From: Diane Hart
To: Pat Pilgrim;
Subject: FW: Urgent
Date: April-01-08 9:38:21 AM
Attachments: Draft ER PR Backgrounder.doc
Lessons Learned Budget.1.doc

From: Pat Pilgrim
Sent: February 20, 2008 7:25 PM
To: Diane Hart; Deborah Collins; Heather Predham; Pam Elliott; Louise Jones; Beverley Clarke; Stephen Dodge; Nebojsa Denic; 'Dan Boone'; 'Daniel W. Simmons'; Donald Cook; Oscar Howell; 'Cathy Dornan'; Terry Gulliver
Subject: FW: Urgent

Here is the information to be released tomorrow by the government. pat

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Eastern Health

From: Thompson, Robert [mailto:rthompson@gov.nl.ca]
Sent: Wednesday, February 20, 2008 7:12 PM
To: Pat Pilgrim
Subject: RE: Urgent

Pat:

Here is: 1) the draft data release backgrounder; 2) the draft “early lessons learned and budget initiatives” backgrounder.

Finally received full approval on the budget initiatives. This is good news, but its slightly different than what Louise submitted. I would be pleased to walk you through this.

As the budget initiatives affect the other RHAs, I will be sending them a copy as well.

We are anticipating receiving from you a backgrounder on how families of the deceased can access the test results.

Glenda is finalizing a draft umbrella news release which will incorporate key messages from all three backgrounders. Of course, we will need your deceased backgrounder to flesh that out.

As for Eastern’s role in the technical briefing, we suggest no role. As for Eastern’s role in the press conference, we suggest the Minister take the lead role and, in Louise’s absence, that you join him on the podium. The Minister’s two big messages are related to budget initiatives and the fact that data has been sent to the commission. Therefore, the key Eastern Health message would be around the data access for families of the deceased.

Of course the media will have many questions, and you can anticipate that they may ask you some of them (why didn’t Eastern know how many people were sent, how come deceased was underestimated, etc). We can discuss all those questions tonight.

Robert

Backgrounder

Budget Initiatives and Other Early Directions for Change: ER/PR Testing

The provincial government has examined the data from the NLCHI Database and the disclosures of the various parties to the Commission of Inquiry on Hormone Receptor Testing. It is clear that early lessons can be learned from the events surrounding ER/PR testing between 1997 and 2005, as well as the retesting process which followed. While the Commission of Inquiry will bring forward recommendations in its final report, some early directions can be identified for action.

1. Data Management

- The knowledge gained through the construction of the ER/PR database shows that better data management and tracking could have provided greater certainty that all negative ER/PR cases were identified and sent to Mount Sinai on a timely basis, and would have aided the patient communication process. .
- As a preliminary response, 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 "decision support 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
- In addition, government will commit $2.1 million in the 2008-09 budget for the following items:

    i. To avoid slow response times and potential for error which can occur when searching different information systems at different sites within a health authority to find information on a patient, $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.
    ii. To ensure that tracking of documents is improved when managing an adverse event (e.g., in the case of ER/PR retesting, the tracking of thousands of letters, test reports, email, correspondence, meeting minutes), $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;

iii. To ensure that every health authority has access to skilled "decision support professionals", $270,000 will be allocated for new personnel to perform "decision support". These people will be accessible by senior management to assign to an adverse event team to ensure that all the data necessary to track and report on the response to an adverse event is brought together and utilized to support rapid and accurate decision-making. These people will also be used to organize information resources throughout their organizations in support of executive decision making on an ongoing basis.

2. Quality Assurance and Monitoring in the Immunohistochemistry Laboratory

- Since 2005, the recommendations of two peer review have been implemented and new external reviews were completed (CCHSA and QMPLS). One of the important lessons learned has been the fundamental necessity of comprehensive quality assurance programs, including the benefits of accreditation of laboratories.
- As a preliminary response:, government has approved an additional $175,000 per annum for Eastern Health to follow through on recommendations made in previous quality reviews regarding education, training and quality assurance activities in immunohistochemistry. In particular, this funding will allow for pathologists and technologists to participate in relevant training programs each year, allow for external reviewers to visit the Eastern Health IHC laboratory to assess current practice against best practices elsewhere, and allow for the hiring of a permanent quality assurance manager.
- In addition, government has decided that it will require the regional health authorities to obtain and maintain appropriate accreditation of their laboratories. Therefore, it has allocated $100,000 in 2008-09 to plan for the establishment of an accreditation system. The funding will pay for professional services necessary to identify the nature and extent of a new accreditation system, and make a proposal to government on the funds necessary to make it a strong and resilient system.
- ER/PR testing is performed at one site in the province but relies upon quality practices not only at its own site, but at many sites throughout the province. A policy is needed to clarify where the authority resides for quality control for tests which require this type of multi-organizational collaboration. It is not appropriate for quality standards to be different for tests which are ultimately performed at a single site. The Department will strike a committee of the regional health authorities to bring forward recommendations to address this issue.
- ER/PR testing is an example of a valuable test that does not have uniform national or industry standards to guide its conduct. The lack of uniform standards does not reduce the value of the test, though it places an extra burden of responsibility on laboratory managers and pathologists to ensure high quality in the absence of widely recognized standards. Quality control procedures and accreditation play an important role in these situations. The Department will seek advice on how tests without widely accepted standards should be conducted in our laboratories.

3. Communication protocols

- The ER/PR testing experience provides many lessons about how to conduct communications with patients and the general public when a large number of people are affected simultaneously. The principles to be observed in these situations include

a patient's right to know and a patient's right to participate in the management of their own care. Other important principles of large group events include advising the media early to avoid the anxiety and uncertainty associated with uncoordinated information going to the media, and allowing for affected patients to self-identify to the RHA when there is uncertainty over whether internal databases will identify all patients in a timely manner. These principles must respect the priority of the patient-doctor relationship, the protection of personal privacy and the urgency and significance of the adverse event. These principles will be used to guide the development of new communications policies for adverse events.

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DRAFT - Backgrounder

Purpose of ER/PR Database

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, from both clinical and communications perspectives.

Context

- 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 have a clinical benefit for the patient.
- On May 17, 2006 Eastern Health reported publicly that the tissue samples of 939 patients were retested at Mount Sinai Hospital for ER/PR hormone receptivity. The original tissue samples were tested between 1997 and 2005. Of the group of 939 patients, 12 patients were known to have original positive results, leaving a balance of 927 with known negative results. As well, of the 939 patients, 763 were reported as living and 176 deceased.
- Detailed retest 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; 317 patients had changed results, mainly from negative to positive, but also some who went from positive to negative; 13 did not have changed results but did require treatment change due to a change in professional opinion as to what constituted a positive result; 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 retesting effort was to retest 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 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 retest results for patients from all regions.

- Data were gathered by NLCHI on such topics as: date of original test, original test result, data of retest, retest 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 retesting process did not contain results on all the patients who had been retested. 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 retesting 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 and Interpretation

Database Results	Interpretation
Patients	
Total Number of 1997-2005 ER/PR cases (or patients) that were sent to/retested at Mount Sinai - 1013	There were 1013 patients whose tissue samples were sent to Mount Sinai for retesting. Most of the extra patients were retested alongside other patients in late 2005 and early 2006 but were inadvertently omitted from the Eastern Health tabulations.
Total number of 1997-2005 ER/PR "negative" cases (or patients) that were sent to/retested at Mount Sinai – 995.	There were 997 patients whose tissue samples were sent to Mount Sinai for retesting. The explanation for the difference is the same as above.

<table>
<tr><td>Total deceased as of November 2006 – 294. Total deceased as of November 2007 – 321.</td><td>The under-reporting of the number of deceased reflects the fact that Eastern Health did not utilize the Provincial Mortality database. The actual number of deceased was higher than reported.</td></tr>
<tr><td colspan="2">Tests</td></tr>
<tr><td>Total number of original ER/PR negative tests that were retested at Mount Sinai – 1112.</td><td>Some patients had more than one original test between 1997 and 2005, so samples for each test were also sent to Mount Sinai.</td></tr>
<tr><td colspan="2">Treatment Change</td></tr>
<tr><td>Number of patients requiring a treatment change.</td><td>When the retest results were reviewed by a panel of physicians in 2005/06, 117 out of the 939 patients were recommended by the panel for a change in treatment. Data has not been collected on the treatment change outcomes of additional patients identified in the ER/PR Database.</td></tr>
<tr><td colspan="2">Change Rate</td></tr>
<tr><td>Proportion of tests with a change in results, 1997-2005</td><td>
<table>
<tr><th>Cutoff Points (%)</th><th>ER Negative Change Rate</th><th>ER-/PR- Change Rate</th></tr>
<tr><td>30/10</td><td>42.8</td><td>33.0</td></tr>
<tr><td>10</td><td>45.6</td><td>33.4</td></tr>
<tr><td>1</td><td>39.8</td><td>19.6</td></tr>
</table>
</td></tr>
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Questions and Answers

If there is an expected false negative rate, is there also an expected false positive rate?

Why is this test performed if there is such a high rate of false results?

Is the false negative rate an “error” rate?

Why did the problem occur?

Did Eastern Health conceal the real number of deceased?

When did the Department know that the number of deceased was not 176 but much higher?

Is the mortality rate for breast cancer higher in this province than elsewhere? If so, would the false negative results be a contributor to this problem?

If the positivity rate was so low, why wasn’t it identified and corrected before 2005? Or before Dr. Ejeckam intervened in 2003?

Will the 2000 positive ER/PR tests be retested? If not, why not?

Why is the Department releasing these results now?

Was Eastern Health involved in this database project?

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