

**Thompson, Robert**

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**From:** Power, Glenda  
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**To:** Matthews, Elizabeth; Turpin, Carmel; Cheeseman, Josephine  
**Cc:** Furlong, Tara; Thompson, Robert  
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Health and Community Services  
February 21, 2008

**Update Provided on ER/PR Database, Minister Outlines Actions to Strengthen Health Care System**

The Honourable Ross Wiseman, Minister of Health and Community Services, today released key results of the ER/PR database compiled by the Newfoundland and Labrador Centre for Health Information, while also providing details on a series of measures the Provincial Government is implementing to strengthen the health care system.

The province engaged the Newfoundland and Labrador Center for Health Information to develop the database to ensure a thorough understanding and documentation of key dates and results related to ER/PR testing and how patients were contacted about the re-testing process. The database is now substantially completed.

"We have examined the most recent data and it reinforces a key learning for us on the inadequacy of the previous record keeping related to the problems with ER/PR testing," said Minister Wiseman. "The database compiled is the most comprehensive one that exists and I am pleased that the Commission of Inquiry will now have this information as a resource for its use in examining the issues related to ER/PR testing. Our goal is that the people of this province have the best understanding possible of what happened with respect to hormone receptor testing for breast cancer patients."

The completed database includes data that reveals changes in previously reported information. In May 2007, Eastern Health reported that the total number of patients re-tested was 939 and that of the patients whose results were re-tested, 176 were deceased. The database shows that at that time 1013 patients had been re-tested and that of those, 273 were deceased. In addition, it has been determined that 49 patients who should have been contacted by Eastern Health were either not contacted or there is no verification of contact.  
CONTACT NOW MADE??

"We certainly have to focus on learning some valuable lessons here and to take action to ensure that the patients of our health care system are never faced with a situation again like we have experienced with ER/PR testing," said Minister Wiseman. "Even though the work of the Commission is underway, there are specific areas where we can take action now. We are committing \$2.3 million today to enhance data management capabilities and quality assurance measures within the health care system."

To enhance data management, Budget 2008-09 will include \$2.1 million for the consolidation of clinical information systems within Eastern Health, a plan for consolidation of similar systems in other regional health authorities, a needs assessment for electronic document tracking systems for each health authority, and funding for 5 new data management professionals throughout the system. These investments will help improve response times and completeness of data when searching for patient information in the future, and ensure that more tools are available when managing a response to an adverse event.

“Enhanced data management is a critical component as we look at the lessons we’ve learned. In addition, we also recognize the fundamental necessity of comprehensive quality assurance programs,” said Minister Wiseman. “That is why our government is initiating province-wide accreditation for all laboratories and diagnostic imaging services – a measure that I know will be embraced by our four health authorities. We are allocating \$100,000 in 2008-09 for the necessary planning for the establishment of an accreditation system.”

The Provincial Government has also approved an additional \$175,000 per year for Eastern Health to follow through on education, training and quality assurance activities related to ER/PR testing. In particular, this funding will allow for pathologists and technologists to participate in relevant training programs each year, and allow for external reviewers to visit the Eastern Health laboratory to assess current practice against best practices elsewhere.

In addition to initiatives related to improvements based on lessons learned with respect to ER/PR testing, Minister Wiseman also outlined two additional measures designed to strengthen the delivery of quality health care programs and services.

“Our government will immediately establish a Quality Network team which will be led by my department to assess quality assurance initiatives, infection control programs, patient safety, risk management programs and clinical practice guidelines within our four regional health authorities,” said Minister Wiseman. The Quality Network team will work to assess processes and ensure standards across the health care system.

“Furthermore, our department will be working with our regions to identify all outstanding issues related to the transition to the four authorities that began in 2005. We want to determine unequivocally what these outstanding issues currently are and what resources are necessary to deal with them in the quickest way possible,” said Minister Wiseman. “I am confident that these actions will serve to strengthen our health care system and thereby enhance the provision of quality health services to all Newfoundlanders and Labradorians.”

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## **BACKGROUNDERS**

### **\$2.3 Million Invested for Enhanced Data Management and Quality Assurance**

#### Data Management

- The Provincial Government will commit \$2.1 million in the 2008-09 budget for the following items:
  1. \$1.3 million will be allocated to Eastern Health to allow for consolidation of clinical information systems onto a single platform (laboratory, diagnostic imaging, medical records, admissions, nursing order entry, pharmacy and patient care inquiry). As the other regional health authorities are at different stages in clinical consolidation, a plan will be developed to ensure clinical consolidation in all areas of the province as soon as possible. In the long term, the adoption of an electronic patient record within each health authority will improve decision making, response to adverse events and patient safety.
  2. \$500,000 will be allocated for all regional health authorities to conduct an Information Management Capacity Assessment, which is the first step towards implementation of electronic document management systems.
  3. \$270,000 will be allocated for new data management personnel.
- The Provincial Government and the regional health authorities will establish a new policy that whenever there is an adverse event that requires communication, testing or treatment for a group of patients, a single official is to be charged with clear organization-wide responsibility for directing patient contact and data management. This official must have access to an appropriately skilled data management professional trained to use or design an information system which can acquire comprehensive data for all events in the response process, provide timely reports, and can be audited

#### Quality Assurance and Monitoring

- The Provincial Government has approved \$175,000 per year for Eastern Health to implement education, training and quality assurance activities in immunohistochemistry (IHC). In particular, this funding will allow for pathologists and technologists to participate in relevant training programs each year, and allow for external reviewers to visit the Eastern Health IHC laboratory to assess current practice against best practices elsewhere.
- The province and regional health authorities have agreed to mandatory accreditation of laboratories and diagnostic imaging services. An allocation of \$100,000 in 2008-09 will allow for a plan for the establishment of an accreditation system.

## **ER/PR Database – An Overview and Findings**

#### Purpose

The purpose of the database is to provide an objective foundation for describing the 2005-

2007 ER/PR (Estrogen Receptor and Progesterone Receptor) testing and retesting process.

### Background

- ER/PR testing is a major factor in determining whether a breast cancer patient is offered Tamoxifen or aromatase inhibitor as part of their post-surgical breast cancer treatment. A positive ER/PR test result indicates that Tamoxifen should be considered; a negative result indicates that Tamoxifen may not be of benefit for the patient.
- On May 18, 2007, Eastern Health reported publicly that the tissue samples of 939 patients were re-tested at Mount Sinai Hospital for ER/PR hormone receptivity. The original tissue samples were tested between 1997 and 2005. Of the 939 patients, 763 were reported as living and 176 deceased.
- Detailed re-test results were reported by Eastern Health for the 763 living patients. Eastern Health said that 381 patients had their original results confirmed at Mount Sinai; 117 patients were recommended for treatment change; 217 patients had changed results but did not require treatment change; and 52 had 'ductal carcinoma in situ' (DCIS) for which no form of treatment would have been recommended.

### Database Approach

- The focus of Eastern Health's re-testing effort was to re-test every ER/PR negative patient that had an original test at the General Hospital site between January 1, 1997 and August 1, 2005. The Department of Health and Community Services asked the Newfoundland and Labrador Centre for Health Information (NLCHI) to construct a database on all patients that fell within the same parameters. Eastern Health endorsed the NLCHI project and cooperated fully in the data collection process.
- Given that Eastern Health is the only site for ER/PR testing in the province, it received tissue samples from many surgical sites in the province between 1997 and 2005, and after the establishment of the testing process in 1997 and 1998 it returned the prepared slides for interpretation by pathologists at these other sites. Therefore, the database reflects test and re-test results for patients from all regions.
- Data were gathered by NLCHI on such topics as date of original test, original test result, data of re-test, re-test result, date of contact with patient, and related patient information.

### Challenges

- The key challenge which NLCHI faced in preparing the database was the lack of a single information system in Eastern Health which contained all the relevant data. Further, the spreadsheets and records used by Eastern Health to coordinate the re-testing process did not contain results on all the patients who had been re-tested. Therefore, the methodology used by NLCHI was to draw data from a variety of information systems, and to cross-check between those systems to make sure all patients were included.
- Between 2005 and 2007, Eastern Health used spreadsheet software to track the re-testing process. The main spreadsheet was regularly updated without maintaining old versions when a new version was created. Consequently, the specific version containing the 939 cases noted above no longer exists and there is no way of recreating it in the absence of knowledge as to which cases were included at that time and which ones were not. This limitation prevented NLCHI from verifying the exact count which was reported by Eastern Health on May 17, 2007, and on previous dates when reports had been provided.
- Despite this limitation, NLCHI was able to construct a database which reflects the known original ER/PR negative patients, plus their retesting results and other related information. The Eastern Health total of 939 was first developed between August 2006 and May 2007, and is not directly comparable to the higher number of cases which has been identified by

NLCHI.

### Results

- Total Number of 1997-2005 ER/PR cases (or patients) that were sent to/retested at Mount Sinai - 1013
- Total number of ER-negative patients that were sent to/retested at Mount Sinai – 995 (accounting for 1112 unique tests)
- Number of deceased, November 2006 – 293 (out of 1013)
- Number of deceased, November 2007 – 321 (out of 1013)
- Change Rate (i.e., the proportion of negative tests that changed to positive upon retesting) – This rate is presented at three different cutoff points corresponding to:
  1. The clinical approach used in Newfoundland and Labrador (1997-2005 negative is less than or equal to 30%; 2001-2005 negative is less than or equal to 10%);
  2. 10% across all years; and
  3. a 1% technical definition used in a laboratory context to evaluate the technical aspects of a test.

This rate is also presented according to two different approaches to inclusion of the PR test: 1) the change rate for ER only, and 2) the change rate for the combination of ER negative and PR negative results for each test.

<b>Cutoff Points (%)</b>	<b>ER Negative Change Rate (%)</b>	<b>ER-/PR- Change Rate (%)</b>
30%: 1997-2000 10%: 2001-2005	42.8	33.0
10%: 1997-2005	45.6	33.4
1%: 1997-2005	39.8	19.6



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