Communications
Options – Aug. 05

Eastern HEALTH

Communications Options
ER/PR Testing at St. John's Hospitals
August 12, 2005

Issue: Eastern Health has made a decision to retest all ER/ PR negative tests performed in our laboratory from 1997 to 2004. This decision has been made in consultation with our Medical Oncologists and other cancer specialists. Following an internal quality investigation we have determined that the rate of conversion of tests from negative to positive results is too high to ignore. A conversion from a negative to a positive ER/ PR may have an impact on current or future treatment for breast cancer patients.

Approach: Eastern Health has begun the process of retesting all negative tests. There are approximately 400 cases to be retested. Urgent cases are being identified by clinicians and addressed immediately. Other specimens are being shipped to Mount Sinai, the leading immunohistology laboratory in the country, for restesting within the next two months. Eastern Health has also initiated an extensive quality review of the laboratory to ensure that our processes meet or exceed national standards.

Eastern Health believes in the principles of open disclosure and has already begun to notifying patients through their medical specialists if there is an impact on their current or future treatment protocol. Unfortunately in terms of the impact this will have on patients, there is no one "blanket" approach; every case must be treated individually.

We have chosen to continue the process of individual notification as test results are returned and analyzed as we feel this is in the best interests of the patients whose needs, health and well being must considered above all else.

Approach	Strengths	Weaknesses
Media Release	According to the Canadian Patient Safety Institute, "Improving the safety of patients is about creating an environment that is open to disclosure and committed to change." By disclosing this issue publicly we reaffirm our commitment to being open. We also gain proactive control of the issue in the public forum as the first message is usually the most pervasive. The media cannot criticize us for attempting to "hide" the issue from the public.	A media release and press conference may be appropriate if we had an announcement to make; if we needed to disclose an error; or if we needed to find a way to reach a large, general audience. In this particular case, there **may** be a system failure but this has yet to be determined. And we know the audience we need to reach – it is a specific group of individuals whose names and addresses we have who deserve and should expect fair and confidential care. Usually, one of the key arguments to "go public" is to be in control of the message. In this unique circumstance, by taking a public approach, we have nothing to gain and, from the perspective of all breast cancer patients – not only the limited number of ER/ PR negative women who will be retested – everything to loose. There is very little that can be done in this circumstance to avoid criticism; even if we had immediately acted on this issue publicly we would be criticized regardless.

Approach	Strengths	Weaknesses
Patient Letter	If we contact every patient whose specimens will be retested we disclose to all potentially impacted women the efforts underway to reassess their cancer treatment protocols. In other cases of quality review, individual patients would be contacted directly by one of our representatives. Because this is a large number of women, a letter would expedite the process.	The challenge is to find the balance between waiting (so that we may give patients good information that does not negatively impact upon their well being) and responding quickly (without causing undo anxiety, confusion and stress). Originally, we proposed sending letters when we believed that the specimens could all be retested within two weeks. Given the fact that our Ventana system is now being reviewed as well, we must send the specimens to an independent laboratory. This delay, while not considered significant by the Oncologists, would be an unnecessary hardship for any patient who had been notified that their tissue was being retested and that their treatment may change. Our medical specialists do not what us to send letters to all patients. They believe that each patient must be treated individually – in fact, some patients may already be taking Tamoxifen or would not be given this drug, regardless their ER/ PR status.
Individual Patient Notification	This is the preferred method of our Medical Oncologists, Surgeons and Cancer Specialists: - It protects patient confidentiality; - It maintains the integrity of the patient/ doctor relationship in determining individual treatment protocols; - It does not cause undo stress to breast cancer patients and their families who are unaffected by this particular situation; - It ensures that all patients whose treatment will change are cared for appropriately and dealt with fairly by the organization. While we run the risk of being criticized by the media for not sharing this information with them, we cannot be criticized for our confidential and appropriate handling of the issue from the patient's perspective. We are in a good position to respond to the media's questions.	It is highly likely that, as the number of patients whose treatment is affected increases, the issue will reach the public forum. Someone will go to the media and we will have to react to this as a media story. We will likely be criticized by the media for not disclosing the issue and they will question our timelines: - *How long have you known about this problem with your older system?* - *Why did it take you so long to admit to this problem?* - *Why are you questioning the validity of the new system?* - *Can we trust our lab results?*

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Key Messages: Process

- We are retesting all ER/ PR negative test results conducted at our laboratory from 1997 to 2004. Urgent cases have been identified by the Oncologists and Surgeons and these specimens are being retested immediately.
- We have identified approximately 400 specimens that are being shipped to Mount Sinai laboratory for retesting. Mount Sinai is considered to be the foremost lab in the country for this type of procedure. The restesting process could take up to two months to couple.
- We have been actively working on this issue since it was first brought to our attention in May. A patient who had tested negative in 2002 for ER/PR was retested using our new technology at the request of the Oncologist. This patient's test converted to positive. At this point we began what has become a major investigation into this particular testing process. First we retested selected samples to determine if this case was unique or if in fact we had uncovered a problem with our former testing process. Many of these cases converted from negative to positive so we began the process of pulling files and specimens from 2002, followed by a decision to pull and retest all negatives from 1997 to 2004, when our new system was installed.
- We believe it is in the best interests of all our breast cancer patients to deal with this matter confidentially. If a patient is retested and that test changes from a negative to a positive result, we notify the physician immediately. Physicians must review this patient's treatment and care to see what if any impact this test conversion has on the patient.
- We are conducting an external review of our laboratory in September and we are actively investigating the best way to improve our quality assurance program.

Key Messages: ER/ PR Tests

- When a breast cancer tumor is removed from the body, tests are used to determine if the cancer cells have estrogen or progesterone receptors. The more estrogen receptors present on those cells, the more likely that anti-estrogen therapy such as Tamoxifen will work against a particular cancer. Breast cancer patients with high level hormone receptors have a slightly better prognosis than those without receptors.
- There are other factors that physicians consider when determining whether a patient will be given hormone therapy aside from ER/ PR receptor status, include the patient's age and how far the cancer has progressed. Some patients who had a negative ER/PR test were given hormone treatment anyway, and some patients who now have a positive ER/PR may not be considered for hormone therapy.
- As with so many cancers and other health issues, treatment has changed over the years as our understanding of these diseases has improved. For example, in 1997 an ER of less than 30% was considered to be negative. Today, negative is considered to be 10% or less.

Key Messages: Understanding immunoperoxidase staining

- From 1997 to 2004, our laboratory used a process for immunoperoxidase staining called the Dako system. This technique required the manual boiling of tissue and measuring of minute mixtures of re-agent. The Dako test was implemented in 1997 to replace a bioassay method for ER/PR receptors. While used nationally with some success, this process leaves room for error and we have had challenges with the process in the past.
- The Ventana method (installed in April 2004) automates this process removing as much manipulation as possible. In addition, all re-agents used on the Ventana system are quality controlled by the company and arrive in the laboratory as "ready for use." The Health Sciences Centre was one of the earliest laboratories to obtain the Ventana system and switch to an automated system.

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Dear

We are contacting breast cancer patients that tested negative for estrogen and progesterone receptors (ER and PR) between 1997 and 2004.

Since your tissue was first tested, there have been improvements in technology and changes in the approach to offering hormone therapy. In addition, upon review of our procedures we have noted some inconsistent test results that have led us to the decision to retest your tissue sample.

As you may know, the presence of estrogen and progesterone receptors is one of the factors doctors consider when determining the most appropriate treatment of breast cancer.

You are not required to have any additional testing and are not required to come to the hospital. Retesting will be conducted with existing tissue samples. It will, however, take several weeks to complete all the retesting. Your sample will be sent to Mount Sinai Laboratory, considered to be one of the best labs in North America to do this sort of testing.

Although we are retesting your tissue sample, this does not mean your treatment will change. Once the results of the retesting are known, the Medical Oncology team and your physician will be notified and any changes to your treatment that may result will be discussed with you at that time. If you are not currently receiving treatment for breast cancer, this new information may be useful for future treatments if and when they should ever be needed.

If you have any questions about this process, you may call our Patient Relations Office at 777-XXXX or 1-888-XXX-XXXX.

Thank-you.