Submission

By

Eastern Regional Integrated Health Authority

To

Commission of Inquiry

on Hormone Receptor Testing

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Table of Contents

I. Introduction

1. This Inquiry was called in May 2007 following a period of intense public and political attention on the results of retesting by Eastern Health[1] of specimens of malignant breast tissue that had originally been tested between 1997 and 2005 for the presence of receptors for the hormones estrogen and progesterone.

2. Of about 3000 patient tests test performed in that period, almost 1000 originally had negative results and were retested.[2] The test results changed to positive for about 40% of the retested specimens.[3] Many of those patients were offered delayed hormonal therapy based on those retest results. Medical research suggests that had hormonal therapy been offered and taken by those patients earlier, the chances for some of them to avoid or delay the recurrence or spread of their disease would have been improved.

3. The public hearing began, and ended, with the stories of those patients and their families. The first other witness to testify was Mrs. Joan Dawe, Chair of the Board or Trustees of Eastern Health. She opened with the following statement:

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1 Eastern Regional Integrated Health Authority

2 Exhibit P-3565, at page 10, reported 995 retested cases and 1101 total retests as of March 11, 2008.

3 Exhibit P-3565, at page 58, reported that 395 tests out of 1101 retests changed from negative to positive using the 30% and 10% cut-off criteria, which is a 35.8% rate of change. The number of changed retests varies depending on the cut-off criteria used. If the 395 changed retests is compared to the approximately 3000 original tests, then the rate of change would be 13.2%

Thank you. Commissioner, this Inquiry is about breast cancer patients, some of whom did not get the treatment that they might have had they received a different original test result. It was important for this Inquiry to start by hearing stories and concerns of patients and their families and that we keep them in mind throughout this process. As Chair of the Board of Eastern Health, I am deeply concerned when I hear that even one person has been affected as a result of the ER/PR testing. I am very sorry for the pain and anxiety that patients and their families have endured. For this, Eastern Health apologizes.

During the course of this Inquiry, many representatives from Eastern Health will give evidence about their involvement in testing, patient care, retesting and communicating the results. We believe that those persons carried out their responsibilities to the best of their abilities. Their motivation was first and foremost to provide the very best possible patient care. That remains Eastern Health's objective today.

I can assure you that Eastern Health is totally committed to this Inquiry and is fully participating in the process. We await the outcome of this Commission, hoping that it will provide resolutions for patients and their families and to assist us to continue to make improvements in our services.

Furthermore, we understand that Canadian medical organizations and pathologists are also calling for the development and implementation of national standards and regulations for immunohistochemistry. So we are confident that learnings from this Inquiry will be used not only to help Newfoundlanders and Labradorians, but to benefit all Canadians. Thank you very much.

4. The mandate of this Inquiry is set out in its terms of reference.[4] The authority of this Commission of Inquiry, with some limitations, is set out in its governing legislation.[5]

[4] O.C. 2007-300, N.L.Gaz. 72/07 (*Public Inquiries Act, 2006)*
[5] *Public Inquiries Act*, 2006, S.N.L. 2006, c. P-38.1

5. More than 3500 documents have been placed in evidence at the public hearing, with testimony from more than 90 witnesses over 128 hearing days. The evidence has been wide ranging in terms of the time period covered, the multiple aspects of laboratory testing and cancer care examined, and the broader issues of health care management and administration considered. Complete and comprehensive comment on all aspects of the evidence and the issues raised by it is beyond the scope of this brief. Instead, this brief will present a overview of the sequence of events with extra emphasis on the most relevant aspects of the evidence, followed by a discussion of suggested considerations related to each term of reference.

6. A supplementary submission made on behalf of the Board of Trustees of Eastern Health is attached as Appendix A.

II. The Evidence

A. Health Care Authorities in Newfoundland and Labrador Before 2005

(i) The First Round of Regionalization

7. The Health Care Corporation of St. John's ("HCCSJ"), and other regional health care boards operating acute care hospitals in Newfoundland and Labrador came into being on April 1, 1995. In the case of the HCCSJ, it was an amalgamation primarily of boards that operated the acute care hospitals and health facilities in St. John's. However, this was not the first regionalization of health care institutions in the Province of Newfoundland and Labrador.

8. In the 1980s financial pressures had lead to amalgamations among the 70 or 80 independent boards operating health care institutions that existed at that time.[6] A 1984 Royal Commission had supported hospital closures and rationalization of services, particularly in St. John's.[7]

9. By 1990, there had been a period of significant reduction in health care funding as the federal government reduced its fiscal transfers to the provinces, resulting in a second wave of regionalization. Between 1994 and 1996 the 54 boards that

[6] Evidence of Joan Dawe, March 28, 2008, page 65, line 23 to page 68, line 6
[7] Exhibit P-3569, The Impact of Restructuring on Acute Care Hospitals in Newfoundland, page 11

remained from the first regionalization were then reduced to 14, one of these being the Health Care Corporation of St. John's.[8]

(ii) The Creation of the Health Care Corporation of St. John's

10. The eight acute care facilities merged into the Health Care Corporation of St. John's included the General Hospital Corporation (the "General Hospital"), St. Clare's Mercy Hospital ("St. Clare's"), the Salvation Army Grace General Hospital ("the Grace") and the Charles A. Janeway Children's Hospital ("the Janeway"). These institutions had been administered independently with different organizational structures, but offered a similar range of acute care services, thus providing opportunities for achievement of efficiencies through amalgamation.

11. The new Health Care Corporation of St. John's was, upon its creation, also given the mandate of closing the Grace and moving the Janeway to new facilities to be constructed adjacent to the General Hospital at the Health Sciences Centre site. The first CEO of the HCCSJ, Sister Elizabeth Davis, took up her position well before the effective date of the amalgamation. She put together a planning team that worked full time for a year before the effective date planning the implementation of the amalgamation.[9] A later study concluded that the HCCSJ

[8] Evidence of Joan Dawe, page 68, line 8 to page 70, line 6
Exhibit P-3569, The Impact of Restructuring on Acute Care Hospitals in Newfoundland, page 11
[9] Evidence of Patricia Pilgrim, September 30, 2008, page 58 line 10 to page 59 line 18

"applied a well-developed strategic plan focused on organizational, clinical and site integration."[10]

(iii) Structure of the Health Care Corporation of St. John`s

12. The overall organization of the HCCSJ had at the apex of the pyramid its Board of Trustees. The Chief Executive Officer, initially Sister Elizabeth Davis, and later, Mr. George Tilley, reported to the Board. The executive positions below the Chief Executive Officer varied in title and composition from time to time. In 2001, for example, there were Vice-Presidents of Quality and Planning, Patient Care Services, Medical Services, Human Resources and Administrative Services.[11] Each Vice-President had a portfolio of programs within his or her jurisdiction. In 2001, for example, the Vice-President of Medical Services had in his portfolio Laboratory Medicine, Ambulatory Care, Cardiac Care, Diagnostic Imaging, Pharmacy, the Bell Island Health Centre and the Ferryland Clinic.

13. In 1996 the HCCSJ adopted the program management model for its organizational structure.[12] This was a move away from the traditional structure in which departments were organized around functions, so that, for example, there was a department of nursing with a director that was responsible for all nursing

[10] Exhibit P-3569, The Impact of Restructuring on Acute Care Hospitals in Newfoundland, page 11 and 12
[11] Exhibit P-0043, page 2
[12] Exhibit P-3569, The Impact of Restructuring on Acute Care Hospitals in Newfoundland, page 12

services provided throughout the institution. Under program management, programs were organized around the types of services provided to the patients. There could, for example, be clinical programs such as emergency medicine, psychiatry, and internal medicine, each encompassing all the services of that type provided by the institution at all sites. Each program would include the physicians, nurses, and other professional and non-professional staff engaged in providing those services. The nurses, instead of reporting up through a supervisory structure to a single Director of Nursing, would report up to the senior leadership in the program in which they worked. Laboratory Medicine, along with Diagnostic Imaging and Pharmacy, were set up as clinical support programs that provided services to the clinical programs.

14. A feature of the program management model is that the senior level of administration in the program or department is shared among a leadership team, typically consisting of an administrative Program Director and a physician Clinical Chief. In many cases, where there is a corresponding medical discipline at the Memorial University School of Medicine, the chief of that discipline would also be a member of the leadership team. This was the model adopted in Laboratory Medicine. The Program Director was the senior administrator responsible for technical and administrative aspects of the services provided. The Clinical Chief was chosen from among the pathologists within the program, and had

responsibility for the services provided by the physicians. The Discipline Chair was a university appointment, but in practice the same pathologist often held both the Clinical Chief and Discipline Chair positions. Those persons worked as a team at equal levels in the organizational structure.

(iv) Structure of the HCCSJ Laboratory Medicine Program

15. Hospital laboratories are functionally divided into specialized areas, each providing a different type of testing and services.[13] Examples are biochemistry, cytochemistry, haematology and microbiology.[14] This inquiry is concerned with the Anatomic Pathology Division of Eastern Health, which for most of the time period under examination was a Division of the Laboratory Medicine Program of the Health Care Corporation of St. John's. Pathology laboratories providing more routine services also exist in Carbonear, Clarenville, Gander, Grand Falls, Corner Brook and St. Anthony.[15] The HCCSJ lab functioned as a referral centre for the province and offered more specialized tests that were not performed elsewhere, such as immunohistochemistry ("IHC").

[13] Exhibit P-2536 page 4 is an organizational chart from the 1997-1998 Laboratory Services Department annual report. It lists the divisions at each of five sites in St, John's and shows the administrative and medical reporting structure.
[14] Exhibit P-0118, page 1
[15] In 2005 Clarenville and Carbonear technically came under the authority of Eastern Health, but in practice the integration of those laboratories into a regional structure is still a work-in-progress.

(v) Newfoundland Cancer Treatment and Research Foundation

16. The Newfoundland Cancer Treatment and Research Foundation (NCTRF) was a separately constituted and governed institution with the primary responsibility for providing cancer care in the Province. It remained an independent entity until the creation of Eastern Health in 2005. Its main facility, the Dr. H. Bliss Murphy Cancer Centre adjoins the HCCSJ's General Hospital site in the Health Sciences Centre building. The Dr. H. Bliss Murphy Cancer Centre has facilities for administration of radiation and chemotherapy treatments, but no in-patient facilities. The NCTRF maintained its own health records, both paper and electronic, for its patients. Medical and radiation oncologists worked within the NCTRF, and also held privileges at the HCCSJ allowing them to care for their admitted patients. Other physicians involved in care of cancer patients, such as surgeons and gynecological oncologists, worked within the HCCSJ structure instead of under the NCTRF. The NCTRF also operated peripheral clinics elsewhere in the province. Oncologists travelled from St. John's to those locations.

(vi) Review of Restructuring

17. In March, 2003, Barrett, et al., delivered a report that set out the results of a study of certain aspects of the restructuring of acute care hospitals in

Newfoundland that had taken place between 1994 and 1996.[16] The study evaluated the impact during and shortly after restructuring in a number of areas. Major findings included:

- Costs had continued to rise, fueled in part by higher human resource expenditures, largely outside the control of regional boards.

- The size of the workforce as a whole did not change, although there was consistent immediate reduction in management positions.

- In St. John's prior to restructuring, an objective had been declared, leadership was provided to achieve the objective, a strategic plan for rationalization was developed, and communication, execution, and evaluation of the plan occurred.

- Opportunities for further integration of boards and rationalization of services and institutions existed; however, strategic planning to implement further rationalization would be required.

- There had been no measurable impact in the short term on quality of care, use, or efficiency attributable to regionalization.

- Considerable employee dislocation occurred during the restructuring in St. John's affecting the morale of those working within the organization.

[16] Exhibit P-3569, The Impact of Restructuring on Acute Care Hospitals in Newfoundland by Barrett, et al.

B. The Health Care Corporation of St. John's Laboratory Medicine Program

18. This section presents background information about the HCCSJ Laboratory Medicine Program relevant to the estrogen and progesterone testing issues prior to the creation of Eastern Health and the discovery of the index case in April 2005.

(i) Laboratory Restructuring Following Amalgamation

19. The pathology laboratories in each acute care hospital that was amalgamated to form the HCCSJ had its own pathologists, managers, technologists, practices and procedures, and its own organizational structure. One of the challenges faced by the new HCCSJ in Laboratory Medicine, and throughout most of its operations, was to implement consistent organizational structures and promote the standardization of policies, practices and procedures in place of existing ones that were well entrenched, and functioning well, within each of the amalgamated institutions. HCCSJ had a mandate to achieve consolidations of those services with the intent of making their overall functioning more efficient and thus more cost effective.

20. By 1997 some consolidation of laboratory services had taken place, but it was not complete. One laboratory Program Director replaced the four Directors at the

St. John's hospitals. The number of laboratory supervisors overseeing the work of the technologists was reduced from about twenty-three to eleven.[17] The number of technologists remained about the same.

21. The Laboratory Program Director then was Mr. Vern Whalen, who reported to the Senior Vice-President for Corporate Affairs[18], who in turn reported to the Chief Executive Officer. Each Division of the laboratory had a Divisional Manager reporting to the Program Director. For most Divisions there was one Divisional Manager with responsibility for all sites where the activities of that Division were carried out. For Pathology there were two Divisional Managers. Mr. Terry Gulliver was the Manager of the General Hospital and Janeway sites, with additional responsibility for immunology, cytogenetics and molecular genetics. Mr. John Murphy was Manager of the St. Clare's and Grace sites.

22. Pathologist Dr. David Haeggert was the Clinical Chief and Discipline Chair. He reported to the Vice-President of Medical Affairs who reported to the Chief Executive Officer.[19] Each of the four sites offering anatomic pathology services, the General Hospital, St. Clare's, the Grace and the Janeway, had a pathologist in the position of Site Chief, all reporting to the Clinical Chief.

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[17] Evidence of Terry Gulliver, October 3, 2008, page 42 line 14 to page 45 line 25

[18] At this point the Clinical Chief and Program Manager reported to different members of the Executive Team. This changed soon after to consolidate the reporting relationship.

[19] Exhibit P-2885, page 3

23. In February, 1999, the Laboratory Medicine Program prepared its annual report for the 1997/1998 fiscal year ending March 31, 1998.[20] The report noted that the Program had undergone changes in that year as a result of continuing restructuring and consolidation. Implementation of many changes had gone quite well but others represented challenges. In particular, the Program had been required to reduce its overall budget by $700,000. The report describes the consolidation of services among sites that had been achieved, but identifies further consolidations as an important objective. There were four goals with subsidiary objectives set out in the report. Quality of the services provided was an important feature of those goals and objectives, but not the only one. Considerable emphasis was placed on financial efficiency.

24. Goal number. 2, “To restructure the service to improve the quality to meet changing conditions” includes as objectives to “consolidate services where possible”, “standardized policies and procedures on all sites” and “combine all laboratory hospital information system models to one corporate model”. These objectives were to be implemented across all divisions and all sites but in a climate where overall demand on laboratory services was increasing and budgets were shrinking.

[20] Exhibit P-2536

25. Mr. Gulliver testified that demand for laboratory services increased annually and that regardless of whether the service volume had been anticipated or budgeted for, the laboratory had to perform the work requested of it.

26. Continuing into 2000, much of the time of those managing laboratory services was taken up with issues surrounding the continuing reorganization and consolidation of health care services in St. John's and in particular, the recent closure of the Grace and the impending move of the Janeway Hospital to its new facilities.[21]

(ii) HCCSJ Budget Deficit and the Hay Group Review

27. In 2001 the Health Care Corporation of St. John's faced an $8.6 million budget deficit. On November 5, the Minister of Health and Community Services announced that Government would be "commissioning a full operational review of the Corporation by external consultants with the first part of their mandate to present a plan to recover the current year deficit as soon as possible, … and to generally contain the growth in costs in the future".[22] That review was carried out by the Hay Group.

[21] See, for example, Exhibit P-2537, Laboratory Management Committee minutes from September 20, 2000.
[22] Exhibit P-0041, page 14

28. The Hay Group began their work in November, 2001 and conducted site visits in January, 2002. In February, 2002, while the Hay Group report was pending, the HCCSJ realigned its management structure and announced a number of cost reduction measures to decrease its projected deficit below $4 million. By March, 2002, the organization announced that it would balance its budget for the 2001-2002 fiscal year. That was ultimately achieved through a combination of measures including bed closures, one-time cost saving measures such as reductions in staff education and building maintenance projects, some additional funding from government and the elimination of staff positions.[23]

29. On March 28, 2002, the Department of Health released the Operational Review Report prepared by the Hay Group. The focus of the Report was on achieving clinical efficiencies so as to reduce costs. At the time, there was considerable internal and public debate about the implications of implementing the recommendations from that report and the concern that they would have a negative impact on patient care.[24]

30. Recommendations 89 to 96 were directed towards laboratory services.[25] The Hay Group recommended continuing the process of consolidating laboratory services, recommended reducing the number of management positions in the

[23] Exhibit P-0041, Response to the Hay Group Operational Review, page 15
[24] Evidence of Joan Dawe, March 28, 2008, page 77 line 7 to page 78 line 8
[25] Exhibit P-0041, page 41 and 42

laboratory, recommended establishing productivity targets and, in Recommendation 96, stated, "the director of laboratory services should reduce staffing in pathology by 2.0 FTEs[26] in Cytology and 1.0 FTE in Histopathology and make investments to train 3 pathology assistants.

31. Prior to release of the Hay Group Report, the laboratory Program Manager, Mr. Gulliver, had prepared a written response to the proposed recommendations that had been circulated for comment.[27] Mr. Gulliver accepted many of the recommendations. He disagreed with further reductions in the number of managers stating, "the laboratory program has recently down sized from 10 division managers to 7. This allows for only one manager for each division corporate wide".[28] Regarding the recommendations that full-time equivalent technologists' positions be eliminated and pathology assistant positions created, he commented,

> This recommendation appears to be a trade off for 3 technologist FTEs to be replaced with 3 pathology assistants. While having 3 pathology assistants would be beneficial in reducing pathologists' workload, it would have an increased financial implication on the division as pathology assistants are paid much more in Canada than technologists.[29]

[26] Full Time Equivalent staff positions.
[27] Exhibit P-0901, March 3, 2002 Memorandum from Terry Gulliver to Dr. Williams
[28] Exhibit P-0901, page 6
[29] Exhibit P-0901, page 6

Pathologists held salaried positions that were funded from a provincial budget separate from the budget for the HCCSJ. He continued,

> What we have already implemented in pathology at the General site is that we have trained technologists to do more than 50% of grossing of surgical specimens which is part of the work of a pathology assistant. [30]

32. The official response of the HCCSJ was that it did not support the Hay Group recommendation to reduce staffing in pathology and add 3 pathology assistants stating, "pathology assistants are not readily available in this province as there is no local training program for pathology assistants. Technologists II have been cross-trained to do some of this work."[31]

33. HCCSJ ultimately achieved cost reductions of $17,750,000, out of a budget of just over $300 million, as a result of implementing Hay Group recommendations.[32] However, in the fiscal years following the Hay Group review, the Laboratory Medicine Program continued to fail to meet its budget targets and continued to be pressured to control expenditures.[33]

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[30] Exhibit P-0901, page 6
[31] Exhibit P-0041, page 42
[32] Exhibit P-3141 October 26, 2004 Executive Management Committee Minutes page 1
[33] Exhibit P-1888, February 28, 2003, Laboratory Medicine Program minutes, page 3
Exhibit P-1894, May 2, 2003, Laboratory Medicine Program minutes, page 2
Exhibit P-1903, January 16, 2004, Laboratory Medicine Program minutes, page 2
Exhibit P-1912, March 26, 2004 Laboratory Medicine Program minutes, page 2

34. The Health Care Corporation of St. John's was facing similar problems with its budget. In 2004 it had been informed by the Department of Health and Community Services that government planned to save $5 million in the health care system through attrition over the coming year.[34] At the Board of Trustees meeting on January 29, 2004, the Finance Committee was projecting a deficit for the then current fiscal year of $971,600. The minutes state:

> A briefing note on the preparation of 2004/2005 budget was circulated for the Board's review and information. This document outlined the processes implemented as our organization assessed all avenues available to address our projected deficit. Concern was expressed regarding the cost restraint measures that would be required to balance the budget if adequate funding was not available.[35]

It was decided that the Board Chair would write the Minister of Health and Community Services outlining the measures that had been identified which would allow it to maintain a balanced budget, including decreasing or limiting access to services. [36]

35. The Health Care Corporation of St. John's submitted its final budget proposal prior to formation of Eastern Health to the Department of Health and Community Services in December, 2004.[37] It stated:

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[34] Exhibit P-2402, April 14, 2004 Medical Advisory Committee minutes, page 1
[35] Exhibit P-2517, January 29, 2004 Board of Trustees minutes, page 4
[36] Exhibit P-2517, page 4
[37] Exhibit P-0700

> Since the regionalization in 1996, aggressive steps have been taken to consolidate and streamline our structure and administrative cost which has resulted in the reduction of 236 management positions. In addition, we have closed 3 sites and financed the new Janeway out of these savings.
>
> The organization has participated in a number of external reviews that have helped us eliminate unnecessary overhead. Some of these reports included the Hay Group Operational Review (net savings of 16.5 million dollars)…".[38]

The HCCSJ had paid down its debt by $5 million in the prior 3 years. Over the same 3 year period, net costs had increased by $18.1 million with net funding increasing only $0.6 million.[39]

36. The impact of this period of fiscal restraint was felt throughout the organization. Two areas in particular where the HCCSJ, and health boards in Newfoundland and Labrador generally, were underfunded compared to equivalent organizations elsewhere in Canada were in administration and in information technology. In the December 2005 budget submission Eastern Health included a chart illustrating how much funding in these areas fell below the national average.[40]

[38] Exhibit P-0700, page 5
[39] Exhibit P-0700, page 14
[40] Exhibit P-0701 page 6

(iii) Goals and Objectives for Laboratory Medicine After the Hay Group Report

37. Dr. Robert Williams, the Vice-President of Medical Services set formal goals and objectives for both the Program Director and Clinical Chief in the Laboratory Medicine Program for the 2002-2003 fiscal year.[41] The majority of the goals and objectives set for the Program Manager were to achieve improvements in the operational efficiency of the program, to achieve the productivity bench marks recommended by the Hay Group and to meet the budget.

38. The budget target for laboratory services was to reduce expenditures by $250,000 compared to the year before. In fact, the Program was $206,000 over budget for the fiscal year ending March 31, 2003. Demand for laboratory services had risen 7% in the year, the budget had been overspent by 1% and the hours worked by laboratory staff had been decreased by 10,000.[42]

39. Dr. Donald Cook was appointed Clinical Chief of the Program on October 11, 2002.[43] His goals and objectives, set in consultation with Dr. Williams,[44] included completing annual reviews of laboratory positions, recruiting pathologists to fill vacant positions, overseeing the startup of a surgical pathology

[41] Exhibit P-0905, Terry Gulliver Performance Goals and Objectives, 2002/2003
[42] Exhibit P-0905, page 10
[43] Exhibit P-0903, October 11, 2002 letter from Dr. Robert Williams to Dr. Donald Cook
[44] Exhibit P-0908, Dr. Donald Cook Performance Goals and Objectives/Clinical Chiefs 2002/2003

review committee, developing a quality control policies and procedures manual for anatomic pathology and cytopathology and following through with implementation of recommendations from the Hay Group Report.

(iv) Laboratory Planning Day

40. On March 24, 2003, the Laboratory Medicine Program, with assistance of and facilitation from the Quality Initiatives Department, held a planning day. There had been a considerable amount of work done beforehand to develop 3 year plans for each of the 7 laboratory divisions.[45]

41. For the Pathology Division, there were 4 major objectives.[46] The first objective, to be benchmarked in the top quartile for productivity within Canada, was consistent with the mandate that had been given to the laboratory following the review by the Hay Group. The second objective was to provide the HCCSJ and/or the province with comprehensive lab services and to expand the test menu to provide in-province lab testing, specifically HER-2neu testing[47] and in-house F.I.S.H. testing.[48] It was also planned to develop a comprehensive training program for grossing by senior technologists, to reclassify those

[45] Evidence of Terry Gulliver, October 8, 2008, page 109 line 19 to page 111 line 20
[46] Exhibit P-2317, March 24, 2003 Laboratory Program Planning Day, pages 4 to 9
[47] HER-2Neu testing is used to assist clinicians in deciding whether to recommend the drug Herceptin for breast cancer patients.
[48] HER-2Neu tests with a particular range of results were known to be less reliable and required verification by this more complex testing method.

positions to allow for additional compensation and to provide formally for pathologists' participation in their training.

42. The third objective was to make available the most up-to-date laboratory technology ensuring that the laboratory program was a leader in Canada. The first action listed under this objective was to implement the technical consolidation of pathology staff allowing the utilization of current technology in a more efficient and expanded manner. Staff and equipment were to be transferred to the General Hospital site and responsibility for implementing this was assigned to Barry Dyer and the technical staff.

43. The second action under the third objective was to acquire new technology for immunopathology to improve quality, efficiency and turnaround time. This was a reference to the expiry of a 5 year contract with Dako, an international pharmaceutical company, under which a semi-automated stainer for immunohistochemistry had been acquired and under which Dako supplied antibodies and reagents, described more fully below. Renovations to the pathology laboratory at the Health Sciences Centre were also included in the plan.

44. The fourth objective was to ensure that there was a proper number of qualified staff, the correct skill mix of staff, and to utilize human resources in an efficient

manner. The principle action under this objective was the consolidation of the technical staff at the General Hospital site leaving an appropriate level of pathology technical services at St. Clare's.[49] Dr. Cook had expressed reservations about the pathology consolidation, mainly around potential quality issues resulting from having a reduced pathology laboratory capacity at the St. Clare's site where a large number of surgeries were performed and the necessity to transport specimens between St. Clare's and the General Hospital.[50]

(v) Pathology Division Consolidation

45. By 2003, consolidation of technical pathology laboratory services between St. Clare's and the General Hospital sites was under active discussion. The issue came up at the regular Laboratory Medicine meeting among Dr. Cook, the Clinical Chief, Mr. Gulliver, the Program Director, and Dr. Williams, the Vice-President of Medical Services, on February 28, 2003. Dr. Cook expressed his concerns and Dr. Williams suggested that the issue be discussed at the upcoming laboratory planning day,[51] resulting in the adoption of the objective described above at paragraph 42.

[49] Exhibit P-2317, page 10 is a more detailed plan for the technical consolidation listing advantages and disadvantages
[50] Exhibit P-1888, February 28, 2003 notes of meeting Laboratory Medicine Program, page 4
[51] Exhibit P-1888

46. However, prior to implementing the technical consolidation, a request was made to the Quality Initiatives Department for review of any risks that might be presented by that initiative. Ms. Heather Predham from the Quality Department was assigned to undertake that task.[52] She presented her report on December 15, 2003 finding no mismanagement issues that would impede the consolidation.[53] Dr. Williams arranged for a meeting where Mr. Gulliver and Dr. Cook could both present their views concerning the proposed consolidation to George Tilley, the CEO.[54] In the absence of consensus on the issue, the determination was made at that meeting that a decision on consolidation would be deferred pending the reorganization of health care that had by this time been announced and the appointment of a new board.[55] By May, 2005, the consolidation of technical services had been completed with only transitional issues remaining to be worked through.[56] In June of that year, Dr. Cook reported to the Medical Advisory Committee that although he had initially been opposed to consolidation, his concerns had been alleviated.[57]

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[52] Exhibit P-1897, September 26, 2003 Laboratory Medicine Program minutes
[53] Exhibit P-3030. Although dated December 15, 2003, the report was not delivered to the Laboratory Medicine Program until March, 2004. See the handwritten notes on this Exhibit.
[54] Exhibit P-1912, March 26, 2004 Laboratory Medicine Program minutes
[55] Exhibit P-1916, June 9, 2004 Medical Advisory Committee Minutes, page 4
Exhibit P-1917, June 25, 2004 Laboratory Medicine Program minutes, page 2
[56] Exhibit P-1924, May 6, 2005, Laboratory Medicine Program minutes, page 2
[57] Exhibit P-1927, May-June, 2005, Laboratory Medicine Program report to Clinical Chiefs and MAC

(vi) Recruitment and Retention of Pathologists

47. Recruitment and retention of pathologists remained a significant problem throughout this period, continuing to the present time. The problem has not been limited to ensuring that all approved pathologists positions at the HCCSJ were filled. The turnover of pathologists as they left and were replaced has been the greater problem. The establishment of well functioning committees and rounds, the development of sub-specialization among pathologists, the encouragement of specialized training and knowledge, and the promotion of quality assurance activities, including monitoring trends in pathology testing and reporting, are all impaired when pathology staffing is not stable and workloads are high.

48. Over a two-month period in April to July, 1999, 4 pathologists, Dr. Khalifa, Dr. Govatsos, Dr. McIntosh ad Dr. Griffin, had left the organization. At least 2 of these positions were not filled until early 2000. Then, between September, 2001 and October, 2002, 5 more pathologists resigned. Three of them, Dr. Lawrence, Dr. Rasty and Dr. Abedi, had only been recruited since the prior exodus in 1999. One of the pathologists who left in 2002 was Dr. David Haegert, who had been long time Clinical Chief of the Program. Two replacement pathologists had been added in July and September of 2002, the later being Dr. Gershon Ejeckam. Two more were added in June and July, 2003, one of who was Dr. Daniel

Fontaine. In the 2001-2003 period, however, there were time spans of many months in which at least 2 pathologists positions were not filled.[58] This is an important period during which many of the ER/PR tests that later changed from negative to positive were performed.

49. Dr. Williams and Dr. Cook recognized that the compensation paid to pathologists in Newfoundland and Labrador, all of whom occupy salaried positions, was among the lowest in Canada. This had been an issue for some time and by the beginning of 2003, they were making representations to the Department of Health about the need for increases in pathologists' salaries and had proposed that block funding be provided, meaning that HCCSJ would receive a budgeted amount and, if not all positions could be filled, then the available funds could be applied to recruit pathologists at higher salaries.[59]

50. Later, Dr. Nebojsa Denic, who replaced Dr. Cook as Clinical Chief took up this cause and has continued to work diligently to improve the compensation arrangements for pathologists, working conditions and quality of laboratory services in Eastern Health and in this Province, thus promoting the objective of achieving stability in pathologist staffing.

[58] Exhibit P-1600, Eastern Health Pathologists staff turnover
[59] Exhibit P-1885, January 31, 2003, Laboratory Medicine Program Meeting Minutes, page 3
Exhibit P-1888, February 22, 2003, Minutes of Laboratory Medicine Program Meeting, page 3

C. The Anatomic Pathology Laboratory and Immunohistochemical Staining

(i) Pathology Laboratory Basics

51. In simple terms, the function of the pathology laboratory and the technologists and pathologists who work within it is to examine patients' tissue samples to diagnose disease and give clinicians information to inform treatment decisions. Tissue samples may be examined fresh but in most cases are preserved, typically by being immersed in liquid formalin fixative in the operating room or other clinical setting upon removal of the tissue from the patient. Tissue samples are transported to the pathology laboratory where a gross examination is performed by a pathologist and a description of that examination is dictated, to be transcribed into a narrative pathology report. For many years at the HCCSJ more basic grossing functions were performed by senior technologists to relieve the workload placed on pathologists. More recently, most gross examination is performed by specialized Pathology Assistants.

52. During the gross examination small samples of tissue are dissected and placed in plastic cassettes. These are placed in a tissue processor, an instrument that over a number of hours progressively exposes the tissue in the cassettes to a series of solutions. The primary purpose of the tissue processing is to remove moisture from the tissue. After completion of the tissue processing, the

dehydrated tissue is embedded in paraffin wax in the plastic cassettes. The formalin-fixed, paraffin-embedded tissue is generally referred to as a “block”. Once preserved in this manner, the block can be stored for years without the tissue suffering degradation. The policy at Eastern Health is to retain the paraffin-embedded tissue blocks for 20 years.

53. Technologists cut thin slices of the tissue from the blocks, using instruments called microtomes, and mount them on glass slides. The tissue is routinely stained using an hematoxylin and eosin, or “H & E” stain to allow the cell structure to be visually examined under a microscope by a pathologist. The microscopic description is dictated by the pathologist to be transcribed into the pathology report. The pathology report is then delivered, either on paper or electronically, to the surgeon or treating physician from whom the tissue sample originated. The pathologist’s objective is to determine whether disease is present in the tissue sample and to diagnose it.

54. In addition to the H & E stain, other special stains can be ordered by the pathologist to assist in the pathologist’s diagnosis of disease. Immunohistochemical stains are one type of special stain. In simple terms, antibodies are applied to tissue mounted on the glass slides. Particular antibodies have affinities for particular antigens, or receptor sites, in malignant or

non-malignant cells. Processes are used to apply stains to make the antibodies that have bound to the receptor sites visible on microscopic examination. The technical aspects of the process are, as the Commission has heard, much more complicated than suggested by this simple explanation.

(ii) The Introduction of Immunohistochemical Staining

55. The Commission has heard that the immunohistochemical staining procedure first began to come into use in the 1980s. Initially, the number of available antibodies were few. That number has gradually increased, as has the usefulness of the information that can be learned by use of IHC staining.

56. Use of IHC techniques had been explored in most laboratories at St. John's hospitals, but by 1995 this procedure was principally done only at the General Hospital laboratory in the Health Sciences Centre. It was a manual process performed without the benefit of automation. Terry Gulliver had been one of the first technologists to prepare IHC stains. After he became Pathology Manager at the General Hospital in 1987, the IHC procedures were performed by two senior technologists, Mary Butler and Peggy Welsh. The procedures that they used were developed with the assistance of pathologist Dr. Chittal.[60] Dr. Chittal had taken an early interest in the procedure. He had worked in the area while on a

[60] Evidence of Terry Gulliver, October 3, 2008, page 23 line 16 to line 22
Evidence of Peggy Welsh, July 8, 2008, page 235 line 2 to line 16

one-year sabbatical in France and had brought information back with him when he returned. In particular, he introduced an IHC staining procedure known as “peroxidase anti-peroxidase”, or “PAP” for short. This is one of several alternative procedures that remain in use. The PAP procedure was written into a step by step procedural document that formed the basis for the IHC procedures used in the HCCSJ pathology laboratory.[61] An outline of the original process is:

a. Tissue sections are cut, mounted on glass slides, and incubated over night.

b. On the next day the procedure begins with deparaffinizing and rehydrating the tissue by passing the slides through a series of solutions, in essence reversing the process used to process the tissue before it was embedded in the paraffin block. Other preliminary steps follow.

c. The primary antibody, the antibody that binds to the target antigen site, was then applied, with step by step instructions concerning washing of the slides with solutions and the time for incubation of the antibody.

d. Application of a secondary antibody followed in a series of steps. The secondary antibody would bind to the primary antibody.

e. The peroxidase staining then had to be “revealed” by application of diaminobenxidine, or “DAB”, which stained the secondary antibody by a prescribed.

f. The final series of steps were the application of a counterstain of haematoxylin to allow the cell structure to be visualized.

[61] Exhibit P-2193

57. Antibodies and other reagents used in the IHC process are procured from commercial suppliers. Each antibody and reagent comes with a manufacturer's specification sheet providing information about the use of that antibody or reagent.[62] While there are text books and research publications on the subject, there was not then, and is not now, any standardized procedure for the steps used in performing immunohistochemistry tests. Each laboratory, guided by its technical and professional pathology staff must find the precise formula or recipe for each antibody stain to produce the optimal result for that laboratory.[63] It is only now, in 2008, that an ad hoc group, including Dr. David Dabbs who testified at the public hearing, has begun a serious attempt at developing guidelines for standardization of testing procedures.[64]

58. Variations in acceptable procedure from laboratory to laboratory include the choice of antibody for a particular IHC test, the concentration of the diluted antibody, the incubation time, which is the length of time the tissue is exposed to the antibody, and other variables. The process of testing variations in the procedural steps for use of an antibody is known as validation of the antibody.

59. First within the General Hospital and then within the HCCSJ, antibodies for new tests that became available were procured when requested by individual

[62] Examples are Exhibits P-2176, P-2177 and P-2310
[63] Evidence of Dr. Khalifa, July 24, 2008, page 201 line 15 to page 203 line 9
[64] Exhibit P-2621

pathologists, subject to the availability of funding within the laboratory budget. The technologists would use the generic PAP procedure and the suggested dilutions and other variables from the specifications supplied with the antibody to produce stained slides for review by the pathologist who had requested the introduction of the antibody.[65] If that pathologist was satisfied with the result, then the antibody would be added to the list of those available for use. As time went on, there is evidence that laboratory management, including Site Chiefs and Clinical Chiefs, had become involved in decisions about whether to add new antibodies.[66]

60. Throughout this time, the H & E stain remained the work horse of pathology and the evidence is that it remains so. Most IHC stains are used as an adjunct to confirm a diagnosis made using the H & E stain, or to differentiate finer characteristics of a diagnosis already made. IHC stains are most often used in panels, meaning that multiple stains are performed on a tissue sample and the combination of positive and negative results from the different stains allows a pathologist to narrow down the diagnostic choices available.[67]

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[65] In the early years Dr. Chittal was available to guide the work of the technologists. Later Dr. Khalifa and Dr. Ejeckam played a similar role. Now, Dr. Elms, as the officially appointed Director of Immunohistochemistry, provides expert assistance to the technologists.

[66] See Exhibit P-1863, the April 22, 1998 Minutes of Site Chiefs Meeting – Anatomic Pathology Health Care Corporation at page 1

[67] Evidence of Dr. Donald Cook, July 2, 2008, page 266 line 17 to page 267 line 10

(iii) The Introduction of Antibodies for Estrogen and Progesterone Testing

61. In 1997, new antibodies for detection of estrogen and progesterone receptors in breast tumor cells were introduced at the HCCSJ pathology laboratory.

62. Prior to 1997, the biochemistry laboratory had performed a different test to measure the quantities of estrogen and progesterone in breast tumor tissue. That test, sometimes referred to in the evidence as a bioassay, or a ligand binding assay ("LBA"), required that a large quantity of tumor tissue be emulsified and treated by biochemical processes to assess the quantity of estrogen and progesterone hormones present in it.

63. The primary treatments for breast cancer are surgery to remove the cancerous tissue followed by radiation or chemotherapy, or both. After the conclusion of the primary treatment hormonal therapy can be considered. It is usually administered for a five-year period and is intended to reduce the risk of recurrence of breast cancer or occurrence of metastatic disease. In some cases, anti-hormonal therapy might be prescribed as an alternative to chemotherapy.

64. Research indicates that those patients whose tumors are receptive to estrogen or progesterone are more likely to benefit from hormonal therapy. Anti-hormonal medications have side effects, such as increased risk of endometrial cancer, so

clinicians, with their patients, have to weigh the likelihood of benefit from administration of the drug against the risk of adverse side effects.[68] A positive bioassay test, based on the measurement of the quantity of hormone detected in the sample exceeding an accepted cut off value, was one factor to be taken into account when that decision was made.

65. The new IHC test, known throughout the Inquiry hearings as the ER/PR test, allows the microscopic examination of tumor tissue for the presence of estrogen and progesterone receptors and has advantages over the bioassay method. Better early detection of breast cancer had meant that by the late 1990s smaller tumors were being surgically removed. The relatively large amount of tumor tissue needed to perform the bioassay test would not always be available. Estrogen and progesterone are present in benign breast tissue which, if unavoidably included in the emulsion made for the bioassay testing, would risk giving an incorrect positive result. Also, the bioassay method destroyed the tissue so that samples were not available for other testing then or in the future.[69]

66. The IHC method requires much smaller samples of tissue and, since it is performed on formalin-fixed, paraffin-embedded tissue, other tests can be

[68] Evidence of Dr. Kara Laing, September 9, 2008, page 37 line 10 to page 40 line 7
[69] Exhibit P-3091, Brown, "Hormone Receptor Testing", Centre for Clinical Research in Cancer, Breast Cancer Update, June 2004, page 5

performed and the tissue can be preserved for many years, a factor that in 2005 made the retesting program possible.

67. Dr. Mahmoud Khalifa joined the HCCSJ in 1995 as a staff pathologist, and joined the staff of the Memorial University Medical School as an Assistant Professor. Dr. Khalifa came to St. John's with impressive credentials in the IHC area. He obtained his initial medical training in Cairo, Egypt. He attended to the Armed Forces Institute of Pathology in Washington, D.C. as a Fullbright Research Scholar in 1987. In 1989, he moved on to be a research fellow at the University of Maryland Medical School in Baltimore and from 1990 to 1993, completed an anatomic pathology residency at the University of Oklahoma Health Sciences Centre. He completed a surgical pathology fellowship in 1994 at George Washington University Medical Centre in Washington, D.C. His background gave him significant exposure to the theory and practice of immunohistochemical staining including ER and PR tests.[70]

68. In 1997 and 1998 Dr. Khalifa oversaw the introduction of the ER and PR antibodies at the HCCSJ pathology laboratory. Initially, the test was done using kits containing all the necessary antibodies and reagents supplied by Dako.[71] The tests were done manually using the same procedures as for other IHC tests,

[70] Exhibit P-2423
[71] Exhibit P-2150

incorporating the specifications from the antibodies and reagents and under the guidance of Dr. Khalifa.

69. During the introductory phase, IHC ER and PR tests were performed in parallel with the bioassay tests, and the latter continued to be reported by the biochemistry laboratory to the treating physicians. Dr. Khalifa used the results of the parallel testing to evaluate the reliability of the results obtained using the IHC method.[72] The method of reporting the results of bioassay and IHC tests for ER and PR was different than that used for the bioassay which reported the concentration of estrogen in the emulsion. The IHC test required the pathologist to visually examine the stained tumor cells microscopically and to report the percentage of cells that showed staining in their nuclei. Clinical studies of the bioassay tests had validated those results by comparing the test scores to the outcome for patients who were offered hormonal treatment. Dr. Khalifa's objective was to assess whether the IHC test results correlated well with the bioassay results. His work is illustrated by a number of exhibits from 1997 and 1998.

70. On April 10, 1997, Dr. Khalifa reported to Dr. Cook, then the St. Clare's Site Chief, on his early conclusions from four sets of comparative test results. He said that,

[72] Evidence of Dr. Mahmoud Khalifa, July 24, 2008, page 85 line 3 to page 89 line 15

> if we follow the suggested cut-off line of 30% on immuno (to achieve the highest possible correlation of the bio), you can see that we seem to be doing very well. Of course, the number of cases is still too low to come to final conclusion but I think, overall, we are not doing bad.[73]

71. On May 13, 1997, there was a meeting of the Anatomic Pathology Site Chiefs and Divisional Managers.[74] Those present included Dr. Khalifa who was then Site Chief at the General Hospital, Dr. Donald Cook, Site Chief at St. Clare's, Dr. Sushil Parai, Site Chief at the Grace, Dr. Pushpanathan, Site Chief at the Janeway, and Divisional Pathology Managers Terry Gulliver, for the General Hospital and the Janeway, and John Murphy, for St. Clare's and the Grace. At that meeting, Dr. Khalifa reported his satisfaction with the correlation of staining using both methods.

72. There was also discussion regarding how pathologists would report the results of the new tests. There was not then, nor is there now, a universally accepted method of reporting the results of ER/PR testing. Variations include reporting either "positive" or "negative", reporting the percentage of stained nuclei in the sample of tumor, use of a method known as the "Allred Score" and use of a method known as the "H Score". Dr. Cook was aware that the Mayo Clinic reported its results as simply "positive" or "negative".[75] At this meeting in May

[73] Exhibit P-1855
[74] Exhibits P-1856 and P-2531, page 3, May 13, 1997 Minutes of Anatomic Pathology Site Chiefs and Divisional Managers Meeting
[75] Evidence of Dr. Donald Cook, July 2, 2008, page 97 line 22 to page 98 line 24

1997 it was decided to bring the question of what reporting method to use to a discipline meeting of all pathologists to seek a consensus. Dr. Khalifa was at that time the only pathologist reporting ER/PR results, and he was doing so only for the General Hospital site.

73. A month later, on June 17, 1997, the matter came up again at the next meeting of Site Chiefs and Divisional Managers.[76] The minutes record that most pathologists at St. Clare's and the Grace wanted to interpret their own ER/PR cases. The standard practice in anatomic pathology was for each pathologist to be responsible to report all aspects of the cases assigned to them rather than for tasks to be divided among different pathologists, none of whom would then see the entire case.

74. The same minutes recorded that the pathologists at sites other than the General Hospital wanted to be provided with control slides. The practice was for the technologists to process IHC slides in batches. In addition to the slides with tissue from patients requiring analysis, a slide or slides would be processed in the same batch using previously tested tissue which had a known result. These slides acted as controls to ensure that the test worked properly. If the control slides did not stain as expected, it was an indicator that the results for the other

[76] Exhibit P-1857, page 3, June 17, 1997 Minutes of Anatomic Pathology Site Chiefs and Divisional Managers Meeting

slides might not be accurate and reliable. The tests might have to be repeated and “troubleshooting” might have to be carried out. Control slides can be for either positive or negative results. Positive controls use tissue that is known to produce a positive test result. A negative control might be tissue that was known to produce a negative result, or might be a second sample of the patient tissue being tested that would be processed in the same manner as the patient’s tissue slide except that the primary antibody would not be applied. The HCCSJ laboratory adopted the use of positive controls but did not adopt negative controls.

75. Positive and negative control slides are known as external controls. A pathologist examining a stained slide can in many cases also look for an internal control. For ER/PR testing if normal, non-malignant breast tissue is included on the sample that is stained, the normal tissue will most often, but not always, show positive staining for estrogen and progesterone receptors. A lack of staining in the normal tissue could indicate that the IHC test did not work and should be repeated.

76. Initially, all ER/PR control slides were being reviewed and assessed by Dr. Khalifa, who was also reporting all the patient tests, but it was not his intention to continue doing so indefinitely. At the June 17, 1997 meeting, Dr. Khalifa agreed to provide pathologists at the other sites with stained slides for a number of

cases to allow them to become familiar with reporting the results, and he offered his assistance to them.

77. By September, 1997, after nine months of parallel testing, Dr. Khalifa prepared a report on the results of the correlation study.[77] Nineteen cases of parallel testing for ER were reported as were seventeen cases of parallel testing for PR. In relation to deciding how to report the results of the ER and PR tests, the issue was to determine what percentage of cells with positive nuclear staining was equivalent to a positive bioassay result, which clinicians had experience with. The idea behind the approach taken by Dr. Khalifa was that previous research gave clinicians guidance about how to use results considered positive or negative by the bioassay method when recommending treatment to a patient. Finding an equivalent percentage cut off for IHC testing would give clinicians the ability to make those same choices using the IHC result rather than the bioassay result.[78]

78. In his analysis, Dr. Khalifa stated that if the cut-off point for determining positivity for the sample tests was set at 30% of stained nuclei, then the sensitivity (the ability of the test to find estrogen receptors when they were present) was 88% and the specificity (the ability of the test to stain only estrogen receptors) was

[77] Exhibit P-1850, page 4
[78] Evidence of Dr. Mahmoud Khalifa, July 24, 2008, page 118 line 11 to page 119 line 1

90%. He referred to a paper published in 1990 in the American Journal of Surgical Pathology and made the statement that, “results of similar studies for estrogen receptors (in a much larger series of cases) showed a sensitivity of 76% and a specificity of 82%”. He continued to state that if a cut-off point of 30% were used for progesterone receptors, the sensitivity would be 86% and specificity 80%. In effect, he was saying that the sensitivity and specificity of his ER results, calling 30% and higher as positive, were comparable to the sensitivity and specificity of the testing reported in the 1990 study.[79]

79. In his report he also noted that for his testing of estrogen receptors, there were discrepancies between the IHC and bioassay method in two of nineteen cases and discrepancies for progesterone receptors in three of seventeen cases. Finally, he stated that it might be good practice to report the results in quantitative format as a percentage of positive cells rather than merely as positive or negative.

[79] Dr. Dabbs interpreted that same study differently and questioned the way that Dr. Khalifa applied it, see Evidence of Dr. Dabbs, September 15, 2008, page 233 line 1 to page 235 line 15. When Dr. Khalifa testified he was not questioned about Dr. Dabbs’ opinion.

80. During that process, for added assurance of the quality of the ER and PR tests, Dr. Cook sent a number of specimens to the Mayo Clinic for additional correlation.[80]

81. On September 23, 1997, Dr. Khalifa sent a set of ten cases of ER and PR slides to Dr. Parai, the Site Chief at the Grace General Hospital, along with a description of his assessment of those cases.[81] He asked that they be returned so he could circulate the collection among all pathologists who would be using the tests, stating that he was seriously considering referring the stained slides to the requesting pathologists without reporting them himself. He was thus giving other pathologists the opportunity to familiarize themselves with his assessment of these slides before they took on the responsibility of reporting their own cases.

82. In the fall of 1997, the laboratory stopped using the ER/PR kits and began performing the tests using pre-diluted ER/PR antibodies and the "Envision Detection Kit" supplied by Dako.[82] Instead of small kits with all materials needed to do the tests included, the purchase of those materials separately in larger volumes was more economical and was consistent with the way most IHC testing was done. The Envision Detection Kit included the reagents and stains to be applied after the ER and PR antibodies and made it possible to visually detect

[80] Evidence of Dr. Donald Cook, July 2, 2008, page 81 line 16 to page 83 line 19.
[81] Exhibit P-2397
[82] Exhibit P-2150, page 1

the antibodies adhering to the antigen sites in the cell nuclei. As time went on, antibodies and reagents used for these and other IHC tests continued to evolve, representing incremental improvements in the ability of the testing process to detect the target antigen sites.[83]

83. The Site Chiefs and Divisional Managers met again on October 8, 1997.[84] Dr. Khalifa presented the results of his correlation study of the 19 cases. The issue of how to report ER/PR test results was unresolved, since there is a note that "standardization of reporting the results of the immunohistochemical assay also seemed to be a problem" and Dr. Khalifa was asked to check with other Canadian medical centres to inquire about their reporting protocols.

84. The Site Chiefs and Divisional Managers next met on December 16, 1997. Dr. Khalifa again raised the issue of pathologists starting to report the own cases. It was suggested that he write up a proposal with cut-off values and distribute it to pathologists for feedback.[85]

85. In January, 1998, Dr, Khalifa prepared drafts of a memo for all pathologists.[86] At the January 8, 1998 Site Chiefs and Divisional Managers' meeting, agreement

[83] Evidence of Dr. Emina Torlakovic, October 9, 2008, page 192 line 2 to page 203 line 10
Evidence of Dr. David Dabbs, September 16, 2008, page 88 line 3 to line 19
[84] Exhibit P-1859
[85] Exhibit P-1860, page 2
[86] Exhibit P-2414

was reached that it was no longer necessary to continue the bioassay method, that individual pathologists could report their own slides and that the tests would be reported as negative or positive with a percentage of positivity given. There was to be a rider placed on each pathology report, the wording of which was to be developed by Dr. Khalifa.[87]

86. At the February 12, 1998 meeting, it was minuted that Dr. Khalifa would write to Dr. Prabhakaran in the Biochemistry Division to ask him to discontinue the bioassay test as of March 1, 1998. Dr. Cook has noted on his copy of the minutes that pathologists were to begin signing out their own cases on that date but that there would be a transition period before Dr. Prabhakaran would be asked to discontinue the bioassay.[88]

87. That approach is reflected in a memo which Dr. Khalifa sent to all Newfoundland pathologists dated February 16, 1998.[89] On March 1, 1998, they were to begin to report their own cases. Stained slides would be provided to them with positive control slides "whenever it is technically possible". Dr. Khalifa stated he would still review the positive controls himself at the General Hospital laboratory and would not send out the patient slides unless he was satisfied there was adequate

[87] Exhibit P-2415
[88] Exhibit P-1861
[89] Exhibits P-1287 and 1850, February 16, 1998 memorandum from Dr. Khalifa to all Newfoundland Pathologists

staining in the control slides. The biochemical assay would not be discontinued until an undetermined future time. There was a period from the introduction of ER/PR testing by the IHC method until the discontinuance of the bioassay method when both sets of results may have been available to clinicians. We do not know if they relied upon the IHC results or continued to use the bioassay. However, in 2005 when retesting was decided upon, the decision was made to be inclusive and to go back to the initiation of IHC testing, regardless of whether the initial IHC tests had been used clinically or not.

88. Dr. Khalifa included a proposal for uniform reporting which he encouraged others to accept but emphasized that it was only a proposal. His suggestion was that if there was any staining of cell nuclei then the test should be reported as positive but that the percentage of stained cells should also be reported. The percentage could be reported either as a fixed number or as a range. If the percentage of stained cells was less than 30%, then he suggested adding a comment that, “evidence from the available literature indicates that estrogen receptor immunoreactivity detected in less than 30% of neoplastic cells would most likely correspond to a negative result in a biochemical assay of the same specimen”,

with a reference to the same 1990 Journal of Surgical Pathology article that he had referred to in his September, 1997 correlation report.[90]

89. This memorandum was distributed to all Newfoundland pathologists. Some pathologists adopted Dr. Khalifa's proposal exactly as set out in his memorandum.[91] Others did not. Dr. Cook gave evidence that, he, as St. Clare's Site Chief, told the pathologists at that institution not to use the comment about scores of 30% or less corresponding to negative biochemical results. He testified that he had been to a conference where there had been debate about the correct cut-off to use and also that he was aware that at the Mayo clinic tests were reported as positive if there was any staining at all.[92]

90. At the Site Chiefs and Divisional Managers meeting on March 19, 1998, Dr. Khalifa reported that the ER/PR reporting transition was going smoothly.[93] By April it is known that tissue samples from Health Boards outside the Health Care Corporation of St. John's began to be sent to Dr. Khalifa's attention for ER/PR testing.[94]

[90] Exhibit P-1850, page 1
[91] Evidence of Dr. Paul Neil, July 10, 2008, page 77 line 12 to page 78 line 4
[92] Evidence of Dr. Donald Cook, July 2, 2008, page 98, line 1 to line 6
[93] Exhibit P-1862
[94] Exhibit P-2226

91. The Site Chiefs and Divisional Managers met on April 22, 1998.[95] Dr. Cook asked about the rider suggested by Dr. Khalifa in his memo to all pathologists to be used when reporting ER results where less than 30% of the nuclei of the cells stained. The minutes state that, "Dr. Khalifa informed him that this rider is a recommendation only and is not part of the formal policy regarding the reporting of breast receptors".[96]

(iv) The Acquisition of the Dako Autostainer and Progressive Changes in Testing Procedures

92. In April, 1998, the HCCSJ pathology laboratory discontinued using pre-diluted ER and PR antibodies and switched to concentrated antibodies. The use of concentrated antibodies allows a laboratory to adjust the dilution to achieve the optimum results for that laboratory. The dilutions are made manually using a laboratory instrument called a pipette to measure a very small quantity of concentrated antibody and to add it to a larger volume of solution. The practice at HCCSJ was to store the diluted antibody in a laboratory refrigerator in a bottle with a label on which the dilution had been recorded. The dilution used was also recorded on the specification sheet that came with the concentrated antibody which was retained in the laboratory and was available for reference at the work bench where IHC testing was carried out.

[95] Exhibit P-1863, April 22, 1998 Minutes of Site Chiefs – Anatomic pathology page 1
[96] Exhibit P-1863, page 2

93. In May, 1998, the Dako Autostainer was acquired.[97] This instrument automated a number of the steps in the IHC staining procedure. The HCCSJ entered into a contract and reagent lease with Dako Diagnostics Canada Inc. dated May 27, 1998.[98] The contract was to be in effect for five years and addressed antibody and reagent purchases, installment payments for the purchase price of the instrument and payment for an annual service contract. The instrument was installed by the manufacturer's representative who provided training to technologists Mary Butler and Peggy Welsh.[99]

94. With the addition of the Autostainer, the procedure for preparing stained ER and PR slides was generally as follows. Formalin-fixed paraffin-embedded blocks of tissue were prepared as they would be for any pathology case. Technologists cut sections from the blocks and mounted them on glass slides. The slides were dried in an oven to adhere the tissue to the glass and would then go through the deparaffinization and rehydration process. For some antibodies, including ER and PR, antigen retrieval was required.[100] An effect of fixation by formalin is to "mask" the antigen sites. Some antibodies will not effectively detect those

[97] Exhibit P-2339 is a color brochure from the manufacturer showing the instrument

[98] Exhibit P-1893

[99] Evidence of Mary Butler, July 16, 2008, page 178 line7 to page 179 line 15
Evidence of Terry Gulliver, October 3, 2008, page 205 line 24 to page 206 line 4
Evidence of Peggy Welsh, July 8, 2008, page 127 line 4 to line 11; page 131 line 12 to page 132 line 18; and page 141 line 9 to line 23

[100] The exact date for first use of antigen retrieval for ER and PR was not established. The purchase records for Dako products, Exhibit P-2889 at page 19, list the first purchase of Dako Target Retrieval Solution as November 11, 1998. Dako specification sheets for Target Retrieval Solution are found at pages 5 to 8 of Exhibit P-2176.

antigen sites unless the antigens are first “unmasked”. An accepted method for doing this for ER and PR testing is heat induced epitope retrieval or HIER. There are several means by which this can be done, as, for example, described in the specification sheets for Dako antibodies and antigen retrieval solutions. The specification sheet for Dako Target Retrieval Solution recommends three alternative methods: “water bath”, “autoclave” and “Black and Decker vegetable steamer”.[101] The objective of using either method is to immerse the slides in the retrieval solution for a prescribed time and within a prescribed range of temperature.

95. The antigen retrieval method adopted at the HCCSJ laboratory was to immerse the slides in heated retrieval solution. At first, this was done by placing a Coplin jar[102] containing retrieval solution in a pot of heated water to raise the temperature of the solution. Using a thermometer placed in the Coplin jar, the temperature of the solution was monitored until it reached the prescribed temperature. The slides were placed in the heated solution and the temperature maintained for the prescribed period of time. The jar was removed from the

[101] Exhibit P-2176 pages 5 and 6
[102] A Coplin jar is a specially designed glass jar with a lid and grooves on the inside to hold slides.

heated water and allowed to cool. The time in the solution was measured using a standard laboratory timer placed on the bench.[103]

96. After a time, a Dako "water bath" was acquired. It was an instrument designed specifically for heating the antigen retrieval solution but was in principle no different from the method used before it was acquired.[104]

97. An undesirable effect of this method of antigen retrieval is that tissue would sometimes become separated from the slides during the process. This was more likely to happen if the tissue was fatty or was incompletely fixed or processed.

98. After antigen retrieval, the Autostainer was used to apply the primary and secondary antibodies and the detection agents. The Autostainer consisted of a rectangular chamber with a transparent cover. Inside the chamber were slots for 48 slides and a robotic arm with an automated pipette. There were also slots to hold vials containing the antibodies, reagents and solutions required. A computer attached to the Autostainer was programmed with the protocols for each antibody to be used on the instrument. The protocol for each test specified the antibody and other solutions to be applied and the lengths of time that they

[103] Evidence of Terry Gulliver, October 15, 2008, page 242 line 13 to page 243 line 21
Evidence of Mary Butler, July 16, 2008, page 179 line 16 to page 184 line 1
[104] Evidence of Mary Butler, July 16, 2008, page 179 line 16 to page 180 line 21

would be allowed to stay on the slide before being washed off. The computer controlled the movements of the robotic arm.

99. To use the machine, the technologist would use the computer to select the protocols to be run on the slides to be placed in the instrument. Different protocols could be run on different slides in a single run or batch. An attached printer was used to print a "reagent map".[105] The map illustrated the correct slot in which to place each antibody, reagent or solution. The computer display also identified the correct slot in which to place each slide. The technologists loaded the instrument according to these instructions and started it in operation. The robotic arm and attached pipette drew the antibodies, reagents and solutions required in sequence and applied them in the correct quantities to the slides, washing them off after the correct incubation time. Concentrated antibodies that were manually diluted by the technologists were used with the Autostainer.[106]

100. While the application of antibodies, reagents and solutions was automated by this system, it was still dependent on the technologists to select the correct protocols, to load the slides, antibodies, reagents and solutions in the correct slots in the instrument, to perform the antibody dilutions and to perform the

[105] For an example see page 5 of Exhibit P-1605
[106] Evidence of Peggy Welsh, July 8, 2008, page 296 line 17 to page 300 line 22; page 368 line 4 to page 380 line 1
Evidence of Ken Green, July 9, 2008, page 141 line 21 to page 158 line 5

antigen retrieval. This instrument allowed the technologists, under direction of the pathologists, to retain control over the precise protocols used by allowing variations in steps such as antibody dilution, antibody incubation time and the duration of antigen retrieval.[107] We know that the Autostainer was capable of printing reports showing the protocols run on slides placed in particular slots. We have one example of this from June 5, 1998, shortly after the Autostainer was installed.[108] Page 7 of that exhibit is a special procedure requisition form with date, patient name, surgical pathology number for the tissue sample, identification of the block being used, reference to the pathologist being Dr. Khalifa and the selection of estrogen and progesterone receptor testing. Peggy Welsh signed the requisition on June 5, 1998, indicating that the test had been completed. Page 8 is the printout from the Autostainer. It includes the surgical number for the sample, the identification of Dr. Khalifa as the ordering physician and Peggy Welsh as the technician but did not include the patient name. Two slides, No. 19 and 20, are identified on it and for each slide information listed is the antibody applied with the antibody dilution and incubation time and the other reagents and solutions applied with the duration for each. The results of the

[107] This feature is more important in a research setting where experimentation is carried out than in a purely clinical setting. The Ventana system now in use still allows for variation in many of these procedural parameters but is designed to provide more automation and for fewer variables to be subject to human intervention and possible error.

[108] Exhibit P-2152, pages 7 and 8.

pathologist's interpretation are not recorded. The practice was not to print and retain such records.[109]

101. The approval of protocols for the antibodies used on the Autostainer did not rest with the technologists or the administrative management of the laboratory. The protocols initially set up when the instrument was put into use were most likely either directly transposed from those already in use and previously approved by a pathologist when a stain was introduced, or were approved by a pathologist at the request of the technologists.

(v) The Departure of Dr. Khalifa

102. On June 30, 1999, Dr. Khalifa left to take up a position at Sunnybrook Hospital in Toronto. He had been at St. John's for just over 4 years and had been Site Chief at the General Hospital for about 3 years. Before leaving, he wrote up a short description of his duties[110] which included the following:

- Responding to technical problems in the laboratory (preparing controls for Immunohistochemistry, trouble shooting with failed tests, supporting staff personality conflicts, etc.).

- Tuesday conference as a tool for the limited QA we have.

[109] Evidence of Peggy Welsh, July 8, 2008, page 368 line 21 to page 372 line 22
[110] Exhibit P-1898, April 19, 1999 "Some of my chores as a Site Chief (1996 – 1999)

- Preparing and following up on policies.

- Maintaining statistics (turnaround time, work load, outstanding case, etc.).

103. Dr. Khalifa's work with the technologists to implement the ER/PR tests was an example of the close working relationship he had with the staff doing IHC testing. He was very highly regarded by the staff,[111] was knowledgeable about IHC testing and provided the staff with useful guidance and instruction.[112] With the pathologists, he had instituted weekly surgical pathology conferences on Tuesdays where pathologists met to discuss cases.[113]

104. Upon Dr. Khalifa's departure Dr. Wadden filled his position temporarily until on May 1, 2000, it was assumed by Dr. Sushil Parai.[114]

105. The Health Care Corporation of St. John's had been fortunate to attract a pathologist with Dr. Khalifa's background and interest in immunohistochemistry. Dr. Khalifa had come to St. John's at a time when, due to a particular set of immigration circumstances in the United States, numbers of physicians with expiring "J1" Visas had to leave that country, some of them coming to Newfoundland. Over time, many of them moved on to other positions elsewhere

[111] Evidence of Terry Gulliver, October 3, 2008, page 92 line 16 and page 94 line 7
[112] Exhibit P-1898
[113] Exhibit P-2421, April 28, 1999 letter from Dr. Khalifa to Dr. Haegert
[114] Exhibit P-1868, page 1

in Canada.[115] The evidence of the technologists performing the IHC testing is that following Dr. Khalifa's departure, there was not a pathologist available to provide the same assistance as had been provided by Dr. Khalifa.[116]

(vi) The Arrival of Dr. Ejeckam

106. Dr. Gershon Ejeckam came to St. John's from Doha, Qatar and took up a pathologist position at the General Hospital in September, 2002.[117] Dr. Ejeckam had obtained his basic medical training in Nigeria and completed a pathology residency in Ottawa in 1978. Dr. Ejeckam had been a staff pathologist at the Grace in St. John's from 1980 to 1983 before returning to Nigeria to practice pathology and teach until 1989 when he took up a position at a new medical facility in Doha, Qatar as head of the division of anatomic pathology.[118]

107. Dr. Ejeckam remained in Doha until 2002 and while there, was involved in the establishment of a separate Immunohistochemistry laboratory. When he came to St. John's in 2002, he brought with him both interest and expertise in immunohistochemical staining.

[115] Evidence of Dr. Donald Cook, Jul 2, 2008, page 26 line 20 to page 34 line 8
[116] Evidence of Terry Gulliver, October 3, 2008, page 272 line 13 to page 276 line 20
Evidence of Peggy Welsh, July 8, 2008, page 189 line 4 to page 200 line 13; and page 221 line 4 to line 10
[117] Exhibit P-1600
[118] Exhibit P-1601, Curriculum Vitae of Dr. Gershon Ejeckam

108. The period when Dr. Ejeckam was in Doha was a time of many advances in immunohistochemical staining and great increase in the number of antibodies which were available. During that time at Dr. Ejeckam's facility, IHC testing evolved into a separate service with its own laboratory. The availability of funding for that purpose was not an issue.[119]

109. When Dr. Ejeckam came to St. John's in 2002, he found that the physical arrangements for IHC testing in the pathology laboratory were similar to those that had existed in Qatar before the establishment of a separate laboratory. IHC staining was performed on a bench in the main pathology laboratory rather than in a separate space with its own climate control and the technologists performing the testing also had other duties in the general pathology laboratory. In the fall of 2002, however, he did not take any initiatives to promote the establishment in St. John's of an IHC laboratory similar to that which he had left behind in Doha.[120]

(vii) Changes in Laboratory Staffing

110. In October, 2001, Mr. Gulliver moved from the position of Manager of the Pathology Division to replace Mr. Whalen as Program Manager.[121] In March,

[119] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 154 line 9 to page 159 line 10
[120] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 164 line 3 to page 169 line 13
[121] Exhibit P-0900, October 10, 2001 Memo to all staff from George Tilley

2002, Barry Dyer, who had come to the Health Sciences Centre with the move of the Janeway to its new facilities and the closing of its separate laboratory, became Pathology Manager.[122]

111. In March, 2002, Ken Green, Senior Technologist from the St. Clare's Pathology Lab, transferred to the General Hospital site and became the third technologist performing IHC testing. His introduction and training were provided by Peggy Welsh, the Senior Technologist in that service.

112. At that time, the three Senior Technologists, Peggy Welsh, Mary Butler and Ken Green, performed their duties on a three week rotation, one week in immunohistochemistry, one week performing gross examination of small specimens and one week in the general pathology lab where they could also cut specimens for IHC staining. There were also special procedures that they were called upon to perform from time to time.[123]

113. In the spring of 2003, Peggy Welsh tendered her resignation and left her position on about April 25, 2003. Prior to that, Les Simms, who after the departure of Ken Green of St. Clare's, had been the senior technologist there, transferred to the General Hospital site and was trained by Ms. Welsh to replace her in the

[122] Evidence of Barry Dyer, June 21, 2008, page 32 line 24 to page 35 line 2
[123] Evidence of Ken Green, June 9, 2008, page 11, line 8 to page 12, line 18

performance of her duties. She described the process as having Mr. Simms spend time with her when they were performing histochemistry and grossing procedures. For a number of days, Mr. Simms would watch her perform the work and she would explain the procedures. She would then have him perform the work while she watched and supervised. For training in IHC staining, she recalled that they spent consecutive weeks training rather than rotating to other duties. The materials available for guidance included the specification sheets for the antibodies and reagents in use and the procedures for operation of the Dako Autostainer.[124] Written procedures were available, although not in consistent formats or collected together in a manual. This was the same training process that Ms. Welsh had used when Mr. Green had transferred earlier. Both Mr. Green and Mr. Simms came to these positions with considerable histology experience.

(viii) Consideration of Pathology Assistant Positions

114. The April 24, 2001 minutes of a meeting of the pathologists at the General Hospital site record that the Clinical Chief, Dr. Haegert, reported that there had been much discussion about the pathologist assistant issue, but there was no money in the budget to fund a position. The Site Chief, Dr. Parai, would talk to Mr. Gulliver about the possibility of training two senior technologists to do

[124] Evidence of Peggy Welsh, July 8, 2008, page 156, line 11 to page 162, line 12

additional grossing.[125] By June 14th, it was reported that 3 senior technologists were willing to do additional grossing if their positions were reclassified.[126]

115. The Hay Group recommendation in early 2002 to eliminate three pathology technologist positions and replace them with pathology assistants has been discussed above.

116. By December, 2003, laboratory leaders were again discussing the need for pathology assistants as a measure to relieve the pathologists from their increased workload,[127] and discussion continued through 2004.[128] On March 17, 2004, Dr. Robb, the Laboratory Medicine Discipline Chair, wrote Dr. Williams making the case for adding $130,000 to the laboratory budget to fund 3 positions for pathology assistants. Justifications given were to free both pathologists and senior technologists from grossing duties to allow them to perform other valuable work.[129]

[125] Exhibit P-2539, page 3
[126] Exhibit P-2540, page 3
[127] Exhibit P-2320, December 11, 2003, Division of Anatomical Pathology Pathologists' Meeting minutes, page 5
[128] Exhibit P-1908, March 2, 2004, Division of Anatomical Pathology, General Hospital Site Pathologists' Meeting minutes, page 2
Exhibit P-1920, October 15, 2004, meeting notes laboratory medicine
Exhibit P-1583, November 2, 2004, Division of Anatomical Pathology, General Hospital Site Pathologists' Meeting minutes, page 3
[129] Exhibit P-0915

117. The response to Dr. Robb's request, in February 2005, was to provide additional training to senior technologists to take on more grossing and relieve the workload on the pathologists in that way[130] and to develop a training program for them.[131]

118. The only impediment to adding pathology assistants during this period was a budgetary one. There continued to be pressure on the laboratory, and throughout the HCCSJ, to control costs limiting new positions.

119. While the value of pathology assistants in ensuring quality and consistency in the preparation of tissue samples at the grossing stage is now well recognized, it was not part of the written record of the discussion about the usefulness of pathology assistants at the time. They were seen instead as a means of relieving the workload on pathologists, which would in turn have a positive effect on quality.

120. Pathology assistant positions were created in late 2005.

(ix) ER/PR Testing Issues Before 2003

121. Between the departure of Dr. Khalifa and the work done by Dr. Ejeckam to optimize ER/PR testing in April and May of 2003, described below, there are few

[130] Exhibit P-1481, February 4, 2005, Laboratory Medicine Program minutes, page 2
[131] Exhibit P-0918, Program Director Performance Goals and Objectives, page 3
Exhibit P-2322 Anatomical Pathology Manager Performance Goals and Objectives, page 2

notes in the documentary record of there being any problems encountered with the quality of the IHC slides being produced. Of all the pathologists who were present at the General Hospital or St. Clare's during that time who testified at the inquiry, few could recall there being any concern before Dr. Ejeckam's interventions about the reliability of the ER/PR test results, other than occasional individual cases that did not represent a pattern of problems.[132]

122. Among the mentions of potential problems that exist in the documentary record, one is an entry in the February 22, 2001 minutes of a Site Chiefs and Divisional Managers meeting[133] stating that,

> There has been a study going on the quality of the immunoperoxidase staining for both sites. It is agreed that control for immunoperoxidase staining be run for every batch. A pathologist will check the control slide before sending the slide to the other site. Dr. S. Parai has agreed to do this. In case he is not available, another pathologist will be looking at the control.[134]

123. The issue came up again at the Site Chiefs and Divisional Managers meeting of April 25, 2001. The minutes state,

[132] Evidence of Dr. Nebojsa Denic, September 11, 2008, page 83 line 22 to page 84 line 3
Evidence of Dr. Ford Elms, September 2, 2008, page 82 line 6 to page 83 line 16
Evidence of Dr. Daniel Fontaine, July 17, 2008, page 170 line 9 to page 176 line 1
Evidence of Dr. Lynn Morris-Larkin, October 7, 2008, page 68 line 14 to page 69 line 22
Evidence of Dr. Donald Cook, July 2, 2008, page 228 line 9 to page 231 line 13
[133] Exhibit P-1874
[134] Exhibit P-1874 page 3

> Generally, the immunos appear to be very good; there appears to be some problems with the estrogen and progesterone receptors. The positive controls are checked daily by a pathologist. However, these need to be documented. Dr. Parai will follow up on this. Note is also made of heavy utilization of immuno services and the high volumes encountered." [135]

124. Four of the five people who attended those meetings, Dr. Cook, Dr. Haegert, Dr. Parai and Mr. Gulliver, testified. None had a clear recollection of what the issue had been that is addressed in these minutes, but neither did any of them recall there being any issue with the reliability of the ER/PR test results that were being reported. It is most likely that the issue referred to in these minutes is the need to have the control slides checked at the General Hospital before they were sent with the patient slides to St. Clare's.[136]

125. In September, 2001, pathologist Dr. Ford Elms reported a breast cancer case and wrote in the pathology report that the IHC staining for ER had been "technically unsatisfactory on 2 occasions" and that a repeat attempt would be made. Within a couple of weeks he reported the results of the repeat testing, which was negative.[137] This case was retested at Mt. Sinai Hospital in 2006 and was reported by Dr. Mullen as 0% for both ER and PR.[138] The nature of ER/PR

[135] Exhibit P-1876, page 1
[136] Evidence of Terry Gulliver, October 3, 2008, page 302 line 16 to page 306 line 24
Evidence of Dr. Donald Cook, July 2, 2008, page 186 line 6 to page 188 line 17; and page 239 line 10 to page 240 line 15
[137] Exhibit C-0225 page 2
[138] Exhibit C-0225 page 1

testing is such that satisfactory slides are not always produced on the first attempt. It is not uncommon for pathologists in any laboratory to order repeat testing.[139] This case is an example where the pathologist took the care to order repeats where the first slides did not meet with his complete satisfaction. While we know that many of the tests from this period had different results when retested in 2005, this particular one remained the same, indicating that the retest ordered by Dr. Elms at the HCCSJ lab in 2001 produced accurate results.

(x) Suspension of Testing by Dr. Ejeckam

(a) The April 4, 2003 Memo

126. On April 4, 2003, Dr. Ejeckam sent a memo to pathologists at the General Hospital, St. Clare's and out-of-town hospitals noting that histochemical stains for 8 antibodies, including ER and PR, "have remained unreliable, erratic, and therefore unhelpful for diagnostic purposes". He stopped the staining with those antibodies until the "reliability, sensitivity and specificity problems" could be resolved and anticipated that a solution would be found within 4 to 6 weeks. The memo was copied to pathology manager, Mr. Dyer, and the technical staff on immunohistochemistry.[140]

[139] Evidence of Dr. David Dabbs, September 15, 2008, page 206 line 14 to page 209 line 8
[140] Exhibit P-0113, page 1

127. Prior to this, Dr. Ejeckam had begun to involve himself in the technical operations of the IHC portion of the pathology laboratory, applying his interest and expertise in the area. This happened more informally than formally. Over time, he came to be recognized as the "point man" for IHC.[141] Later, in October, 2005, Dr. Ejeckam was formally given the role of overseeing all aspects of the IHC service with direct supervision over the technologists in the area and authority to give direction to pathologists involved in IHC interpretation.[142]

128. Dr. Ejeckam took this initiative on April 4, 2003, as a result of discussions among pathologists at lymphoma rounds, regular meetings of pathologists to discuss lymphoma cases. Four of the stains mentioned in the memo, CD3, CD5, CD20 and CD79 are part of a lymphoma panel, a series of stains done on a specimen to assist the pathologist in classifying a malignancy. Dr. Ejeckam described what happened at the lymphoma rounds as follows:

> So during these conferences, we came to the conclusion that some of the stains that we were receiving were not helping us in making a diagnosis because they were not properly - they were not interpretable. So there was a consensus among us that somebody has to do something about them and I showed interest in this and they were also, my colleagues realized that I've got some measure of interest in the subject. So I took that up and then in the process of supervising that, we identified the stains as one that we needed to watch very closely to make sure they're interpretable and also used for diagnose purposes. That's why I then had

[141] Exhibit P-0067, May 24, 2005 letter from Dr. Cook to Dr. Williams, page 2
[142] Exhibit P-0637, October 13, 2005 letter from Dr. Cook to Dr. Ejeckam

> to stop, because there's no point doing them and they're not using them. So I had to stop them.[143]

129. Dr. Ejeckam then continued,

> Using - doing the stain and not using them for diagnosis. So I had to stop the process of this antibodies. Now there are still lots of other antibodies that were being done. So we didn't shut down the immunohistochemistry laboratory. What we did was to stop some of the antibody stains to make sure that they are - we are having reproducible and interpretable results.[144]

130. Regarding the stain identified on the April 4, 2003 memo as CKHMW-34BE12 (referred to as 34 Beta 12), Dr. Ejeckam testified that this stain was discussed at rounds also. It was included among those for which testing was suspended because pathologists "couldn't be sure that it was positive or negative" and it "wasn't then helpful".[145] The CEA stain was also identified for inclusion in the list at tumor rounds.[146]

131. Regarding the ER and PR stains, Dr. Ejeckam testified,

> The same process that we noticed that possibly you would have the stains done and when you want to use it to make an interpretation of being positive or negative, the stains were not crisp enough or they were not immediately interpretable. We needed to have nuclear stain to say it's positive and if the stain's done and you start finding lots of cytoplasmic stain, then you start wondering what went wrong. So what happened - and then sometimes, you know, you get a good stain today and tomorrow,

[143] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 204 line 6 to line 23
[144] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 205 line 2 to line 10
[145] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 209 line 1 to page 211 line 13
[146] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 211 line 25 to page 212 line 16

> the same block may not show the same thing. So we thought we needed to look at it and be sure what we're dealing with".[147]

132. Importantly, Dr. Ejeckam testified that if the ER/PR stains were not satisfactory, in his words, "if it didn't work", then the pathologists would not report results.[148]

133. Mr. Dyer recalled that Dr. Ejeckam explained to him that the problem was with consistency in the staining. Neither Mr. Dyer nor Mr. Gulliver had previously had problems of this sort brought to their attention concerning these stains.[149]

134. Many witnesses were asked about their interpretation of the language used by Dr. Ejeckam in this memo, which, on the face of it, suggests that problems with the identified stains may have resulted in incorrect results being reported to clinicians. However, the best evidence on how to interpret the language used by Dr. Ejeckam in his own explanations given in his testimony. The decision to temporarily suspend testing for those antibodies was made not by him alone but in consultation with pathologists from the General Hospital and St. Clare's at the weekly rounds and the lymphoma panel. The problems he described that were being encountered with the stains were cases where the pathologists recognized that there were quality deficiencies in the stains that prevented them from

[147] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 213 line 5 to line 18
[148] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 222 line 9 to line 20
[149] Evidence of Barry Dyer, July 21, 2008, page 212, line 9 to page 220, line 4

reporting results. Dr. Ejeckam's evidence is that in those cases, results were not being reported.

135. There was no evidence that anyone involved at that time recognized any need to consider whether incorrect results had been reported that would necessitate retesting.

136. There is some question in the evidence regarding the effectiveness of the distribution of this memo to pathologists outside St. John's. Pathology reports were routinely sent by mail to those pathologists by clerical staff in the pathology division of the laboratory. Those staff had to maintain current addresses for all Newfoundland and Labrador pathologists for that purpose.[150] Dr. Dankwa in St. Anthony, Dr. Gallagher in Gander and Dr. Neil in Corner Brook testified that they did not receive this memo. Dr. Dalton in Grand Falls could not recall. Dr. Baker in Carbonear recalled knowing that there was a period of 3 to 4 weeks when he was not to send in ER/PR samples for testing and said that it was likely that he received the memo.[151]

[150] Evidence of Barry Dyer, July 21, 2008, page 241 line 24 to page 243 line 12

[151] Evidence of Dr. Dankwa, July 11, 2008, line 7 to line 18
Evidence of Dr. Paul Neil, July 10, 2008, page 131 line 18 to 132 line 1
Evidence of Dr, Gallagher, July 25, 2008, page 85 line 18 to page 86 line 8
Evidence of Dr. Maurice Dalton, July 18, 2008, page 217 line 16 to page 218 line 9
Evidence of Dr. Gary Baker, September 5, 2008, page 108 line 7 to page 109 line 9, and page 120 line 7 to line 20

137. Dr. Ejeckam considered that he had sufficient authority to direct that the reporting of these stains be stopped without involving the Clinical Chief, Dr. Cook, or reporting to the Vice President of Medical Services, Dr. Williams.[152] He regarded it as a matter to be dealt with in the laboratory and felt it was sufficient that the laboratory leadership were aware.

138. After sending out the memo Dr. Ejeckam then began working with technologist Mary Butler to adjust the protocols for the 8 stains to improve the staining quality, starting with the ER and PR stains. Dr. Ejeckam recalled beginning by identifying new positive control tissues, next varying the length of time for the antigen retrieval process and then adjusting the dilutions of either the primary or secondary antibodies.[153] That process continued until some time within the first 6 weeks following suspension of testing when Dr. Ejeckam was satisfied that appropriate results were being achieved.[154] Mary Butler prepared the stained slides but the variations in procedure were all selected and assessed by Dr. Ejeckam.[155]

[152] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 220, line 5 to line 16
[153] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 224, line 16 to page 232, line 12
[154] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 232, line 14 to 21
[155] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 231, line 13 to page 232, line 12

139. The same process was followed for the other suspended antibodies. Mary Butler recorded the variations in testing protocol requested by Dr. Ejeckam on daily worksheets which logged all IHC tests performed each day.[156]

140. Technical assistance for staining issues was available from Dako. Pathology Manager Mr. Dyer was aware of the work being carried out by Mary Butler and Dr. Ejeckam and suggested contacting Dako for advice. The service representative who had originally set up the Autostainer and trained the technologists reviewed information provided by Mrs. Butler and responded in writing with comments and suggestions on April 22, 2003.[157] He commented that since control tissues appeared to be staining acceptably, it was reasonable to think that variability in staining was due to variability in the preparation of tissue coming to the laboratory from different sites throughout the province. He suggested giving other hospitals guidelines for fixing specimens, specifying that they should be in 10% neutral buffered formalin for 18 to 24 hours. He made comments and suggestions for variations in the protocols for the antibodies being worked on in the laboratory. He suggested lengthening the time that the slides were exposed to the primary antibody. He did not suggest any change to the antigen retrieval method, which he described as being done by "using Target Retrieval Solution (S1699) by your previously-employed Visionware boiling

[156] Exhibit P-2190. See page 5 for an example of variations in antibody dilutions for ER and PR.
[157] Exhibit P-2155.

method". He suggested that ER and PR primary antibody dilution should be 1 in 50. If those steps did not achieve satisfactory results, then he suggested trying a different antigen retrieval solution and a different detection system.[158]

(b) The May 2, 2003 Memo

141. On May 2, 2003, Dr. Ejeckam circulated a memo to the same group of pathologists that were addressed on his April 4 memo stating "I am glad to inform you that we have rectified the difficulties related to the immuno stain of ER/PR, therefore, we can now resume regular request for these antibody stains".[159]

142. Prior to the suspension of ER testing, that antibody had been diluted in a proportion of 1 to 50.[160] As a result of Dr. Ejeckam's work the dilution had been changed to 1 in 20.[161] This change is recorded on the specification sheets kept at the IHC workbench and would also be noted on the stock bottle containing the diluted antibody. A change in the incubation time for the antibody would have been programmed in the protocol on the Autostainer computer and would have been applied to all staining done using that protocol in the future. Changes in antigen retrieval time would have been recorded on written notes posted in the IHC work area.

[158] See Exhibit P-2150 page 2. The lab did switch from the Envision detection kit to the recommended Envision + in December 2003.
[159] Exhibit P-0113, page 2
[160] Exhibit P-2177, page 7
[161] Exhibit P-2177, page 11

143. There were only 3 technologists who carried out these tests. Although they performed IHC testing in rotation, they remained in communication with each other. In particular, a technologist doing the general laboratory rotation was working in the same room and no more than a couple of benches away from the IHC area. So, although the IHC service did not have a comprehensive manual of policies and procedures and it was not the practice to separately write up all steps in the procedure for each antibody in a single source document, it would have been expected at the time that the technologists would have been aware of the protocol changes made by Dr. Ejeckam.

144. Dr. Ejeckam testified that after reinstating the stains, the quality of the slides that were being produced was “as good as anywhere else”.[162]

145. No memo was circulated regarding the reinstatement of the other 6 stains that had been suspended. Instead, Dr. Ejeckam brought the slides produced after his adjustments back to the pathologists at rounds and when all were satisfied with the results, they began reordering those stains.[163]

146. Dr. Ejeckam’s May 2, 2003 memo also included information for pathologists regarding how the results of IHC staining might be affected by tissue fixation and

[162] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 234, line 14 to page 235, line 1
[163] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 233, line 12 to page 234, line 12

processing, the breast cancer types where a particular test result would be expected, the use of normal breast tissue as internal control, and options from the literature for the percentage of staining to be considered a positive result.[164] Regarding fixation, he stated that "the optimal fixation time for immuno stains is 18 to 24 hours in 10% neutral buffered formalin", in accordance with the suggestion from the Dako representative that other hospitals sending tissue samples be given this information.

147. This memo is the first evidence available of any written communication to pathologists about the examination of the slides for presence of positive internal controls. Dr. Cook's evidence was that this was the first time that such information had been circulated.[165] Some pathologists who testified were aware of the use of internal controls of this test before this memo and others were not.

148. Regarding the reporting of positive results, Dr. Ejeckam stated that there was literature to support considering 1% staining, 5% staining or 10% staining of the nucleus of the cells to be reported as positive. He referred to the NIH

[164] Exhibit P-0113
[165] Evidence of Dr. Donald Cook, July 2, 2008, page 165 line 1 to line 19

consensus statement from 2000[166] but did not express any opinion about which approach he considered most appropriate.

149. Dr. Neil in Corner Brook and Dr. Baker in Carbonear testified that they did receive this memo. Dr. Dankwa in St. Anthony and Dr. Dalton in Grand Falls said they did not. [167] Barry Dyer confirmed that at the General Hospital, it was posted in the pathologist's grossing room.[168]

150. There are three instances of pathology reports of repeated ER/PR tests during this time period.

151. On May 6, 2003, Dr. Morris Larkin reported specimen 03:SU4821, a breast biopsy, stating "the stains have been delayed due to unavailability in the lab. When compared to controls, the specimen is negative for HER-2 Neu, ER and PR".[169] That specimen had been tested on April 30.[170] On May 7, after Dr. Ejeckam had reinstated testing, it was tested again[171] and on May 9, Dr. Morris Larkin reported that "the ER and PR were repeated due to quality assurance

[166] See paragraph 470
[167] Evidence of Dr. Paul Neil, July 10. 2008, page 132 line 3 to line 8
Evidence of Dr. Gary Baker, September 5, 2008, page 108 line 16 to page 109 line 5
Evidence of Dr. Dankwa, July 11, 2008, page 219 line 20 to page 220 line 10
Evidence of Dr. Dalton, July 18, 2008, page 222 line 7 to page 223 line 14
[168] Evidence of Barry Dyer, June 21, 2008, page 277 line 4 to line 24
[169] Exhibit C-0175
[170] Exhibit P-2190, page 11
[171] Exhibit P-2190, page 16

issues. The repeated stains show the following: ER positive in 80% of the cells, PR positive in 10% of the cells. This replaces the previous report (phoned cancer clinic - voicemail on May 9/03)".[172]

152. On May 28, 2003, Dr. Vaze reported a repeat ER/PR test "as requested".[173] The test had originally been reported on March 17, 2003 as ER "occasional positive cells less than 1%" and PR "15% positivity" with the statement "no controls available". When retested, ER was 40% positive and PR 73% positive. Dr. Vaze included a note that on this occasion, the controls were positive. There was no other evidence available to explain the circumstances of this retest.

153. The third reported retest was originally reported on August 29, 2002 by Dr. Elms as 15% PR positive and ER negative. On June 11, 2003, he reported that it had been retested at the request of oncologist Dr. Zaidi, now showing PR positivity of approximately 75% and faint ER positivity in approximately 10 to 15% of the cells.[174] Dr. Elms testified that he could not recall this case and could not provide any more information concerning the circumstances of it.[175]

[172] Evidence of Dr. Carolyn Morris Larkin, October 7, 2008, page 86 line 9 to page 95 line 8
[173] Exhibit C-0228
[174] Exhibit P-2173, page 56 is the requisition form for the retest dated May 23, 2003 noting "repeat ER/PR requested by Dr. Zaidi"
[175] Evidence of Dr. Ford Elms September 2, 2008, page 113, line 10 to page 115, line 17

154. In each of these three cases, the original test was carried out before the reinstatement of ER/PR testing by Dr. Ejeckam on May 2, 2003 and the retest was performed after that date. Each of the three cases involved different pathologists and treating physicians. Unless either pathologist had considered the circumstances significant enough to bring the matter up at rounds, the fact that there had been more than one changed result on retesting after Dr. Ejeckam's intervention would not have become known.

155. By early June, 2003, Dr. Robert Williams went on leave from his position as Vice-President of Medical Services and did not return until September.[176] Neither the suspension of antibody testing nor the memos of April 4 or May 2 had been brought to his attention before he went on leave.[177]

(c) The June 19, 2003 Memo

156. On June 19, 2003, Dr. Ejeckam wrote a third memo, this one directed to the Program Director, Mr. Gulliver, and copied to Clinical Chief Dr. Cook, who was also Site Chief at St. Clare's, to Dr. Parai, the Clinical Chief at the General Hospital, to Dr. Robb, the Discipline Chair, and to Barry Dyer, the Pathology Manager. He thus included the entire leadership team of Laboratory Medicine

[176] Exhibit P-1390, Executive Management minutes have Dr. Williams in attendance on June 5, 2003 but not on June 10 or June 24

[177] Evidence of Dr. Robert Williams, May 20, 2008, page 119 line 24 to 121 line 8; and page 123 line 21 to page 124 line 23

but did not go further and address it to the Vice-President of Medical Services. In this memo, Dr. Ejeckam uses direct and forceful language to make the case for moving the IHC service into a physically separate space in the laboratory, dedicating the technologists to performance of IHC staining only and placing more emphasis on giving the technologists the opportunity to increase their knowledge and expertise about IHC staining and troubleshooting. In the memo, he says that the quality of IHC staining performed in the HCCSJ laboratory is fairly good but that if diagnosis were based on inappropriate stains, it would jeopardize patient care and might even expose the corporation to litigation.[178]

157. What Dr. Ejeckam was promoting was an arrangement for the laboratory similar to that which he left behind in Doha.

158. In his testimony, Dr. Ejeckam described his reasons for writing this memo as follows:

> I did this because after working with a technologist and trying to get some good stains, I still realized that we don't have an optimal condition and to have optimal condition would be to move the immunohistochemistry into a different room, have dedicated staff and then have a number of them that would need to … yeah, so that was the reason. I mean, I was just trying to ensure that we recognize even though we are getting some good stains that this is not optimal and that we need to look at the future and look at

[178] Exhibit P-0113, page 5

> what we have and work to improve and make sure we have optimal condition.[179]

159. Dr. Ejeckam testified that after delivering the memo, he had spoke separately to Dr. Robb, to Mr. Gulliver and to Dr. Cook, but did not consider it necessary for him to bring these concerns to the attention of Dr. Williams.[180]

160. Dr. Ejeckam had brought up the idea of dedicated technologists and separate space for the IHC service with Mr. Dyer prior to his memo of June 19, 2003. After he prepared the memo, Mr. Dyer and Mr. Gulliver discussed how they could achieve those goals within the fiscal resources available to the lab. Mr. Dyer testified that they met with Dr. Ejeckam concerning that. They then identified another senior technologist, who was not involved in IHC testing, to be trained to perform the grossing function, replacing the IHC technologists. Over the course of a number of months, that measure was implemented. After that the three IHC technologists spent about 90% of their time in the IHC service.

161. Within 6 months of Dr. Ejeckam's memo, separate space for the IHC lab became available when the immunology lab moved from a room adjacent to the main

[179] Evidence of Dr. Gershon Ejeckam June 3, 2008, page 284, line 20 to page 286, line 3
[180] Evidence of Dr. Gershon Ejeckam, June 3, 2008, page 287, line 1 to page 289, line 11

pathology laboratory and the IHC service was moved into that space when the new Ventana staining instruments were installed at the end of 2003.[181]

162. A third measure that was viewed by Mr. Gulliver as responsive to Dr. Ejeckam's concerns was the move to more automated staining at the end of 2003.

(xi) The Acquisition of the Ventana Benchmark Automated Stainer

163. By October, 2003, the five year contract arrangements with Dako had expired. Mr. Gulliver and Mr. Dyer had become aware that new technology was available which automated processes that still had to be performed manually using the Dako Autostainer system. Most notably, newer technology offered by Ventana automated the antigen retrieval phase, using a process that did not require heating in solutions, and performed it on the same machine that applied the antibodies and other reagents. It also offered the advantages of bar coding for positive identification of patient materials, antibodies and reagents.[182]

[181] Evidence of Barry Dyer, June 21, 2008, page 294 line 10 to page 305 line 3, and page 308 line 18 to page 310 line 14

[182] Exhibit P-2150
Exhibit P-2321, December 18, 2003, Division of Anatomical Pathology, Health Care Corporation of St. John's, Meeting of Site Chiefs and Divisional Manager minutes, page 4
Exhibit P-1903, January 16, 2004, Laboratory Medicine Program minutes, page 1
Exhibit P-1906, February-March, 2004 Report of Laboratory Medicine Program to Clinical Chiefs and MAC, page 1

164. A representative from Ventana came to St. John's in January, 2004 to set up the equipment and conduct training. Ken Green and Barry Dyer were trained as key operators. They also travelled to the Ventana facility in Arizona for additional training.[183]

165. The Ventana representative had used slides that she had brought with her to process on the equipment and ensure that it was functioning properly. Validation of specific antibodies on the new equipment was then carried out between January and April, 2004 by Mr. Green and Mr. Dyer with involvement by Dr. Ejeckam and other pathologists. Patient samples continued to be processed on the Dako Autostainer system by Mary Butler during that time. It was those test results that were reported by the pathologists until validation on the new system was completed.[184]

166. For each antibody, the technologists processed slides using the same control tissue that was being used for runs on the Dako Autostainer. Although the Ventana system used prediluted antibodies, so that the dilution could not be varied, different antigen retrieval protocols could be selected and the incubation

[183] Evidence of Ken Green, July 9, 2008, page 218 line 21 to page 223 line 20
Evidence of Barry Dyer, July 21, 2008, page 408 line 10 to page 411 line 21; page 416 line 8 to page 417 line 4
Exhibit P-2394, Barry Dyer's Certificate of Ventana training, March 1, 2004

[184] Evidence of Ken Green, July9, 2008, page 77 line 15 to page 880 line 15, page 103 line 3 to line 6, page 198 line 22 to page 218 line 10

time for the antibody could be varied. For each control, a grid of different protocols was run. The results were examined by pathologists who determined which was best and that protocol was adopted for the new system. Each test run during the validation period was recorded on the Ventana computer and these records are available as a partial record of the validation process.[185] Numerous variations of protocols for both ER and PR were run during this validation process. Aside from the information recorded on the Ventana machines itself, other permanent records of the validation process were not created.

167. The minutes of a meeting of Site Chiefs and Divisional Managers, attended by Dr. Cook, Dr. Parai and Dr. Robb, but from which Mr. Dyer was absent, on March 31, 2004, which was just prior to completion of the validation process for the new Ventana staining technology, record that "the immunoperoxidase stainer appears to be working generally well. However, there continues to be some problems with estrogen and progesterone receptors".[186]

168. No witnesses were able to recall anything about there being any problems at that time with ER and PR testing of patient samples. Neither could any witnesses recall what was being referred to in these minutes. A reasonable interpretation

[185] Exhibit P-2357, Ventana Benchmark Staining Run Records
[186] Exhibit P-1913, March 31, 2004, Site Chiefs and Divisional Managers minutes

however, is that the problem with the estrogen and progesterone receptors must have been related to the validation of those on the Ventana system. There is no indication that those problems, whatever they may have been, were not resolved prior to the commencement of testing of patient samples on the Ventana system.

169. When the Ventana equipment was set up in the new IHC laboratory space the Dako Autostainer was left on the old IHC benches in the general pathology lab. Use of it was discontinued in April 2004. It was still there in November 2004 when that area was flooded by a pipe broken during construction. Not long after that Joe White, an independent service technician who did instrument repairs at the laboratory, knowing that the instrument would be discarded if no one wanted it, made a series of requests for it to Mr. Dyer and Mr. Gulliver. After it had been determined that the College of the North Atlantic laboratory program was not interested in the machine, Mr. White was allowed to take it, including the attached computer.

170. Near the end of the public hearing the instrument and computer were located by Mr. White for the Commission and a copy of the data remaining on the computer has been obtained by the Commission.

D. Quality Assurance

(i) Health Care Corporation of St. John's Quality Framework

171. In April, 1999, the Health Care Corporation of St. John's approved a quality planning document for the organization.[187] The quality framework defined the roles of the Quality Initiatives Department and the other programs and departments in relation to ensuring the delivery of quality services, and, among other things, described the quality model adopted by the organization, the role of the Corporate Quality Initiatives Committee, the process of developing and implementing a quality plan for a program or department and the use of process improvement teams. This framework remained in place until replaced in 2007 after the formation of Eastern Health. The accountability for quality is placed on the programs and departments as follows:

> Accountability for quality of care of service rests with the program/department leadership and staff. A formal structure will exist to ensure that:
>
> - A comprehensive quality plan is in place,
> - Evaluation is ongoing,
> - Evidence based practices are pursued,

[187] Exhibit P-0042

- Results of evaluations are analyzed, and

- Improvements are undertaken to address priority areas identified.

> Formal structures include Internal Advisory Committees, peer review activities, External Advisory Committees, indicator monitoring and quality improvement activities. Accountability is to the applicable Vice-President. Quality reports will be reviewed in detail within the department/program before being presented to the Corporate Team.[188]

172. The Corporate Quality Initiatives Committee is described as follows:

> This Committee is comprised of the Corporate Team and a Director of Quality Initiatives. All programs/departments/professional practice groups and some committees will be required to report annually (personally or through written report) on their quality indicators, their annual planning priorities and achievements. The committee will provide feedback and recommendations following the review. (Reference policies on internal reporting - Appendix A).[189]

173. The role of the Quality Initiatives Department is described thus:

> The Department of Quality Initiatives exists to provide leadership and support to all programs and departments of the corporation in their efforts to continually improve the quality of care and service delivered. The main areas of focus are risk management, utilization management, consumer feedback, performance measurement, and outcome evaluation. As well, the Department provides an assortment of educational sessions to support these activities.[190]

174. The primary responsibility for ensuring delivery of quality services rested with the programs and departments, since that was where the knowledge and expertise

[188] Exhibit P-0042, page 12.
[189] Exhibit P-0042, page 13
[190] Exhibit P-0042, page 50

lay to enable effective quality initiatives to be identified and implemented. The role of the staff in the Quality Initiatives Department was to support those programs and departments in their activities with their knowledge of quality processes and principles but was not to engage in the evaluation of technical matters related to promotion of quality in the programs and departments.[191]

175. The Corporate Quality Initiatives Committee was part of the administrative structure of the HCCSJ and received annual reports from the programs and departments. The Board of Trustees of the HCCSJ had its own Quality Initiatives Committee which received reports from the Executive of the HCCSJ and which reported to the Board on quality issues.

(ii) Quality Assurance Measures in Anatomic Pathology

176. An important quality assurance activity carried out within pathology laboratories is external proficiency testing. It takes various forms and is offered by a number of agencies including the College of American Pathologists (CAP), the American Society of Clinical Pathology (ASCP) and the United Kingdom National External Quality Assessment Service (UK-NEQAS), and is under development by Canadian Immunohistochemistry Quality Control (cIQc).

[191] Evidence of Pamela Elliott, October 28, 2008, page 311 line 13 to page 312 line 20

177. The UK-NEQAS Program had been developed for the United Kingdom and accepts submissions from laboratories in other countries. It had initiated an external proficiency testing program for ER and PR detection, which included assessment of the technical performance of staining by laboratories, in 1994.[192]

178. By 1999 there was attention being paid within the HCCSJ Laboratory Medicine program to external proficiency testing programs. The pathologists at the General Hospital had been subscribing to a CAP external proficiency testing program[193] which assessed their interpretations of slides and diagnosis of cases but which did not assess the laboratory's technical proficiency in preparation of IHC slides. The pathologists at St. Clare's participated in a similar program from ASCP.[194]

179. The June 28, 2000 Laboratory Management Committee minutes record that Dr. Whitman, from the Haematology Division, updated the meeting on proficiency programs across Canada and the lack of them in Atlantic Canada.[195] The February 28, 2001 minutes of the same committee state that the latest external CAP Proficiency Reports were presented and that excellent reports had been

[192] Exhibit P-1851, Rhodes et al., "Frequency of oestrogen and progesterone receptor positivity by immunohistochemical analysis in 7016 breast carcinomas: correlation with patient age, assay sensitivity, threshold value, and mammographic screening", page 2
[193] Exhibit P-1866, November 24, 1999 Laboratory Management Committee Minutes, page 2
Exhibit 2398, May 31, 2000 Laboratory Management Committee Minutes, page 2
[194] Evidence of Dr. Donald Cook, July 2, 2008, page 225 line 4 to page 227 line 7
[195] Exhibit P-3614, page 2

received for all Divisions.[196] The committee met on June 6, 2001, and under the heading “Proficiency Programs”, the minutes record “considerable discussion on the pros and cons and the option to join into an already existing program from another province was entertained. Dr. Whitman and Dr. Hutchinson to follow up as to what is available and conditions”.[197]

180. On June 26, 2001 the Clinical Chief, Dr. Haegert, met with Site Chiefs Dr. Cook and Dr. Parai. The meeting minutes present a good review of the quality assurance measures in place for anatomic pathology at that time. They include mention of the external proficiency testing materials supplied by CAP and by ASCP, and listings of the various rounds attended by pathologists at both St. Clare’s and the General Hospital sites.[198] Rounds are important opportunities to discuss difficult cases, obtain the advice of colleagues and to identify issues that may need to be addressed. Rounds listed in the minutes are:

- Medicine/Pathology Interdepartmental Rounds at the General Hospital
- Gynecology/Pathology Interdepartmental Rounds at the General Hospital
- Medical Grand Rounds at the General Hospital

[196] Exhibit P-2400
[197] Exhibit P-2401
[198] Exhibit P-1877, June 26, 2001 Minutes of the Meeting, Site Chiefs and Divisional Managers, Division of Anatomical Pathology, Health Care Corporation of St. John’s, pages 3 and 4
See also the Evidence of Dr. Gerson Ejeckam, June 3, 2008, page 188 line 23 to page 190 line 12, and page 205 line 16 to page 207 line 22, for a description of the rounds in place in September 2002.

- An Interdepartmental Lymphoma Board at the General Hospital
- Weekly Pathology slide rounds at the General Hospital
- Weekly Pathology Lymphoma Round at the General Hospital, attended by St. Clare's pathologists also[199]
- Weekly Surgical Pathology Rounds at St. Clare's
- Monthly Inter-hospital Pathology Rounds for all pathologists and residents

181. Consultations among pathologists at the same or different sites on a case by case basis and referrals of cases to other centres for consultations also provided an important opportunity for quality assurance.[200]

182. The Pathology Manager, Program Director and technologists regarded the involvement of the pathologists in the assessment of control slides and the interpretation of the results of staining of patient tissue as a quality control check on the work of the technologists.[201] The technologists could perform the basic assessment of the control slides to ensure that staining was present, and if it was not would know to repeat the tests rather than send the slides to the pathologists

[199] Evidence of Dr. Gerson Ejeckam, June 3, 2008, page 207 line 10 to line 22.
[200] Exhibit P-1877, June 26, 2001 Minutes of the Meeting, Site Chiefs and Divisional Managers, Division of Anatomical Pathology, Health Care Corporation of St. John's, page 4
Evidence of Dr. Donald Cook, July 3, 2008, page line 5 to line 23
[201] Evidence of Terry Gulliver, October 15, 2008, page 209 line 15 to page 211 line 7
Evidence of Ken Green, July 9, 2008, page 92 line 20 to page 93 line 4

for reporting. All controls were assessed either by the pathologist reporting a case or a pathologist who had taken the responsibility for doing so. The pathologists were also known to come to the technologists if they were not satisfied with the results of staining, thus providing feedback on the quality of their work product. In 2003 a log book was placed in the pathologists' reading room at the General Hospital site for the purpose of recording any problems noted with pathology slides in general.[202]

183. By 2003, work had been underway to develop a comprehensive written Quality Assurance Program for pathology. Dr. S. Parai was preparing a draft of a Quality Assurance Manual that was reviewed at pathologists' meetings.[203] Dr. Ejeckam had provided Dr. Parai with a copy of a manual from his previous position in Doha.[204]

184. Development of a Quality Control Policy and Procedure Manual for anatomic pathology was one of the program objectives reported on quarterly by Dr. Cook

[202] Exhibit P-2356 logbook
Exhibit P-2320, December 11, 2003, Division of Anatomical Pathology Pathologists' Meeting Health Care Corporation of St. John's Minutes page 3
[203] Exhibit P-1576, September 24, 2003 Division of Anatomical Pathology Pathologists' Meeting, General Hospital site, page 2
Exhibit P-2320, December 11, 2003, Division of Anatomical Pathology Pathologists' Meeting, Health Care Corporation of St. John's, minutes, page 3
Exhibit P-2321, December 18, 2003, Division of Anatomical Pathology, Health Care Corporation of St. John's, meeting with Site Chiefs and Divisional Manager, Page 2
Exhibit P-1913, March 31, 2004, Division of Anatomical Pathology Meeting, Site Chiefs and Divisional Manager, page 1
[204] Exhibit P-2408

to Dr. Williams. Dr. Cook described the first draft as complete and under review by the leadership team by January 1, 2003. The second draft had been completed and put out for review by April 1, 2003 and on October 1, 2003, work continued to progress. Feedback had been received on the drafts and after revisions were made, it would be circulated more widely in the program.[205]

185. Dr. Beverly Carter took up a full-time pathologist position at St. Clare's in August, 2004, having previously worked as a locum pathologist for a short period of time.[206] Dr. Carter came to St. John's with specialized training in breast pathology and an interest in that area.

186. On August 31, 2004, Dr. Carter gave Dr. Cook a proposal for establishing a new Quality Control and Quality Assurance Committee for surgical pathology.[207] Her proposal focused on developing a coordinated program of review of the work of the pathologists.

187. The first meeting of the QA/QC Committee was held on November 9, 2004.[208] The Pathology Manager, Mr. Dyer, attended with Dr. Carter and secretarial support. Regrets were received from Dr. Ejeckam. Two aspects of the

[205] Exhibit P-0908, Performance Goals and Objectives for the Clinical Chief, page 5
Exhibit P-2404, Draft Manual "Quality Assurance and Division of Anatomic Pathology, Health Care Corporation of St. John's
[206] Exhibit P-2440, Curriculum Vitae of Dr. Beverly Carter
[207] Exhibit P-1919, August 31, 2004 Memo from Dr. Carter to Dr. Cook
[208] Exhibit P-2426, November 9, 2004, minutes of the QC/QA meeting, HCCSJ

Committee mandate were identified. The first was "developing of a monthly quality control and quality assurance procedure for the Health Care Corporation of St. John's, Division of Anatomical Pathology and Autopsy Pathology". The second was "development of a policy and procedure manual". At that first meeting it was decided to develop the monthly QA/QC reviews first and, once that aspect was functioning well, to turn attention to developing a policy and procedure manual.

188. In his February, 2005 report to Clinical Chiefs and the Medical Advisory Committee, Dr. Cook reported on Dr. Carter's work describing her as the Quality Assurance Coordinator for the Division of Anatomical Pathology.[209]

(iii) Surgical Pathology Review Committee

189. After Dr. Cook had become Clinical Chief, he asked Dr. Ejeckam if he would be willing to chair a Surgical Pathology Review Committee to carry out quality assurance activities for the anatomical pathology service.[210] The Committee, comprised of physicians from various disciplines, met for the first time on April 15, 2003.[211] The Committee adopted terms of reference that included reviewing

[209] Exhibit P-1395, January/February, 2005 Report of Laboratory Medicine Program to Clinical Chiefs and MAC
[210] Evidence of Dr Donald. Cook, July 2, 2008, page 221 line 15 to page 222 line 8
[211] Exhibit T-0904, April 15, 2003 Surgical Pathology Review Committee Agenda
Exhibit P-1572, April 15, 2003 Surgical Pathology Review Committee Minutes

the standardized reporting of pathology specimens, performing tissue audits on surgical specimens, and serving as a forum for interesting or difficult cases. The Committee would meet every two months and would report directly to the Vice-President of Medical Services.[212] Dr. Ejeckam reported to Committee members, including a medical oncologist, at that first meeting that testing for ER and PR receptors was not being performed for the next 6 weeks due to technical problems, thus passing that information on to clinicians in areas where those tests were used.[213] At the Committee meeting on September 23, 2003, Dr. Ejeckam reported that the technical problem with staining for ER and PR stains had been solved.[214]

190. When he had suspended testing in April of 2003, Dr. Ejeckam had not considered there to be any risk that patients had not been appropriately treated due to problems with the quality of the stains prepared in the laboratory. His evidence was that the quality problems that were discussed at the pathology rounds and lymphoma panel were issues that caused pathologists not to use the slides that were delivered to them, rather than issues that called into question the reliability of the results that they reported. Had Dr. Ejeckam thought otherwise, then it would have been expected that he would have dealt with this issue

[212] Exhibit P-0904
[213] Exhibit P-1572, page 2
[214] Exhibit P-1575, September 23, 2003 minutes of the Surgical Pathology Review Committee

differently when reporting to the other members of the Surgical Pathology Review Committee in April and September.

191. Much of the work of the Surgical Pathology Review Committee concerned the completeness and accuracy of clinical histories included on requisitions for pathological examination of specimens.[215] On September 30, 2003, Dr. Ejeckam gave Dr. Williams a written report with recommendations from the Committee regarding that issue and also regarding requests for second opinions from pathologists.[216] Dr. Williams had returned to his duties as Vice-President of Medical Services on about September 2, 2003.[217] In his report to Dr. Williams, Dr. Ejeckam made no reference to the suspension of testing in April nor to his memo to Mr. Gulliver and the laboratory leadership team suggesting changes in the IHC service. Dr. Williams testified that Dr. Ejeckam did not raise with him or bring to his attention any concern that the issues raised in his June, 2003 memo had not been addressed to his satisfaction.[218]

[215] Exhibit P-1573, April 21, 2003 memo to all pathologists from Dr. Ejeckam requesting copies of incomplete requisitions for review
[216] Exhibit P-0906, September 30, 2003 memo from Dr. Ejeckam to Dr. Williams
[217] Exhibit P-1390, September 2, 2003, Executive minutes
[218] Evidence of Dr. Robert Williams, May 21, 2008, page 97, lines 14-22

(iv) Laboratory Accreditation

192. The Canadian Counsel on Health Services Accreditation ("CCHSA") conducted an accreditation survey for the Health Care Corporation of St. John's between October 14 and 19, 2001. The accreditation process used did not involve more than a cursory review of Laboratory Medicine. Laboratory Medicine was not one of the areas directly commented upon in the accreditation survey report. This had not always been the approach taken by the agency that accredited the St. John's hospitals. Before the mid 1990s there had been a more in depth review of practices and procedures in the laboratory. [219]

193. The Health Care Corporation of St. John's was again reviewed for accreditation by the Canadian Council on Health Services Accreditation between October 17 and 22, 2004. Just as in 2001, little attention was paid to laboratory medicine.[220]

194. The accreditation report was reviewed at the Corporate Quality Initiatives Committee meeting on October 28, 2004.[221] The Committee recognized that the CCHSA accreditation had not provided a detailed review of laboratory medicine and recognized the absence of any specific laboratory accreditation or inspection program, noting that in some parts of Canada, accreditation and inspection of

[219] Evidence of Terry Gulliver, October 7, 2008, page 301 line 1 to line 14, page 318 line 13 to page 323 line 4
[220] Evidence of Terry Gulliver, October 7, 2008, page 321 line 15 to page 323 line 4
[221] Exhibit P-0029, page 16

laboratories was mandated by the provinces. This was noted to be seen as a major gap in this province.[222]

195. At Dr. Williams' request, Mr. Gulliver provided him with a memo on December 8, 2004 outlining those accreditation and proficiency testing processes that were utilized in various Divisions of the laboratory.[223]

196. The issue of laboratory accreditation came up again at the Corporate Quality Initiatives Committee on March 24, 2005[224] and April 28, 2005.[225] Committee member Dr. Whitman had reported that laboratory accreditations in other provinces were provincial initiatives and it was decided that the planned integration of health boards would be an opportunity to lobby the provincial government to pursue a provincial approach. Dr. Williams agreed to raise that issue with Mr. Tilley, who by then had been selected to be the new CEO of Eastern Health and the April 28, 2005 minutes record that the issue was being raised with the Department of Health & Community Services.

[222] See also Evidence of Dr. Robert Williams, May 21, 2008, page 105 line 14 to page 113 line 24
[223] Exhibit P-3113, December 8, 2004 memo from Terry Gulliver to Dr. Williams
Evidence of Terry Gulliver, October 7, 2008, page 365 line 20 to page 375 line 5
Exhibit P-1923, December 10, 2004, Laboratory Medicine Program minutes, page 2
[224] Exhibit P-0030, page 16
[225] Exhibit P-0030, page 23

197. The availability of laboratory accreditation came up at the Laboratory Management Committee Meeting on March 13, 2003.[226] The absence of any legislation requiring laboratories to be accredited or licensed in Newfoundland was noted. It was suggested at the meeting that an overall quality assurance program for the laboratory should be a goal for the next several years and also suggested that a position should be created in the laboratory medicine program for a quality officer. At that time, there were no positions in laboratory medicine devoted exclusively to quality issues. Responsibility for quality control and quality assurance rested with the managers and staff who had to perform the daily duties of providing laboratory services to clinical areas of the hospital.

(v) External Controls in IHC

198. The Site Chiefs and Divisional Managers minutes from February 22[227] and June 26, 2001[228] raised the issue of checking the external control slides. On the latter date the minutes note that controls for the ER and PR stains were checked by the Site Chief or by the on call pathologist when the Site Chief was not available.[229]

[226] Exhibit P-1890, March 13, 2003, Laboratory Management Committee Meeting, page 2
[227] Exhibit P-1874
[228] Exhibit P-1877
[229] See exhibit P-1886 for an example of an ER/PR test requisition with a note that the controls had been checked by Dr. Chittal.

199. The Autostainer capacity, and to some extent the cost of antibodies and reagents, limited the number of control slides that could be run with each batch of slides. It was not always possible to run enough control slides to distribute a set to each pathologist who had requested ER/PR testing. The process in place to address this concern varied somewhat over time. Initially, Dr. Khalifa read and retained all the controls. As described above, when he delegated the reporting of the cases to the requesting pathologist, he continued to review the controls to satisfy himself that the testing had been satisfactorily performed before sending the test slides out to the other pathologists.

200. Later, the technologists endeavored to run enough controls to distribute a set to each site from which tests had been requested. At the General Hospital site, the controls would be placed in the pathologist's reporting room and each pathologist with a case to report could examine the control slides there. If more than one case was sent to St. Clare's, the technologists would note on the returned requisition forms which case included the positive control slides. As noted in the minutes described above, in 2001 Dr. Parai took on the responsibility for checking the control slides that went to St. Clare's or other locations in the province before they left the General Hospital site.

(vi) Internal Controls in IHC

201. As described above, the first formal notification that pathologists should pay attention to internal controls for ER/PR tests was Dr. Ejeckam's memo of May 2, 2003. Prior to that whether internal controls were used as a quality assurance measure depended on the knowledge of the individual pathologist.

(vii) Perioperative Policies and Procedures Affecting Tissue Fixation

202. Pre-analytical factors that can affect the quality of a stained slide include the fixation, or preservation of the tissue, the processing of it to remove water and the embedding of it in paraffin.

203. The process of preserving the tissue samples testing begins in the operating room. Throughout the time period from which retested specimens were drawn, breast surgeries had been performed at the Grace before it closed in 2000, at St. Clare's and at the General Hospital. Sample operating room policies and procedures for specimen handling are available and have been placed in evidence for the General Hospital.[230]

[230] Exhibit P-3089 is a General Hospital procedure for care and handling of pathology/histology specimens, originally issued January, 1986 and revised September, 1991 and August, 1994

204. Like all operating room procedures, specimen handling protocols were to be strictly adhered to. Specimens were, at the direction of the surgeon, promptly immersed in formalin in containers in the operating room. The General Hospital policy, revised in 1994, for example, emphasizes that the containers be large enough to allow 10 times the volume of fixative to the volume of the specimen and that tissues should be completely covered in formalin. [231] Maria Tracey, the Perioperative Program Director testified that operating room nurses were instructed to ensure that the tissue specimens were to be placed in sufficient quantities of formalin so that they could float free of contact with the bottom and sides of the container.[232]

205. Like other HCCSJ programs, following amalgamation, the Perioperative Program had to standardize the policies and procedures in effect in the operating rooms at each site. This was a process that took time to complete since it had to be done carefully to ensure that the best practices from each site were adopted.[233] During the transition appropriate and adequate policies were already in place at each site and would continue to apply until standardized policies were gradually developed.

[231] Exhibit P-3089
[232] Evidence of Maria Tracey, September 29, 2008, page 333 line 1 to page 335 line 18
[233] Evidence of Maria Tracey, September 29, 2008, page 326 line 9 to page 329 line 21

206. Work on developing a standardized specimen handling policy involved consultation with pathology.[234] By January 29, 2003, minutes of the Operating Room Practice Committee, the group responsible for developing standardized policies, recorded as follows:

> The three specimen policies had been redrafted based on feedback from Committee members, head nurses, pathology department and quality initiatives (QI). QI also contacted the RNC for input in the legal specimen policy. The following policies were again reviewed:
>
> - Legal specimens
> - Specimen care
> - Guidelines for the management of specimens
>
> Revisions were made. The Committee agreed to have these policies, with revisions, to be sent to the managers for review/signing".[235]

207. The Perioperative Program, unlike the Laboratory medicine Program, for some time had had dedicated nurse educators on staff whose role included in-service education and orientation of operating room nurses and work on issues such as policy development. Nevertheless, the demands on staff in the program were such that it was often difficult to find time for activities like policy development. The work done for development of policy in January, 2003 was made possible in

[234] Exhibit P-2830, November 29, 2001 OR Practice Meeting minutes
[235] Exhibit P-2729, January 29, 2003 Operating Room Practice Meeting minutes

part because of a physician strike that had reduced activity in the operating rooms.[236]

208. New operating room specimen handling policies, standardized for all sites, were approved in May, 2003.[237]

209. Those guidelines describe the type of fixative to be used for different specimens. For those placed in formalin, the volume was now to be 20 times the volume of the specimen.

210. The perioperative program has a well-established program for orientation for nurses who are new to the operating room. The orientation is the responsibility of the clinical nurse educators and includes familiarization with all policies and procedures in place in the operating room, including the specimen handling policies. Nurses must satisfactorily complete written examinations before completing the orientation process.[238]

[236] Exhibit P-2730, January 30, 2003, Perioperative Program Clinical Educators Meeting minutes
[237] Exhibit P-3082, May 2003, Specimen Care Policy
Exhibit P-3087, May 2003, Guidelines for the Management of Specimens
Exhibit P-2827 is a March, 2004, revision to the Guidelines for the Management of Specimens.
[238] Exhibit C-0268, February, 1999 General Hospital Post-Orientation Examination
Exhibit C-0269, 2005 St. Clare's Post-Orientation Examination
Exhibit C-0270, 2006 St. Clare's Post-Orientation Examination
Exhibit C-0271, April, 2007 Eastern Health Post-Orientation Examination
Exhibit C-0272, July, 2007 Eastern Health Post-Orientation Examination

211. The guidelines described a process to be used for regular transportation of the specimens to the pathology laboratory. Despite this, there is evidence that there could have been occasions when specimens from surgeries done late in the day could be left, in formalin, in the operating rooms overnight or even over a weekend before being transported to the pathology laboratory. For many specimens that might not affect the quality of the tissue samples. For certain specimens there was a special process in place to ensure timely transport, however mastectomy specimens were not included in that protocol.

212. To achieve effective penetration of formalin and preservation of the tissue a breast specimen should be thinly sliced within hours of the surgery. Since that was done after the specimen reached the pathology lab, if such specimen were left overnight before it was transported to the lab, then the quality of tissue samples taken from it could be compromised.

E. Change in the ER/PR Cut-Off for Initiation of Hormonal Treatment

213. It appears that when Dr. Khalifa introduced IHC testing for ER/PR in 1997/1998, and drafted the form of report for the test results that referred to 30% staining as equivalent to a positive result from the bioassay test, that 30% became adopted by at least some clinicians as their cut-off for consideration of hormonal therapy.

214. The medical literature discussed below demonstrates that there is considerable variation in what is and has been considered to be the correct cut-off percentage for treatment.

215. Medical oncologist and Clinical Chief Dr. Kara Laing testified that when she came to the NCTRF the pathology reports often referred to 30% and she accepted that. Then she attended the international San Antonio breast cancer conference in 2000 where she heard at a panel discussion that even though the cut-off was not well defined, clinicians were starting to recognize that it should be as low as 10%. This was the first reference she had heard to a 10 % cut-off. She returned from maternity leave in 2001 and began to apply 10% in her practice and to discuss it with her colleagues. [239]

[239] Evidence of Dr. Kara Laing, September 9, 2008, page 131 line 20 to page 136 line 21

216. In July, 2001, Dr. Joy McCarthy joined the Newfoundland Cancer Treatment and Research Foundation in St. John's as a medical oncologist. When considering whether to recommend hormonal therapy for her breast cancer patients, she applied the same 10% cut off for ER and PR testing that she had been using in Toronto before coming to St. John's. She testified that to the best of her knowledge, all her colleagues at the NCTRF were by then also using 10% as the cut off for consideration of treatment.[240]

217. In the summer of 2005, when the decision had been made to retest all the negative ER/PR results, Dr. Cook consulted with Dr. Laing and they determined that the best approach would be to regard specimens with original test results reported as 30% or less up to December 31, 2000, as negative, and to use 10% or less after that date. This decision was made in the belief that all treating physicians would have started using the 10% threshold before January 1, 2001.

[240] Evidence of Dr. Joy McCarthy, September 19, 2008, page 24 line 6 to page26 line 18

F. The Creation of Eastern Health in 2005

218. In the meantime, the former HCCSJ was in the midst of another major reorganization of the health care system. Minutes of the HCCSJ Board of Trustees meeting of September 30, 2004 record as follows:

> The Board Chair received a letter from Minister Marshall dated September 10, 2004 announcing that government is proceeding with the integration of provincial health care and community services boards. The existing 14 boards will be transformed into 4 regional integrated health authorities. The Health Care Corporation of St. John's will now become part of the Eastern Regional Integrated Health Authority. It is expected that the existing boards will remain in place during a yet to be determined transition period. A new Board of Trustees will be established and the transfer of powers anticipated to take effect January, 2005.[241]

219. Unlike the amalgamation that formed HCCSJ, this regionalization not only expanded the geographic area to be administered by the new Eastern Regional Integrated Health Authority (Eastern Health) but also brought together the continuum of delivery of health care services. Acute care services, long term care, child youth and family services and a range of other health care activities previously operated under different government structures or directly by the Department of Health and Community Services were now all to be brought together as Eastern Health. The amalgamation also included the NCTRF.

[241] Exhibit P-2518, September 30, 2004 HCCSJ Board of Trustees minutes

220. After a competition to recruit a Chief Executive Officer for the new organization, Mr. George Tilley moved from the position of CEO of HCCSJ to Eastern Health in January 2005.[242] Joan Dawe was appointed Chair of the new Board of Trustees. They both then had the task of building a structure from the ground up for the administration of the Authority and the functioning of the Board. Within Eastern Health, positions from the CEO down had to be created, the duties defined and competitions held to fill them.

221. At the same time, every constituent part of the organization had to continue to provide health care services without interruption.

222. For Mrs. Dawe and the Board, this created an opportunity to move to a true policy governance model.[243] For Mr. Tilley and the Senior Executive of Eastern Health, it was an opportunity to create a new organization that would put the emerging principles of patient safety foremost.[244]

223. When the HCCSJ had been created, Sister Elizabeth Davis was in the Chief Executive Officer position, with her Executive Team in place, for more than a year dedicated to planning for the operational takeover by the new corporation of the operations of the acute care hospitals in St. John's. The task given to those

[242] Exhibit P-0315
[243] Evidence in Joan Dawe March 26, 2008 page 44 line 16 to page 45 line 9
[244] Evidence of George Tilley May 13, 2008, page 317 line 4 to page 322 line 20

providing leadership to the new Eastern Health organization was bigger and broader with less time to bring it into effect.

224. At the time of its creation, Eastern Health assumed the legacy of fiscal restraint that had affected its predecessor constituents over the previous decade. In particular, the Organization assumed $79 million in accumulated debt.[245] The mandate given to Eastern Health by government was to maintain a balanced budget while paying down that debt. For the first two years of its existence, Eastern Health achieved small surpluses in its operating budget and as a result, paid about $7 million against the debt.[246]

225. After Mr. Tilley moved to the Eastern Health CEO position, Dr. Williams assumed the position of acting CEO of HCCSJ. On May 10, 2005, he was appointed to the position of Vice-President for Quality, Diagnostic and Medical Services for Eastern Health. Ten days later, the new Executive of Eastern Health held their first meeting on May 20, 2005.[247] Between May 20 and June 21, the Executive Team met 7 times for a total of 9 days.[248] The topics under discussion ranged from the shape of the organizational chart for Eastern Health to the recruitment of Executive Assistants and filling of Director level positions to the development of

[245] Evidence of Joan Dawe, March 28, 2008, page 76, line 16-21 and page 83, line 17 to page 84, line 7
[246] Evidence of Joan Dawe, March 28, 2008, page 102, line 24 to page 104, line 15
[247] Exhibit P-3147, May 20, 2005 minutes of the first executive team meeting
[248] Exhibits P-0486, P-1510, P-1511

common Medical Staff By-laws for the Organization. Through that time period and continuing well into 2005, the minutes show that there was little capacity for the Executive as a group to engage in operational issues because there were many important issues related to the amalgamation of the 14 diverse boards that had to be dealt with.

G. Events from April 2005 to May 2007

(i) The Index Case

226. Mrs. Margaret Deane was diagnosed with aggressive breast cancer in 2002. The diagnosis reported by pathologist Dr. Ford Elms was a mixture of lobular carcinoma insitu with invasive lobular carcinoma and both components in some areas had a somewhat ductal appearance. ER staining was reported as negative and PR staining as weak in less than 10% of lesional cells.[249] An ER/PR test was requisitioned on June 26, 2002.[250] The test was performed by Peggy Welsh on July 4, 2002.[251]

227. Mrs. Deane was treated by Dr. Kara Laing at the NCTRF in St. John's and was not offered hormonal therapy in 2002. Between 2002 and 2005, Mrs. Deane's cancer progressed rapidly and she was treated with a variety of regimes. In early

[249] Exhibit C-0156, Pathology Report with Addenda
[250] Exhibit C-1073
[251] Exhibit C-0173

2005, Mrs. Deane had travelled to Sunnybrook Hospital in Toronto for a consultation with Dr. Margaret Trudeau, a noted medical oncologist and specialist in breast cancer. Dr. Trudeau reviewed her case and could offer no different treatment than that which had been provided in St. John's.[252]

228. On April 9, 2005, Dr. Laing emailed Dr. Clifford Hudis at Memorial Sloan-Kettering Cancer Centre in New York describing Mrs. Deane's case and asking if he might be aware of any clinical trials available in the United States that she could benefit from.[253] Dr. Hudis replied that it would be very rare to see a negative ER and PR result for an invasive lobular breast cancer and suggested trying hormonal therapy.[254]

229. Dr. Laing contacted Dr. Elms who arranged to have the original specimen retested. The retesting was done using the Ventana Staining System and were positive. Mrs. Deane had been admitted to hospital on April 12 and the new ER/PR results were communicated verbally by Dr. Elms to oncologist Dr. Rorke, who was covering for Dr. Laing. Dr. Laing had left instructions with Dr. Rorke

[252] Evidence of Dr. Robert Deane, March 25, 2008, page 19 line 21 to page 26 line 4
[253] Exhibit P-0489, email messages between Dr. Kara Laing and Dr. Clifford Hudis
[254] When Dr. Ejeckam had listed those cancers expected to be ER/PR positive in his May 2, 2003 memo, he neglected to mention lobular cancers.

that if the test was positive, Mrs. Deane should be started on Tamoxifen, which he did. She was discharged from hospital on April 20, 2005.[255]

230. Mrs. Deane succumbed to her illness in August, 2005.

(ii) Follow Up from the Index Case

231. On May 6, 2005, Dr. Laing saw another patient with invasive lobular carcinoma and an original ER score of 1% and PR of 2%. She asked to have that test repeated and it came back strongly positive. Dr. Laing called her patient to report those results and on June 10, 2005, she began adjuvant hormonal treatment.

232. In the meantime, Dr. Laing had been consulting with her colleagues at the NCTRF, including Dr. Joy McCarthy about the change in test results. On May 11, 2005, Dr. McCarthy contacted Dr. Cook, the Clinical Chief of Pathology. The result was that a meeting was arranged for May 17, 2005.[256]

233. On May 11, 2005, Dr. McCarthy had seen a breast cancer patient with lobular cancer who had negative ER/PR results from a test done in 2002, the same year that Mrs. Deane's test had been performed. She asked to have that specimen

[255] Exhibit C-0167
[256] Exhibit P-0067, May 24, 2005 letter from Dr. Cook to Dr. Williams

retested also.[257] By this time, Dr. Laing and Dr. McCarthy had begun to wonder whether there were other lobular carcinomas that had incorrect ER/PR results reported and they began to watch out for them. While the type of cancer diagnosis was recorded in narrative form in material in individual patient files, the NCTRF did not have a central source of information which would allow them to systematically identify patients who had that diagnosis.

234. By the time of the meeting on May 17, 2005, the retest results for Mrs. Deane and at least one other patient were known. The meeting was attended by Dr. Cook, breast pathologist Dr. Carter, Mr. Dyer, and Dr. McCarthy and Dr. Laing. The outcome was a decision to retest all negative ER and PR tests for the year 2002 and possibly 2001, with the intention of assessing whether there were only a few isolated cases or whether there was a larger problem. If there were few conversions, it was decided that the oncologists would inform the patients of those results directly. If there was a larger problem, then those at the meeting felt that the Quality Department would have to be consulted for guidance on how best to disclose the information which would involve patients not only in the St. John's region but also elsewhere in the Province.[258]

[257] Exhibit C-0243
[258] Exhibit P-0067, page 3

235. Dr. Cook wrote Dr. Williams on May 24, 2005 with a full report of events to that time. He provided Dr. Williams with a detailed description of the testing and the use made of it by the treating clinicians. Based on his research up to that time, he reported that it was estimated that between 50 and 85% of all breast cancers have positive ER results. He reported that ER and PR status influenced whether patients received hormonal therapy and whether chemotherapy might be avoided. He described how the Ventana Automated system had replaced the Dako Autostainer in April, 2004 and how Dr. Ejeckam had suspended staining in April, 2003.

236. He closed his letter with 4 recommendations that he described as requiring additional manpower and funding levels over those that currently existed. They were: (1) the immediate establishment of an external proficiency testing and monitoring program for immunoperoxidase testing; (2) the establishment of a separate immunoperoxidase service with at least 3 technologists solely dedicated to immunoperoxidase testing with separate testing facilities; (3) the training of immunoperoxidase technologists in a major immuno-referral lab that has a well-established quality control and troubleshooting program; and (4) appropriate continuing medical education funding for these technologists.

237. By this time, four patients in addition to Mrs. Deane had been retested with changed results. All were originally tested in 2002 and had types of cancer that caused the oncologists to now suspect that their results should have been positive.

238. The regular Laboratory Medicine Program meeting among Dr. Cook, Dr. Williams and Mr. Gulliver took place on May 27 and the minutes record discussion regarding issues around "false negative results from breast cancer patients over the past several years". [259] On the same date, Dr. Williams noted on his copy of the May 24 letter to copy it to Heather Predham in the Quality.[260] Heather Predham testified that she first heard of the issue from Dr. Williams while attending a separate meeting with him and that he provided her with a copy of the May 24 letter but did not want her to initially take any action.[261]

239. Dr. Cook then enlisted the assistance of Mr. Gulliver to identify the negative ER/PR tests from 2002. HCCSJ maintained records of the care provided to patients in traditional paper charts and also electronically using a system known by it trade name, Meditech. Meditech had been in use to record information from the laboratories in each of the acute care hospitals that had been amalgamated to form the HCCSJ. However, there were variations in the way in

[259] Exhibit P-1926, May 27, 2005 Laboratory Medicine Program minutes.
[260] Exhibit P-0067
[261] Evidence of Heather Predham, October 16, 2008, page 81 line 18 to 82 line 15

which the system had been implemented, in the type of information recorded and in the manner in which it was recorded. Just as it had taken time and effort to standardize and consolidate other practices and procedures within HCCSJ, it had been a substantial project to implement a single Meditech system for Laboratory Medicine. A single system had been implemented for recording pathology test results from both St. Clare's and the General Hospital however, historical information from the Grace before it closed and earlier information from St. Clare's had to be accessed separately from the main database.[262]

240. Unlike the test results from many other divisions in the laboratory, in pathology most of the information was reported in narrative form pathology reports dictated by the pathologist who did the gross and microscopic examination[263]. While some text in these reports had been standardized, known as synoptic reporting, there were considerable variations in the way in which ER and PR test results were reported in the narrative pathology reports.[264]

241. The Meditech system was also used in the laboratory to record workload measurements for the purpose of tracking and analyzing efficiency and productivity, an important function because of the emphasis on efficiency during the decade prior to 2005. As one of these workload measurements, the

[262] Evidence of Terry Gulliver, October 14, 2008, page 24 line 13 to page 28 line 14
[263] For small cases the gross examination was dictated by the senior technologist.
[264] Evidence of Terry Gulliver, October 14, 2008, page 66 line 7 to page 67 line 23

technologists recorded in the system each ER/PR test that was ordered by a pathologist with information allowing the specimen and patient to be identified. Unfortunately, the system was not set up to separately capture the results of the tests, either by recording the percentage of staining or by indicating “positive” or “negative”.

242. Mr. Gulliver and Mr. Dyer were both very familiar with the Meditech system and were able to search it for the year 2002 to identify all ER/PR tests performed. They then printed the narrative pathology report for each test and manually reviewed them to identify those that had negative results. The search of the Meditech system was able to identify all tests performed regardless of the board or institution from which the request had originated but pathology reports could only be printed for those that had been reported by pathologists within the HCCSJ.

243. By June 3, 2005, Dr. Cook noted that 160 cases had been identified that had been reported from the HCCSJ in 2002. Eighty of those, or 50% had been originally reported to be negative.[265]

244. On June 13, 2005, Dr. Cook sent a memo to Dr. Fontaine, who was the General Hospital Site Chief, and to the pathologists who were laboratory directors at

[265] Exhibit P-0490

Carbonear, Clarenville, Gander, Corner Brook and St. Anthony. He explained that there were a number of negative ER/PR tests that had changed to positive when retested on the new Ventana system, which he described as more sensitive than the technique used with the older Dako method. He asked that they send all their negative ER/PR cases for the year 2002 to the attention of Mr. Dyer for retesting.[266] In this memo, Dr. Cook did not offer any guidance as to how the laboratory directors were to determine which test results to regard as negative. It was not until later that the issue of how to properly determine a cut-off percentage for separating negative and positive results became an issue.

245. On the next day, June 14, 2005, Dr. Cook provided a second reporting letter to Dr. Williams.[267] In addition to the information described above, Dr. Cook also noted that the oncologists continued to identify cases for retesting that they regarded as suspicious in addition to those from 2002. Some of these from 1999 and 2000 had "converted" when retested. For any tests with changed results, the oncologists would be notified and an addendum was issued to the pathology report.

246. On June 22, 2005, Dr. McCarthy saw a breast cancer patient with metastatic disease who had originally tested ER/PR negative but who had been retested at

[266] Exhibit P-0491, June 13, 2005 memo from Dr. Cook to laboratory directors
Exhibit P-0492
[267] Exhibit P-0493, June 14, 2005 letter from Dr. Cook to Dr. Williams

Dr. McCarthy's request and was now strongly positive. Dr. McCarthy had presented her case at the "Tumor Board" and the group had agreed that she should try hormonal therapy. The Tumor Board was a regular meeting of oncologists and other physicians involved in the treatment of breast cancer where difficult cases could be presented and advice sought. It could also function informally as a forum where information such as issues with the ER/PR testing could be more widely communicated among the physicians.[268]

247. On June 29, 2005, Dr. Carter and Dr. Cook reported by letter to Dr. McCarthy with the results of retests of the first 25 specimens. Sixteen of those were from 2002. The others were originally tested between 1999 and 2003. Dr. Cook and Dr. Carter reported that 16 of those retests had produced positive results.[269]

248. Dr. McCarthy testified that when she received this list, she reviewed each patient's electronic chart on the OPIS system at the cancer clinic (which was a separate system unconnected to the Meditech system in use at the former HCCSJ sites). If her review showed that the patient was not already receiving hormone treatment, then she ensured that the change in test result was brought to the attention of the treating oncologist.[270] Dr. Cook also prepared addenda to the original pathology reports which, in the normal course, would be printed and

[268] Exhibit C-0245
[269] Exhibit P-0496, June 29, 2005 letter from Dr. Cook and Dr. Carter to Dr. McCarthy
[270] Evidence of Dr. Joy McCarthy, September 19, 2008, page 148 line 21 to page 150 line 9

placed in the mail slots for the oncologists who were recorded as the treating physicians.

(iii) July and August 2005

249. Dr. Carter faxed a copy of her June 29 letter to Dr. McCarthy to Dr. Williams on June 30, 2005.[271] When Dr. Williams received the letter he realized that the problem with test results might not be confined to 2002 because there were changes in results from other years. He decided then that he needed to involve the CEO, Mr. Tilley.[272] Until he received this correspondence Dr. Williams had been aware of no more than four test result changes for cases confined to the 2002 period and the index case. Until this time he had not considered there to be any need to bring the issue to the level of the Chief Executive Officer of the organization.

250. A period of intense activity then followed.

251. George Tilley recalled receiving the call from Dr. Williams on July 7 or 8, 2005. Dr. Williams gave him basic information about the situation and told him that those involved felt that this was more than just an isolated situation. Mr. Tilley

[271] Exhibit P-0495
[272] Evidence of Dr. Robert Williams May 15, 2008, page 108, line 19 to page 113, line 12

kept a few short notes that reference being told about both the change in testing technology and about Dr. Ejeckam.[273]

252. Dr. Williams said that he contacted Mr. Tilley because he felt that they had a major systemic problem that was going to be a major challenge to deal with.[274] Dr. Williams' note of his call with Mr. Tilley, made July 8, records that he raised the issue of public rather than case by case follow-up of test results.[275] This is the first notation of the necessity of making a public disclosure.

253. On July 12, 2005, there was the first of a series of meetings among Dr. Williams, Dr. Cook, Mr. Gulliver and Ms. Predham.[276] Prior to this time the efforts had been largely confined to retesting the individual cases identified by the oncologists, and all negatives from 2002 with the intention of advising clinicians of any changed results and assessing whether there was likely to be a large scale or systemic problem instead of only isolated cases.

254. Dr. Williams, Dr. Cook, Mr. Gulliver and Ms. Predham met again on July 14, 2005 when a number of priorities were identified.[277] The first was to identify all people who had ER and PR Receptor Testing done. This would have to be done by Mr.

[273] Exhibit P-0321, page 10
[274] Evidence of Dr. Robert Williams, May 15, 2008, page 125, line 9 to page 126, line 9
[275] Exhibit P-0497
[276] Exhibit P-0501, page 3, July 12, 2005, transcribed notes of Dr. Williams
Exhibit P-2940, page 1, notes of Heather Predham
[277] Exhibit P-0504

Gulliver (Mr. Dyer was on vacation for the month of July) using the same search strategies as had been used to identify those who had tests done in 2002. Then those tests which had negative results were to be retested using the new system. There was also to be a meeting with surgeons and oncologists. Current testing standards were to be assessed by cross referencing them with another laboratory. The public was to be advised. External technical consultation was to be used to assess the quality of the service at the laboratory once more information was known on the magnitude of the problem.

255. Dr. Cook had also been asked to speak to Dr. Ejeckam about the stoppage of testing in 2003. Dr. Cook testified that he spoke to Dr. Ejeckam on July 12 or 13 and was told of the types of changes to the testing process that Dr. Ejeckam had initiated to improve the quality of the staining. Dr. Cook had copies of two of the three memos from that time period and had Dr. Ejeckam provide him with a copy of the third. He reported this to Dr. Williams.[278]

256. At 5:00 p.m. on July 14 there was a meeting among oncologists Dr. McCarthy and Dr. Laing, surgeons Dr. Felix and Dr. Kwan, Director of the Cancer Centre Dr. Gardner, Dr. Cook, Heather Predham, Susan Bonnell and Deborah Thomas from the Eastern Health Communications Department, and Dr. Williams. Dr.

[278] Evidence of Dr. Donald Cook, July 3, 2008, page 143, line 4 to page 148, line 1

Williams, Dr. Cook and Dr. Laing reported to the other physicians and those present on the general background, testing process and retesting to that date.[279]

257. On the same day, July 14, Dr. Carter wrote Dr. Cook, copied to Dr. Williams, presenting a plan for review of the ER/PR tests She wanted the pathology reports for 1997 to 2004 collected and original slides organized for review by her. Tissue blocks would then be pulled and retests done. She suggested sending ten percent of the cases randomly selected for outside quality assurance testing. She had been in contact with Dr. Frances O'Malley at Mount Sinai Hospital who had agreed to do that.[280] On July 19 Dr. Cook wrote Dr. Carter stating that he accepted her proposal and would ensure she received the necessary resources.[281]

258. Also on July 14 Dr. Carter sent Dr. O'Malley 13 blocks for staining and interpretation. Dr. Carter described these as quality control cases with a mixture of high, low and moderate ER and PR expression.[282] Dr. Carter's recollection was that when these results were returned there were some differences between the results obtained in St. John's and the results from the Mount Sinai testing and

[279] Exhibit P-0505, Transcribed Notes of Dr. Williams
Exhibit P-0940, Notes of Heather Predham, page 6
[280] Exhibit P-0069
[281] Exhibit P-0072
[282] Exhibit P-1697 and Evidence of Dr. Beverly Carter, July 29, 2008, page 73, line 19 to page 74, line 9

that these results contributed to the suspicions she expressed later that the Ventana testing system was giving false positive results.[283]

259. On the next day, Friday, July 15, Dr. Williams, Dr. Cook and Mr. Gulliver met again to decide on steps necessary to identify the patients for retesting and get retests done as quickly as possible. Mr. Gulliver was to assign one or two people to start the process of identifying patients and pulling slides and tissue blocks and was to assign technologist Mary Butler to cut and test these specimens. Dr. Cook was to contact pathologists elsewhere in the Province to have their cases submitted. Heather Predham was to investigate whether the Cancer Registry at the Cancer Centre could provide a list of patients that were alive and those that were deceased.[284]

260. On Monday, July 18, Dr. Cook and Dr. Carter reported by letter to Dr. McCarthy with the results of a second batch of retests. Of 32 specimens originally tested and reported as negative, all in 2002, 22 changed to positive or weakly positive.[285]

[283] Evidence of Dr. Beverly Carter, July 29, 2008, page 75, line 5 to line 22
See also Dr. Cook's note from July 29, 2005, at Exhibit P-1934
[284] Exhibit P-0506, Transcribed Notes of Dr. Williams
Exhibit P-0507, Notes of Dr. Cook
[285] Exhibit P-0508

261. In the meantime, preparations had been underway for a public announcement and for letters to affected patients. By July 18 a draft "briefing note" was being worked on and Deborah Thomas had drafted several versions of potential press releases for discussion.[286] The press releases are clearly marked "Draft" and do not represent collectively agreed upon content of what a public statement would have looked like at that time. They do, however, reflect the view held by many at that time that the change in testing technology from the semi-automated Dako system to the more fully automated Ventana system had removed steps where the opportunity for human error existed and might be an important factor in the changes in test results.

262. Ms. Thomas' thinking about this issue is reflected in an e-mail message she wrote to Susan Bonnell on July 15 where she says "hoping this could just be a matter of a dramatic improvement in technology (if indeed all controls were in place)". [287]

263. This is the same e-mail message where Ms. Thomas stated "George wants to disclose this info to the Board next week, Dr. Williams is trying to talk him out of it," citing Ms. Predham as the source of her information. Ms. Predham denied

[286] Exhibit P-0071
[287] Exhibit P-0070

that[288] and Dr. Williams testified that he did not try to talk Mr. Tilley out of notifying the Board, but he did want to make sure that the Minister's office was notified.[289]

264. On July 18 a short memo was prepared for Mr. Tilley attaching a copy of Dr. Cook's letter to Dr. Williams on May 24, 2005. It reported that 16 of the first batch of 25 retests had changed results, that approximately 12 of those patients had been informed of the changes by their oncologists and that testing was being done on 33 more patients. The memo also stated,

> The public will have to be informed. Corporate Communications have been involved and, as at least 5 patients are aware of this information already, disclosure has to be made quickly. After meeting the surgeons and oncologists, it was decided to wait until we were able to get more information regarding retesting, the anticipated time lines and a support line established. This support line for patients will be coordinated through QSI. Legal counsel will review the proposed media release before it is distributed.[290]

265. Early that day Ms. Predham had circulated her draft of this memo to Dr. Williams, Dr. Cook and Mr. Gulliver for their review. In her message she mentioned that she had not included any information regarding Dr. Ejeckam's memos from 2003. Mr. Gulliver replied that he would not include Dr. Ejeckam's letter. The memo went to Mr. Tilley without express mention of Dr. Ejeckam's memos, however the

[288] Evidence of Heather Predham, October 16, 2008, page 376 line 6 to page 377 line 11
[289] Evidence of Dr. Robert Williams, May 15, 2008, page 290 line 16 to line 20
[290] Exhibit P-2951

attached May 24 letter from Dr. Cook did described Dr. Ejeckam's suspension of testing in 2003.

266. On the same day Heather Predham and Nancy Parsons from the Quality Department, Deborah Thomas and Susan Bonnell exchanged drafts of a letter proposed to go to patients to inform them that their samples would be retested.[291]

267. Finally, also on July 18 Ms. Bonnell reported having spoken to Ms. Thomas who said that the Department of Health had been notified and was involved and would like the letter sent to each patient outlining the problem and the steps that were being taken to address it.[292]

268. In the memo prepared for Mr. Tilley on July 18 Ms. Predham had included a statement that HIROC would be contacted to see if they were aware of any other issues with the Dako testing system. HIROC, or the Health Insurance Reciprocal of Canada, is a reciprocal insurer whose members are health care providers in Canada. HIROC offers liability insurance to its subscribers and other services designed to assist subscribers to improve the quality of their services. Ms. Predham's role in the Quality Department included that of Risk Manager. She

[291] Exhibit P-0071, page 14
Exhibit P-2832
Exhibit P-2949
[292] Exhibit P-0300

was normally the point of contact between HIROC and Eastern Health, and HCCSJ before that.

269. Early in the morning of July 19 she reported by e-mail to Dr. Williams, Dr. Cook, Mr. Gulliver, Ms. Bonnell and Ms. Thomas about a telephone conversation with the representatives of HIROC the previous evening. They had informed her that they were defending a class action law suit brought against Health Labrador concerning the manner in which patients potentially affected by a problem with sterilization equipment had been notified. She stated that Health Labrador's vulnerability came from the lack of weighing out the risk of harm from the sterilizer problem against the anxiety caused to the patients when they were informed of the potential problem. She then stated, "this leads us to our situation. It's not that they don't want us to disclose, they just don't want us to disclose until we are sure of our facts."[293]

270. Susan Bonnell replied arguing that a public statement should be made and reporting that she had been speaking with Carolyn Chaplin, the Communications Director at the Department of Health and Community Services.[294] The contact

[293] Exhibit P-0073
[294] Exhibit P-0509

with Carolyn Chaplin apparently initiated a series of e-mail discussions within Government.[295]

271. George Tilley and Minister of Health and Community Services, John Ottenheimer, had an appointment for lunch at 12:30 that day.[296] Mr. Tilley's recollection was that the lunch meeting did not go ahead but that they did speak by telephone. Mr. Tilley has very brief notes in his telephone call notebook.[297] Following the call Deputy Minister John Abbott e-mailed Mr. Tilley asking for a meeting on Thursday, July 21, and to have a briefing note provided to him by Wednesday, July 20.[298]

272. Following the circulation of Ms. Predham's e-mail a meeting was arranged for lunchtime on July 19 with Dan Boone, a lawyer with the law firm retained by HIROC to act for Eastern Health on legal claims brought against it and to provide advice.[299] The meeting included Dr. Williams, Heather Predham, Susan Bonnell, Dr. Cook and Terry Gulliver and concluded before about 2:00 that afternoon. Much of the meeting was spent explaining the background to Mr. Boone. Mr. Gulliver explained that within two or three days he would have completed an

[295] Exhibit P-1484
Exhibit P-0312
[296] Exhibit P-0133
[297] Exhibit P-0321, page 16
[298] Exhibit P-0800
[299] Evidence of Daniel Boone, October 29, 2008, page 24, line 2 to page 40, line 1

analysis of yearly positivity rates for ER/PR testing, a task that had been assigned to him on July 12,[300] and that information would allow them to determine if there were time periods where they would not anticipate having a problem with test results. There was discussion of the Health Labrador claim and Mr. Boone provided background information but gave no advice concerning the course of action to be taken by Eastern Health in notifying patients or the public. He testified that it was the consensus of those at the meeting to withhold taking any further action until the result of the analysis of positivity rates were known.[301]

273. George Tilley has a note of speaking with Susan Bonnell following that meeting to the effect that the scope of the problem might be restricted on the basis of a review of the positivity rates.[302] That note is followed on the same sheet by a note of a 3:00 p.m. conversation with Dr. Williams which, among other things, notes "legal counsel cautions release pending full results", which would be a reference to Mr. Boone's positive response to a question from Dr. Williams at the end of the meeting as to whether or not he agreed with awaiting the results of the positivity rate review before further action was taken.[303]

[300] Exhibit P-0501
[301] See also the evidence of Heather Predham October 17, 2008, page 104, line 13 to page 107, line 14
[302] Exhibit P-0329
[303] Evidence of Daniel Boone, October 29, 2008, page 39, line 10 to page 40, line 2

274. Ms. Predham has some scant notes dated the following day, July 20, including the lines “by making an exposure we will create a” and “can’t expect HIROC to pay for it”. Ms. Predham described this note as representing a conversation she had with Dr. Williams on July 20 and described the quoted statements as “an understanding that we always had”, rather than as anything she had been told by HIROC or its legal counsel.[304]

275. Mr. Boone testified that he was absolutely certain that there was no discussion between himself and Ms. Predham or anyone else at Eastern Health on July 19 or 20 connected with the idea that HIROC would refuse to pay for something that Eastern Health had done and that HIROC had cautioned against. He further testified that on those dates he had not been asked whether or not Eastern Health should communicate with individual patients either directly by phone call or by letter.[305]

276. Susan Bonnell confirmed that on July 19 and 20 the information concerning positivity rates caused them to think that the problem might not be as big as they

[304] Evidence of Heather Predham October 17, 2008, page 133, line 9 to page 135, line 1
[305] Evidence of Daniel Boone October 29, 2008, page 222, line 12 to page 223, line 8

had believed, which influenced the decision not to immediately issue a public statement.[306]

277. Early on Wednesday, July 20, Mr. Tilley contacted the Chair of the Eastern Health Board, Joan Dawe, by e-mail to inform her of the issue.[307] After a brief statement of the background, he described the current situation as,

> The challenge now is to determine whether the new results are a consequence of the more sensitive technology we have acquired or an error in the way it was handled these tests in the past, and if it is the latter, whether it has been on ongoing problem or isolated to a particular year."

The Minister had been contacted and was edging them to go public, but,

> Late yesterday the size of the issue began to shrink as managers compared the results of these tests with national benchmark outcomes and found that in 2003 we were consistent. I am expecting a briefing later this morning when the results of this comparison are made for other years.

278. Shortly before noon that day Mr. Gulliver circulated the results of his analysis of positivity rates for 2000 to 2005.[308] Information available by then suggested that 75% positivity was an acceptable rate. The calculations for 2001, 2003 and 2004/5, including tests that were characterized as "positive" and "weak positive", exceeded that rate. The calculations for 2000 and 2002 were lower.

[306] Evidence of Susan Bonnell June 3, 2008, page 69, line 25 to page 70, line 10
[307] Exhibit P-0074
[308] Exhibit P-0514

279. At 2:30 that day Mr. Tilley met with Dr. Williams, Dr. Cook, Mr. Gulliver, Ms. Predham and Ms. Thomas.[309] The positivity rate table prepared by Mr. Gulliver was reviewed. Other new information noted at this meeting includes that the cut-off rate used to assess whether treatment should be recommended had at some point changed from 30% to 10%; that many factors go into determining whether to recommend hormone therapy in addition to the ER/PR test result; that there are no national standards for ERPR testing; that Mount Sinai reports a positivity rate of 75%; that pathology texts states a range of 52% to 85% and that arrangements had been made to bring a technical consultant from Mount Sinai to review the laboratory on September 12, 2005.

280. Much of this information was then incorporated into the briefing note which was finalized late that afternoon and sent to Ms. Chaplin at the Department of Health and Community Services.[310]

281. At 9:00 a.m. on Thursday, July 21, Mr. Tilley, Dr. Williams, Dr. Cook and Ms. Bonnell met at the Department of Health and Community Services with Minister Ottenheimer, Deputy Minister Abbott, Ms. Chaplin and Darrell Hynes. Discussion at the meeting reflected the information then available to those at

[309] Exhibit P-0132 George Tilley Calendar
Exhibit P-0521 Transcript of Dr. Williams' meeting notes
Exhibit P-1527 Deborah Thomas Meeting notes
[310] Exhibit P-1530
Exhibit P-0075

Eastern Health who had been involved in the matter and that was contained in the briefing note delivered the day before.[311] The outcome of that meeting was to hold off on any public announcement or notification to all patients until more investigation could be carried out.[312]

282. Following the meeting with the Minister, Susan Bonnell engaged in a discussion with George Tilley about how to proceed with notification to patients and disclosure to the public and was invited by him to put her thoughts on paper. She prepared at least two versions of a memo, one dated July 21 and the second dated July 22.[313] These memos were not circulated any further and were not considered by those subsequently involved in decision making about disclosure.[314] The testimony of those who worked with Ms. Bonnell was that she was a a consistent advocate for public disclosure. These memos, however, reflect the view that the priority would be to notify individual patients instead of having them hear of retesting from a public announcement.[315]

283. Other events occurring on Thursday July 21 were:

[311] Exhibit P-0469, George Tilley notes, page 54
Exhibit P-0136, Darrell Hynes notes
Exhibit P-0159, Carolyn Chaplin notes
[312] Evidence of Susan Bonnell, June 3, 2008, page 71, line 6 to page 72, line 5
[313] Exhibit P-0304
[314] Evidence of Susan Bonnell, June 3, 2008, page 82, line 17 to page 83, line 19
[315] Evidence of Susan Bonnell, June 3, 2008, page 78, line 9 to page 82, line 14

a. Dr. Williams met with Dr. Carter and Dr. Cook. Dr. Carter argued that in addition to a problem with testing in 2002 the Ventana testing system was too sensitive.[316]

b. Dr. Cook had started making calls to counterparts in other regions and had begun learning that others did not know their positivity rates.[317]

c. Dr. Williams met with Terry Gulliver and Dr. Cook to discuss giving Dr. Carter the resources necessary for her to carry out her proposed work.[318]

284. On Friday, July 22:

a. Dr. Cook met with Dr. Carter and Mr. Gulliver regarding Dr. Carter's work and the information that she needed.[319]

b. Dr. Williams prepared his own draft of a public announcement.[320]

[316] Exhibit P-0515
[317] Exhibit P-1998
[318] Exhibit P-0516
[319] Exhibit P-0518
[320] Exhibit P-1529

c. Deborah Thomas sent Susan Bonnell two draft press releases, one titled "Eastern Health Reviews ER and PR Test Results" and the other titled "Laboratory Testing Review to be completed by Outside Consultant".[321]

285. On Sunday, July 24:

a. Mr. Gulliver sent Dr. Williams a new table of positivity statistics now including 1999.[322]

b. Dr. Gallagher from Grand Falls emailed Dr. Carter double checking the criteria for the patient specimens he was to identify and sent to St. John's, indicating that by this time, he was aware that the retesting program would cover the period from January, 1997 to December, 2004.[323]

c. A meeting was held among George Tilley, Dr. Williams, Dr. Gardiner, Dr. Laing, Dr. Cook, Dr. Kwan, Mr. Gulliver, Ms. Bonnell, Ms. Predham, Ms. Thomas and Mr. Boone.[324] The information discussed at that meeting included a report on retesting to that date. Dr. Williams noted that there

[321] Exhibit P-1528
[322] Exhibit P-0522
[323] Exhibit P-2360
[324] Exhibit P-053-, George Tilley notes
Exhibit P-0520, Dr. Williams' notes
Exhibit P-1527, Deborah Thomas notes
Exhibit P-2940, page 15, Heather Predham notes
Exhibit P-2001, Dr. Cook notes

"may be problem with methodology or the lab". Dr. Laing expressed concern about wanting to ensure that the Ventana system was not overly sensitive. Dr. Kwan expressed the view that a large percent of the changes appeared to be due to technical change. There was a need to check the Ventana results and it was proposed to take some of the samples that had changed from negative to positive and have them retested at Montreal General which used the same Ventana equipment.

286. The next morning, in response to an inquiry from Deputy Minister Abbott, Mr. Tilley informed him of the Sunday morning meeting saying

> We are clearly not at a point yet where we can be confident that we have a problem and if so, the extent of it. The physicians are feeling a little more comfortable based on the recent information provided, but more is needed to get to the bottom of this.[325]

287. Also on July 25:

a. Dr. Cook enlisted help from the Quality Department to conduct a survey of other centers concerning positivity rates, types of technology used and whether they had experienced changes and test results.[326]

[325] Exhibit P-0306
[326] Exhibit P-1936

b. Dr. Cook made contact with Dr. Watters in Montreal to make arrangements for testing on their Ventana system.[327]

288. On Tuesday, July 26th, Dr. Cook sent all Eastern Health pathologists a memo with standard wording for use in pathology reports for reporting the results of ER/PR testing.[328] By this time Dr. Cook would have been aware that Mr. Gulliver and Mr. Dyer were encountering variations in the way that the test results had been reported.

289. On the same day, Dr. Cook had a conversation with Dr. Dogan at the Mayo Clinic.[329] Dr. Cook learned from Dr. Dogan that his institution was reviewing their ER and PR testing, did not know whether they were overcalling or undercalling their results, did not have positivity rates available, had identified a huge variability in staining and reporting, and that the testing was described as a huge problem. The following day, Dr. Cook contacted a pathologist at the Sloan Kettering Facility and learned that their positivity rates were not available.[330] Cook reported these results at a meeting late that day attended by Dr. Williams,

[327] Exhibit P-0929
[328] Exhibit P-0527
[329] Exhibit P-1996
[330] Exhibit P-2000

Dr. Kwan, Dr. Gardiner, Dr. Laing, Dr. McCarthy, Mr. Gulliver, Ms. Thomas, Ms. Bonnell, Ms. Predham and Mr. Boone.[331]

290. On July 28:

a. Dr. Cook and Dr. Carter distributed a memo to Eastern Health pathologists on the use of internal and external negative and positive controls.[332] Dr. Carter and Dr. Cook had looked at the original slides from a number of the retested cases and had observed that there were issues with the quality of the slides, with the interpretations of the pathologists reporting them and with lack of internal controls or internal controls that were present but failed to stain adequately.[333]

b. Dr. Cook spoke to Dr. Fontaine, the General Hospital Site Chief, (Dr. Ejeckam was on vacation), about beginning to run negative controls for ER/PR testing.[334]

[331] Exhibit P-0513, Dr. William's notes
Exhibit P-1995, Dr. Cook's notes
Exhibit P-2940, page 24, Heather Predham's notes
Exhibit P-1527, page 9, Deborah Thomas' notes
[332] Exhibit P-0076
[333] Evidence of Dr. Donald Cook, July 3, 2008, page 335, line 11 to page 336, line 11
[334] Exhibit P-0532

c. Heather Predham began inquiring about the UK-NEQAS Proficiency Testing Program.[335]

d. Dr. Cook continued his calls to pathologists in other centers and Janet Laidley reported the results of the survey she had been carrying out for him.[336]

291. On July 29, 2005, Dr. Carter and Dr. Cook reported more retest results to Dr. McCarthy, again with a large number of changes from the original negative results.[337] By this time, the results of the retesting of the 13 cases that Dr. Carter had sent to Mt. Sinai were available showing some disagreement with the results obtained in St. John's. Dr. Cook and Dr. Carter spoke to Mr. Dyer and told him to put a hold on all ER and PR testing.[338] On the following Monday, August 1st, Dr. Cook advised Dr. McCarthy not to report the ER and PR conversions from the last correspondence to patients until after a meeting planned for 5 p.m. that day.[339]

[335] Exhibit P-0934
Exhibit P-2953
[336] Exhibit P-1995
Exhibit P-1933
Exhibit P-0935
[337] Exhibit P-0535
[338] Exhibit P-1934
[339] Exhibit P-1934

292. That meeting was attended by Mr. Tilley, Dr. Cook, Mr. Gulliver, Mr. Dyer, Dr. Carter, Dr. Laing, Dr. Williams, Ms. Bonnell, Patricia Pilgrim, Ms. Predham, Dr. McCarthy and Dr. Kwan. Earlier that day, Dr. Cook had met with a number of staff pathologists to formally inform them of what was happening.[340] An hour before the 5:00 meeting, Dr. Williams had spoke to Mr. Tilley who noted being told that there had not been any consistency in the manner of reporting the test results, that the Ventana System was "over-calling" and that there were some discrepancies from the cases sent to Mt. Sinai for correlation with St. John's laboratory.[341]

293. The meeting at 5:00 covered a wide range of information.[342] Points coming out of that meeting included:

- A plan was developed to calibrate the Ventana testing system by using the results of the samples tested at Mt. Sinai as controls.

- Patients with negative test results were to be identified and retested on the Ventana system as quickly as possible.

[340] Exhibit P-1936
[341] Exhibit P-0321, page 26
[342] Exhibit P-0539, notes from Dr. Williams
Exhibit P-0540, notes from Susan Bonnell
Exhibit P-2940, page 49, notes from Heather Predham

- Oncologists would be advised not to change treatments for patients already retested until further retesting of those with changed results.

- In the meantime, testing in St. John's would be suspended. New cases would be sent to Mt. Sinai for testing.

294. There was some disagreement at this meeting between Dr. Carter and Mr. Gulliver, which some witnesses recalled and others did not. It seemed to center around the assertion by Dr. Carter that there was a period of time in which no positive test results had been reported from the lab and Mr. Gulliver's defence of the quality of the work done by the technologists.

295. By August 1, Heather Predham and Donald Cook had been researching the medical literature and articles they had found were being circulated among those involved. The fact that there were no accepted standards for how ER/PR testing was performed and interpreted and the fact that there was considerable interlaboratory variability reported from other countries had by this time made its way into the discussions among those involved.[343]

296. On Tuesday, August 2:

[343] Exhibit P-2993

a. Dr. Williams noted “key points” including that Mt. Sinai would do all new ER/PR cases with reports going to St. Clare’s, that Terry Gulliver was arranging for a technical expert from Ventana to make a site visit to evaluate the testing and that Heather Predham was to start a quality review of the ER/PR testing that morning.[344]

b. Dr. Cook made contact with Dr. Diponkar Banerjee, Director of the British Columbia Cancer Agency, and sought his advice.[345] Following that, Dr. Banerjee was requested to come to Newfoundland to conduct the external review of the pathology service.

c. Ms. Predham began to conduct a review of the IHC laboratory by interviewing the technologists and Dr. Fontaine and Dr. Cook.[346] She determined that the review was beyond the scope of her expertise and that the work should be left for the technical and pathology experts who were to be conducting external reviews.[347] One issue reported by Ms. Predham to Dr. Cook and Dr. Williams following her interviews that morning was the technologist’s concerns that they would receive requests

[344] Exhibit P-0080
[345] Exhibit P-1992
[346] Exhibit P-2940, page 43
[347] Evidence of Heather Predham, October 17, 2008, page 295 line 23 to page296 line 14

from multiple pathologists and would prefer these to come from a single source.[348]

d. Dr. Cook circulated a memo to all pathologists at Eastern Health informing them that Dr. Ejeckam was currently the resource person for immunohistochemistry and all inquires should be referred to him. In the event he was not available, inquiries would be referred to Dr. Fontaine, the Site Chief at the General Hospital site.[349]

e. Dr. Cook wrote Dr. Kenneth Pritzker, the Director of the Pathology Laboratory at Mount Sinai Hospital in Toronto regarding the retesting to be carried out by Mount Sinai.[350]

f. Dr. Carter wrote Dr. Cook that she was withdrawing from her investigational role, questioning laboratory management's understanding of the technical requirements for ER and PR testing and stating that the current administrative structure allowed decisions to be made by persons

[348] Exhibit P-0545
[349] Exhibit P-0542
[350] Exhibit P-0543

in the laboratory other than physicians. She said she would remain available to provide advice and assist as requested.[351]

297. On August 4, Dr. Cook spoke to the laboratory manager at Mount Sinai and was informed that the turnaround time for cutting slides from 500 paraffin blocks, preparing stains and having them interpreted by a pathologist would be 3 to 4 weeks.[352] The next day, Dr. Cook spoke to Dr. Pritzker noting that he advised not to go public and that Eastern Health was the first laboratory known to handle this type of situation by large scale retesting.[353]

298. At 10:00 in the morning on Friday, August 5, Mr. Tilley and Dr. Williams met with Minister Ottenheimer, Deputy Minister Abbott, and Assistant Deputy Minister Moira Hennessey. The discussion included a summary of activities within Eastern Health, information learned from medical literature research, information obtained from the survey of other laboratories, that Mt. Sinai would perform tests on new samples and that they expected to be able to complete retests in 3 to 4 weeks, that external reviews of the laboratory would be done by a pathologist

[351] Exhibit P-0079
Exhibit P-0546
[352] Exhibit P-1732
Exhibit P-1935
[353] Exhibit P-1935

and a technologist and that a technician from Ventana was reviewing the system.[354]

299. Also on August 5:

a. Dr. Cook had a second meeting with pathologists who presented him with a document outlining concerns about reviews of physicians' work and that such reviews should be carried out in an appropriate manner.[355]

b. The Ventana representative completed her review and delivered a short report that both Ventana Benchmark instruments were performing within specifications, that she had run tests achieving good results, that the protocols being used for ER and PR staining were those recommended by Ventana and in use in other institutions in Canada and that the technologists were properly trained and able to troubleshoot if problems occurred. Her only concern was that the recommended monthly and quarterly maintenance procedures had not been done. Arrangements were immediately put in place to ensure that the maintenance was carried out in the future. She concluded, "I feel confident that the technicians

[354] Exhibit P-0554, George Tilley's notes
Exhibit P-1430, Moira Hennessey's notes
[355] Exhibit P-0555

know what they are doing, they know how to use the instruments and that the Benchmark instruments are staining as they should be".[356]

c. Dr. Cook prepared a draft of a letter for Dr. Williams listing seven recommendations for changes in the IHC service, which are similar to recommendations that later came from the external reviews, and concluding,

> I would like to end by saying that over the last few years, there has been a lot of emphasis placed on utilization management and living within our budgets. The emphasis now has to be placed on quality assurance with the additional human and financial resources this requires.[357]

300. Late on August 5, Dr. Williams met with Dr. Cook, Dr. Gardner, Dr. Laing, Ms. Predham and Ms. Pilgrim to review the steps being taken to identify patients for retesting and also noting that 10 to 11 patients who had changed test results had been informed, that reactions had been good to date and that they had been told that there was a problem with the testing but the clinicians did not yet know why.[358]

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[356] Exhibit P-0552
Exhibit P-0549
[357] Exhibit P-0556
[358] Exhibit P-0551, notes from Dr. Williams
Exhibit P-0954, page 8, notes from Heather Predham
Exhibit P-1935, notes from Dr. Cook

301. On August 8, 2005, Dr. Williams met with Dr. Cook and Mr. Gulliver[359] and following that Dr. Cook sent out a series of memos. One went to the technologists informing them that there would be a hold on reporting all ER/PR tests by pathologists but tests would still be requisitioned and slides prepared. The paraffin blocks would then be sent to Dr. Carter at St. Clare's who would forward them on to Mount Sinai to be tested there as well.[360] Dr. Cook prepared a second memo directed to Eastern Health pathologists at St. John's hospitals directing them to place a hold on reporting ER/PR tests but to interpret the slides prepared in the lab and forward their results to Dr. Carter.[361]

302. The intention was to use the Mount Sinai retest results to validate the testing in St. John's and to enable it to be restarted as quickly as possible. However, once the external reviews were carried out in September and it was decided to first address the recommendations coming out of those reports, the plan for parallel testing and interpretation of current specimens in St. John's and Mount Sinai was abandoned.

303. Dr. Cook's third memo was to pathologists at Eastern Health informing them of the plan for retesting cases originally reported between May 1997, and August 9,

[359] Exhibit P-0557
[360] Exhibit P-0559
[361] Exhibit P-0560

2005.[362] At this time it was intended to retest all negative cases from May, 1997, to March 31, 2004, and, because doubt had been raised about the reliability of the results from testing on the Ventana, to retest all cases done between April 1, 2004, and August 9, 2005. Also on August 8 Dr. Carter had written Dr. Cook with an analysis of retesting results that were available and expressing her view that the testing on the Dako system had underestimated the number of positive results and the testing on the Ventana system was overestimating the number of positive results.[363]

304. Prior to Dr. Carter's withdrawal from the investigational process on August 2, 2005, Mr. Gulliver had given her a box of pathology reports to be reviewed to identify negative original test results. After August 2 he retrieved that information and, with assistance from Mr. Dyer, reviewed each pathology report, logging information on tables that had been formatted by Dr. Carter.[364]

305. An issue arising out of that was settling the criteria to be applied to determine which tests would be regarded as positive and which as negative. Dr. Cook noted speaking to Dr. Laing on August 10 for confirmation that up until the end of

[362] Exhibit P-0412
[363] Exhibit P-0081
[364] Exhibit P-0565, page 2
Exhibit P-2359 is an example of the tables created by Mr. Gulliver and Mr. Dyer

2000 tests reported at less than 30% were considered negative and after that date a less than 10% cut-off was used.[365]

306. Heather Predham had also been involved in creating a database in the form of a computer spreadsheet listing the ER/PR tests identified from Mr. Gulliver's search of the Meditech system. She intended to combine it with information from the Cancer Registry in an effort to ensure that no cases were missed and to identify patients who were deceased, since the intention was to test living patients' specimens first. However, she had determined that combining the databases would be difficult and that there were issues with the completeness and accuracy of the Cancer Registry information.[366] On the next day, August 10 she went on annual leave and did not return until September.

307. The results of testing of the blocks sent to Montreal General for correlation testing were returned on August 10, 2005.[367] It was originally thought that Montreal General had used their Ventana system as requested. It was later discovered, however, that Montreal General had used their Dako system to perform the tests.[368] Interestingly, review of the results showed that the testing in Montreal using their Dako system correlated better with the original results of

[365] Exhibit P-0942 Evidence of Heather Predham, October 20, 2008, page 53, line 5 to page 54, line 19
[366] Exhibit P-0785
[367] Exhibit P-1938
[368] Evidence of Dr. Donald Cook, July 3, 2008, page 279, line 13 to page 280, line 8, page 332, lines 1-17 and July 4, 2008, page 155, line 23 to page 159, line 11

testing on the St. John's Dako system than with the retests on the St. John's Ventana system.[369]

308. By August 10 preparations were underway to make telephone support available for patients who would require more information following the public announcement that was still planned to be made, although the timing had not been decided upon.[370]

309. There was then a meeting among Dr. Williams, Dr. Cook, Dr. Laing, Mr. Tilley and Ms. Pilgrim. Reports were given on the status of work to that date.[371] Mr. Tilley had received an e-mail inquiry from Deputy Minister Abbott the day before about the status of letters to patients.[372] Dr. Laing argued for waiting until more information was available and until patients could be given answers to their questions before sending out letters. Her concern was the creation of unnecessary anxiety for many patients.[373]

310. It was recognized at that time that because some patients had already been notified of retest results that there was a risk that the matter could become

[369] Exhibit P-2005, Exhibit P-0568
[370] Exhibit P-0785
[371] Exhibit P-0564
[372] Exhibit P-0163
[373] Exhibit P-0564, pages 5 and 6
Exhibit P-0563
Exhibit P-0566

publicly known. The consensus, however, was that the opinions of the clinicians who were in the best position to directly assess the impact on patients from premature disclosure outweighed other concerns.[374]

311. Mr. Tilley then contacted Moira Hennessey at the Department of Health and Community Services informing her of the oncologists' preference not to contact all patients at that time. Ms. Hennessey called back to say that the Minister remained uncomfortable and asked for a meeting with Dr. Laing.[375] That meeting took place at 9:00 a.m. on Monday, August 15.[376] In attendance were Minister Ottenheimer, Assistant Deputy Minister Hennessey, Dr. Fleming from the Department, Carolyn Chaplin, George Tilley, Dr. Cook, Dr. Laing and Dr. Williams. It was reported to the Department that 400 patients who required retesting had been identified and that Mount Sinai required 6 to 8 weeks to complete the testing.[377] Dr. Laing presented the case for waiting until more information was known before writing all patients and said that she had the support of Dr. McCarthy and radiation oncologist Dr. Ganguly. Minister

[374] Evidence of Susan Bonnell, June 3, 2008, page 73, line 9 to page 77, line 8
[375] Exhibit P-0321, page 31
[376] Exhibit P-0571, notes from Dr. Cook
Exhibit P-0570, notes of Dr. Robert Williams
Exhibit P-0160, notes of Carolyn Chaplin
Exhibit P-1432, minutes from Moira Hennessey
[377] The 3 to 4 weeks quoted to Dr. Cook plus additional time to identify blocks and send them to Mount Sinai.

Ottenheimer remained a supporter of public disclosure but gave considerable weight to the opinions of the clinicians and agreed to accept them.[378]

312. On Friday, August 12, Susan Bonnell had prepared a memo for Mr. Tilley's use outlining strengths and weaknesses of different approaches.[379] Ms. Bonnell described this memo as something put together quickly.[380] There is no indication in the evidence that this memo was circulated to anyone else or used or referred to later either at the meeting with the Minister on August 15 or otherwise.

313. By Monday August 15 Mr. Gulliver and Mr. Dyer had worked through the weekend to pull the blocks for all the specimens identified for retesting from the records of HCCSJ. The blocks then were reviewed by Dr. Cook and Dr. Fontaine to ensure that the tissue samples were appropriate for testing.[381] The first batches of 115 and 130 blocks for the time period from 1999 to 2004 were sent to Mount Sinai by August 18, 2005.[382] On August 26 Dr. Cook was informed that test results could be expected from Mount Sinai by September 10.[383] Dr. Cook

[378] Evidence of John Ottenheimer, March 31, 2008, page 190, line 19 to page 191, line 2 and page 207, line 8 to page 209, line 6
[379] Exhibit P-0331
[380] Evidence of Susan Bonnell, May 30, 2008, page 183, line 15 to line 23
[381] Exhibit P-0568
Exhibit P-0569
Exhibit P-0572
Exhibit P-0573
[382] Exhibits P-0574, P-0575
[383] Exhibit P-1734

passed this information on to Mr. Tilley[384] who reported it by e-mail to Moira Hennessey at the Department of Health and Community Services.[385] However, Mount Sinai began to encounter delays in carrying out the work.[386]

314. Regarding the specimens to be obtained from sites outside St. John's, Dr. Cook had begun making phone calls to his counterparts on August 10, 2005, to inform them of the requirements and continued the process over the next three weeks.[387] Dr. Cook followed these calls up with a memo on September 6, 2005.[388] By as early as August 23, blocks were being received from the regions and forwarded to Mount Sinai, both as a result of the earlier request for 2002 specimens and also for specimens from the broader time period.[389]

315. By August 18, based on the review of the original slides by Dr. Carter and Dr. Cook, Dr. Cook recorded that tissue fixation appeared to be a problem in at least 15 to 20% of the cases with changed results.[390] He followed up this observation on August 23 with a memo to Maria Tracey, the Program Director of the Perioperative Program asking that care be taken to ensure that mastectomy specimens were completely immersed in formalin and immediately forwarded to

[384] Exhibit P-0321, page 39
[385] Exhibit P-0139
[386] Exhibits P-0589, P-0592, P-0173
Exhibit P-1945
[387] Exhibits P-1936, page 6, P-0579, P-0581, P-0589, P-2234
[388] Exhibit P-0590
[389] Exhibits P-0577, P-0579
[390] Exhibit P-0576

the Pathology Lab where the specimen could be appropriately sectioned. Dr. Cook asked that cases not be left overnight or over the weekend, that after hours the pathologist on call should be notified and that every attempt should be made to ensure that cases are done early in the day.[391] The issue came to Dr. Cook's attention again following the exit interviews with the external consultants in September. Dr. Cook wrote Dr. Williams and an appropriate memo was circulated to the Perioperative Program.[392] Changes to the Operating Room schedule to accommodate mastectomy surgeries early in the day, when more complex cases are normally scheduled, were not practical and alternative measures were taken to ensure that specimens obtained late in the day were appropriately dealt with.[393]

(iv) The Return of the First Mount Sinai Retest Results

316. On September 26, 2005 the retest results for the first 142 cases were sent by Mount Sinai pathologist Dr. Brendan Mullin to Dr. Cook in the form of a spreadsheet, or table, of test scores,[394] instead of in the form of narrative

[391] Exhibit P-0578
[392] Exhibit P-1290
Exhibit P-1946
Exhibit P-3083
[393] Evidence of Maria Tracey, September 29, 2008, page 389 line 3 to page 392 line 4
[394] Exhibit P-1782
Exhibit P-1783
Exhibit P-1786

pathology reports as would usually be used for consultations from one institution to another.

317. Dr. Cook sent those first results to Ms. Predham, who immediately reviewed them with Dr. Laing and Dr. McCarthy. They sorted them into 3 groups; patients whose tests were confirmed to be negative and who would be called by staff from the Quality Department and informed of their results, patients whose results had changed but who needed further review before action was taken, and patients who the Cancer Centre physicians wanted to deal with directly.

318. The preparations for communications with the affected patients and the public at large that had been started in July and August, and then not developed further after the August 15 meeting with the Minister, now had to be revived. The minutes from the September 28 Executive Team meeting report Dr. Williams to have said that, "we are positioned to move with a communication strategy when required,"[395] and it was likely those plans that he was referring to.

319. First steps towards reactivating a plan for communicating with affected patients were taken by Ms. Predham and Ms. Bonnell in late September.[396] On the morning of Friday, September 30 they met in Ms. Bonnell's office to revisit the

[395] Exhibit P-0486, page 39
[396] Evidence of Heather Predham October 18, 2008 page 172 line 24 to page 175 line 15

letter that had been drafted in the summer to notify patients that their tissue samples would be retested for ER and PR. At this point it was still their own initiative and had not yet been taken up with Dr. Williams or others who were involved in managing the retesting.[397]

320. On August 15 it had been thought that Mount Sinai would have delivered all retest results within 6 to 8 weeks. By September 30 just more than 6 weeks had elapsed and only a portion of the test results had been returned. Ms. Bonnell understood that more and more patients were becoming aware of the retesting and felt that it was time to reconsider contacting all patients.[398]

(v) The Retesting Becomes Publicly Known

321. Ms. Predham and Ms. Bonnell did not get the chance to take this initiative any further, because during their meeting they were given a message that there had been a call from a journalist with the Independent newspaper inquiring whether there was a problem with mammography testing. Ms. Bonnell called the reporter back and told her about the ER/PR retesting.[399] Dr. Williams and Dr. Laing became involved, Dr. Laing gave an interview by telephone from Toronto where

[397] Evidence of Heather Predham October 22, 2008, page 440 line 1 to page 442 line 8; and page 455 line 6 to page 457 line 1
[398] Evidence of Susan Bonnell May 30, 2008 page 209 line 20 to page 211 line 16
[399] Evidence of Susan Bonnell May 30, 2008 page 211 line 11 to page 218 line 7; and June 3, 2008, page 91, line 22 to page 95, line 4

she was attending a conference and, despite requests from Ms. Bonnell and Dr. Laing for the Independent to hold off on the report to allow an opportunity to make direct contact with the patients,[400] the story was published on Sunday, October 2, 2005.[401]

322. The Department of Health and Community Services was notified of these events and a briefing note was prepared and forwarded late on Friday, September 30.[402] Background events were briefly summarized and reference was made to the external reviews by Dr. Banerjee and Ms. Wegrynowski. It is noted that 153 samples in total had been reported by Mt. Sinai, 73 of which had been reviewed and 16 to 20 of which were for patients whose treatment could have been impacted. At this point, that statement could only have been based on the preliminary review of test results done by Dr. Laing and Dr. McCarthy with Ms. Predham during that week.

(vi) Public Communications

323. Following the publication of the Independent article, Eastern Health did not issue a press release. There was some discussion with representatives from the Department of Health and Community Services about whether a press release

[400] Evidence of Dr. Kara Laing September 10, 2008 page 326 line 9 to page 333 line 6
Exhibit P-0340, page 3
[401] Exhibit P-0342, page 2
[402] Exhibit P-0601

was necessary.[403] However, Eastern Health had begun immediately to communicate with the public through the media with Dr. Williams acting as spokesperson. He gave many interviews in print and the electronic media from Monday, October 3 until the end of the year.[404]

324. One of the first news stories, the Telegram article of October 5, 2005, written by Deana Stokes-Sullivan provides extensive information from Dr. Williams and is an effective summary of a complex story. Like any news story, the content is determined by interaction between the reporter and the people being interviewed and the choices made by the reporter and the media editors about what information is considered newsworthy. The task of a spokesperson like Dr. Williams in those circumstances is to attempt to convey the complex information in a way that is understandable to a journalist who does not have a background understanding of the issues and who is new to the story. The challenge for an organization like Eastern Health in such circumstances is to present information in a way that is understandable and usable to the journalists and the challenge for the journalists is to work within their typically short deadlines to prepare as full and fair an account as possible.

325. A story in the Telegram on October 5, 2005 reported that,

[403] Exhibit P-0142
[404] Dr. Williams is quoted in many news stories including those found at Exhibits P-3153 and P-0345, pages 2, 3, 4, 5, 6, 9, 10, 23.

> About 350 of the tests are done annually in this Province, with 60% of the samples from Eastern Health Authority patients and 40% from patients treated at other regional centres.
>
> Most of the tests performed were positive, Williams said, "We had about 73% of tests that were positive, so we are only retesting the 27% or so that were negative."
>
> And from the early results, Williams said "it appears only about 10% of the overall tests performed over the past 7 years showed different results".[405]

326. Dr. Williams explained that he arrived at his estimate that 10% of all ER/PR tests performed might change in two ways.[406] By this time, Mr. Gulliver had calculated that the overall positivity rate for all tests done between 1999 and 2003 to be 73%.[407] Dr. Williams understood that the best information available in the literature was that the positivity rate could be as high as 82 or 83%.[408] If the overall positivity rate moved to that level when all specimens that had originally had negative results were retested, then there would be change in about 10% of all tests. The second approach used by Dr. Williams took into account that among the first batch of retests received from Mount Sinai about one-third had changed. The negative specimens to be retested represented 27% of the total tests done. If the one third proportion held for the balance of the retesting, then one third of 27%, or about 10% of all tests be expected to change.

[405] Exhibit P-0345, page 2
[406] Evidence of Dr. Robert Williams, May 16, 2005, page 291, line 4 to page 294, line 3
[407] Exhibit P-0522
[408] See Exhibit P-1933 where Dr, Cook was told by Dr. Rock of Ventana to expect a positivity rate of between 80% and 85%

327. Most early media reports described Dr. Williams' 10% estimate correctly[409], but as time went on, some media reports began to mistakenly state that Eastern Health had said that only 10% of the retests would change. There is no evidence that Dr. Williams presented the information in any way other than as set out in the October 5 Telegram story.[410]

328. In addition to the media interviews given by Dr. Williams, in October 2005 Eastern Health also posted information on its website and ran newspaper advertisements.[411]

(vii) Patient Communications

329. The discussion about direct communication with the patients that had been revived by Ms. Predham and Ms. Bonnell on September 30 continued following the publication of the Independent story until October 18, 2005, when the decision was made to make telephone calls to inform affected patients that their

[409] Exhibits P-0624
Exhibit P-0345 page 5
[410] Drafts of a written response to questions from a reporter with the memorial University student newspaper the Muse had initially presented the expected rate of change differently, but the final copy , Exhibit P-0665, says "We anticipate that less than 10% of patients will be affected."
[411] Exhibits P-0608
P-0354
P-0358
P-0355
P-0886

ER/PR tests were being repeated and to inform patients whose retest results had been returned and had remained negative.

330. On Monday October 3 there was a meeting among physicians and others involved in the process within Eastern Health to consider steps to be taken now that retest results were available. [412] Initial decisions made at that meeting included:

- to not follow up on testing of samples for deceased patients until those for living patients had been completed,

- for pathologists to issue addenda to the original pathology reports to record the change in test results,

- for a letter to be prepared to go to physicians to inform them of the situation, and

- for a “clearing house” to be set up for information and patient contact.

The latter responsibility soon fell on Ms. Predham.

[412] Exhibit P-0603
Exhibit P-0610

331. The letter to physicians was prepared by Eastern Health and circulated by the Newfoundland and Labrador Medical Association which also posted it on its website.[413] An important point made in the letter was that Tamoxifen could benefit a patient up to 10 years after diagnosis and that it was therefore important to consider offering delayed hormone therapy to patients.[414]

332. On October 11, Eastern Health officials consulted with representatives from the other health boards about issues related to the retest results and patient notification.[415]

333. On October 17, work continued on drafting a letter to go to the patients to advise them that their samples were being retested.[416] At a meeting held among Dr. Williams, Dr. Cook, Dr. Laing, Ms. Pilgrim, Ms. Predham, Ms. Bonnell and others on that day, Ms. Bonnell was assigned responsibility for preparing information for the public and Ms. Predham was given the task of finalizing the letter. For those patients whose results were already back and confirmed negative, the Quality

[413] Exhibit P-0620
Exhibit P-0616
Exhibit P-2958
Exhibit P-0618
Exhibit P-3154
Exhibit P-0626
[414] Exhibit P-2958, page 2
[415] Exhibit P-0338
Exhibit P-2736
ExhibitP-2909
[416] Exhibit P-0645

Department was to begin contacting them by telephone to give them that information.[417]

334. Shortly after 1:00 p.m. on the following day, Tuesday, October 18, Ms. Predham circulated her draft of the patient letter to Dr. Laing, Dr. Williams, Ms. Bonnell and Ms. Pilgrim. She noted on her email that she was going to send it to lawyer Dan Boone as well and that she was not sure how the insurer would feel about notifying people at that time, and whether they might feel that the media attention had made such a notification unnecessary.[418]

335. Ms. Predham testified that before she sent this message, she had a telephone call from Mr. Boone on another issue and discussed this topic briefly with him. She understood his reaction to be that he was hesitant about what Eastern Health was proposing to do but did not get into any more detail with him.[419]

336. She understood that Mr. Boone's initial reaction was that he did not see the necessity of communicating with the patients whose retest results had not been received at that time. She then left to attend another meeting with Dr. Williams, Dr. Cook, Dr. Laing, Mr. Tilley, Ms. Pilgrim and Ms. Bonnell. At that meeting,

[417] Exhibit P-2863
[418] Exhibit P-0308
[419] Evidence of Heather Predham October 20, 2008 page 183 line 1 to page 184 line 7; and page 195 lines 6 to 21

she told of her conversation with Mr. Boone. She did not understand his comments to be restricted to communicating by letter as opposed to by telephone and did not explain them in that way. The form of the letter to patients had been under discussion for some time and Ms. Predham recalls that at that meeting, Dr. Williams made the decision that all patients would be contacted by telephone. She testified that,

> Dr. Williams understood that it would take us a few days to--or about a week to get the letters actually out, and I distinctly remember that there was the discussion around the table about who was sending the letters out, how would we coordinate it, would it be registered, all those logistics, and he put his fist down on the table and said, call them all. I said, pardon me, and he said, call everybody. So then that was the decision that was made.[420]

337. Dr. Williams has notes of that meeting that record:

- get information to the media in print, which was a reference to the newspaper ads that were then run,

- phone patients who were to be retested,

- phone patients who had been retested and were confirmed negative,

[420] Evidence of Heather Predham October 20, 2008 page 188 lines 6 to 19; and page 198 line 24 to page 205 line 2

- contact physicians with results for patients whose cases were considered by the Tumor Board (discussed below) and

- Western Health and Central Health were to telephone their own patients.[421]

338. Shortly after 2:00 p.m. on Tuesday, October 18th, Mr. Boone emailed Ms. Predham his comments on the proposed letter saying he did not agree with sending it at that time. The reasons he gave would have been just as applicable to telephone calls as to letters.[422] Ms. Predham did not receive this email until after the meeting where it had been decided to make the telephone calls.[423] Ms. Predham forwarded Mr. Boone's email to Dr. Williams, Ms. Bonnell and Ms. Pilgrim the following morning without comment.[424] Ms. Bonnell replied that she disagreed with Mr. Boone's position[425] but there was no further discussion of the issue and on October 20, Quality Department Staff began making the telephone calls.[426] Ms. Predham reported regularly to Dr. Williams on the progress being made in contacting patients and with the numbers of patients who had not been

[421] Exhibit P-0925
[422] Exhibit P-0092
[423] Evidence of Heather Predham October 20, 2008 page 184 line 20 to page 187 line 13
[424] Exhibit P-0092
[425] Exhibit P-1496
[426] Exhibits P-0655, P-2969, P-0664, P-0095

contacted. There were a small number of patients that Eastern Health staff were unable to contact by telephone.[427]

339. Throughout October, there were also numerous contacts between Eastern Health and the other health authorities at multiple levels.[428]

(viii) The Physician Panel

340. In some cases, patients with changed retest results were actively under the care of physicians in the Cancer Center or elsewhere. Others, however, were discharged from a specialist's care and were likely being followed only by a family physician. In some cases, due to the turnover of oncologists in the Cancer Center in the earlier years of the retesting period, the treating physician was no longer available. These issues, and the concern that the retesting presented an unusual set of circumstances where clinicians might benefit from the views of their peers prompted the use of a Physician Panel to review all cases where there were changed test results and to make recommendations for changes in

[427] Exhibits P-0664, P-0095, P-2982
[428] Exhibits P-1492, P-0091, P-0349, P-0630, P-0338, P-2253, P-2738, P-2739, P-0653, P-1311, P-2932, P-2914, P-0670

treatment. The suggestion originated with Dr. Kwan and Dr. Laing and was implemented by Dr. Williams on October 12, 2005.[429]

341. Use of the physician panel was similar in many ways to the practice of physicians bringing unusual or difficult cases to rounds where they sought the advice of their peers.

342. The first Panel meeting was held on October 13, 2005.[430] Dr. Laing chaired the Panel. It included representation from oncologists, pathologists and surgeons. Ms. Predham attended the meetings as a resource person and to assist in providing logistical support.

343. At first, Ms. Predham and Dr. Laing would meet before the meetings to review Mount Sinai retest results and separate the changes from the confirmed positives. That soon changed so that all results were brought to the Panel, at least for their confirmation that they did not need to be reviewed.

[429] Exhibit P-0350
Evidence of Dr. Robert Williams May 21, 2008, page 55, line 16 to page 56, line 10, page 65, line 16 to page 66, line 7
Evidence of Dr. Robert Williams May 16, 2008, page 313, line 2 to page 315, line 4
[430] Exhibit P-1309

344. For each Panel meeting, Ms. Predham and the Quality Department staff ensured that the necessary medical charts either in paper or electronic format, were available for review by the physicians.

345. Where the Panel confirmed that there was no clinically relevant change in the test results, the patients were considered "confirmed negative" and were informed by telephone by Quality Department staff. When the Panel considered a patient's case, a letter was prepared to go to the attending physician, and copied to other physicians identified on the patient's chart. Standard formats for the letters were adopted. The recipients of the letters were informed of the change in test results, whether any change in treatment from that disclosed in the patient's chart was recommended, and that the physician should communicate the information to the patient as soon as possible. Physicians were advised that patients could be referred to a medical oncologist at the Cancer Centre for further evaluation.[431]

346. The Panel continued to meet on October 20, 2005,[432] November 4, 2005,[433] November 10, 2005,[434] November 17, 2005,[435] November 27, 2005 and

[431] Exhibit P-2553
[432] Exhibits P-2552, P-1384
[433] Exhibit P-1324
[434] Exhibit P-2558
[435] Exhibit P-2560

December 1, 2005.[436] By the latter date, the Panel had exhausted all retests reported from Mount Sinai and the next 5 weekly meetings were cancelled while the group waited on more retest results.

347. After each meeting, Ms. Predham provided a report on the numbers of retests considered by the Panel and the results of that reconsideration to Dr. Williams by e-mail.[437]

348. On November 24, Ms. Predham reported to Dr. Williams that the Panel had been classifying patients as being "converted with or without recommendations" and that Dr. Kwan had suggested that she should track patients who may have been potentially harmed. For example, a patient whose cancer had metastasized resulting in treatment with Tamoxifen before the retest was carried out would have no recommended change of treatment from the Panel but might have benefited had Tamoxifen been made available when the original test was done. Ms. Predham agreed that this was relevant information to track and after that date, she attempted to do so.[438]

[436] Exhibit P-2561
[437] Exhibits P-0650, P-0657, P-1320, P-0677, P-1327
[438] Evidence of Heather Predham, October 20, 2008, page 89 line 24 to page 97 line 15
Exhibit P-0684

349. Panel meetings resumed on January 12, 2006, when a large batch of results had been returned from Mount Sinai.[439] In February arrangements had been made for the panel to meet on two Saturdays, instead of just the usual Thursday evening once a week, in order to finish its work more quickly.[440] The panel meetings continued regularly until the beginning of March when all the retests, aside from special cases, had been dealt with.[441]

350. The panel held follow-up meetings on May 4, 2006 to review cases that had previously been deferred,[442] on June 8, 2006 to review "DCIS" cases where there were suggestions of different diagnoses based on the Mount Sinai review,[443] and September 7 to review DCIS and other special cases.[444]

[439] Exhibit P-2034
[440] Exhibit P-1100
Exhibit P-1102
[441] Exhibit P-2034
Exhibit P-2041
Exhibit P-1085
Exhibit P-1090
Exhibit P-2045
Exhibit P-3003
Exhibit P-1100
Exhibit P-1358
Exhibit P-1360
Exhibit P-3015
[442] Exhibit P-3022
Exhibit P-3692
[443] Exhibit P-3026
[444] Exhibit P-2568

(ix) Progress of the Retesting by Mount Sinai

351. In late September 2005 the last St. John's cases were sent from Eastern Health to Mount Sinai. These were cases from 1997 and 1998.[445] Cases continued to be sent in from other health authorities[446]. The last blocks from Corner Brook arrived at St. John's on October 27, 2005.[447] The last 25 cases from St. Anthony were not sent to St. John's until January 20, 2006.[448]

352. By mid-October Mount Sinai was having capacity problems and was encountering delays in returning retest results.[449] As a result, on October 13, 2005, Dr. Cook decided that for the specimens from 2004 and 2005 that had been originally tested using the Ventana system, the negative results would be given priority and retesting of positive results would be deferred.[450] As time went on the concern from the summer of 2005 about whether the Ventana testing was overcalling positives diminished and eventually it was not considered necessary to retest the positive results from that period.[451]

[445] Exhibit P-0607
[446] Exhibits P-0602, P-0605, P-2241, P-2243, P-1739, P-2245, P-2247, P-3094, P-2248, P-2252, P-2255, P-2230
[447] Exhibit P-2257
[448] Exhibit P-1081
[449] Exhibit P-1798
[450] Exhibit P-0638
[451] One of the factors suggesting that there were too many positive results using the Ventana system was the calculation of the rate of positives that Mr. Gulliver had done in July 2005, Exhibit P-0514, that

353. Dr. Williams engaged Mr. Tilley on the issue of the retesting delays and he contacted Dr. Pritzker, the Director of the laboratory at Mount Sinai to see if anything could be done to expedite the process.[452] Through the remainder of 2005 and into 2006 Dr. Cook diligently kept in contact with Mount Sinai to encourage them to return results as quickly as possible.[453]

354. It had been recognized that among the specimens forwarded to Mount Sinai were ones from patients who had since become deceased. In an effort to speed up the retesting process, Ms. Predham identified as many of those that she could with the information available to her and on November 3, at the request of Dr. Cook and Dr. Williams, sent that information to Mount Sinai asking that they defer testing of those specimens.[454]

355. Mount Sinai sent 40 more retest results on November 4, 2005.[455] On December 20 Dr. Pritzker assured Dr. Cook that retests would be completed by the end of

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showed 90% for the 2004/5.In June 2006 Mr. Gulliver recalculated that rate to be 82.6%, Exhibit P-1135.

[452] Exhibit P-0340

[453] Exhibits P-1740, P-0673, P-0681, P-0682, P-1333

[454] Exhibit P-1336

[455] Exhibit P-1966

January.[456] At the end of November, Dr. Cook had inquired of Montreal General to see if they had capacity to do testing but was informed that they did not.[457]

356. The bulk of the remaining retests were reported by Mount Sinai to St. John's on January 20, 2006.[458] The last small number of retest results were provided on February 14[459] and on April 5, 2006.[460]

(x) External Review Reports

357. An external review of the immunohistochemistry service was conducted by Dr. Banerjee, Executive Medical Director of the British Columbia Cancer Centre Pathology Laboratories, on September 15 and 16, 2005. The review, like that subsequently carried out by Trish Wegrynowski, the Chief Technologist from the Mount Sinai Pathology Laboratory, between September 20 and 23, 2005,[461] was considered by the administration of Eastern Health to be an activity of a "Quality Assurance Committee" and to therefore be subject to protection under section 8.1 of the *Evidence Act*. HCCSJ had developed and adopted a specific policy for carrying out peer review of physicians. In the absence of the adoption of a new policy within Eastern Health, that policy continued to apply to those

[456] Exhibit P-0695
[457] Exhibit P-0686
[458] Exhibit P-1811
[459] Exhibit P-1813
[460] Exhibit P-1815
[461] Exhibit P-0047

circumstances. HCCSJ had not developed a similar policy for protected quality assurance activities but had in the past obtained such reports and reviews and had regarded them as having the protections afforded by the *Evidence Act*.[462]

358. In this case Williams had made a request to Ms. Predham for preparation of quality assurance terms of reference.[463] Ms. Predham prepared terms of reference that she sent to Dr. Williams and Dr. Cook.[464] Dr. Cook sent them on to Dr. Banerjee on September 13, 2005,[465] and to Ms. Wegrynowski on September 14, 2005.[466]

359. Dr. Banerjee completed his review on September 16, 2005, and gave an exit interview. Dr. Cook recorded him saying that the service provided was comparable to the rest of Canada and in some areas above average. Dr. Banerjee identified issues including concerns about tissue fixation, the need for a highly specialized IHC service with dedicated technologists, the need for proper documentation of the work performed including the antigen retrieval methodology and the need for sub-specialization of pathologists with an adequate compensation package.[467] Dr. Cook testified that he had reviewed slides from

[462] Evidence of Heather Predham, October 18, 2008, page 101 line 25 to page 102 line 17
[463] Evidence of Dr. Robert Williams May 21, 2008, page 88, line 3 to page 93, line 25
[464] Exhibit P-1283
[465] Exhibit P-1985
[466] Exhibit P-1747
[467] Exhibit P-2148

original ER/PR tests with Dr. Banerjee, and that Dr. Banerjee had commented to him that he had seen slides from many other institutions across Canada and, in his opinion, the slides from St. John's were "in the middle of the pack".[468]

360. Dr. Williams testified that at the exit interview Dr. Banerjee said that,

> He had reviewed a number of other labs in various jurisdictions and he felt that our lab was performing in the middle of the pack, that's what he said. Some labs are better and some labs are worse. He went on to give us then some information on some labs that he had seen. He didn't name them by lab, but some of the issues that had arisen in this particular area.[469]

361. Dr. Williams, Dr. Cook, Dr. Laing, Ms. Predham and Mr. Gulliver attended the exit interview with Ms. Wegrynowski on September 22.[470] Ms. Wegrynowski had come to St. John's from Ontario where all laboratories are licensed and accredited by the Quality Management Program for Laboratory Services (QMPLS) and have been for some time. Mount Sinai, which operates a research laboratory in addition to its clinical service is also accredited by the College of American Pathologists.

362. Ms. Wegrynowski had come to Newfoundland anticipating that she would perform an audit of the IHC laboratory in a manner similar to that which would be

[468] Evidence of Dr. Donald Cook, July 4, 2008, page 259, lines 8-17
[469] Evidence of Dr. Robert Williams, May 20, 2008, page 149, line 18 to page 150, line 11
[470] Exhibit P-0596
Exhibit P-1737

done at an Ontario laboratory and for this purpose brought CAP checklists. After the first day of her visit she determined that the relative lack of formal policies, procedures and documentation of processes and quality control activities made it more appropriate for her to take a general approach. In her exit interview she identified a number of issues similar to those raised by Dr. Banerjee and additional issues related to technical testing performance, quality control and laboratory policies, procedures and documentation.

363. Based on the information obtained in the exit interviews and on observations made by Dr. Cook and Mr. Gulliver themselves, they had on October 13 prepared a report supporting their request for the funding needed to implement many of the improvements that were ultimately described in the reviewer's reports.[471]

364. Dr. Banerjee's report was received on October 17, 2005, and copies were distributed to Dr. Cook, Dr. Williams, Mr. Gulliver and Ms. Predham.[472] Ms. Wegrynowski's report was submitted on November 9, 2005, and distributed to the same persons.[473] A primary purpose of the reviews was to evaluate the testing for ER and PR before reinstating that suspended service. The reports

[471] Exhibit P-0121
[472] Exhibit P-0046
Exhibit P-1323
[473] Exhibit P-0047
Exhibit P-1763

identified many deficiencies and made many recommendations which it was recognized would have to be addressed before testing could be reinstituted.

365. There was some limited dissemination of the detailed findings from the reports within the organization, such as by Dr. Cook reading a copy of Dr. Banerjee's report to the pathologists, but because of the confidentiality associated with reviews of this type, circulation of the documents was controlled and discussion of the explicit findings was confined to a small group. The facts that the external reviews had been done and who had done them was freely disclosed, both to Government and publicly, such as in an interview given by Dr. Williams on VOCM radio on October 25, 2005.[474]

366. On November 23 Dr. Williams asked Dr. Cook and Mr. Gulliver to prepare a spreadsheet capturing the recommendations from both review reports in order to track their implementation.[475] The spreadsheet was updated periodically to track the progress of implementation of the recommendations.[476]

367. In February 2006 Dr. Williams and Dr. Cook invited Dr. Banerjee and Ms. Wegrynowski to return to St. John's to assess the progress that had been made

[474] Exhibit P-0345, page 26
[475] Exhibit P-0909
[476] Exhibit P-0277
Exhibit P-1757

in the IHC laboratory.[477] Ms. Wegrynowski conducted a follow up visit on March 31, 2006[478] and delivered a report on May 2, 2006.[479] Dr. Banerjee visited on April 25, 2006[480] and his report followed on May 21, 2006.[481] They both reported on many important improvements, such as the hiring of pathology assistants, the appointment of a pathologist as technical director for the IHC lab and the enrolment in external proficiency testing. Ms. Wegrynowski reiterated many of her recommendations and added specifics to others. Dr. Banerjee reported that most of his recommendation had been implemented or were in progress. His recommendations included that "ER and PR tests may be resumed immediately".

(xi) National Initiatives

368. By the fall of 2005, Mr. Tilley had recognized that there was a role for a national initiative to address the lack of standards and interlaboratory variability for ER/PR testing that had was discussed in the international medical literature The need for it was also suggested by the informal survey carried out by Dr. Cook and the Quality Department staff in August. Mr. Tilley undertook a number of initiatives:

[477] Exhibit P-2052
[478] Exhibit P-2148
[479] Exhibit P-1367
[480] Exhibit P-0944
[481] Exhibit P-0049

(a) He contacted Robert Bell, the CEO of the University Health Network in Toronto,[482]

(b) He contacted Dr. Pritzker at Mount Sinai Hospital,[483]

(c) He contacted Philip Hassen, the Chief Executive Officer of the Canadian Patient Safety Institute,[484]

(d) He encouraged Dr. Cook to make national standards for immunohistochemistry an issue for the Canadian Association of Pathologists, which Dr. Cook did by contacting the President of that organization, Dr. Banerjee.[485] Dr. Cook was successful and Dr. Banerjee placed the issue on the agenda for the November, 2005 meeting of the Association.[486] After the November meeting, Dr. Cook reported that Canadian Association of Pathologists and the Canadian Association of Oncologists had committed to promote the development of a set of national standards. At the next meeting of the Canadian Association of Pathologists, Dr. Emina Torlakovic presented her proposal for what has become the cIQc Proficiency Testing

[482] Exhibit P-0364
[483] Exhibit P-1306
[484] Exhibit P-1307
Exhibit P-0663
[485] Exhibits P-0659 and P-0662
[486] Exhibits P-1332, P-0679 and P-0682

Program.[487] Dr. Torlakovic testified at the inquiry and described efforts that are underway to develop national standards and implement an effective proficiency testing program through cIQc.

(xii) 2006 Media Coverage

369. At the beginning of 2006, Eastern Health was concentrating on completing the retesting and paneling process and on getting information into the hands of treating physicians and patients. It was felt that there was little new information to be given to the media until that process was complete and an analysis of the results of the retesting had been performed.

370. There were a number of media inquiries to the Eastern Health Communications staff in late January, 2006. Information was given but no interviews were provided.[488]

371. Beginning in February, media inquiries began to come in concerning a law suit that had been filed against Eastern Health the prior fall. According to the established practice of not commenting on matters that were in litigation,

[487] Exhibits P-0412 and P-2273
[488] Exhibits P-1080, P-1082, P-1083, P-1084 and P-1089

comment was declined. In response to at least one inquiry, the journalist was referred to the lawyer representing Eastern Health.[489]

372. One journalist, Mark Quinn, from CBC, had filed an access to information request for material concerning the ER/PR retesting. On May 17, an offer was made to him to bring a group together to brief him once he had reviewed the access to information materials.[490]

373. In July, 2006, the class action litigation was started and more media inquiries were received regarding it.[491] The Independent published an article on July 30, 2006[492] that prompted a request for a briefing note from the Department of Health and Community Services.[493] Ms. Predham prepared a document that was an update of a memo she had done earlier concerning the status of the DCIS and retro-converter cases and added brief comment on the two legal claims.[494] By August 11, 2006 Ms. Predham had prepared another briefing note for government, this time with a breakdown of the results of the retesting.[495] Marilyn McCormack was assigned within the Department of Health and Community Services to prepare a briefing note in government's standard form and

[489] Exhibits P- 1094, P-1095, P.1096, P-1097, P-1098, P-1101 and P-1114
[490] Exhibit P-1127
[491] Exhibits P- 1149, P-1152 and P-1153
[492] Exhibit P-2850
[493] Exhibits P-0813 and P-0191
[494] Exhibit P-3037
[495] Exhibit P-1447

incorporated information from the two documents that had been prepared by Ms. Predham. She called Ms. Predham for more information. Ms. McCormack was new to the issue and unfortunately not all information in the final note is accurate. Ms. Predham, although described on it as an author, did not draft the document and was not given a copy.

374. In August, the CBC National Radio Program "The Current" prepared a story and invited comment from Eastern Health. The timing was bad with key people on vacation[496] but a written statement was prepared, reviewed by Mr. Tilley at home, and provided to the program.[497]

(xiii) The December 11, 2006 Media Briefing

(a) Preparation

375. By early fall, Susan Bonnell was promoting the idea of providing the press with a briefing on the results of the retesting process. The principal impediment to doing that at that time seemed to be the capacity to complete an analysis of the retesting statistics and prepare presentations.[498]

376. By November 20, 2006, a presentation had been organized and delivered by Dr. Denic, Dr. Elms, Dr. Cook and Dr. Carter for physicians, laboratory staff and

[496] Exhibit P-0420
[497] Exhibits P- 1157, P-1155, P-1159 and P-3171
[498] Exhibit P-0420

other interested persons in the lecture theatre at the medical school in the Health Sciences Centre and also made available remotely at locations in other health care institutions in the province.[499]

377. The next day, November 21, a shortened presentation was given to the Eastern Health Executive Team.[500]

378. On November 22, 2006, a CBC reporter contacted the Department of Health and Community Services expressing frustration about being unable to get an interview with someone at Eastern Health about the status of the retest results.[501] A request then came from the Department to Eastern Health for a briefing for Minister Tom Osborne.[502] That meeting took place on Thursday, November 23. Either shortly before or at the meeting the Minister had been provided with a briefing note with a summary of the retesting results, which was substantially the same as the information provided to the Department in August.[503]

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[499] Exhibit P-1405
Exhibit P-1190
[500] Exhibit P-0774
[501] Exhibit P-0176
[502] Exhibit P-0177
[503] Exhibit P- 3053
Exhibit P-1407
Exhibit P-0125, page 42

379. Key information presented was that a total of 2760 cases had been reviewed from 1997 to August of 2005. 939 had been retested. 176 of those were for specimens from patients known to be deceased. Out of that 176, 101 had been retested and results received but no action had been taken to review them or communicate the information to the families.

380. The remaining 763 cases were divided into categories as follows:

- 433 had no change in test result and no change in treatment,
- 13 had no change in results but did require a change in treatment because the definition of negative has changed from below 30% to below 10%,
- 213 had a change in results but did not require a treatment change, and
- 104 had a change in results and did require a treatment change.

Three of those categories were further subdivided.

381. Discussion at the meeting included that the most significant statistic was the number of patients who had a change of treatment. Minister Osborne noted that fact on his copy of the briefing note[504] and added together 2 of the categories

[504] Exhibit P-0314, page 10

with 104 and 13 patients respectively for a total of 117 patients who had changes in treatment.

382. At the time of that meeting the content of the planned media briefing had not been determined. It was not until shortly before the December 11 briefing that decisions were made within Eastern Health about what numbers would be released.

383. A key issue considered among those preparing for the December 11 media briefing was whether to calculate and present a rate of error for the original tests. Another was how much information could be disclosed about causative factors with litigation outstanding over that issue.

384. An “error rate” had not been calculated. The testing had been undertaken as a clinical exercise meant to identify patients who could benefit from changes and treatment, not as a research exercise. The objective was not to gather data that would allow a scientifically accurate rate of error to be calculated. What was therefore available in December, 2006 was a set of data which could not easily be used for that purpose. The two simplest alternatives were to divide the number of changed test results by the number of samples tested, or to divide the number of changed results by the total number of tests originally performed.

385. The problem with the first approach was that it resulted in a rate of change for the tests that were originally negative, which were the ones suspected to have been incorrectly performed in the first place, that would not be representative of the total population of tests. The problem with the second approach was that not all the original tests had been retested, so it would not be correct to include the retested negative tests with the positives that had not been retested.

386. Further complications were that not all the negative samples for deceased patients had been retested, and those that were had not been reviewed in the way that the retests for living patients had been. There were also the DCIS cases to take into account where Mount Sinai had not done retests, and those that had changes in treatment not because the test result had changed but because a 10% cut-off was being applied instead of the 30% cut-off in use when the test was originally performed. A proper study with the objective of finding a rate of testing error would have had to have been designed to take into account and eliminate these factors in order to obtain a valid result.

387. Ms. Predham did attempt to do her own calculation of an error rate, taking some of these factors into account.[505] Ms. Predham testified that after she sent that calculation to Ms. Bonnell and it was circulated to Dr. Howell, she had a telephone conversation with them both in which the difficulties of calculating a

[505] Exhibit P- 1083

rate of error were recognized and in which Dr. Howell suggested that the important number, consistent with the original objective of the retesting, was the number of treatment changes and that was what should be released instead of a rate of error.[506]

388. After consulting with Dr. Denic, Ms. Predham, Mr. Boone and Dr. Howell, Ms. Bonnell circulated revised copies late on Saturday, December 9.[507] She said that the most significant change from the original material was the removal of reference to a "rate of error". A copy also went to Mr. Tilley, who had not been involved in preparation for the technical briefing.[508]

389. Questions regarding an error rate had been coming from the media representatives periodically during 2006 but it was not a question that was being specifically asked of Eastern Health by individual patients.[509] Calculation of an error rate, while of interest to the public at large, was not a matter of clinical significance in the treatment of the affected patients and neither was it something that needed to be determined in order to put into effect appropriate changes to ensure the future quality of the testing results.

[506] Evidence of Heather Predham, October 22, 2008, page 146 line 16 to page 147 line 4
[507] Exhibit P-0184
[508] Exhibit P- 0189
[509] Evidence of Susan Bonnell, June 3, 2008, page 101, line 1 to page 102, line 4

(b) The Briefing

390. At the media briefing, the journalists were explicitly told that there were restrictions on the information that would be provided to them. An important reason given for that was that litigation was underway. The accepted practice was not to speak about matters that were "before the Courts", and holding this media briefing was an exception to the way such matters had been handled previously. So, while the media was presented with information about changes that had been made in the Laboratory Medicine Program to ensure the quality of the work done, there was no discussion of whether what had happened amounted to "error".

391. In fact, those involved in this issue within Eastern Health believed that they were unable to accurately identify what the causes of the test failures were.

392. The most direct statement on reasons for test failure was contained in Dr. Banerjee's first report. While it is tempting to treat his review as a conclusive determination of the factors causing ER/PR results to be different when retested, it should be remembered that Dr. Banerjee was primarily reviewing the Laboratory Medicine ER/PR testing as it existed at the time of his visit, that his visit was for a period of 2 days only and that the conclusions he stated regarding reasons for test failure were based on his review, with Dr. Cook, of original slides

for the specimens retested at St. John's in June and July. Those specimens were drawn mostly from 2002 and would not be representative of the quality of work done between 1997 and 2005.

393. In addition to the work done by Dr. Banerjee, Dr. Cook, Dr. Denic and others also had the benefit of the literature research that had been done and the surveys of practices elsewhere in Canada, all suggesting that there was a larger problem than a simple failure to perform some aspect of the test correctly in the laboratory in St. John's. What was known was that there were a wide range of factors, any one of which could have contributed to the failure of an original. Not all of those factors would necessarily apply in every patient's case and without in depth case by case investigation, it was impossible to tell any individual what had gone wrong in their case. Just as for the question of deciding on an error rate, there was no internal consensus on how to answer the question "what went wrong?"

394. Regarding the results of the retesting program, the media were told that 117 patients had treatment changes recommended to them by the physician panel.[510] This was not a statement that only 117 patients had been or might have been

[510] Exhibits P-1654 page 20 and P-0196 page 2

affected by retesting. The media representatives were advised that they were not being the total number of tests that had changed.[511]

395. Although the existence of litigation was given to the media as a reason for limiting the information disclosed to them,[512] Ms. Predham testified that this was not based on any advice from legal counsel and that the issue of what information could or could not be disclosed to the media was not discussed with legal counsel.[513]

396. It had at one point been planned to brief Mr. Peter Dawe, the Executive Director of the Newfoundland and Labrador Branch of the Canadian Cancer Society in advance of the media briefing.[514]

397. Mr. Dawe was briefed by Dr. Oscar Howell on the afternoon of December 11 following the meetings with the media. Ms. Bonnell testified that based on media interviews given by Mr. Dawe, shortly before that date,[515] there was some

[511] Exhibits P-1410 page 1 and P-0825 page 1
[512] Evidence of Susan Bonnell, May 30, 2008, page 346, line 8 to page 347, line 10
[513] Evidence of Heather Predham, October 22, 2008, page 173, line 9 to page 184, line 8
[514] Exhibit P-0178
[515] Exhibit P- 0180

concern that if he was given an advance briefing, then he might disclose information to the media prior to Eastern Health's media briefing.[516]

398. The information provided at the media briefing, with comment that not all information available to Eastern Health had been disclosed, was reported extensively.[517]

(xiv) Public Disclosure of the Number of Changed Results and the Events that Followed

399. On about February 15, Mark Quinn from CBC sent Eastern Health an access to information request.[518] The request was for the original test results and the retest results for all patients whose ER/PR specimens were retested. Eastern Health replied on March 16, 2007 that this was considered personal information and would not be disclosed.[519] The letter came from Marian Crowley of the Quality Department who was the access to information coordinator for Eastern Health. After discussing the matter with Ms. Predham and making contact with legal counsel, the letter to Mr. Quinn included the statement that,

> For your information, an affidavit outlining a summary of the results of the ER/PR testing has been filed in the Registry of the Supreme Court of

[516] Evidence of Susan Bonnell, June 2, 2008, page 9, line 15 to page 12, line 3
[517] Exhibit P-0185 page 1
[518] Exhibits P-3467 and P-1567
[519] Exhibit P-1567

Newfoundland. This is available to the public; the case number is 200601T2966CP.[520]

400. On May 15, 2007, CBC reported the number of changed test results from the affidavit.[521] The story was immediately picked up by other media.[522] The reports made direct comparisons between the statement originally made in the fall of 2005 that it might be expected that 10% of the test results would change and a conclusion, based on the numbers reported in the affidavit, that 42% of the results had changed.

401. In fact, 10% of all tests performed would have equaled 276, based on the total number of tests reported in the affidavit.[523] The 42% figure was arrived at by dividing 317, the number of ER/PR tests reported to be different when retested, by 763, the total number of retests for which results were available. On the face of it, 276 predicted change results does not compare unfavorably with 317 actual changes. Some media reports, however, portrayed the actual error rate as 42% which was well in excess of the 10% said to have been reported by Eastern Health. This is despite the fact that Eastern Health, in December, 2006, had deliberately chosen not to present a rate of error.

[520] Exhibit P-3467 and P-3179
[521] Exhibit P-0106, page 3
[522] Exhibit P-0011
[523] Exhibit P-2543, page 5

402. For example, a CBC news story on May 16 stated that,

> Eastern Health said in December that 763 breast cancer patients who had been given hormone receptor tests since 2005 could expect a 10% error rate. The tests determine what kind of treatment for breast cancer a woman receives. On Monday, CBC news revealed that 42% of the test results, involving 317 patients, were wrong. Court documents show that Eastern Health knew in December that the margin of error was higher than was expected".[524]

403. With the class action certification hearing to take place within two weeks,[525] Eastern Health's initial response was to refuse any comment to the media.[526] The government then came under fire from the opposition which issued a press release stating that litigation was more of a concern for the government than patients' health.[527]

404. On May 17, 2007, Deputy Minister John Abbott was called upon to make a presentation on the issue to the Cabinet.[528] The result was that Eastern Health was then asked to hold a public briefing, to be followed by a briefing for members of the House of Assembly.[529]

[524] Exhibit P-0433, page 7
[525] Evidence of George Tilley, May 13, 2008, page 343, line 1 to page 344, line 11
[526] Exhibit P-1213, P-1214, P-1215, P-1216
[527] Exhibit P-0824
[528] Exhibit P-0799
[529] Exhibits P-1222 and Exhibit P-0884

405. Mr. Tilley and staff at Eastern Health worked late into the evening on May 17[530] and at 12:30 p.m. the next day, Mr. Tilley held a press conference which received national media coverage.[531] A statement of statistics with all results from the retesting process was released and Mr. Tilley made a statement apologizing for the confusion resulting from Eastern Health not having released that information in December, 2006.[532] Mr. Tilley gave extensive media interviews following the news conference.

406. In his statement, Mr. Tilley also said

> At no time did Eastern Health withhold any personal information from any of the patients impacted by our decision to retest for estrogen and progesterone receptors, or ER/PR.
>
> It is important for everyone to know that we contacted each and every patient who was affected by the ER/PR test review, making sure they received all the information and support they required".

407. On May 24, an article published in the Globe & Mail Newspaper included a statement to the effect that once the problems had been discovered in 2005, "breast cancer patients and the public were told nothing". The article and that statement attracted the attention of Mr. Tilley and the personnel in the Department of Health and Community Services. Mr. Tilley was concerned that it

[530] Exhibit P- 0831
[531] Exhibit P- 0110
[532] Exhibit P- 0443

left the implication that Eastern Health had chose not to tell patients about their retest results.[533] Letters were prepared to go to the Globe & Mail from both Mr. Tilley and Mr. Wiseman.[534] In Mr. Tilley's letter, he said:

> The most concerning point to me is his assertion that we told breast cancer patients and the public nothing. This is not accurate. A core team of health care providers were brought together to make personal contact with every single patient whose original tissue we were sending to Mount Sinai for estrogen receptor testing. We also did numerous media interviews and posted information on our website and placed advertisements in local newspapers. Furthermore, as the test results were returning to us, we made sure that every individual had their personal information, whether there was a change from their original test result or not.

408. The purpose in making the statement that all patients had been contacted was to counter the published statements that suggested that none had been. Mr. Tilley did believe his statement that all patients had been contacted to be true. But, had a more thorough inquiry been made within the organization about that issue, it is likely that statement would have been qualified to recognize that there were some patients who had not been successfully contacted.

409. On May 24, Dr. Ejeckam's memo from June 23, 2007 was sent by Dr. Oscar Howell to Deputy Minister Abbott.[535] It quickly found its way to Minister Wiseman and then to the Premier who released it in the House of Assembly and to the

[533] Evidence of George Tilley, May 13, 2008, page 339, line 3 to page 340, line 14
[534] Exhibits P-0453, P-0216, P-1256
[535] Exhibit P- 0111

media. In response to the resulting media attention, Eastern Health released the April 4, 2003 and May 2, 2003 memos and minutes of the Surgical Pathology Review Committee at a news conference called for that purpose.[536]

410. On June 2, 2007, Eastern Health published newspaper notices including the statements that, “an impression has been left with the public that patients affected by the ER/PR review were not contacted or given their own health information. This is not true”, “we called all patients whose samples were being retested,” and, “we informed all patients and their doctors of their individual test results”. [537]

[536] Exhibit P-1595
[537] Exhibit P-1268, page 2

H. The Commission of Inquiry, the Task Force on Adverse Events and Questions about Patient Contact

411. By the end of June 2007, other events included the announcement of this Commission of Inquiry by government, the announcement of the Task Force on Adverse Health Events to be conducted by Robert Thompson and the departure of Deputy Minister Abbott from government following his refusal of a transfer from his Deputy Minister position.

412. Following the publication of Eastern Health's newspaper advertisement, questions were raised in the House of Assembly about its accuracy concerning contact with all affected patients.[538] Mr. Thompson began making inquiries and in an exchange of email messages involving Mr. Tilley and Ms. Predham, there was discussion of the fact that the efforts to telephone all affected patients in October, 2005 and to notify all patients, through their physicians, of changed test results had not resulted in every patient being contacted.[539]

413. At the same time that these events were unfolding through May and June of 2007, Eastern Health and government were also publicly engaged in the review of the work of a radiologist on the Burin Peninsula, heightening the public pressure on both during this period.

[538] Exhibit P-0230
[539] Exhibit P-0013, P-0014, P-0236, P-1063, P-1272 and P-1273

414. On July 9, 2007, Mr. Tilley resigned his position as CEO of Eastern Health and was replaced on an interim basis by Louise Jones, who continues to hold that position.

(i) NLCHI Database Review

415. The Newfoundland and Labrador Centre for Health Information (NLCHI) was engaged through Robert Thompson to construct a database of retest results and patient contact information. The project began with a "scoping document" on July 6, 2007, setting out the original plan for completing the task.[540] It was thought that the work could be completed by about September, 2007, however, the complexity of both the original retesting project and of the collection and analysis of data from the four health authorities made it impossible to complete it within that time frame.

416. Dr. Reza Alaghenbandan worked with Mr. Gulliver and Ms. Predham at Eastern Health to use original source records to extract the information needed. Materials were obtained from the other health authorities and from Mount Sinai. As time went on, various requests were made by NLCHI staff for more information and to resolve discrepancies as they were uncovered.

[540] Exhibit P-3563

417. As a result of the process, a number cases of negative ER/PR tests that had not been retested and a number of patients who had not been contacted were identified and action was taken. Reports providing statistical data on retest results and patient contact were prepared and presented to the Commission of Inquiry and the Minister of Health and Community Services has periodically made public announcements with updated information as the work has progressed.

418. The total number of cases sent for retest has been determined, as a result of the NLCHI review, to be 995. The total number of tests, since some cases had more than one block tested, was 1,101.[541] The NLCHI reports present tables sorting the retest results by various criteria including by applying different percentage cut-offs for determination of whether tests were positive or negative but do not take clinical treatment considerations into account.

(ii) New Patients Identified for Retesting

419. The original list of ER/PR tests with negative results was developed in a methodical way within Eastern Health. As described above, the Meditech Laboratory Module database was searched to identify all patients who had had ER/PR tests performed. For those tests originating in St. John's hospitals, the

[541] Exhibit P-3565

pathology reports were printed and manually reviewed to identify those that had produced negative results. At that time, Clarenville and Carbonear had become part of the Eastern Health organization, however, their laboratory operations and medical records systems had not been integrated with those in St. John's. Dr. Baker, the pathologist in Carbonear, was therefore asked by Dr. Cook to conduct his own review of his records to identify patients with negative test results. This initial review was delegated by him to laboratory staff. In September 2007 Dr. Baker was asked by Mr. Gulliver to get together the ER/PR pathology reports for review by Dr. Alaghehbandan. Dr. Baker then reviewed them and discovered that 10 cases that had results between 10% and 30% before the cut-off date of January 1, 2001 had been erroneously put in the positive group and had not been retested.[542]

420. The Clarenville laboratory had been sending all ER/PR tests to Mount Sinai since 1999.[543] The pathologist there reviewed their records from before that date to identify cases for retesting. Pathologists in the other authorities undertook their own reviews, depending upon the type of records they had available. Details of those reviews were presented recently in material provided to the Commission from Mr. Thompson's office.

[542] Evidence of Dr. Gary Baker, September 5, 2008, page 247 line 19 to page 251 line 7
[543] Exhibit P-1936

421. While these measures were believed to have produced a complete list of results at the time, it has been discovered that there were cases, in addition to the ten from Carbonear, that were missed. As a result of the extensive publicity around this issue, there have been patients who have “self identified” by calling the patient information line made available by Eastern Health or who have made contact by other means. By early 2008, the number of such cases was small, however as the Commission hearings continued, the number increased. For those cases originating from the St. John’s hospitals, the reason they were not picked up in 2005 is that the order for the ER/PR test had not been posted in the Meditech system, a fact that was previously unknown and had not been anticipated. Consequently, the computer search did not identify those cases and their pathology reports were not printed and reviewed.

422. Two other potential sources of data for identification of patients who had ER/PR tests performed might have been the Cancer Registry at the Cancer Centre and the computer records of tests run on the Dako Autostainer.

423. Ms. Predham had attempted to use the Cancer Registry records early in the process but discovered that the historical data was not complete. Sharon Smith,

the Program Director for Cancer Care has testified concerning the history of the Cancer Registry and the efforts being undertaken to improve its quality.[544]

424. The Dako Autostainer was disposed of without preserving any data that may have been recorded on its computer. In theory, every specimen for which an ER/PR test was run might have been recorded on that system and that data might have been a useful secondary check of the Meditech information. In 2005 however there was no reason to doubt the completeness of the Meditech search and there would have been no reason to take any steps to look for the Autostainer and determine if any such information was still available. The data that was available is now in the possession of the Commission.

425. The only other method that has been identified to conduct a search for any remaining missing cases is to electronically search the text of all pathology reports in the Laboratory Module of Meditech at Eastern Health. Because the reporting of ER/PR testing had not been standardized and because variations in terminology have been used by different pathologists throughout the period under consideration, only the broadest search terms can be used.[545]

[544] Exhibit P-3567
[545] Exhibit P-3555

426. In August, 2008, Dr. Alaghehbandan from NLCHI and pathology manager Mr. Dyer, conducted tests of search strategies.[546] By this time, specimens had now been sent to Mount Sinai for retesting for 10 newly identified patients.[547]

427. The Department of Health and Community Services has agreed to provide the health authorities with assistance with the additional resources needed to undertake this review and it has now begun. The search term “breast” will be used. The review will involve manual examination of what was estimated to be 8,000 pathology reports from within Eastern Health alone. A comprehensive database of all test results, not just the negative test results which have previously been catalogued, will be created during that process. The review is being conducted in cooperation between NLCHI and Eastern Health and it is anticipated that it will take several months to be completed.

428. Early in the public hearings breast cancer patient Mrs. Daphne Coffin testified. Hers was a case that had original test results with an ER score of 23% and PR 0% in September 2001, so her test did not fall within the selection criteria for the retesting program. She considered hormonal therapy in 2002, but opted not to take it. One factor considered when that decision was made was the low percentage of stained cells. She saw a physician at the Cancer Clinic in March

[546] Exhibit P-3534
[547] Exhibit P-3648

2006 who decided to send a consult for a retest. The result was ER 95% and PR <1% and she then chose to try hormonal treatment.

429. This case prompted a reconsideration by Eastern Health of whether there are other “weak positive” cases that need to be reviewed. Expert advice from outside the province was sought in late spring of 2008 and a decision has now been made to proceed with a review that is being done in collaboration with NLCHI. It is anticipated that it will take three to six months to complete.

(iii) Patient Communication Challenges

430. Managing contact with patients through the retesting process proved to be a complex task with unanticipated difficulties. A key lesson learned from the exercise is the necessity of applying sufficient resources and assigning people with the dedicated time and appropriate skills and providing them with the information management supports they need at the beginning of the process.

(a) Telephone Contacts

431. By October 20, 2005, calls began to be made to patients to inform them that their specimens would be retested and, in some cases, to tell them that their retest results had been confirmed to be negative. Ms. Predham had constructed a database on her computer for patients whose results were to be retested. This

included the cases identified from St. John's hospitals and those sent in by other authorities. Calls were made from the Quality Department by Ms. Predham and others to the Eastern Health patients. The counterparts at Central and Western Health were asked to initiate their own calls to those patients that had been identified for retesting within their jurisdictions.

432. There were a number of difficulties encountered and not all patients could be contacted despite repeated attempts. That fact was reported through the fall of 2005 by Ms. Predham.[548] Attempts to contact patients by telephone to inform them that their samples would be retested continued into 2006 but were eventually dropped for the small number of patients who could not be located.

433. It appears that there was also a misunderstanding between personnel at Eastern Health and Central Health such that not all patients originating from Central Health were contacted by telephone.[549]

(b) Coordination of Retest Results Returned from Mount Sinai

434. As test results were returned from Mount Sinai, those that were confirmed negative were contacted by telephone by staff of the Quality Department and the cases with changes in test results had to be prepared for presentation to the

[548] For example, Exhibits P-0095 and P-1090
[549] Exhibits P-2915, P-2932, P-2914, P-1350 and P-2919

Physician Panel. Ms. Predham acted as the coordinator for these activities and was sent the spreadsheets with retest results from Dr. Cook when he received them from Dr. Mullen.

435. One complication with this process, that Ms. Predham was not initially aware of, was that oncologists and other physicians would from time to time send requests for retesting of ER/PR specimens to Mount Sinai as "consults". Some of these requests were for people whose test results did not meet the retesting criteria used to generate the original list and others were used to prioritize retests for patients who were under active care. These consults were reported from Mount Sinai individually and not on the spreadsheets of retests results that were forwarded to Dr. Cook. Not all of these consults found their way to Ms. Predham, and they were therefore not included in the numbers that she was reporting to others. Some of them were discovered during the NLCHI review.[550]

(c) Communication of Panel Recommendations

436. The method used to communicate panel recommendations for patients whose test results changed was to send letters to the most responsible physician identified from the patient's record. This approach was consistent with the manner in which test results are normally communicated. Laboratory test results

[550] Evidence of Heather Predham, October 21, 2008, page 315 line 5 to page 316 line 24

are not sent directly to patients. They are sent to the physicians who order them and the physicians are responsible to act on the results and communicate them as needed to their patients. In addition, the ER and PR scores reported by Dr. Mullen for specimens originating from St. John's hospitals were added to the patients' pathology reports by Dr. Cook as addenda, and those reports would then in the normal course be printed for delivery to the physicians who had received of the original reports. Dr. Cook communicated with his counterparts in the other Authorities to advise them of this process.[551]

437. Cases eventually began to come to light, however, where it was learned that the physician to whom the panel letter was directed was no longer available or no longer actively caring for the patient. Many patients had been discharged from care at the Cancer Clinic and were now being followed by general practitioners. Some had moved out of the province.

438. In August of 2006, Nancy Parsons and the Quality Department reviewed all the panel letters that had been sent to physicians and created lists of the letters that needed to be followed up to ensure that physicians had communicated the

[551] Exhibit P-1091

information to their patients.[552] Ms. Parsons faxed lists to the staff at the Cancer Clinic.[553] She also faxed lists to Western Health[554] and to Central Health.[555]

439. Ms. Parsons received responses from many of the physicians at the Cancer Clinic and some information from the other Authorities. She attempted to contact community physicians by telephone herself but encountered difficulties either reaching the physicians by telephone or getting physicians and their staff to respond to her requests. This initiative was eventually abandoned without completing the verification of physicians' contact with their patients.[556]

440. Eastern Health, in conjunction with the NLCHI review, conducted a quality review of physician contact with patients during the summer of 2008. All contacts were verified and there are now no remaining cases outstanding where patients whose test results had changed and whose physicians were informed by letter have not been informed of those results.

(d) Deceased Patients

441. When cases were being selected for retesting at Mount Sinai in the summer of 2005, an attempt was made to identify patients who were deceased by using

[552] Exhibit P-2854
[553] Exhibits P-1177, P-1178, P-2856, P-2857, P-2858 and P-2859
[554] Exhibits P-2860 and P-2861
[555] Exhibits P-2862 and P-2928
[556] Evidence of Nancy Parsons, September 24, 2008, page 240 line 1 to page 253 line 11

data available from the Cancer Registry. A number of cases with negative results were put aside to be dealt with after living patients' samples had been retested.

442. When calls were made to patients beginning on October 20, 2005, the Quality Department staff soon began to encounter cases where patients had died but their names were still on the retest list. By the time the November 23, 2006 briefing note was prepared for the Minister of Health and Community Services, it was known that 176 patients were deceased and that samples had been retested and results received for 101 of them. In a few cases, there had been contact from patients' family members and the results had been given to them. In most cases, there had been no communication with representatives of the deceased patients.

443. Dr. Cook had raised the issue of what to do with the results for deceased patients in May, 2006 with Dr. Williams.[557] An ethics consultation was arranged to obtain advice on how to deal with this issue. It was facilitated by Dr. Rick Singleton on June 20, 2006.[558] The advice from the consultation was that families had a negative right to access the information about their deceased family member, meaning that the information should be available to them if they wanted it but that

[557] Exhibit P-1122
[558] Exhibit P-0782

the choice to seek the information should rest with the family. It was recommended that there should be a public announcement that the information was available and that it would be disclosed upon request. Action on this recommendation was deferred until results for all living patients had been dealt with.

444. By May, 2007, no further action had been taken. In the public statements made by Mr. Tilley at that time, he confirmed that Eastern Health would retest all specimens from deceased patients.[559] Arrangements for completing this retesting project began on May 31, 2007,[560] however Mount Sinai was unable to complete the testing until late 2007.[561]

445. In the meantime, there was considerable discussion within Eastern Health about how to provide information to families of the deceased in response to anticipated questions about whether the incorrect results would have affected the outcome of their family member's disease. Due to the workload placed on oncologists in the Cancer Program, they were unable to commit to a review process for these results. Consideration was given to finding an oncologist from another province to conduct a review, but this proved impractical. Eventually, it was decided to make the results available and to deal with family requests for additional

[559] Exhibit P-0446
[560] Exhibit P-2680
[561] Exhibit P-3198

information on a case by case basis. Cancer Program physicians have been available to speak with families when requested.

446. On February 22, 2008, Eastern Health began the process of publicly informing families that retest results were available by issuing a press release and participating in a news conference.[562] This continued into April with public service announcements placed in newspapers throughout the Province and in a national newspaper, and on local radio in Newfoundland and Labrador.[563]

447. Inquiries from families were directed to Sharon Smith, the Program Director in the Cancer Program, who has a nursing background in oncology, who had assistance from the Quality Department. They dealt with inquiries that were within her scope of practice and arranged for callers to speak with physicians at the Cancer Program when needed.

[562] Exhibit P-3227
[563] Exhibit P-3279

I. The Special Cases

(i) DCIS Cases

448. DCIS refers to ductal carcinoma in situ, a particular type of non-invasive breast cancer diagnosis.

449. The practice at Mount Sinai, which has been adopted at Eastern Health[564], was to not perform ER/PR tests on malignancies with a DCIS diagnosis. Dr. Mullen, who reviewed all the retest slides at Mount Sinai and reported them to Dr. Cook, assessed a number of cases that had ER/PR tests originally performed in St. John's, to be DCIS, so ER/PR tests were not carried out or reported to St. John's. In some cases, this was because the particular block that had been sent did not contain the portion of the tumor that showed invasive characteristics. For those, another block was identified and sent and the test was conducted and reported. However, in a limited number of cases, this process resulted in the discovery of a misdiagnosis.

450. Three such cases originated from patients treated in St. John's. Other cases of possible DCIS misdiagnosis were investigated by the other health authorities.

[564] Exhibit P-1333

451. By June 30, 2006, the review of these cases had reached a point where the patients could be notified.[565] Heather Predham reported to Dr. Williams, Mr. Tilley and others on the status of the DCIS case review on July 4, 2006.[566]

452. Dr. Laing, Dr. Denic and Ms. Parsons from the Quality Department met with these 3 patients on July 12, 2006 to disclose the information to them.[567] A meeting was held to disclose to an additional patient on July 11, 2007.[568]

453. In 2008 a further review was conducted of all cases reported as DCIS from Mount Sinai. As a result two additional cases of misdiagnosis were found from among cases reported for the Province.

(ii) Retro-Converters

454. Patients identified during the paneling process as having had results that changed from being considered clinically positive to clinically negative were termed “retro-converters”.

455. Patients whose results had been considered positive using the definition of greater than 30% staining before January 1, 2001 and greater than 10% staining

[565] Exhibit P-1138
[566] Exhibit P-0411
[567] Exhibits C-0233, C-0234 and C-0235
[568] Exhibit C-0237

after that date, had not been selected for retesting. The cases that fell into the "retro-converter" category were ones that actually had "negative" original test scores of 30% or less before January 1, 2001 or 10% or less after that date, but had been treated with hormonal therapy as if they had been positive. When retested, their test results were 0% for ER and 0% PR, so that there was no longer any indication for hormonal treatment.

456. Analysis of this category began in May, 2006, when Dr. Cook gave Ms. Predham a list of 17 potential retro-converters.[569] By May 17, Ms. Predham had organized the list on an electronic spreadsheet and had sent it to Dr. Denic who, as the new Clinical Chief, would be following up on any pathology review required.[570] Ms. Predham reviewed that list with Dr. Laing to select those cases where there was potential for the patient to have been placed on Tamoxifen[571] and on May 18, sent a reduced list of 7 cases to Dr. Denic.[572] On the next day, Dr. Denic asked Dr. Mullen at Mount Sinai to repeat the testing on those cases.[573] The results came back on June 1, 2006.[574] By July 10, 2006 those cases had been reviewed and the number considered to be retro-converters had been reduced to four.[575]

[569] Exhibit P-2082
[570] Exhibit P-2642
[571] Exhibit P-3027
[572] Exhibit P-1373
[573] Exhibit P-1130
[574] Exhibit P-1825
[575] Exhibit P-1377

457. The first plan had been to contact these patients by letter and drafts were prepared.[576] However, later there were meetings with the patients who resided in the Eastern Health region.[577] Information regarding the other two patients was forwarded to the Western and Central regions.[578]

458. Dr. Denic reviewed the original slides for the four retro-converters and in his opinion there was excessive staining on the whole of the cells rather than just the nuclei. The slides had therefore been misinterpreted as positive and were not false positives in the sense that they would have been had the nuclei stained when it should not have.[579]

459. When the decision was made in August 2005 to retest, the consensus view among those involved, including Dr. Cook and Dr. Laing was that the problem with ER/PR tests was false negatives, not false positives, and that retesting of positive results was not necessary.[580] The medical literature, including many of the publications referred to in this submission, identify worldwide problems with false negative ER/PR results, but there is no similar body of literature documenting false positive results.

[576] Exhibit P-1822
[577] Exhibit C-0236
[578] Exhibits P-1142, P-1158 and P-1269
[579] Evidence of Dr. Nebojsa Denic, September 15, 2008, page 94 line 19 to page 96 line 24
[580] Evidence of Dr. Donald Cook, July 4, 2008, page 87 line 5 to page 89 line 8

460. Dr. Denic testified that there has been a group of 10 patients with originally positive results who had asked to be retested in 2008. Their specimens were retested at Mount Sinai, all with positive results.[581]

461. Throughout the whole ER/PR retesting process, those involved had concluded that there was no evidence to suggest that there would be a problem with false positives and no directed retesting of the positive results has been undertaken.

462. Eastern Health is now in the process of reviewing that position. The questions being considered are:

- whether the question can be addressed by reviewing the original test slides for interpretation errors; or
- whether specimens would have to be retested; and
- in either case, whether a statistical sampling methodology can be used.

No definitive decision has been made.

[581] Evidence of Dr. Nebojsa Denic, September 15, 2008, page 4 line 5 to page 8 line 2

J. The Medical Literature

463. In this section publications from the medical literature and other sources that have been introduced as evidence are reviewed in order of publication.

Reliability of immunohistochemical demonstration of oestrogen receptors in routine practice: interlaboratory variability in the sensitivity of detection and evaluation of scoring systems[582]

464. In 2000, Rhodes et al. published this landmark study in the Journal of Clinical Pathology. Dr. Rhodes and his collaborators conducted a study by sending tissue samples to 200 laboratories from 26 countries that were participating in the UK-NEQAS Proficiency Testing Scheme for IHC. The tissue samples were sections from breast cancers having low, medium and high levels of ER expression. Samples were stained at the participating laboratories and returned for evaluation by four independent assessors. They were evaluated using threshold cut-off values of 1% and 10% and also the threshold cut-offs in use at the participating laboratories. The results were that over 80% of the laboratories were able to demonstrate ER positivity on the medium and high expressing tumors but only 30% of the laboratories performed adequately on the low expressing tumors. One-third failed to show any staining at all on those tissues and another third showed only minimal positive staining.

[582] Exhibit P-2993, page 34

465. The conclusion stated in the abstract of the paper is,

> There is considerable inter-laboratory variability, especially in relation to the detection of breast cancers with low estrogen receptor positivity, with a false negative rate of between 30% and 60%. This variability appears to be caused by minor differences in methodology that may be rectified by fine adjustment of overall technique.

466. The paper also included a discussion of the difficulty of setting standard cut-off values for determining the percentage of positive cells needed to be demonstrated to consider the test positive, stating that the degree of variability between laboratories in testing results would make it impossible to set a standard cut-off threshold.

467. The paper includes a table of the cut-off values used by the participating laboratories. 50% of the laboratories considered a test positive if 10% or more of tumor nuclei were stained. 6.1% used a cut-off of “20% or 25% and more”. About 1% used a cut-off of 50% or more. 8% used the “H score” method and about 3% used the “quick score” method.

Delayed adjuvant tamoxifen: 10-year results of a collaborative randomized controlled trial in early breast cancer (TAM-02 trial) [583]

468. This paper was published in 2000 by Delozia et al. The prevailing philosophy had been that the benefits from use of Tamoxifen would be realized if it was

[583] Exhibit P-2582

administered immediately after the conclusion of primary breast cancer treatment and for a duration of 5 years. In this study, women who received delayed hormonal treatment that was initiated 2 or more years after their primary treatment were followed for a period of 10 years from diagnosis. The authors concluded that there were benefits for those patients who received the delayed treatment.

469. In 2005 this paper was cited by Dr. Laing in support of the proposition that patients who had originally been tested some years before could still benefit from retesting if their estrogen and progesterone receptor status changed and hormone therapy could then be offered.

Adjuvant Therapy for Breast Cancer, National Institutes of Health, Consensus Development Conference Statement, November 1-3, 2000[584]

470. The National Institutes of Health in the United States published this consensus statement[585] in November 2000. In response to the question, "for which patients should adjuvant hormonal therapy be recommended?", the response includes the statement that,

> Adjuvant hormonal therapy should be recommended to women whose breast tumors contain hormone receptor protein, regardless of age,

[584] Exhibit P-2616
[585] Information about the NIH Consensus Development Program can be found at http://consensus.nih.gov/FAQs.htm

> menopausal status, involvement of axillary lymph nodes, or tumor size. While the likelihood of benefit correlates with the amount of hormone receptor protein in tumor cells, patients with any extent of hormone receptor in their tumor cells may still benefit from hormonal therapy.[586]

NIH has added a qualifier to the current version of this consensus statement cautioning that it is more than 5 years old and "thus some of the material is likely to be out of date, and at worst, simply wrong", illustrating the rapidly changing nature of research in this area.

Assessment of Tissue Estrogen and Progesterone Receptor Levels: A Survey of Current Practice, Techniques and Quantitation Methods[587]

471. On November 3, 2000, Layfield et al. published this article in The Breast Journal. The authors surveyed 300 laboratories in the United States about their practices for assessment of ER and PR status in breast cancer tissue specimens, receiving 80 usable responses. They found wide variation among laboratories in virtually every aspect of the performance and evaluation of the test. The abstract concludes,

> Our survey indicates that a majority of laboratories performed their steroid hormonal receptor analysis in-house using IHC. There is considerable variability in the antibodies utilized, the dilutions applied, and the quantitation method and the level of expression used to dichotomize specimens into positive and negative groups. Finally, no universal control for inter-laboratory standardization appears to exist.

[586] Exhibit P-2616 page 4
[587] Exhibit P-2617

472. As in Rhodes' study in the UK, there was considerable variability in the thresholds used by pathologists at different laboratories to classify tests as positive or negative. 34% of respondents called tests positive if 10% or more of the nuclei stained. 28% required 5% staining. 9% reported positivity if there was any nuclei staining. 4% used 20% staining for positivity for ER and a lower percentage for PR. Smaller numbers used combinations of percentage staining and intensity of staining, the "H score" or the "San Antonio score".

473. The authors had also surveyed haematologists and oncologists in the same institutions about the cut-offs they used to stratify positive and negative ER results that were reported to them from their laboratories. From most of these clinicians, there was either no response or the response was that they didn't know what cut-offs were used, but for those that did provide information, one clinician used 1% staining as the threshold for positivity, two used 5%, five used 10% and three used 30%.

Breast Cancer Committee of the Victorian Co-operative Oncology Group in Victoria, Australia[588]

474. The June, 2004 Breast Cancer Update includes an editorial in which the editor describes being presented with a patient with primary breast cancer diagnosed 3 years earlier with negative ER test results. The patient now had metastatic

[588] Exhibit P-3091 page 4

disease which was ER positive. Testing was repeated on the original specimen and changed to ER positive. The editor wrote,

> She rightly asks "Would adjuvant Tamoxifen have made a difference to my prognosis?" What could be done about our difficulties with HR testing? Surely, we should be setting up QI systems and guidelines (including minimum case loads for doing ER) nationally.

475. "Hormone Receptor Testing" by Dr. Robert Brown, published in the same newsletter, gives a brief overview of the introduction of ER/PR testing by immunohistochemistry and of the different scoring methods used for the test. It states that the majority of laboratories in Australia used 10% of cells showing any staining as the cut-off for positivity.[589]

476. The author mentions United Kingdom and German studies showing interlaboratory variability in ER/PR test results and states that in 2003, the "Australian QAP" conducted 2 reviews on hormone receptors, reporting that in the first only 26% of reviewed ER tests were considered satisfactory and in the second only 41% were considered satisfactory. PR tests were better at 75% and 76%.

[589] Exhibit P-3091, page 5

Immunohistochemical Assessment for Estrogen Receptor and Progesterone Receptor Status in Breast Cancer: Analysis for a Cut-Off Point as the Predictor for Endocrine Therapy[590]

477. Ogawa et al published this analysis in the journal "Breast Cancer" in 2004. The abstract begins,

> An Immunohistochemical (IHC) method is commonly used for determining estrogen receptor (ER) and progesterone receptor (PR) status in breast cancer. However, the proper cut off points of IHC have not been established. Cut off points for ER and PR status as predictive factors for endocrine therapy are needed.

478. Two Hundred and forty-nine breast cancer patients were enrolled in the study, 152 of whom received hormone therapy. The authors found that the differences in disease free survival between the 2 groups were most significant when a cut-off of 3 using a proportional score which indicated more than 10% of stained cells was used. They found that using a combination analysis of ER and PR and that cut-off point revealed a noticeable prognostic difference. The abstract concludes, "a 10% staining proportion may be an acceptable cut-off point for both ER and PR status by IHC, in terms of predicting response to endocrine therapy in breast cancer".

Consistency of Staining and Reporting of Oestrogen Receptor Immunocytochemistry within the European Union - An Inter-laboratory Study[591]

[590] Exhibit P-2993, page 40

479. In June, 2004, Dr. Clive Wells, who testified at the public hearings, was one of the authors of this study. Dr. Wells testified that the study slides were circulated in 1999 and 2000 among laboratories belonging to the European Working Group for Breast Cancer Screening. These labs were nominated as leading laboratories by their National Authorities. Concordance for negative and strongly positive slides was good but concordance with weakly positive slides was not as good as Dr. Wells had expected it would be. This study, unlike the UK-NEQAS studies, included interpretation as well as technical staining as criteria being evaluated. The paper recommends external quality assurance, use of weak positive controls and auditing of the percentage of positive results achieved annually.

Immunohistochemistry of estrogen and progesterone receptors reconsidered: experienced with 5,993 breast cancers[592]

480. In January, 2005, Nadji et al. published this study in the American Journal of Clinical Pathology. This was a large scale review of ER and PR tests. The abstract states a number of conclusions:

- Tests for estrogen receptors using antibody 1D5 and antigen retrieval usually show “all or nothing” and quantification of results beyond stating “positive” or “negative” is unnecessary.

[591] Exhibit P-3631
[592] Exhibit P-2993, page 46

- Even with antigen retrieval, inadequate fixation can cause false negative results.

- Evaluation of internal positive controls is imperative.

- Estrogen receptor positivity and negativity are predictable in certain types and grades of cancers. Pure tubular, colloid and infiltrating lobular carcinomas were ER positive.

Bimodal frequency distribution of estrogen receptor immunohistochemical staining results in breast cancer: an analysis of 825 cases[593]

481. This article published by Collins et al. in the same edition of the American Journal of Clinical Pathology looked at 825 breast cancer tests for estrogen receptors to assess the frequency of weakly positive tumors, stating that the "lack of standardization has raised concerns that weakly ER positive tumors often are classified erroneously as ER negative". This study concluded that the cases examined were overwhelmingly either completely negative or strongly positive and that weak ER staining was rare.

Estrogen Receptor Analysis for Breast Cancer: Current Issues and Keys to Increasing Testing Accuracy[594]

[593] Exhibit P-2993, page 48
[594] Exhibit P-2993, page 30

482. In January, 2005 this article by Diaz and Sneige was published in the journal Advances in Anatomic Pathology. The authors wrote that studies conducted by Rhodes colleagues under the auspices of the UK-NEQAS found a high rate of interlaboratory variability among laboratories participating in that proficiency testing scheme. The second study by Rhodes strongly suggested that pre-analytical variables of tissue handling, fixation and processing did not greatly affect ER testing results using IHC. In a third study, the length of time for heat induced antigen retrieval was identified as the most important variable for improving ER testing standardization.

483. Studies carried out in Australia and Sweden demonstrated interlaboratory variability and those authors concluded that improvements in testing could be made through automation and training.

484. A German study demonstrated poor reproducibility of ER testing with failure rates similar to those reported for the UK-NEQAS Program.

485. The only study published up to that time for interlaboratory comparisons of ER testing in the United States using unstained slides was the Layfield study showing poor standardization for ER testing. Based on that publication and on data from a related study by Allred, the authors concluded that “significant interlaboratory variability for ER testing does occur in the United States.”

486. The authors wrote

> Currently, there are legitimate concerns worldwide that ER immunohistochemical testing methodologies are insufficiently standardized and that clinically significant false negative rates exist. The interlaboratory comparisons of Rhodes et al and Layfield et al have convincingly revealed interlaboratory variability in ER testing methodologies and results. A concerted effort by laboratories to adopt reproducible and clinically validated testing standards for ER IHC will be necessary to properly address this problem. If successfully implemented, standardization of ER testing could serve as a paradigm for multitude of predictive markers that will likely assayed by IHC in the future.

Recommendations for Improved Standardization of Immunohistochemistry[595]

487. In June, 2007, the Journal of Applied Immunohistochemistry and Molecular Morphology published these recommendations, by Goldstein et al. The abstract begins,

> Immunohistochemistry (IHC) continues to suffer from variable consistency, poor reproducibility, quality assurance and disparities, and the lack of standardization resulting in poor concordance, validation, and verification. This document lists the recommendations made by the Ad-hoc Committee on Immunohistochemistry Standardization to address these deficiencies. Contributing factors were established to be under fixation and irregular fixation, use of nonformalin fixatives and ancillary fixation procedures divested from a deep and full understanding of the IHC assay parameters, minimal or absent IHC assay optimization and validation procedures, and lack of a standard system of interpretation reporting.

[595] Exhibit P-1767

Quantitative Immunohistochemistry of Estrogen Receptor in Breast Cancer - "Much ado about nothing!" [596]

488. In March, 2008, the Journal of Applied Immunohistochemistry and Molecular Morphology published Dr. Nadji's article in which he challenges the view that estrogen receptor testing by the IHC method is a reliable predictor of response to hormonal therapy, saying that the usefulness of the test should be approached realistically and not given more weight than it deserves. He concludes by saying,

> Today, we use IHC - a technique that does not yield itself to reliable quantitation - to measure an analyte, ER, which may or may not be biologically active in breast cancer. We then semiquantitate the staining results by setting arbitrary thresholds and assume that our numerical report will have an impact on patient's response to endocrine therapy. As it turns out, although the presence or absence of ER in breast cancer is of certain predictive value, the amount of it is not.
>
> We have to remind ourselves, therefore, that at the present time the ER-IHC is only the best available predictive test for breast cancer. The search is on, nevertheless, to identify and validate clinically relevant biomolecular profiles that could guide clinicians to a more personal and tailored-made approach to the management of each patient with breast cancer. Until that time, we have to accept ER-IHC for what it is and not for what we would like it to be.

[596] Exhibit P- 2630

Consensus Recommendations on Estrogen Receptor Testing in Breast Cancer by Immunohistochemistry[597]

489. An article to be published this year in the same Journal was presented to the Commission by Dr. Dabbs. The abstract reads,

> Estrogen Receptor (ER) status in breast cancer is currently the most important predictive biomarker that determines breast cancer prognosis after treatment of endocrine therapy. Although immunohistochemistry has been widely viewed as the gold standard methodology for ER testing in breast cancer, lack of standardized procedures, and lack of regulatory adherence to testing guidelines has resulted in high rates of false negative results worldwide. Standardized testing is only possible after all aspects of ER testing – preanalytical, analytical and postanalytical have been closely controlled. A meeting of the "ad-hoc committee" of expert pathologists, technologists, and scientists representing academic centers, reference laboratories and various agencies issued standardization testing recommendations, aimed at optimization of clinical ER testing environment, as a step toward improved standardized testing".

Hormone Receptor Testing in Breast Cancer: A Distress Signal from Canada[598]

490. On November 5, 2008, the Oncologist journal published this commentary by Dr. D. Craig Allred, who comments on the events under consideration by this Commission of Inquiry and citing them as an example of more universal problems in estrogen and progesterone receptor testing. Dr. Allred poses these questions, "How did it happen? Is it happening elsewhere? What is being done to prevent it?"

[597] Exhibit P-3634
[598] Attached to this submission as Appendix C

491. Concerning the first question, he refers to what he describes as the “well-known problems associated with measuring proteins by IHC, particularly proteins requiring quantified results such as ER”.

492. Regarding the second question, he says,

> Unfortunately, the problem with ER testing by IHC is not restricted to Newfoundland and Labrador … The results [of UK-NEQAS surveys] identified error rates in some laboratories rivaling those in Newfoundland and Labrador, as well as the major technical problems causing them … There is compelling anecdotal evidence suggesting that problems in the US are also substantial … While far from being scientific, the false-negative rate of IHC testing for both receptors in my consulting practice over the past 10 years is about 30%, which is similar to that of other experienced consulting pathologists I have spoken with on the issue.

493. Concerning his third question, he writes,

> Given the critical need for accurate ER and PgR results in all patients with breast cancer, and the widespread difficulty obtaining them, it is clear that something must be done to remedy the problem … ultimately, however, it is unrealistic to expect that even perfect tests for ER and PgR alone, by IHC or any other methods, will be sufficiently powerful to predict the response of all breast cancer patients to hormonal therapy because the biology involved is so complex.

III. The Terms of Reference

A. What Caused the Changes in Test Results?

The commission of inquiry shall inquire into why the estrogen and progesterone hormone receptor tests done between 1997 and 2005 in the Newfoundland and Labrador health system resulted in a high rate of conversions when re-tested.

494. None of the witnesses who testified before the Commission had been able to provide a precise answer to the question of what exactly caused the changes in test results. What the Commission has heard described is a list of factors that may have contributed to the changes in test. Some of those factors were likely more significant contributors to the changes than others, but quantification of the degree of contribution of any particular factor is difficult, if not impossible. Even more difficult is the question of which factors were at a play in any individual case of changed results. The question can therefore only be answered by identifying the circumstances that existed that might have contributed to an incorrect test result being produced, reported and relied upon without detection of the error.

495. Early in the public hearing and at the symposium sponsored by the Commission, the Swiss Cheese Model was described. The premise is that processes in health care are analogous to the slices of Swiss cheese. Each slice has holes in different places. If a line can start at one end of the slices and reach through the holes in every slice to get to the far end, it produces an error. In most cases, the

line may pass through holes in some slices but is stopped before it reaches the end. The more holes there are, the more likely it is that more lines will pass through all the slices and more errors will occur. The precise causes of each error will depend on which holes in which slices the line has passed through and they will not always be the same.

496. Once an error has occurred and been detected, there are two approaches that can be taken in response. One is to identify exactly which holes the line passed through and fill them. That ensures that the same error is not repeated (assuming that the correct holes were identified, which might be difficult to do if the slices have been moved) but it does not prevent other errors from occurring.

497. The second approach is to identify as many holes as possible in all the slices and fill as many as possible, without having to identify which holes had lined up when the error occurred. That approach should be effective not only at preventing the error which actually occurred but also in preventing other errors which might occur in the future.

498. That analogy is directly applicable here. In effect, it is what Eastern Health did beginning in the summer of 2005 once it was discovered that there were errors in ER/PR testing.

499. The first step taken was to stop performing more tests. Even though holes in the cheese still existed, no more ER/PR lines could pass through them. The second was to arrange for retesting of all negative results, thus addressing the issue of providing appropriate care to people who may have had incorrect results, regardless of what the cause of those incorrect results might have been. The third was to determine what had to be done to ensure that testing could be resumed in St. John's without risk of such errors occurring in the future. The approach adopted was not to narrowly investigate only what had caused the errors in the past. Instead, it was to conduct a broader investigation, relying in large part on the external assessments by Dr. Banerjee and Ms. Wegrynowski to find as many holes in as many slices of the cheese as possible and then to work at filling holes one by one until the point was reached where the risk of errors occurring was reduced to as low a level as possible.

500. The contributing factors to the changes in ER/PR testing results may be considered to fall into two general types. The first is technical factors that could have directly contributed to testing failures. The second is underlying conditions that allowed the technical factors to exist and to remain undiscovered and unaddressed.

501. The literature and the experience of witnesses appearing before the Inquiry allow us to identify many technical factors that have the potential to influence an ER/PR test result. Unfortunately, our ability to precisely determine whether those factors affected results between 1997 and 2005 in St. John's, or to what extent any factor affected results, is limited by the unavailability of extensive quality control records. The lack of detailed records of testing procedures carried out for each specimen means that we cannot assess the rigor with which testing procedures were applied a particular times.

502. Technical contributing factors include the quality of tissue samples, test procedure optimization, performance of the testing procedures, selection of controls, interpretation of the slides and changes in technology.

Tissue Quality

503. Since the specimens originated from all pathology laboratories in Newfoundland and Labrador and since there were no universally applied standards for tissue fixation, the potential for variability in the quality of fixed and processed tissue fixation is a factor. Testing procedures optimized using controls originating at the General Hospital laboratory site would not necessarily be optimized for tissue samples fixed and processed using variations in procedure at other sites. The

same factor would apply if there were variations in the tissue fixation and processing within the same site where the testing is carried out.

504. Fixation protocols existed for the operating rooms in St. John's hospitals and elsewhere. The policies and procedures in place may not have been well enough integrated between the programs where tissues originated and the laboratory where they were processed and stained to ensure that the time in formalin was within an acceptably uniform range. The evidence suggests that in most cases there would be no problems, but the potential existed, particularly for large specimens such as mastectomy specimens that may have been left overnight or over a weekend or may have had to have been transported for a long period before being sectioned to allow for even penetration of the formalin.

505. After gross examination of specimens, small samples are placed in cassettes and processed in a tissue processor. The effectiveness of the processing can be influenced by the size of the tissue. Gross examination was performed by many different pathologists and residents and variations could exist in the size of the tissue samples, resulting in variations in the effectiveness of fixation and processing.

506. Any failure in the functioning of tissue processing equipment, or less frequent than optimal changes in processing chemicals could have affected the quality of processed tissues.

Test Procedure Optimization

507. It is important to adjust antigen retrieval techniques and timing, antibody selection, dilution and incubation time and other similar parameters to achieve optimal results for the tissues being stained in the laboratory.

508. Records for optimization of ER and PR testing from 1997 to 2005 were not maintained. The role of technologists and pathologists in performing that optimization was less well defined than it is now. It is outside the scope of the work of the technologists to conduct optimization on their own, but there was not always a pathologist with the specialized interest and knowledge available to take charge of the optimization process. It is therefore possible that at times the ER/PR testing protocols were not optimized.

Performance of Testing Procedures

509. Once optimized, the procedures for ER/PR testing must be carried out in rigorously standardized ways to ensure that each test is performed in exactly the

same way. Protocols and procedures were available to the technologists but not in as easily accessible and standardized formats as they are now. Portions of the technologists workflow were recorded on worksheets as they went through the procedural steps, but the performance of each step was not recorded in detail, and the records were not maintained and audited, so as to provide for thorough quality control over the manner in which the testing procedures were performed. It is therefore possible that subtle variations in matters such as antibody dilution and antigen retrieval time could have affected the accuracy of the tests performed.

Selection of Controls

510. The selection of control tissue appears to be as much art as science and requires the assistance of knowledgeable pathologists. It is possible that if control tissues were not selected in an optimal way, then the test results could have been affected.

511. The technologists' training to read the control slides was limited to assessing whether staining had occurred. Final determination of whether the control had stained appropriately was left to the pathologists. The process for review of control slides by pathologists varied over time. Individual pathologists often had to rely on their colleagues for assessment of the positive control slides.

Variations in assessment of controls by technologists and pathologists may potentially have contributed to inaccuracy of test results.

512. Positive external controls were run but negative controls were not. Positive controls selected were for strongly positive tissue. After 2005, the laboratory adopted the procedure of using strong positive, weak positive and negative external controls.

513. The usefulness of assessing the slides for the presence of appropriately stained internal controls was not generally recognized until Dr. Ejeckam circulated his memo of May 2, 2003. Whilst the presence of a positive internal control is not absolutely necessary to allow the slide to be read and reported, had the practice existed of selecting tissue samples for the presence of normal breast tissue and had all pathologists been assessing the presence and staining of internal controls, then some inaccurate tests results might have been avoided.

Interpretation

514. Interpretation of an ER/PR slide requires subjective evaluation of the percentage of stained nuclei in the malignant tissue. It is well accepted that there is inter-observer variability among different pathologists. Issues with interpretation of slides may have contributed to the inaccuracy of some results.

Technological Changes

515. While there were few changes in the choice of antibody used for ER and PR testing during the time period under review, there were changes in other reagents and solutions such as detection kits. Changes in these materials represent advances in medical science intended to produce increasingly accurate results. Technical experts who testified at the Inquiry agreed that improvement in the detection of positive receptors will result from these incremental changes in technology.

516. Dr. Emina Torlakovic described how, since 1997, there have been changes in areas such as antigen retrieval and detection systems that have resulted in increased sensitivity for ER and PR testing, meaning that laboratories using newer reagents and techniques can detect more true positive results than before those reagents or techniques had been adopted.[599]

517. The most significant change in the equipment used to perform ER/PR testing was the discontinuance of the Dako Autostainer in 2005 in favor of the Ventana Benchmark staining system. In the early stages of the investigation into this matter, it appeared obvious that the change from one system to another could be related to the change in test results since specimens that had tested negative

[599] Evidence of Dr. Emina Torlakovic, October 9, 2008, page 192 line 2 to page 203 line 10

when the Dako System was used were then testing positive using the Ventana System.

518. As time went on, it has become clear, however, that the Dako semi-automated system can produce just as accurate a result if appropriate rigor is applied to the technical testing processes.

519. The significant difference between the two systems is that the automation of steps on the Ventana Benchmark removes the chance of human error in the performance of those steps, bringing greater consistency to the way that the test procedures are carried out. This is likely a factor that has contributed to the improvement of test results after the acquisition of the Ventana Benchmark System.

520. The reports of Dr. Banerjee and Ms. Wegrynowski, the literature filed as exhibits and the testimony of the medical experts at the hearing all provide greater detail and explanation of the technical factors that may contribute to an ER/PR test failure.

521. Some of the underlying conditions include the effect of the prolonged period of fiscal restraint in health care; issues with licensing, accreditation and other

oversight; pathologist recruitment and retention; and education and training for technologists, among others.

Fiscal Restraint

522. The fiscal restraint that affected the health care system in Newfoundland and Labrador between 1997 and 2005 when the problematic tests were performed is an important background factor. Government has a responsibility to use the taxpayers' resources wisely and must balance competing demands from every sector. Health care will not always be able to get all the funding for everything that it needs. Nevertheless, the fiscal and budgetary circumstances of the Health Care Corporation of St. John's do play an important role.

523. The Laboratory Medicine Program was affected in several ways. Cutbacks and consolidations in the 1990s substantially reduced the number of managers available to carry out the day to day supervisory and administrative work of the Program. This was perhaps true for the whole of the Health Care Corporation of St. John's and the other health authorities in the Province. Fewer managers, and none dedicated to activities such as quality assurance, meant that the day to day activities with immediate demands for keeping the workflow moving and results going out to the clinicians took priority. There was less time for initiatives

in the areas such as quality control, quality assurance and innovation and less opportunity to step back and recognize where weaknesses in the program exist.

524. A second effect is that, from senior management in Laboratory Medicine on down through the ranks, the objectives set for the program by necessity emphasized efficiency. The demands on the laboratory kept growing and the number of people available to do the work did not. The budget that the laboratory was given frequently shrank. While the importance of quality was always recognized, it had to compete with the fiscal realities for attention.

Licensing, Accreditation and other Oversight

525. Within the Health Care Corporation of St. John's, responsibility for quality rested with the programs. The Quality Department was a facilitator and promoter of quality activities. It would not have been practical to develop a specialized expertise outside of Laboratory Medicine, and within the Quality Department, to do effective audits of quality within the laboratory service.

526. In many areas of health care, there are organizations that provide that specialized external expertise to do audits and accreditations of programs and services. In Newfoundland and Labrador, laboratories do not have to be licensed and no provincial accreditation or inspection program or set of

mandatory standards exists. Newfoundland and Labrador does not license or regulate the practice of laboratory technologists.

527. Responsibility primarily rests on the laboratory itself to adopt and use the best practices and procedures available for performing its work, however, the reality was that if the people in the laboratory were working at capacity to do their everyday duties, and if there were no externally imposed standards that the service was required to measure itself against, the potential existed for lapses in quality control and quality assurance.

Recruitment and Retention of Pathologists

528. The role of the pathologists in providing knowledge, expertise and guidance to the work of the technologists, in monitoring the quality of the work produced by the technical laboratory and in reporting accurate results to the clinicians is of vital importance. Individually, there is no reason to believe that any pathologist who has been involved in the ER/PR testing was not qualified and competent to do the work called upon. Collectively, there was a high rate of turnover in pathology positions and frequently there were stretches of time where vacant positions meant that the workloads on the remaining pathologists increased. For a time, the pathologists who came to Newfoundland likely viewed it as a

transitional career opportunity and may not have integrated themselves as fully into the professional workplace as they might have otherwise.

529. These factors may have compromised the ability of the pathologists as a whole to develop standardized practices and procedures and to maintain consistent and effective quality assurance reviews of the quality of the laboratory medicine work.

530. It has been increasingly recognized that the growing sophistication of anatomical pathology requires some sub-specialization by pathologists. For that to be effective there has to be a stable group of pathologists to draw upon. Frequent turnover means the department as a whole can often lose specialized expertise in an area where the remaining pathologists are no longer well prepared to fill the gap. The example this year of the suspension of ER/PR testing following Dr. Cook's leave and Dr. Carter's resignation is a stark example of the challenges in achieving and maintaining sub-specialization.

531. The inability to establish such sub-specialization between 1997 and 2005 and the reading of relatively small numbers of ER/PR slides by a large number of pathologists may have contributed to problems with results, since no single pathologist or group of pathologists was in a position to recognize trends in results or to develop particularly specialized expertise in interpreting them.

532. It should be mentioned as well that during the time period when the ER/PR tests under review were reported and acted upon there were significant problems in recruiting medical oncologists. Medical oncology services were provided by radiation oncologists, surgeons and others. While there is no reason to doubt the quality of the services provided by those physicians, understaffing could create the same issues of continuity and impairment of the ability to recognize trends as for the pathologists.

Education and Training of Technologists

533. Specialized training for IHC technologists has not been readily available in Newfoundland and Labrador or elsewhere. It is not taught as a specialized subject in laboratory technologist programs. The evidence is that in St. John's, as at sites like Mount Sinai in Toronto, senior technologists who already have advanced skills are trained in-house to carry out specialized IHC procedures. This can be enhanced by having technologists attend conferences and short courses when available and by having them visit other laboratories for one on one interaction with other technologists.

534. Technologists Mary Butler and Peggy Welsh learned IHC testing on the job at a time when it was being introduced and developed. Ken Green and Les Simms were instructed in the technique by Ms. Welsh. Within the budgetary limitations

of the Division, some periodic opportunities were provided for attendance at conferences and text books were available for reference. Pathologists such as Dr. Ejeckam were willing to provide one on one instruction. A formalized documented training program did not exist.

535. Had it been possible to provide a more formalized training program with the resources necessary, then the technologists may have been able to better recognize opportunities for improvement in the quality of their work.

B. Could It Have Been Detected Sooner?

The commission of inquiry shall inquire into why the problem with the estrogen and progesterone hormone receptor tests was not detected until 2005, whether it could have been detected at an earlier date, and whether testing protocols during that period between 1997 and 2005 were reasonable and appropriate.

536. This term of reference poses 3 questions. The third, “whether testing protocols during that period between 1997 and 2005 were reasonable and appropriate”, relates more to the first term of reference than to the question of whether changed test results could have been detected before 2005 and has been dealt with in the section above.

537. This term of reference does not direct an inquiry into whether the erroneous test results “should” have been detected earlier. It asks whether they “could” have been detected earlier.

538. That question has to be answered in the affirmative since there were events that occurred that, had circumstances been different, “could” have lead to an earlier recognition that there was a testing problem.

539. A missed opportunity was the suspension of testing by Dr. Ejeckam in 2003. However, in his assessment, and that of the pathologists at the tumor rounds and lymphoma board where the discussion that precipitated the testing suspension took place, the problems they saw with the test slides caused them to not use or

report results from those slides. In the case of the ER/PR slides it appears that no one recognized that there were deficiencies that were affecting the cases that were being reported.

540. We know that at that time, there were at least three instances where ER/PR results that had been first been reported as negative changed to positive when the specimens were retested. These were done before the introduction of the Ventana technology, but after Dr. Ejeckam began work to optimize the performance of the staining. Either of those instances alone would not have been enough to suggest a larger systemic problem, but had someone been in a position to know of all three, then the possibility exists that there would have been enough doubt about the reliability of past testing to trigger the kind of review that took place in 2005.

541. From 1997 until 2005, no analysis of the rate of positive tests results was performed. Had a system been in place to record such information and provide such an analysis, then it is possible that for a number of the years in question, low rates of positivity could have been recognized and could have triggered some inquiry.

542. The survey conducted in the summer of 2005 for Dr. Cook and the evidence of the experts who testified at the hearing show that recording and analyzing

positivity rates is carried out to varying degrees, or not at all at other institutions. Also, the literature reports a wide variation in what is considered an acceptable positivity rate and does not set a very clear standard against which to assess any particular laboratory's experience.

543. No external proficiency testing of IHC staining in particular was available to the St. John's laboratory until enrollment in the UK-NEQAS program in 2005. None of the proficiency programs with which the laboratory personnel were familiar before that offered such a service. Had enrollment in the UK-NEQAS program happened before 2005, it is possible that the proficiency testing results would have pointed out quality deficiencies.

544. Whether that would have resulted in a look back at old tests instead of just the implementation of measures to improve the quality of future staining is an entirely different question. There has been extensive experience in Europe where studies and literature have identified interlaboratory variability, which obviously indicated that some laboratories were performing substandard testing that was missing positive test results. However, there is no indication that any laboratory ever undertook the kind of retrospective testing program that was undertaken in Newfoundland and Labrador. Nevertheless, since we know that the events of 2005 did trigger such a retrospective testing program here, it remains possible

that had there been proficiency testing demonstrating inadequacies earlier, then the retesting might have occurred here earlier.

C. Was Response to and Communication with Patients Timely?

The commission of inquiry shall inquire into whether, once detected, the responsible authorities responded and communicated in a timely manner to those women and men who needed re-tests and those who were being tested for the first time.

(i) Background Factors

545. The ER/PR testing problems were discovered when Eastern Health was in its infancy and the breadth of responsibilities across the continuum of health care that it was to take on was greater than any of the new senior executive had prior experience with. Their immediate task was to develop the organization, plan for integration of the services now under its jurisdiction and begin filling the new regional management positions that had to be created. This was no small task and at the best of times would have involved the full time attention of the executive team for a considerable period of time. There had been little opportunity for advance planning so Eastern Health had hit the ground running, developing its structure at the same time as continuing to provide all the health care services now within its jurisdiction. [600]

546. Among the institutions amalgamated to form Eastern Health there was limited administrative capacity compared to national averages, which had come about as a result of the fiscal restraint of the previous decade. For example, people

[600] Evidence of Patricia Pilgrim, September 30, 2008, page 202 line 14 to page 205 line 13

with the project management skills described by by Dr. MacDonald were not available.

547. The ability to identify patients to be retested was affected by the limitations of the electronic health record management systems in the organization.

548. The Health Care Corporation of St. John's had adopted guidelines for disclosure of adverse events in September of 2004 after an extensive consultation process. After the creation of Eastern Health these policies continued to apply to the portions of the organization formerly included within HCCSJ, until new guidelines could be approved for Eastern Health.

549. Although an adverse event is defined broadly in the guidelines, they were developed with the intention that they would be applicable to the type of single patient occurrence that those in the organization were familiar with. The idea that there would be a need to make large scale disclosures of events that affected many patients was not something that was within the contemplation of those involved in the guideline development.

550. The presentations of the participants at the symposium arranged by this Commission discussed disclosure principles almost exclusively in that same limited context.

551. In 2007 the Canadian Patient Safety Institute developed model guidelines for disclosure of adverse events to patients and those too deal primarily with small scale occurrences.[601] There is only one paragraph in the document that deals with "multi-patient disclosure" as follows:

> In some situations there may be a need to disclose to more than one patient about the same adverse event. Privacy and confidentiality remain important. The disclosure discussion should be with only one patient at a time and in person if possible. If disclosure cannot be in person, it should be done by registered mail and/or telephone with opportunities for follow-up made available. In addition disclosure should be timed, if possible, to occur with all patients involved at approximately the same time and, if possible, prior to any informing process, especially media coverage, being considered.[602]

552. In the Summer of 2005 when personnel within Eastern Health charged with investigating and managing the ER/PR issue had to make decisions about disclosure of information to patients, the HCCSJ guidelines seem to have not been explicitly considered. Although many of the people involved in the issue were the same ones who had not long before been involved in the adoption of the guidelines, the situation that they were faced with was so different from that which they had been anticipating when the guidelines were developed, that, in effect, they had to go back to basic principles instead of attempting to directly apply the written guideline document, which had been developed for another purpose.

[601] Exhibit P-0161
[602] Exhibit P-0161, page 25

(ii) The In-House Retests

553. After the discovery of the index case there were four more individual cases of lobular cancers identified by the oncologists for whom they requested ER/PR retests. Those were patients under active care of the oncologists and the results were dealt with by the oncologists with their patients directly.

554. The first systemic response to investigate the issue occurred after Dr. Cook was notified in May. It was then suspected that the problem might be originating from events in 2002 and it was decided to retest all negative results from that time period in-house on the Ventana system. This was an appropriate response in order to assess how serious the problem of false results was and whether it was confined to a limited time period.

555. The manner in which these in-house retests were dealt with can be viewed as a transitional phase between the first few retests that were dealt with by the treating physicians on a case by case basis, and the Mount Sinai retests that were dealt with as a structured project. The in-house retest results were reported to the oncologists by letters from Dr. Cook and Dr. Carter, who interpreted the retest slides, to Dr. McCarthy, who coordinated the dissemination of the information to treating physicians for their action.

556. For the first batch of 25 results, 16 changed from negative to positive. Twelve of those patients were directly notified by oncologists in the Cancer Centre and the other 4 were patients of other physicians, including surgeons at the General Hospital site. These cases continued to be treated as clinical matters between the physician and the patient. No particular steps were taken to notify those patients whose samples had been retested and confirmed to be negative.

557. The first and second batches were communicated to Dr. McCarthy in the same way. There is little direct evidence about whether or not the results of the second batch were communicated to patients in the same manner as the results of the first batch. For the third batch a conscious decision was made not to act on the results or communicate them to patients because of the concern that had developed about the accuracy of the Ventana system.

558. All of these cases were subsequently retested at Mount Sinai and communication of those results to the patients was handled in the same manner as all other Mount Sinai retest results.

(iii) Notification that Specimens would be Retested

559. When it became clear at the beginning of July, 2005 that the scope of the problem was not going to be confined to a few isolated cases, it was apparent to

Dr. Williams and others that there would have to be a public announcement and communication to all affected patients to let them know that their samples would be retested. Preparation for disclosure continued based on that premise while efforts were made to better delineate the scope of the problem during July and into August. By August 10 oncologists were presenting the concern that there could be harm to patients by disclosing the potential for their test results to be wrong and them having then wait for weeks until the retest results were known. On August 15 the decision was confirmed to defer notifying patients of retests in the anticipation that retest results would be available within 6 to 8 weeks and that patients could be given substantive and useful information then. There were risks with this approach, principally that since some patients had been notified the retesting might become publicly known before all patients had been directly contacted.

560. There was no clear right or wrong way to approach the question of communicating information to these patients at that time. The Canadian Patient Safety Institute disclosure guidelines adopted two years after these events discuss the general principles to be considered in such a situation, as described above. The approach described in that document is remarkably similar to the objectives of Eastern Health in the Summer of 2005 when the approach to patient notification was adopted.

561. Although the liability insurer of Eastern Health had been contacted in July and had communicated advice that disclosure should be approached with caution, testimony of all those involved is that that actor played little, if any, role in the decisions that were made. The deciding factor was the strong opinions of the oncologists who were the physicians in closest contact with the patients and in the best position to assess what the impact on them would be.

562. When the retesting did become public on October 2, 2005, the issue of contact with individual patients had to be revisited. Telephone calls were chosen over letters. Again, the evidence of the witnesses involved is that legal advice or insurer's concerns played no part in that choice.

563. Patients were given the opportunity to follow up by calling back to the Patients Relations Officer, consistent with the approach to multi-patient disclosure described later in the CPSI Guidelines.

564. It appears that the option of following up telephone contact with letters was not considered. It is now recognized that that could have been a valuable and appropriate additional measure.

565. Reasonable efforts were made at the time to track the progress of contact with patients and to identify and follow up those patients who had not been reached

by telephone. After a time it appears that the process of contacting those remaining patients to inform them that their specimens would be retested was overtaken by the management of the retest results being returned from Mount Sinai. The fact that the retesting had by then been widely publicized in the media with Dr. Williams making himself available for numerous interviews, that a letter had gone to physicians and that information was available on the Eastern Health website also mitigated the effects of not having been able to contact every patient to inform them that their specimens would be retested.

(iv) Retest Results

566. The timing of the ability to respond to patients with information about retest results and recommendations for changes in treatment was affected by the delays in obtaining retests from Mount Sinai. The first estimate given to Dr. Cook in the summer of 2005 was that it would take 3 to 4 weeks to process 500 blocks. The estimate given to the Department of Health and Community Services in August, and used by the oncologists when they recommended delaying contact with patients, assumed that it would take 6 to 8 weeks to have retest results available.

567. A combination of factors interfered with obtaining retest results within that time frame. The number of cases to be retested proved to be greater than had been

anticipated. Mount Sinai encountered capacity problems and had to replace one of their stainers part way through the process. Retest results were reported in a couple of batches in October of 2005 with the bulk of the remaining tests not being reported until mid January 2006.

568. When the first results came in at the beginning of October, 2005, the logistics of dealing with them had not been fully worked out. In particular, the likelihood that physicians then responsible for the care of the patients would require advice from specialists on whether or not to institute hormone therapy had to be considered. In the normal course, a patient would be referred to a specialist such as an oncologist for a decision of that nature. Had test results just been sent to the physician then responsible for the patient's care, or to the patient with instructions to contact their doctor, it is likely that a large proportion of them would have had to wait for referrals to specialists before any decisions could have been made about their use of hormonal therapy.

569. The use of the physician panel to make recommendations to the physicians responsible for the patient's care meant that additional time would pass before the patients would become aware of the results and before their physicians would be in the position to institute hormonal treatment if appropriate. Whether the time that was added to the process by use of physician panel was greater or

less than what many patients would have encountered while awaiting specialists' consultations is unknown.

570. For those patients who were under active care of Cancer Program oncologists, the retest results were available on the addenda to the pathology reports, and we know from the evidence that in some cases those patients had treatment changes instituted before their cases were considered by the Physician Panel.

571. Through the fall of 2005, the Panel dealt efficiently with the test results that were available. There was then an interval when the Panel had no test results to consider. This also meant that when most remaining results were delivered in a large batch in January 2006, it took time for the Panel to work through those. Had it been possible for Mount Sinai to deliver the test results more quickly, or at a steady rate, the paneling process would also have been completed sooner.

572. For those patients whose retests confirmed the original negative results, telephone calls were made to notify them of that information. Again, it is now recognized that follow-up letters would have been useful and appropriate in those circumstances.

573. The effectiveness of communicating retest results to patients with changed results by writing their most responsible physician was not questioned until after

the paneling process had been completed. To all involved in the process, this would have been consistent with the way that all test results were communicated. It provided an opportunity for a patient to deal directly with a known and trusted caregiver who, if they could not answer their questions, would know what to do for them to find the answers. The relationship between the physician and a patient is a strong and important one.

574. The problems with communicating in this manner are described earlier in this submission. Had it been anticipated that there would be cases where the physician recorded as being responsible for the patient's care would be unavailable, or would have difficulty contacting the patient, then it would have been useful and appropriate to adopt a process of early follow up with physicians to confirm contact with their patients.

575. Within the Quality Department, lists were maintained of patients who had to be contacted with confirmed negative results and efforts were made to track and follow up any that could not be immediately contacted. Lists were kept of patients whose changed results had to be considered by the Physician Panel. The panel letters sent to physicians could be, and eventually were, reviewed to track whether all patients had been paneled and their physicians informed. These records were maintained in the Quality Department.

576. The other Regional Health Authorities undertook responsibilities regarding contact by telephone with patients originating in their regions, adding an additional level of complexity. Problems occurred with patient contact by Central Health and Western Health as well.

577. One of the important lessons learned from the ER/PR retesting experience is that those involved in managing the process did not have the specific kind of project management background that would have been useful and appropriate to apply to management of the retesting and communication. Donald McDonald explained it well when he said that the real issue is not one of information technology, it is one of information management. He said that there is a lack of people with developed information management skills throughout health care.[603]

(v) The Special Cases

578. The DCIS cases were discovered as a by-product of the ER/PR retesting. They were a collection of a small number of cases where diagnosis errors had been discovered. There were no immediate treatment ramifications for those patients and disclosures were conducted in the manner consistent with the disclosure guidelines. The retro converter cases were similar. Had they not been wrapped

[603] Evidence of Dr. Donald MacDonald, October 23, 2008, page 23 line 19 to page 30 line 6

up in the larger ER/PR process it is possible that there would have been capacity to arrange for some of these disclosures sooner than they were.

(vi) Apology

579. Early in the public hearings Mrs. Joan Dawe, the Chair of the Eastern Health Board, delivered a public apology on behalf of the organization. Later, letters of apology were sent to affected patients.

580. Disclosure policies and the principles underlying them encourage appropriate apologies to patients affected by adverse events. In many cases an apology is just the right thing to do.

581. The effect of apologies is a matter of legal uncertainty. There may be a concern that an apology can be used to establish legal liability where none may otherwise exist. Even if that is not the legal effect of an apology, it may still be used by a plaintiff in a lawsuit to create an issue that those responsible for defending the claim have to respond to.

582. Some jurisdictions in Canada and the United States have enacted “apology legislation” in an effort to alleviate concerns that apologies can create legal liability that would not exist otherwise. In 2008 the lack of such legislation in

Newfoundland and Labrador did not prevent Eastern Health from issuing the apologies that it has, however the potential benefits that might accrue from such legislation are matters that the Commission may want to consider.

(vii) Content of Disclosures to Patients

583. Two issues that have potential to affect the content of disclosure to patients about the causes of adverse events are the protection of information obtained through the Peer Review and Quality Assurance processes and the potential impact on legal claims brought against the organization or the health care providers. For convenience those two issues will be discussed in the next section dealing with disclosures to the public.

D. Was Communication with the Public and within the Health System Timely and Appropriate?

The commission of inquiry shall inquire into whether, once detected, the responsible authorities communicated in an appropriate and timely manner with the general public and internally within the health system about the issues and circumstances surrounding the change in test results and the new testing procedures.

584. The extent of obligations, legal or otherwise, to make disclosures to the public about adverse events and the content of such public disclosures is an area that is less well developed than disclosure to affected patients. When ER/PR retesting first became an issue in 2005, there were no policies, procedures or other forms of guidance available within Eastern Health or its predecessor organizations, or in the health care system in Newfoundland and Labrador generally, to help frame the discussion about when and to what extent notification to the public should be made.

585. Eastern Health looks forward to the comments and recommendations of the Commission, and the Task Force on Adverse Events, concerning the development of such policies.

586. By 2005 when these issues arose health care organizations were beginning to become more active in initiating public disclosures of adverse events. Eastern Health has, as it has grown and developed since 2005, placed increasing emphasis on the importance of initiating public communications about events

occurring within the health care system, and supports the concept that the public has a right to know about such events, whether they are good or bad. It is a publicly funded system that we all rely upon to deliver quality health care. We all have a stake in what happens within it. Prompt public disclosures of adverse events promote accountability on the part of health care providers and should encourage confidence in the management of the health care system. The extent of the information that should be disclosed about adverse events is an area that requires further development.

587. There is still much room for work to be done to help guide those who now have to undertake the responsibility of instilling that confidence through appropriate public disclosure of adverse health care events.

588. A number of issues related to public disclosure arise out of the events explored by the Commission in the public hearing.

589. In July, 2005, when it became apparent that the ER/PR testing problems were not limited to isolated cases, the initial response of the small group then involved, including Mr. Tilley, Dr. Williams, Dr. Cook, Mr. Gulliver, Ms. Bonnell and Ms. Predham, was that a public announcement would have to be made promptly. When Minister of Health and Community Services John Ottenheimer was informed of the problem, he held the same view.

590. A public announcement at that time could have served two purposes. One is to inform the public of an adverse event for the purposes described above. The other is that, with hindsight, it could have allowed the small number of people who needed retesting and who were not identified internally by the health authorities to come forward sooner. In a case where it is known or suspected that there may be people who need to identify themselves for personal or public health reasons, a public announcement would be a necessity.

591. In this case, once the decision was made to defer the timing of informing patients that their samples would be retested, then any form of public announcement had to be deferred as well.

592. In October 2005, when the news of the retesting became public, Eastern Health's public communications were prompt, open and appropriate, primarily, through Dr. Williams who acted as spokesperson. Through 2006, however, the organization refused many requests for media interviews. It is now recognized that during this period it would have been more appropriate to respond to those requests with as much information as could be provided at the time rather than to elect to wait until the processing of the retest results was completed.

593. The focal point for discussion about what information should or should not be discussed publicly was the December 11, 2006 media briefing. Those involved

in preparing for the briefing admit having underappreciated the significance and impact of choosing to limit the information to be disclosed in the manner in which they did. In particular, they confirmed in their testimony that all the statistics regarding the retesting results should have been released at that time. This is a point where Eastern Health clearly could have done better. Had all the numbers that had been compiled for the November 23, 2006 briefing note for Government been publicly released at that time, the events of May, 2007 may have unfolded very differently, and the public confidence in Eastern Health may not have been undermined to the extent that it was.

594. The question of how much to say at the December 11, 2006, media briefing about causative factors for the test changes is a more complex issue. It is affected by the existence of litigation in which cause was alleged and was being defended, and by the confidentiality believed to be afforded to the external review reports both by law and as a matter of health care policy.

595. Whether a law suit is commenced against a health authority over an adverse events is a matter completely beyond the control of the authority. The only fiscally responsible way to plan for such claims is to ensure that sufficient liability insurance is in place. In those circumstances, the insurer normally assumes

conduct of the defence of the claim and will play a very important role in determining whether the claim is settled by negotiation or defended in Court.

596. Despite the fact that the class action litigation was well underway by December 2006, the evidence supports the view that it was left completely to Eastern Health's discretion to determine what factual information it disclosed about factors that may have contributed to the changes in test results.

597. Nevertheless, there was a commonly held view, not restricted to Eastern Health or confined to the health care sector, that once a matter is "before the Courts", it is not appropriate to comment publicly on issues that the Court will be called upon to decide. The "cause" of test result changes was such a matter.

598. Choosing not to speak publicly about a matter that is subject to a law suit is not an issue for a private individual or a private company. But for a public body there are competing interests promoting open and transparent disclosure that have somehow to be balanced. This is an area where the guidance of the Commission will be helpful.

599. Until January, 2008, the external review reports were regarded as being subject to the protections afforded by Section 8.1 of the *Evidence Act*[604]. Those restrictions would limit the use that could be made in legal proceedings of those reports and the investigations that led to them.

600. More broadly, however, the principles set out in the materials filed with the Supreme Court by Eastern Health on the application concerning use by the Commission of those reports describe the underlying principles for maintaining confidentiality of information disclosed to the reviewers and the opinions expressed by them. The objective is to ensure that there is full disclosure of all information that needs to be considered in order for the reviewers to understand an adverse event and make appropriate recommendations to prevent its recurrence. Full and frank disclosure to the reviewers is encouraged by assuring people that there will be no repercussions because of their participation in the review. Similarly, the reviewers are free to present their opinions frankly without concern that they will become involved in legal proceedings. These are valuable and useful principles that have been well recognized in law and in health care.

601. Since the *Evidence Act* provisions were enacted, there has been a greater move towards full disclosure of adverse events to patients and towards public

[604] RSNL 1990 Chapter E-16

accountability for them. In a sense, that movement and the principles underlying the reasons for protection of peer review and quality assurance reports share a common goal, that of promoting the quality of health care. This case, however, illustrates how the two can come into conflict and the difficulties of resolving that conflict.

602. But it should not come down to having to make a choice to reject one approach completely in favour of the other. The ability to carry out effective peer and quality review in health care has been shown to have considerable value and needs to be preserved. At the same time the growing awareness of the values of openness and transparency must be fostered.

603. The recommendations from the external review reports were key pieces of information used to implement the quality improvements necessary for ER/PR testing. However, everyone involved on behalf of Eastern Health felt a responsibility to protect the integrity of the quality review process.

604. How to deal with facts that are not protected from disclosure but nevertheless form part of the information collected in confidence by reviewers, and how to protect opinions that are the basis for actions taken in response to a problem are difficult questions for a health care administrator or physician in the midst of managing an issue to resolve. Little guidance is available about how to manage

these difficult issues and this is an area where the advice of the Commission about where to go from here will also be very valuable.

605. Communications between Eastern Health and the other health authorities have not been canvassed in detail in this submission. Each health authority is a separate entity with separate jurisdiction and responsibilities. There are some forums where representatives from the authorities come together to exchange information and promote cooperation but there are no formal provincial structures that allow for the coordination of activities such as the retesting of the ER/PR samples and the communication of results to the patients.

606. By default, Eastern Health took a lead role in ER/PR retesting and communications with patients, but each authority made its own arrangements for identifying cases to be retested and carrying out parts of the communication process.

607. Issues developed, in particular concerning the communication of information to patients, that would have benefited from a more structured and better resourced approach.

E. Are Best Practices in Place?

The commission of inquiry shall advise whether the estrogen and progesterone hormone receptor testing systems and processes and quality assurance systems currently in place are reflective of "best practice".

608. In the fall of 2005, the template that was adopted for implementing improvements in ER/PR testing and the immunohistochemistry lab was built around the recommendations contained in Dr. Banerjee's and Ms. Wegrynowski's reports. As with any set of recommendations, it is up to the institution to determine to what extent, how and when those recommendations can be implemented. Not all recommendations may be accepted. Not all may be implemented in the way that the reviewers anticipated. The improvements implemented may nevertheless achieve a "best practice" result. In this case Eastern Health has accepted all recommendations from the external reviewers (except the implementation of Sakura Express tissue processing system), and has worked diligently at implementing them.

609. Significant changes that have been made[605] include:

- Reorganization of the management structure in laboratory medicine to create a single senior management position reporting to the Vice-President of Medical Services.[606]

[605] Exhibit P-3224 is a list of improvements compiled in February 2008

- Appointment of a pathologist to the position of Director of Immunohistochemistry and providing him with specialized training.[607]

- The creation of the Program Manager position for Safety and Quality Management for Medical Services and Diagnostics reporting to the Vice-President responsible for that portfolio.[608]

- The creation of a position within the pathology division staffed by a technologist dedicated solely to quality assurance functions.[609]

- The creation of a new senior technologist position within the immunohistochemistry service staffed by a PhD prepared technologist.[610]

- The creation of positions for four pathology assistants and the creation of a formal training and competency assessment program for them.[611]

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[606] Evidence of Dr. Oscar Howell, May 26, 2008, page 20 line 4 to line 15
[607] Exhibits P-2076. P-2303
Evidence of Dr. Oscar Howell, May 22, 2008, page 91 line 12 to line16, page 92 line 24 to page 93 line 13
Evidence of Dr. Nebojsa Denic, September 12,2008, page 96 line 12 to page 101 line 5
[608] Exhibit P-3588
[609] Evidence of Terry Gulliver, October 14, 2008, page 203 line 16 to line 25
[610] Evidence of Dr. Ford Elms, September 2, 2008, page 366 line 1 to page 369 line 1
Evidence of Terry Gulliver, October 3, 2008, page 151 line 2 to line 11, October 7, 2008, page 281 line 2 to line 21
Evidence of Barry Dyer, July 22, 2008, page 86 line 8 to line 23
[611] Exhibits P-0049, P-1742 page 3, P-2115

- Complete dedication of IHC technologists to IHC testing relieving them of responsibilities for other duties.[612]

- Measures to enhance and maintain the knowledge, training and expertise of the IHC technologists including a move towards formalized and documented in-house training.[613]

- Establishment of a quality control/quality assurance committee for pathology.[614]

- The creation of a sub specialty breast group within pathology.[615]

- The formation of an interdisciplinary breast disease site group.

- Development of comprehensive, standardized, structured policy and procedure manuals for immunohistochemistry and anatomic pathology.[616]

- Enrollment in multiple proficiency testing programs.[617]

[612] Evidence of Ken Green, July 15, 2008, page 37 line 22 to page 38 line 7
[613] Evidence of Lynn Wade, October 27, 2008, page 144 line 13 to page 146 line 4
[614] Exhibit P-1919
[615] Exhibit P-2389
[616] Exhibit P-2157

- Validation of a minimum of 10% of all ER/PR tests performed by correlation testing at Mount Sinai laboratory.[618]

- Adoption of standardized reporting of ER/PR testing by pathologists.[619]

- Distribution of standardized fixation policies among all health authorities in Newfoundland and Labrador.[620]

- The development of a formal Quality Management Program under the supervision of the QC/QA Committee.

- Consolidation of the pathology service to a single St. John's site.

- Improvements in compensation and continuing education opportunities for pathologists to encourage recruitment and retention.

610. Three independent assessments of aspects of the IHC lab and ER/PR testing have been conducted.

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[617] Exhibits P-3592, P-3595, P-3597, P-3598, P-3599, P-3600, P-3602, P-3603
[618] Exhibit P-2725
Evidence of Dr. Nebojsa Denic, September 12, 2008, page 299 line3 to page 303 line 2
[619] Exhibits P-0527, P-2639
[620] Exhibits P-2272, P-3607, P-3609

611. On December 7, 2007, Dr. Gregory Flynn, Managing Director of the Quality Management Program-Laboratory Services of the Ontario Medical Association, Mr. Bryan Hewlett, the QMP-LS External Quality Assurance Technical Coordinator and Ms. Laurie Mason, the QMP-LS Anatomic Pathology Committee Chair conducted an on-site review of the Eastern Health Immunohistochemistry laboratory in St. John's.

612. QMP-LS is the organization which conducts mandatory accreditation of laboratories in Ontario, including the Mount Sinai laboratory. A written report was delivered following the consultation.[621] The consultants reviewed the facilities, the laboratory personnel, the staff workload, the equipment, the technical methods and procedures used, documentation and record keeping, quality assurance measures, manuals, staff education and availability of text books and journals. Some recommendations were made for further improvement, however, many were for continuation of work that had begun following the external reviews of 2005, such as continuing the completion of the process of developing standardized policy and procedure manuals. The statements made in the conclusion include,

> The laboratory is functioning at a comparable level to similar labs in Ontario. The lab has a demonstrated commitment to external quality assurance and to service excellence.

[621] Exhibit P-0051

> In conclusion, the IHC laboratory is producing good results which would be interpretable anywhere. There are improvements that could be made to the selection use and recording of control material, but these are incremental in nature. The administration should be confident that at this time, the IHC laboratory is operating a high quality controlled ER/PR program. Maintaining that quality requires professional and technical oversight on an ongoing basis, particularly as the IHC laboratory will experience significant turnover and there is nothing that will change the geography of Newfoundland and Labrador. Communication and cooperation with the referring hospitals will also be required to promote standardization and ensure high quality results. Participation in external quality assurance programs is an essential part of monitoring such a sophisticated testing system that is sensitive to many potential variables.

613. The Canadian Counsel on Health Services Accreditation conducted an accreditation survey of Eastern Health between September 23 and 28, 2007.[622] Unlike previous accreditations, a new process had been adopted by CCHSA which involved a more extensive review of laboratory services. Eastern Health was one of the institutions that participated voluntarily as a pilot of this program. It will become mandatory for future accreditations of all hospitals.

614. The review process involved assessing the laboratory against established criteria requiring the laboratory to prepare in advance the documentation to establish its compliance. The accreditation report was positive and assisted, as an accreditation report should, in identifying areas where further improvement can be achieved.

[622] Exhibit P-0745

615. In September, 2008, the Commission commissioned Mr. Hewlett, who had been one of the consultants who prepared the QMP-LS report in December, 2006, and Mr. William Parks to conduct a process review at the pathology laboratory's General Hospital and St. Clare's sites.[623]

616. The focus of this review was on tissue fixation and processing, manuals and documentation and technologist staffing.

617. Their observations regarding the processes and procedures for tissue fixation and the quality of fixed tissue were very positive. They suggested acquiring a different commercial formalin product with higher PH and a conventional phosphate buffer in place of the product currently purchased in bulk through the Newfoundland and Labrador Hospitals Association for use throughout the province. The tissue processors at the General Hospital site had been replaced a number of months prior to the consultant's visit. They identified a problem with the technical functioning of the system in that there was excessive zylene in one of the solutions. The manufacturer's representative was contacted immediately, came to St. John's and determined that the problem could be traced to a charcoal filter which needed to be changed on a more regular basis. It was subsequently determined that the maintenance checklist for the tissue

[623] Exhibit P- 3119

processors had not specified the replacement interval of the charcoal filter and that deficiency was immediately rectified.

618. Mr. Hewlett and Mr. Parks in their evidence confirmed that this particular tissue processing problem could make it more difficult to cut tissue from the blocks to make slides, but would not affect the results of ER/PR testing.[624] Mr. Parks and Mr. Hewlett also suggested a change in the sequence of solutions in the tissue processor. The sequence used in St. John's had been to expose the tissue to formalin in the first two processing cycles. In the past, when there had been issues regarding the adequate fixation of tissue placed in cassettes, the extra time in formalin in the tissue processor allowed for additional fixation of the specimen. Since there were no longer any issues with tissue fixation prior to the processing phase, the sequence of solutions could be changed to eliminate one formalin cycle and add an extra alcohol cycle for enhanced dehydration of the tissue.

619. Mr. Hewlett and Mr. Parks had positive comments for the work that had been done on developing the policy and procedure manuals stating that the completed sections were equivalent to and in some cases superior to accredited laboratories in other jurisdictions. They had suggestions for better familiarization

[624] Evidence of Bryan Hewlett and William Parks, October 10, 2008, page 355 line 21 to page 359 line 7

of staff with the new policies and procedures and recommended that better use be made of the quality control information that was being generated.

620. Their concluding statement regarding compliance is,

> We believe that the laboratory's efforts to date, in regard to the handling of fresh breast and other specimens, fixation policies/procedures and the grossing practices places them well in compliance with, and even exceeds, the important pre-analytic portions of the Canadian Consensus Guidelines for HER2/Neu testing, the ASCO/CAP Guidelines for HER2 testing and the soon to be released Ad-hoc Committee ER Testing Guidelines. With further modifications to the tissue processing and embedding protocols correcting any potential remaining processing insufficiencies, the effects of poor tissue preparation on IHC testing would be a thing of the past.

F. What Recommendations are Necessary and Advisable?

The commission of inquiry shall make the recommendations that the commission of inquiry considers necessary and advisable relating directly to the matters of public concern referred to in paragraphs (a) to (e).

621. It is for the Commission to decide upon the recommendations that it considers either necessary or advisable in order to address the matters that are of public interest and that have arisen out of the issues inquired into under the first five terms of reference. Eastern Health does not propose to present the Commission with specific suggestions for recommendations in this submission. The summary of "lessons learned" attached as Appendix B to this submission includes a number of the areas for which recommendations should be considered. This document has been prepared since the public hearings concluded and includes contributions from a number of Eastern Health personnel who participated in the Inquiry process.

622. Eastern Health suggests that the Commission consider recommendations addressing the following issues:

- Licensing and accreditation of medical laboratories in the Province,
- Licensing and professional regulation of medical laboratory technologists,
- Measures to promote and maintain stability of staffing of pathologists and medical laboratory technologists in the Province,

- Measures to provide access for pathologists and technologists, province wide, to continuing education to ensure that laboratory services keep pace with technical and medical advances,
- Provincial processes to adopt common policies and procedures, where appropriate, to ensure the accuracy and reliability of laboratory testing,
- Assessment of present and future information technology and information management needs, both internal to Regional Health Authorities and, where appropriate, integrated among the Authorities,
- The appropriateness of the Eastern Health and CPSI model disclosure policies for disclosure of adverse events to patients,
- Guidance for the development of policies for the disclosure of multi-patient or large scale adverse events to patients,
- Guidance for the disclosure of adverse events to the public,
- Guidance on the best approach to the direct involvement of patients and of patient advocacy groups in decision making about the response to adverse events and the disclosure of them to patients and the public,
- Guidance about fostering relationships with the media to promote effective communication of matters of interest to the public,
- Guidance regarding how to balance the need to carry out effective peer review and quality review activities with open disclosure of information about adverse events to affected patients and the public,

- Guidance regarding the effect, if any, on disclosure where the adverse event is the subject of legal proceedings,
- Measures to build capacity within the Regional Health Authorities to respond effectively to unforeseen events such as the ER/PR retesting.

623. In many of these areas specific recommendations can be made and will be welcomed. In others the Commission may consider recommending further processes to be used to develop the best response. An example of the latter is the tension that has developed between confidentiality of peer review and quality review processes on the one hand and open disclosure of adverse events to patients and the public on the other discussed beginning at paragraph 599 above.

624. To adequately address an issue such as that legislative changes may be required. Academic contributions would be needed. A broader public discussion should be part of the process. As thorough as this Commission's public hearing process has been, this Commission may not be in a position to make specific recommendations for action now on such issues. Instead it may be advisable for the Commission to identify the issues, set goals for resolution of them and recommend the processes to be used to get there.

IV. Conclusion

625. The impact on breast cancer patients and their families of ER/PR tests that were originally negative, but that changed to positive when retested, cannot be reversed. Had those original tests been positive, more women and men would have been considered for, and likely would have been administered, adjuvant hormonal therapy. While no one can say who would have benefited, or to what extent, as a group there is no doubt that there would have been benefits.

626. On May 18, 2007, Eastern Health CEO George Tilley said publicly,

> We felt that if there was even the possibility that one patient may benefit from retesting, we had an obligation to retest all patients, regardless of the consequences.[625]

627. Just as there is little doubt that hormone positive patients who do not receive hormonal therapy are at greater risk for recurrence of breast cancer or for metastatic disease, there is also a reduction in that risk even if hormonal therapy is started later than it could have been. From that perspective the choice to initiate the retesting has had positive effects for breast cancer patients in this Province.

[625] Exhibit P-0443 page 3

628. The medical literature illustrates that the type of variability in ER/PR results seen in Newfoundland and Labrador has been known among laboratories in Europe and elsewhere since 2000. Dr. Allred, an authority in the field of immunohistochemistry, has written in The Oncologist just last month that there is no reason to suspect that laboratories are doing any better in the United States.[626] But there has been no evidence produced from the medical literature, and no examples given by the expert witnesses who testified at the public hearings, of any other example of a health authority choosing to do what Eastern Health did when confronted with information that its testing results might be unreliable.

629. The decision to retest all negative specimens was the single most important response to the discovery of potential unreliability of the original tests. That response was an unprecedented one. It was taken in the interest of the patients. Those involved recognized that there would certainly be negative consequences, and possibly quite serious ones, for the organization and for the people in it.

630. Undertaking the retesting has not been without consequences for Eastern Health, but they have not all been negative. The scrutiny placed on the laboratory and the delivery of cancer care, and on the capacity of health care authorities to manage such a project has highlighted the weaknesses that had

[626] Appendix C

developed over time and has attracted the attention and resources needed to bring about changes that will benefit patient care in many areas in addition to ER/PR testing alone. There is momentum towards continually improving quality assurance which will continue.

631. The challenge now for Eastern Health and all stakeholders in the health care system is to act on the lessons learned. Together we must ensure that the best possible quality assurance measures are in place in the Province, that any future adverse events are dealt with as effectively and openly as possible, and that the public can be confident in the quality of health services provided.

Respectfully submitted this 1st day of December, 2008.

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White, Ottenheimer & Baker
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Appendix A

Submission on Behalf of the Board of Trustees of the Eastern Regional Integrated Health Authority

1. This memorandum examines corporate governance in the not-for-profit corporate sector, with a particular emphasis in the field of health care boards and the Board of Trustees of the Eastern Regional Integrated Health Authority ("Eastern Health"). As will be demonstrated, the guidance provided to the Board of Trustees was somewhat limited, with little direction from the legislation (which prior to the 1 April 2008 coming in force of the *Regional Health Authorities Act* was the *Hospitals Act*) or the Government as to the proper role for the Board of Trustees as the corporate governing body.

Two Models of Corporate Governance

2. There exists a dichotomy between the two prevailing models of corporate governance employed in most not-for-profit corporations ("NFPC's"). The traditional model sees the directors manage the affairs of the organization, with the board making most of the substantive organizational decisions. This model, also known as the "administrative governance board" model, resembles more closely the hands-on type of board that is seen in most for-profit corporations. The second model, also known as the oversight role, sees the directors entrusted

with ensuring that the organization is effective and accountable. This model requires that the board of directors set policy (in operational and other areas) and focus on the vision, mission, values, and strategic priorities of the organization but leaves the implementation of those policies and day-to-day management in the hands of the officers and employees of the organization. This model is also known as the "policy governance board" and such a board acts as a steward for the stakeholders of the organization. It should be noted at the outset that most organizations, including most NFPCs, do not necessarily adhere strictly to one model or the other and most are a mixture of the two models in varying degrees.

Literature and Secondary Sources

3. Regardless of the model used, as noted by John Carver and Miriam Carver in Carver's Policy Governance Model in Nonprofit Organizations[627], a board of directors, while having total authority over an organization, is almost forced to rely on others to exercise the authority of the organization and fulfill the accountability. Those authors recommend that this delegation occur through a single point: the Chief Executive Officer (CEO). This permits the board of directors to express its expectations through a single channel rather than

[627] John Carver and Miriam Carver, "Carver's Policy Governance Model in Nonprofit Organizations", [online] www.carvergovernance.com/pg-np.htm, originally published in *Gouvernance - revue internationale*, Vol. 2, No. 1, Winter 2001, pp. 30-48

requiring the board to work through the internal divisions of labour. While the use of a CEO in this fashion facilitates the work of the board of directors, it also causes the board to rely heavily on the CEO to ensure that direction set by the board is followed within the organization.

4. John and Miriam Carver also note that it is those persons who are directly responsible for producing ends who should decide what means to use. They state that as the board of directors is charged with defining the ends instead of producing them,

> "it is to the board's advantage to allow the staff maximum range of decision-making about means, for skill to do so is exactly why staff were employed. If the board determines the means of its staff, it can no longer hold the staff fully accountable for whether ends are achieved, it will not take advantage of the range of staff skills, and it will make its own job more difficult."

This permits the separation of policy making from implementation, and ensures that both the board and the staff (including the CEO) are aware of their proper roles.

5. The degree of delegation in NFPCs often exceeds that in a typical, for-profit corporation. In many typical for-profit organizations, the board of directors is often comprised of shareholders who are the actual owners of the corporation and who have a vested financial interest in the success of the corporation. As stated by

Donald J. Bourgeois in his article "Board Governance – When Does it Become Director's Negligence"[628], the correct mixture between management and oversight for a board of directors is organization and time specific. Bourgeois states:

> "There are practical limits to the abilities of directors to manage the affairs of large organizations with many employees. It is physically impossible for these directors to make all of the decisions that are required to be made on a day-to-day basis. Arguably, these directors could be negligent if they attempted to do so because decisions would not be made by the person most competent to do so, the decisions would not be made in a timely manner and the directors would be wasting the skills and talents of its employees."

632. Bourgeois then goes on to examine the factors which tend to suggest toward which end of the spectrum between the "administrative governance model" or the "policy governance model" a given board of directors should find itself. Those factors are:

1) The legal authority of the directors, officers, and the organization itself;
2) Statutory or common-law obligations or restrictions;
3) Letters patent, by-laws, constitution, or other constating documents;
4) Culture of organization, which is often at variance with the organizational documents and at times with the legal requirements;

[628] Donald Bourgeois, "Board Governance - When Does it Become Director's Negligence?" [online] www.charitylaw.ca/articles.html

5) Views and perspectives of key stakeholders, who sometimes are not sensitive to the legal niceties or are overly demanding of compliance with policies that are not relevant to the organization;

6) Skills, competence and training of staff;

7) Size and type of operations and activities carried out by the organizations and their complexity; and

8) Due diligence requirements of the directors and of the officers.

6. Bourgeois recognizes that although there are certain paramount decisions and issues that should only be determined by the board of directors of all organizations (such as budgets), the correct mix of “administrative governance” and “policy governance” varies for any given organization, given the circumstances.

7. John and Miriam Carver also remark that the members of a board of directors should not be recruited to their positions based on their skills mirroring those of the staff and employees. Boards of directors, they argue, ought to be persons who can think conceptually and in the interests of long-term planning. It is not necessary, therefore, to require that the members of the board have expertise in the particular affairs of the organization.

Legislation

8. The legislation applicable to Eastern Health, and its Board of Trustees, until 1 April 2008 was the Hospitals Act, R.S.N.L. 1990, c. H-9, as amended. On that date it was replaced with the Regional Health Authorities Act, S.N.L. 2006 c. R-7.1.

9. The Hospitals Act had a number of provisions which related to the Board of Trustees. Section 4 of the Act gave authority to the Lieutenant-Governor in Council to establish hospital boards to "manage and control the operation" of designated hospitals and provided that any such hospital boards are corporations. Section 7 of the Act required the number of members of a hospital board to be between 8 and 18 persons. All residents of the province were deemed "qualified" to be members of such a board except members of the medical staff of a hospital operated by the Board or an employee of the Board. Sections 16 and 17 of the Act are the only provisions which shed any light upon the correct role for the Board of Trustees and to illustrate the vague direction provided by same, they are reproduced as follows:

> **Appointment of staff**
> 16. Subject to the regulations, a hospital board may appoint an administrator of a hospital under its jurisdiction who may also perform the duties of secretary, and other medical, nursing, technical, administrative, clerical, secretarial, accounting and other staff that it considers necessary for exercising and

carrying out the powers and duties referred to in section17, and may provide the salaries or the other remuneration for them that it thinks appropriate.

1971 No81 S17

Powers and duties of board

17. (1) The powers and duties of a hospital board are

(a) to maintain, manage and operate the hospital under its jurisdiction and to provide in them accommodation for the treatment and care of all patients, whether suffering from disease or accident, and, subject to the regulations, to fix fees and arrange terms for services rendered to patients and to enter into contracts for the admission and care of those patients;

(b) to provide facilities for proper medical and surgical attendance, nursing, food and medicine, and all things and appliances of a medical, surgical, dietetic and sanitary character that may be required for the treatment of patients;

(c) subject to the approval of the minister, to add to or extend the hospital or its facilities named to build or provide additional buildings for the purposes of the hospital, including nurses' home or staff quarters that it may consider expedient;

(d) subject to the approval of the minister to educate and train nurses and other hospital personnel;

(e) to accept subscriptions and donations, whether lands, buildings, money or other property and devises and bequests, for 1 or more of the purposes referred to in paragraph (a) and (d) and, subject to the approval of the minister, to sell and dispose of or to lease and accept surrenders of leases of and manage all land, buildings and other real property, except real property referred to in paragraph (g), so received and not required to be or capable of being occupied or used for the purposes of the hospital;

(f) to take steps by personal or written appeals, public meetings or otherwise that it may consider appropriate for the purpose of obtaining contributions, in the form of

donations or annual subscriptions or otherwise, to the funds of the hospital or the hospital board;

(f.1) subject to the approval of the minister, to receive loans from government, municipal or other bodies, public or private, or from other persons and to pay interest and establish sinking funds on those loans and to repay those loans;

(g) to administer, in furtherance of the objects of the hospital board, all funds which it may receive and to sell and dispose of or to lease and accept surrenders of leases of and manage all real property donated or devised to the hospital board; and

(h) generally to do all those things that it considers appropriate for the purpose of the attainment of the above objects.

(2) The powers and duties conferred on a hospital board buy subsection (1) are subject to those qualifications, modifications, limitations and restrictions that may be imposed by this Act and the regulations.

(3) Nothing in this Act prevents a hospital board from inviting a member of the medical staff or the administrator of a hospital operated by it, an employee or the board or other person to attend a meeting of the board.

1971 No81 S18;1991 c44 s1

10. It is especially important to note that the delegation of the board's power and duties as found in s. 17 is expressly recognized and permitted in the language of s. 16. There was, unfortunately, no further direction provided by the Hospitals Act with respect to the proper role and function of the Board of Trustees, nor was there any indication as to the standard of care applicable to the members of the Board in discharging their duties. Although technically governed by the Hospitals Act, the 18 volunteer-member Board of Trustees recognized in 2005 that the governance structure of the organization must be more clearly defined. With this in mind, and in preparation for the coming in force of the new Regional Health Authorities Act, the Board of Trustees took on the task of identifying the appropriate model of corporate governance.

11. The Board of Trustees was able to draw upon the additional guidance provided by the *Regional Health Authorities Act* (hereinafter "RHAA") and the *Transparency and Accountability Act*, which has helped remedy the problem of poor role definition posed by the former *Hospitals Act*. Although the RHAA was not in force until 1 April 2008, the legislation received royal assent in 2006 and the contents were in the public domain, permitting the Board of Trustees to draw upon the direction found therein. Section 5 of the RHAA gives authority to the Minister of Health to provide directions to a Board of Trustees regarding objectives, priorities, guidelines, and coordination with third party entities. Section 8 of the RHAA established the Board of Directors (Trustees) of the health authorities and provides that "the management and affairs of an authority shall be directed by a board of trustees appointed by the minister in accordance with the

regulations." The RHAA permits the Board of Trustees to make by-laws at section 10. Section 14 requires the Board of Trustees to appoint a CEO (subject to approval by the Minister of Health) and makes clear that the CEO is "under the direction of the board, responsible for the day to day management and conduct of the affairs of the authority." Sections 16 and 17 set out, in detail, the responsibility and powers of the health authorities, respectively. Section 25 explicitly states that no action for damages lies against trustees, officers, or employees of a health authority for anything done or omitted, in good faith, in the performance of their duties. The *Transparency and Accountability Act* requires Eastern Health to develop a strategic plan every three (3) years, and provides direction as to the contents of same. The Transparency and Accountability Office provided to the members of the Board of Trustees (as part of their orientation upon assuming their positions) a document entitled "Excellence in Governance: A Handbook for Public Sector Bodies"[629]. This document was reviewed and thoroughly discussed by all Board members and provided the Board with practical guidelines regarding its role. The Board of Trustees sought additional direction from the Minister of Health at the time, the Hon. John Ottenheimer, regarding the particular application of the relevant legislation to the Board. The conduct of the Board of Trustees has been consistent with the provisions of the *RHAA*, the *Transparency and Accountability Act*, and with the guidelines provided in "Excellence in Governance: A Handbook for Public Sector

[629] Government of Newfoundland and Labrador (Transparency and Accountability Office), "Excellence in Governance: A Handbook for Public Sector Bodies" [Revised June 2005] [online] www.exec.gov.nl.ca/exec/cabinet/transacc/publications.htm

Bodies" and the Board of Trustees drew heavily upon all of these resources in developing the particular governance model it has adopted.

A New Governance Model for Eastern Health

12. The Board of Trustees engaged in considerable examination of the then-current practices at Eastern Health, national accreditation standards, relevant legislation (including the *RHAA*, the *Hospitals Act*, and the *Transparency and Accountability Act*), and literature regarding corporate governance, including "Excellence in Governance: A Handbook for Public Sector Bodies". Following lengthy analysis, the Board of Trustees concluded that a modified policy governance model was most appropriate for the organization and this model was consistent with the guidance provided in the aforementioned documents as well as direction provided by Government. The Board of Trustees felt that such a model would more clearly distinguish the role of the Board from that of the executive, permit the Board to focus more on vision and planning for the organization as a whole, strengthen relationships with stakeholders, and define ends policies and executive limitations. The Board recognized the necessary separation of policy formulation from implementation and has assured that the strategic plan (as developed by the Board) would be implemented through a monitoring system which includes internal and external sources, including regular compliance statements from the CEO. This monitoring system permits the identification of areas of variance and allows for the development of action plans to remedy any identified deficiencies. This system provides the Board with information

regarding policy implementation that is focused and permits the monitoring of areas such as quality control in an efficient and highly effective manner.

13. The Board of Trustees developed the first strategic plan (*Eastern Health Strategic Plan: 2006-2008*) of the organization, which set out the values, mission, vision, and strategic issues facing the organization. As part of this process, the Board of Trustees began community-based health needs assessments throughout the region, the first involving the Burin Peninsula. Focus groups, informant interviews, telephone interviews, public submissions, and information contained in administrative databases (among other sources), all combined to provide the Board with the necessary data to identify priority areas and develop recommendations to improve the health and well-being of persons residing on the Burin Peninsula.

14. The Board of Trustees has also taken great strides to comply with the standards developed by Accreditation Canada for sustainable governance. The Board is already in compliance with the 2009 standards, which focus on a number of key areas including:

- Developing a clear direction for the organization;
- Building knowledge through information;
- Internal development of the governing body to function effectively;
- Development of the organization to achieve strategic goals, including CEO recruitment and evaluation;
- Maintaining positive relationships with stakeholders; and

- Accountability and organizational performance, including achievement of goals, quality improvement, risk management, and financial planning and control.

Evidence at Commission of Inquiry on Hormone Receptor Testing

15. The RHAA has codified what the witnesses before the Commission have stated to be their understanding of the role of the Board of Trustees within Eastern Health, even before that Act came into being. The rationale for this role as policy maker is logical given the size of Eastern Health, the complexity of health-related operational matters, and the lack of medical expertise of Board members (it being comprised mainly of laypersons and those with little to no medical training).

16. In his testimony before the Commission of Inquiry on Hormone Receptor Testing, former CEO of Eastern Health, George Tilley, stated on 13 May 2008, in response to questioning from Jennifer Newbury, that Eastern Health was working toward a policy governance model[630]. Although Mr. Tilley recognized that the policy governance model did make it appropriate for the Board to engage in significant operational issues, his comments appeared to limit the role of the Board in such instances to one of discussion and information rather than the Board determining how key operational issues would be handled.

17. This view as to the proper role of the Board of Trustees was echoed by the Hon. John Ottenheimer, Minister of Health, in his testimony before the Commission on

[630] Evidence of George Tilley, 13 May 2008, page 106

7 April 2008 in response to questioning from Daniel Simmons. Mr. Ottenheimer agreed that the role of the Board of Trustees is to set policy, given the size of Board and the size of the operations of Eastern Health, and to respond to the Department of Health when called upon to do so.[631] In response to questioning from Rolf Pritchard on 8 April 2008, Mr. Ottenheimer stated that the Board of Trustees would be responsible for providing the Department of Health with an annual report outlining roles and responsibilities, the strategic plan, and information regarding budgetary issues.[632]

18. The chair of the Board of Trustees of Eastern Health, Joan Dawe, also expressed her view during testimony before the Commission that the role of the Board is, and was, a policy-making role and not an operational role.[633] Ms Dawe also indicated that the conscious decision was taken in 2005 for the Board to adopt a policy governance model, modified slightly to respond to the particular circumstances of the organization.[634] Ms. Dawe also confirmed that the operationalization of the policies and strategic direction set by the Board is delegated by the Board to the Chief Executive Officer and his or her staff within the organization.[635]

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631 Evidence of Hon. John Ottenheimer, 7 April 2008, pages 283-286

632 *Ibid.*, page 15

633 Evidence of Joan Dawe, 26 March 2008, pages 41-42

634 *Ibid.*, pages 44-45

635 *Ibid.*, page 51

19. In her 26 March 2008 testimony before the Commission of Inquiry on Hormone Receptor Testing Ms. Dawe went into significant detail regarding the policy governance model employed by Eastern Health, as well as the historical roots of same. Ms. Dawe recounted that the time she became Chair of the Board of Trustees, in April 2005, was a period of considerable transition for the health care sector in the Province. At that time, although the governing legislation was the aforementioned *Hospitals Act,* Eastern Health and the Board of Trustees were in the process of preparing for the coming in force of the *Regional Health Authorities Act* as well as the *Transparency and Accountability Act*. Ms. Dawe described the efforts of the Board in attempting to govern itself in accordance with the spirit and intent of the new RHAA as that would soon be the applicable legislation. The new Board focused on understanding its proper role as the strategic management of Eastern Health, in contrast to the operational management, which is the responsibility of the CEO.[636] Ms. Dawe went on to characterize the policy governance model employed by the Board of Trustees as a modified policy governance model, as guided by the RHAA and the *Transparency and Accountability Act*. In order to assist the Board in understanding this role, the Board engaged a facilitator from Prince Edward Island with considerable experience in policy governance in the Summer 2005 to lead a retreat for Board members which explored the various governance models.[637] Ms. Dawe further noted that the Board regularly monitored and

[636] *Ibid.*, pages 40-44

[637] *Ibid.*, pages 44-45

evaluated its own functioning on a regular basis. To accomplish this, the Board of Trustees, assigns one trustee at each meeting to monitor processes and the Board. Following each meeting, the Board as a whole reviews the evaluation. This regular group evaluation process is used in conjunction with annual individual and Board performance evaluations.[638]

20. Ms. Dawe also noted that the Board sought direction as to the proper role of the Board of Trustees from the Minister of Health at the time, John Ottenheimer. Mr. Ottenheimer wrote a letter to Ms. Dawe, date stamped 23 November 2005, in which the Minister outlined what the Department of Health and Community Services regarded as the responsibilities of the Board of Trustees.[639] As can be seen from the contents of that letter, the direction from the Minister and the Department clearly laid out a role for the Board of Trustees as strategic managers of the organization. The only reference in that letter to anything which would be characterized as an operational role is the Board's requirement to prepare and monitor the annual budget of Eastern Health; all other references to roles were above the operational level.

Conclusions

21. As can be seen from the foregoing, the Board of Trustees of Eastern Health have developed a modified policy governance model and have taken great strides to adopt that model for the organization. In order to do this, the Board of Trustees

[638] *Ibid.*, pages 48-49

[639] Exhibit P-0099

relied upon a variety of sources, and has developed a model suited to the specific organizational needs of Eastern Health. Given the size of the organization and the extremely complex nature of health-care services, it is reasonable and prudent for the Board of Trustees to rely upon the advice and guidance of the professionals employed by Eastern Health with regards to the day-to-day management of the organization, all the while focusing its efforts on strategic planning, policy making, and accountability to the stakeholders.

Appendix B: Lessons Learned from ER/PR Sentinel Event

The Lessons Learned have been summarized from the collective experience of:

- Executive Management
- Leadership Team of Laboratory Management
- Quality and Risk Management Personnel
- Strategic Communications Personnel
- Leadership Team of the Cancer Care Program

Process	Lessons Learned

Assessment of the Issue and Organizing the Response	• Designate an Executive Lead.
	  o Person with Responsibility for the Service or Program
	• Clarify and designate roles of other Executive.
	  o Quality and Risk Management
	  o Information Management and Technology
	• Designate an overall leadership and decision making structure/team - Core Team.
	• Identify Core Team members and clarify roles and expectations of each member in writing. Include Strategic Communications, IM&T and Ethics on the original Core Team.
	• Consider the need for external expertise.
	  o NLCHI
	  o Researchers
	  o Consultants
	• Designate Project Lead.
	  o Full Time to Begin
	  o Oversees the work and progress of all Working Groups
	• Develop Project Plan – review/revise as necessary and communicate progress to all on a regular basis.
	• Clearly identify the need for and obtain extra resources (obtain executive support for this).
	• Provide dedicated secretarial support for the Core Team and Project Manager.
	• Employ Communications Logging throughout the Process of Assessment and Management of the event.
	• Need for acquiring or developing personnel with skill sets such as Project Management who would assume the Project Lead role.

Client Disclosure	• Ensure policies on Client Disclosure include guidelines for individual and multi-patient disclosure, beyond that currently in the CPSI Disclosure Guidelines. • Document all decisions made around Disclosure to Clients in minutes and through careful Document Control management of all forms of deliberation and communication. • Designate a Lead Person to manage and coordinate all aspects of disclosure to clients whether in person, by phone or by mail. • Include key stakeholders in decision making regarding process of disclosure and the information to be shared. • Include and document an Ethics Review. • Educate all those involved in disclosure to ensure adherence to the Disclosure policy. o Plan for the necessary ongoing support of clients and their families. • Ensure the disclosure process and content are documented in client records. • Ensure primary care physicians are aware of the event and details of disclosure to their respective clients either by a phone call or letter to primary care physician. • If using mail-outs, consider use of Registered Mail, taking into consideration privacy issues especially in small communities. • When organizing a multiple patient mail-out: o Plan the timing to allow time for preparation and checking to ensure accuracy. o Designate a team with a leader to perform and record the task, keeping all records. o Double check all correspondence to ensure accuracy of information, names, addresses, etc. o Use envelopes with windows for the address to ensure there is no discrepancy between address on the letter insert and on the envelope. o Record the chronology of events. o Ensure the disclosure Team Lead is the person who receives any feedback from the mail-out and completes a report with a timeline to the Project Lead. o Require daily updates of progress in writing with disclosure to the person with Lead responsibility for Disclosure.

	• Identify key stakeholders who should have input into the content for disclosure to maximize the accuracy of the message. • Set definite timelines for updates to the Core Team and “adhere to them”. • If using direct calls to patients, carefully discuss the disclosure issues that may be encountered and plan for them. • If using phone calls as the means of disclosure to clients and using staff other than the primary care providers, ensure staff have appropriate skill and knowledge and are as prepared as possible. Consider such questions as: o Who best to do calling? o What are the limitations? o What support do these staff need? • Where possible, consider following up phone calls with a letter. • Staff involved must be educated as to the: o particulars of the event or occurrence, o the particular messages they are conveying, o the disclosure policy, and o their role in interacting with clients/families further questions or requests for clarification. • Plan for and provide staff necessary access to additional information and support to complete the disclosure process. • Dedicate time for this by taking people away from other duties and document these decisions in Core Team Meeting Minutes. • Institute a Hot Line that has all communication recorded. Later have this transcribed. • Ensure staff involved in disclosure have the ability to record this in a central, coordinated fashion, preferably directly into database with “user friendly” mode. • Consider the need for apology and ongoing communication and support and plan for these…follow CPSI guidelines. • If using others to disclose to clients, such as primary care physicians, ensure any direct communication to them is followed up with a letter. Institute a process to verify that they have completed the disclosure.

Informing the Public and Other Stakeholders	• Need to develop and periodically exercise a Crisis Communication Plan to guide client disclosure and Public Notification. o Plan will ensure timely, automatic transition into disclosure and informing the public. • When making decisions, include all key internal stakeholders. • Employ an Ethics Consultation with any issues relating to Public Notification. • Document all considerations and decision making components. • Include in the Plan, the needs of other key stakeholders for information and involvement in making decisions , e.g. advocacy groups. • Early consultation with DOHCS. • Establish role of the Board and rules of engagement with Government. • Effective Media Management Plan. • Clarify role and relationship with Insurers in this process. • Provide regular updates to the Board as part of a pre-determined plan by the Core Team. • Consideration of Privacy and ATIPP requests. • Designate a primary spokesperson or spokespersons. • Carefully consult with involved physicians, establish their role and prepare them for this role.
Peer Reviews/Quality Reviews	• Need clearly articulated policies that integrate Board By-laws with policies and committees regarding protection of Peer Reviews and Quality reviews. • Clarify the whether there are differences in the protection of quality reviews compared to peer reviews. • Carefully follow established policies to the letter. • Educate all key staff in the disclosure process. • Ensure accountability for reviews and follow-up is clearly designated to the person/s with responsibility for the service or program, e.g. the Leadership Team of a clinical program. • Document all processes to ensure adherence to the policies. • Educate stakeholders regarding the changing regulatory environment and implications for protection of reviews.

	• Develop Action Plans for all recommendations from Peer or Quality Reviews and ensure timelines are monitored. • Ensure Peer Review updates on Action Plans given and documented in RQC and Board Minutes.
Multi – RHA Events	• Designate the responsibility to the Executive Lead to make contact with other RHA's. • Enlist involvement of DOHCS to plan for the coordination of activities involving multi-RHA reviews. • Decide on process and responsibilities of all RHA's preferably with DOHCS coordination. • Designate a coordination role and responsibilities. • Schedule regular meetings. • Document and share all decisions. • Ensure that each RHA is accountable for their region through the coordination process.
Anticipating Risk Areas	• Through ongoing Quality Improvement processes for all programs and services ensure basic standards are being employed in all areas including: o Policy and Procedure Manuals are accessible and current, o Standard Quality Controls are in place, o Appropriate Quality indicators are in place and being monitored, o Audits and other methods to ensure compliance are in place, and o All biomedical equipment is being serviced through biomedical engineering department.
Quality Assurance and Improvements in the Laboratory Medicine Program	• Continue to strengthen the leadership structure of the Laboratory Medicine Program, ensure clear direction and clarity of accountabilities. • In case of a major adverse event, designate a dedicated Laboratory Team with clearly defined roles and responsibilities. o Designate a Team Lead for the Laboratory. o Develop and monitor the implementation of a clear Action Plan. o Consult with other national and international experts on complex issues especially those for which there are not clear standards. o Consider the use of an external consultant in

	Laboratory Medicine as member of the Laboratory Team or the Core Team. o Ensure that involved staff/physicians are given dedicated time to devote to the response to the adverse event. • Develop a plan for Continuing Education for Pathologists and Technologists, in particular those who provide highly specialized services and do not have strong networks in the province. o Explore the options for staff to become involved in national and international networks. • Continue to strengthen the Quality Management Program(QMP) within Laboratory Medicine including: o Quality Manager dedicated to the QMP. o Identification of other resources needed to strengthen quality such as the recent introduction of the scientist position within the IHC service. o Continued implementation of all recommendations from external reviews, QMPLS review and the Parks Hewitt review of the IHC service as part of the continuous QMP process. o Search for and implementation of best practices in policy and procedure development. o Identification of key quality indicators for all laboratory services with monitoring of performance regarding each indicator and use of internal and external benchmarking. o Strengthening of Laboratory Medicine Program orientation programs for technologists and pathologists employing a competency based approach. o Use of a standard of proficiency testing using external as well as internal approaches. o Ensuring standards for quality control and preventive maintenance of equipment are implemented and compliance monitored. • Participation in recognized Accreditation Processes . • Planning to improve the integration standardization of laboratory services within Eastern Health. • Improvement plan for further development of integrated information systems in Laboratory Medicine within Eastern Health and throughout the province. • Development of a structure for ongoing collaboration with other provincial laboratories to share knowledge and enhance quality of services.

Role of Risk Manager	• Ensure there is no perceived conflict with quality and claims management role of the Risk Manager. • Need to clarify the role of the insurer in giving advice. • Need to document the advice given and response to it. • Preserve role of Risk Manager as consultant and "over-viewer", not a project leader and "doer".
Communications-Progress	• Ensure any staff involved are given the information they need for their role and feel comfortable in this role. • Communicate "the issue" and provide regular updates to all stakeholders and to staff. • Arrange for ongoing counseling and support of staff. • Through Crisis Communication's Plan, ensure there is a process for regular communication with external stakeholders and with the media.
Information Development and Management	• Designate a Lead IT person as part of the original Core Team. • Develop a database containing key information elements to support all components of the review and response to an adverse event: o Document all alternatives considered to identify patients involved, alternative chosen and those involved in the decision. o Seek expert advice. • Employ database management processes to ensure data quality including: o Restrictions to altering database. o Retention of all versions of the database. • Ensure all necessary information is entered directly into the database and not recorded in other files and documents. • Improve capability for Document Control within Eastern Health. • Continue to improve the capacity of information systems and the ability to integrate varying databases within Eastern Health and across the province. • Establish timelines for reporting of the progress of database development. • Ensure that any information reported from the database comes from one source and is consistent with ongoing updates and reports. • Continue to develop capacity and expertise in information development within Eastern Health.

Analysis and Communications of Results of Reviews	• Include this component with clear timelines. • Inform patients of results first as well as other stakeholders.

Appendix C

Commentary: Hormone Receptor Testing in Breast Cancer:

A Distress Signal from Canada

By D. Craig Allred

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Commentary: Hormone Receptor Testing in Breast Cancer: A Distress Signal from Canada

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Recent events in Canada underscore substantial problems with estrogen receptor (ER) testing by immunohistochemistry (IHC) in breast cancer [1, 2]. In 2005, a woman there was diagnosed with invasive lobular carcinoma. Her tumor was tested for ER expression by IHC in a laboratory managed by Eastern Health, the provincial health care provider in Newfoundland and Labrador. The results were negative, which is unusual for this type of tumor, so her physicians had it retested in another laboratory. The new IHC results came back positive, and the discrepancy led Eastern Health to investigate the accuracy of testing in Newfoundland and Labrador. Eventually, over 2,000 originally ER-negative cases were retested in another laboratory in Ontario, and nearly 40% were found to be ER-positive. An official inquiry was convened in July 2007, to determine the scope and causes of the problem, and to develop policies to prevent it from happening in the future (Commission of Inquiry on Hormone Receptor Testing at http://www.cihrt.nl.ca/transcripts.html). The conclusions of this inquiry are still forthcoming.

In current clinical practice, ER testing is mandatory in all newly diagnosed breast cancers, and accurate results are critical in determining the use of adjuvant hormonal therapy. This type of therapy significantly improves the outcome of many patients with ER-positive tumors, but it is ineffective with ER-negative disease. For this reason, most of the erroneous ER-negative patients in Newfoundland and Labrador were not treated with hormonal therapy, and some were almost certainly harmed because of it. This tragic outcome was avoidable and raises several urgent questions that should concern all of us: How did it happen? Is it happening elsewhere? What is being done to prevent it?

There are many well-known problems associated with measuring proteins by IHC, particularly proteins requiring quantified results such as ER [3, 4]. Some problems involve preanalytical issues unrelated to IHC itself, such as delayed or inadequate fixation of tissue, allowing proteins to degrade. Others are analytical in nature, such as the use of diverse reagents with unequal sensitivities [5–8], or antigen-retrieval procedures that inadequately re-expose proteins masked during fixation [4]. Most IHC assays rely on enzymatic detection systems with very rapid kinetics that are difficult to control,

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and it is very challenging to quantify results in an accurate and reproducible manner [9]. Postanalytical events may also contribute in the sense that tumors with very low levels of receptors (e.g., 1%–10% positive cells) may respond to hormonal therapy [6, 7, 10], and some laboratories use arbitrary definitions of positive that are too high (e.g., >10% positive cells). Fastidious oversight by highly experienced and knowledgeable personnel is required to recognize, resolve, and avoid these problems, and some or all of them may have contributed to the debacle in Canada.

Unfortunately, the problem with ER testing by IHC is not restricted to Newfoundland and Labrador. Perhaps the best evidence for this comes from the United Kingdom National External Quality Assessment Service (NEQAS). This organization has conducted and published the results of several studies on the accuracy and reproducibility of evaluating ER by IHC based on proficiency testing of 150 laboratories in 26 countries worldwide [4, 11–14]. The results identified error rates in some laboratories rivaling those in Newfoundland and Labrador, as well as the major technical problems causing them. The U.S. does not participate in NEQAS, and information regarding the accuracy of ER testing in this country is hard to find. Although many laboratories in the U.S. participate in proficiency testing offered by the College of American Pathologists (CAP), many do not, and the evaluation of ER by the CAP is less comprehensive than that of the NEQAS, so detailed results are not available. However, there is compelling anecdotal evidence suggesting that problems in the U.S. are also substantial. For example, in a recent large international clinical trial comparing hormonal therapies in receptor-positive breast cancer, a subset of >100 patients was enrolled with ER-negative/progesterone receptor (PgR)-positive tumors based on local laboratory results from several countries, including the U.S., who was a major contributor to the trial [15]. Repeat testing in an expert central laboratory revealed a 69% false-negative rate for ER in this subset of patients. Furthermore, there was a 44% false-negative rate for PgR in the group of >1,200 ER-positive/PgR-negative patients enrolled based on local laboratory results, so the problem is larger than ER alone. While far from being scientific, the false-negative rate of IHC testing for both receptors in my consulting practice over the past 10 years is about 30%, which is similar to that of other experienced consulting pathologists I have spoken with on this issue.

Given the critical need for accurate ER and PgR results in all patients with breast cancer, and the widespread difficulty obtaining them, it is clear that something must be done to remedy the problem. On one hand, it should be relatively easy to resolve because several comprehensively validated IHC methods have been published for other laboratories to emulate [5–7, 10, 16, 17]. On the other hand, it is remarkably difficult to persuade laboratories on a global scale to adopt the same methods, or to rigorously standardize and validate their own. A few years ago, a similar widely publicized predicament regarding human epidermal growth factor receptor (HER)-2 testing in breast cancer led to the development of rigorous guidelines by the CAP and the American Society of Clinical Oncology (ASCO) [18], and laboratories in the U.S. must soon comply with these guidelines to maintain CAP accreditation. The CAP and ASCO are also aware of the need to improve ER and PgR testing, and they are in the process of developing enforceable guidelines for these biomarkers as well. However, CAP accreditation is currently not required in the U.S. for laboratories to conduct these tests, and most laboratories are not CAP accredited. The situation is similar in other countries and it will take considerable resources, education, and persistence to achieve universal compliance in the use of assays that are comprehensively standardized and validated in an equivalent manner.

Ultimately, however, it is unrealistic to expect that even perfect tests for ER and PgR alone, by IHC or any other methods, will be sufficiently powerful to predict the response of all breast cancer patients to hormonal therapy because the biology involved is so complex. New more powerful predictors are needed, and they will most likely be based on multiple biomarkers. In this regard, there are many promising new approaches on the horizon at varying stages of development and validation, including onco*type* DX® (Genomic Health, Inc., Redwood City, CA, http://www.genomichealth.com) [19, 20], the *HOXB13/IL17BR* gene ratio [21–23], and estrogen-regulated gene signatures determined by microarrays [24], to name a few. Hopefully, these and other approaches will lead to significant improvements in predicting response to hormonal therapies, and it will be important for them to avoid making the same mistakes concerning proficiency and standardization that have plagued ER, PgR, and HER-2 testing by IHC.

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