

Thompson, Robert

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Health and Community Services
February 21, 2008

Update Provided on ER/PR Database, Minister Outlines \$2.3 Million Investment to Strengthen Health Care System

The Honourable Ross Wiseman, Minister of Health and Community Services, today released key results of the Estrogen Receptor/ Progesterone Receptor (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, including the establishment of a Quality Network team to ensure best standards across the system.

In May, 2007, the Provincial Government appointed Robert Thompson as Secretary to Cabinet for the Management of Health Issues. In this role, Mr. Thompson has responsibility for preparing the Provincial Government for full and open participation in the upcoming Commission of Inquiry on Hormone Receptor Testing. This work included the engagement of the Newfoundland and Labrador Center for Health Information to develop a 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 critical 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."

DRAFT "We understand this has been a long and difficult process for patients and families," said Pat Pilgrim, Chief Operating Officer for Cancer Care, Quality/Risk Management with Eastern Health. "We have worked diligently in cooperation with the Center for Health Information to help ensure this new database is as comprehensive as possible and I am certain it will be very helpful to the Commission."

The most recent database includes data changes from previously reported information. Overall, 1013 patients have been re-tested and of those, 293 were deceased by late 2006. 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. In addition, it has been determined that 49 patients who should have been contacted about their re-testing were either not contacted or there is no verification of contact. While Eastern Health undertook a province-wide information campaign to ensure broad public awareness and provide contact information for patients, the regional health authorities have been asked to contact these 49 people immediately.

"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."

"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 best practices 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.

"Our government is also committing \$2.3 million today to enhance data management capabilities and quality assurance measures within the health care system," said Minister Wiseman. "This investment is a necessary one that will build on our lessons learned as we move forward."

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.

"I am confident this array of actions by our government will strengthen our health care system as we continue to work to ensure the provision of quality health care services and programs for the people of this province," said Minister Wiseman.

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BACKGROUND

\$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.
 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.



Technical Briefing ER/PR Database

February 19, 2008

DRAFT



Introduction

- Technical briefing on the conclusion of the ER/PR database project
- No clinical opinions; no evaluations of ER/PR testing performance.



Background

- June 2007 – questions asked about patient contact. Was everyone contacted?
- Department asked Newfoundland and Labrador Centre for Health Information (NLCHI) to prepare database on communications and clinical information. Eastern Health endorsed and provided cooperation.
- Will assist work of Commission.
- July 2007 – work commences (2 full time staff)

Content and Methodology

- Content
 - Original scores/Mount Sinai scores
 - Dates of testing/retesting
 - Region
 - Gender
 - Type of contact/date of contact
- Methodology
 - Data linked to source documents where available
 - Multiple sources cross-checked
 - All four RHAs involved

Database Limitations

- Multiple sources of data needed reconciliation
- Many paper-based systems still in use
- Information systems did not always “talk” to each other
- Data up to ten years old
- Some retests were done on different samples than original tests

Number of Patients

- 2006-11-23 – Eastern Health reported 939 patients were retested.
- ER-negative was main criterion for retesting.
- 2007-11-02 – Ministerial update – approximately 1000
- Database Result – 1013 people were retested at Mount Sinai; 995 of which were ER-negative.
- 995 patients had 1112 ER/PR tests

Number of Deceased

- 2006-11-23 (and 2007-05-17) Eastern Health reported 176 deceased out of the 939 patients sent to Mount Sinai.
- Did not use Provincial Mortality Database (PMD) to identify deceased patients.
- PMD measures “all source” mortality
- Database result - 293 patients were deceased on 2006-11-23 (321 one year later)
- This issue is one of data; not patient care or treatment.



Contact with Families of Deceased

- Some families of deceased have already obtained results.
- In May 2007 Eastern committed to test all deceased and make results available.
- Eastern will announce that data is now ready for families to access.



What is a Change Rate?

- The proportion of negative tests that changed to positive after retesting
- E.g., conversion rate; false negatives

Cutoff Points

- Clinical context:
 - 1997-2000: less than 30% staining is negative; greater than 30% is positive.
 - 2001-2005: less than 10% staining is negative; greater than 10% is positive
- Technical Context:
 - Any staining is positive (e.g., 1% or greater)

Studies which address issue of false negatives in IHC Testing



Authors	Cutoff	Findings
Rüdiger et al (2002)	Unknown	11% false negative rate
Layfield et al (2003)	Variable cutoffs	Arbitrary cut point - 26% disagreement between labs Uniform cut points used – 28% disagreement between labs
Allred (2005)	1%	Approximately 20% for Estrogen Receptor
Rhodes et al (2001)	10%	Reliable assays found in only 36% of labs (24/66).
Regitnig et al (2002)	10%	Unstained slides False positive rate was 0% and the false negative rate was 1%. Stained slides False positive was 3% and the false negative rate was 2%.
Viale et al (2007)	10%	False negative rate as a percentage of negatives was 70% (73/105 tumors locally ER negative were positive i.e., > 10%); 7.6% or 8/105 had 1% to 9% positive cells.
Mann et al (2005)	0, <10% and ≥ 10%	False negative rate for core biopsies. ER (14%, 95% CI , 7.9% to 23.4%) PR (15%, 95% CI , 7.6% to 24.7%) HR (10%, 95% CI , 4.7% to 18.1%)
Rhodes et al (2000)	1% and 10%	Only 37% scored adequately on low expressing tumors
Collins et al (2008)	1% and 10%	1% cutoff 21.3% false negative rate as a % of negatives and 5.1% false negative rate as a percentage of total tests. 3.5% false positive rate as a % of positives and 2.7% false positive rate as a percentage of total tests. 10% cutoff 20.0% false negative rate as a % of negatives and 4.7% false negative rate as a percentage of total tests. 12.9% false positive rate as a % of positives and 9.8% false positive rate as a percentage of total tests



Expert Opinions which address false negatives in IHC testing

Allred (2004)	Community data - 30% false negative rate Repeat ER testing in difficult cases - conversion rate from negative to positive is 20-30%
Moshin (2004)	30% false negative rate
Magliocco (2005)	20% false negative rate

Database Change Rate, 1997-2005

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



Contact with Patients

- Large scale patient contact regarding retesting started in October 2005
- Followed by contact regarding test results
- Various channels used



Communications

- 49 people were not contacted (by a Health Authority) or it is uncertain if they were contacted.
 - 38 of 49 are living.
 - 6 of 38 had changed results, ER-negative to positive
- RHAs have been asked to contact these people ASAP, with priority on 6 changes.



Follow-up contact process

- Each RHA has been given records of patients not contacted to immediately ensure contact is made. Priority on people with changed results.



Questions