Susan Bonnell

From: Susan Bonnell
Sent: Tuesday, November 06, 2007 7:54 PM
To: Heather Predham; Terry Gulliver; Donald Cook; Nebojsa Denic; Pat Pilgrim
Subject: Report from tonight
Attachments: Why was Eastern Health unable to provide a complete and accurate list of all individuals retested for ER.doc

Hi, everyone:
I haven't even really proofed this yet for spelling, but I wanted to get it sent as they are shutting down email at 8pm tonight. Welcome your thoughts, suggestions, etc.!!

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Why was Eastern Health unable to provide a complete and accurate list of all individuals retested for ER/PR and then contacted by the organization following the retest, and how could individuals be missed in the process?

The retesting ER/PR for breast cancer patients from 1997 to 2005 has been the most complicated process this organization has ever faced and is, to our knowledge, unprecedented in Canada.

In the past two years, multiple individuals from a number of programs and disciplines have been involved in this process, each with their own roles to play. However, until the appointment of Patricia Pilgrim in 2007, there has not been any one individual with responsibility to coordinate all the various efforts.

It is important to note that the ER/PR retest was not a research project but was a patient safety process, intended to put critical patient information into the hands of individuals and their physicians and, secondly, to ensure quality service delivery from our immunohistochemistry laboratory. In fact, when officials were asked to pull together the first list of patients the focus was not in fact on retesting at all but rather to analyze positivity rates in the laboratory year-to-year from 1997 until the installation of the Ventana system in 2005.

There was never a dedicated task force assigned to this issue and the data collection and analysis process, while important, was a secondary focus of all key individuals, particularly at the onset, when the most important consideration was getting the retest done as quickly as possible.

Although one of the key learnings from this experience has been the importance of establishing one central list, at the time in 2005 there was simply not enough time to focus on setting up a database as all energy was concentrated on collected and sending blocks and slides away with haste. This is because we primarily wanted to get this review done as soon as possible to see what if anything must be done to ensure that patients were receiving appropriate treatment – remembering that in 2005 it was unknown what the results of the retesting would in fact be. Secondly, we knew that patient disclosures had begun and we were focused on finding out quickly what additional public disclosure would be required.

Eastern Health uses the Meditech system, an internally recognized medical records program, to manage and store patient information. Meditech is a leader in the health care sector and is considered to be industry standard. However, Meditech is set up to track and secure patient information based not on the service a client receives but rather on the client themselves. It is simply not set up to do this kind of review. Hence, it would be easy to run a report of all services one client receives or for that matter to identify all women born in 1975 to whom we provided treatment. What is complicated is mining through thousands of patient records to find commonalities, especially when there is not a searchable "field" associated with the issue in question. There is no single field for ER/PR results.

In order to arrive at a list of potential patients, officials were required to undertake a complicated and detailed review of thousands of patient records. This began with a search of all patients in the specific time range; all ages; every procedure; and for which there was an ER/PR test recorded in the order entry field.

We have discovered that in some cases, although an ER/PR test was conducted it was not typed into the original order entry. Handwritten orders for ER/PR tests not transferred to the

electronic record contributed in a small number of cases to individuals not being included in the retesting process. We would not be aware of these patients had they not been either identified by their physicians or had the patients themselves not contacted us inquiring about their results.

From the thousands of test results the initial query produced, officials were required to print copies of each report and then review each patient individually to include or exclude them from the process, using the predetermined criterion.

The official time range for the review was from May 1997 to ? 2005 – the period during which the laboratory at the HSC used immunohistochemistry to conduct ER/PR testing. Officials used all of 1997 to keep the search as broad as possible, but it has recently been identified as patients have come forward that some patients with surgeries in 1996 that were not tested for ER/PR until 1997 were unintentionally excluded from the review. This is because the surgical number with a 1996 date was used to determine who should be included in the review. A very small number of patients have been identified in this category.

ER/PR results are identified in a text report, imbedded within the patient record. Further complicating the process is the fact that there was not, during this broad time range, one standardized way of reporting ER/PR. For example, results may have been recorded as "ER 25 PR 30" or "estrogen negative" or even "sample shows hormone receptor positivity."

It is especially important to note that the Laboratory Information System (LIS) for Eastern Health was not at this point consolidated. Within St. John's, the three separate LIS's were not consolidated until 2000 and there are significant differences in the records from 1997 to 1999 for each of the three hospitals – the Grace, St. Clare's and the HSC.

In fact, in 2005 when this retesting began, the Laboratory Program for Eastern Health was not yet created and the Director and the Clinical Chief for the Health Care Corporation of St. John's were managing this process for Eastern Health.

Although all tests from across the province were conducted at the HSC Lab, our officials did not in the early days have access to patient systems in Carbonear, Clarenville or elsewhere in the province and had to rely on others to submit blocks and slides initially and then, in the case of the other health authorities, follow-up with patients on results.

Eastern Health was able to generate a list of all patients who had breast cancer from 1997 to 2005 and were tested in our laboratory for ER/PR using this process. However, one regret of the officials who compiled and verified the list is that Eastern Health did not cross reference our list of patients from outside the region with the data provided by other regions.

Between 2005 and 2007, four separate lists emerged:

- the original list from the Meditech search and the HSC Lab, combined with information supplied from the other regions (Director's list)
- a verification list, cross referencing the original with information collected from the breast cancer registry and an audit from Information Management and Technology (Quality's list)
- a list of results as they were returned to the organization and used form immediately pushing patients who converted through to the panel for review (Clinical Chief's list)
- a final list supplied by Mt. Sinai and identified by them as "all ER/PR tests we have conducted for Eastern Health": this list became the main source list for

communications with patients and for identifying the total number retested (Mt. Sinai list)

During this time, a number of patients were added to one or more of these lists.

Oncologists were requesting urgent consults on individual patients. These patients were "plucked" from the pool. Also, consults were requested from across the other regions that sometimes our team were not aware of. These individuals may not have been counted amongst those retested.

In addition, Eastern Health advertised a number for patients to call, partially because we could never be 100% certain that we had identified all patients through the initial process for all the reasons previously outlined. Between 2005 and 2007, patients have called that number and have been retested but may not have been counted amongst those retested.

While it is evident today and was certainly acknowledged at the time that one list would have been beneficial, creating a database was simply not the focus at the time. The key preoccupation was on how long the review process was taking, the growing public and patient complaints about timely information and the desire to let patients know their results as quickly as possible.

ER/PR has been a complicated and overwhelming issue for Eastern Health, with new revelations and ongoing management needs since it was first raised in 2005. Strategies around this issue have always included the plan to develop a complete patient database, but patient and media needs have always risen to prevent its completion.

Although the number 939 has been discussed in the media and in court affidavits, Eastern Health has always indicated that this number referred to a point in time and was defined to the best of our abilities at that time.

We were not surprised that the number identified by NLCHI was higher but we are disappointed that the implication is that we cannot manage patient data as a result.

It is worth noting that, even after having a dedicated team of 10 or more statisticians with no patient safety, patient notification or quality improvement responsibilities, working on this file for more than four months, NLCHI itself is still unable to define an exact number and, moreover, there are recognized issues with the data as it was presented to the Commission of Inquiry in late October.