IN THE MATTER OF the Commission of Inquiry on Hormone Receptor Testing

Pursuant to the *Public Inquiries Act*, 2006 by Order dated July 3, 2007

SUBMISSIONS ON BEHALF OF THE CANADIAN CANCER SOCIETY, NEWFOUNDLAND AND LABRADOR DIVISION

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TO: **COMMISSION OF INQUIRY ON HORMONE RECEPTOR TESTING**
The Honourable Madam Justice Margaret A. Cameron, Commissioner
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Introduction

1. The Canadian Cancer Society, Newfoundland and Labrador Division ("Cancer Society") is a community based organization of volunteers whose mission is the eradication of cancer and the enhancement of quality of life of people living with cancer.

2. Peter Dawe, Executive Director, described the mandate of the Cancer Society. There are two main objectives, the eradication of cancer and the support of people living with cancer: "*We talk about prevention, advocacy, research, information and support, and if you drill down into any one of those areas, you'd find different programs and services that we deliver that are trying to achieve a certain objective, and that objective then would relate back to the two mega objectives I talked about, eradication and support*."[1] The Cancer Society works towards the eradication of cancer by promoting the prevention of cancer and finding a cure. It provides support through various means, ranging from emotional support to helping to ensure the patient receives access to adequate treatment.

3. In light of this mandate, the Cancer Society was eager to delve into the ER/PR issues when they publicly came to light in the Independent newspaper article on 02 October 2005. In keeping with it's mandate, Mr. Dawe as spokesperson for the Cancer Society,

[1] Testimony of Peter Dawe, 03 September 2008, at pages 21, line 23 to page 22, line 6.

frequently responded to media inquiries. The Cancer Society was motivated to do so as it was hearing from patients and the public that there were questions and concerns not yet being addressed by Eastern Health in relation to the ER/PR problem.

4. In keeping with its mandate, the Cancer Society is also very pleased to be given an opportunity to participate in the inquiry and to provide written submissions to the Commissioner. The Cancer Society believes it has a unique role in representing cancer patients, their families and people who might be affected by cancer in the future.

5. The Cancer Society will focus its submission on the following areas: (1) Cancer Registry and Monitoring; (2) Quality: National Standards and Occurrence Reporting; (3) Patient Right to Effective, Timely Communication and the Public Right to Know; (4) Hormone Positive Test Results and Retro-Conversions; and (5) Comments and Recommendations.

6. The Cancer Society recognizes that health care organizations face many challenges arising from years of financial restraint, often coinciding with rapid advances in medical knowledge. At times, new medical techniques are introduced before a consensus is reached in the medical community as to best practices. In this environment, extra vigilance is required to monitor new methods and to keep pace with relevant literature and other educational opportunities available to health care practitioners.

7. The Cancer Society believes there are many dedicated and talented people working within the ranks of Eastern Health. The greatest challenge facing Eastern Health is one of management, learning how to channel its talent to maximize the health of all people who use its services and to ensure public confidence in the health care system, particularly at times when health care practitioners or other resources are in short supply.

8. Ultimately the health care system must be focused on the people it serves. The collective actions of the system must have the absolute best interests of these people at the core of its policies and practices. In turn, these policies and practices must be transparent to the general population; that is they must be visible outside the healthcare system. Finally, the system must be directly accountable to the people it serves. Accountability and transparency must not be passive but systematic and meaningful. Individual patients and the public have a right to vigorous proactive demonstrations of transparency and accountability from public institutions such as the healthcare system.

Cancer Registry & Monitoring

9. A fully-resourced and complete Cancer Registry should have enabled Eastern Health and the other Regional Health Authorities to identify patients in 2005 whose specimens required re-testing. The Cancer Registry should also have been a resource for pathologists, technologists and oncologists to obtain data for monitoring, prior to 2005.

Information Sought from Cancer Registry to Assist with Retesting Program

10. In the summer of 2005, Heather Predham, Risk Management Consultant/Assistant Director, Quality and Risk Management, sought information from the Cancer Registry, as suggested by Dr. Joy McCarthy, oncologist, primarily to ascertain the living/deceased status of breast cancer patients[2]. The Cancer Registry provided Ms. Predham with a list of patients who had breast cancer.[3] Ms. Predham initially thought the Registry included all cancer patients including all those with breast cancer. This was also Dr. Cook's expectation, according to his note "*Cancer Registry has list of every breast cancer*", made at a 14 July 2005 meeting with Drs. Kwan, Felix, Williams, McCarthy, Laing, Gardiner, Heather Predham and Susan Bonnell.[4]

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[2] Testimony of Heather Predham, 18 October 2008, page 33, lines 19-23.

[3] Testimony of Heather Predham, 18 October 2008, pages 25, line 21 to page 26 line 4.

[4] P-0503: Meeting Notes of Laboratory Medicine dated July 14, 2005 regarding ER/PR Receptor Results with handwritten notes of Dr. Donald Cook.

11. Following her efforts to obtain information about breast cancer patients, Ms. Predham formed the impression that the registry included only those patients registered at the Cancer Clinic[5]. Other evidence, outlined below, indicates the reason the Cancer Registry did not capture all breast cancer patients was due to problems with case ascertainment as opposed the Cancer Registry being intentionally restricted to Cancer Clinic patients.

12. Notwithstanding the limitations in the data, the Cancer Registry was a source of some useful information for Eastern Health in the summer of 2005. The Registry contained the names of some breast cancer patients, their MCP number and surgical/specimen number, the living/deceased status of some of the patients listed in the registry,[6] patient addresses,[7] and patient phone numbers.[8] Ms. Predham also discovered that, for about 1230 breast cancer patients (less than half), the Cancer Registry captured hormonal status. However, the Registry did not distinguish between ER and PR, nor did it state the actual percentage of positivity.[9]

13. Ms. Predham learned that aside from not recording all breast cancer patients, the

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[5] Testimony of Heather Predham, 18 October 2008, pages 26, lines 13-20 .

[6] Testimony of Heather Predham, 16 October 2008, page 348, line 16-21.

[7] Testimony of Heather Predham, 17 October 2008, page 146, lines 5-11.

[8] Testimony of Heather Predham, 20 October 2008, page 245, line 7-14.

[9] Testimony of Heather Predham, 18 October 2008, page 31, lines 9-14.

information obtained from the Registry was lacking with respect to death information.[10] In this regard, she was surprised that the Cancer Registry wasn't as complete as she thought it would be - she thought that the Cancer Registry was linked with Vital Statistics, but learned that this was not the case.[11]

Death Clearances and the Cancer Registry

14. Canadian Cancer Statistics Reports have for some years been highlighting problems with death information contained in the Newfoundland and Labrador Cancer Registry[12]:

15. Most recently, in 2008, the Canadian Cancer Statistics report stated:

> *"While the completeness of registration of new cancers is generally very good across the country, there are exceptions. For example, death certificate information has not been available for registry purposes in Newfoundland and Labrador and this falsely lowers the number of newly diagnosed cases, mainly among those cancers with a poor prognosis such as lung and pancreatic cancer (see Appendix II: Data Sources and Processing)."*

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[10] P- 0558: Email dated August 8 2005 from Heather Predham to Pamela King-Jesso, Deanne Emberley, David McCormack regarding Overall database.

[11] Testimony of Heather Predham, 16 October 2008, page 349, lines 12 to page 351, line 8.

[12] P-786: Canadian Cancer Statistics 2005, pages 26 and 98; P-787: Canadian Cancer Statistics 2006, pages 23 and 101; P-788: Canadian Cancer Statistics 2007, pages 20 and 98; and P-789: Canadian Cancer Statistics 2008, pages 18 and 89.

"For all cancers, even those with poor survival such as pancreas and lung, the annual number of incident cases is expected to be similar to, or larger than, the number of deaths. However, there are situations in which the number of deaths, either observed or projected, is larger than the corresponding number of new cases. In the case of Newfoundland and Labrador, this is caused by the Registry not receiving information on death certificates that mention cancer. The limitation of not having access to death certificates is greater for cancers with a poor prognosis. This results in an underestimate of the number of cases for the years used to generate the estimates. Once the Newfoundland and Labrador Registry begins receiving information in order to register these cases the difference will disappear."[13]

16. Sharon Smith, Program Director, Cancer Centre, explained her understanding of the issues relating to death clearances. The first relates to capturing deaths from cancer:

"Death certificate is completed within the province and it goes to Vital Statistics. The cause of death, and we know there's problems with completion of death certificates, they're not all 100 percent accurate. So the cause of death might be listed as pneumonia, and the contributing factor could be lung cancer. I'll just use that as an example. That information is recorded and is sent to Vital Statistics. Vital Statistics, as I said yesterday to the Commissioner about the person with the

[13] P-789: Canadian Cancer Statistics 2008:, at pages 18 and 89.

magic ball, they do have a member on their staff who has developed rules and expertise around looking at cause of death. So while we in the province would have pneumonia as the cause of death, and a death number, it would not appear as a cancer death."[14]

17. A second issue relates to case ascertainment:

"... if an individual comes into the emergency department and is quite ill, gets admitted to an in-patient unit, and dies and it's determined that that person died of cancer, that information will be on the death certificate. However, we would not have that case in our file at all. That wouldn't be there as an incident case, it wouldn't appear in our records. That information would then go to Vital Statistics. Once we get our local process, when we do our data linkage with our local information from Vital Stats, we'll be able to say this individual appeared to have a cancer death, here's the death registration number, let's follow up and see exactly what happened, get this information and register that case."[15]

18. It was the first issue, failing to capture all deaths from cancer, that impeded Ms. Predham's attempt to obtain more reliable information about the living/deceased status of breast cancer patients.

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[14] Testimony of Sharon Smith, 31 October 2008, page 48 line 11 to page 49, line 2.

[15] Testimony of Sharon Smith, 31 October 2008, page 50, line 21 to page 51, line 12.

19. According to Dr. Donald MacDonald, Director, Research and Evaluation, the Centre for Health Information ("NLCHI") previously provided the Cancer Registry with death clearance information as far back as six or seven years ago, electronically, so that they could link it with their systems and identify those patients identified as deceased. He couldn't recall why this process stopped.[16] Because there was no direct link with the Cancer Registry, NLCHI would download the mortality information onto a CD and deliver it to the staff of the Cancer Registry. While there were much more efficient ways of doing that now with the technology available, the process did work and the Cancer Registry staff would convert the downloaded information back into their platform.[17]

20. Dr. MacDonald also noted that there have been challenges with the provincial mortality system, in which (multiple) causes of death may be listed, without a guarantee that the main cause will be the first one identified. Also the absence of a unique identifier posed a problem with linking the information.[18]

21. Ms. Smith understood that sometime prior to Eastern Health assuming responsibility for the Cancer Registry in the spring of 2005, a decision had been made by the prior administration, Newfoundland Cancer Treatment and Research Foundation ("NCTRF"),

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[16] Testimony of Donald MacDonald, 24 October 2008, page 54, lines 6-15.

[17] Testimony of Donald MacDonald, 24 October 2008, page 55, line 15 to page 56, line 2.

[18] Testimony of Donald MacDonald, 24 October 2008, page 57, line 8, to page 58, line 10.

to discontinue the process of obtaining electronic data from the NLCHI. Apparently, the individual who transferred the electronic data to the Cancer Registry did so of her own accord and when she left, so did her expertise. NCTRF determined it did not have the resources to continue with the exercise as a manual process. Since 2005, Ms. Smith approached the Centre for Health Information to discuss resuming the electronic process.[19]

22. Dr. MacDonald confirmed that in the past year and a half, NLCHI began discussions with the Cancer Registry about providing death clearance data again, and he expects that this process should be revived very soon.[20]

Case Ascertainment by Cancer Registry

23. As discovered by Heather Predham, the Cancer Registry did not provide a complete list of breast cancer patients. Eastern Health has not, to date, conducted a review of the Cancer Registry to ascertain how many of the breast cancer patients ultimately identified for retesting were actually reported in the Cancer Registry, so the extent to which the data is deficient is not known precisely. Sharon Smith has recently had some discussion with Susan Ryan, of the Cancer Registry, about potentially linking the ER/PR database

[19] Testimony of Sharon Smith, 31 October 2008, page 58, line 14, to page 59, line 13.

[20] Testimony of Donald MacDonald, 24 October 2008, page 54, line 22 to page 55, line 6.

back to the registry to see what cases were missed.[21]

24. Dr. Kweku Dankwa, pathologist, Charles S. Curtis Memorial Hospital in St. Anthony, has not been registering tumour reports for many years, due to objections raised by a patient about the release of personal health information. Dr. Dankwa contacted the NCTRF, which was in charge of the Registry at the time, to no avail.[22] It would appear there is no legislation which specifically addresses this issue.[23] It is recommended that if any new legislation is indeed required to address the concerns of Dr. Danwka, or any other physicians who might share his concerns, then this should be promptly pursued by the Regional Health Authorities and/or the Department of Health and Community Services.

25. Ms. Smith noted that one of the challenges in case ascertainment is to capture patients whose cancer is diagnosed through means other than a pathology report, such as when the diagnosis of cancer is at the advanced stages or when the cancer is diagnosed through other means such as diagnostic imaging[24]. When ER/PR testing is conducted, however, a pathology report would be produced. Therefore, this particular challenge for case ascertainment would not have posed a problem in identifying breast cancer patients

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[21] Testimony of Sharon Smith, 31 October 2008, page 39, lines 2-9.

[22] Testimony of Dr. Dankwa, 11 July 2008, page 375, lines 5-15.

[23] Testimony of Dr. Dankwa, 11 July 2008, pages 373, line 6 to page 375, line 20.

[24] Testimony of Sharon Smith, 30 October 2008, page 342, lines 13-23.

who had ER/PR testing.

26. In any event, Ms. Predham was unable to obtain a complete list of breast cancer patients through her contact with the Cancer Registry data and the reasons for this ought to be investigated by Eastern Health and corrected.

Certification of Cancer Registry

27. The goal of the Cancer Centre is to achieve certification of the Cancer Registry through the North American Association of Cancer Registries (NAACR). Newfoundland and Labrador has never achieved certification of its Cancer Registry, even though many other Canadian provinces have. Ms. Smith states that this is primarily due to two issues: problems with case ascertainment and with death clearances.[25]

28. There should be an analysis of the reasons why numerous breast cancer patients were not included in the registry information obtained by Heather Predham in the summer of 2005. This would be of assistance in ascertaining any root causes of deficiencies in the Cancer Registry which have yet to be identified. The correction of such deficiencies, along with the known deficiencies relating to death clearances and case ascertainment, would be necessary and perhaps sufficient steps for Eastern Health to achieve NAACR certification.

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[25] Testimony of Sharon Smith, 30 October 2008, page 337, lines 4-18.

Analytical Capacity of Registry

29. The Cancer Registry does not presently have any analytical capacity. To optimize the benefits of a Cancer Registry, it is beneficial to at least have an epidemiologist on staff. This deficiency in the resources of the Cancer Registry has been acknowledged and identified by Sharon Smith as an area for which funds are required. [26]

30. Peter Dawe of the Canadian Cancer Society also identified a need for the Cancer Registry to have resources to engage in epidemiological analysis of the registry data:

> *"We believe that it is an absolute foundational block of healthy, good healthy public policy, in this case, cancer policy, to have cancer registry and affiliated services, so that you're not just collecting data, but you're actually mining the data from an epidemiological perspective...*
>
> *...But we would suggest that a registry working properly would have the possibility, if it was being analyzed properly on a go-forward basis, to actually even pick up issues like how many people are testing positive and negative for tests like ER/PR and proactively looking for systematic problems in the population as it relates to cancer control."*[27]

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[26] Testimony of Sharon Smith, 30 October 2008, page 343, lines 15-16.

[27] Testimony of Peter Dawe, 04 September 2008, page 368, lines 14-20 and page 369, lines 4-12.

The Value of Monitoring Regional Trends and Individual Anomalies in Pathology

31. It is desirable for a laboratory medicine program to have some means of monitoring its data such as ER/PR test results.

32. Dr. David Dabbs, pathologist, UPMC-Magee Women's Hospital, Pittsburgh, PA, testified about the importance of metrics: *"It is highly desirable to maintain laboratory metrics for each prognostic predictive test results in order to monitor for potential analytic drift. For example, published literature indicates that 70-80 percent of breast cancers are ER positive. This should be a benchmark for each laboratory to monitor."*[28]

33. Dr. Emilia Torlakovic, Associate Professor, Department of Pathology and Laboratory Medicine, College of Medicine, University of Saskatchewan also noted the value of monitoring trends. Experts will take into account all available guidelines and knowledge and monitor test results accordingly. In Saskatoon, their breast pathologist monitors the test results by histologic type and percentage of positivity, to ensure the results are in line with published evidence. This pathologist also *"goes back and retests, reviews, and re-scores a certain number of specimens throughout the year and so on to make sure that we don't get – that you notice trends if they're developing at the time."*[29]

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[28] Testimony of Dr. Dabbs, 15 September 2008 at page 175, lines 2-9.

[29] Testimony of Dr. Torlakovic, 09 October 2008, page 279, line 13, to page 280, line 10.

34. Dr. O'Malley, Pathologist, Mount Sinai Hospital, Toronto, indicated that immunohistochemistry lab at Mount Sinai collects and monitors data about the positivity rates for ER and PR. She also is involved in this as well, and makes it her business to know what these rates are.[30]

35. Aside from monitoring trends on a institutional or regional basis, there is reason to review individual cases as well. For certain types of breast carcinomas, even one unexpected result might warrant some investigation. As noted by Dr. Dabbs, tubular cancers, classic papillary cancers, and other tumours such as invasive lobular carcinomas are all high expressors uniformly "*and so if something like that came negative, especially in the face of a negative control, that would be a red alert to stop and have this repeated and in fact, look at the entire batch run for the day, and go from there and process that problem.*"[31]

36. Dr. O'Malley shared the same view about positivity rates for lobular carcinoma, stating "*It does happen, but it is very rare that a classic invasive lobular cancer would be negative for both ER and PR.*"[32]. Dr. O'Malley also testified that only the occasional ER positive/PR negative tumour would be expected, and an ER negative/PR positive tumour would be

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[30] Testimony of Dr. O'Malley, 23 June 2008, page 121, line 11 to page 122, line 18.

[31] Testimony of Dr. Dabbs, 15 September 2008, at page 224, lines 2-15.

[32] Testimony of Dr. O'Malley, 23 June 2008, page 63, line 20-22.

extremely rare. [33]

Provincial Trends that Were Missed

37. There were no formal or informal procedures in place to look for trends at Eastern Health for the ER/PR test results, such as overall positivity rates or the positivity rates for different types of breast carcinomas. In retrospect, there were trends to be spotted, if a monitoring program had been in place.

38. The index patient, based upon her diagnosis of lobular carcinoma, was expected most likely to be ER positive as opposed to ER negative. Dr. McCarthy, among other oncologists at Eastern Health, was aware that at least 80% of lobular, tubular carcinomas and well-differentiated ductals were expected to be ER positive: "*The exact numbers that were often discussed in my teaching were between 80 to 90 percent on average, we'll say 85%, but certainly not 100%.*"[34]

39. It wasn't universally expected that 100% of lobular carcinoma cases would be ER positive, so one case on its own with an ER negative result may not necessarily have caused alarm. However, some physicians such as Dr. Dabbs were of the view that even one such case would warrant further examination. In any event, if statistics were

[33] Testimony of Dr. O'Malley, 23 June 2008, page 59, lines 13-20.

[34] Testimony of Dr. McCarthy, 19 September 2008, page 36, line 19, to page 37, line 2.

maintained and reviewed periodically, an unexpected trend of ER negative lobular or tubular or well differentiated ductal carcinoma would no doubt have been detected much earlier.

40. Likewise, ER negative/PR positive results for breast cancer are rare, less than five percent.[35] Between 1997 and 2005, a significant number of ER negative/PR positive test results were, in fact, produced by Eastern Health's laboratory. This pattern was apparent to Dr. Beverly Carter, pathologist, when the Physician Review Panel was reviewing a large number of ER/PR cases at the same.[36]

41. The annual rates of positivity from the original ER/PR testing, as outlined in tables compiled in July 2005 by Terry Gulliver, Program Director, Laboratory Medicine Program,[37] were below or at the low end when compared with the expected positivity rates from the literature and medical community, which suggests that about 75 to 80 percent of cases would be ER positive[38].

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[35] Testimony of Dr. Mullen, 27 June 2008, page 324, lines 2-3.

[36] Testimony of Dr. Carter, 29 July 2008, page 81, line 19 to page 82, line 22.

[37] P-0514: Document showing Tables for 2002 by Month ER and PR Results; P-0522: Document printed for Dr. Bob Williams dated July 24, 2005 (12:53 PM) providing Review of ER/PR Stats from 1999 to 2004-05 containing handwritten notes

[38] Testimony of Dr. Dabbs, 16 September 2008, page 193, lines 19-21; Testimony of Dr. Mullen, 27 June 2008, page 323, line 25, to page 324 line 4; Testimony of Dr. O'Malley, 23 June 2008, page 142, lines 11-12.

Current Status of Monitoring Within Laboratory Unclear

42. It is not clear what monitoring is currently taking place at Eastern Health with regard to ER/PR or IHC testing. Dr. Carolyn Morris-Larkin, pathologist, stated that the Quality Management Program does not have any data on this yet, but this is seen as something that needs to be done. She thought there might be some monitoring within the lab itself, but could not speak to this.[39] Terry Gulliver was unable to state whether there was any current monitoring of positivity rates.[40] Dr. Ford Elms, pathologist, did not specifically itemize monitoring of positivity rates for ER/PR testing as one of the QA activities currently in place.[41] Dr. Donald Cook, pathologist, was unsure how one could now go about retrieving information from the information systems to monitor ER/PR positivity rates. He would now approach the quality supervisor for assistance, but was not sure what types of information would be available to her.[42]

Capacity of Cancer Registry to Provide Data for Trend Monitoring

43. During times of fiscal restraint, when human and financial resources are limited, it is necessary for management to maximize the use of all of its existing resources.

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[39] Testimony of Dr. Morris-Larkin, 07 October 2008, page 247, line 12 to page 248, line 2.

[40] Testimony of Terry Gulliver, 08 October 2008, page 322, lines 17-22.

[41] Testimony of Dr. Elms, 02 September 2008, page 321, line 21 to page 322, line 17.

[42] Testimony of Dr. Cook, 07 July 2008 pages 158, line 7 to page 160, line 19.

44. The Cancer Registry, notwithstanding its deficiencies, is an example of a resource which could have been better utilized between 1997 and 2005 to monitor trends when a separate or more sophisticated monitoring program was not available within the Laboratory Medicine Program itself.

45. Dr. Adam Brufsky, Director, Breast Cancer Program, University of Pittsburgh, testified that in his organization, the cancer registry participates in monitoring of trends. This is in addition to the formal monitoring by pathologists, and individually on an informal basis by oncologists. The chief registrars of the Cancer Registry work in conjunction with an oncologist, for example, when breast cancer was the subject of a QA project for a particular year: *"If we decided to look at breast cancer that year, we would have one of the chief registrars, who's familiar with the registry, as well as one of the members of the cancer committee do the project together."*[43]

46. Indeed, Canadian cancer registries are required to include much information that would be useful for monitoring. In addition to demographic information, data is to be reported about the tumour diagnosis, including histology and stage as identified by Stats Canada:

> *"The data elements that are collected are identified through a national organization known as the Canadian Council of Cancer Registries, and the data elements that are collected are dictated by that organization. So we collect*

[43] Testimony of Dr. Brufsky, 06 October 2008, page 197, line 22, to page 200, line 15.

demographic information, name, date of birth, sex, the health number, address, telephone number and the next of kin, and we collect the case identification, the site of the cancer, histology, the date of diagnosis, the hospital they came from, attending physician and attending oncologist, and the stage at diagnosis."[44]

47. There had, in fact, been some effort by the local Cancer Registry staff to include data which would have been pertinent to a monitoring program. Dr. Carter noted the Cancer Registry staff would contact her from time to time for assistance in interpreting pathology reports - whether an infiltrating ductal with lobular features, for example, would be reported as an infiltrating ductal or an infiltrating lobular cancer. Dr. Carter stated, "*I would just answer the questions and they wanted to know when they should put the patients in as estrogen receptor positive and when they should put them in as estrogen receptor negative...*"[45]

48. If the histology information and hormone positivity rates had been tracked though some method of monitoring then the ER/PR problems would likely have been detected earlier. If examined, it should have been noticed that there were a higher than expected number of hormone negative lobular carcinomas. This information may very well have been available in the Cancer Registry before 2005. Even a rudimentary examination of

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[44] Testimony of Sharon Smith, 30 October 2008, page 333, line 20, to page 334, line 8.

[45] Testimony of Dr. Carter, 31 July 2008, page 30, line 12, to page 32, line 5.

the information that did exist in the cancer registry should have revealed to pathologists and oncologists that there were anomalies in the positivity rates, as apparent from the data collected by Heather Predham in the summer of 2005: "*Overall ER positivity by year (and remember this is rough) is 2003: 61%, 2002: 48% and 2001: 46%*".[46]

49. Had the registry data been reviewed periodically, the anomalous ER/PR results would surely have been prompted an earlier review of the ER/PR testing program.

Recent Efforts to Enhance Data Elements in Cancer Registry

50. The Cancer Registry, as it existed prior to 2005, did not contain information which could have been used to detect all trends, such as the frequency of ER negative/PR positive test results, and ER positive/PR negative test results. As noted by Heather Predham, the Cancer Registry only specified overall hormone status, and did not include rates of positivity for both ER and PR.

51. This has recently been changed in the Cancer Registry, with a move to include more detailed information about tumour diagnosis for certain types of cancers, including breast cancer, based upon collaborative stage data collection. For breast cancer, the Registry typically collects tumour size, whether the tumor extends, the number of nodes

[46] P- 0558: Email dated August 8 2005 from Heather Predham to Pamela King-Jesso, Deanne Emberley, David McCormack regarding Overall database.

examined, how many are positive, whether or not there's metastases, the ER/PR and HER2/neu status, Ms. Smith noted "*In the past, those ER/PR results were only collected as positive or negative, but now we have the fields changed so that we can put in what the actual percent was and whether that was considered a positive or negative result.*"[47]

Awareness of Cancer Registry and Capabilities

52. It does not appear, from the evidence of the numerous oncologists and pathologists that testified, that the Cancer Registry readily came to mind as a resource of information to monitor such trends or even as a basic source of information about the patients who had breast cancer.

53. Among the pathologists from outside St. John's who testified, only Dr. Paul Neil of Corner Brook thought to contact the Cancer Registry to assist with identifying the patients that needed re-testing[48]. Upon doing so, Dr. Neil was quickly provided with a list of breast cancer patients who had been registered.[49]

54. This general lack of awareness about the Cancer Registry as a potential resource is consistent with Ms. Smith's own observations, upon assuming the role of Director of the

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[47] Testimony of Sharon Smith, 30 October 2008, page 334, line 8, to page 335, line 13.

[48] Testimony of Dr. Neil, 10 July 2008, pages 286-287.

[49] P-2253: Fax Transmission from Callista Silver for Susan Ryan to Dr. Paul Neil dated October 14, 2005 with attached patient spreadsheet.

Cancer Centre, in October 2005 that the Cancer Registry was not a well known database. This has been identified as an issue, and the Cancer Clinic has made some preliminary efforts to provide education about the Cancer Registry. Ms. Smith noted, *"I think this whole commission has certainly brought it to light as well."* [50]

Comments

55. A more complete list of breast cancer patients from the Cancer Registry which contained all of the essential data elements would have been a powerful tool for Eastern Health in the summer and fall of 2005. A comprehensive list of breast cancer patients for the years 1997 through 2005, which included information such as the living/deceased status for all or most patients (recognizing that some lag time in death clearances may be unavoidable), the patients' ER/PR status and demographic information would have allowed Eastern Health to conduct the re-testing program more expeditiously and reliably.

56. From a patient care and communications perspective, this would have placed Eastern Health in a much more favourable position. The ability to respond in a timely and complete fashion to such a multi-patient adverse event would likely have enabled Eastern Health to better maintain patient and public confidence in the health care system in this province. It would enable Eastern Health to alleviate the psychological

[50] Testimony of Sharon Smith, 31 October 2008, page 28, lines 6-7.

stress experienced by many patients caused by the general confusion of who was included in the-retesting group. It also would have prevented many, if not all, of the cases which were missed in the initial re-testing.

57. The Cancer Registry was not established for the primary purpose of responding to a multi-patient adverse event. The Registry collects data for a variety of other worthwhile objectives - for use in surveillance, cancer control, research, policy development and decision making.[51] However, the fact that the Cancer Registry can be a source of data to enable a health organization to respond to an adverse event involving cancer patients, is yet one more reason why the Cancer Registry should be fully supported with the financial and human resources necessary to enable it to achieve certification pursuant to the North American Association of Cancer Registries, at the very least.

58. The long-standing undetected problem with ER/PR test results highlights the need for a monitoring program in the Laboratory Medicine Program. A formal program should be established to monitor the results produced by the Immunohistochemistry lab including ER/PR test results. Cancer Registry data would be valuable to incorporate into any monitoring program. If the registry data is properly maintained and analyzed, this should aid in early detection of any similar problems which might occur in the future.

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[51] P-3567: Presentation by Sharon Smith on Cancer Registry, page 2.

Quality: National Standards and Occurrence Reporting

National Standards & Guidelines

59. The ER/PR problems which came to light publicly in 2005 has demonstrated that laboratory medicine programs in Canada would benefit greatly from a national program which sets standards and guidelines for immunohistochemical testing.

60. Dr. Torlakovic, who helped to establish the European NordiQC program in Norway before moving to Canada in 2003, was surprised to learn that a country as large as Canada did not have its own national external quality assurance program, and relied upon the College of American Pathologists' program: *"I found it unusual that it's totally dependent on CAP program, and at the same time some provinces have their own, like, they are separate country or something, and it's just--it was unusual that there is such big border between the provinces."*[52]

61. In light of this perceived gap, Dr. Torlakovic started to explore with Dr. Blake Gilks of British Columbia the possibility of establishing a Canadian program for external quality assurance:*"The idea was to create a program that is going to have both--provide testing that are adequate for immunohistochemistry, quality assurance, but also to provide education, and what we wanted the most, actually, Dr. Blake Gilks and I, is to create a*

[52] Testimony of Dr. Torlakovic, 09 October 2008, page 83, line 25, to page 84, line 11.

program that will have transparency."[53]

62. Dr. Gilks and Dr. Torlakovic developed a proposal in July 2006 which was submitted to the Canadian Association of Pathologists.[54] The goal was to establish a national external quality assurance program for clinical/diagnostic immunohistochemistry. The proposal was well received by the CAP and a National Standards Committee for immunohistochemistry was formed.

63. CAP has stated that "*Canada is lacking a national quality assurance program to link laboratories, provide support and administer national standards*" and in recognition of this, CAP is calling for an appropriately resourced national system to promote excellence in laboratory medicine in Canada.[55] CAP has now developed a CAP Five-Point Plan which includes: *"1. Mandatory certification for each prognostic and predictive test performed by a medical laboratory; 2. An external validation system where test results from one laboratory would be verified by another, independent external laboratory (external quality assurance program); 3. Dissemination and use of the Canadian National Checklists for Diagnostic IHC. 4. Creation of a national body, separate from government, to accredit all medical laboratories in Canada and ensure they need quality and critical*

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[53] Testimony of Dr. Torlakovic, 09 October 2008, page 86, line 23, to page 87, line 5.

[54] P-0412: George Tilley file entitled Memos / Letters on ER/PR issues for 2005 and 2006 at page 20.

[55] P-3361: Presentation by Emina Torlakovic entitled Quality Control / Quality Assurance in Diagnostic Immunohistochemistry, at page 25.

mass standards; and 5. Immediate and ongoing support from federal, provincial, and territorial governments to address the critical workforce and resource shortages undermining laboratory medicine."[56]

64. Through the efforts of Dr. Torlakovic and Dr. Gilks, and with the support of the Canadian Association of Pathologists, a Canadian external quality assurance program ("cIQc") has been founded. There is no official affiliation between CAP and cIQc. The cIQc is in its infancy with limited funding and resources available at present. National support is required from governments, hospitals, laboratories, pathologists, technologists and professional organizations to ensure that cIQc is successful.

65. It is recommended that Eastern Health and the other Regional Health authorities, the provincial government, pathologists and technologists work actively to support CAP and the cIQc in their goal to implement national standards and accreditation for immunohistochemical testing.

Occurrence Reporting

66. Occurrence reporting and follow-up provides an opportunity for early detection of systemic problems in the laboratory and should be viewed as an essential component

[56] P-3361: Presentation by Emina Torlakovic entitled Quality Control / Quality Assurance in Diagnostic Immunohistochemistry, at page 25.

of an effective quality control and quality assurance program.

Historical Practice of Occurrence Reporting: Missed Chances to Detect ER/PR Problems

67. There were several instances between 1997 and 2005 in which a robust occurrence reporting system would likely have exposed problems with the ER/PR testing.

68. Bryan Purcell testified about the circumstances surrounding a re-test for his late wife, Christine Purcell, who ultimately died of breast cancer in March 2000. She was initially diagnosed with breast cancer in June 1998 and determined to be ER 5% and PR negative. Ms. Purcell was not offered Tamoxifen because of her ER/PR status. Unfortunately, she was determined in April 1999 to have stage IV breast cancer which was incurable.

69. On the suggestion of a relative, a family physician practicing in Boston, the Purcells had Ms. Purcell's file reviewed in Boston. Her ER/PR was repeated and determined to be ER/PR positive. Mr. Purcell testified that it was a shock to learn that the results of the ER/PR testing were different than that done in St. John's:

> *"It was quite a shock to find out. And you know, I think it's fair to say, as well, that we were new to the whole cancer care scene, it wasn't something that we were very familiar with, so we didn't know how often an ER test would come back incorrect. However, the comments from the physician in Boston suggested that*

this wasn't a common occurrence and that this was something serious."[57]

70. In light of this finding, the Purcell's requested a repeat ER/PR test in St. John's, to verify the Boston results. As noted by Mr. Purcell, *"we presented it and requested that in light of this finding that it be retested locally to confirm. Obviously we didn't expect them to take the word of another physician 1500 miles away."*[58] This request was honoured and Ms. Purcell's ER/PR was determined upon repeat testing to be: *"Estrogen receptors, weakly positive, approximately 50 percent of invasive tumour. Progesterone receptors, weakly to moderately positive, 10-15 percent of invasive tumour."*[59]

71. There was also a cluster of three re-tests completed within a one month period in 2003 in which re-testing of ER/PR gave different results. In each case, both the original and the repeat ER/PR test were the subject of an addendum in the pathology report.[60] There is no evidence that an investigation was conducted into possible systemic problems as a cause of the original inaccurate test results, or a review was conducted to determine if any other patient's test results were similarly affected by the problems which caused

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[57] Testimony of Bryan Purcell, 24 March 2008, page 124, lines 13-31.

[58] Testimony of Bryan Purcell, 24 March 2008, page 125, lines 10-14.

[59] C-0099: Specimen Inquiry of Christine Jean Purcell dated July 7, 1998.

[60] C-0175: Final Surgical Pathology Report on 03:4821 Patient Name Redacted; C-0228 Immunoperoxidase Request Form and Final Surgical Pathology Report 2003 SS960 Patient Name Redacted; C-0174: Final Surgical Pathology Report on 02:SS5231 Patient Name Redacted.

these three inaccurate test results. This is particularly troublesome, considering that these events occurred shortly after concerns were raised by Dr. Gershon Ejeckam, pathologist, about immunohistochemical testing.

Definition of Occurrence

72. Ms. Purcell's change in ER/PR results upon retesting in 1999 and the cluster of repeat tests in 2003 with changed results are all circumstances which arguably satisfied the definition of an "*occurrence*" in effect on those dates. Unfortunately, no occurrence reports were filed for any of these events, nor is there any other documentation to demonstrate that some other form of corrective action or investigation was taken to ascertain and correct the cause of the differing test results.

73. The term "*occurrence*" was defined in the Administrative Policy manual for the Health Care Corporation of St. John's, in the policy entitled "*Occurrence Reporting*", dated 22 October 1997[61], in which an occurrence is defined to be *"any event, accident, error or circumstance which is not in keeping with expected process or outcome of care or service. Occurrences may result in an injury to an individual, damage or loss of equipment or property*." [62]

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[61] P-0056, Health Care Corporation of St. John's Policies dated 1997 to 2004, page 12.

[62] P-0056, Health Care Corporation of St. John's Policies dated 1997 to 2004, page 12.

74. If these events had been properly regarded as occurrences at the time, and thoroughly investigated, the ER/PR problems would most likely have been detected and rectified much earlier than the spring of 2005.

75. Mr. Purcell recognizes the significance of this missed opportunity regarding his wife's re-test: *"We were also unaware, in 1999, of the extent of these problems. You know, we only had knowledge of our own test. I can tell you that if we had known how extensively the problem existed, we would have pursued it further. Maybe we wouldn't be sitting here today and thousands of people wouldn't be in the state they're in."* [63]

76. Similarly, Ms. Predham recognized that the absence of occurrence reporting for the cluster of repeat tests in 2003, with changed results, was also a missed opportunity. She indicated that if she had known in 2003 about the three repeat tests with changed results, a full review would have been conducted, similar to what happened following the discovery of Ms. Dean's changed results in 2005. She added, *"I think that highlights the importance of the people who are doing the work valuing occurrence reporting, because if they know of things and they don't tell anybody about it, really can't, as an organization, you can't do anything about it."*[64]

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[63] Testimony of Bryan Purcell, 24 March 2008, page 171, lines 3-10.

[64] Testimony of Heather Predham, 16 October 2008, page 244, lines 9-25.

Need for Improved Awareness of Benefits of Occurrence Reporting

77. From the totality of the evidence, the failure to report an occurrence and to engage the appropriate follow-up for these events can likely be attributed to the failure by Eastern Health staff to recognize that such events actually constituted an occurrence, rather than an unwillingness to comply with a policy.

78. Heather Predham has observed it has been a challenge to ensure that front-line staff can recognize whether some events should be classified as an occurrence:

> *"...occurrence reporting is a very challenging area because you have frontline staff who are, you know, taking the time, they have identified something and then they have to be able to recognize that as an occurrence and then identify the need to fill out an occurrence report, but also they have to see that there's a purpose of doing this, that there's going to be some benefit at the end of the day."*[65]

79. Ms. Predham testified that each program and department had been encouraged over the years to identify occurrences in their area themselves, and to communicate with the front-line staff about what constitutes an occurrence. She believed this exercise would have been done by the Laboratory Medicine Program, but has no idea whether there would be any documentation to demonstrate this.[66]

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[65] Testimony of Heather Predham, 22 October 2008, page 304, line 23 to page 305, line 7.

[66] Testimony of Heather Predham, 22 October 2008, page 297, lines 5-16.

80. It is essential that steps be taken to ensure that all occurrences, including near misses, be readily identifiable as such by technologists and pathologists, so that they can be acted upon in accordance with any and all applicable policies.

Present Procedure for Occurrence Reporting

81. Under the current policy regime, when there is an occurrence in the IHC Division of the laboratory, there now appears to be a choice between an internal laboratory policy, "*Corrective Actions for IHC Occurrences*"[67] or the corporate-wide occurrence reporting policy, or perhaps both policies would apply.

82. Dr. Morris-Larkin stated that if there is a repeat test with a different result, such as some of the examples from 2002 and 2000, it would be preferable for such an issue to be reported internally through the Pathology Laboratory's corrective action policy:

> *"So for instance, if there's some significant discrepancy in one of the stains when you order a repeat test, you would bring that to the immunohistochemistry lab, they have corrective action logs and things like that. So that's the kind of thing I would think would be much more relevant within the lab itself, because when we talk about occurrence reports, as you are referring to, we're talking about corporate wide and things go way up the level, and in terms of, you know, going*

[67] P-2157: Eastern Health Pathology Policies and Procedures Manual, 2008, "*Corrective Action for IHC Occurrences*"at page 177.

to quality risk and initiatives management, it's something that they may not be as effective in dealing with as we would be in the lab, so it's like there are two different levels of occurrence reporting."[68]

Advantages of Corporate-Wide Occurrence Reporting in Addition to Corrective Actions

83. It is suggested that the application of the corporate-wide policy be generously applied, to capture situations such as Ms. Purcell's repeat test with changed results, and the cluster of repeat tests with changed results in 2003, as well as the broader, general concerns such as those outlined by Dr. Ejeckam in his 2003 memos.

84. In responding to a repeat immunohistochemical test which generates different results, it would be most prudent to follow the corporate-wide occurrence reporting policy, in addition to any applicable internal laboratory policies. This is particularly so if a pathology report had been generated for the original test.

85. A changed test result upon repeat testing is significant cause for concern. It ought not to matter that a repeat test with a changed result occurs one day or one year after the original test. It ought not to matter that the repeat test was performed within the laboratory or at a referral laboratory. The important factor is that a test of a particular specimen was not reproducible.

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[68] Testimony of Dr. Morris-Larkin, 07 October 2008, page 236, line 8, to page 238, line 14.

86. In such a situation, it is imperative that the technologists and pathologists ascertain the reason for this, to determine which of the two tests is correct and to determine why one of them was not. It may be due to heterogeneity of the specimen or perhaps there was a problem with the fixation or the staining. Determining the cause of the differing results is essential for the care of the patient who owns the specimen and also to ensure that no other patients could be negatively impacted by any systemic problems such as with antigen retrieval on a particular run or with fixation during a particular week.

87. There may be some merit for the argument that if the initial test is immediately recognized to be flawed, before the results ever leave the laboratory, then the internal corrective action is sufficient. However, the moment that a pathology report is generated based upon a test result which is later determined to be inaccurate or questionable then it is preferable that an occurrence report pursuant to the corporate-wide policy be filed in addition to any applicable internal laboratory policies.

88. While some might regard this as unnecessary duplication, it should instead be viewed as a built-in redundancy, the presence of which is beneficial in the health care setting.

89. It is a serious concern when a different test result is obtained upon a repeat, especially after an original report for the test has been generated. Requiring technologists and/or pathologists to file an occurrence report pursuant to the corporate-wide policy, as well

as internal laboratory procedures, would emphasize the seriousness of such a situation, the appreciation of which was historically lacking as demonstrated by the various missed opportunities between 1997 and 2005 to detect the ER/PR problems earlier.

90. Furthermore, the corporate-wide policy for Occurrence Reporting, administered by the Quality and Risk Management department, is more comprehensive than the Corrective Action for IHC Occurrences, administered by the Pathology Laboratory (Immunohistochemistry). The current version of corporate-wide policy generally provides more guidance than the current version of the internal corrective action policy. The corporate-wide occurrence reporting policy, for example, refers to and defines a near miss, an *"event or circumstance which has the potential to cause serious physical or psychological injury, unexpected death, or significant property damage, but did not actualize due to chance, corrective action and/or timely intervention."* [69] There is no such reference in the existing version of the internal laboratory procedure.

91. Filing an occurrence report would also trigger the involvement of the Quality & Risk Management Department, with a mandate and presumably the resources, to improve the safety of services delivered.

92. The purpose of the Occurrence Reporting Policy is considerably broader than that of the

[69] P-0057: Eastern Health Policies dated 2007, Occurrence Reporting, page 5 at page 10.

Corrective Action for IHC Occurrences. Its purpose is to "*Provide a database of clinical safety issues and the corrective actions taken; Promote consistency and timeliness in reporting occurrences; Facilitate response by the Quality and Risk Management department to potential liability exposure; Monitor, track and trend so that high priority areas for improvement can be identified and actioned and reoccurrences prevented; Use as a tool in the improvement of the quality of patient/client/resident care; Provide opportunities to provide feedback, dialogue and problem solve.*"[70]

93. In comparison, the Corrective Action for IHC Occurrences simply states that its purpose is to provide: "*guidance for the reporting and documentation of suboptimal staining and corrective actions undertaken.*"[71]

94. The broader perspective offered by a fully-resourced Quality & Risk Management Department would enable the prompt detection of problems which may cross departments. Ms. Predham provided a "good concrete example" of how occurrence reporting to a centralized location and monitoring of trends can detect problems and enhance patient care and safety:

> *"....we had one trend that we picked up fairly quickly with a certain type of suction machine that we ..... but it was because we were trending the issues that*

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[70] P-0057: Eastern Health Policies dated 2007, "*Occurrence Reporting*" page 5 at page 7.

[71] P-2157: Eastern Health Pathology Policies and Procedures Manual, 2008 *"Corrective Action for IHC Occurrences"* page 177 at 177.

we picked up that we had an issue, because we had an issue in DI, diagnostic imaging, we had an issue on a surgery floor, we had an issue on the medicine floor and we had an issue in critical care. So they were very similar and because they were similar, we picked up that trend...."[72]

95. Ideally, the response to occurrences should involve both the Quality and Risk Management Department and the Immunohistochemical Division of the Pathology Laboratory, working together as a team. The Quality and Risk Management department would ensure that investigations of occurrences by the laboratory are thorough and complete and provide the necessary resources and support to enable the laboratory to do so. It would also monitor corporate-wide trends in occurrences, looking for trends that may cross departments. The IHC division would report occurrences, conduct necessary investigations and look for trends occurring within its division.

Comments

96. It is recommended that Eastern Health and the other Regional Health authorities, the provincial government, pathologists and technologists actively work with CAP and the cIQc in their goal to implement national standards and accreditation for immunohistochemical testing in Canada.

[72] Testimony of Heather Predham, 15 October 2008, page 367, line 19 to page 369, line 12.

97. It is recommended that the Laboratory Medicine Program generally, and the Immunohistochemical Division in particular, develop a comprehensive but non-exclusive list of examples of events that would constitute an occurrence. Such a list would provide greater clarity for, and encourage routine occurrence reporting by, members of the Laboratory Medicine Program, on a topic for which there remains some confusion. This exercise would be useful for the current manual reporting system and for the electronic reporting system which will soon be implemented.

98. It is recommended that the corporate-wide policies of Eastern Health and the internal policies of the Pathology Lab be revised to clarify the procedures for reporting of occurrences, including near misses. Measures should be put in place to ensure compliance with these policies. It is recommended that internal Pathology Laboratory occurrence reporting policy be a supplement to, rather than a replacement of, the corporate-wide Occurrence Reporting policy.

Patient Right to Effective, Timely Communication & the Public Right to Know

99. Many witnesses who testified during the inquiry have expressed a need for more effective and timely communication from Eastern Health. These views have been expressed by patients whose results changed, and those whose results remained the same; by family members of deceased patients; and by witnesses expressing a concern on behalf of the public. The overwhelming theme is a need for openness and transparency, particularly when errors are discovered by a health care organization.

100. The evidence of patients such as Beverly Green and Daphne Coffin demonstrates that effective and timely communication with a patient about information relating to his or her health is essential to provide optimal patient care and to maintain that patient's confidence in treatment. Most demand to be involved in their own health care, rather than having all decisions of treatment decided for them.

101. Also important is the need to maintain public confidence in the health care system. A multi-patient adverse event will no doubt heighten public concern about the ability of an organization to provide proper patient care. When faced with the reality of a large adverse event, public confidence will not be restored by minimizing the event. It is only when the organization publicly acknowledges the full extent of the problem, and can demonstrate that it is doing all that is necessary to correct the problem, that the public can once again gain trust in the ability of the organization to deliver proper health care.

102. The evidence indicates that there are many facets of Eastern Health's disclosure strategies that require improvement: not just what and when to disclose, but who should participate in the communication with patients and the public and how to communicate effectively.

Disclosure about Problems in Lab

103. Perhaps one of the more startling revelations since 2005 is the existence of three 2003 memos authored by pathologist Dr. Ejeckam.[73] The memos highlighted serious problems in the Immunohistochemistry Lab with several stains including that for ER/PR. Notwithstanding the seriousness of these issues, the memos and concerns discussed therein had very limited distribution within Eastern Health. Even Dr. Robert Williams, the VP of Medical Services, and Dr. Kara Laing and Dr. Joy McCarthy, oncologists in the Cancer Clinic, were unaware of Dr. Ejeckam's memos or his concerns until the summer of 2005.[74] Dr. Jehan Siddiqui, oncologist and member of the Surgical Pathology Review Committee, learned about some problems with ER/PR testing in the lab in April 2003.[75] Dr. Siddiqui was not, at the time, provided with copies of any of Dr. Ejeckam's memos,[76]

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[73] P-0113: Dr. G. Ejeckam Memos dated April 4, 2003, May 2, 2003, and June 19, 2003 regarding Immunohistochemical Stains and September 23, 2003 Minutes of Surgical Pathology Review Committee.

[74] Testimony of Dr. Williams, 15 May 2008, page 143, lines 8-13; Testimony of Dr. Laing, 09 September 2008, pages 195, line 4 to page 196, line 11; Testimony of Dr. McCarthy, 19 September 2006, page 43, line 8 to page 44, line 2.

[75] P-1572: Surgical Pathology Review Committee Minutes dated April 15, 2003.

[76] Testimony of Dr. Siddiqui, 05 September 2008, page 385, line 5 to page 386, line 16.

and would have relied on the pathologists to have considered all variables before sending him any reports.[77]

104. The possibility of unreliable and erratic results should at the very least have been made known to all oncologists who rely upon such reports to make treatment recommendations for their patients. If oncologists have any reason for concern about any of their patient's test results, then this should, in turn, be conveyed to their patient.

105. Dr. Robert Deane testified that if he and his wife, Peggy Deane, were made aware that such problems were occurring in the laboratory within a year of Ms. Dean's diagnosis then they would have taken steps then to ensure that Ms. Deane was receiving the best available treatment: *"I know that there have been problems prior to her and that the system was aware of problems in the lab. I wish we had known. We would have had it independently tested elsewhere."* [78]

106. Peter Dawe also testified that if there are significant problems or issues inherent in a particular test then this information too should be available to the patient. The Canadian Cancer Society believes it is not appropriate, from an accountability perspective, for the public not to be aware of such matters. The health care system should be much more

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[77] Testimony of Dr. Siddiqui, 05 September 2008, page 380, lines 18-20.

[78] Testimony of Dr. Dean, 25 March 2008, page 100, line 22, to page 101, line 1.

open for individual patients and the public.[79]

Decision to Postpone Disclosure about Re-testing

107. When Eastern Health embarked upon a program of re-testing during the summer of 2005, there was some internal debate about whether to disclose these circumstances to the patients and to the public. Notwithstanding Minister Ottenheimer's immediate reaction that the patients and public should be informed, Eastern Health opted not to do so. The matter became public through an article in the Independent newspaper on 02 October 2005, more than two months after the decision to commence mass re-testing.

108. There was no clear statement on the records of Eastern Health as to the reasons why they postponed disclosure. The written record and the testimony of witnesses indicated there was a desire by oncologists to avoid any anxiety by their patients. As explained by Dr. Laing, the patients: "*...would have some anxiety related to a change in their results, that they would be worried, that they would, you know, be concerned for a period of time without knowing what the answer was"* and "*so you're trying to balance, you know, causing anxiety in a large group of people versus waiting until you have that information to be able to give to the patients, and really, in one step, if you will, address the issue"*[80]

[79] Testimony of Peter Dawe, 04 September 2008, page 354, line 15, to page 355, line 9.

[80] Testimony of Dr. Laing, 10 September 2008, page 246, lines 3-7 and page 246, lines 20-25.

109. There was also some documentation to suggest that Eastern Health was concerned about the preferences of their insurer, Healthcare Insurer Reciprocal of Canada (HIROC), with respect to patient notification. [81] Dr. Robert Williams, VP Medical Services, George Tilley, Chief Executive Officer, and Heather Predham, among others, stated during their respective testimony at the inquiry that it was the oncologists' desire to avoid causing patients unnecessary anxiety that prompted Eastern Health to postpone disclosing its concerns to patients or the public in the summer of 2005[82] as opposed to any concerns that HIROC may have had.

110. With regard to any reservations of HIROC, as understood and described by Heather Predham in her email of 19 July 2005,[83] Mr. Tilley stated that this simply coincided with another concern about whether Eastern Health was within the national benchmarks. The latter issue, in his view, was the actual reason the organization initially decided to pause briefly, instead of immediately proceeding with disclosure.[84]

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[81] P-0073: E-mails dated July 19, 2005 from Heather Predham to various Eastern Health officials regarding information from HIROC.

[82] Testimony of Dr. Williams, 16 May 2008, pages 191-196; Testimony of George Tilley, 17 April 2008, page 103, line 10, to page 104, line 19; and page 108, line 1, to page 109, line 14; Testimony of Heather Predham, 17 October 2008, page 119, line 14, to page 120, line 22.

[83] P-0073: E-mails dated July 19, 2005 from Heather Predham to various Eastern Health officials regarding information from HIROC.

[84] Testimony of George Tilley, 16 April 2008, page 247, lines 1-18.

Absence of Official Record for Decision

111. There is no official record stating the basis for Eastern Health's decision not to immediately disclose the ER/PR problems and re-testing to the patients or public. Nor is there a clear list of participants in the decision and a list of any dissenters. It is not even plain and obvious which date this decision was made. These questions must now be answered by reviewing the documentary evidence and witness testimony in an effort to draw the appropriate inferences.

112. In fact, Eastern Health did not maintain any official record of its overall response to the ER/PR problem. Despite the large number of documents produced by Eastern Health, and others, there is no clearly articulated chronology of key events and decisions. Many important points can now only be gleaned by resort to information such as handwritten notes, frequently incomplete and vague, and the memory of witnesses several years later. The limitations that might be posed by relying upon witness memory, in the absence of adequate documentation, was demonstrated by an exchange between Heather Predham and Commission Counsel, regarding differences in her evidence between the date of her interview with Commission Counsel, and the date of her evidence at the inquiry.[85]

113. The absence of some form of an official record, such as a report of Eastern Health's CEO

[85] Testimony of Heather Predham, 17 October 2008, page 77, line 8, to page 79, line 20.

or the leadership team, raises a concern about accountability for its decisions. An important decision, such as postponing disclosure, should be clearly documented, specifying the participants in the decision, the date of the decision and the reasons for the decision. Eastern Health should never be in the position when asked to explain its decision sometime later that it cannot promptly produce a record with this answer.

114. Additionally, the absence of an official record raises a concern that Eastern Health had not engaged in sound decision making in the first place. This concern is heightened when the various witnesses cannot all point to a common understanding about the date, reasons and participants in the decision to postpone disclosure. It may very well be that there was no clear, common understanding among the various participants about this decision, and this would have impeded sound decision making by the organization.

115. An adverse event of this magnitude warrants a formal, comprehensive and accurate official report or series of reports, not only to have a permanent record for the purpose of accountability, but to promote sound decision making by the organization.

Patients and Family Members Views About Disclosure

116. Regardless of the reason for the decision, many patients and family members found Eastern Health's decision not to promptly disclose to be unacceptable:

117. As Dr. Deane observed:

> *"Well, there certainly has been delay in disclosure. A certain amount of delay is acceptable because you have to get all your facts together and your ducks in a row before you go in front of the media, get all your information correct. Stories we're hearing in the press right now, there's been a lot of delays in informing patients of this problem, which certainly seemed rather excessive, if the patients' accounts are correct."*[86]

118. Rosalind Jardine was hospitalized for a recurrence of her breast cancer shortly before she learned about the ER/PR re-testing. Ms. Jardine was admitted for surgery in September of 2005 and learned shortly after that her cancer had metastasized. Dr. Laing advised her in October 2005, that her ER/PR results had changed upon re-testing. Ms. Jardine stated that this has caused her to lose trust in the medical system, and to second guess everything. Nevertheless, she still felt fortunate to learn this information in the manner that she did, in comparison to the stories of other patients. Regarding Eastern's Health handling of this matter, Ms. Jardine stated:

> *"I think they behaved very poorly. It's very sad because timing and then diagnose and then proper treatment is crucial. It is so crucial that there won't be a reoccurrence. I just come up with sad. I'm just very sad with how this happened,*

[86] Testimony of Dr. Deane, 25 March 2008, page 100, lines 2-11.

how it's being played out, how it was played out previous to hitting the media, how we were informed, and I feel fortunate, I feel fortunate and blessed that I was informed as I was. Other stories are not so fortunate."[87]

119. Ms. Jardine also emphasized the need for honesty and transparency*: "…. But it's so important to be honest and have a transparent system that there's nothing being withheld because that oncologist, that radiologist, that GP and that patient, unless they're working as a team, the results are not going to be as effective or long lasting, as we are seeing results from this procedure."*[88]

120. The Canadian Cancer Society was not consulted in the summer of 2005 about whether or not to notify patients or the public of retesting. If it had, it might have been able to offer a different perspective about patient disclosure:

"From the Canadian Cancer Society perspective, you know, the reality is that they chose non-disclosure over disclosure at various points in their process, and I think from the Canadian Cancer Society perspective, if we were putting the cancer patients first, the people with cancer and their loved ones, even people who had passed away, we would have given a different perspective on how to communicate and it would have been full disclosure at the earliest possible time….

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[87] Testimony of Rosalind Jardine, 24 March 2008, page 74, line 14, to page 75, line 4.

[88] Testimony of Rosalind Jardine, 24 March 2008, page 75, line 20 to page 76, line 2.

....We would have been advocating for full disclosure at the earliest possible time based on, you know, not just because we made it up, but based on practises around adverse events, based on, you know, belief in a patient right to know what's happening with their treatment processes and diagnosis processes and their prognosis."[89]

Anxiety of Patients an Insufficient Reason to Delay Disclosure

121. As noted above, Dr. Laing and other oncologists expressed a preference not to immediately disclose the re-testing to patients, as this would cause anxiety for the patients. The preference was to await the retest results before approaching patients with any information about the re-testing.[90]

122. A decision to delay disclosure was considered by Geri Rogers to be inappropriate, in this day and age. Ms. Rogers discussed this with Dr. Laing:

"And I asked her why nobody returned my calls, and she said that she had wanted Eastern Health to contact the patients, and I couldn't understand the rationale that it was to save people stress. I said, you know, 'it's not 1955. It's 2005 and we're grown adult women. Many who have been – who've had surgery, who've

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[89] Testimony of Peter Dawe, 03 September 2008, page 51, line 2 to page 52, line 1.

[90] P-0138: Typed Notes (Note #19) of Dr. Robert Williams regarding the August 15, 2005 meeting with the Minister on ER/PR Receptor Issues.

had horrible chemotherapy, who've gone through radiation, and we're adults, and we're smart, and we take part in our health care. We have to make decisions.'"[91]

123. Ms. Rogers also voiced the opinion that withholding information from a patient for a period of time to avoid patient anxiety was actually counterproductive and created more confusion, fear and mistrust. Ms. Rogers' described her discussion with patient relations officer, Nancy Parsons:

"...I asked her, why they had – why did Eastern Health never call me back and why didn't Eastern Health speak directly to the women who were involved, because there was so much confusion. There was so much fear, and which I think mistrust grew out of that as well, and she said 'well, we didn't want to frighten women', and I said again, you know, that makes no sense. It's – we're adults who take part in our health care, and that, in fact, what they did was exactly the opposite. They caused fear. They caused confusion. They caused mistrust. They caused unnecessary anxiety..."[92]

124. The views of Ms. Rogers were echoed by Peter Dawe.:

"... we're at the stage in health care where if you look in best practises, if you look at how to manage systems, that, you know, from a patient perspective, and if you

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[91] Testimony of Geri Rogers, 25 March 2008, page 155, line 19 to page 156, line 4.

[92] Testimony of Geri Rogers, 25 March 2008, page 160, lines 11-24.

have a philosophical belief in putting patients first, then it ends up being parochial or even patronizing or misguided to withhold information based on the fear that it might cause some concern, that in the day and age we live in with the baby boomer population, the internet, and people have control of their lives now more than they ever have before, and certainly in health care, people demand control of their health care, both on an individual and social level more than they ever have before, that it's a bit misguided to think that withholding information of this nature which would have such a major impact on a prognosis, ultimately on particular treatment, and that people have a right, that's what it comes down to, they have a right to know about such things. Even more so than having a right to know about it, they have a right to actually understand it, so they have a right to processes being put in place by institutions that ensure in some way that not just was there an attempt to deliver a message, but that the message was understood..."[93]

125. Patricia Pilgrim, Chief Operating Officer, has acknowledged the need to improve patient involvement in decision making and observed that the health care system, including Eastern Health, is viewed by many as paternalistic.[94]

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[93] Testimony of Peter Dawe, 03 September 2008, page 53, line 10, to page 54, line 14.

[94] Testimony of Patricia Pilgrim, 02 October 2008, page 188, line 11, to page 190, line 18.

126. A patient's entitlement to his or her health information is described in the recently published Canadian Patient Safety Institute ("CPSI") Canadian Disclosure Guidelines:

> *"Patients are entitled to information about themselves and about their medical condition or illness, including the risks inherent in healthcare delivery. Autonomy, the patient's right to control what happens to his or her body, is the cornerstone of the informed consent discussion. At times this will mean that information will be provided about possible unexpected and undesired results."*[95]

127. There is no caveat, in the CPSI Disclosure Guidelines, for withholding or delaying any obligation to disclose based upon concerns about patient anxiety. These particular guidelines, of course, were not available in the summer of 2005.

128. The CPSI Disclosure Guidelines outline several guiding principles:

> *"**Patient-centered healthcare**: An environment of patient-centered healthcare fosters open, honest and ongoing communication between healthcare providers and patients. Healthcare services should be respectful, supportive and take into consideration the patient's expectations and needs at all times.*
>
> ***Patient autonomy**: Patients have the right to know what has happened to them in order to facilitate their active involvement and decision making in their ongoing healthcare.*

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[95] P-0161: Canadian Disclosure Guidelines by the Canadian Patient Safety Institute 2008, at page 8.

> ***Healthcare that is safe****: Patients should have access to safe healthcare services of the highest possible quality. Lessons learned from adverse events should be used to improve the practices, processes and systems of healthcare delivery.*
>
> ***Leadership support****: Leaders and decision makers in the healthcare environment must be visible champions of disclosure as part of patient-centered healthcare.*
>
> ***Disclosure is the right thing to do****: Individuals involved at all levels of decision-making around disclosure must ask themselves what they would expect in a similar situation.*
>
> ***Honesty and transparency****: When an adverse event occurs, the patient should be told what happened. Disclosure acknowledges and informs the patient, which is critical in maintaining the patient's trust and confidence in the healthcare system."*[96]

129. The guidelines pertaining to patient-centred healthcare, patient autonomy, and honesty and transparency are of particular importance when considering Eastern Health's decision to postpone disclosure.

130. The Disclosure Guidelines also explains the importance of disclosure from the patient perspective:

> "*An emerging body of literature describes the patient's perspective about*

[96] P-0161:Canadian Disclosure Guidelines by the Canadian Patient Safety Institute 2008, at page 9.

disclosure and the importance of being told whenever harm occurs. Patients want to know:

- *The facts about what happened.*
- *The steps that were and will be taken to minimize the harm.*
- *That the healthcare provider regrets what happened.*
- *What will be done to prevent similar events in the future.*

Patients may lose trust, or become anxious or fearful when they sense that information is being withheld. This loss of trust can negatively affect the therapeutic relationship. Patients may be more understanding of adverse events when there has been open disclosure. Disclosing an adverse event to the patient shows respect, involves the patient in the clinical decision-making process, and facilitates future safe and appropriate clinical care."[97]

131. Peter Dawe suggests it should be clearly articulated by patient advocacy and support groups, governments and health care organizations what the public should expect when they enter the health care system. As an example, the Canadian Prostate Cancer Network developed a Charter of Rights, which spells out what the basic rights of patients should be in this country, for prostate cancer patients[98]. Mr. Dawe explained that a statement of rights would be beneficial for all cancer patients:

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[97] P-0161:Canadian Disclosure Guidelines by the Canadian Patient Safety Institute 2008, at page 10 (see reference for footnotes cited within test).

[98] P-2438: The Canadian Prostate Cancer Charter of Rights.

"What the Canadian Cancer Society would put forward was that was people actually have a right to actually understand, not just to know and be told, but to understand information being given to them. And if you look at this particular exhibit, you get that sense that they're not just--these people have said we're not just looking for information, we want to be a full partner in our own health care, and that's what it comes down to for the Canadian Cancer Society."[99]

No Contingency Plan to Communicate with Patients When Media Broke Story

132. There was admittedly a significant risk that the news about problematic ER/PR tests would spread and ultimately make its way into the media.[100] Notwithstanding this risk, Eastern Health persisted in its plans to await the re-test results, prior to notifying the patients whose specimens were being re-tested. At the end of September 2005, Heather Predham and Susan Bonnell, Director, Corporate Communications, had just started to informally discuss re-visiting this decision, when the ER/PR issue became public through a media report.[101]

133. The concerns about the ER/PR test results came to the attention of the media and a story

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[99] Testimony of Peter Dawe, 04 September 2008, page 349, lines 6-16.

[100] Testimony of Susan Bonnell, 30 May 2008, page 79, lines 18-24 and P-0304; Memos dated July 21, 2005 from Susan Bonnell to George Tilley and July 22, 2005 from Susan Bonnell to George Tilley and Dr. Bob Williams regarding ER and PR Testing Public Disclosure at page 2.

[101] Testimony of Heather Predham, 18 October 2008, page 173, line 16, to page 175, line 15.

was published in the Independent newspaper on 02 October 2005[102]. As a result, breast cancer patients were hearing the news about the ER/PR testing problems for the first time through the media. As noted by breast cancer patient Geri Rogers *"I don't think that the media is the ideal place for me to get my health care information. I was quite astounded actually"*.[103]

134. Ms. Goobie also testified that the media communication was not appropriate: *"I don't think that was done right. I think they should have called us instead of we having--if I didn't hear it on the radio that day, I wouldn't know anything about it. So I think they should have called us really, got in touch with us or sent a letter or called or something*."[104]

135. Even though this media involvement was not unexpected by Eastern Health officials addressing the ER/PR problems, Dr. Williams testified there was no contingency plan in place in the event the issue became public in the media before Eastern Health initiated

[102] P-0086: October 2, 2005 Article by Clare-Marie Gosse of The Independent entitled: Questionable Results.

[103] Testimony of Geri Rogers, 25 March 2008, page 149, lines 3-5.

[104] Testimony of Patricia Goobie, 20 March 2008, page 66, line 14, to page 67, line 2.

patient and public disclosure.[105] Mr. Tilley was also unaware of any such plan.[106]

136. Ms. Rogers testified that when she initially heard about the ER/PR issue, even her family physician had not been informed of the issues by Eastern Health and was therefore not equipped to respond to her questions. Dr. Wagoner told her she had not been contacted, and other patients were worried and afraid. She asked Ms. Rogers to let her know if she heard anything.[107]

Direct Physician Contact Preferable as Source of Patient Care Information

137. Madame Teletchea, a resident of St. Pierre and Miquelon, was first alerted to the concern about her ER/PR test result by gynecologist Dr. Peaudecerf. He provided her with some basic information and endeavoured to contact physicians at Eastern Health to obtain additional information. In the interim, Madame Teletchea gained a better appreciation of the ER/PR issues when she turned to the internet for more information. As related by the interpreter for Madame Teletchea:

> *"A doctor in St. Pierre called her to tell her that she needed to take another test or a new treatment -- a new treatment, so he read her the letter and the letter stated that she needed to take a particular medication, Tamoxifen, and the doctor*

[105] Testimony of Dr. Williams, 16 May 2008, page 273, line 25, to page 274, line 13.

[106] Testimony of George Tilley, 17 April 2008, page 177, line 20 to page 178, line 8, and page 175 to 178 generally.

[107] Testimony of Geri Rogers, 25 March 2008, page 181, lines 8-18.

in St. Pierre said that he couldn't understand why because it was five years later, and she asked this doctor to take further information before she was administered that medication. So she went home and looked on internet to get some information on Tamoxifen, and she fell on this site that explained that there were mistakes and that there were two persons who were in the final phase because of the mistakes made here in St. John's.[108]

138. In fact, Madame Teletchea first learned, through her own research on the internet, of Arimedex as an alternative treatment option to Tamoxifen.

139. The lack of a more direct and timely method of communication with Madame Teletchea was compounded, in her case, by the fact that her native tongue is French and there was some delay in accessing a physician who could speak to her from first-hand knowledge of the issues pertaining to the ER/PR test results. There will be circumstances in which a family physician or other physician may be appropriately or necessarily relied upon as an intermediary between the specialist and patient. In these circumstances, care should be taken that the intermediary physician is provided up front with as much information as possible, so that he or she can be in a position to answer the patient's questions in a timely and effective manner.

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[108] Testimony of Madame Teletchea, 01 August 2008, page 24, line 21, to page 25, line 11.

Delay in Disclosure to Patients of their Re-test Results

140. It became apparent during the inquiry that it sometimes took months or longer for retest results to be communicated to the patients. Any such delays could have had impact upon patient care if any necessary change of treatment was not implemented as expeditiously as possible. Furthermore, the delay in communicating test results was a potential cause of anxiety for patients, many of whom became aware on 02 October 2005 or thereafter that their initial ER/PR tests results may be incorrect.

141. Daphne Coffin testified about a six-month delay, in her case, between the Mount Sinai re-test results being entered on her medical chart[109] and being informed of these results. Ms. Coffin first heard about the ER/PR issue and the re-testing while attending a breast cancer support meeting in about January 2006. She subsequently contacted the cancer clinic and asked to be re-tested.[110] Ms. Coffin attended a breast cancer retreat in May 2006, and a nurse she met there offered to follow-up for Ms. Coffin to see if her re-test results were back. In about July or August of that year, she received a call from the cancer clinic and was told that her results had changed and an appointment was made for her to see Dr. Laing[111]. Ms. Coffin met with Dr. Laing in September 2006 and learned at that time that Mount Sinai showed her to be ER ninety-five and PR less than

[109] C-0056, Pathology Report of Daphne Coffin dated August 28, 2001, addendum number 3.

[110] Testimony of Daphne Coffin, 20 March 2008, page 100, line 18 to page 101, line 6.

[111] Testimony of Daphne Coffin, 20 March 2008, page 107, line 12 to page 108, line 25.

one percent.[112] After some discussion with Dr. Laing regarding her treatment options, she agreed to try Arimidex.[113] Ms. Coffin had no idea then that the re-testing had actually been completed in March 2006, and only learned about this six month delay during an interview with Commission Counsel in early 2008.[114]

142. Patricia Goobie testified about how she and her late sister, Geraldine Avery, learned of their ER/PR re-test results. Ms. Goobie heard on the radio that many of the results for re-testing were back, so she called for her results and was informed they were okay. Her sister also called, but did not get the same quick response.

143. Ms. Avery was initially diagnosed with cancer of the left breast in 1999 and tested ER/PR negative and had recurrence of her cancer in 2002 and early 2005. In November 2005, a fourth cancer, primary gastric cancer, was diagnosed. Ms. Avery's clinical chart indicates she was advised on 14 December 2005 that her ER/PR test results had converted to positive upon re-testing.[115] Ms. Goobie stated that Ms. Avery finally received her results three or four weeks after Ms. Goobie received hers[116]:

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[112] Testimony of Daphne Coffin, 20 March 2008, page 108, line 23, to page 109, line 5.

[113] Testimony of Daphne Coffin, 20 March 2008, page 111, lines 7-12.

[114] Testimony of Daphne Coffin, 20 March 2008, page 121, lines 9-13.

[115] C-0055, Dr. H. Bliss Murphy Cancer Centre Medical Records of Geraldine Avery (deceased sister of Patricia Goobie) August 18, 1999 to May 17, 2006, at page 20 (Progress Note of Dr. McCarthy, dated 14 December 2005, for Geraldine Avery).

[116] Testimony of Patricia Goobie, 20 March 2008, page 23, line 25 to page 24, line 6.

"And she called many times and she didn't get her results. She was a long time getting them, until finally she got a bit upset and she said, "You know, I want to know my results." But she phoned me after and she said, "I think I'm getting the run around, you know, because they're not giving me no results," and I got mine immediately. So hers came back positive. And to it's like a cover up and that's what she felt, the same thing."[117]

Role of Physician Review Panel and Impact Upon Communication with Patients

144. A special Physician Review Panel was established specifically to deal with changed ER/PR re-test results. The rationale for the Physician Review Panel was to provide better recommendations for patient care, in keeping with the mandate of tumour boards in place at Eastern Health and other health care organizations.

145. On the surface, the Physician Review Panel established for the ER/PR re-testing appears to be an excellent idea to enhance patient care. However, the manner in which the Physician Review Panel was organized and performed its services was deficient in several respects and lacked the typical tumour board structure and the benefits thereof.

146. In many instances, the panel process caused delay in the communication with patients awaiting re-test results or who were yet to be informed about the re-testing. This delay

[117] Testimony of Patricia Goobie, 20 March 2008, page 15, lines 1-10.

was often quite significant. Due to the numbers of patients chosen to be reviewed by the panel, and the time and resources made available to do so, the paneling process took several months to complete. Furthermore, the method of communicating the recommendations of the panel to the patients - indirectly through the most responsible physician via a letter from the panel - introduced further delay.

Tumour Panel Would Benefit from Presence of Treating Physician

147. The Physician Review Panel did not, by design, require the attendance of the patient's treating physician. Sometimes, a patient's treating physician might attend the panel meeting when her case was reviewed, but only if the patient's oncologist sat on the Physician Review Panel and happened to be present on the appropriate date. It was not a requirement for the panel process. Patients who were discharged from the Cancer Clinic, being followed by a family physician, or being followed by an oncologist who did not sit on the panel, did not have the benefit of their treating physician being present for the panel discussion.

148. This later proved to be an impediment to effective communication with the patient about treatment options, as experienced by Norman White. Mr. White also experienced a significant delay in being informed of his re-test results. He was diagnosed and treated for breast cancer in 1999. He moved to Alberta for six months, on 14 March 2006. The Physician Review Panel met to discuss his treatment on 04 March 2006. By the time

efforts were made to contact Mr. White by telephone, he had already left for Alberta.[118] His family doctor did not have a telephone number for him and there was no effort to contact him by mail.[119] He learned of the re-test results and the panel recommendations when he returned to the province in the fall of 2006 and was contacted by his family doctor.

149. No one explained to Mr. White what the Physician Review Panel was or why no hormonal treatment was being recommended in spite of the significant change in his ER/PR results.[120] He was originally determined to be ER 1-5 and PR 0 and upon re-testing was determined to be ER 60 and PR 0. Mr. White explained how the communication was handled and his concerns in this regard:

> *"... When I learned of this--from this letter here then I said to myself, what in the heck is going on here? All this five years and this has been there and suddenly, you know, a sledgehammer comes down and you're devastated. They say now that I may not need the hormone therapy at this time. Who knows, you know, I've lost all faith, confidence in people who we put a lot of trust in, but no, it's very disturbing that I didn't get any information from any of the doctors or staff,*

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[118] Testimony of Norman White, 19 March 2008, page 188, lines 15-17 to page 189, lines 4-7.

[119] Testimony of Norman White, 19 March 2008, page 197, lines 5-21.

[120] Testimony of Norman White, 19 March 2008, page 193, line 15, to page 194, line 18.

whatever."[121]

150. Dr. Brufsky, an oncologist and breast specialist for Magee's Women's Hospital at the University of Pittsburgh, testified how tumour board rounds are structured at his institution. It is a priority for the patient's treating physician to be present for the tumour board discussion, and if not, the case wouldn't be presented that day. This is necessary since the treating physician will ultimately have to communicate the treatment options to be patient.[122]

Tumour Panel Should Not Delay Patient Treatment

151. Another priority is for the timeliness of all prospective reviews of a patient treatment. At Magee's Women's Hospital, the Cancer Standards Program requires that 10% of all cases be reviewed by their tumour board (multi-disciplinary committee) and 75% of these cases are to be reviewed prospectively, before patient treatment. Dr. Brufsky's stated, *"So for the prospective ones, they have to be done within, you know, the time of treatment, for example, you know, a patient's two week's post-operative. She sees me in my clinic. I'll present her that next Thursday at our breast conference. So that's within three weeks basically and we try to encourage that for prospective cases at least."* If, for whatever reason, the case could not be dealt with by the tumor board within these

[121] Testimony of Norman White, 19 March 2008, page 193, line 15, to page 194, line1.

[122] Testimony of Dr. Brufsky, 06 October 2008, page 191, line 16 to page 193, line 3.

timelines, then it would be presented on another date, but not as a prospective case.[123]

Physician Review Panel Recommendations Lacking Patient Input

152. Effective communication between physician and patient is crucial. It ensures that the patient has all of the relevant information she needs, to make a decision about her own health. It also ensures that the physician has all the information that the physician needs to make an appropriate recommendation for the patient.

153. There were occasions that the Physician Review Panel recommended that there be no change in a patient's treatment, in spite of changed ER/PR test results, based upon the patient's original decision to decline Tamoxifen as gleaned from the patient's existing health record. Due to the panel procedure, recommendations were often made without any direct or indirect patient input.

154. Geri Rogers, for example, testified that her original decision to decline Tamoxifen was based upon her original pathology that indicated that she was ER negative. If she had known she was ER positive then she would have made a different decision "*Absolutely I would have taken Tamoxifen*".[124]

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[123] Testimony of Dr. Brufsky, 06 October 2008, page 196, line 14 to page 197, line 20.

[124] Testimony of Geri Rogers, 25 March 2008, page 147, line 20 to page 148, line 8.

155. Ms. Green was another patient who initially declined Tamoxifen based upon her initial ER/PR test results, following discussions with her physicians. Ms. Green was not pleased that the Physician Review Panel recommended no change in treatment for her based upon her original decision to "refuse" Tamoxifen when offered:

> *"...I know absolutely none of these people. No one contacted me to discuss my care with me. No one even considered me to be a person really. That's how I--you know, I was really insulted and, you know, first I was very angry. I was like, who are these people? Who do they think they are?...*
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> *:*
>
> *...I wasn't acknowledged whatsoever."*[125]

156. Ms. Green thought it was unfair for the panel not to recommend Tamoxifen based upon her original decision, since she was originally thought to be ER negative. She believed the reason for her original decision to decline Tamoxifen was quite obvious, and noted this decision was supported by some of her doctors at the time.[126]

157. These witnesses were understandably upset that the Physician Review Panel would simply presume a patient who initially declined hormonal therapy would do so again even though her ER/PR results had changed upon re-testing. Such inferences were often

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[125] Testimony of Beverly Green, 19 March 2008, page 76, lines 5-22.

[126] Testimony of Beverly Green, 19 March 2008, page 76, line 23 to page 77, line 8.

made without appreciation of the patient's initial decision to decline hormonal therapy, or without considering the patient's present views about hormonal therapy. The panel did not consider that a patient's risk-benefit analysis of taking hormonal therapy might differ, with significant new information about her particular ER/PR test result, or with new information about the risks or benefits of hormonal therapy.

Process of Communicating Panel Recommendation to Patients was Ineffective

158. The Physician Review Panel's method of communicating its recommendations was cumbersome, lacked accountability and was at times entirely ineffective.

159. The patients for whom the panel recommended a treatment change were to be notified promptly, by the treating physician, upon receipt of the panel letter. This did not always occur.[127]

160. Similarly, patients for whom the panel recommended no treatment change were not necessarily contacted promptly by their treating physicians who received panel letters.

161. The panel letters for such patients typically requested that the re-testing information and the panel's recommendation be communicated to the patient "*as soon as possible*".[128]

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[127] P-2569 and Testimony of Dr. Laing, 18 September 2008, at pages 32 and 33;

[128] C-229: Tumor Panel Letters from Dr. Kara Laing, Patient Names Redacted at pages 2, 5, 6, 8, 9, 11, 16, 18, 19, 20, 21, 25.

However, another procedure was endorsed, upon the direction of Dr. Laing following consultation with the oncologists. Dr. McCarthy explained that if there was no recommended change of treatment, the oncologists could await the next regularly scheduled appointment, to relay this information to their patients. As regular appointments are often made every six months, or yearly, a patient may have had to wait several months to obtain her results.[129]

162. When asked if there was any consideration that these patients may be anxiously awaiting their re-test results, Dr. McCarthy indicated that if any patients called to inquire then the oncologists would meet with them at their request, or they could call the hotline for this information.[130] Nancy Parsons, however, testified that she would not release such information to patients, or even advise them it was available, as it was outside her scope of practice. Ms. Parsons felt her only option was to advise the oncologist that the patient had called looking for this information. [131]

163. Notwithstanding the endorsement of the procedure of awaiting the next regular appointment where no treatment change was recommended, not all oncologists followed this approach. Dr. McCarthy testified that she promptly called all the patients

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[129] Testimony of Dr. McCarthy, 19 September 2008, page 392, line 2, to page 393, line 13.

[130] Testimony of Dr. McCarthy, 19 September 2008, page 394, line 11 to page 396, line 16.

[131] Testimony of Nancy Parsons, 24 September 2008, pages 46 and 50.

who were paneled, regardless of whether or not there was a recommended change.

164. However, Dr. Siddiqui testified that if there was no recommended change of treatment for his patient, he would wait for the next regular appointment to advise the patient. He believed that this was what most oncologists were doing.[132] He was unaware of any other parallel process of notifying patients for whom the panel recommended no treatment change, about their retest results.[133]

165. Ms. Green was one such patient whose treatment was reviewed by the Physician Review Panel but for whom no treatment change was recommended. Ms. Green's results from her mastectomy specimen were among the early re-test results received from Mount Sinai. An addendum to her pathology report was entered on October 20, 2005, indicating that her original results of ER negative, PR 70 was retested by Mount Sinai, and the results were ER 20, PR 85-90. She was not advised of these re-test results at the time, even though she was still being seen by the Cancer Clinic.[134]

166. Ms. Green was not, in fact, advised of the re-test results until much later. Dr. Siddiqui's notes indicate that such results were brought to her attention on 17 November 2006.

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[132] Testimony of Dr. Siddiqui, 08 September 2008, page 61, line 12 to page 63, line 10.

[133] Testimony of Dr. Siddiqui, 08 September 2008, page 164, lines 5-17.

[134] Testimony of Beverly Green, 19 March 2008, page 47, line 7 to page 48, line 7.

Ms. Greene does not have any recollection of being advised at that time.[135] After a visit with Dr. Siddiqui on 17 April 2007, she thought he was acting out of character following her request for some chart information. She visited her family doctor and wondered if he had any information for her. It was then that she learned about the panel letter dated 08 May 2006 which outlined the change in her ER/PR status.[136]

167. The lengthy delay in communicating to Ms. Green her re-test results, at a time when she was being investigated and subsequently determined to have had a metastasis of her breast cancer, highlights the serious flaws in the panel's communication approach.

168. Dr. Laing emphasized that the recommendations of the panel were to be considered just as that - recommendations only. The decision would ultimately be made by the patient and treating physician.[137] However, the procedure endorsed by the oncologists - awaiting the next regular appointment to discuss treatment for those patients whom the panel recommended no change of treatment change - does not respect the patient's right to timely involvement in her treatment decision.

169. Furthermore, the lack of participation by the patient's treating physician in the panel

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[135] Testimony of Beverly Green, 19 March 2008, page 60, lines 4-16.

[136] Testimony of Beverly Green, 19 March 2008, page 66-68.

[137] Testimony of Dr. Laing, 17 September 2008, page 80, line 9 to page 81, line 17.

discussion did not always permit an informative discussion between the treating physician and the patient, as happened with Madame Teletchea and Norman White.

170. The oncologists' lack of attention in late 2005 and 2006 to the anxiety of patients awaiting re-tests results is remarkable in light of their position the summer before. In the summer of 2005, the oncologists as a group were so concerned about patient anxiety that it justified withholding information about the re-testing until all the results were back. It is particularly troubling that in the following year this same group would endorse a procedure whereby the physicians need not immediately contact certain patients, but rather could wait perhaps several months for the patient's next appointment. While concerned patients could contact their family physician or oncologist, the patients would not typically know when physicians received new information about their re-test results.

Unfounded Assurances that All Patients Were Contacted

171. Shortly after the story broke in the Independent newspaper, Eastern Health published an announcement, which included the statement, *"All patients who are being re-tested are being contacted. Our first priority is to notify patients whose results have changed because of the re-testing. If there is a change to your result and your treatment is affected, you will be contacted directly by your oncologist or treating physician. You will also be notified if there is no change in your ER and PR status."*[138]

[138] P-0622: Article dated October 5, 2005 A Message to Breast Cancer Patients.

172. In December 2006, in conjunction with a press conference, Eastern Health's spokesperson, Dr. Oscar Howell, VP Medical Services, was quoted *"Our clinical team members have communicated individually with all patients impacted by this review"*.[139]

173. Eastern Health's decision to make public statements that all patients would be contacted, and later on to state publicly that all patients had been contacted, created a false sense of security to breast cancer patients. Patients, such as Beverly Green, assumed that no news from Eastern Health was good news, and that if they had not been contacted about the re-testing then they were not in any way affected.[140] This also applied to family members of deceased patients, who may have assumed that their loved one was not affected if they did not hear from Eastern Health.

174. Eastern Health did not have any basis to speak so confidently that all patients had been contacted. Heather Predham, who was primarily responsible for developing and maintaining the patient list and contacts, did not have any such confidence.[141] It would have been more prudent for Eastern Health to have stated that while efforts were being made to identify and contact affected patients, they could not be certain that their efforts were foolproof. It would also have been appropriate for Eastern Health to publicly define

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[139] P-104: E-mail dated December 11, 2006 from Susan Bonnell to Tansy Mundon with final attachments for the December 11, 2006 Media Technical Briefing on ER/PR at page 4.

[140] Testimony of Beverly Green 19 March 2008, page 44, line 19-24.

[141] Testimony of Heather Predham, 22 October 2008, pages 71, line 3 to page 73, line 23.

the parameters of the re-testing program, including the dates in questions, and to encourage anyone who felt they met this description to self-identify if they had not been already contacted. This would have provided one more method to assist Eastern Health in capturing all patients in order to help to compensate for deficiencies in the data information systems of Eastern Health and the other Regional Health Authorities.

Method of Communicating With Patients

175. Patients were advised of their re-test results through a variety of methods, including: an appointment with or phone call from their treating oncologist; an appointment with or telephone call with their family physician; by being given a copy of the Physician Review Panel from the family physician; a telephone call from or to the patients relations officer or another member of the Quality and Risk Management Department. The patient or family members did not always understand the information being provided. They did not always receive timely, accurate or complete information.

176. It is important that a patient receive vital health information from a physician or other health care provider who is in the best position to respond to the patient's questions or concerns. The use of telephone and message machines can play a valuable role in making contact with a patient or to follow-up, or where the patient has specifically indicated that a phone call or message is acceptable. Otherwise, relaying vital health information by phone or answering machine message instead of in a face-to-face

meeting should not be considered a best practice and ought to be used only in a time of urgency. An organization should be particularly cautious of using the telephone as a primary means of communicating information to a patient when the patient does not have an established relationship with the caller. A timely meeting in person, followed by written conformation, would be more appropriate and closer to a truly patient-centred practice.

Communication of the Reasons for Inaccurate ER/PR Results

177. Predictably, some patients and family members expressed a desire to learn why certain ER/PR test results were inaccurate, particularly when such discovery was made many months or years after the original test procedure. The fact that there were so many inaccurate test results, over such a long period of time, also piqued the interest of patients and family members about the cause of the testing errors.

178. Dr. Deane, like many other families and patients, testified that he was not told by Eastern Health the cause of the problem with the ER/PR test results.[142]

179. Daphne Coffin likewise was not informed of the cause and expressed a desire to learn what went wrong with the testing and why her specimen was not initially re-tested: *"I really would like to know what actually went wrong with this whole thing. How could*

[142] Testimony of Dr. Deane, 25 March 2008, page 110, line 18, to page 111, line 1.

something that was so flawed go on for so long? And who decided who was retested and who wasn't and was cost maybe a factor in that?" [143]

180. Patients and family members are not just interested in learning generally about the cause of testing errors within the Laboratory Medicine Program. There have been expressions of concern and a desire to learn why there was, at times, a lack of effective communication with patients and families about the ER/PR re-testing and other information pertinent to the health of patients.

181. Beverly Green did not learn about the re-testing of her specimen, and the resulting changes in her ER/PR test results, for many months, even though she was been followed at the Cancer Clinic in the interim. Her ER/PR test result for her mastectomy specimen was entered on her chart on 20 October 2005. She finally learned about her changed ER/PR test results in the spring of 2007:

> *"Well, I think it was totally--you know, the whole way it was handled was very unprofessional, very sneaky, deceiving, just everything that builds even more resentment and more doubts and I think it just could have been a lot better....*
>
> *.... It was just very--it was almost like we weren't adult even to learn, or there's, you know, there's a lot more mistakes than we're aware of and we can obviously see by going through my chart. Now before I went to my chart, I didn't have any*

[143] Testimony of Daphne Coffin, 20 March 2008, page 122, lines17-23.

of those knowledge of those things that had went wrong. So you know, there just could have been a better way to do it."[144]

182. Ms. Green stated it would have been preferable for them Eastern Health to have admitted its mistakes to the individuals affected:

"I think if we had been, you know, approached on an individual basis and things were admitted to us. I mean, everyone makes mistakes and we--and you know, sometimes we're much more forgiving when we are told straight out than when we are led to be mislead or deceived."[145]

183. Elizabeth White, from Carbonear, was diagnosed and treated for breast cancer in 1999. She was not part of the group re-tested by Eastern Health in 2005, even though her original results were 20-30% for ER and 10% for PR. Ms. White was only identified to be a candidate for re-testing when, upon hearing about the issue in the media, she called the cancer clinic starting in mid-July 2007 to ascertain the status of her ER/PR test results. She placed follow-up calls to the Cancer Clinic in September 2007 and November 2007. In September, she was told that her specimen was in Carbonear and that they would be in touch and take it from there; and in November, she was told that her specimen had been sent to Mount Sinai for re-testing.

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[144] Testimony of Beverly Green, 19 March 2008, page 78, line 16 to page 79, line 12.

[145] Testimony of Beverly Green, 19 March 2008, page 79, line 15 to page 80, line 9.

184. Ms. White's re-test results were received and reviewed by the panel in December 2007. The results were communicated to her that month through a phone message and her emergency contact.[146] She understood that she was missed, in the initial re-testing, because her test results for ER might be considered positive to some,[147] even though in 1999 her ER results were considered negative.[148]

185. Regarding Eastern Health's response to the ER/PR issues, Ms. White would like to know how something like this could have happened and how mistakes could they have gone on for such a long period of time. She would also like an explanation why she was not notified to have her specimen retested and how she fell through the cracks. Nobody has offered her any explanation about these matters.[149]

Privilege Claimed for Reports Containing Information About Cause of Flawed Results

186. Eastern Health declined to release known information about the cause of the flawed ER/PR test results. It claimed that such information was contained in external review reports of Dr. Banerjee and Ms. Wegrynowski and that these reports were the subject to a claim of quality assurance and peer review privilege. This claim for privilege was

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[146] Testimony of Elizabeth White, 19 March 2008, pages 143.

[147] Testimony of Elizaebth White, 19 March 2008, at page 155, lines 13-24.

[148] Testimony of Elizabeth White, 19 March 2008, page 116, lines 3-7.

[149] Testimony of Elizabeth White, 19 March 2008, page 169, line 18, to page 160, line 12.

ultimately rejected by the Supreme Court Trial Division.

187. As Heather Predham indicated in her testimony, much information in these reports was factual and could have been released to patients and the public, even if other aspects of the report were the subject of a privilege claim.[150] Furthermore, Dr. Carter and Dr. Cook had relevant information, from their summer 2005 slide review, about problems with the ER/PR testing which clearly did not attract a claim of privilege.

188. A more patient-centred approach by Eastern Health would have ensured, from the outset, that it would be in a position to communicate the facts about what happened as soon as this information became available.

Statements that Cause of Testing Errors Unknown for Individual Patients

189. Statements by Eastern Health emphasizing that it may never know the exact cause of problems with a particular test on a particular day, or that it doesn't believe that anyone will be able to determine exactly what happened, have persisted and are not helpful. Eastern Health investigated the ER/PR testing problems as a multi-patient event, rather than conducting individual investigations into the cause of each flawed test result. From its global investigation, much information is known about the systemic deficiencies in the ER/PR testing and the causes of the inaccurate test results when considered collectively.

[150] Testimony of Heather Predham, 16 October 2008, pages 140, 169-171.

Most, if not all, of the systemic errors have been identified, and steps taken by Eastern Health to correct these errors. To emphasize that it may never know exactly what went wrong is not likely to instill confidence in the public and patients, who would expect that the causes of the flawed testing had been identified and corrected before testing resumed.

190. The primary reason why Eastern Health may not now know the cause of individual flawed results is that the external consultants or the physicians and technologists within Eastern Health were never asked to investigate the causes on an individual case basis. Given the number of patients involved, and considering that eventually all of the ER negative patients identified were retested, then the systems approach to the investigation of cause is likely sufficient for the purpose of correcting the problems in the laboratory.

191. Eastern Health's communications should reflect that its decision to proceed in this manner is the reason it cannot now identify the cause of flawed test results on a patient-by-patient basis. Furthermore, Eastern Health could no doubt identify for many individual patients that her flawed results were likely caused by one or more of a several problems now known to have existed in the lab between 1997 and 2005.

192. Eastern Health has identified and corrected many deficiencies in the lab over the past three years and will hopefully continue work to improve its policies and procedures. It

has done so based upon a tremendous amount of knowledge and expertise regarding deficiencies that existed before 2005. It has not identified the causes of individual flawed results because of its systems-based approach to the investigation. The communication of this message would be more patient-centred and more likely to restore confidence and demonstrate openness and transparency, instead of comments emphasizing that the organization may never know exactly what happened.

Communication with Families of Deceased Patients

193. Bryan Purcell testified that Ms. Purcell specimen was not re-tested at Mount Sinai in 2005, because they had already been re-tested back in 1999, and the final result was a positive result. He learned this upon calling the Cancer Clinic, to ascertain the status of re-testing for Ms. Purcell.[151]

194. Mr. Purcell was asked about his views about communication about the ER/PR issues, from his perspective, as the family member of a deceased patient: *"I think it's been terrible. I think it borders on negligent, although I'm not a lawyer. I think that what I have seen in public, because I didn't get any communication otherwise, what I have seen in public leaves the impression that there's an attempt to minimize. There's an attempt to, I won't use the word "cover up" but to prevent the information from coming out fully and*

[151] Testimony of Bryan Purcell, 24 March 2008, pages 169-170.

openly."[152]

195. Ken McDonald's wife, Christine McDonald, was diagnosed with metastatic breast cancer in the summer of 1997 and died in January 2000. When Mr. McDonald heard in the media reports about inaccurate test results pertaining to breast cancer patients he contacted the phone number published in the Telegram newspaper for inquiries about this topic. He spoke with Nancy Parsons, who confirmed that Ms. McDonald was originally tested negative. Ms. Parsons advised that her specimen would be put on the list for retesting, but the specimens for living patients would be re-tested first, which Mr. McDonald understood.[153]

196. Mr. McDonald called two or three times after, to check if Ms. McDonald's test results were back. He ultimately learned from a press conference, probably the one held on 11 December 2006, that all of the retesting was done.[154] He was left with the impression that the specimens for deceased patients would not be re-tested.[155]

197. Mr. McDonald learned, during an interview with Commission Counsel on 12 March

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[152] Testimony of Bryan Purcell, 24 March 2008, page 172, line 18, to page 173, line 1.

[153] Testimony of Ken McDonald, 24 March 2008, page 190.

[154] Testimony of Ken McDonald, 24 March 2008, page 191.

[155] Testimony of Ken McDonald, 24 March 2008, page 192, lines 22-25.

2008, that Eastern Health announced in February 2008 in a press conference that the specimens of deceased patients had in fact been retested. He also learned in the interview that Ms. McDonald's retest results had actually been entered as an addendum to her pathology report on 30 November 2007 and signed out by a pathologist on 03 December 2007.[156]

198. Notwithstanding Mr. McDonald's requests in 2005 and 2006 that he be informed of his wife's retest results, Eastern Health did not initiate contact with him after November 2007 when the results were received. He only officially learned of the re-test results from Eastern Health when he called them in March 2008.[157]

199. Mr. McDonald was understandably disappointed with Eastern Health's lack of follow-up with him:

> *"Well, for my own situation, I guess, they've handled it somewhat poorly to some extent. I mean, you phone, being, as you said, a layperson when it comes to medical terminology, basically I was just looking for information when I called first about the ER/PR testing and retesting and as a family member of a patient, I had to go looking for that and I had to continue looking for it until finally I stopped looking and until I met with yourself and co-counsel, but nobody has sent any*

[156] C-0085, Final Surgical Pathology Report of Christine Mary McDonald dated August 5, 1997 and Testimony of Ken McDonald, 24 March 2008, pages 196-197.

[157] Testimony of Ken McDonald, 24 March 2008, pages 211-213.

notification, nothing. There's been no contact whatsoever to myself as a family member."[158]

Direct Communication with Family Members of Deceased Patients Appropriate

200. Mr. McDonald's unfortunate experience also demonstrates that a general press release, as a sole method of communication, is not an effective means of advising relatives of deceased patients that re-test results are available.

201. It is recommended that Eastern Health directly communicate with the next-of-kin of deceased breast cancer patients involved in the re-testing to advise that they have the option to obtain their loved one's re-test results. It may very well be that some next-of-kin may choose not to obtain the results or perhaps wait until a later date to do so. A general press release as a sole method of communication, however, is not the most reliable means of ensuring that family members, or patients for that matter, are advised of important medical issues.

Value of an Apology to Patients and Families

202. Ms. Henley-Andrews has expressed anger that she first learned, from a 15 February 2008 interview with Commission Counsel, that her specimen had indeed been re-tested in November 2005 at Mount Sinai and the results of the retesting then entered into her

[158] Testimony of Ken McDonald, 24 March 2008, page 227, lines 4-17.

patient file. Ms. Henley-Andrews first contacted Eastern Health in the fall of 2005, to ascertain her own test results, but learned that her tissue sample had not been sent to Mount Sinai for testing because her diagnosis was DCIS. She asked to have the specimen re-tested anyway and understood that it would be done for her. When hearing that all of the re-test results were back from Mount Sinai she contacted Eastern Health for her results but was told that her specimen had not in fact been retested. Ms Henley-Andrews stated: *"And I was disappointed obviously, but I mean, I also knew that I had been asking a favour when I'd asked to have it sent in the first place, and so I kind of thought that was the end of it."*[159]

203. Regarding the value of an apology from Eastern Health, Ms. Henley-Andrews stated:

> *"... when Louise Jones spoke last week in answer to the question 'well, you know, what does it mean for me to apologize, and there'll be further evidence coming'. I thought a lot about that, and I think it means a lot for her to apologize on behalf of Eastern Health to those patients who now have new information with respect to their cancers that they didn't have before. When I go to a wake, I always say to the people who are there that I'm sorry. It doesn't mean that I killed their loved one or that I somehow contributed to the death of their loved one. It means that I'm very sorry that it has happened to them, and I think Eastern Health can be very sorry that it has – that these things have happened to all of these women without*

[159] Testimony of Janey Henley-Andrews, 25 March 2008, page 251, line 22, to page 252, line 4.

admitting liability, and I think it means a lot, and I don't accept the explanation."[160]

204. Marie-France Teletchea also spoke of an apology that she had received, in the form of a letter from Louise Jones, CEO of Eastern Health, in French, which she received in about July 2008. Madame Teletchea said she was aware that Canadian patients had received a similar letter a year ago and felt that in her case it was a bit late for such an apology letter. She acknowledged that Dr. Farrell was the only other person that showed regret for her not being informed earlier.[161]

205. Bryan Purcell expressed disappointment about the absence of an apology:

"Eastern Health itself, again, as a layman, looking at this from the outside, I have been very disappointed with their reaction up to and including, if I may say it, on Thursday when the acting head of Eastern Health was interviewed by the press. She was asked several times if she would like to apologize, even for the incident that was raised here early in the week about charts allegedly being thrown at patients. She did not apologize. So yeah, I've been extremely disappointed, extremely surprised that an organization that large, with that level of responsibility, dealing with that level of complexity in the mandate that it has, would not be

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[160] Testimony of Janet Henley-Andrews, 25 March 2008, page 272, lines 4-23.

[161] Testimony of Madame Teletchea, 01 August 2008, pages 76 -78.

more open and responsible and accountable."[162]

206. Elizabeth Finlayson's specimen was only retested in April 2008, following inquiries from Ms. Finlayson and her daughter Jane Hopkins. She then learned that her original ER/PR results of ER negative and PR 40-50 had changed upon re-testing at Mount Sinai to ER 30% and PR 60%. Ms. Finlayson had a recurrence of breast cancer in 2006, and was placed upon Femara at that time. Prior to that, she was never offered Tamoxifen or other hormonal therapy, even though her PR results show some positivity.

207. Ms. Finlayson's initial inquiry about her ER/PR test results was made on her behalf by her daughter who called Nancy Parsons March 27, 2008.[163] The re-testing at Mount Sinai was completed and Dr. Denic, pathologist, signed an addendum on 15 April 2008 with the Mount Sinai test results. Ms. Hopkins called Nancy Parsons in late April to ascertain the re-test results but was told that while the re-test results were back and Ms. Finlayson's case would have to be paneled.[164]

208. The panel met and a letter with the panel's recommendations was prepared, dated 09

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[162] Testimony of Bryan Purcell, 24 March 2008, page 173, lines 7-23.

[163] Testimony of Jane Hopkins, 31 October 2008, page 184, line 21, to page 185, line 5.

[164] Testimony of Jane Hopkins, 31 October 2008, page 195, line 4-8.

June 2008.[165] Dr. Zulfiqar, the recipient of the panel letter, then called Ms. Finlayson on 02 July 2008 to advise that he had received a report of the panel. She couldn't understand everything he said on the phone so it was agreed that they would discuss it further at a clinic visit scheduled for 14 August 2008. In the meantime, Ms. Finlayson had already picked up a copy of her letter from her family doctor in June 2008. Ms. Hopkins explained that when reading the letter she couldn't understand why the panel concluded there was no recommendation for a change in treatment because her mother had not been on any hormone treatment from the time of diagnosis, until the recurrence in 2006.[166]

209. Notwithstanding the change of her results and the fact that she was not identified for re-testing until she self-identified in 2008, Eastern Health apparently determined that in her case no apology letter was to be sent.[167]

210. The CPSI Disclosure Guidelines emphasizes the value of an early apology, and subsequent expressions of regret, by the health care provider:

"When patients feel they have received a sincere statement saying sorry, they feel

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[165] C-306: Letter dated June 9, 2008 from Dr. Kara Laing to Dr. M. Zulifiqar regarding Elizabeth Finlayson.

[166] Testimony of Jane Hopkins, dated 31 October 2008, page 209, line 20, to page 210, line 2.

[167] C-307: Notes of meeting dated June 20 and July 3, 2008 held with Pat Pilgrim, Nancy Parsons, Janet Laidley and Heather Predham.

respected, cared for, validated and their trust is often restored...

...In principle, apology as part of disclosure of an adverse event (for example related to a system failure or provider performance) is consistent with patient-centered care, honesty and transparency, and intuitively is the right thing to do."[168]

Disclosure Before Impact Upon Individual Patients Is Known

211. By late July 2005, it ought to have been apparent to the physicians, technologists and management of Eastern Health that the ER/PR test results for patients who had originally tested negative were now considered unreliable and it was reasonable to anticipate that many of the patient's results from 2005 and earlier would convert upon retesting

212. It is the unreliability of the ER/PR negative tests results, and the need for re-testing, which ought to have been promptly disclosed to patients. For any given patient there was a fairly significant chance that her ER/PR results would change upon re-testing.

213. The guiding principles of patient autonomy and patient-centred healthcare should inform such a decision about timing of disclosure.

[168] P-0161: Canadian Disclosure Guidelines by the Canadian Patient Safety Institute 2008, at page 23.

214. The CPSI discussion about disclosure of close calls demonstrates that disclosure need not be limited to situations where a patient is actually known to have been harmed but includes situations that the patient possibly has been or will be harmed:

> *"In deciding whether to communicate to the patient regarding a close call, providers should consider whether an ongoing safety issue exists for the patient or whether the patient is aware of the event....*
>
> *...In addition, if a patient is aware of a close call, an explanation may alleviate concerns and maintain trust. Where an event reached the patient but does not result in harm, healthcare providers and organizations should consider whether a reasonable person would want to know about the event under the given circumstances."* [169]

Public Right to Know

215. Ms. Rogers spoke of the need for the public to be informed of the issues pertaining to the ER/PR test problems:

> *"... we need transparency and accountability, that we need to be treated with respect. And I was amazed at the insistence of Eastern Health to try and suppress the information about Dr. Banerjee's and Trish Wegrynowski's reports, when I just thought let's get all the information out and let's make it better for everyone and move on, because there's reconciliation that has to happen, there's healing that*

[169] P-0161:Canadian Disclosure Guidelines by the Canadian Patient Safety Institute 2008, at page 18.

has to happen and the public has to have their faith or their trust and confidence restored in the health care system."[170]

216. Premier Williams also emphasized the public right to know about matters of this nature:

"So this becomes a question of public confidence in the system. I don't think this had a dramatic affect on any individual patient because people who weren't retested and the error rate wasn't disclosed; however, again, it's the patients' and people affected rights to know what the magnitude of the problem is and also if there appears to be any kind of a concealment and I'm not saying that the Department concealed this because I don't think they did, Eastern Health chose not to give this information for their own reasons, which I think and I understand were for legal reasons. But it's a question of public confidence and confidence in the health care system and it's these kind of things that erode that confidence and these are the reasons why on a daily basis I have to respond to the term 'crisis'."[171]

Patient Navigator

217. Throughout the inquiry, concerns were expressed about many aspects of communications. The receipt of accurate, understandable and timely information was particularly troublesome for patients and family members.

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[170] Testimony of Geri Rogers, 25 March 2008, page 200, lines 2-21.

[171] Testimony of Danny Williams, 28 October 2008, page 207, line 10, to page 208, line 4.

218. In light of this, the presence of patient navigators, with the appropriate authority to access and discuss with a patient any information that he or she needed, would have been beneficial.

219. As explained by Peter Dawe, the need for patient navigation has evolved over the past ten years or more, out of the growing complexity of the health care system:

> *"One of the beliefs that we had is that a patient navigation system is ideal for Newfoundland and Labrador and we presented this idea. We've talked about this with Eastern Health and with the provincial government. But in this particular case, with Eastern Health and with when these mistakes were made and when a group of people were affected, you could quite quickly see how the patient navigation concept would get to the heart of the matter for the people involved in giving them a particular person of contact who would help them navigate through, in this case, what could be an even, and what turned out to be an even more complex and complicated health delivery system because of the retesting, because of new treatment for many people and because of the need for new information."*[172]

220. Dr. Brufsky also described the role of the patient navigators at the Magee Women's Hospital. There are currently three patient navigators, who assist the medical oncologists

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[172] Testimony of Peter Dawe, 04 September 2008, page 360, line 17, to page 363, line 10.

in communications with patients, and in a sense, they act as advocates for the patients throughout the system:

> *"We've taken the social workers away and called them patient navigators now, but they attend the meetings and they're very helpful in kind of helping us figure out how things should be communicated to patients. Breast cancer is a very emotional disease, you know. The issues surrounding it are very emotional. And they're very useful because they're very in tune, from the support groups, for what the issues really are, at least in how things are communicated to women."*[173]

Value of Criticism and Dissent

221. The demand by patients and the public for openness, transparency and accountability came to a head in May 2007 when more information about the magnitude of the ER/PR testing errors became public in a media report.

222. Eastern Heath should have anticipated long before this date that the information released by the organization was not sufficient to meet the expectations of the patients and public. The organization persisted, however, in releasing scant information about the cause and size of the ER/PR testing problems. It did not explore the downside of being circumspect with its disclosure, nor did it heed the calls for more information from individuals such as Peter Dawe, Ches Crosbie and Geri Rogers. Eastern Health even

[173] Testimony of Dr. Brufsky, 06 October 2008, page 210, line 13 to 24.

dismissed as "alarmist" some reactions within its own organization, as it did with Dr. Carter. It would have been more prudent and patient-centred at the time if Eastern Health acknowledged that this was indeed an alarming event, and to openly treat it as such, rather than trying to downplay the consequences of the ER/PR testing errors.

223. It would be beneficial for Eastern Health, when faced with such an issue again, to be receptive of and actively seek out contrary opinions and expertise, both internal and external to the organization, including from patient advocacy groups or other individuals who have some knowledge of patient and public concerns. It is through the thoughtful consideration of such dissenting views that it can learn about the pitfalls of it's own action plan, and perhaps choose a different course of action, or at least guard against obstacles or missteps and develop a contingency plan to cope with any setbacks that may be encountered.

Comments

224. It is recommended that Eastern Health and the other regional health authorities implement policies that promote timely and effective communication with patients, in the event of an individual or multi-patient adverse event or occurrence.

225. It is recommended that the policies include redundancy, such as a combination of letters, face-to-face meetings, telephone calls and public announcements, where

appropriate, to ensure that the effectiveness of the communication. There should be a follow-up system, such as follow-up telephone call to the patient or family member to ensure that the letter was received and understood. The communication should include available written resource information, such as a pamphlet, pertaining to the diagnosis or treatment in question. There should be an opportunity for follow-up, to allow the initial information to be absorbed and to discuss any questions or concerns that may arise subsequently.

226. The Canadian Disclosure Guidelines produced by the Canadian Patient Safety Institute would be a valuable guide to the regional health authorities in the development of their policies and should be adopted as a minimum standard.

227. The hiring of patient navigators, whose primary responsibility is to communicate with and on behalf of the patient, is advisable. Upon consent of the patient, such individuals should be given full access to the patient's medical information and be given authority to disclose such information to the patient. Patient navigators should be considered as an advocate for the patient, and have sufficient flexibility and authority within the organization to respond to the patient's needs.

228. A statement of rights for patients should be developed, with input from patients, families, patient advocacy and support groups, the Regional Health Authorities, other healthcare

providers, and professional organizations such as the Newfoundland and Labrador Medical Association ("NLMA"). Once established, the statement of rights should be made readily available through the websites and pamphlets of health care providers and patient advocacy and support groups. This should create a common understanding of a person's rights when engaged with the health care system. It should address the related issue of the public's right to transparency and accountability within the health care system.

Hormone Positive Test Results & Retro-Conversions

229. The re-testing program which evolved during the summer of 2005 primarily included ER negative patients.

230. The 24 May 2005 letter from Dr. Cook to Dr. Williams, with reference "*False Negative Results for Estrogen and Progesterone Receptor (ER & PR)*", identifies the problem which led to the re-testing:

> *"On May 11, 2005, I received a phone call from Dr. Joy McCarthy, a Medical Oncologist, informing me of an ER & PR reported negative in a patient with infiltrating lobular carcinoma of the breast diagnosed in 2002. When retested in May, 2005, the ER & PR were reported as strongly positive. Dr. McCarthy also expressed concern over what appears to be a high rate of infiltrating lobular carcinomas that were reported as ER & PR negative. She stated that usually 95% of lobular carcinomas are ER & PR positive, while 5% are negative. Dr. McCarthy requested that two other patients with infiltrating lobular carcinoma who were reported as ER & PR negative in 2002 also be retested."*[174]

Dr. Carter's Preliminary Review to Include ER Positives

231. Dr. Carter, Eastern Health's resource person for breast pathology, was invited to attend a meeting on 17 May 2005 with Dr. Cook, Dr. Laing, Dr. McCarthy and Barry Dyer,

[174] P-0067: Letter dated May 24, 2005 to Robert Williams from Dr. Donald Cook regarding False Negative Results for ER and PR.

Manager, Anatomic Pathology. She subsequently agreed to assist with an investigation of ER reports, initially focusing on reports generated between 1997 and 2004.[175]

232. Dr. Carter proposed that a preliminary review would include both ER negative and ER positive patients with priority given to ER negative patients. In Dr. Carter's 14 July 2005 letter to Dr. Cook, she proposed:

> *"As quickly as possible, I would like to know the estrogen receptor status of every patient tested in our laboratory between 1997 and 2004. From that information, I would also like an estimate of the total of positive patients given out per year. I would need all of the reports pulled from the computer for review. Patient demographics, including name, age, and MCP number, should be collated along with their surgical number, their histologic type of carcinoma and the histologic grade. All of the slides from the cases including the estrogen receptor slides need to be pulled and organized. All slides then need to be reviewed by me, both estrogen receptor negative and estrogen receptor positive patients. Estrogen receptor negative patients should be given priority. Blocks will be pulled from those cases and estrogen receptor/progesterone receptor status reordered. This test should be carried out as quickly as possible. 10% of cases*

[175] P-0069: Letter dated July 14, 2005 to Dr. Donald Cook from Dr. Beverley Carter on estrogen receptor status reports 1997 to 2003.

should be randomly selected for outside quality assurance consultation."[176]

233. Dr. Carter testified on 31 July 2008 that while the initial proposal contemplated looking at ER positive results, the focus was not on any possible concerns with ER positive results at that point. Dr. Carter further testified, however, that had she been asked at the time she would not have been able to give assurances that there was no possibility of problems with false positives either on the Ventana equipment or before.[177]

234. Shortly after this letter Dr. Carter resigned her role in the investigation.[178] On 08 August 2005, Dr. Carter wrote to Dr. Cook providing him with figures compiled with respect to Estrogen Receptor and Estrogen Receptor testing for cases seen at HCCSJ in 2002[179]. With regard to the preliminary numbers, Dr. Carter stated:

> "*From these very preliminary and very raw numbers I believe that the idea that the DAKO system - both it's performance and interpretation - greatly underestimated the number of women who would benefit from Hormonal manipulation of their breast cancer and should be investigated. From these*

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[176] P-0067: Letter dated May 24, 2005 to Robert Williams from Dr. Donald Cook regarding False Negative Results for ER and PR, at page 1.

[177] Testimony of Dr. Beverly Carter, 31 July 2008 at 65-69.

[178] P-0079: Letter dated August 2, 2005 to Dr. Donald M. Cook from Dr. Beverley A. Carter regarding withdrawal of role in the investigation of ER/PR testing

[179] P-0081: Letter dated August 8, 2005 to Dr. R. Williams and Dr. D. Cook from Dr. Beverley Carter regarding figures for ER/PR testing for 2002.

numbers it would also appear that the Ventana system is overestimating the number of patients who are ER positive. Couple this finding with the recent 60% disagreement with Mount Sinai Hospital; on crude progesterone status (positive vs. negative and not percentile staining) and it appears that we have another system that needs investigating".[180]

235. The Ventana equipment was checked by a Ventana representative and found to be in acceptable working order as of the date of her review.[181] However, there has been no formal targeted review of the specimens that caused Dr. Carter to question whether ER positive results were being overestimated.

236. When Eastern Health embarked upon its retesting program for ER negative test results more false positives (or retro-conversions as they were called by Eastern Health) were revealed. However, notwithstanding additional instances of false positives or retro-conversions, there was still no comprehensive review by Eastern Health, either internally or by the external reviewers who visited the laboratory, to determine why all of these retro-conversions had occurred.

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[180] P-0081: Letter dated August 8, 2005 to Dr. R. Williams and Dr. D. Cook from Dr. Beverley Carter regarding figures for ER/PR testing for 2002 at 1.

[181] P-0552: Letter dated August 5, 2005 from Carole Quevillon to Terry Gulliver regarding Ventana Benchmark instruments.

Eastern Health Says False Positives Rare According to Literature/Experts

237. Eastern Health, in deciding against retesting or otherwise investigating the ER positive test results, has relied on statements in the literature and by experts that false positives ought to be rare.

238. Dr. Denic testified that according to the literature, the occurrence of false positives is not considered a common problem. He also testified that all of the four false positive slides that he reviewed were due to overcalling of background staining. When questioned if such overcalling of a slide staining could have occurred but in other ER/PR positive test slides, he replied:

> *"Well, you cannot be absolutely sure about anything, as such, that happened. You know, these are some of the pitfalls in testing and interpreting that it's recognized, you know. But the literature states, really, that this is not a common problem. This is not a problem, as you can see, with the false negatives you know. So could we find one or two more, we may or we may not, you know, so I cannot state with any degree of certainty what are there."*[182]

239. Dr. Mullen was not asked to review any potential problems with ER/PR positive.[183] He stated that as a concept, you would be unlikely to get a false positive *"if you have a*

[182] Testimony of Dr. Denic 15 September 2008, page 13, lines 14-24.

[183] Testimony of Dr Mullen 27 June 2008, page 315, lines 7-13.

properly validated antibody".[184]

Eastern Health Identified Four "Official" Retro-Converters

240. In deciding whether the incidence of known retro-conversions was acceptable, Eastern Health inexplicably focused only on those few retro-conversions for which the patient is still alive and required a change of treatment.

241. Early on in the investigation of the ER negative test results Heather Predham summarized her understanding of the issue of false positives. She did so in an email dated 26 October 2006, to Dr. Howell, Dr. Denic, Terry Gulliver, Pam Elliott, Pat Pilgrim, Susan Bonnell, Sharon Smith and Dr. Laing:

> *"(name redacted) was diagnosed with breast cancer in 1999. Her original ER/PR was 30% and 40%. Upon retesting her ER/PR was 0/0. This was rechecked twice by Mount Sinai and still no staining was revealed. The original slides were assessed by pathology and it was found that the original interpretation was accurate. She was one of four patients that we classified as "retro converters". In other words she original stained positive but now was coming back negative, the opposite of our concern.*
>
> *She had been treated with Tamoxifen from 1999 until 2004. This was switched to Femara for extended adjuvant therapy. The Femara was discontinued in*

[184] Testimony of Dr. Mullen, 27 June 2008, page 156, line 19 to page 157, line 4.

October 2005 because of side effects." [185]

242. In a subsequent email dated 16 November 2006 to Dr. Denic, Ms. Predham identified the twelve confirmed positives and four retro-converters. The confirmed positive cases were described as: *"These patients' original test results were considered to be positive by the treating clinician and treated appropriately. There was a slight change in the patient's ER/PR status but review by the panel confirmed the ER/PR status as still being positive. No action other than notification is required."* [186]

243. Almost two years later, when testifying at the inquiry, Chief Operating Officer, Patricia Pilgrim, on 02 October 2008, maintained that there are only four official retro-converters: "*Well, what I can tell you is there are four official retroconverters in the database and all of those patients have been reviewed. I know that much."*[187]

244. Ms. Pilgrim referred to these four official retro-converters as the "*bona fide retroconverter group*".[188] Ms. Pilgrim further stated: "*I can only tell you that if you*

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[185] P-1402: Email dated October 26, 2006 (11:47 AM) from Denise Dunn to Michelle Gregory regarding FW Another Issue with ER/PR, at page 2.

[186] P-2662: Email dated November 16, 2006 (10:57 AM) from Heather Predham to Nebojsa Denic regarding ER/PR Numbers, at page 2.

[187] Testimony of Patricia Pilgrim, 02 October 2008, at page 346, lines 5-8.

[188] Testimony of Patricia Pilgrim, 02 October 2008, page 351, line 9.

went into the database now, there would be four confirmed retroconverters alive, living."[189] Ms. Pilgrim was aware from early on that there could be retro-conversions for deceased patients. Indeed, Ms. Pilgrim referred to one such case in August 2006. In an email to Sharon Smith and Heather Predham dated 07 August 2006, Ms. Pilgrim discussed the notification of retro converters and said, *"We know that there are 4 cases who are living and have not been notified and a case who is deceased whose husband has been calling requesting information*."[190]

245. For whatever reason, when tallying the number of retro-conversions that were incidentally revealed during its re-testing program, Eastern Health also excluded living patients for whom there was no change of treatment recommended. Ms. Predham confirmed this in her testimony and confirmed that the total number of retro-convertors would be much higher than four. She agreed it would not be appropriate to consider only the 4 or 5 retro-conversions in assessing whether their false positive rate was acceptable, nor should this assessment be limited those retro-conversions resulting in a treatment change.[191]

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[189] Testimony of Patricia Pilgrim, 02 October 2008, page 339, p. 23 to 340, p. 1.

[190] P-010:, E-mail dated August 8, 2006 from Heather Predham to Patricia Pilgrim and Sharon Smith regarding ER/PR Review Process at p. 2.

[191] Testimony of Heather Predham, 22 October 2008, page 83, line 17 to page 86, line 4.

Decision Against Retesting Not Based Upon Known Retro-Conversions

246. Eastern Health officials who decided not to re-test or otherwise investigate the positive results did so without counting and reviewing the total number of retro-conversions detected incidentally through its re-testing of the ER negative test results.

247. Dr. Laing, when explaining why Eastern Health opted not to retest all the positives: "*And because there was such a low number and because it had been in the people with very weak staining, we never felt that there was a signal or indication strong enough that would warrant a review of all of the hormone receptor positive tests done over that time period.*" Dr. Laing also noted that the pathologists involved in the ER/PR matter looked at the slides for the retro-conversions and determined that they wouldn't have called the slides positive, as the staining was more background staining.[192]

248. However, the key personnel decision makers were seemingly unaware of the total number of retro-conversions that had in fact been detected.

249. Patricia Pilgrim, when asked if an up-to-date list of all retro-converters existed, said "*you can go into the NLCHI database and do a search for the retro-convertors*".[193] Ms. Pilgrim thought that Dr. Denic might have done so, in order to review the original

[192] Testimony of Dr. Laing, 10 September 2008, page 53, line 13, to page 55, line 1.

[193] Testimony of Patricia Pilgrim, 02 October 2008, page 322, line 24-25.

slides. However, Dr. Denic only reviewed the slides of four retro-converters.[194]

250. Terry Gulliver did not know how many retro-converters had been found and thought it would be fewer than ten. Neither he, nor Barry Dyer to his knowledge, compiled such a list. He thought Dr. Denic would be the best one to answer, or otherwise he guessed Heather Predham might know if such a list was prepared and by whom. Mr. Gulliver did not prepare such a list as he felt it was a clinical issue.[195]

251. While Ms. Predham has acknowledged during her testimony at the inquiry that the number of retro-convertors would be some figure greater than four, she had no idea what the actual number would be. She thought that Wayne Miller, Patricia Pilgrim, Dr. Denic and Mr. Gulliver were involved in an analysis of this issue but had no idea how this was progressing, as she was not involved.[196]

Forty-Four Retro-Conversions According to NLCHI Data

252. A request was submitted by the Cancer Society to NLCHI for the redacted re-test results for which the original ER or the original PR was positive or weakly positive or was greater than or equal to 10 AND the Mount Sinai ER and PR were both less than

[194] Testimony of Patricia Pilgrim, 02 October 2008, page 324, line 24; Testimony of Dr. Denic, 15 September 2008, page 8, line 20-21 and page 13, line 2-7.

[195] Testimony of Terry Gulliver, 15 October 2008, page 93, line 1 to page 95, line 23.

[196] Testimony of Heather Predham, 22 October 2008, page 357, line 6, to page 359, line 9.

10. In response to this request NLCHI provided a spreadsheet with forty-four entries[197]. From a laboratory perspective, it is submitted that these forty-four sets of retest results would more accurately reflect the actual incidence of false positives or retro-conversions incidentally detected to date.

253. It would be more appropriate for Eastern Health to consider all forty-four of these cases when assessing the potential for false positives. Eastern Health should start with an investigation of these forty-four "technical" retro-conversions to ascertain the root cause the inaccurate results.

254. In addition to the forty-four cases in the NLCHI spreadsheet, there are other re-test results of concern in which the original relative high ER and/or PR test result changed to somewhat lower one upon re-testing. The information in the following table is extracted from the data compiled for Mark Quinn in response to an ATIPP request[198]:

[197] P-3712: Centre for Health Information Communications Events Database (as of October 31, 2008) Retests Results for which Original ER or Original PR is Positive or Weakly Positive or is Greater than or Equal to 10 and Mount Sinai ER and PR are both less than 10.

[198] P-0720: Email dated August 8, 2007 (11:40 AM) from Marian Crowley to Louise Jones regarding Data and letter.

	Original ER	Original PR	Mount Sinai ER	Mount Sinai PR
55	<30	<40	10	5
243	5	40	0	10
254 (2 of 2)	neg	50-60	10	0
268	5 to 10	5 to 10	0	0
394 (2 of 2)	neg	50-60	10	<1
404	5 to 10	5 to 10	0	0
411	neg	5 to 10	0	0
750 (2 of 2)	20-30	neg	10	0

255. Whether these cases are considered individually, or as part of a multi-patient event, further investigation is warranted. On an individual basis, the foregoing eight results and the forty-four entries in the NLCHI spreadsheet appear, at the very least, to fit the definition of a near miss, which is defined in Eastern Health's Occurrence Reporting policy as *"An event or circumstance which has the potential to cause serious physical or psychological injury, unexpected death, or significant property damage, but did not actualize due to chance, corrective action, and/or timely intervention*." [199]

256. Ms. Predham believes the ER/PR problem would be considered collectively as one critical occurrence or sentinel event, although each patient case itself would also be

[199] P-0057: Eastern Health Policies dated 2007 at page 10.

considered an adverse event. [200]

257. A sentinel event is defined as *"an unexpected incident, related to system or process deficiencies, which leads to death or major and enduring loss of function for a recipient of health care services."*[201] An adverse event is defined in one of three ways: *"(1) An unexpected and undesired incident directly associated with the care or services provided to the patient; (2) An incident that occurs during the process of providing health care and results in patient injury or death; (3) An adverse outcome for a patient, including an injury or complication."*[202]

258. Whether the retro-conversions are considered individually or collectively as occurrences or adverse events or sentinel events, further investigation is warranted.

259. At a minimum, the retro-conversions should be considered to be occurrences. The occurrence reporting process is a key component of Eastern Health's Quality and Risk Management Framework in pursuit of improved patient/client/resident safety.[203] Investigation of occurrences *"provides opportunities to improve the safety of services*

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[200] Testimony of Heather Predham 20 October 2008, page 283-284.

[201] P-0057: Eastern Health Policies dated 2007 at page 10.

[202] P-0057: Eastern Health Policies dated 2007 at page 9.

[203] P-0057: Eastern Health Policies dated 2007 at page 5.

delivered". [204] The occurrence reporting policy states, "*Investigating errors requires evaluating all systemic factors that may have contributed to errors instead of focusing on individuals to blame.*"[205]

260. There is nothing to indicate that Eastern Health has made any effort to identify the systemic factors, or other factors, that contributed to the above-noted retro-conversions. Without further investigation of the retro-conversions, the goal of the Occurrence Reporting policy has arguably not been achieved.

Further Investigation of ER Positive Results

261. At the very least, Eastern Health should investigate the root cause of the forty-four retro-conversions, as well as the eight cases for which significantly lower ER/PR results were obtained upon re-testing. In doing so, it would be beneficial for Eastern Health to seek external expertise.

262. Subsequently, a decision about the re-testing or investigation of the remaining ER positive results would be best informed by the results of the review of all the existing retro-conversion cases. This decision would also benefit from outside consultation, particularly since the actual rate of false positives arguably exceeds what was expected

[204] P-0057: Eastern Health Policies dated 2007 at page 6.

[205] P-0057: Eastern Health Policies dated 2007 at page 6.

according to the literature and the experts.

263. It may very well be that something in between an "all-or-nothing" approach would be warranted, with respect to review of the hormone positive test results. For example, if most or all of the forty-four retro-conversions were due to an over-interpretation of background staining then a further slide review of the remaining ER positive test results might be an appropriate response.

264. Dr. Denic confirmed that the four retro-converter cases that he reviewed were attributable to a mistaken interpretation of cytoplasmic staining, and some background staining, for nucleii staining.[206] Dr. Denic agreed that a slide review to verify the interpretation could, if necessary, be conducted of the 1500 ER positive and 1500 PR positive test results. This could be done by identifying and locating the original slides to determine whether there was nuclei staining which was not attributable to background staining.[207]

265. Dr. Denic testified that for a slide review, it would take about ten minutes on average to per slide. Some may take a minute or two, if you have a bright, pre-stained slide. Others may take 15 or 20 minutes and may require a review by a second pathologist.

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[206] Testimony of Dr. Denic, 15 September 2008, page 94, line 19, to page 95, line 2.

[207] Testimony of Dr. Denic, 15 September 2008, page 97, lines 1-19.

There may also be a limit per day on the total that can be comfortably be read by a pathologist.[208]

266. Alternatively, or perhaps additionally, a review of a larger random sampling of ER positive test results might be warranted, to determine how best to respond to any lingering concerns about the remaining ER positive test results. This would be in keeping with Dr. Carter's original suggestion that a percentage of cases be randomly selected for outside quality assurance consultation.

267. Ultimately, the decision by Eastern Health whether full re-testing of hormone positive tests results is required or some alternative form of review should be based upon all of the available data including known incidence of retro-conversion in the laboratory, and with the assistance of external consultants who are apprised of all of this data.

Eastern Health Underestimating the Rate of Known False Positives

268. Dr. Denic testified that the rate of false positives is well within accepted limits: "*So if you look at these are four cases which were picked up from 1000 of patients, they needed to be taken off the Tamoxifen because they fell in a group of false positive, that's far below even a point five percent of the such*."[209]

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[208] Testimony of Dr. Denic, 15 September 2008, page 98, line 25 to page 100, line 6.

[209] Testimony of Dr. Denic, 15 September 2008, page 17, lines 4-9.

269. Heather Predham, in her 26 October 2006 email to Dr. Howell, Dr. Denic, Terry Gulliver, Pam Elliott, Pat Pilgrim, Susan Bonnell, Sharon Smith and Dr. Laing, when discussing the issue of false positives stated, "*I can only assume that Mr. Crosbie will now have another story. I anticipate that he will call for a total retest of all ER/PR results. We did discuss that at the panel level, but there is a documented false positive rate with this test and five out of 962 falls well within that range*."[210]

270. While Ms. Predham has acknowledged in her testimony that these numbers are not appropriate there is no indication that anyone at Eastern Health has attempted to ascertain the actual rate of false positives, based upon accurate and up-to-date data.

271. Since Eastern Health had not actually included all the retro-conversions when assessing its false positive rate, any conclusions drawn about the acceptability of the false positive rate are not well-founded.

Statistical Significance Of Retro-Conversion Data

272. Dr. Denic testified that he did a rough statistical analysis based upon the known retro-conversions, using 2700 tests as a denominator, 380 tests that had a negative ER, using 15 instead of four as the number, to get better statistics, and the remaining number are

[210] P-1402: Email dated October 26, 2006 (11:47 AM) from Denise Dunn to Michelle Gregory regarding FWAnother Issue with ER/PR, at p. 2.

the positives*:*

> *"And based on the test that we did, the statistical analysis positive predictive value which means what does it – how objective is the test to pick up positives. That number is 99 percent. So in 99 percent based of this rough analysis, I'm not saying that this is – you know, I think it should be done a different way, but this is my rough analysis of this. So in 99 percent we should be able to pick up positives."* [211]

273. However, the numbers required to do such a statistical analysis are much higher, according to the evidence of Dr. MacDonald: *"I can be comfortable with saying probably if we had 2000 positives, I'd be – anywhere from 300-400 would be required. ..... to have any confidence that you can infer the result of your sample back to the population."*[212]

274. Furthermore, a proper statistical analysis would have to be based upon a sample that was randomly selected.[213]

275. It is suggested that if a statistical analysis is to be included in any review by Eastern

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[211] Testimony of Dr. Denic, 15 September 2008, page 8, line 5 to page 9, line 13.

[212] Testimony of Dr. MacDonald, 24 October 2008, page 75, lines 3-6.

[213] Testimony of Dr. MacDonald, 24 Octoner 2008, page 75,,line 17, and page 76, line 6.

Health's into the possibility of retro-conversions, that expertise of NLCHI or another external statistician be engaged to verify the approach.

ER Positive Tests between 1997 and 2005 Lacking Quality Assurance and Quality Control

276. Any decision of Eastern Health whether to proceed with additional testing of the original ER positive test results ought to take into account the deficiencies in the quality control and quality assurance procedures for the ER/PR testing between 1997 and 2005.

277. Trish Wegrynowski, in her 09 November 2005 report entitled *"Quality Review of the Immunohistochemistry Laboratory Health Care Corporation of St. John's"*[214] outlined the need to evaluate the sensitivity and specificity of test results: *"Documented evaluation must be performed to ensure the sensitivity and specificity of the test results. Each component used in IHC staining must be optimized and validated individually to ensure the outcome and assist in troubleshooting. Presently this is not being done."*[215]

278. With regard to controls Ms. Wegrynowski noted that while positive tissue controls are placed on every patient tested slide, no negative controls are used. There was no daily assessment and documentation of the controls performed in the IHC Laboratory.

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[214] P-0047: External Review of Ms. Trish Wegrynowski dated November 9, 2005.

[215] P-0047: External Review of Ms. Trish Wegrynowski dated November 9, 2005. at p. 11.

Without assessing the controls, no troubleshooting of the procedure is occurring.[216]

279. During her testimony, Ms. Wegrynowski stated that negative controls are important for "*the sensitivity of your testing, you want to ensure that you are not getting any non-specific staining*."[217]

280. Regarding quality assurance generally, Ms. Wegrynowski was concerned that neither External Quality Assurance nor Inter-Laboratory comparison (excluding Mount Sinai Hospital Retrospective analysis) was performed. Documentation had not been provided about internal quality assurance for either the technical and professional components. These procedures are necessary to ensure the quality of the Laboratory's results. There should also be a mechanism to evaluate the interobserver variability amongst all the Pathologists interpretation of IHC staining.[218]

281. In answer to the question, "*Is the Ventana System too sensitive?*", Dr. Banerjee stated in his 17 October 2005 report "*External Quality Review of the Immunohistochemistry Service*": "*There is no evidence that the Ventana system creates false positive results.*

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[216] P-0047: External Review of Ms. Trish Wegrynowski dated November 9, 2005. at p. 15.

[217] Testimony of Trish Wegrynowski, 24 June 2008, at page 74.

[218] P-0047: External Review of Ms. Trish Wegrynowski dated November 9, 2005, at p. 17.

However, the system still requires optimisation to avoid non-sepcific staining." [219]

282. Dr. Banerjee then noted that inadequate or no attention is being paid by the reporting pathologists to the status of internal controls and there was inappropriate, exclusive reliance on external positive controls. In the event that poor fixation resulted in internal control failure of all available blocks the case should have been reported as uninterpretable due to failure or absence of internal controls.[220]

283. Dr. Banerjee stated that it is important to look for internal controls because this is the best indicator that the test actually worked. For any particular marker you're looking for there's bound to be some normal counterpart in that tissue that should be positive. It is also important to look for cells that should not be expressing their protein in normal cells. If they are positive then the specificity of the test is questionable. If there's excessive background staining then something could look positive, just because of non-specific staining. He has seen examples of this from many labs where they're not paying attention to that particular issue, resulting in a false positive test.[221]

284. Dr. Banerjee indicated that he did not have any particular concern about false positive

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[219] P-0046: Report of Dr. D. Banerjee dated October 17, 2005, at p. 4.

[220] P-0046: Report of Dr. D. Banerjee dated October 17, 2005, at pages 4-5.

[221] Testimony of Dr. Banerjee, 30 July 2008, page 48.

results, *"because if you see the staining in the cytoplasm, you disregard that in your assessment. It has to be nuclear stain."*[222]

285. Dr. Banerjee expected that pathologists would be aware that one shouldn't interpret non-specific cytoplasmic staining to be a positive test. The issue that would be more of a concern would be optimization of the technique. He didn't see such an example but if the nuclear staining intensity was the same as the cytoplasm then he would be concerned as it would be difficult to know if it was all non-specific staining. There was nothing of concern in the 20 slides as it pertains to false positive results. [223] However, there was no evidence that Dr. Banerjee, or any other external consultants experts, were asked to review the slides for the retro-convertors.

286. The pathologists who testified at the inquiry all indicated that they were aware that ER/PR was a nuclear stain.[224] Indeed, Dr. Khalifa's memo of 16 February 1998 to all Newfoundland pathologists indicated that *"each pathologist will be asked to report results of his or her own cases as indicated by the brown staining of nuclei of the invasive*

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[222] Testimony of Dr. Banerjee, 30 July 2008, page 288, line 8-10.

[223] Testimony of Dr. Banerjee, 30 July 2008, page 288, line 8 to page 290, line 14.

[224] Testimony of Dr. Neil, 10 July 2008, at page 159, line 22, to page 160, line 9; Dr. Morris Larkin, 07 October 2008, page 16-17; Dr. Baker, 05 September 2008, page 75; Dr. Dalton, 18 July 2008, page 165; Dr. Dankwa, 11 July 2008, at page 139; Dr. Gallagher, 25 July 2008, page 56-57; Dr. Parai, 25 July 2008, pages 265-267; Dr. Cook, 02 July 2008, page 154-156; Dr. Haegert, 04 September 2008, pages 10-11; Dr, Denic 11 September 2008, page 38; Dr. Fontaine, 17 July 2008, page 141-142; Dr. Elms, 02 September 2008, page 11.

neoplastic cells." [225]

287. Dr. Ejeckam later reiterated the role of nuclear staining in a memo of 02 May 2003 addressed to pathologists, in all hospitals in the province stating *"any positive nuclear ER immunostaining is considered to be a positive result and should be a definitive reason for instituting antiestrogen therapy for a patient",* and also stated that *"all cytoplasmic staining in ER and PR immunostain are to be considered negative."*[226]

288. By comparison, there was somewhat limited awareness about the role of internal controls. Several pathologists only became aware of the role of internal controls when Dr. Ejeckam circulated his memo in 2003, and even then internal controls were not necessarily considered to be of the same significance as external controls[227].

289. The concerns of Dr. Banerjee and Ms. Wegrynowski are consistent with Dr. Carter's early findings, outlined in her 14 July 2005 report. Dr. Carter found that in the slide review of the sixteen patients converting from estrogen receptor negative to estrogen

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[225] P-1850 Memo dated February 16, 1998 from Dr. Mahmoud Khalifia to All Newfoundland Pathologists regarding reporting of estrogen and progesterone receptor immunohistochemical results, page 2.

[226] P-0113 Dr. G. Ejeckam Memos dated April 4, 2003, May 2, 2003, and June 19, 2003 regarding Immunohistochemical Stains and September 23, 2003 Minutes of Surgical Pathology Review Committee, page 3.

[227] Testimony of Dr. Neil, 10 July 2008, at pages 92-93; Dr. Morris Larkin, 07 October 2008, page 18-19; Dr. Baker, 05 September 2008, pages 98-99; Dr. Dalton, 18 July 2008, page 234;Dr. Gallagher, 25 July 2008, page 81; Dr. Parai, 25 July 2008, pages 27-28; Dr. Haegert, 04 September 2008, pages 244; Dr. Elms, 02 September 2008, page 14.

receptor positive, there are clearly problems with the technique of estrogen receptor testing and the interpretation of same. She was unable to review paperwork from 1997-2003 with regards to protocols, quality practice, and controls.[228]

Other Possible Causes of False Positives

290. As indicated above, overcalling a slide due to background staining or cytoplasmic staining is one potential source of a false positive.

291. Dr. Denic testified that, in preparing for the inquiry, he did some research into potential problems from tissue reprocessing . The only issue he came across was in a 2007 article of Clive Taylor and Goldstein which says that while alcohol can be used as a fixative, it can cause a false positive result.[229]

292. Dr. Dabbs testified about the possibility of false positives results arising either from improper fixation followed by exposure to alcohol or false nuclear staining due to overantigen retrieval. He has not seen a false positive hormone receptor result, other than something that was fixed primarily in alcohol. If a tissue is improperly fixed in formalin, it would next be exposed to alcohol in the tissue processor. Therefore, if a

[228] P-0069: Letter dated July 14, 2005 to Dr. Donald Cook from Dr. Beverley Carter on estrogen receptor status reports 1997 to 2003, page 1.

[229] Testimony of Dr. Denic, 11 September 2008, page 71, line 18 to page 73, line 7.

specimen is getting very minimal exposure to formalin, it's theoretically possible to obtain a false positive result based on alcohol fixation. Another possible cause of a false positive would be from over antigen retrieval giving a simulated nuclear expression of something which happens to be biotin. This could possibly happen in using the ABC method but should be exceedingly rare.[230]

Eastern Health Concerned Re-testing All Positives Could Impact Laboratory Services

293. Dr. Denic explained if there are patients who would like to be re-tested, Eastern Health will do so. However, he believes that mass re-testing all 1500 positive results could bring other work in the laboratory to a halt as there are still hundreds of new patients that require test procedures.[231]

294. If it is determined that full-retesting of ER positive test results is necessary then it is recommended that resources be made available to the Laboratory Medicine Program to enable it to conduct such retesting without impeding existing operations. Such resources could be made available through Eastern Health's own budgetary sources, or with the assistance of the Department of Health if necessary. Robert Thompson has already indicated that if further re-testing of ER positives is deemed appropriate, the Department

[230] Testimony of Dr. Dabbs, 16 September 2008, page 59, lines 1-22.

[231] Testimony of Dr. Denic, 15 September 2008, page 17, line 19, to page 18, line 10.

would encourage and support that resources be made available.[232]

Comments

295. It is recommended that a further, scientifically-based investigation be conducted into the reasons for each of the retro-conversions found to date, regardless of whether the specimens are for patients who are deceased, or are for living patients for whom no treatment change was ultimately required. It should be decided based upon the results of this review what type of further action is required with respect to the ER positive test results which have not been re-tested to date.

296. It is recommended that Eastern Health engage external reviewers to assist with the investigation and decision as to further action required for the remaining hormone positive test results, since false positives were expected to be rare. Eastern Health's own experience has arguably defied this expectation.

297. If a full-scale re-testing is ultimately determined to be warranted then additional resources should be made available to the Laboratory Medicine Program, by Eastern Health or with the assistance of the Department of Health.

[232] Testimony of Robert Thompson, 24 October 2008, at pages 253-255.

Conclusion and Recommendations

298. Eastern Health has made many great strides since the ER/PR problem came to light in the spring of 2005. Eastern Health obtained external professional and technical reviews of the Laboratory Medicine Program and overtime responded to these recommendations. It designated a director for the IHC Lab and provided additional training for the technologists and a pathologist. A breast disease site group was established, although subsequently suspended due to loss of breast specialists. Testing for ER/PR and Her2Neu was sent to an outside laboratory, before ER/PR testing re-established at Eastern Health, and again when the breast disease site group was suspended. It enrolled in external proficiency programs. It has started to develop policies and procedures for the IHC division of the pathology laboratory. It has established a quality management program, involving a pathologist, senior pathology technologists and secretarial support. A process was established for verifying internal and external controls. Pathology assistants have been hired to assist with standardization of grossing and tissue fixation.

299. The Cancer Society believes that the following recommendations, if implemented, would further enhance the treatment of breast cancer patients, restore public confidence, and respond to any remaining concerns pertaining to ER/PR tests conducted between 1997 and 2005:

Cancer Registry and Monitoring

300. The long-standing undetected problem with ER/PR test results highlights the need for a monitoring program in the Laboratory Medicine Program. A formal program should be established by Eastern Health to monitor the results produced by the Immunohistochemistry lab including ER/PR test results. The Cancer Registry data would be a valuable tool to incorporate into any monitoring program. If the registry data is properly maintained and analyzed then should aid in early detection of any similar problems which might occur in the future.

301. An investigation of the reasons the Cancer Registry did not contain all breast cancer patients should be conducted and deficiencies corrected. The known problems with case ascertainment and death clearances should be corrected. If any new legislation is required to address any concerns about the release of personal health information, then this should be promptly addressed by the Department of Health and the Regional Health Authorities. The Cancer Registry should be supported in its efforts to achieve NAACR certification, with any financial and human resources, including the addition of an epidemiologist and other expertise as necessary to attain reasonably analytic capacity.

Quality: National Standards and Occurrence Reporting

302. It is recommended that Eastern Health and the other Regional Health authorities, the provincial government, pathologists and technologists actively work with CAP and the

cIQc in their goal to implement national standards and accreditation for immunohistochemical testing in Canada.

303. It is recommended that the Laboratory Medicine Program generally, and the Immunohistochemical Division in particular, develop a comprehensive but non-exclusive list of examples of events that would constitute an occurrence. Such a list would provide greater clarity for and encourage routine occurrence reporting by members of the Laboratory Medicine Program on a topic for which there remains some confusion. This exercise would be useful for the current manual reporting system and for the electronic reporting system which will soon be implemented.

304. It is recommended that the corporate-wide policies of Eastern Health and the internal policies of the Pathology Lab be revised to clarify the procedures for reporting of occurrences, including near misses. Measures should be put in place to ensure compliance with these policies. It is recommended that internal Pathology Laboratory occurrence reporting policy be a supplement to, rather than a replacement of, the corporate-wide Occurrence Reporting policy.

Patient Right to Effective Timely Communication and the Public Right to Know

305. It is recommended that Eastern Health and the other regional health authorities implement policies that promote timely and effective communication with patients in the

event of an individual or multi-patient adverse event or occurrence.

306. It is recommended that the policies include redundancy, such as a combination of letters and telephone calls plus public announcements, where appropriate, to ensure the effectiveness of the communication. There should be a follow-up system, such as follow-up telephone call to the patient or family member to ensure that the letter was received or the information was relayed by her physician during a clinic visit, for instance. The communication should include any useful written documentation that may be helpful to the patient, such as a general description letter or pamphlet pertaining to the diagnosis or treatment in question. There should be an opportunity for the patient or family member to have a follow-up communication, to allow the patient or family member to absorb the initial information being disclosed and to discuss any questions or concerns that may arise subsequently.

307. The Canadian Disclosure Guidelines produced by the Canadian Patient Safety Institute would be a valuable guide to the regional health authorities in the development of their policies and should be considered a minimum standard.

308. The hiring of patient navigators, whose primary responsibility is to communicate with and on behalf of the patient, is advisable. Upon consent of the patient, such individuals should be given full access to the patient's medical information and be given authority

to disclose such information to the patient. Patient navigators should be considered as an advocate for the patient, and have sufficient flexibility and authority within the organization to respond to the patient's needs.

309. A statement of rights for patients should be developed, with input from patients, families, patient advocacy and support groups, the Regional Health Authorities, other healthcare providers, and professional organizations such as the NLMA. Once established, the statement of rights should be made readily available through the websites and pamphlets of health care providers and patient advocacy and support groups. This should create a common understanding of a person's rights when engaged with the health care system. It should address the related issue of the public's right to transparency and accountability within the health care system.

Hormone Positive Test Results & Retro-Conversions

310. It is recommended that a further, scientifically-based investigation be conducted into the reasons for each of the retro-conversions found to date, regardless of whether the specimens are for patients who are deceased or are for living patients for whom no treatment change was ultimately required.

311. It should be decided, based upon the results of this review, what type of further action is required with respect to the ER positive test results which have not yet been re-tested.

312. It is recommended that Eastern Health engage external consultants to assist with the investigation and decision as to any further action required for the remaining ER positive test results, given that false positives were expected to be rare. Eastern Health's own experience has arguably defied this expectation.

313. If a full-scale re-testing is ultimately determined to be warranted then additional resources should be made available to the Laboratory Medicine Program, by Eastern Health or with the assistance of the Department of Health.

Epidemiological and Psychological Study of ER/PR Group

314. The Cancer Society views the events surrounding the hormone receptor testing mistakes and the unfortunate response from Eastern Health as preventable, with devastating consequences for many patients and families involved. Many lives were negatively impacted and the Cancer Society believes that all patients and families involved deserve to be heard on an on-going basis, not just in a clinical sense but also from a research and epidemiological perspective. The stories of the patients and families should be followed on a long-term basis, for the benefit of the group as lessons are learned, and also to educate health care policy makers with an interest in patient-centred practice.

315. The Cancer Society believes that stakeholders in the local research community would be interested in an ongoing research agenda which includes, but would not be limited to:

(1) implications of the various regimes for patients in the re-test group, ie. Hormone therapy delivered well after primary therapy; (2) psychosocial research on the experiences of the people who had mistakes made in determining their diagnosis, prognosis and treatment; and (3) policy research on the disclosure of adverse events for patients, family members and the general public.

316. It is recommended that resources be made available to conduct appropriate research. This would benefit those affected by the ER/PR testing errors and their need for ongoing evaluation and would create invaluable knowledge for the health care system.

All of which is respectfully submitted.

Dated at St. John's, Province of Newfoundland and Labrador, this 1st day of December 2008.

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