dieu Grace Hospital

Dr. Barbara Heartwell has been a member of Hôtel-Dieu Grace Hospital's medical staff since 1981. She is a Fellow of the Royal College of Physicians and Surgeons of Canada. According to Dr Heartwell, about 50% of her practice is related to the surgical management of breast disease. The rest of her practice includes cholecystectomies, hernia repairs, some colon surgery, parathyroidectomies and thyroidectomies. Dr. Heartwell reported that she attends the Multidisciplinary Cancer Conferences (MCCs) at Hôtel-Dieu but rarely attends the Friday morning MCCs held in conjunction with the Windsor Regional Cancer Centre which focus on breast cancer. Dr. Heartwell also attends the monthly Morbidity and Mortality rounds at Hôtel-Dieu Grace Hospital.

The four-person Surgical Review Team conducted a comprehensive review of 128 surgical cases performed by Dr. Heartwell from 2000 to 2010. In addition, Dr. Robin McLeod, the Surgical Team Lead, reviewed the 19 additional cases of concern, and conducted interviews with 23 individuals about surgery and Dr. Heartwell's practice. The following observations and recommendations about Dr. Heartwell are based on this information.

In the opinion of the Surgical Review Team, Dr. Heartwell generally appeared to provide good care to her *breast cancer patients*. Before their surgery, patients were adequately evaluated in most instances. The Surgical Team did note, however, that most patients had a chest x-ray, bone scan and ultrasound of the abdomen before surgery. Although this work-up before surgery is thorough, the current Cancer Care Ontario guideline does not recommend that these investigations need to be performed pre-operatively in most patients having surgery for breast cancer.¹⁵ The Team also noted that at least some patients had definitive surgery for their breast cancer based on cytology obtained by a fine needle aspirate rather than by performing a core biopsy, which provides a larger sample of tissue.

The Surgical Team noted that despite the fact that Dr. Heartwell performed a large number of breast cancer surgeries, she had not been performing sentinel lymph node

¹⁵ Cancer Care Ontario, *Baseline Staging Tests in Primary Breast Cancer. Practice Guideline Report #1-16*. www.cancercare.on.ca.

biopsy (SLNB) until recently.¹⁶ The Surgical Team observed that other surgeons at Hôtel-Dieu have also been late to adopt SLNB. Finally, the Surgical Team observed that a high proportion of Dr. Heartwell's patients seemed to undergo modified radical mastectomies rather than lumpectomies. The Surgical Team recognised, however, that it only reviewed a sample of breast patient charts, that the procedure was an acceptable option and may have been due, in part, to patient preferences.

After their breast cancer operations, Dr. Heartwell referred her breast cancer patients appropriately for chemotherapy and radiation therapy. Following discharge, Dr. Heartwell stated that she saw all her patients in her office after she received the pathology report of the tissue removed during surgery (usually 10 days to 3 weeks although it may be 1-2 months if the pathology is sent out for external review outside of Windsor). Dr. Heartwell appeared to follow her breast cancer patients regularly (every six months) and ordered appropriate follow-up tests.

With regard to the care of *non-breast cancer patients*, Dr. Heartwell appeared to provide adequate workup and management of patients. The Surgical Team noted that Dr. Heartwell did not perform laparoscopic appendectomies and cholecystectomies, and did not seem to perform tension-free mesh inguinal hernia repairs. These procedures have been adopted by many surgeons throughout Ontario.

The Surgical Review Team were of the opinion that – notwithstanding the specific cases of concern that were brought to their attention and were reviewed (including cases that received public attention) – Dr. Heartwell generally performed safe surgery and provided safe care. Based on a comprehensive review of a representative sample of Dr. Heartwell's surgical cases and considering additional information collected during the Investigation (interviews, other case reviews), the Surgical Review Team did not find issues at a level of concern that, in their opinion, supported a recommendation for ongoing restrictions of Dr. Heartwell's General Surgery practice.

The Surgical Team had some concerns that Dr. Heartwell may not be keeping up-to-date with advances in the surgical management of patients and was slow to adopt new surgical techniques. In the Surgical Team's opinion, this did not have a significant impact on the quality of the surgery she performed. The Surgical Team identified communication issues with both patients and colleagues that may have led to hasty decisions without careful consideration of pre-operative assessment. As well, Dr. Heartwell would have benefited from attending the Multidisciplinary Cancer Conferences (MCCs) at Windsor Regional Cancer Centre which focus on breast cancer (also see Recommendation 15).¹⁷

¹⁶ Sentinel lymph node biopsy (SLNB) helps identify the first lymph node into which tumour cells drain. A SLNB involves using a radioactive isotope and/or a blue dye to find the first lymph node (the "sentinel" node) that the cancer drains into. The sentinel lymph node is removed and tested for cancer cells. If cancer cells are found in the sentinel node, further surgery to remove all the lymph nodes (lymphadenectomy) may be needed. If cancer cells are not found, it means the cancer has not spread into the lymph nodes which impacts on the treatment that is selected.

¹⁷ Multidisciplinary Cancer Conferences (MCCs) are regularly scheduled meetings where healthcare providers discuss the diagnosis and treatment of individual cancer patients. MCCs are supported by Cancer Care Ontario as a best practice for cancer care. Their primary function is to ensure that all appropriate

In addition, at the start of each surgical case, Dr. Heartwell should ensure that the pre-operative diagnostic tests – including biopsy results – are reviewed as part of the surgical checklist at the start of all of her surgeries.

It is recommended that:

R9 Hôtel-Dieu Grace Hospital re-consider its current position that Dr. Barbara Heartwell’s practice be restricted given the findings of the review conducted by the Surgical Review Team.

It is further recommended that:

R10 Dr. Barbara Heartwell be required to attend and participate in quality and continuing professional development initiatives that include: i) regularly attending the Breast Multidisciplinary Cancer Conferences held at the Windsor Regional Cancer Centre; ii) training in the use of sentinel lymph node biopsy; and iii) attending continuing medical education events that focus on evidence-based best practices. It is further recommended that Dr. Heartwell review all pre-operative diagnostic tests, including biopsy results, as part of the surgical checklist at the start of all of her surgeries.

C4. THE RELATIONSHIP BETWEEN MEDICAL AND HOSPITAL LEADERSHIP AT HÔTEL-DIEU GRACE HOSPITAL

The Investigation Team conducted 12 site visits to Windsor and interviewed or met with over 75 individuals over the course of the Investigation (see Appendix C). The site visits and extensive consultations gave the Team an excellent opportunity to hear about and observe the relationships between the medical and hospital leadership at the three Essex County Hospitals and, most notably, at the Hôtel-Dieu Grace Hospital. Hospital leadership includes senior management staff, medical leaders and the Board of Directors.

Respectful, trusting relationships between medical and hospital leadership and members of the Board of Directors are essential for a safe, high quality, well-functioning hospital. Over the course of its review, the Team heard about long-standing unproductive relationships at Hôtel-Dieu that were characterised by an alarming lack of respect between medical leaders, senior management and the Board of Directors. Many of these unhealthy relationships appear to have existed for more than a decade. The Team also heard many stories about how poor relationships between leaders at various levels of the organisation have wasted significant amounts of time and energy, and have resulted in the

diagnostic tests, all suitable treatment options, and the most appropriate treatment recommendations are generated for each cancer patient and discussed prospectively in a multidisciplinary forum. MCCs also provide a forum for continuing education and contribute to quality improvements in patient care. Source: http://www.cancercare.on.ca/toolbox/mcc_tools/

development of an unhealthy culture that is, at times, characterised by distrust and disrespect.

Generally, medical and hospital leadership do not feel well supported by each other. Some physician leaders feel they are excluded from decision making, and that hospital leadership is inclined to make unilateral decisions about issues impacting on medical staff without consulting them. Concerns were also expressed by physician leaders about the lack of following agreed-upon due process.

The Team recognises that Hôtel-Dieu has had significant turnover in its senior leadership over the last 10 years. Although there have been recent attempts to improve relationships with some success, the Team believes that Hôtel-Dieu needs to put significant efforts into fostering better relationships. This will be critical for advancing a hospital-wide quality improvement agenda.

It is recommended that:

R11 Medical Leaders, Senior Management Staff, and the Board of Directors at Hôtel-Dieu Grace Hospital foster mutually-supportive relationships based on trust and due process. Mechanisms to develop such an environment include regular medical-hospital leadership meetings to discuss issues and solutions, and a team-based approach to strategic planning and hospital management particularly in relation to how care is provided, how patients are kept safe, and how quality is improved.

C5. SUPPORTING A QUALITY AND SAFETY AGENDA FOR THE BENEFIT OF PATIENTS

INTRODUCTION

On May 3, 2010, Government introduced Bill 46, the *Excellent Care for All Act*. Soon afterwards (June 3), the Bill was passed by the legislature with the support of all parties (third reading) and is now awaiting Royal Assent. Bill 46 requires healthcare organisations to establish and maintain a Quality Committee that reports to the organisation's responsible body. The Quality Committee will be responsible for:

- Monitoring and reporting to the Board on quality issues and the overall quality of services provided in the hospital, with reference to appropriate data.
- Considering and making recommendations to the Board on quality improvement initiatives and policies.
- Ensuring that best practices information supported by available scientific evidence is translated into materials that are distributed to employees and persons providing services in the hospital, and monitoring the use of these materials by these people.
- Overseeing the preparation of annual quality improvement plans.
- Carrying out any other responsibilities provided for in the regulations.

In addition to Bill 46, Ontario also amended Regulation 965 under the *Public Hospitals Act* that relates to quality and safety. Effective July 1, 2010, critical incidents must be reported to the Medical Advisory Council and the hospital administrator, and a system established to analyse critical incidents and develop action plans to avoid or reduce the risk of recurrence.

The introduction of the *Excellent Care for All Act* and the change to Regulation 965 provide an opportunity for all hospitals to revisit their policies and practices regarding quality improvement and patient safety. The sections below make recommendations in the context of these legislative and regulatory changes and, more broadly, in the interest of enhancing overall quality of care. The sections include:

- Quality and safety at Hôtel-Dieu Grace Hospital
- Quality and safety at the three Essex County Hospitals
- Quality and safety in pathology across Ontario

QUALITY AND SAFETY AT HÔTEL-DIEU GRACE HOSPITAL

Hôtel-Dieu is working to improve quality and patient safety, and has identified improving quality of care as a priority in its strategic plan. The hospital has implemented a number of important quality and safety initiatives in recent years. For example, the *Patient Safety Monitor* is a quarterly public newsletter that includes information on quality and safety indicators. The Surgical Safety Checklist was initiated in the spring of 2010 with a high proportion of surgeons purportedly complying.

Most recently, Hôtel-Dieu announced a leadership re-organisation which includes a new position of Vice President Medical and Academic Affairs. Held by a physician, this position will have a major role in enhancing quality and patient safety. To ensure that patient safety and quality initiatives are coordinated across the hospital's core clinical programs, the medical and nursing leaders of these programs will report jointly to this position and the Vice President Patient Services.

Hôtel-Dieu is also in the process of planning a fall Safety Symposium in partnership with the Henry Ford Hospital. In addition, senior leadership has a 90-Day Plan that includes working with the Medical Advisory Committee to jointly develop a framework for a system to improve quality and safety. The Chief of Staff and the Chief Nursing Executive will lead this initiative.

The Investigators are encouraged that Hôtel-Dieu is continuing to improve patient safety and quality. Creating the Vice President Medical and Academic Affairs position is a positive step towards advancing patient safety and improving quality. In the Team's view, it is critical that an experienced medical leader with the confidence and support of the medical staff be chosen to fill this new position. This medical leader should also be highly collaborative and respected by the medical staff in all three Essex County Hospitals. In addition to this leadership position, the Team believes that Hôtel-Dieu needs to support ongoing leadership training and education in quality and safety for its

Board, senior management and clinical leaders. This training should focus especially on the roles that leaders must play in Hôtel-Dieu in light of the new *Excellent Care for All Act*.

It is recommended that:

R12 Hôtel-Dieu Grace Hospital support ongoing leadership training and education in quality and safety for its Board, Senior Management Staff and Medical Leaders. In light of the new *Excellent Care for All Act*, potential educational sessions might include: i) the roles and responsibilities of medical leadership for credentialing and quality of care; ii) the roles of the Board of Directors, Senior Management and Clinical Leaders in quality improvement and patient safety; and iii) the respective roles of the Medical Advisory Committee and the Board Quality Committee for advancing a quality agenda.

In 2002, Hôtel-Dieu first introduced a Sentinel Event and Disclosure Policy which has been revised a number of times. This policy defines a sentinel event as “a serious, undesirable and unexpected outcome or event that involves actual or potential loss of life, limb or major and enduring loss of function, or has a significant potential to adversely affect public perception and confidence.” Hôtel-Dieu requires that all sentinel events be reported at the time of the event, or as soon as they are identified as a sentinel event.

Over the course of the Investigation, it became clear that many physicians do not know about the policy or the process for reporting errors and near misses (an unplanned action that did not result in injury or illness but had the potential to do so). Many physicians expressed concerns that they will be criticized or blamed if they bring errors or near misses forward. Research on safety has shown that “blaming cultures” have a negative impact on improving performance. Organisations that want to advance a patient safety and quality improvement agenda need to develop “learning cultures” where people learn from errors and near misses and work to improve their performance. This is critically important in light of the *Excellent Care for All Act* and the amendment under the *Public Hospitals Act* about reporting critical incidents and avoiding or reducing risks of recurrence (noted earlier).

It is recommended that:

R13 All medical staff be educated about Hôtel-Dieu Grace Hospital’s sentinel event policy and the processes for reporting errors and near misses. To support a focus on safety and quality, Hôtel-Dieu Grace Hospital should continue to develop a cultural environment that focuses on quality improvement, building on lessons learned and high performance.

QUALITY AND SAFETY AT THE THREE ESSEX COUNTY HOSPITALS

The Investigators met with and interviewed the executive and medical leaders of the three Essex County hospitals and the CEO of the Erie St. Clair Local Health Integration Network. The Investigators also conducted interviews with senior management and medical staff. Over the course of these consultations, the Investigation Team identified areas for enhanced joint quality and safety initiatives at the three Essex County Hospitals.

One area is greater collaboration to advance patient quality and safety at all levels of the three hospitals. There is a broad range of potential integration and communication opportunities that would improve care especially for patients treated in more than one hospital and for physicians working in more than one hospital. Opportunities could include setting up formal communications about critical incidents and quality of care, greater sharing of medical information to avoid duplication and errors, developing protocols to enhance smooth and safe transfers of patients from one organisation to another, common credentialing for medical staff across the hospitals, and an integrated Human Resource Plan.

The importance of greater collaboration to support quality care and patient safety is highlighted in the following example of patients treated for breast cancer. Currently, some patients have their core biopsies performed at Windsor Regional. The record of the biopsy and pathology report are kept in the patients' medical records at Windsor Regional and are not available on Hôtel-Dieu's medical records system. If these patients have cancer surgery at Hôtel-Dieu, their admission and their surgical and post-surgical pathology reports will only appear in their Hôtel-Dieu medical record. If these surgical patients are then referred – as many are – to Windsor Regional Hospital's Cancer Centre for consultation and treatment by a medical or radiation oncologist, these results will go on their medical records at Windsor Regional only. This example presents a tangible area where there should be increased collaboration in the multi-disciplinary and multi-hospital management of patients treated for breast cancer.

To advance collaboration among the physicians treating individual patients at the two sites and to minimize the risk of error due to miscommunication, a common medical record is especially recommended. This will require collaboration amongst the three Essex County hospitals. The Erie St. Clair LHIN could play an important role facilitating joint initiatives to advance quality and safety.

It is recommended that:

R14 The three Essex County Hospitals continue to collaborate to advance patient quality and safety at all levels – Boards of Directors, management, Quality Committees, Medical Advisory Committees, medical and hospital staff – for the benefit of all Essex County patients. Integration and communication initiatives that should be initiated and/or continued include, but are not limited to: i) formal communications about critical incidents and quality of care where there are common departments with single medical leadership or where physicians work in more than one hospital; ii) sharing of medical information (in keeping with the requirements of privacy legislation) especially when physicians need to access laboratory or diagnostic imaging results at another hospital or where a patient is receiving care in more than one hospital (e.g., cancer care); iii) protocols that support the seamless movement of patients between hospitals for episodes of care; iv) common credentialing processes for medical staff who work in more than one hospital; and v) an integrated Human Resources plan with opportunities for joint recruitments.

A second area for joint quality and safety initiatives are Multidisciplinary Cancer Conferences. MCCs are regularly scheduled meetings where healthcare providers discuss the diagnosis and treatment of individual cancer patients. There are MCCs for different types of cancers. Hôtel-Dieu, Leamington District Memorial Hospital and Chatham-Kent Health Alliance link by video-conference for MCCs. Generally, however, Hôtel-Dieu surgeons do not attend MCCs held at Windsor Regional Hospital; likewise, Windsor Regional surgeons do not attend MCCs at Hôtel-Dieu. This is a real concern when a particular MCC is at one hospital and a physician performs procedures for this type of cancer at the other hospital. Currently, Hôtel-Dieu hosts Gastrointestinal MCCs and Windsor Regional hosts Breast MCCs, neither of which are routinely attended by surgeons from the other hospital.

Physicians working in particular cancer areas need to attend the appropriate MCC. In addition to improving quality, safety and ongoing professional development, this practice will help improve collaboration between surgical staff and pathologists across the hospitals, and between surgeons and medical and radiation oncologists.

It is recommended that:

R15 Surgeons at Hôtel-Dieu Grace Hospital who perform breast cancer surgery be required to attend Breast Multidisciplinary Cancer Conferences (MCCs) held at Windsor Regional Hospital. Likewise, surgeons at Windsor Regional Hospital who perform gastrointestinal cancer surgery should be required to attend Gastrointestinal MCCs held at Hôtel-Dieu Grace Hospital. To help support safety, quality and ongoing professional development, the three Essex County Hospitals should work towards developing joint MCCs.

A third initiative that will help improve quality and safety in the three Essex County Hospitals is a greater focus on formalising the roles, responsibilities and expectations for medical leaders. The Investigators found that the roles and responsibilities for a number of the medical leadership positions are out-of-date (some are almost a decade old). As well performance reviews have not been done consistently in recent years. The Investigators believe there is a need to update the roles and responsibilities of medical leaders, ensure clear lines of responsibility and accountability, set term limits, maximize the opportunities for cooperation between the three organisations, identify performance expectations for quality and safety, and conduct regular performance reviews.

It is recommended that:

R16 The three Essex County Hospitals review the current roles and responsibilities of medical leadership positions including Chief of Staff, Vice-President Medical, Medical Director of Surgical Services, Surgeon-in-Chief, Chief of Pathology, Surgical Oncology Lead and other positions. This review should ensure that the terms of reference for these positions include clear roles, responsibilities and term limits, and are supported with performance expectations targeted at quality and safety, and regular performance reviews.

QUALITY AND SAFETY IN PATHOLOGY ACROSS ONTARIO

The Investigation highlighted the critical importance of quality and safety in pathology. Although individual hospitals can do a lot to improve their pathology processes, there is a need for a broader provincial quality assurance system to guide individual efforts. A recent symposium of key stakeholders involved or interested in quality assurance for Ontario's laboratory physicians came to the same conclusion.¹⁸ The stakeholders noted that a major gap is a comprehensive framework for quality management. Although various organisations and jurisdictions have developed quality assurance practices based on peer assessment, auditing and correlational analyses, there is no consistent approach to pathology quality assurance in Ontario.

A provincial quality assurance system for pathology should consider the following factors:

- Any quality system should be primarily based on enhanced peer assessment that includes prospective reviews and retrospective auditing of selected cases, most notably cancer cases.
- Second opinion pathology consultation should be enhanced with improved access to inter-institutional consultation. In recent years, regulatory, financial and human resource issues appear to have impeded some of these second opinion pathology

¹⁸ The symposium, *Clarifying Roles, Responsibilities and Critical Elements in Quality Management Systems as Applied to the Professional Work of Ontario's Laboratory Physicians* was held on November 27, 2009. The symposium was hosted by Path2Quality in conjunction with the Health Policy Department of the Ontario Medical Association. Path2Quality is a collaborative initiative of the Ontario Medical Association Chapter on Laboratory Medicine and the Ontario Association of Pathologists.

consultations. These specific factors should be considered as part of advancing appropriate second opinion consultations.

- There is currently a shortage of pathologists. This shortage needs to be addressed to build an optimal province-wide system based on improved peer assessment and second opinion consultation.
- To ensure a quality program that is accessible across the province, the specific role of digital scanning technology and remote review needs to be examined.

The Investigators believe that a quality assurance system for pathology needs to be developed and implemented across the province. This initiative will support Ontario's efforts to improve quality and safety in healthcare.

It is recommended that:

R17 The Ministry of Health and Long-Term Care support the development and implementation of a provincial quality assurance system for pathology that includes standards and guidelines and considers similar plans for other areas of interpretive diagnostic medicine. The provincial system should include: enhanced peer assessments; an improved system for second opinion pathology consultations with consideration for appropriate regulatory, financial and human resource supports; an assessment of the role of digital scanning technology and remote review; and a human resource review of the number of pathologists and other personnel required to support the provincial system.

It is further recommended that:

R18 The Ministry of Health and Long-Term Care (Ministry) work with the Path2Quality group (made up of members of the Ontario Medical Association and the Ontario Association of Pathologists), the College of Physicians and Surgeons of Ontario, the Ontario Hospital Association and other key stakeholders to develop and, where appropriate, implement the provincial standards and guidelines. The Ministry should consider establishing a focused Expert Panel to conduct this work. It is further recommended that the Ministry require – by March 31, 2011 – a recommended standard for a pathology quality assurance program in Ontario along with a plan to identify the requirements to support the standard.

C6. NEXT STEPS

The Investigation Team has made recommendations that focus on Hôtel-Dieu Grace Hospital (pathology, surgery, interactions between medical and hospital leadership, quality and safety), the three Essex County hospitals (pathology, quality and safety), and the province (quality and safety in pathology). In the view of the Investigators, a

significant amount of time, attention and effort will be required to plan for and implement the recommendations, as appropriate. This level of time, attention and effort go beyond what may reasonably be expected of current hospital, medical and LHIN leadership. For this reason, the Team believes that the Ministry of Health and Long-Term Care should consider appointing a facilitator to address the recommendations of the Investigators' Report.

A Facilitator, if appointed, could:

- Assist in developing an implementation plan for the recommendations.
- Strengthen organisational capacity by working with the physicians, senior management and Boards at the hospital(s) to ensure a mutual understanding of their leadership roles and responsibilities.
- Assist Hôtel-Dieu's Board and management to develop a strategy to ensure the maintenance and growth of the local community's perception and confidence in the health care services.
- Seek the advice and assistance of Cancer Care Ontario to improve clinical quality and safety especially for cancer services in the three Essex County Hospitals.
- Act on specific recommendations of the report, as appropriate.
- Be available, upon request, to provide advice and counsel related specifically to implementation of the recommendations and participate in any hospital or LHIN committees that have been established for this purpose.
- Re-interview Board, Management and Medical Leadership six months following this report to monitor progress and make further recommendations, as appropriate, for any additional measures deemed necessary to enhance quality of care.

It is recommended that:

R19 **The Ministry of Health and Long-Term Care consider appointing a facilitator to address the recommendations of the *Report of the Investigators of Surgical and Pathology Issues at Three Essex County Hospitals: Hôtel-Dieu Grace Hospital, Leamington District Memorial Hospital and Windsor Regional Hospital.***

PART D: CONSOLIDATED LIST OF RECOMMENDATIONS**PATHOLOGY****Pathology at Hôtel-Dieu Grace Hospital***It is recommended that:*

- R1 The current pathology reporting processes be reviewed by the leadership of pathology and surgery at Hôtel-Dieu Grace Hospital, and consensus be reached on a new standard report format, policies and processes for obtaining and recording a second review, standards for follow-up, and processes for effective communications and clarification.
- R2 All pathologists participate in continuing professional development under the guidance of the Department Chief. Training should focus on the use of: i) standardized, contemporary approaches to investigating disease; ii) current terminology; iii) current classification systems; and iv) current grading and staging schemes.
- R3 The College of Physicians and Surgeons of Ontario consider undertaking a clinical competency assessment of Dr. Olive Williams if she decides to resume clinical practice in Ontario.

Pathology in the Three Essex County Hospitals*It is recommended that:*

- R4 All pathologists working in Windsor adopt the Quality Assurance Program for Pathology developed by the Chief of Pathology which includes peer assessments, auditing and correlational analysis. Appropriate laboratory physician and administrative resources should be allocated to support the Program.
- R5 The group of Windsor pathologists be centralized on one site – Windsor Regional Hospital – to support the successful development of the quality assurance plan, improve inter-professional communication, support increased specialisation in pathology, and enhance education opportunities (including multi-disciplinary cancer conferences and routine prospective multi-headed microscope slide conferences). To ensure optimal care at the Hôtel-Dieu Grace Hospital, a rotating pathologist should be available on this site daily. The pathologist should interact and communicate openly with the Hôtel-Dieu Grace Hospital clinicians and be readily available for consultations and rounds.
- R6 The Essex County Hospitals improve the process of preparing cytological specimens through the use of contemporary liquid-based cytology systems.

- R7 The three Essex County Hospitals examine the role of digital scanning technology to facilitate second opinion consultations and improve timely diagnosis in specialized areas such as neuropathology.
- R8 The existing collaboration between the Essex County Hospitals and their academic health sciences partner, London Health Sciences Centre, be enhanced especially with respect to specialized areas of pathology including neuropathology, hematopathology and other areas.

SURGERY

SURGERY AT HÔTEL-DIEU GRACE HOSPITAL

It is recommended that:

- R9 Hôtel-Dieu Grace Hospital re-consider its current position that Dr. Barbara Heartwell's practice be restricted given the findings of the review conducted by the Surgical Review Team.
- R10 Dr. Barbara Heartwell be required to attend and participate in quality and continuing professional development initiatives that include: i) regularly attending the Breast Multidisciplinary Cancer Conferences held at the Windsor Regional Cancer Centre; ii) training in the use of sentinel lymph node biopsy; and iii) attending continuing medical education events that focus on evidence-based best practices. It is further recommended that Dr. Heartwell review all pre-operative diagnostic tests, including biopsy results, as part of the surgical checklist at the start of all of her surgeries.

THE RELATIONSHIP BETWEEN MEDICAL AND HOSPITAL LEADERSHIP AT HÔTEL-DIEU, GRACE HOSPITAL

It is recommended that:

- R11 Medical Leaders, Senior Management Staff, and the Board of Directors at Hôtel-Dieu Grace Hospital foster mutually-supportive relationships based on trust and due process. Mechanisms to develop such an environment include regular medical-hospital leadership meetings to discuss issues and solutions, and a team-based approach to strategic planning and hospital management particularly in relation to how care is provided, how patients are kept safe, and how quality is improved.

SUPPORTING A QUALITY AND SAFETY AGENDA FOR THE BENEFIT OF PATIENTS

QUALITY AND SAFETY AT HÔTEL-DIEU GRACE HOSPITAL

It is recommended that:

- R12 Hôtel-Dieu Grace Hospital support ongoing leadership training and education in quality and safety for its Board, Senior Management Staff and Medical Leaders. In light of the new *Excellent Care for All Act*, potential educational sessions might include: i) the roles and responsibilities of medical leadership for credentialing and quality of care; (ii) the roles of the Board of Directors, Senior Management and Clinical Leaders in quality improvement and patient safety; and (iii) the respective roles of the Medical Advisory Committee and the Board Quality Committee for advancing a quality agenda.
- R13 All medical staff be educated about Hôtel-Dieu Grace Hospital's sentinel event policy and the processes for reporting errors and near misses. To support a focus on safety and quality, Hôtel-Dieu Grace Hospital should continue to develop a cultural environment that focuses on quality improvement, building on lessons learned and high performance.

QUALITY AND SAFETY AT THE THREE ESSEX COUNTY HOSPITALS

It is recommended that:

- R14 The three Essex County Hospitals continue to collaborate to advance patient quality and safety at all levels – Boards of Directors, management, Quality Committees, Medical Advisory Committees, medical and hospital staff – for the benefit of all Essex County patients. Integration and communication initiatives that should be initiated and/or continued include, but are not limited to: i) formal communications about critical incidents and quality of care where there are common departments with single medical leadership or where physicians work in more than one hospital; ii) sharing of medical information (in keeping with the requirements of privacy legislation) especially when physicians need to access laboratory or diagnostic imaging results at another hospital or where a patient is receiving care in more than one hospital (e.g., cancer care); iii) protocols that support the seamless movement of patients between hospitals for episodes of care; iv) common credentialing processes for medical staff who work in more than one hospital; and v) an integrated Human Resources plan with opportunities for joint recruitments.

- R15 Surgeons at Hôtel-Dieu Grace Hospital who perform breast cancer surgery be required to attend Breast Multidisciplinary Cancer Conferences (MCCs) held at Windsor Regional Hospital. Likewise, surgeons at Windsor Regional Hospital who perform gastrointestinal cancer surgery should be required to attend Gastrointestinal MCCs held at Hôtel-Dieu Grace Hospital. To help support safety, quality and ongoing professional development, the three Essex County Hospitals should work towards developing joint MCCs.
- R16 The three Essex County Hospitals review the current roles and responsibilities of medical leadership positions including Chief of Staff, Vice-President Medical, Medical Director of Surgical Services, Surgeon-in-Chief, Chief of Pathology, Surgical Oncology Lead and other positions. This review should ensure that the terms of reference for these positions include clear roles, responsibilities and term limits, and are supported with performance expectations targeted at quality and safety, and regular performance reviews.

QUALITY AND SAFETY IN PATHOLOGY ACROSS ONTARIO

It is recommended that:

- R17 The Ministry of Health and Long-Term Care support the development and implementation of a provincial quality assurance system for pathology that includes standards and guidelines and considers similar plans for other areas of interpretive diagnostic medicine. The provincial system should include: enhanced peer assessments; an improved system for second opinion pathology consultations with consideration for appropriate regulatory, financial and human resource supports; an assessment of the role of digital scanning technology and remote review; and a human resource review of the number of pathologists and other personnel required to support the provincial system.
- R18 The Ministry of Health and Long-Term Care (Ministry) work with the Path2Quality group (made up of members of the Ontario Medical Association and the Ontario Association of Pathologists), the College of Physicians and Surgeons of Ontario, the Ontario Hospital Association and other key stakeholders to develop and, where appropriate, implement the provincial standards and guidelines. The Ministry should consider establishing a focused Expert Panel to conduct this work. It is further recommended that the Ministry require – by March 31, 2011 – a recommended standard for a pathology quality assurance program in Ontario along with a plan to identify the requirements to support the standard.

NEXT STEPS*It is recommended that:*

- R19 The Ministry of Health and Long-Term Care consider appointing a facilitator to address the recommendations of the *Report of the Investigators of Surgical and Pathology Issues at Three Essex County Hospitals: Hôtel-Dieu Grace Hospital, Leamington District Memorial Hospital and Windsor Regional Hospital*.

APPENDICES**APPENDIX A: TERMS OF REFERENCE FOR THE INVESTIGATION****Terms of Reference for Investigators for Hôtel-Dieu Grace Hospital, Leamington District Memorial Hospital, Windsor Regional Hospital (hereinafter referred to as the “Hospitals”)**

1. The Investigators will investigate and report on issues relating to the following matters at Hôtel-Dieu Grace Hospital (HDGH):
 - f) The quality of care and treatment of patients at HDGH, analysis of any errors with particular reference to pathology results and recent reports of any surgical errors over the last two years;
 - g) The processes and practices employed by HDGH to measure and improve the clinical appropriateness and quality of surgical care and the quality of pathology services;
 - h) Review of surgical leadership structure, the process for previewing adverse events, the structure and culture of communication between pathologists and surgeons, and the recorded frequency of Multidisciplinary Case Conferences (MCCs) for cancer patients at HDGH;
 - i) The executive and board monitoring of patient care and professional staff conduct with specific reference to whether HDGH has appropriate patient care practices and procedures to protect the safety and security of their patients.
 - j) The role of HDGH’s Medical Advisory Committee in fulfilling its responsibilities under the *Public Hospitals Act*.
2. Based on the findings relating to the issues set out in paragraph 1 for HDGH, the Investigators will determine whether similar or other issues should be reviewed at Leamington District Memorial Hospital and Windsor Regional Hospital.
3. The Investigators will investigate and report on issues relating to shared pathology services at the Hospitals.
4. The Investigators will review the status of recommendations from all relevant previous studies, strategies and reports regarding medical care quality, surgical services and pathology services at the Hospitals.
5. The Investigators will provide specific systemic recommendations to promote accountability among hospital boards for the quality of the pathology processes and surgical care (beyond the role of Medical Advisory Committee).
6. The Investigators will make recommendations and identify next steps for the Hospitals and the LHIN to respond to issues identified in the Investigation.
7. The Investigators will actively liaise with: the CEO of the Erie St. Clair Local Health Integration Network, the Boards, CEOs and senior clinical staff of the hospitals, the former CEO of Windsor Regional Hospital, and other relevant stakeholders, including Cancer Care Ontario.
8. The Investigators may seek external resources as appropriate to assist in completing their mandate.

9. The Investigators will provide regular updates to the Deputy Minister, Ministry of Health and Long-Term Care and/or Assistant Deputy Minister, Health System Accountability and Performance Division.
10. The Investigators will report to the Minister of Health and Long-Term Care as required. The Investigators will provide a written report to the Minister of Health and Long-Term Care upon completion of Duties no later than June 30, 2010.

**APPENDIX B: ONTARIO REGULATION 150/10 MADE UNDER
THE *PERSONAL HEALTH INFORMATION PROTECTION ACT*,
2004**

Personal Health Information Protection Act, 2004

ONTARIO REGULATION 150/10

DISCLOSURE BY AND TO HOSPITAL INVESTIGATORS

Consolidation Period: From April 28, 2010 to the e-Laws currency date.

Note: This Regulation expires on December 31, 2010. See: O. Reg. 150/10, s. 3.

Last amendment: O. Reg. 150/10.

This is the English version of a bilingual regulation.

Disclosure

1. Despite subChapter 49 (1) of the Act,
 - (a) an investigator appointed under Chapter 8 of the *Public Hospitals Act* in respect of Hôtel-Dieu Grace Hospital, Leamington District Memorial Hospital and Windsor Regional Hospital may disclose personal health information to a College within the meaning of the *Regulated Health Professions Act, 1991* for the purpose of the administration or enforcement of the *Drug and Pharmacies Regulation Act*, the *Regulated Health Professions Act, 1991* or an Act named in Schedule 1 to that Act; and
 - (b) a College mentioned in clause (a) shall disclose personal health information to an investigator appointed under Chapter 8 of the *Public Hospitals Act* in respect of Hôtel-Dieu Grace Hospital, Leamington District Memorial Hospital and Windsor Regional Hospital where it is necessary or advisable to do so for the purpose of the investigator's investigation under subChapter 8 (1) of that Act. O. Reg. 150/10, s. 1.

Temporary regulation

2. This Regulation is a temporary regulation for the purposes of subChapter 74 (10) of the Act. O. Reg. 150/10, s. 2.
3. OMITTED (PROVIDES FOR THE EXPIRATION OF THIS REGULATION). O. Reg. 150/10, s. 3.
4. OMITTED (PROVIDES FOR COMING INTO FORCE OF PROVISIONS OF THIS REGULATION). O. Reg. 150/10, s. 4.

APPENDIX C: SITE VISITS, MEETINGS AND INTERVIEWS

Date	Event
March 3, 2010	<p>Investigators in Windsor, Hôtel-Dieu to discuss the review format and scope.</p> <ul style="list-style-type: none"> • Dr. Barry McLellan (Team Lead) <p>Group Meeting</p> <ul style="list-style-type: none"> • Gary Switzer – CEO Erie St. Clair LHIN • Warren Chant – President and CEO, Hôtel-Dieu • Gid Sovran – Chair, Board of Directors, Hôtel-Dieu • Dr. G. Vail – Chief of Staff, Hôtel-Dieu • Dr. K. Tracey, Chief Advisor, Medical Affairs, Hôtel-Dieu • Anita Harris – Vice President Clinical Affairs and Chief Privacy Officer, Hôtel-Dieu • Kim Spirou – Vice President Communications and Development, Hôtel-Dieu • Pat Somers – Vice President Operations/Chief Nursing Executive, Hôtel-Dieu • John Stenger – President and CEO, Leamington District • John Cervini – Chair, Board of Directors, Leamington District • Dr. E. Ghumman – Chief of Staff, Leamington District • Sarah Padfield – Vice President Corporate Services, Leamington District • Roberta Jarecsni – Interim, Vice President Patient Services and Chief Nursing Executive, Leamington District • David Musyj – President and CEO, Windsor Regional • Michael Ray – Chair, Board of Directors, Windsor Regional • Dr. G. Ing – Chief of Staff, Windsor Regional • Karen McCullough – Vice President, Acute Care Services and Chief Nursing Executive, Windsor Regional • Ron Foster – Vice President, Public Affairs, Communication and Philanthropy, Windsor Regional • Dr. D. Shum – Chief of Integrated Pathology Services at Hôtel-Dieu, Windsor Regional and Leamington District Hospitals • Alison Anderson – Integrated Director of Health Information Management, Hôtel-Dieu/Leamington District • Claudia denBoer Grima – Integrated Vice President Clinical Support Services (Hôtel-Dieu/ Windsor Regional) • John Ratchford – Senior Consultant and General Counsel, Navigator Limited
March 15, 2010	<p>Investigators in Windsor, Hôtel-Dieu</p> <ul style="list-style-type: none"> • Dr. John Srigley (Pathology Lead), Dr. Robin McLeod (Surgical Lead) and Dorothy Zwolakowski (Project Coordinator) <p>Individual Meetings</p> <ul style="list-style-type: none"> • Warren Chant – President and CEO, Hôtel-Dieu • Dr. E. Ghumman – Chief of Staff/Surgery, Leamington District (<i>teleconference</i>) • Dr. G. Ing – Chief of Staff, Windsor Regional • Dr. D. Shum – Chief of Integrated Pathology Services at Hôtel-Dieu, Windsor Regional and Leamington District Hospitals • Pat Somers – Vice President Operations/Chief Nursing Executive, Hôtel-Dieu

Date	Event
	<p>Review of Selected Cases</p> <ul style="list-style-type: none"> • Dr. John Srigley reviewed pathology cases • Dr. Robin McLeod reviewed surgical cases
March 19, 2010	<p>Investigators in Windsor, Hôtel-Dieu</p> <ul style="list-style-type: none"> • Dr. Barry McLellan (Team Lead) and Dorothy Zwolakowski (Project Coordinator) <p>Individual Meetings</p> <ul style="list-style-type: none"> • Warren Chant – President and CEO, Hôtel-Dieu • Dr. E. Ghumman – Chief of Staff/Surgery, Leamington District (teleconference) • Dr. S. Horen – Medical Staff Association President, Leamington District (teleconference) • Dr. G. Ing – Chief of Staff, Windsor Regional • Dr. W. Liang – Medical Staff Association President, Windsor Regional • Dr. D. Shum – Chief of Integrated Pathology Services at Hôtel-Dieu, Windsor Regional and Leamington District Hospitals • John Stenger – President and CEO, Leamington District
March 29, 2010	<p>Investigators in Windsor, Hôtel-Dieu</p> <ul style="list-style-type: none"> • Dr. Robin McLeod (Surgical Lead) meets with staff surgeons and others. <p>Individual Meetings</p> <ul style="list-style-type: none"> • Dr. A. Forse, Surgeon in Chief, Medical Director Surgery, Medical Director Trauma (Hôtel-Dieu), Surgical Oncology Lead for Erie St. Clair LHIN • Dr. B. Heartwell, Surgeon, Hôtel-Dieu • Dr. D. Laschuk, Chief of Surgery, Windsor Regional • Dr. K. Tracey, Chief Advisor, Medical Affairs, Hôtel-Dieu • Dr. G. Vail, Chief of Medical Staff, Hôtel-Dieu <p>Group Meeting</p> <ul style="list-style-type: none"> • Dr. E. Ravid-Einy • Dr. A. Elalem
April 12, 2010	<p>Investigators in Windsor (Review of Surgical Cases), Hôtel-Dieu</p> <ul style="list-style-type: none"> • Dr. R. McLeod (Surgical Lead) accompanied by three Surgical Fellows reviewed a random sample of Dr. Heartwell's cases.
April 13, 2010	<p>Investigators in Windsor, Hôtel-Dieu</p> <ul style="list-style-type: none"> • Dr. Srigley (Pathology Lead) meets with staff pathologists and laboratory administration. <p>Individual Meetings (Pathologists)</p> <ul style="list-style-type: none"> • Dr. P. Allevato • Dr. M. Alomari • Dr. O. Hakim • Dr. X. Nguyen • Dr. P. Ra • Dr. S. Shukoor • Dr. D. Shum • Dr. P. Smith • Dr. A. Tbakhi

Date	Event
	<p>Meeting (Laboratory Administrators)</p> <ul style="list-style-type: none"> • France Champoux – Laboratory Manager • Claudia denBoer Grima – Integrated Vice President Clinical Support Services (Hôtel-Dieu/ Windsor Regional) • Marion McChesney – Regional Laboratory Director
April 16, 2010	<p>Investigators in Windsor, Hôtel-Dieu</p> <ul style="list-style-type: none"> • Dr. B. McLellan (Team Lead) and D. Zwolakowski (Project Coordinator) <p>Group Meeting (CEO Update)</p> <ul style="list-style-type: none"> • Warren Chant – President and CEO, Hôtel-Dieu • Brad Keeler – Erie St. Clair LHIN (<i>teleconference</i>) • David Musyj – President and CEO, Windsor Regional • John Stenger – President and CEO, Leamington District <p>Individual Meetings</p> <ul style="list-style-type: none"> • Dr. J. Cohen – Chair, Ethics and Credentials Committee, Hôtel-Dieu • Dr. D. Laschuk – Chief of Surgery, Windsor Regional (<i>teleconference</i>) • Dr. J. Speirs – President, Medical Staff Association, Hôtel-Dieu • Dr. K. Tracey – Chief Advisor, Medical Affairs, Hôtel-Dieu
April 30, 2010	<p>Investigators in Windsor, Hôtel-Dieu</p> <ul style="list-style-type: none"> • Dr. Barry McLellan (Team Lead) and Dorothy Zwolakowski (Project Coordinator) meet with staff <p>Group Meeting (CEO Update)</p> <ul style="list-style-type: none"> • Warren Chant – President and CEO, Hôtel-Dieu • Brad Keeler – Erie St. Clair LHIN (<i>teleconference</i>) • David Musyj – President and CEO, Windsor Regional • John Stenger – President and CEO, Leamington District <p>Individual Meetings</p> <ul style="list-style-type: none"> • Dr. Callahan – Nephrology, Hôtel-Dieu • Warren Chant – President and CEO, Hôtel-Dieu • Dr. J. Cohen – Chair, Ethics and Credentials Committee, Hôtel-Dieu • Dr. A. Forse – Surgeon in Chief, Medical Director Surgery, Medical Director Trauma (Hôtel-Dieu), Surgical Oncology Lead for Erie St. Clair LHIN • Dr. D. Shum – Chief of Integrated Pathology Services at Hôtel-Dieu, Windsor Regional and Leamington District Hospitals • Dr. K. Tracey – Chief Advisor, Medical Affairs, Hôtel-Dieu • Dr. G. Vail – Chief of Medical Staff, Hôtel-Dieu
May 21, 2010	<p>Investigators in Windsor, Hôtel-Dieu</p> <ul style="list-style-type: none"> • Dr. B. McLellan (Team Lead) and D. Zwolakowski (Project Coordinator) <p>Group Meeting (CEO Update by teleconference)</p> <ul style="list-style-type: none"> • Warren Chant – President and CEO, Hôtel-Dieu • David Musyj – President and CEO, Windsor Regional • John Stenger – President and CEO, Leamington District • Gary Switzer – CEO Erie St. Clair LHIN <p>Group Meeting</p> <ul style="list-style-type: none"> • Warren Chant – President and CEO, Hôtel-Dieu • Pat Somers – Vice President Operations/Chief Nursing Executive, Hôtel-Dieu <p>Group Meeting</p> <ul style="list-style-type: none"> • Warren Chant – President and CEO, Hôtel-Dieu • Pat Somers – Vice President Operations/Chief Nursing Executive, Hôtel-Dieu • Dr. G. Vail – Chief of Medical Staff, Hôtel-Dieu

Date	Event
	<p>Individual Meetings</p> <ul style="list-style-type: none"> • Dr. A. Kadri – Chief of Medicine, Hôtel-Dieu • Pat Somers – Senior Vice President Operations/Chief Nursing Executive, Hôtel-Dieu • Dr. J. Speirs – President, Medical Staff Association, Hôtel-Dieu • Dr. K. Tracey – Chief Advisor, Medical Affairs, Hôtel-Dieu
May 31, 2010	<p>Investigators in Windsor, Hôtel-Dieu</p> <ul style="list-style-type: none"> • Dr. Robin McLeod (Surgical Lead) and Dorothy Zwolakowski (Project Coordinator) <p>Group Meeting</p> <ul style="list-style-type: none"> • Warren Chant – President and CEO, Hôtel-Dieu • Pat Somers – Vice President Operations/Chief Nursing Executive, Hôtel-Dieu <p>Group Meeting</p> <ul style="list-style-type: none"> • Dr. K. Tracey – Chief Advisor, Medical Affairs, Hôtel-Dieu • Dr. G. Vail – Chief of Medical Staff, Hôtel-Dieu <p>Individual Meetings</p> <ul style="list-style-type: none"> • Dr. A. Forse – Surgeon in Chief, Medical Director Surgery, Medical Director Trauma (Hôtel-Dieu), Surgical Oncology Lead for Erie St. Clair LHIN • Dr. Ghumann – Surgeon in Chief, Leamington • Dr. Moodley – Division of General Surgery • Dr. T. Takahashi – Division of General Surgery <p>Review of Selected Cases</p> <ul style="list-style-type: none"> • Case reviews (Health Records)
June 4, 2010	<p>Investigators in Windsor, Hôtel-Dieu</p> <ul style="list-style-type: none"> • Dr. Barry McLellan (Team Lead) and Dorothy Zwolakowski (Project Coordinator) <p>Group Meeting (CEO Update by teleconference)</p> <ul style="list-style-type: none"> • Warren Chant – President and CEO, Hôtel-Dieu • David Musyj – President and CEO, Windsor Regional • John Stenger – President and CEO, Leamington District • Gary Switzer – CEO Erie St. Clair LHIN <p>Individual Meetings</p> <ul style="list-style-type: none"> • Warren Chant – President and CEO, Hôtel-Dieu • Dr. T. Dang – Chief, Neurosurgery, Hôtel-Dieu • Gid Sovran, Board Chair, Hôtel-Dieu • Dr. S. Thomas – Vice President, Medical Staff Association • Dr. B. Wilson – Past Chief of Medicine, Hôtel-Dieu
June 17, 2010	<p>Investigators in Windsor, Hôtel-Dieu</p> <ul style="list-style-type: none"> • Dr. John Srigley (Pathology Lead) <p>Individual Meetings</p> <ul style="list-style-type: none"> • Dr. Helde – Pathologist, Hôtel-Dieu • Dr. O. Williams – Pathologist (retired), Hôtel-Dieu <p>Review of Selected Cases with Dr. Shum</p> <ul style="list-style-type: none"> • Case reviews

APPENDIX D: DOCUMENTS AND REPORTS

Hôtel-Dieu Grace Hospital Documentation

1. Accreditation Canada. Final Report of the Hôtel-Dieu Grace Hospital October 19-23, 2008 Accreditation Survey. June 9, 2009.
2. Hôtel-Dieu Grace Hospital. Application for Appointment to Staff by Barbara Heartwell. May 27, 1981.
3. Hôtel-Dieu Grace Hospital. Application for Appointment to Staff by Olive Williams. August 14, 2003.
4. Hôtel-Dieu Grace Hospital. Ethics and Credentials Committee Duties Bylaw 1.14.4. No date.
5. Hôtel-Dieu Grace Hospital. Ontario Laboratory Accreditation Report. Five Year Certificate Issued March 26, 2007.
6. Hôtel-Dieu Grace Hospital. Medical Advisory Committee Terms of Reference.
7. Hôtel-Dieu Grace Hospital. Medical Staff Bylaws, Part 1. No date.
8. Hôtel-Dieu Grace Hospital. Medical Staff Bylaw 1.4 (Appointment to Professional Staff), 1.5 (Reappointment) and 1.6 (Changes of Privileges). No date.
9. Hôtel-Dieu Grace Hospital. Mortality Multidisciplinary Review Team Review Process. April 2008. Revised June 2008.
10. Hôtel-Dieu Grace Hospital. Organisational Chart.
11. Hôtel-Dieu Grace Hospital. Patient Safety and Quality Care Committee Terms of Reference. Revised February 2010. Original September 6, 2006.
12. Hôtel-Dieu Grace Hospital. Policy and Procedures: Disclosure of Critical Incidents. Effective December 14, 2007. Last Review Date February 1, 2010.
13. Hôtel-Dieu Grace Hospital. Policy and Procedures: Safety Reporting System. Effective December 14, 2007. Last Review Date February 1, 2010.
14. Hôtel-Dieu Grace Hospital. Policy and Procedures: Sentinel Event Handling. Effective December 16, 2010. Last Review Date February 16, 2010.
15. Hôtel-Dieu Grace Hospital. Quality Improvement Plan. Revised March 2010. Original August 14, 2008.
16. Hôtel-Dieu Grace Hospital. Special Meeting of the MAC – Recommendation to the Board of Directors, Hôtel-Dieu Grace Hospital. March 2, 2010.
17. Hôtel-Dieu Grace and Villa Maria Policy for application to the Medical/Dental staff. No date.

Leamington District Memorial Hospital

1. Accreditation Canada. Accreditation Report Leamington District Memorial Hospital. November 29, 2009 to December 2, 2009 Accreditation Survey. December 14, 2009.
2. Leamington District Memorial Hospital. Case Reviews: Guidelines for Program Directors and Clinical Managers. Date of Origin: December 2000. Revision Dates May 14, 2007.
3. Leamington District Memorial Hospital. Credentials Paperwork for Professional Staff Privileges. No date.

4. Leamington District Memorial Hospital. Guide to Completing Incidents Forms (Appendix 1). No date.
5. Leamington District Memorial Hospital. Hospital By-laws (Part VI: Professional Staff By-laws). Approved June 29, 2005.
6. Leamington District Memorial Hospital. Medical Advisory Committee Terms of Reference.
7. Leamington District Memorial Hospital. Ontario Laboratory Accreditation Report. Five Year Certificate Issued March 26, 2007.
8. Leamington District Memorial Hospital. Organisational Chart.
9. Leamington District Memorial Hospital. Policy: Disclosure of Harm. Date of Origin: September 21, 2005. Approval Date: December 19, 2008.
10. Leamington District Memorial Hospital. Policy: Disclosure of Harm. eLearning Tool. No date.
11. Leamington District Memorial Hospital. Policy: Incident Reporting System. Date of Origin: May 13, 1999. Revision Dates November 24, 2009.
12. Leamington District Memorial Hospital. Policy: Quality of Care Committee. Date of Origin: August 3, 2005. Revision Dates November 25, 2008.
13. Leamington District Memorial Hospital. Policy: Risk Management Policy. Date of Origin: May 13, 1999. Review Date: November 25, 2008.
14. Leamington District Memorial Hospital. Professional Staff Rules and Regulations. No date.
15. Leamington District Memorial Hospital. Quality Council Report Schedule 2010/2011.
16. Leamington District Memorial Hospital. Quality Council Terms of Reference. October 19, 2009.
17. Leamington District Memorial Hospital. Quality of Care Case Review Record Form. No date.
18. Leamington District Memorial Hospital. Risk Management Program. Date of Origin: May 13, 1999. Review Date: November 25, 2008.

Three Essex County Hospitals

1. Integrated Hospital Laboratories Service Windsor-Essex. Quality Assurance Within the Anatomical Pathology Department of Laboratory Service. No date.
2. Hôtel-Dieu Grace Hospital, Windsor Regional Hospital, Leamington District Memorial Hospital, Erie St. Clair Local Health Integration Network. Pathology Review. March 3, 2010.
3. Hôtel-Dieu Grace Hospital, Windsor Regional Hospital, Leamington District Memorial Hospital Agreement with Windsor-Essex Pathology Associates (WEPA). November 8, 2009.

Windsor Regional Hospital

1. Windsor Regional Hospital. Medical Advisory Committee Terms of Reference.
2. Windsor Regional Hospital. Memo from Gary Ing, Chief of Staff to B. McLellan on Overview of the Professional Staff Appointment Process. March 24, 2010.

3. Windsor Regional Hospital. Memo from Gary Ing, Chief of Staff to B. McLellan on Overview of the Professional Staff Re-appointment Process. March 24, 2010.
4. Windsor Regional Hospital. Ontario Laboratory Accreditation Report. Five Year Certificate Issued March 26, 2007.
5. Windsor Regional Hospital. Organisational Chart.
6. Windsor Regional Hospital. Professional Staff Appointment Process. No date.
7. Windsor Regional Hospital. Professional Staff Re-appointment Process. No date.
8. Windsor Regional Hospital. Policy: Disclosure of Harm Policy. Effective July 2005.
9. Windsor Regional Hospital. Policy: Unusual Occurrence Reporting (Incident/Event). Effective May 1998. Last Revision Date May 2008.
10. Windsor Regional Hospital. Policy: Management of Sentinel Event. Effective March 2, 2010.
11. Windsor Regional Hospital. Incident Management Systems (IMS) Model. No date.

Additional References

Grey Bruce Health Services. *Statement: Conclusion of GBHS Pathology Review*. May 14, 2010.

Kronz, J. D. and W. H. Westra. The role of second opinion pathology in the management of lesions of the head and neck. *Curr Opin Otolaryngol Head Neck Surg* 2005 13:81-84. 2005.

Nakleh, R.E. "What is quality in surgical pathology?" *J Clin Pathol* 2006 59: 669-672.

Nakhleh, R. E. and P. L. Fitzgibbons (editors). 2005. *Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction*. Illinois: College of American Pathologists.

Quality Management Program – Laboratory Services (QMP-LS). *Professional Interpretation and its Quality Management (PIQM) Task Force Report*. December 22, 2009.

Raab, S.S, R.E. Nakhleh and S. G. Ruby. 2005 (April). "Patient Safety in Anatomic Pathology: Measuring Discrepancy Frequencies and Causes." *Arch Pathol Lab Med* Vol. 129, 459-466.

The Royal College of Pathologists (London). *Review of the Categorisation of Discrepancies in Histopathology*. November 2008.

The Royal College of Pathologists of Australia. *Procedure for Investigation of Allegations of Poor Professional Performance in Anatomical Pathology (Histopathology and Cytopathology)*. Approved March 2001.

The Royal College of Pathologists (Professional Standards Unit and Professional Performance Panel). *Concerns About Performance in Pathology: Guidance for Healthcare Organisations and Pathologists*. February 2006.

Willoughby, K. A. and D. Schattenkirk. *Make No Mistake: Reducing Errors in Hospital Pathology Samples and Information Flow*. Unpublished manuscript. No date.

Windsor-Essex Pathology Associates Quality Assurance System.

APPENDIX E: STANDARD PATHOLOGY REVIEW TEMPLATE

Review of Dr. Williams' Pathology Cases - Windsor-Essex Investigation											
Reviewer: Type name				Instructions: Mark appropriate column with an "x"							
				Clinical Diagnosis/Information		AGREE		DISAGREE			
						A	B	C	D	E	F
Case #	# of specimens	Specimen <small>(click on cell to select from list)</small>	Biopsy or Resection	Adequate	Inadequate	Agree with original diagnosis	Agree More workup recommended	Disagree More workup recommended	Minor disagreement No effect on patient care	Disagreement Potential clinical significance (clinician input may be required)	Disagreement Significant clinical impact

REPORT QUALITY <small>(typographical errors, inconsistencies, ambiguities)</small>			COMMENTS
1	2	3	
No concerns	Concerns: <u>unlikely</u> to have any clinical significance	Concerns: <u>potential</u> clinical significance	

APPENDIX F: DISTRIBUTION OF PATHOLOGY SPECIMEN TYPES

Specimen Type	2003	2004	2005	2006	2007	2008	2009	Grand Total
Gastric	4	7	8	8	10	414	378	829
Colorectal	27	76	65	50	42	303	262	825
Breast	42	120	97	111	77	160	168	775
Skin	4		1	8	1	337	250	601
Bowel						254	227	481
Prostate	25	65	38	65	66	74	99	432
Lung	14	40	44	43	30	98	61	330
Gallbladder	4					127	112	243
Cytology fluid	6	9	5	6		119	79	224
Small bowel	1			4		84	82	171
Esophagus		6	1	16	5	78	51	157
Bronchus	3	51	20	15	3	28	24	144
Hernia						68	62	130
Lymph Node	4	20	17	9	8	24	19	101
Liver	5	13	8	1		34	30	91
Cyst						29	33	62
Synovium						33	25	58
Appendix	1			1		31	22	55
Bladder	3	1	5	4	1	23	15	52
* Other	13	36	22	32	4	402	433	942
Grand Total	156	444	331	373	247	2720	2432	6703

* Other: Includes less than 50 cases of specimen types such as pancreas, kidney, thyroid, spleen, etc.