

CIHRT Exhibit P-0126 Page 1
DEPARTMENT OF HEALTH AND COMMUNITY SERVICES
BRIEFING NOTES - 2007

1. Question and Answers Briefing Note entitled ER/PR Testing, Eastern Health prepared by Beverley Griffiths and approved by Moira Hennessey dated March 9, 2007
2. Question and Answers Briefing Note entitled ER/PR Testing, Eastern Health prepared by Beverley Griffiths and approved by Moira Hennessey dated April 19, 2007
3. Email from Josephine Cheeseman to Carmel Turpin et al dated May 15, 2007 Subject, Litigation more of a concern for government than patients' health, charge opposition
4. Question and Answers Briefing Note entitled ER/PR Testing, Eastern Health prepared by Beverley Griffiths and approved by Moira Hennessey dated May 16, 2007
5. Question and Answers Briefing Note entitled ER/PR Testing, Eastern Health prepared by Beverley Griffiths and approved by Moira Hennessey dated May 16, 2007 (HMQ 6-9)
6. Estrogen and Progesterone Receptors (ER/PR) Testing, Briefing for Cabinet, May 17, 2007 Confidential
7. Cabinet Directive dated May 25, 2007
8. Email from Tansy Mundon to Susan Bonnell dated May 18, 2007 Subject, Briefing Note
9. Briefing Note–Question Period entitled ER/PR testing for Breast Cancer drafted by Dr. C. Bradbury dated May 24, 2007
10. Issue Monitoring Report entitled Retesting of Breast Cancer Patients-ER/PR dated May 25, 2007
11. Question and Answers Briefing Note entitled ER/PR Testing, Eastern Health prepared by Beverley Griffiths and approved by Moira Hennessey dated May 28, 2007
12. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR Contact person Bev Griffiths dated May 31, 2007
13. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR Contact person Bev Griffiths dated June 1, 2007

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DEPARTMENT OF HEALTH AND COMMUNITY SERVICES
BRIEFING NOTES - 2007

14. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated June 7, 2007
15. Question and Answers Briefing Note entitled ER/PR Testing, Eastern
Health prepared by Beverley Griffiths and approved by Moira Hennessey
dated June 14, 2007
16. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated June 15, 2007
17. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated June 22, 2007
18. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated June 28, 2007
19. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated June 29, 2007
20. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated July 6, 2007
21. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated July 6, 2007
22. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated July 13, 2007
23. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated July 13, 2007
24. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated July 20, 2007
25. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated July 26, 2007
26. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated August 3, 2007
27. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated August 3, 2007
28. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated August 10, 2007

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DEPARTMENT OF HEALTH AND COMMUNITY SERVICES
BRIEFING NOTES - 2007

29. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated August 10, 2007
30. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated August 16, 2007
31. Issue Monitoring Report on Retesting of Breast Cancer Patients-ER/PR
Contact person Bev Griffiths dated August 17, 2007

Question and Answer Briefing Note
Department of Health and Community Services

Title: ER/PR Testing, Eastern Health

Issue: Eastern Health released the outcome of its review of ER/PR testing in December. A mistake in testing may have led to incorrect treatment for 117 women in this province suffering from breast cancer. Legal proceedings have begun.

Anticipated Questions:

- Why has it taken more than one year for Eastern Health to go public and release the results of the ER/PR testing review?
- When will breast cancer screening test resume at the laboratory in St. John's?
- What has Government done to ensure the reliability and accuracy of the ER/PR testing at the St. John's hospitals?
- Are pathologists or laboratory staff to blame for the incorrect ER/PR test results?

Key Messages:

- Providing quality health services to the people of this province is a priority for our Government. We regret that the past two years (since May 2005) has been a stressful period for some patients and their families.
- When the ER/PR testing problem was discovered in May 2005, arrangements were put in place quickly for an independent laboratory to review the test results and complete ongoing work. Eastern Health took the time it felt was necessary to review the test results from Mount Sinai and conduct an extensive quality review of the laboratory prior to releasing the outcomes to the public in December 2006.
- Eastern Health's first priority was its patients. Clinical team members communicated individually with all patients impacted by this review. The organization has acted in what it determined to be in the best interest of its patients.
- Eastern Health resumed ER/PR testing in St. John's on February 1, 2007. We are confident that Eastern Health has implemented the appropriate new measures to ensure the highest standard of care for breast cancer patients.
- There were multiple factors involved in the ER/PR testing. There has been no blame assigned within Eastern Health. Since legal proceedings have been initiated, Government will have to allow the legal process to determine if in fact error has occurred.

Other Suggested Response(s):

- Eastern Health has put a number of measures in place to provide a high standard of ER/PR testing. These measures include a quality management program, seeking national accreditation for the laboratory and ensuring all technologists and pathologists receive special training.
- Eastern Health has implemented the recommendations from two external reviews and a dedicated laboratory has been established to perform the ER/PR testing with 3 designated technologists, a lab medical director, and a dedicated cutter. A centre of excellence for breast cancer cases has been established at Eastern Health so

that examination and reporting will be directed to a dedicated group of pathologists.

Background:

- In May 2005, the laboratory at the Health Sciences Centre discovered inconsistent results in breast tumour samples. The tests examine hormone receptors Estrogen (ER) or Progesterone (PR) in breast cancer cells to help physicians determine what course of treatment to follow for each patient (eg. chemotherapy, radiation).
- In the review period from 1997 to 2005, there were 2760 ER/PR tests conducted at the laboratory. Nine hundred and thirty-nine (939) of these tests were originally negative and were sent to Mount Sinai for retesting. This number represents about 34% of the patients tested for breast cancer. All retesting has been completed. The chronology of the ER/PR retesting is attached as Annex I.
- Eastern Health did not initially advise patients of the retesting (despite the Department’s suggestion that it should consider doing so) and many learned of it from the media before they were contacted by Eastern officials last Fall. Eastern waited for the actual results before disclosing information to the patients instead of telling them that they may or may not be impacted by the review; Eastern didn’t know what this would mean for them without the results. Eastern also did not want to unnecessarily raise alarm for individuals who may not be affected.
- The details on the test results are as follows:

-	Total Cases Reviewed 1997-2005	2760
-	Total Patients Retested	939
-	Patients Requiring Treatment Changes	117
- The 939 patients included 176 individuals who are deceased. One hundred and one (101) patients were retested and results received. There were two (2) patients who were retested upon request. The remaining 73 will not be retested unless the families request it.
- Last Spring (2006), the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.
- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. Ches Crosbie is representing the approximately 40 plaintiffs; Dan Boone is representing Eastern Health and Judge Carl Thompson is assigned as case management judge.
- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health has filed an affidavit in court on December 15, 2006. The lawyers for the plaintiff and the defendant have filed documents for certification and case law with the court on February 9, 2007. A hearing of the certification application is scheduled for May 23-25, 2007.
- Eastern Health has also taken measures to address the system issues including a review by two laboratory experts from outside the province, investments in

technology, recruitment of four pathology assistants, accreditation with the CCHSA and consolidation of pathologist review of breast tissue samples.

Drafted by: Beverley Griffiths, 729-0717

Approved by: Moira Hennessey

Date: March 9, 2007

ANNEX I – CHRONOLOGY OF ER/PR RETESTING

- May 2005 – an oncologist discovered inconsistent test results on a patient who tested ER/PR negative in 2002 on a DAKO system and ER/PR positive in 2005 on the new VANTANA system.
- July 2005 – decision made to retest internally all patients who were ER/PR negative from 1997 to 2004. Technology has changed over time and is more sensitive to picking up ER/PR negatives and positives.
- Late July 2005 – decision made to arrange for an independent laboratory to complete retesting (Mount Sinai) and ongoing work.
- August 2005 - process of collecting packaging and shipping negative test results to Mount Sinai began.
- October 2005 – Tumor board, consisting of two oncologists, two surgeons, two pathologists, one rep from quality department and one support person, was established to review the results as they arrived back from Mount Sinai and made treatment recommendations for each patient. Patients were contacted about specimens being sent away for retesting.
- February 2006 – the last test results were received from Mount Sinai.
- February to May 2006 – Tumor board reviewed test results, wrote recommendations and disclosed information to patients.
- June to November 2006 – the new chief pathologist and new VP – Medical Services established a centre of excellence for breast cancer pathology, assigned a head pathologist for immunohistochemistry and prepared to resume ER/'PR testing in St. John's and in September the accreditation process for the lab was initiated.
- Late November 2006 – Eastern Health completes its quality review.
- December 11, 2006 – Eastern Health releases outcomes of laboratory review to the public. A technical briefing was also provided to the media and since that time, one client issue was identified. The individual had not been seen by a doctor to obtain her test results despite a number of attempts by Eastern Health to establish contact. She has since received follow up by the physician.

**Question and Answer Briefing Note
Department of Health and Community Services**

Title: ER/PR Testing, Eastern Health

Issue: Eastern Health released the outcome of its review of ER/PR testing in December. A mistake in testing may have led to incorrect treatment for 117 women in this province suffering from breast cancer. Legal proceedings have begun.

Anticipated Questions:

- Why has it taken more than one year for Eastern Health to go public and release the results of the ER/PR testing review?
- When will breast cancer screening test resume at the laboratory in St. John's?
- What has Government done to ensure the reliability and accuracy of the ER/PR testing at the St. John's hospitals?
- Are pathologists or laboratory staff to blame for the incorrect ER/PR test results?

Key Messages:

- Providing quality health services to the people of this province is a priority for our Government. We regret that the past two years (since May 2005) has been a stressful period for some patients and their families.
- When the ER/PR testing problem was discovered in May 2005, arrangements were put in place quickly for an independent laboratory to review the test results and complete ongoing work. Eastern Health took the time it felt was necessary to review the test results from Mount Sinai and conduct an extensive quality review of the laboratory prior to releasing the outcomes to the public in December 2006.
- Eastern Health's first priority was its patients. Clinical team members communicated individually with all patients impacted by this review. The organization has acted in what it determined to be in the best interest of its patients.
- Eastern Health resumed ER/PR testing in St. John's on February 1, 2007. We are confident that Eastern Health has implemented the appropriate new measures to ensure the highest standard of care for breast cancer patients.
- There were multiple factors involved in the ER/PR testing. There has been no blame assigned within Eastern Health. Since legal proceedings have been initiated, Government will have to allow the legal process to determine if in fact error has occurred.

Other Suggested Response(s):

- Eastern Health has put a number of measures in place to provide a high standard of ER/PR testing. These measures include a quality management program, seeking national accreditation for the laboratory and ensuring all technologists and pathologists receive special training.
- Eastern Health has implemented the recommendations from two external reviews and a dedicated laboratory has been established to perform the ER/PR testing with 3 designated technologists, a lab medical director, and a dedicated cutter. A centre of excellence for breast cancer cases has been established at Eastern Health so

that examination and reporting will be directed to a dedicated group of pathologists.

Background:

- In May 2005, the laboratory at the Health Sciences Centre discovered inconsistent results in breast tumour samples. The tests examine hormone receptors Estrogen (ER) or Progesterone (PR) in breast cancer cells to help physicians determine what course of treatment to follow for each patient (eg. chemotherapy, radiation).
- In the review period from 1997 to 2005, there were 2760 ER/PR tests conducted at the laboratory. Nine hundred and thirty-nine (939) of these tests were originally negative and were sent to Mount Sinai for retesting. This number represents about 34% of the patients tested for breast cancer. All retesting has been completed. The chronology of the ER/PR retesting is attached as Annex I.
- The details on the test results are as follows:

-	Total Cases Reviewed 1997-2005	2760
-	Total Patients Retested	939
-	Patients Requiring Treatment Changes	117
- The 939 patients included 176 individuals who are deceased. One hundred and one (101) patients were retested and results received. There were two (2) patients who were retested upon request. The remaining 73 will not be retested unless the families request it.
- Eastern Health did not initially advise patients of the retesting (despite the Department’s suggestion that it should consider doing so) and many learned of it from the media. Eastern waited for the actual results before disclosing information to the patients as Eastern didn’t know what this would mean for individuals without the results. Eastern also did not want to unnecessarily raise alarm for individuals who may not be affected.
- Last Spring (2006), the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.
- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. There are approximately 40 plaintiffs.
- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health filed an affidavit in court on December 15, 2006. The lawyers for the plaintiff and the defendant have filed documents for certification and case law with the court on February 9, 2007. A hearing of the certification application is scheduled for May 23-25, 2007.

Drafted by: Beverley Griffiths, 729-0717
Approved by: Moira Hennessey
Date: April 19, 2007

ANNEX I – CHRONOLOGY OF ER/PR RETESTING

- April 2004 – The former HCCSJ installed a new VENTANA system for the immunohistochemistry lab to replace the DAKO system.
- May 2005 – An oncologist noted that a patient, diagnosed in 2002 with breast cancer who tested negative* on the DAKO system, converted to positive in 2005 on the new VENTANA system. Oncologists decided further retest 25 negative patients from 2002. Of the 25 retested, 12 converted to positive. An additional 32 negative tests were retested and 25 of the 32 converted to positive on the VENTANA system.
- June 2005 – decision made to retest all patients who were ER/PR negative for the year 2002.
- Early July 2005 – decision made to retest all patients who were ER/PR negative between May 1997 and August 8, 2005.
- Late July 2005 – decision made to arrange for an independent laboratory to complete retesting (Mount Sinai) and all new patients. All testing of ER/PR at the Health Sciences laboratory was stopped.
- August 2005 - process of collecting, packaging and shipping negative test results to Mount Sinai Hospital in Toronto began.
- October 2005 – Tumor board, consisting of two oncologists, two surgeons, two pathologists, one representative from quality department and one support person, was established to review the results as they arrived back from Mount Sinai and made treatment recommendations for each patient. Patients were contacted about specimens being sent away for retesting. This Board met weekly from October 2005 to May 2006 to review individual patient files, assess the impacts and make treatment recommendations.
- Mid October 2005 – Media interviews conducted and advertising purchased to inform the public of specimens sent for retesting.
- December 2005 – Mt. Sinai Hospital contacted by Eastern Health to express concerns on the slow pace of having the testing completed and the reports sent back (manpower issues reported by Mt. Sinai).
- December 7, 2005 – A statement of claim was filed in the Supreme Court of NL Trial Division on behalf of Michelle B. Hanlon.
- February 2006 – the last test results were received from Mount Sinai.
- February to May 2006 – Tumor board reviewed test results, wrote recommendations and disclosed information individually to each patient.
- May 11, 2006 A Statement of Defence is filed with the Supreme Court of NL on behalf of Michelle B. Hanlon.
- June to November 2006 – the new chief pathologist and new VP – Medical Services established a centre of excellence for breast cancer pathology, assigned a head pathologist for immunohistochemistry and prepared to resume ER/PR testing in St. John’s and in September the accreditation process for the lab was initiated.
- Late November 2006 – Eastern Health completes its quality review.

- December 11, 2006 – Eastern Health releases outcomes of laboratory review to the public. A technical briefing was also provided to the media and since that time, one client issue was identified. The individual had not been seen by a doctor to obtain her test results despite a number of attempts by Eastern Health to establish contact. She has since received follow up by the physician.
- February 2007 - An affidavit was filed in the Supreme Court of NL between Verna Doucette (plaintiff) and Eastern Health (Defendant)
- February 2007 – lawyers for the plaintiff and the defendant have filed documents for certification and case law.

**The definition of “negative” has changed within this 7 year period. Oncologists previously believed that tumours with less than 30% positivity for ER/PR should be considered negative. With advancing understanding of cancer and treatment, the negative rate has dropped down to 10% and now to 1%. Today, oncologists believe that any positive result is worthy of hormonal therapy.*

From: Josephine Cheeseman
To: Carmel Turpin, Donna Ivey; Elizabeth Matthews, Tansy Mundon, Tara Furlong
Date: Tue, May 15, 2007 4:59 PM
Subject: Fwd: Litigation more of a concern for government than patients' health, charges Opposition

>>> Liberal Opposition 5/15/2007 4:58 34 PM >>>

Litigation more of a concern for government than patients' health, charges Opposition

Dwight Ball, MHA for the District of Humber Valley and Opposition Critic for Health and Community Services, says the minister's admission that his department placed litigation concerns before patients health, already compromised by faulty testing, is regrettable and unacceptable

The Minister of Health and Community Services was questioned by Ball in the House of Assembly on the significantly high rate of error that has occurred in test results for a hormone receptor that would identify the course of treatment for breast cancer patients. It was exposed that close to 50 per cent of those testing positive for this disease had been provided false information that prevented them from receiving the appropriate life-saving treatment. In a media scrum following Question Period, the minister further revealed that government knew for months the high numbers of women affected, but was advised not to reveal them because of litigation risks. Of the close to 1000 women who were retested, 317 were given wrong results, with 117 of these requiring alternate treatment.

"I find it a very unfortunate that the minister of health would be more concerned about litigation than he would be about the health concerns of patients," says Ball. "It certainly raises concerns about this government's commitment to openness and accountability and to the patients who are facing these health concerns.

"We as an Opposition have always challenged this government's so-called commitment to openness and accountability. If this government is willing to conceal this sort of critical information from the public, it begs the question as to what type of other information is being cloaked and hidden by this administration

"As it stands now, this testing tragedy has been further marred by the reprehensible actions of this government. Not only have individuals and families had their lives compromised and disrupted by this faulty testing scandal and the level of public trust in the health care jeopardized, confidence in this government's moral accountability to public health and safety may have reached an all-time low "

- 30 -

Media Contact: Kim Ploughman Caucus Communications
Office of the Official Opposition
tel (709) 729-6427 e-copies at www.liberal.nf.net

**Question and Answer Briefing Note
Department of Health and Community Services**

Title: ER/PR Testing, Eastern Health

Issue: CBC has reported both provincially and nationally on May 15th that court documents show that Eastern Health got many more ER/PR test results wrong that it reported months ago.

Anticipated Questions:

- In December, Eastern Health reported that 117 of 939 breast cancer patients had to have treatment changes because of the ER/PR retesting. Why are court documents obtained by CBC showing that almost three times as many tests were wrong?
- It took more than a year for Eastern Health to go public and release the results of the ER/PR testing review. Are they hiding the real numbers?
- Why has Eastern Health not released the test results for 176 patients who have died since the original tests?
- Now that testing has resumed in St. John's, what has Government done to ensure the reliability and accuracy of the ER/PR testing at the St. John's hospitals?
- Are pathologists or laboratory staff to blame for the incorrect ER/PR test results?

Key Messages:

- Eastern Health has been accountable to the public. A technical briefing was held on December 11, 2006 at which time information on the number of patients retested at Mount Sinai and those requiring treatment changes was released to the media.
- Eastern Health sent 939 original ER/PR test results to Mount Sinai for retesting. The retesting results were reviewed by an expert panel of oncologists, pathologists, and surgeons in St. John's. At this time, 117 patients are identified as requiring treatment changes.
- The expert panel recommended that the focus of the retesting should be on patients who are alive. Eastern Health has been working with families of deceased patients on an individual basis.
- Providing quality health services to the people of this province is a priority for our Government. We regret that the past two years (since May 2005) has been a stressful period for some patients and their families and this news further adds to the anxiety that these patients as well as newly diagnosed patients are experiencing.
- Eastern Health resumed ER/PR testing in St. John's on February 1, 2007. We are confident that Eastern Health has implemented the appropriate new measures to ensure the highest standard of care for breast cancer patients.
- There were multiple factors involved in the ER/PR testing. There has been no blame assigned within Eastern Health. Since legal proceedings have been initiated, Government will have to allow the legal process to determine if in fact error has occurred.

Other Suggested Response(s):

- When the ER/PR testing problem was discovered in May 2005, arrangements were put in place quickly for an independent laboratory to review the test results and complete ongoing work. Eastern Health took the time it felt was necessary to review the test results from Mount Sinai and conduct an extensive quality review of the laboratory prior to releasing the outcomes to the public in December 2006.
- Eastern Health has put a number of measures in place to provide a high standard of ER/PR testing for new breast cancer patients. These measures include a quality management program, seeking national accreditation for the laboratory and ensuring all technologists and pathologists receive special training.
- Newly diagnosed patients should be assured that these high standards are in place and staff have the necessary training to ensure accurate results are obtained.
- Eastern Health has implemented the recommendations from two external reviews and a dedicated laboratory has been established to perform the ER/PR testing with 3 designated technologists, a lab medical director, and a dedicated cutter. A centre of excellence for breast cancer cases has been established at Eastern Health so that examination and reporting will be directed to a dedicated group of pathologists.

Background:

- Prior to April 2004, the Dako testing technique was used at Eastern Health’s laboratories which required the manual boiling of tissue samples and the measurement of minute mixtures of immunoperoxidase staining.
- In April 2004, Eastern Health installed the Ventana system for conducting ER/PR testing. This new system automated the process, thereby removing much of the human manipulation of samples.
- In May 2005, a patient who was diagnosed in 2002 with breast cancer and had been determined to be negative using the Dako system, converted to positive after further ER/PR testing using the Ventana system.
- In June – July 2005, Eastern Health conducted a case review of negative ER/PR tests it obtained in 2002. Of 57 cases retested, 37 converted from negative to positive.
- In early July 2005, Eastern Health decided to retest all negative ER/PR tests performed between May 1997 and August 8, 2005. In the review period from 1997 to 2005, there were 2760 ER/PR tests conducted at the laboratories. Nine hundred and thirty-nine (939) of these tests were originally negative and were sent to Mount Sinai for retesting. This number represents about 34% of the patients tested for breast cancer. All new cases were sent to Mount Sinai for ER/PR testing. The chronology of the ER/PR retesting is attached as Annex I.
- The details on the test results are as follows:

-	Total Cases Reviewed 1997-2005	2760
-	No. of Tests sent to Mount Sinai	939
	- Live Patients	763
	- Deceased Patients	176

- Live Patients Whose Samples were Retested	763
- Patients with no change in ER/PR results and no change in treatment recommended	433
- Patients with no change in ER/PR results but a change in treatment recommended by expert panel	13
- Patients where ER/PR test results were different following retesting	<u>317</u>
	763
- Patients who required a change in treatment	104
- Deceased Patients Whose Original ER/PR Test Results were Negative	176
- Patient samples that were retested and results received	101
- Patient samples that have been retested on request	2
- Patient samples that will not be retested unless requested by the families	<u>73</u>
	176

- The May 15th CBC story is reporting that of the 763 live patients, upwards of 42% of the test results were wrong (317 of 763 alive patients). The story is also focused on why Eastern Health has not released the test results for 176 deceased patients. The story quotes a US pathologist, a leading expert on hormone receptor tests in North America, as saying laboratories across the US are having the same problems with these tests.
- In the December press release, Eastern Health stated that 117 of the 939 patients required treatment changes. This appears to be a 12% error rate. In the court affidavit filed by Eastern Health, the 117 patients include 104 patients who required a treatment change due to a change in ER/PR test results and a further 13 patients who saw no change in their ER/PR test results but a change in treatment was recommended. The US pathologist also states that the average error rate in the US is probably as high as 20%. Eastern Health advises that it is very difficult to confirm an actual error rate as ER/PR testing is a complicated procedure that involves more than 40 steps.
- Eastern Health did not initially advise patients of the retesting (despite the Department's suggestion that it should consider doing so) and many learned of it from the media. Eastern waited for the actual results before disclosing information to the patients as Eastern didn't know what this would mean for individuals without the results. Eastern also did not want to unnecessarily raise alarm for individuals who may not be affected.
- Last Spring (2006), the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which

would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.

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Drafted by: Beverley Griffiths, 729-0717

Approved by: Moira Hennessey

Date: May 16, 2007

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HMQ 6

→ 2 reviews.
8:30am

Question and Answer Briefing Note
Department of Health and Community Services

Title: ER/PR Testing, Eastern Health

Issue: CBC has reported both provincially and nationally on May 15th that court documents show that Eastern Health got many more ER/PR test results wrong than it reported months ago.

Anticipated Questions:

- What can government say to the individuals who were affected as a result of inaccurate test results?
- During a media briefing in December, Eastern Health reported that 117 of 939 breast cancer patients had to have treatment changes because of the ER/PR results. Court documents filed by Eastern Health earlier this year, and obtained by CBC, state that test results changed for 317 patients. Why did Eastern Health withhold this information?
- Why has Eastern Health not released the test results for 176 patients who have died since the original tests?
- NDP leader Lorraine Michael stated in the media yesterday "If I were a woman who was dealing with breast cancer I think I would not want to deal with our system here in Newfoundland and Labrador." Should the public have confidence in Eastern Health and its ability to treat breast cancer patients?
- Will Government undertake an independent review of how Eastern Health handled this case?
- Has Eastern Health now notified all affected patients of the results of retesting and why wasn't this done sooner?
- Yesterday during Question Period, NDP leader Lorraine Michael asked the Minister if he would communicate to Eastern Health the need for a public information campaign with details so that people would feel confident in receiving treatment in Newfoundland and Labrador?

Key Messages:

- Government is very sympathetic to the individuals impacted by this situation. We regret that the past two years (since May 2005) has been a stressful period for some patients and their families. However, I think it's important for those directly impacted and the public to understand the background of this situation. Eastern Health first became aware of a problem with test results in May 2005 and immediately conducted an internal review. In July 2005 they made a responsible decision to retest all negative ER/PR tests done between May 1997 and August 2005 to ensure that if there was one patient who could benefit as a result of a change in their test result and subsequent treatment change that it was important that this be done.
- Eastern Health was advised by its legal counsel to withhold this information pending court action. Should this information have been provided as part of a technical briefing for media in December 2006 when further information regarding those requiring treatment changes (117) was released? In the spirit of

openness and transparency, yes, I believe that it should have been released at that time.

- An expert panel, comprised of oncologists, pathologists and surgeons in St. John's, recommended that the focus of retesting should be on patients who are alive. Eastern Health has been working with families of deceased patients on an individual basis and has provided retesting results upon request.
- There were multiple factors involved in the ER/PR testing. There has been no blame assigned within Eastern Health. Since legal proceedings have been initiated, Government will have to allow the legal process to determine if in fact error has occurred.
- The public should have every confidence in Eastern Health. The fact that the authority made a voluntary decision to retest ER/PR results over a period of time goes beyond what has been done anywhere else in the country. Furthermore, Eastern Health has conducted two independent quality reviews of the laboratory and has implemented a number of measures to provide a high standard of ER/PR testing for new breast cancer patients. These measures include a quality management program, seeking national accreditation for the laboratory and ensuring all technologists and pathologists receive special training. In addition, as a measure of quality control, some tests are sent to Mount Sinai to ensure accuracy of results over time. Eastern Health resumed ER/PR testing in St. John's on February 1, 2007. We are confident that Eastern Health has implemented the appropriate new measures to ensure the highest standard of care for breast cancer patients.
- Government is satisfied that through two independent reviews already conducted and new quality measures now in place that this situation will not occur in future. Our priority is on ensuring quality health care services for the residents of Newfoundland and Labrador.
- Eastern Health has notified all affected individuals through communication with their physician. Information was shared once retesting was completed. It was felt that informing patients of retesting prior to individual results being received would create anxiety without further information to be shared.
- Residents should feel confident that we are the only province in Canada to have undertaken retesting of ER/PR results and to implement quality assurance practices to ensure accurate testing in future.

Other Suggested Response(s):

- Newly diagnosed patients should be assured that these high standards are in place and staff have the necessary training to ensure accurate results are obtained.

Background:

- Prior to April 2004, the Dako testing technique was used at Eastern Health's laboratories which required the manual boiling of tissue samples and the measurement of minute mixtures of immunoperoxidase staining.
- In April 2004, Eastern Health installed the Ventana system for conducting ER/PR testing. This new system automated the process, thereby removing much of the human manipulation of samples.

- In May 2005, a patient who was diagnosed in 2002 with breast cancer and had been determined to be negative using the Dako system, converted to positive after further ER/PR testing using the Ventana system.
- In June – July 2005, Eastern Health conducted a case review of negative ER/PR tests it obtained in 2002. Of 57 cases retested, 37 converted from negative to positive.
- In early July 2005, Eastern Health decided to retest all negative ER/PR tests performed between May 1997 and August 8, 2005. In the review period from 1997 to 2005, there were 2760 ER/PR tests conducted at the laboratories. Nine hundred and thirty-nine (939) of these tests were originally negative and were sent to Mount Sinai for retesting. This number represents about 34% of the patients tested for breast cancer. All new cases were sent to Mount Sinai for ER/PR testing. The chronology of the ER/PR retesting is attached as Annex I.
- The details on the test results are as follows:

• Total Cases Reviewed	1997-2005	2760
• No. of Tests sent to Mount Sinai		939
	(763 live; 176 deceased)	
• Live Patients Whose Samples were Retested		763
Patients with no change in ER/PR results		433
and no change in treatment recommended		
Patients with no change in ER/PR results		13
but a change in treatment recommended		
by expert panel		
Patients where ER/PR test results were		317
different following retesting		
• Deceased Patients Whose Original ER/PR		176
Test Results were Negative		
Patient samples that were retested and		101
results received		
Patient samples that have been retested		2
on request		
Patient samples that will not be retested		73
unless requested by the families		

Eastern Health had independent external reviews conducted by the Chief Pathologist at the BC Cancer Institute and the Chief Technologist and Mount Sinai Hospital in Toronto, and has implemented the recommendations from these reviews. In addition, a dedicated laboratory has been established to perform the ER/PR testing with 3 designated technologists, a lab medical director, and a dedicated cutter. A centre of excellence for breast cancer cases has been established at Eastern Health so that examination and reporting will be directed to a dedicated group of pathologists.

- The May 15th CBC story is reporting that of the 763 live patients, upwards of 42% of the test results were wrong (317 of 763 live patients). The story is also focused on why Eastern Health has not released the test results for 176 deceased patients.

The story quotes a US pathologist, a leading expert on hormone receptor tests in North America, as saying laboratories across the US are having the same problems with these tests.

- In the December press release, Eastern Health stated that 117 of the 939 patients required treatment changes. This appears to be a 12% error rate. In the court affidavit filed by Eastern Health, the 117 patients include 104 patients who required a treatment change due to a change in ER/PR test results and a further 13 patients who saw no change in their ER/PR test results but a change in treatment was recommended. The US pathologist also states that the average error rate in the US is probably as high as 20%. Eastern Health advises that it is very difficult to confirm an actual error rate as ER/PR testing is a complicated procedure that involves more than 40 steps.
- Eastern Health did not initially advise patients of the retesting (despite the Department's suggestion that it should consider doing so) and many learned of it from the media. Eastern waited for the actual results before disclosing information to the patients as Eastern didn't know what this would mean for individuals without the results. Eastern also did not want to unnecessarily raise alarm for individuals who may not be affected.
- Last Spring (2006), the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.
- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. There are approximately 40 plaintiffs.
- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health has filed an affidavit in court on December 15, 2006. The lawyers for the plaintiff and the defendant have filed documents for certification and case law with the court on February 9, 2007. A hearing of the certification application is scheduled for May 23-25, 2007.

Drafted by: Beverley Griffiths, 729-0717

Approved by: Moira Hennessey

Date: May 16, 2007



Estrogen and Progesterone Receptors (ER/PR) Testing

Briefing for Cabinet
May 17, 2007

Confidential

Department of Health and Community Services

Outline



- Background
- What the Department knew and when
- Public Communications Issues
- Quality Assurance



Background

- What is ER/PR testing?
- How was the problem discovered?
- Internal review completed
- Decision made to retest all negative ER/PR results from May 1997 – August 2005



Background (cont.)

- **July 2005** - ER/PR testing ceased at Health Sciences Centre.
- **August 2005** - Tests sent to Mount Sinai (Toronto) for retesting and newly diagnosed cases.
- **September 2005** – External reviews conducted.



Background (cont.)

- **October 2005**
 - First results received from Mount Sinai
 - Tumour Board established to review individual cases and make recommendations on treatment
- **February 2006** – Final test results received from Mount Sinai for retested patients.
- **February 2007** – Testing resumed at Health Sciences Centre.



Background (cont.)

- **Total Cases Reviewed – 2,760**
- **Negative Tests sent to Mt. Sinai – 939**
(763 live; 176 deceased)
- **Test results changed for 317 (of 763)**
 - Treatment changed for 117 of the 317 patients retested.
 - No treatment change for 200.
 - All patients notified of test results.
- **103 of 176 deceased test results retested – results provided on request.**

What the Department knew and when



- **July 20, 2005** – Briefing note from EH outlining chronology dating back to May 11, 2005 when issue discovered.
- **July 21, 2005** – Minister Ottenheimer briefed by CEO and officials with EH.
- **July 25, 2005** – Email update from CEO to Deputy Minister

What the Department knew and when (cont.)



- **August 5, 2005** – Briefing with officials of EH and Dept to inform all tests going to Mt. Sinai and quality review to commence.
- **September 1, 2005** – Email from ADM to CEO seeking another update for the Minister

What the Department knew and when (cont.)



- **September 5, 2005** – Email from ADM to CEO seeking briefing for Minister post September 10th, when first test results due back from Mount Sinai.
- **October 28, 2005** – DM asked CEO to brief the Minister on November 14th in preparation for opening of the HOA.

What the Department knew and when (cont.)



- **October 3, 2005** – BN for Minister
- **November 7, 2005** – HOA briefing note
- **December 5, 2005** – Updated HOA BN
- **February 23, 2006** – HOA Briefing Note
- **April 27, 2006** – Updated HOA BN
- **May 18, 2006** – Updated HOA BN

What the Department knew and when (cont.)



- **August 18, 2006** – BN prepared by Cabinet Secretariat for information
- **October 24, 2006** – BN for Minister
- **November 23, 2006** – Briefing for Minister Osborne by Eastern Health before media briefing
- **November 27, 2006** – Updated HOA BN following EH briefing with Minister.
- **December 12, 2006** – Updated HOA BN

What the Department knew and when (cont.)



- **March 9, 2007** – HOA BN for Minister
- **April 19, 2007** – Updated HOA BN
- **May 15, 2007** – Briefing for Minister Wiseman by Eastern Health
- **May 15, 2007** - Updated HOA BN
- **May 16, 2007** – Updated HOA BN

Public Communications Issues



- Issue first reported by The Independent in October 2005. Statement of Claim filed in December 2005.
- Periodic statements provided by Eastern Health.
- Media technical briefing provided in December 2006. Numbers provided: (939 tests sent for retesting; 117 individuals had treatment changes).
- Further details unveiled in court affidavit.
- Current media focus on confidence, personal cases and perceived “cover-up” on error rate.



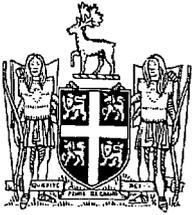
Quality Assurance

- **EH has implemented a number of quality control measures:**
 - Established dedicated laboratory to perform ER/PR testing
 - Established a Centre of Excellence
 - Seeking national accreditation for laboratory
 - Ensuring all pathologists/technologists receive special training.
 - Random samples sent to Mount Sinai as a quality control check.

Conclusion



- **Next steps?**
- **Questions/Comments**



CABINET DIRECTIVE

*The following is a Copy of a Directive
passed by Cabinet at a Meeting held on
2007/05/25*

MC2007-0384

XX2007-054.

A Recommendation on Briefing Note Circulation was received from the Clerk of the Executive Council.

Approval was given for the following procedure for circulation of briefing notes, effective immediately:

Ministerial Briefing Notes

- 1) All briefing notes prepared for a Minister, whether prepared for the Minister's orientation, general information, a Cabinet meeting, the House of Assembly, to make a decision, to attend a meeting, to attend a federal/provincial conference or any other similar purpose, shall be signed or initialed by the Minister after he/she reviews it;
- 2) A copy of the signed/initialed briefing note shall be maintained in the Minister's files by the Secretary to the Minister;
- 3) The files shall be appropriately indexed and stored so that retrieval can be made without difficulty;

Briefing Notes Circulated to Premier's Office by Cabinet Secretariat

- 1) All briefing notes prepared by a department for Cabinet Secretariat to circulate to the Premier's Office, or prepared by Cabinet Secretariat substantially based on information from a department, shall also be provided to the Minister. The "Issues" section of the briefing note shall state who initiated the briefing note and for what reason;
- 2) The Minister shall sign or initial the briefing note, indicating that it has been received and read. A copy of the signed/initialed note will be returned to Cabinet Secretariat for filing;
- 3) Where possible, the signature or initials of the Minister will be obtained before the note is circulated to the Premier's Office, but it is recognized that the timely preparation of a note

P
All Ministers
All Deputy
Ministers
Deputy Clerk
File



CABINET DIRECTIVE

*The following is a Copy of a Directive
passed by Cabinet at a Meeting held on
2007/05/25*

may not permit the obtaining of a signature or initials before Cabinet Secretariat forwards it to the Premier's Office. It is important for timeliness and responsiveness that departmental officials respond to requests from Cabinet Secretariat for information in the timelines requested.

COPY

Deputy Clerk of the Executive Council

From: Tansy Mundon
To: Bonnell, Susan
Date: 18/05/2007 9:06:59 am
Subject: Briefing note

**Question and Answer Briefing Note
Department of Health and Community Services**

Title: ER/PR Testing, Eastern Health

Issue: CBC has reported both provincially and nationally on May 15th that court documents show that Eastern Health got many more ER/PR test results wrong than it reported months ago.

Anticipated Questions:

- What can government say to the individuals who were affected as a result of inaccurate test results?
- Was there an attempt by the Department and/or Eastern Health to “cover up” the findings of the test results?
- Why has Eastern Health not released the test results for 176 patients who have died since the original tests?
- NDP leader Lorraine Michael stated in the media yesterday “If I were a woman who was dealing with breast cancer I think I would not want to deal with our system here in Newfoundland and Labrador.” Should the public have confidence in Eastern Health and its ability to treat breast cancer patients?
- Has Eastern Health now notified all affected patients of the results of retesting and why wasn’t this done sooner?
- Why was Government and Eastern Health more concerned with the risk of litigation than patient care?
- Will Government undertake a judicial inquiry?

Key Messages:

- Government is very sympathetic to the individuals impacted by this situation. We regret that the past two years (since May 2005) has been a stressful period for some patients and their families. However, I think it’s important for those directly impacted and the public to understand the background of this situation. Eastern Health first became aware of a problem with test results in May 2005 and immediately conducted an internal review. In July 2005 they made a responsible decision to retest **all** negative ER/PR tests done between May 1997 and August 2005 to ensure that if there was one patient who could benefit as a result of a change in their test result and subsequent treatment change that it was important that this be done.
- Absolutely not. There was full disclosure with patients and their families once test results became available. The Department first became aware of the issue in July 2005 and was briefed on Eastern Health’s decision to retest results back to 1997 and to conduct an external review. The first results were received by Eastern Health in October 2005. An expert panel was established to review cases and individuals were contacted. Eastern Health has commented publicly on this issue and has provided a briefing for media. Unfortunately, test results came back at different times and there was a delay in the retesting process which led to some patients feeling they were not informed in a timely fashion. Ultimately, Eastern Health’s primary concern was notifying all affected individuals. The affected individuals received full disclosure regarding their results.

- An expert panel, comprised of oncologists, pathologists and surgeons in St. John's, recommended that the focus of retesting should be on patients who are alive. Eastern Health has been working with families of deceased patients on an individual basis and has provided retesting results upon request.
- The public should have every confidence in Eastern Health. The fact that the authority made a voluntary decision to retest ER/PR results over a period of time goes beyond what has been done anywhere else in the country. Furthermore, Eastern Health has conducted two independent quality reviews of the laboratory and has implemented a number of measures to provide a high standard of ER/PR testing for new breast cancer patients. These measures include a quality management program, seeking national accreditation for the laboratory and ensuring all technologists and pathologists receive special training. In addition, as a measure of quality control, some tests are sent to Mount Sinai to ensure accuracy of results over time. Eastern Health resumed ER/PR testing in St. John's on February 1, 2007. We are confident that Eastern Health has implemented the appropriate new measures to ensure the highest standard of care for breast cancer patients.
- The context in which I stated that was with respect to why Eastern Health did not release the number of changed test results during a media briefing in December. As Minister, do I feel the number should have been released at that time? Yes, I do. Eastern Health and Government's primary concern is always that of the patient. The action taken by Eastern Health (retesting, quality assurance program, establishing an expert panel and expert reviews) and full disclosure to patients demonstrates that the patient and the families and is the primary concern.
- We are currently reviewing our options in this regard.

Other Suggested Response(s):

- Newly diagnosed patients should be assured that these high standards are in place and staff have the necessary training to ensure accurate results are obtained.

Background:

- Prior to April 2004, the Dako testing technique was used at Eastern Health's laboratories which required the manual boiling of tissue samples and the measurement of minute mixtures of immunoperoxidase staining.
- In April 2004, Eastern Health installed the Ventana system for conducting ER/PR testing. This new system automated the process, thereby removing much of the human manipulation of samples.
- In May 2005, a patient who was diagnosed in 2002 with breast cancer and had been determined to be negative using the Dako system, converted to positive after further ER/PR testing using the Ventana system.
- In June -- July 2005, Eastern Health conducted a case review of negative ER/PR tests it obtained in 2002. Of 57 cases retested, 37 converted from negative to positive.
- In early July 2005, Eastern Health decided to retest all negative ER/PR tests performed between May 1997 and August 8, 2005. In the review period from 1997 to 2005, there were 2760 ER/PR tests conducted at the laboratories. Nine hundred and thirty-nine (939) of these tests were originally negative and were sent to Mount Sinai for retesting. This number represents about 34% of the patients

tested for breast cancer. All new cases were sent to Mount Sinai for ER/PR testing. The chronology of the ER/PR retesting is attached as Annex I.

- The details on the test results are as follows:

• Total Cases Reviewed 1997-2005	2760
• No. of Tests sent to Mount Sinai (763 live; 176 deceased)	939
• Live Patients Whose Samples were Retested	763
- Patients with no change in ER/PR results and no change in treatment recommended	433
- Patients with no change in ER/PR results but a change in treatment recommended by expert panel	13
- Patients where ER/PR test results were different following retesting	317
• Deceased Patients Whose Original ER/PR Test Results were Negative	176
- Patient samples that were retested and results received	101
- Patient samples that have been retested on request	2
- Patient samples that will not be retested unless requested by the families	73

Eastern Health had independent external reviews conducted by the Chief Pathologist at the BC Cancer Institute and the Chief Technologist and Mount Sinai Hospital in Toronto, and has implemented the recommendations from these reviews. In addition, a dedicated laboratory has been established to perform the ER/PR testing with 3 designated technologists, a lab medical director, and a dedicated cutter. A centre of excellence for breast cancer cases has been established at Eastern Health so that examination and reporting will be directed to a dedicated group of pathologists.

- The May 15th CBC story is reporting that of the 763 live patients, upwards of 42% of the test results were wrong (317 of 763 live patients). The story is also focused on why Eastern Health has not released the test results for 176 deceased patients. The story quotes a US pathologist, a leading expert on hormone receptor tests in North America, as saying laboratories across the US are having the same problems with these tests.
- In the December press release, Eastern Health stated that 117 of the 939 patients required treatment changes. This appears to be a 12% error rate. In the court affidavit filed by Eastern Health, the 117 patients include 104 patients who required a treatment change due to a change in ER/PR test results and a further 13 patients who saw no change in their ER/PR test results but a change in treatment was recommended. The US pathologist also states that the average error rate in the US is probably as high as 20%. Eastern Health advises that it is very difficult

to confirm an actual error rate as ER/PR testing is a complicated procedure that involves more than 40 steps.

- Eastern Health did not initially advise patients of the retesting (despite the Department's suggestion that it should consider doing so) and many learned of it from the media. Eastern waited for the actual results before disclosing information to the patients as Eastern didn't know what this would mean for individuals without the results. Eastern also did not want to unnecessarily raise alarm for individuals who may not be affected.
- Last Spring (2006), the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.
- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. There are approximately 40 plaintiffs.
- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health has filed an affidavit in court on December 15, 2006. The lawyers for the plaintiff and the defendant have filed documents for certification and case law with the court on February 9, 2007. A hearing of the certification application is scheduled for May 23-25, 2007.

Drafted by: Beverley Griffiths, 729-0717

Approved by: Moira Hennessey

Date: May 17, 2007

Briefing Note – Question Period

Issue: ER/PR testing for Breast cancer

Background:

Eastern Health (St. John's site) suspended the testing of ER/PR specimens for breast cancer patients in August, 2005. Since August 2005, Mount Sinai has been testing new specimens as well as retesting all ER-negative specimen reported between 1997 and 2005.

Anticipated Questions

1. What is the current status of ER/PR testing in the province?

- ER/PR testing has resumed in St. John's as of February 01, 2007 for the St. John's sites only. ER/PR specimens for all other sites outside of St. John's continue to be tested and interpreted by Mount Sinai Hospital.
- At the same time that ER/PR testing was being referred out to Mount Sinai, a new protocol was instituted to do Her-2-neu testing in conjunction with ER/PR testing. The St. John's labs are in the process of validating their testing for HER-2-neu using this new protocol and hope to finalize the validation by the end of the summer. At that time, they plan to reinstate Her-2-neu testing for St. John's sites. In the interim, all Her-2-neu testing for the province is being completed at Mount Sinai.

For ER/Pr and Her-2-neu:

Pre – 2005:

Specimens prepared (fixed) and processed regionally, tested centrally, and sent back to the region for interpretation and reporting.

August 01, 2005 to January 31, 2007:

Specimens prepared regionally and forwarded to Mount Sinai for testing, interpretation and reporting.

February 01, 2007:

For ER/PR testing: Processing, testing, interpretation and reporting reinstated for St. John's sites. All other specimen outside of St. John's continue to be sent to Mount Sinai.

For Her-2-neu: All specimens continue to be sent to Mount Sinai.

2. What is the province's plan for ER/PR testing on a go-forward basis?

With agreement of the four RHA's and the Department of Health and Community Services it is intended that the testing, interpretation and reporting of all specimens in the province for ER/PR and Her-2-neu will occur at the St. John's site – "center of excellence:.

3. What changes have been implemented following the external review of ER/PR testing to ensure quality reporting?

Eastern Health has undergone an extensive external review of its policies and procedures related to ER/PR testing and are in the process of implementing recommendations arising from the review. Examples of these actions include, but are not limited to:

- Development and implementation of a province-wide policy to standardize the sampling and preparation (fixation) of specimens;
- Establishment of a separate Immuno-histochemistry Department for hormone-based testing;
- Recruitment of four Pathology assistants;
- Upgrading of the Vantana system (automated process for the retrieval of hormone markers);
- Dedicated technologists and Pathologists to report on these tests, who have received additional training in this area;
- Implementation of a new Director of Immuno-histochemistry;
- External Quality assurance program for proficiency testing (receive blind samples from the UK for testing here and comparison to international results and the College of American Pathologists)
- Continuing to send current, random samples to Mount Sinai for reconfirmation of interpretation and results (to date there have been 100% concurrence with Mount Sinai results)

Drafted by: Dr. C. Bradbury
May 24, 2007

Issue Monitoring Report
Department of Health and Community Services
May 25, 2007

Issue: Retesting of Breast Cancer Patients – ER/PR

Activities/Developments To Date:

- In December 2006, Eastern Health released the outcome of a laboratory review of ER/PR retesting of breast cancer patients. The review involved 939 patients with negative ER/PR test results between 1997 and August 2005.
- This issue has been in the public domain since Fall, 2005.
- Prior to the December 2006 release of the test results, two court cases were initiated – one case is by a family of a deceased breast cancer patient and the second case is a class action suit by about 40 plaintiffs.
- In early May 2007, the media obtained court affidavits which include additional details about the test results. The affidavits state that the 939 patients include 763 live and 176 deceased patients. The information also states that 317 of the 763 live patients had changes in their test results, including the 117 women who had recommended treatment changes.
- The ER/PR retesting issue resurfaced in the public domain during the May 14 week.
- On May 18, Eastern Health held a media briefing and the CEO apologized for the confusion that has ensued about ER/PR retesting results. He stated that ‘at no time did Eastern Health withhold any personal information from any of the patients impacted by our decision to retest for ER/PR’.
- This issue has received a lot of media attention in the past two weeks, provincially and nationally. Eastern Health and the Government have been accused of covering up test results. The HCS Minister has been asked a lot of questions by the Opposition in the media and the House of Assembly.

Activities/Developments This Week:

- On May 22, Government announced it will undertake a judicial Commission of Inquiry on ER/PR testing for breast cancer patients. The Commission’s report will endeavour to get answers to what happened to ensure that this situation will not reoccur. The Commission’s report will be released publicly.
- A hearing on the certification for the class action suit took place in Supreme Court, May 23-25, 2007. The number of plaintiffs who have joined the lawsuit has increased following events of the past two weeks.
- Ms. Gerrie Smith, Solicitor, Department of Justice, is monitoring the legal proceedings with Eastern Health’s lawyer.

- 2 -

Expected Activities/Developments in the Next Week:

- The ER/PR testing results will likely garner further attention in the media and the House of Assembly. The Department will continue to monitor this situation and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Beverley Griffiths, 729-0717

Issue: Radiology Services – Burin

Activities/Developments to Date:

- Eastern Health announced on May 22 that it had commenced a review of services provided by a radiologist who commenced work at the Burin Peninsula Health Centre in November 2006. The review involves 6034 services provided to 3,475 patients up to April 24, 2007.
- Eastern Health became aware that there may be a problem in February 2007. On February 22, 2007, the Manager of Diagnostic Imaging in Burin sent a letter to the local Clinical Chief expressing concerns by the technologists at that site about the radiologist's technical ability to perform examinations. However, further analysis was required to confirm if in fact, there was an issue. Subsequently, the matter was referred to a peer review process (per Eastern Health's Medical Staff By-laws).
- The peer review started on February 28, 2007. Eastern Health initially selected 50 patient records to be reviewed independently by two senior radiologists in St. John's. The peer review report was received by Eastern Health on May 9 and the region suspended the radiologist's privileges on May 10, 2007.
- A peer review of an additional 50 samples was initiated and the preliminary results were received on May 23, 2007. Based on the two peer review reports, Eastern Health is working through the details on its termination of the radiologist. The suspension will remain in place until the current review process is finalized.
- All 6034 reports will be reviewed by a team of radiologists. It is estimated that the full review will take approximately two weeks to complete.
- The area Opposition member has spoken in the media and in the House of Assembly criticizing Eastern Health for not releasing information on a potential problem with the accuracy of the radiology tests more quickly.
- Eastern Health has issued a print ad to patients to advise them that the review is underway and the results of tests will be communicated to the physician who ordered the test. Patients are being referred to phone line and staff at Burin Peninsula Health Centre for further information.

Activities/Developments This Week:

- As above.

- 3 -

Expected Activities/Developments in the Next Week:

- Eastern Health will continue to work through the details on its future relationship with the radiologist.
- Eastern Health will provide posters to physicians' offices as soon as possible
- The review of the approximately 6000 radiology test results will continue.
- The Department will continue to monitor this situation and provide updates to the HCS Minister and Premier's Office as required.

Contact Person: John Rumboldt, 729-3105

Issue: Healthy Aging Plan

Activities/developments in the previous week:

- Continued work on Healthy Aging Policy Framework and Plan.
- Adjustments/updates to the Perspectives on a Healthy Aging Plan: A Summary of Consultations document
- Ongoing development of Year 1: 2007-8 implementation plan
- Continued work on development of accountability structure.
- Continued budgetary considerations.
- Continued "Draft" development of cabinet paper.
- Meeting with Interdepartmental Working Group including Regional Health Authority representatives.

Expected activities/developments in the next week:

- Final work on "Draft" Healthy Aging Policy Framework and Implementation Plan documents for review of Ministerial Council on Aging and Seniors.
- Integration of recommendations from Accountability and Transparency perspective.
- Final adjustments/updates to the Perspectives on a Healthy Aging Policy Framework and Plan: A Summary of Consultations document
- Final work on development of "Draft" Year 1: 2007-8 implementation plan.
- Continued work on development of accountability structure.
- Continued budgetary considerations.
- Continued "Draft" development of cabinet paper.
- Meeting of Ministerial Council on Aging and Seniors – May 30, 2007.

Contact Person: Suzanne Brake, Director, Aging and Seniors Division

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Issue: Influenza Pandemic Planning

Activities/developments in the previous week:

- Reviewed M5's latest draft content and layout of pandemic pamphlet.
- Requested quotes for facilitator for Pandemic Committee planning meeting.
- Discussed progress of work on preparing the pandemic web site and pandemic pamphlet.
- Continued discussions with P/T counterparts and PHAC over concerns regarding the development of PHAC run Health Emergency Response Teams (HERT) to address surge capacity needs.
- Completed arrangements with PHAC for a HERT strategic planning and exercise meeting, in Ottawa, on the revised direction in the development of Health Emergency Response Teams (HERTs).
- Revised draft terms of reference for pandemic steering committee.
- Completed weekly update for issues monitoring of pandemic influenza planning.

Eastern Region

- Traveled to Burin Peninsula area to meet with site emergency planning committees.
- Discussed emergency planning in general and pandemic influenza planning initiatives.
- Working on creation of a sub-committee to discuss topics and content related to our pandemic influenza planning for inclusion on our intranet and web site. Two meetings had to be rescheduled.
- Completed weekly update for issues monitoring of pandemic influenza planning.

Central Region

- Health Emergency Management (HEM) Coordinator is on extended leave until at least June 28, 2007.
- Central Region will have a new Medical Officer of Health (MOH) in place on July 23, 2007. Until this time, MOHs from other regions are taking turns providing coverage for Central Health.
- There is nothing new to report. HEM Committee is continuing to work on completion of unfinished annexes for Central Region Pandemic Plan

Western Region

- Met with Materials Management staff to review status of stockpiling needs (Pandemic related materials) and space requirements.
- Assisted with the development of a "Patient Tracking Log" form which would be useful during a Pandemic event.
- Participated in an Ocean Guardian III planning meeting and discussed the "infectious disease element" inject.

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- Met with Regional Director with Transportation and Works to discuss access to one of their building as an alternate Emergency Operations Centre.
- Reviewed Emergency Preparedness efforts in relation to Western Health's accreditation review process, Pandemic preparedness efforts were reviewed at length during this process.
- Completed weekly update for issues monitoring of pandemic influenza planning.

Labrador Grenfell Region

- HEM coordinator attending meetings in Labrador City and is unable to report this week.

Activities/developments anticipated for the following week:

- Receive several quotes for a facilitator for the May 13 Department/RHA meeting re the revitalization of the Pandemic Steering Committee.
- Complete revision to the Terms of Reference and participate in a meeting to discuss preparation for pandemic planning steering committee meeting.
- Meet with PHAC for a HERT strategic planning and exercise discussion meeting, in Ottawa. The development of HERTs is to address surge capacity needs during disasters throughout the country which could include a possible public health response during the early stages of pandemic
- Hold teleconference with the provincial HEM planning team.
- Complete weekly update for issues monitoring of pandemic influenza planning.

Eastern Region

- Participate in Health Emergency Management teleconference.
- Discussions around a tabletop exercise to be conducted in the Fall, 2007 on mass immunization centres and the logistical considerations that would entail.
- Continue to work on updates to our pandemic planning document. Complete weekly update for issues monitoring of pandemic influenza planning.

Central Region

- The regional HEM Committee is scheduled to meet on May 29, 2007. One of the items to be discussed at this meeting will be an action plan for the HEM Coordinator Extended Leave Period.
- Also, this committee is continuing to work on completion of unfinished annexes for Central Region Pandemic Plan.

Western Region

- Provide an Emergency Preparedness presentation at a Long Term Care Managers meeting. This will include a backgrounder on Pandemic planning and preparedness.

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- Participate in a Code Green (Evacuation) working group meeting. Discussion at this group includes: reception centres, relocation of clients/patients, surge capacity, etc.
- Participate in Health Emergency Management teleconference.
- Participate in a Code Orange plan (Mass Casualty) review session this would include Directors from different departments discussing similar issues as noted in the Code Green meeting.
- Complete weekly update for issues monitoring of pandemic influenza planning.

Labrador Grenfell Region

- HEM coordinator attending meeting in Labrador City and is unable to report this week.
- Complete weekly update for issues monitoring of pandemic influenza planning.

Contact Person: Dennis Davis, 729-3912

Issue: Turner Report Follow up

Activities/Developments in the Previous Week:

- Finalized curriculum for a provincial orientation program.
- Began planning for the entry of historical CYFS files into CRMS.
- Met with the Regional Directors of CYFS.
- Met with the OCIO to begin prioritizing of project initiatives for CYFS.
- Met with CRMS Steering Committee.
- Met with the School of Social Work regarding Duty to Report - Information Sharing working group.
- Met to review budget initiatives, priorities and timelines.
- Ministerial Sub-Committee met on two occasions.

Expected Activities/Developments in the Next Week:

- Continue to advance the recruitment process for the provincial positions.
- Continue development of the work plan related to the budget initiatives.
- Meet with the consultant completing the legislative review.
- Meet with the Child and Youth Advocate regarding system advocacy issues.
- Conference call with the regions on status of new initiatives.

Contact Person: Susan Walsh, 729-7289 / Jennifer Jeans, 729-5864

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Issue: Low Income Drug Program Implementation**Activities and developments in the previous week:**

- Applications for the Drug Program continue to arrive at a pace of approximately 489 per week and are being processed quickly.
- 20,487 individuals have been deemed eligible as of May 20, 2007.
- As of May 21, 2007 we have approximately 185 pharmacies out of 187 adjudicating in real time submitting 15,000 real-time claims per day.
- Most issues raised during pilot phase are now addressed. Largest remaining issue is still related to the small percentage of residents that are deemed eligible through the regional health authorities. These are largely residents of nursing or personal care homes. A focused effort is continuing towards cleaning up these residents on a per pharmacy basis.
- Cards that did not reach beneficiaries continue to be re-directed. IT issues associated with these inaccurate addresses continue to be addressed.
- The remaining Income Support clients who do not have their MCP numbers in the new system (which would allow the issue of their permanent drug cards) have been identified and a process put in place to follow-up.
- The approximately 30,000 rejected pharmacy claims continue to be analyzed for clean-up. A number of them had been cleaned up on the Apr 26/07 pay run, however some pharmacies are resubmitting previously submitted claims and we have no way to determine the number of duplicates vs. new rejections to come up with an accurate number. Xwave is currently assessing the rejected claims for these high-volume pharmacies (that the Division has validated all client card numbers for) to determine the relative number of claims that may have already been resubmitted by the pharmacies.
- Staff of the Pharmaceutical Services Division have been working with those providers with high numbers of rejects associated with wrong ID numbers and are addressing these on a priority basis. In each case a fax is being sent to the pharmacy indicating what the problem was with the ID number, or providing a new correct ID number that can be used for the client. Pharmacies completed to date account for approx 7500 claim rejections and \$325,000 in the value of the rejected claims. In addition to correcting the identifiers, eligibility issues (such as duplicate records) were corrected at the same time to remove other potential causes for rejection.
- The Tentative Agreement reached with the Pharmacists Association of NL (PANL) remains unsigned pending cabinet approval.
- PANL has advised the Department that pharmacies are having difficulty getting through to PSD, Xwave and Stephenville and are kept waiting on the line for 25-40 minutes. This is resulting due to extreme increases in the volume of phone calls to these offices. PSD has added an extra phone line, and continues to explore options and/or modifications to the current information manager, to accommodate the additional calls. Phone messages are being cleared on a regular basis and messages received with any detail provided are being returned as soon as

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possible. A request has also been made to the Office in Stephenville to have a similar analysis of their phone system conducted.

- PANL has also expressed concern regarding some provider's inability to access/read their payment statements. PSD is in the process of trying to obtain more detailed and current information on this, as a number of issues re these statements that had been previously identified are also ready rectified since the initial posting of the statements.
- A number of critical issues and questions have been identified with regards to the design and implementation of the enhancements to NLPDP for high drug costs, with operational and technical implications on the new drug claim adjudication system. Timely resolution of those issues will be critical to meeting the October 2007 launch target for the new drug plan. A number of these have been addressed, and progress is being made in the other areas, through the newly formed implementation team.

Expected activities and developments over the next week:

- Continue the roll-out of the real-time system to the remaining pharmacies, as they are ready. Roll-out of the remaining pharmacies will be limited to their pace. Some are in the process of converting to other vendor software systems or have not yet filled out their applications.
- Continue to work on data clean-up issues, focussing on the nursing home clients who have duplicate and un-linked records.
- Continue to work with Xwave on the reprocessing of rejected batch claims, with the goal of minimizing resubmissions by the pharmacies.
- Continue to prepare communication materials (application forms, information sheets, etc) so as to begin social marketing of the program as soon as the new computer system is operating smoothly.
- Continue with work on Phase II requirements for the real time system (projected implementation date of July 2007). These enhancements should further streamline the adjudication system resulting in more timely access to special authorization medications.

Contact Person: Patricia Clark, 729-1623

**Question and Answer Briefing Note
Department of Health and Community Services**

Title: ER/PR Testing, Eastern Health

Issue: Ongoing concerns regarding ER/PR testing at Eastern Health.

Anticipated Questions:

- Was there an attempt by the Department and/or Eastern Health to “cover up” the findings of the test results?
- Has Eastern Health now notified all affected patients of the results of retesting and why wasn’t this done sooner?
- At what time did former Ministers of Health become aware of this issue and why didn’t they disclose the magnitude of the problem?
- Why was Government and Eastern Health more concerned with the risk of litigation than patient care?
- Can women’s groups be consulted on how the judicial inquiry will be carried out?

Key Messages:

- Absolutely not. There was full disclosure with patients and their families once test results became available. Eastern Health contacted each patient who was affected by the ER/PR test review or their family physician to make sure they received all the information and support they required. They were told either one of three things:
 - That their tissue had been retested and there was no change in the original results;
 - That their tissue had been retested and that Eastern Health was recommending a change in their treatment; or
 - That although there was a change from their original test result, no change in treatment was recommended.
- This issue has also been in the public domain since late 2005. Eastern Health placed an ad in local papers in October 2005 to provide further details and a number where those with questions could call. The accusation that there was a “cover-up” is unfounded.
- The inquiry will address these questions. However, I must reiterate that all patients who were affected by the ER/PR test review were contacted, media interviews were conducted in late 2005 and early 2006, and an ad was placed in the paper in late 2005. There was no attempt to “cover up” this issue. The focus was on the patients who were impacted.
- The context in which I stated that was with respect to why Eastern Health did not release the number of changed test results during a media briefing in December. As Minister, do I feel the number should have been released at that time? Yes, I do. Eastern Health and Government’s primary concern is always that of the patient. The action taken by Eastern Health (retesting, quality assurance program, establishing an expert panel and expert reviews) and full disclosure to patients demonstrates that the patient and the families are the primary concern.

- The Commissioner will determine who he/she will need to hear from during the inquiry. Individuals or groups can apply to the commission to participate in the inquiry.

Background:

- Prior to April 2004, the Dako testing technique was used at Eastern Health’s laboratories which required the manual boiling of tissue samples and the measurement of minute mixtures of immunoperoxidase staining.
- In April 2004, Eastern Health installed the Ventana system for conducting ER/PR testing. This new system automated the process, thereby removing much of the human manipulation of samples.
- In May 2005, a patient who was diagnosed in 2002 with breast cancer and had been determined to be negative using the Dako system, converted to positive after further ER/PR testing using the Ventana system.
- In June – July 2005, Eastern Health conducted a case review of negative ER/PR tests it obtained in 2002. Of 57 cases retested, 37 converted from negative to positive.
- In early July 2005, Eastern Health decided to retest all negative ER/PR tests performed between May 1997 and August 8, 2005. In the review period from 1997 to 2005, there were 2760 ER/PR tests conducted at the laboratories. Nine hundred and thirty-nine (939) of these tests were originally negative and were sent to Mount Sinai for retesting. This number represents about 34% of the patients tested for breast cancer. All new cases were sent to Mount Sinai for ER/PR testing. The chronology of the ER/PR retesting is attached as Annex I.
- The details on the test results are as follows:

• Total Cases Reviewed 1997-2005	2760
• No. of Tests sent to Mount Sinai (763 live; 176 deceased)	939
• Live Patients Whose Samples were Retested	763
- Patients with no change in ER/PR results and no change in treatment recommended	433
- Patients with no change in ER/PR results but a change in treatment recommended by expert panel	13
- Patients where ER/PR test results were different following retesting	317
• Deceased Patients Whose Original ER/PR Test Results were Negative	176
- Patient samples that were retested and results received	101
- Patient samples that have been retested on request	2
- Patient samples that will not be retested unless requested by the families	73

Eastern Health had independent external reviews conducted by the Chief Pathologist at the BC Cancer Institute and the Chief Technologist and Mount Sinai Hospital in Toronto, and has implemented the recommendations from these reviews. In addition, a dedicated laboratory has been established to perform the ER/PR testing with 3 designated technologists, a lab medical director, and a dedicated cutter. A centre of excellence for breast cancer cases has been established at Eastern Health so that examination and reporting will be directed to a dedicated group of pathologists.

- The May 15th CBC story is reporting that of the 763 live patients, upwards of 42% of the test results were wrong (317 of 763 live patients). The story is also focused on why Eastern Health has not released the test results for 176 deceased patients. The story quotes a US pathologist, a leading expert on hormone receptor tests in North America, as saying laboratories across the US are having the same problems with these tests.
- In the December press release, Eastern Health stated that 117 of the 939 patients required treatment changes. This appears to be a 12% error rate. In the court affidavit filed by Eastern Health, the 117 patients include 104 patients who required a treatment change due to a change in ER/PR test results and a further 13 patients who saw no change in their ER/PR test results but a change in treatment was recommended. The US pathologist also states that the average error rate in the US is probably as high as 20%. Eastern Health advises that it is very difficult to confirm an actual error rate as ER/PR testing is a complicated procedure that involves more than 40 steps.
- Eastern Health did not initially advise patients of the retesting (despite the Department's suggestion that it should consider doing so) and many learned of it from the media. Eastern waited for the actual results before disclosing information to the patients as Eastern didn't know what this would mean for individuals without the results. Eastern also did not want to unnecessarily raise alarm for individuals who may not be affected.
- In December 2005, the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.
- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. There are approximately 40 plaintiffs.
- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health has filed an affidavit in court on December 15, 2006. The lawyers for the plaintiff and the defendant have filed documents for certification and case law with the court on February 9, 2007. A hearing of the certification application is scheduled for May 23-25, 2007.

- On Friday, May 18th, Eastern Health provided a media briefing in which CEO George Tilley publicly apologized for any confusion created as a result of not disclosing the total number of changed test results (317).
- Government held a news conference on Tuesday, May 22, to announce that it will undertake a Judicial Commission of Inquiry, with further details to be provided in the coming days.
- There are now calls for women's groups to be consulted on how the judicial inquiry into the faulty breast cancer will be carried out.

Drafted by: ^o Beverley Griffiths, 729-0717

Approved by: Moira Hennessey

Date: May 28, 2007

ANNEX I – CHRONOLOGY OF ER/PR RETESTING

- April 2004 – The former HCCSJ installed a new VENTANA system for the immunohistochemistry lab to replace the DAKO system.
- May 2005 – An oncologist noted that a patient, diagnosed in 2002 with breast cancer who tested negative* on the DAKO system, converted to positive in 2005 on the new VENTANA system. Oncologists decided further retest 25 negative patients from 2002. If the 25 retested, 12 converted to positive. An additional 32 negative tests were retested and 25 of the 32 converted to positive on the VENTANA system.
- June 2005 – decision made to retest all patients who were ER/PR negative for the year 2002.
- Early July 2005 – decision made to retest all patients who were ER/PR negative between May 1997 and August 8, 2005.
- Late July 2005 – decision made to arrange for an independent laboratory to complete retesting (Mount Sinai) and all new patients. All testing of ER/PR at the Health Sciences laboratory was stopped.
- August 2005 - process of collecting, packaging and shipping negative test results to Mount Sinai Hospital in Toronto began.
- October 2005 – Tumor board, consisting of two oncologists, two surgeons, two pathologists, one representative from quality department and one support person, was established to review the results as they arrived back from Mount Sinai and made treatment recommendations for each patient. Patients were contacted about specimens being sent away for retesting. This Board met weekly from October 2005 to May 2006 to review individual patient files, assess the impacts and make treatment recommendations.
- Mid October 2005 – Media interviews conducted and advertising purchased to inform the public of specimens sent for retesting.
- December 2005 – Mt. Sinai Hospital contacted by Eastern Health to express concerns on the slow pace of having the testing completed and the reports sent back (manpower issues reported by Mt. Sinai).
- December 7, 2005 – A statement of claim was filed in the Supreme Court of NL Trial Division on behalf of Michelle B. Hanlon.
- February 2006 – the last test results were received from Mount Sinai.
- February to May 2006 – Tumor board reviewed test results, wrote recommendations and disclosed information individually to each patient.
- May 11, 2006 A Statement of Defence is filed with the Supreme Court of NL on behalf of Michelle B. Hanlon.
- June to November 2006 – the new chief pathologist and new VP – Medical Services established a centre of excellence for breast cancer pathology, assigned a head pathologist for immunohistochemistry and prepared to resume ER/PR testing in St. John's and in September the accreditation process for the lab was initiated.

- Late November 2006 – Eastern Health completes its quality review.
- December 11, 2006 – Eastern Health releases outcomes of laboratory review to the public. A technical briefing was also provided to the media and since that time, one client issue was identified. The individual had not been seen by a doctor to obtain her test results despite a number of attempts by Eastern Health to establish contact. She has since received follow up by the physician.
- February 2007 - An affidavit was filed in the Supreme Court of NL between Verna Doucette (plaintiff) and Eastern Health (Defendant)
- February 2007 – lawyers for the plaintiff and the defendant have filed documents for certification and case law.
- On May 23-25, a hearing of the certification application is scheduled in Supreme Court.

**The definition of "negative" has changed within this 7 year period. Oncologists previously believed that tumours with less than 30% positivity for ER/PR should be considered negative. With advancing understanding of cancer and treatment, the negative rate has dropped down to 10% and now to 1%. Today, oncologists believe that any positive result is worthy of hormonal therapy.*

Issue: Retesting of Breast Cancer Patients – ER/PR**Activities/Developments To Date:**

- In December 2006, Eastern Health released the outcome of a laboratory review of ER/PR retesting of breast cancer patients. The review involved 939 patients with negative ER/PR test results between 1997 and August 2005.
- This issue has been in the public domain since late 2005. During a media briefing on December 11, 2006 Eastern Health reported that 939 patients were retested and 117 patients were recommended for treatment changes based on a review of the test results by a Tumour Board.
- Prior to the December 2006 release of the test results, two court cases were initiated – one case is by a family of a deceased breast cancer patient and the second case is a class action suit by about 40 plaintiffs.
- In early May 2007, the media obtained court affidavits which include additional details about the test results. The affidavits state that the 939 patients include 763 live and 176 deceased patients. The information also states that 317 of the 763 live patients had changes in their test results, including the 117 women who had recommended treatment changes.
- The ER/PR retesting issue resurfaced in the public domain during the May 14 week.
- On May 18, Eastern Health held a media briefing and the CEO apologized for the confusion that has ensued about ER/PR retesting results. He stated that 'at no time did Eastern Health withhold any personal information from any of the patients impacted by our decision to retest for ER/PR'.
- This issue has received a lot of media attention in the past two weeks, provincially and nationally. Eastern Health and the Government have been accused of covering up test results. The HCS Minister has been asked a lot of questions by the Opposition in the media and the House of Assembly.

Activities/Developments This Week:

- On May 22, Government announced it will undertake a judicial Commission of Inquiry on ER/PR testing for breast cancer patients. The Commission's report will endeavour to get answers to what happened to ensure that this situation will not reoccur. The Commission's report will be released publicly.
- A hearing on the certification for the class action suit took place in Supreme Court, May 23-25, 2007. The number of plaintiffs who have joined the lawsuit has increased following events of the past two weeks.
- Ms. Gerrie Smith, Solicitor, Department of Justice, is monitoring the legal proceedings with Eastern Health's lawyer.

Expected Activities/Developments in the Next Week:

- The ER/PR testing results will likely garner further attention in the media and the House of Assembly. The Department will continue to monitor this situation and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths Number: 729-0717

May 31/07

Issue: Retesting of Breast Cancer Patients – ER/PR**Activities/Developments This Week:**

- On May 28, Justice Carl Thompson certified a class action suit on hormone receptor testing. The lawyer, Ches Crosbie, who filed the certification advised the media that there is a possibility of an out of court settlement before the matter is heard again in court.
- On May 29, The Telegram reported that according to Mr. Crosbie, there could be about 2,800 women who received a hormone receptor test between 1997 and 2005 are now eligible to sign on to the class action. This number, according to Mr. Crosbie includes: “mental distress claimants” whose results were not found to be wrong but may have suffered distress due to Eastern Health failing to provide information in a timely manner.
- Ms. Gerrie Smith, Solicitor, Department of Justice, is monitoring the legal proceedings on the class action suit with Eastern Health’s lawyer.
- Eastern Health has ten days (from May 28) to appeal the certification decision to the Court of Appeal.
- The litigation process includes: notification (of all potential claimants, exchanges of documents), discovery (questioning of the parties, witnesses) and settlement process (conference, pre-trial and if issues are not resolved a trial).
- There continues to be local media attention, including a focus on a 2003 letter written by a pathologist about concerns related to ER/PR testing.

Expected Activities/Developments in the Next Week:

- Approximately 2,700 potential class members will be notified of the certification and legal counsel for Eastern Health will meet with the plaintiff’s counsel to discuss the notification process next week.
- The Department will continue to monitor this situation and provide updates to the HCS Minister and the Premier’s Office as required.

Contact Person: Bev Griffiths
June 1, 2007

Number: 729-0717

Issue: Retesting of Breast Cancer Patients – ER/PR**Activities/Developments This Week:**

- On May 28, Justice Carl Thompson certified a class action suit on hormone receptor testing.
- Eastern Health has ten days (from May 28) to appeal the certification decision to the Court of Appeal. The Department does not have any indications to date that Eastern will appeal the decision.
- Approximately 2,700 potential class members will be notified of the certification. Legal counsel for Eastern Health met with the plaintiff's counsel to discuss the form of the notification and the certification order on June 6.

Expected Activities/Developments in the Next Week:

- The Department will continue to monitor this situation and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths
June 7, 2007

Number: 729-0717

**Question and Answer Briefing Note
Department of Health and Community Services**

Title: ER/PR Testing, Eastern Health

Issue: Ongoing concerns regarding ER/PR testing at Eastern Health. On May 28, Justice Carl Thompson of the NL Supreme Court certified a class action suit on behalf of up to 100 individuals. The Opposition may ask about Government settling the matter out of court.

Anticipated Questions:

- Will Government consider settling this out of court rather than go through litigation?
- Was there an attempt by the Department and/or Eastern Health to “cover up” the findings of the test results?
- Has Eastern Health now notified all affected patients of the results of retesting and why wasn’t this done sooner?
- At what time did former Ministers of Health become aware of this issue and why didn’t they disclose the magnitude of the problem?
- Why was Government and Eastern Health more concerned with the risk of litigation than patient care?
- Can women’s groups be consulted on how the judicial inquiry will be carried out?

Key Messages:

- The Judge’s decision on the certification of the class action suit was made on May 28. It is premature to determine next steps. We understand from the media that Mr. Crosbie will be speaking to Eastern Health’s lawyer and we will monitor these discussions. I will be refraining from any further public comment.
- Absolutely not. There was full disclosure with patients and their families once test results became available. Eastern Health contacted each patient who was affected by the ER/PR test review or their family physician to make sure they received all the information and support they required. They were told either one of three things:
 - That their tissue had been retested and there was no change in the original results;
 - That their tissue had been retested and that Eastern Health was recommending a change in their treatment; or
 - That although there was a change from their original test result, no change in treatment was recommended.
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- Government held a news conference on Tuesday, May 22, to announce that it will undertake a Judicial Commission of Inquiry, with further details to be provided in the coming days.
- There are now calls for women's groups to be consulted on how the judicial inquiry into the faulty breast cancer will be carried out.
- In December 2005, the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but

on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.

- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. There were approximately 40 plaintiffs when the claim was filed.
- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health filed an affidavit in court on December 15, 2006. The lawyers for the plaintiff and the defendant filed documents for certification and case law with the court on February 9, 2007.
- A hearing of the certification application for the class action suit was held on May 23-25, 2007. On May 28, Justice Carl Thompson certified the class action suit. The lawyer, Ches Crosbie, who filed the certification advised the press that there is a possibility of an out of court settlement before the matter is heard again in court.
- On May 29, The Telegram reported that according to Mr. Crosbie, there could be about 2,800 women who received a hormone receptor test between 1997 and 2005 are now eligible to sign on to the class action. This number, according to Mr. Crosbie includes: "mental distress claimants" whose results were not found to be wrong but may have suffered distress due to Eastern Health failing to provide information in a timely manner.
- Ms. Gerrie Smith, Solicitor, Department of Justice, is monitoring the legal proceedings with Eastern Health's lawyer. **She advised that on June 6 the legal counsel for Eastern Health met with the plaintiff's counsel to discuss preparing the certification order and the process for notification.**
- The Class Action Litigation process has been implemented and Eastern Health has ten days from when the certification order is completed to appeal the certification decision to the Court of Appeal. Common issues for the class action will be tied together and any individual issues related to liability or damages will be with the individual.
- The litigation process includes: notification (of all potential claimants, exchanges of documents), discovery (questioning of the parties, witnesses) and settlement process (conference, pre-trial and if issues are not resolved a trial).
- DHCS, the Centre for Health Information (NLCHI) and Eastern Health met on June 14 to discuss the data base management process to be implemented this week. This process will focus on when patients were contacted to inform them of the retesting as well as when patients were informed of the test results.

Drafted by: Beverley Griffiths, 729-0717

Approved by: Moira Hennessey

Date: June 14, 2007

Issue: Retesting of Breast Cancer Patients – ER/PR**Activities/Developments This Week:**

- On May 28, Justice Carl Thompson certified a class action suit on hormone receptor testing.
- Eastern Health has ten days after the certification order (yet to be completed) to appeal the certification decision to the Court of Appeal.
- Approximately 2,700 potential class members will be notified of the certification order. Legal counsel for Eastern Health met with the plaintiff's counsel on June 6 to discuss the process for notification and completion of the certification order.
- On June 14, Government announced that the Honourable Justice Margaret A. Cameron will be appointed as Commissioner of the Judicial Commission of Inquiry on estrogen and progesterone receptor testing for breast cancer patients. Justice Cameron will officially begin her work as Commissioner on July 3, 2007 and will deliver her final report to the Minister of Health and Community Services on July 30, 2008.

Expected Activities/Developments in the Next Week:

- The Department will continue to monitor this situation and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths
June 15, 2007

Number: 729-0717

Issue: Retesting of Breast Cancer Patients – ER/PR**Activities/Developments This Week:**

- The NL Centre for Health Information (NLCHI) is working with Eastern Health to develop a data base to reflect Eastern Health's activities around the retesting of ER/PR test results and communication with patients and physicians. The estimated timeframe is six – ten weeks.
- A Globe and Mail headline this week was "No Room for Secrecy when Lives are at Stake". The article says that women were betrayed by a health system that did not have checks and balances in place and were treated dismissively by officials. The reporter calls on the need for openness, communication and accountability in the health system.

Expected Activities/Developments in the Next Week:

- The Department will continue to monitor this situation and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths
June 22, 2007

Number: 729-0717

**Issue Monitoring Report
Department of Health and Community Services
June 28, 2007**

Issue: Retesting of Breast Cancer Patients – ER/PR

Activities/Developments This Week:

- The NL Centre for Health Information (NLCHI) is continuing its work with Eastern Health to develop a data base to reflect Eastern Health's activities around the retesting of ER/PR test results and communication with patients and physicians. The estimated timeframe for completion is six – ten weeks.

Expected Activities/Developments in the Next Week:

- The Department will continue to monitor this situation and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Beverley Griffiths, 729-0717

Issue: Retesting of Breast Cancer Patients – ER/PR**Activities/Developments This Week:**

- The NL Centre for Health Information (NLCHI) is continuing its work with Eastern Health to develop a data base to reflect Eastern Health's activities around the retesting of ER/PR test results and communication with patients and physicians. The estimated timeframe for completion is six – ten weeks.

Expected Activities/Developments in the Next Week:

- The Department will continue to monitor this situation and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths
June 29, 2007

Number: 729-0717

Issue: Retesting of Breast Cancer Patients – ER/PR**Activities/Developments This Week:**

- The NL Centre for Health Information (NLCHI) commenced development of a data base on July 3rd to reflect the testing results and communication with patients and physicians. The estimated timeframe for completion of the data base is six – ten weeks. The Department expects to receive a scoping document from NLCHI on July 6.
- The Department has received three requests, under the ATIPP Act for information respecting the ER/PR hormone receptor testing issue. A review of the relevant documents in the context of the Act is underway.
- The Terms of Reference for the Judicial Commission of Inquiry on ER/PR Hormone Receptor Testing for Breast Cancer Patients were released this week. There was local and national media coverage. The Opposition Justice Critic issued a media release seeking clarification on the terms of reference.

Expected Activities/Developments in the Next Week:

- The response date for the ATIPP requests is July 12, 2007. The Department plans to reply by that date.
- Justice Margaret Cameron is expected to provide further details to the public regarding process and timelines next week.
- The Department will continue to monitor the work being done by NLCHI and other issues that may arise and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths
July 6, 2007

Number: 729-0717

**Issues Monitoring Report
Department of Health and Community Services
July 6, 2007**

Issue: Retesting of Breast Cancer Patients – ER/PR

Activities/Developments This Week:

- The NL Centre for Health Information (NLCHI) commenced development of a data base on July 3rd to reflect the testing results and communication with patients and physicians. The estimated timeframe for completion of the data base is six – ten weeks. The Department expects to receive a scoping document from NLCHI on July 6.
- The Department has received three requests under the ATIPP Act for information respecting the ER/PR hormone receptor testing issue. A review of the relevant documents in the context of the Act is underway.
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Expected Activities/Developments in the Next Week:

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- Justice Margaret Cameron is expected to provide further details to the public regarding process and timelines next week.
- The Department will continue to monitor the work being done by NLCHI and other issues that may arise and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Beverley Griffiths, 729-0717

Issue: Retesting of Breast Cancer Patients – ER/PR**Activities/Developments This Week:**

- The Department reviewed a scoping document provided by the Newfoundland and Labrador Centre for Health Information (NLCHI) on July 6 and provided direction to NLHC on July 9. NLCHI will now start to develop a patient master list (n=2760) and complete the communication event fields as required by the Department. The estimated timeframe for completion of this project is eight – ten weeks.
- The Department has completed its review of three requests under the ATIPP Act for information respecting the ER/PR hormone receptor testing issue. A letter was provided to the applicant on July 12 stating that the Department will provide upon payment of the required fee, the briefing notes requested but some information will be severed under specific sections of the ATIPP Act.

Expected Activities/Developments in the Next Week:

- Subject to release of the briefing notes requested under the ATIPP request, it is expected that there will be renewed media attention on this issue.
- The Department will continue to monitor the work being done by NLCHI and other issues that may arise and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths
July 13, 2007

Number: 729-0717

Issue: Retesting of Breast Cancer Patients – ER/PR

Activities/Developments This Week:

- The Department reviewed a scoping document provided by the Newfoundland and Labrador Centre for Health Information (NLCHI) on July 6 and provided direction to NLHC on July 9. NLCHI will now start to develop a patient master list (n=2760) and complete the communication event fields as required by the Department. The estimated timeframe for completion of this project is eight to ten weeks.
- The Department has completed its review of three requests under the ATIPP Act for information respecting the ER/PR hormone receptor testing issue. A letter was provided to the applicant on July 12 stating that the Department will provide upon payment of the required fee, the briefing notes requested but some information will be severed under specific sections of the ATIPP Act.

Expected Activities/Developments in the Next Week:

- Subject to release of the briefing notes requested under the ATIPP request, it is expected that there will be renewed media attention on this issue.
- The Department will continue to monitor the work being done by NLCHI and other issues that may arise and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Beverley Griffiths, 729-0717

Issue: Retesting of Breast Cancer Patients – ER/PR**Activities/Developments This Week:**

- The work being done by the Newfoundland and Labrador Centre for Health Information (NLCHI) on the development of a patient master list is ongoing. Data sources being used include patient lists from the four regional health authorities, the provincial Cancer Tumour Registry, and the patient list from Mount Sinai Hospital. Once the patient master list is completed, it will be populated with the test results and the communication event fields as requested by the Department.
- The Department provided a reply to the ATIPPA request on the ER/PR hormone receptor testing on July 17. There has been no media attention at this time.
- Madame Justice Cameron announced that Bernard Coffey and Sandra Chaytor were appointed as co-legal counsel for the Commission of Inquiry into the ER/PR Hormone Receptor Testing.

Expected Activities/Developments in the Next Week:

- The Department will continue to monitor the work being done by NLCHI and other issues that may arise and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths
July 20, 2007

Number: 729-0717

Issue: Retesting of Breast Cancer Patients – ER/PR**Activities/Developments This Week:**

- The work being done by the Newfoundland and Labrador Centre for Health Information (NLCHI) on the development of a patient master list is ongoing. Development of database of breast cancer patients from 1997-2005 is now be worked on full-time with completion expected by August 17th. Regional Authorities are submitting their data to the Centre. A letter has been sent to Mt. Sinai Hospital, Toronto requesting client data.

Expected Activities/Developments in the Next Week:

- The Department will continue to monitor the work being done by NLCHI and other issues that may arise and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths
July 26, 2007

Number: 729-0717

Issue: Retesting of Breast Cancer Patients – ER/PR**Activities/Developments This Week:**

- The work being done by the Newfoundland and Labrador Centre for Health Information (NLCHI) on the development of a patient master list is ongoing and is expected to be completed in early September.
- The focus on the review is on the patients who had samples sent to Mount Sinai for retesting.

Expected Activities/Developments in the Next Week:

- The Department will continue to monitor the work being done by NLCHI and other issues that may arise and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths
August 3, 2007

Number: 729-0717

**Issue Monitoring Report
Department of Health and Community Services
August 3, 2007**

Issue: Retesting of Breast Cancer Patients – ER/PR

Activities/Developments This Week

- The work being done by the Newfoundland and Labrador Centre for Health Information (NLCHI) on the development of a patient master list is ongoing and is expected to be completed in early September.
- The focus on the review is on the patients who had samples sent to Mount Sinai for retesting.

Expected Activities/Developments in the Next Week:

- The Department will continue to monitor the work being done by NLCHI and other issues that may arise and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths, Number: 729-0717

Issue: Retesting of Breast Cancer Patients – ER/PR**Activities/Developments This Week:**

- The work being done by the Newfoundland and Labrador Centre for Health Information (NLCHI) on the development of a patient master list is ongoing and is expected to be completed in early September. The focus on the review is on the patients who had samples sent to Mount Sinai for retesting.
- Eastern Health has responded to an ATIPPA request on the release of hormone receptor test results that were sent for retesting to Mount Sinai. The information includes the original result and the result for each retest. Since the ATIPPA request was from an individual working with the Canadian Broadcasting Corporation, there is potential for further public attention to this matter.

Expected Activities/Developments in the Next Week:

- The Department will continue to monitor the work being done by NLCHI and other issues that may arise and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths
August 10, 2007

Number: 729-0717

**Issue Monitoring Report
Department of Health and Community Services
August 10, 2007**

Issue: Retesting of Breast Cancer Patients – ER/PR

Activities/Developments This Week

- The work being done by the Newfoundland and Labrador Centre for Health Information (NLCHI) on the development of a patient master list is ongoing and is expected to be completed in early September. The focus on the review is on the patients who had samples sent to Mount Sinai for retesting.
- Eastern Health has responded to an ATIPPA request on the release of hormone receptor test results that were sent for retesting to Mount Sinai. The information includes the original result and the result for each retest. Since the ATIPPA request was from an individual working with the Canadian Broadcasting Corporation, there is potential for further public attention to this matter.

Expected Activities/Developments in the Next Week:

- The Department will continue to monitor the work being done by NLCHI and other issues that may arise and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths, Number: 729-0717

Issue: Retesting of Breast Cancer Patients – ER/PR**Activities/Developments This Week:**

- The work being done by the Newfoundland and Labrador Centre for Health Information on a master patient list is ongoing.
- A Notice of Hearing was published in the Telegram on August 15 to advise of the appointment of Justice M. Cameron as the Commissioner of the Inquiry on Hormone Receptor Testing. The inquiry is divided into two parts. I) the Commission will inquire into/report on problems with tests conducted between 1997 and 2005 and examine protocols and steps taken by the responsible authorities upon becoming aware of the problem, and II) policy focus to include a review of the policy and legal issues raised by the Terms of Reference. The second part of the review will also include an examination of the testing systems/processes/quality assurance systems in place that are reflective of best practices. Applications are invited by interested individuals/organizations for standing and funding in relation to Part I and II of the inquiry and will be heard on September 19, 20 and 24, 2007. No evidence will be heard during these times.
- On August 15, the Telegram also printed a notice of Breast Cancer Testing Class Action to the attention of Breast Cancer Patients of Eastern Health, Estates of the Deceased Patients and other affected persons. The notice involves information related to the action being taken, the fees and disbursements and advises on the process for patients who wish to opt out of the class action. The notice advises that no action is required if you wish to continue with the class action. Information contacts are listed as Ches Crosbie Barristers and Eastern Health.
- There has been no media coverage this week.

Expected Activities/Developments in the Next Week:

- The Department will continue to monitor the work being done by NLCHI and other issues that may arise and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Bev Griffiths
August 16, 2007

Number: 729-0717

**Issue Monitoring Report
Department of Health and Community Services
August 17, 2007**

Issue: Retesting of Breast Cancer Patients – ER/PR

Activities/Developments This Week:

- The work being done by the Newfoundland and Labrador Centre for Health Information on a master patient list is ongoing.
- A Notice of Hearing was published in the Telegram on August 15 to advise of the appointment of Justice M. Cameron as the Commissioner of the Inquiry on Hormone Receptor Testing. The inquiry is divided into two parts. I) the Commission will inquire into/report on problems with tests conducted between 1997 and 2005 and examine protocols and steps taken by the responsible authorities upon becoming aware of the problem, and II) policy focus to include a review of the policy and legal issues raised by the Terms of Reference. The second part of the review will also include an examination of the testing systems/processes/quality assurance systems in place that are reflective of best practices. Applications are invited by interested individuals/organizations for standing and funding in relation to Part I and II of the inquiry and will be heard on September 19, 20 and 24, 2007. No evidence will be heard during these times.
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- There has been no media coverage this week.

Expected Activities/Developments in the Next Week:

- The Department will continue to monitor the work being done by NLCHI and other issues that may arise and provide updates to the HCS Minister and the Premier's Office as required.

Contact Person: Beverley Griffiths, 729-0717