STATEMENT OF STATISTICS

(AS FILED IN COURT AFFIDAVITS DATED FEBRUARY AND MARCH 2006)

Eastern Health reviewed 2709 ER/PR tests conducted between 1997 and August 2005. Of those cases reviewed, 939 of the tests were originally reported as ER-negative. The negative test samples were sent to Mount Sinai Hospital to be retested. Results were obtained and reviewed for 763 patients.

Of the 763 patients whose samples were retested and results obtained, 433 patients saw no change in their ER/PR results and therefore no change in treatment was recommended. Specifically,

- 341 patients were confirmed negative by Mount Sinai;
- 28 patients were confirmed negative by the Tumor Board;
- 12 patients were confirmed positive; and
- 52 patients were determined to have ductal carcinoma in situ, and therefore no form of treatment would have been recommended.

A further 13 patients saw no change in their ER/PR test results but a change in treatment was recommended as the standard for interpretation of what constituted an ER-positive test result had changed between the time of original testing and the Tumor Board's review.

The ER/PR test results were different for 317 patients following retesting.

Of the 317 patients, 104 patients required a change in treatment.

- 96 of these patients were recommended for treatment with Tamoxifen or another aromatase inhibitor;
- 4 of these patients saw a change in their original diagnosis; and
- 4 of these patients originally had a degree of ER positivity but were negative on retesting.

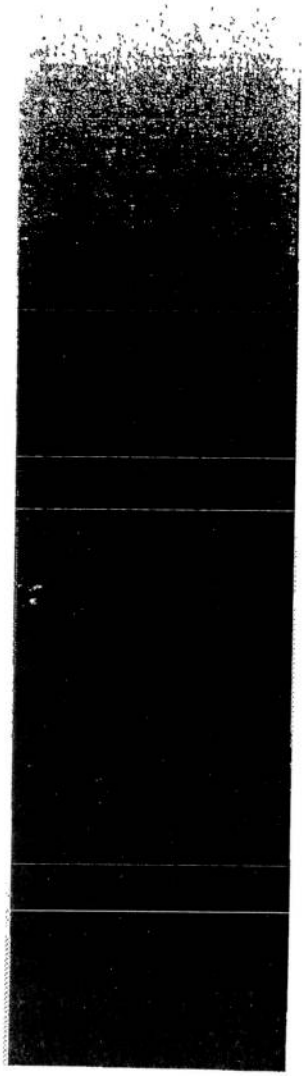
The remaining 213 patients whose ER/PR tests results were different on retesting did not require a change in the treatment that had been originally recommended for them because:

- 60 of these patients had a very low risk of recurrence;
- 148 of these patients had previously been treated with Tamoxifen or another aromatase inhibitor either at their request or their oncologist's recommendation following a review of the test results and their particular medical and family histories; (13 of these patients were not placed on Tamoxifen for their original disease but for subsequent metatstatic disease);
- 5 of these patients received no treatment as they required assessment prior to any recommendation being made.

176 of the patients whose ER/PR tests were originally reported as negative are deceased. Of these 176 patients:

- 105 patient's samples were retested and results have been received;
- Of those 105, 68 saw no change in their results, 1 originally clinically positive result retested as clinically negative, and 36 patient's test results changed from clinically negative to clinically positive.

2214 of the ER/PR breast tissue tests were conducted in the Dako system from 1997 to April 2004. 495 tests were conducted in the Ventana system from April 1, 2004 to August 1, 2005.



HMQ 2

ER/PR RETESTING CHRONOLOGY

MAY 18, 2007

Eastern Health

April 2004: Eastern Health (then the Health Care Corporation of St. John's) installed a new Ventana system for use in our immunohistochemistry laboratory. This more extensively automated system replaced the Dako System, a complicated, manual and multi-phase procedure with more than 40 steps. The Dako system was an advance from biochemical assay, used prior to 1997.

May 2005: One of our oncologists was treating an individual whose ER/PR was originally tested in 2002 (using the Dako system) and shown to be negative. Given the nature of this woman's cancer, her age and other factors, the oncologist requested that the test be repeated. The second test was conducted on the new Ventana system, and converted to a positive result.

Representatives from the Laboratory Program met with oncologists to discuss this new result and a decision was made to retest five more negative patients, who all converted to positive.

June 2005: It was decided to retest all negative results from 2002 to determine if these were isolated cases or symptomatic of a bigger issue. The chief of pathology wrote to all Laboratory directors in the province to return all negative ER/PR specimens for the year 2002 for retesting on the new, more sensitive Ventana system.

Early July 2005: A meeting was scheduled and the decision was made that all patients who were ER/PR negative from 1997-2004 would be retested internally on the Ventana System with testing to take place over the next number of weeks.

Late July 2005: The decision was made to stop reporting ER/PR in our laboratory and to arrange for an independent and external laboratory to complete our retesting as well as ongoing work.

August 2005: Mt. Sinai Hospital, considered to be a "gold standard" laboratory internationally, agreed to take on the project. Our laboratory began the process of collecting, packaging and shipping all negative* test results from 1997-2005 to Toronto.

** The definition of "negative" has changed within the seven year period in question. Originally, oncologists believed that tumors with less than 30% positivity for ER/PR should be considered negative. With advancing understanding of cancer and treatment, the negative rate has dropped, first to 10% and now to 1%. Today, oncologists believe that any positivity may be worth treating with hormonal therapy.*

Early October 2005: The first set of results arrived from Mt. Sinai.

Mid October 2005: The organization established a Tumor Board comprised of two (2) oncologists, two (2) surgeons, two (2) pathologists, one (1) representative from the Quality Department and one (1) support person. The Tumor Board was tasked with reviewing the results as they arrived, reviewing charts, and making treatment recommendations for each patient. The Tumor Board met once a week from October 2005 to May 2006 reviewing individual cases and making recommendations.

Mid October 2005: The organization conducted the first of numerous media interviews, and provided whatever background information was available at that time. Advertising was also purchased informing the general public of the retesting.

October 2005: Patient Relations representatives from Eastern Health telephoned all individuals whose specimens were being sent away for retesting. The laboratory conducted the first of a number of external review processes. During this period, the laboratory also attempted to gain insight from other laboratories across Canada regarding their experiences with ER/PR testing.

November/ December 2005: The organization expressed concerns to Mt. Sinai about the slow pace of reports. However, they were experiencing unexpected manpower issues and were unable to move the tests through the system any faster.

Late January 2006: The last batch of samples arrived at Eastern Health from the other provincial health authorities. They were forwarded to Mt. Sinai for review.

February 2006: The last test results were received from Mt. Sinai.

February - May 2006: Concentrated effort of the Tumor Board to review test results, write recommendations and conduct disclosures. A six month period *(May to October)* follows to ensure that the organization has completed all the disclosures possible and that every patient has had every opportunity to contact their physicians.

June – November 2006: The new Chief Pathologist and the new Vice-President, Medical Services worked on the results of the quality review process; established a centre of excellence for breast cancer pathology; assigned a head pathologist for immunohistochemistry; and generally prepared for the continuation of ER/PR testing in our laboratory.

September 2006: A statistical review was initiated to examine the numbers and arrive at conclusions. This information will form the basis of the quality review. Analysis is continuing.

Late November 2006: The organization completes its quality review.

December 2006: Public release of results and media briefing.

February 1, 2006: Testing begins again in our laboratory.

STRATEGIC COMMUNICATIONS
T: 709-777-1339 • F: 709-777-1344
www.easternhealth.ca

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Media Statement

Introduce Panel

We want today to clarify some of the misinformation about estrogen and progesterone testing that has been in the public this week and to ensure the public that Eastern Health is taking this issue very seriously.

Let me say first of all that this issue is not about breast cancer screening. This is about a test that is taken once a breast cancer diagnosis has been made. It is used to determine if a breast cancer patient might benefit from hormonal therapy. At no time has there been any question of the accuracy of mammograms or biopsy results to diagnosis Breast Cancer.

Next let me say that as the President and Chief Executive Officer of Eastern Health, I am sorry for the confusion that has ensued over this issue. I take full responsibility for the organizations actions in talking about this issue and we are steadfast in our attempt to clarify the situation to ensure there is no more confusion about who is affected and what it all means.

At no time did Eastern Health withhold any personal information from any of the patients impacted by our decision to retest for estrogen and progesterone receptors, or ER/PR.

It is important for everyone to know that we contacted each and every patient who was affected by the ER/PR test review, making sure they received all the information and support they required.

Furthermore, once we became aware of the potential issues with the ER/PR test, we immediately suspended our own testing and began using an out-of-province testing facility. (JULY 2005)

In 2005 when we discovered that there were inconsistencies in a small number of ER/PR tests we made a decision, as an organization, to go back and review all the ER/PR tests we had conducted since 1997.

We did this because we know that hormonal therapy may still be of benefit to a breast cancer patient who was diagnosed that long ago.

We felt that if there was even the **possibility** that one patient may benefit from retesting, we had an **obligation** to retest all patients, regardless of the consequences.

It took us about a year to complete all the retesting and to conduct external and internal reviews in our laboratory. This is longer than any one of us would have liked, and we shared the distress of our patients resulting from this long delay.

However, as you know we had to rely on another facility in another province to conduct our retesting which took longer than at first anticipated.
Additionally, as test results came back to us it was necessary to assess all the results that had any change in them to see if we would recommend a treatment change for those patients.

These assessments were conducted by a panel of experts in cancer care, using the best knowledge available to us today on cancer treatment.

Before we talked about our results with the public we felt that had an obligation to contact each and every patient who was involved in the retesting to tell them either:

- that their tissue had been retested and there was no change in the original results;
- that there tissue had been tested and that we were recommending a change in their treatment; or
- that although there was a change from their original test result, no change in treatment was recommended.

This process was never a research project.
Nor was it quality review exercise.
It was about this organization redoing a test to provide every treatment opportunity possible for our patients.

In December when we issued an assessment of the review to the media, we did so because we felt that the public at large deserved to know as much as we could tell them about the results.

Let me explain the numbers:

- There were 939 patient with ER negative reports
- Of the 763 patients that we reviewed, 317 patients had a change in result
- 104 of those patients had a resulting change in treatment
- An additional 13 patients are added to these 104 because although their test results didn't change the definition of negative changed, meaning that hormonal therapy was possible for these individuals.

At that time, we focused on the 117 individuals whose treatment plans changed.

I acknowledge that we did not identify at that time the additional patients who had a change in test result but no change in treatment plan.

We believed at the time that the decision to focus on the 117 was the right one because this was, in our estimation, the critical piece of information. That being said, given the reaction that has come from not releasing the second number, I regret that decision and apologize for any confusion this has caused.

The total group of 317 patients who tests results changed appears to be the source of much confusion.

I need to stress that this is not a new group of patients and in fact includes the 117 individuals that we have already publicly indicated required a treatment change.

I also appreciate that this issue must be causing incredible anxiety for the families of the women who have passed away. We sincerely regret that.

Unfortunately we simply do not know how many of these patients may have benefited from hormonal therapy.

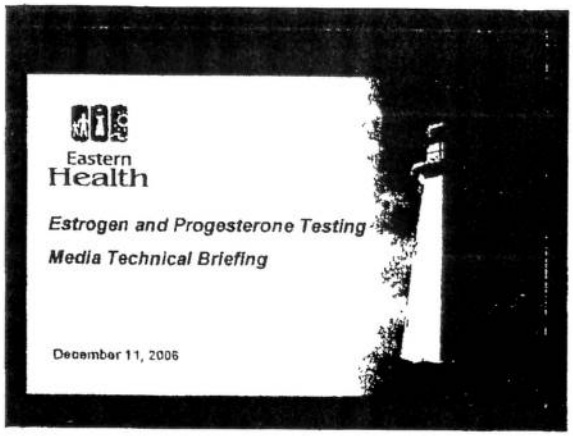
We are committed to being responsive to all our patients and their families and if a systematic review of these tissue samples would help to alleviate any concerns, than I am committed to ensure that this is completed and that all patient's families are contacted for follow-up.

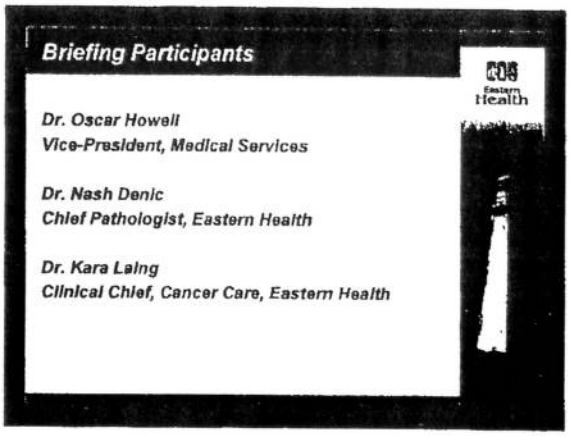
This has been a learning experience for this organization, but I must reiterate that Eastern Health has acted and will continue to act in the best interests of our patients.

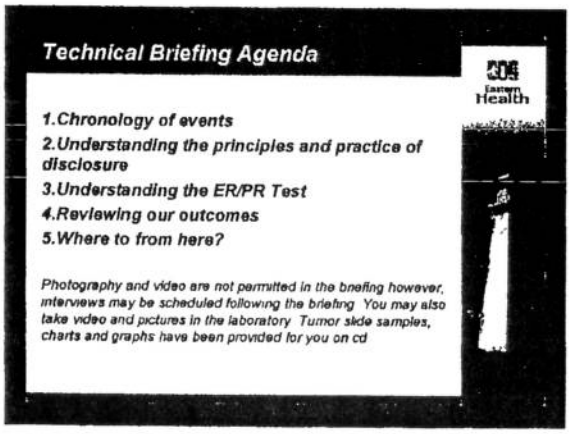
They are our first priority, and patient safety is important to us.

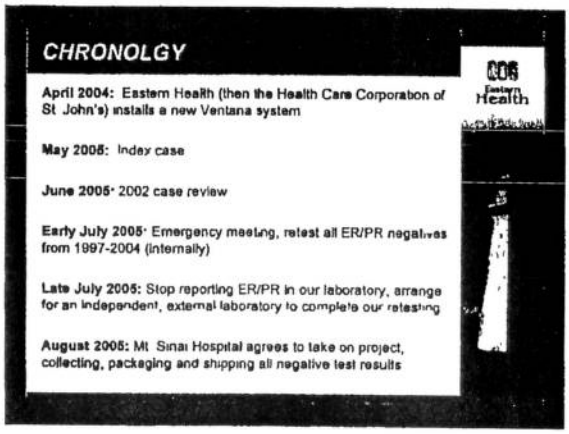
Our staff and physicians have been and will continue to be available to all the patients and their families impacted by this review. And I certainly encourage any patient or their family members with questions or concerns to bring them to us through our client services officers, physicians and other care providers.

I will now take your questions.


Eastern
Health
Estrogen and Progesterone Testing
Media Technical Briefing
December 11, 2006


Briefing Participants
Eastern Health
Dr. Oscar Howell
Vice-President, Medical Services
Dr. Nash Denic
Chief Pathologist, Eastern Health
Dr. Kara Laing
Clinical Chief, Cancer Care, Eastern Health


Technical Briefing Agenda
Eastern Health
1.Chronology of events
2.Understanding the principles and practice of disclosure
3.Understanding the ER/PR Test
4.Reviewing our outcomes
5.Where to from here?
Photography and video are not permitted in the briefing however, interviews may be scheduled following the briefing You may also take video and pictures in the laboratory Tumor slide samples, charts and graphs have been provided for you on cd


CHRONOLGY
Eastern Health
April 2004: Eastern Health (then the Health Care Corporation of St John's) installs a new Ventana system
May 2005: Index case
June 2005: 2002 case review
Early July 2005: Emergency meeting, retest all ER/PR negatives from 1997-2004 (internally)
Late July 2005: Stop reporting ER/PR in our laboratory, arrange for an independent, external laboratory to complete our retesting
August 2005: Mt Sinai Hospital agrees to take on project, collecting, packaging and shipping all negative test results

CHRONOLGY

Eastern Health

October 2005: First results come in from Mt Sinai

Tumor Board begins reviewing and making treatment recommendations

Organization conducts media interviews

Phone contact with all individuals being retested

External review process begins

November/ December 2005 Mt Sinai concerns

Late January 2006 Final samples arrive, forwarded to Mt Sinai

February 2006. Last test results received

CHRONOLGY

Eastern Health

February - May 2006: Tumor Board work continues

June – November 2006: Quality review process, establish centre of excellence for breast cancer pathology, assign head pathologist for immunohistochemistry, prepare for continuation of ER/PR testing

September 2006: Statistical review

Late November 2006: Quality review completed

DISCLOSURE

Eastern Health

"Disclosure is the imparting, by health care workers to patients or their significant others of information pertaining to any health-care event affecting (or liable to affect) the patient's interests "

The Canadian Patient Safety Dictionary, Davies et al

Eastern Health is committed to candid and timely disclosure of adverse events, particularly those that may cause risk to a patient

DISCLOSURE

Eastern Health

Our Policy States:

(a) Concentrate on what happened and the possible consequences Avoid too much detail and technical language

(b) Remain factual

(c) Take the lead in disclosure

(d) Outline a plan of care to rectify the harm and prevent recurrence for this patient and others

(e) Offer to obtain second opinions where appropriate

DISCLOSURE

The Policy States:

(f) *Offer the option of a family meeting*
(g) *Document the discussion in the patient's health record*
(h) *Determine the need for follow-up meetings and who should attend*
(i) *Be prepared for strong emotions and offer personal support and support from others*
(j) *Accept responsibility for outcomes*
(k) *Apologies are appropriate*

DISCLOSURE

"The obligation to disclose is proportional to the degree of actual harm to the patient (or the realistic threat of such) arising from an untoward event."

(CPS Dictionary)

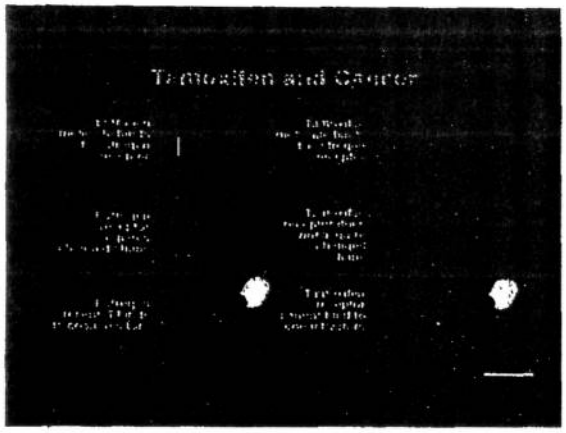
Our goal, from the beginning, was to improve the system and ensure that our patients have every care and treatment opportunity possible, regardless of the negative consequences for the organization

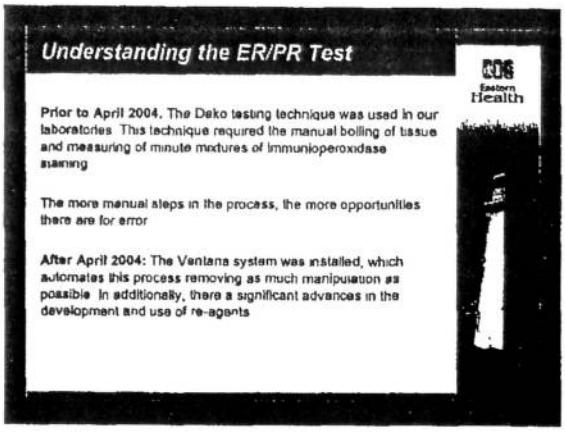
A COMPLICATED DISCLOSURE

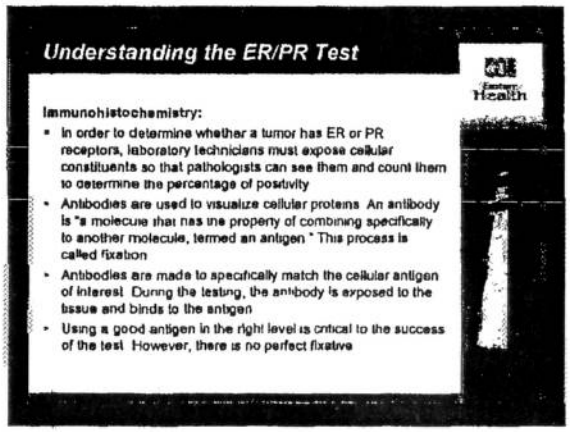
- Systems issue, not a typical medical error
- Oncology practice has changed
- Laboratory technology has changed
- Pandora's box
- No patient specific information to disclose
- National implications
- Class action lawsuit

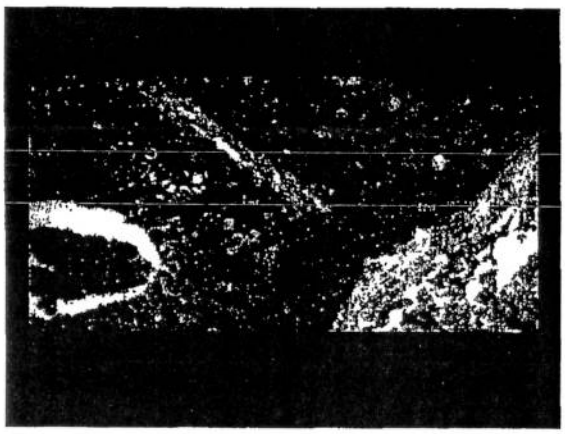
Understanding the ER/PR Test

- 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
- Literature suggests about 75% of breast cancers are estrogen–receptor–positive (or "ER-positive"), "positive" meaning that a significant number of cancer cells have receptors present
- When a cancer shows few if any estrogen receptors (when it is "ER-negative"), anti-estrogen therapy is not as effective But anti-estrogen therapy may also be useful in cases where progesterone receptors are present ("PR-positive")


Tamoxifen and Cancer


Understanding the ER/PR Test
Eastern Health
Prior to April 2004, The Deko testing technique was used in our laboratories This technique required the manual boiling of tissue and measuring of minute mixtures of immunoperoxidase staining
The more manual steps in the process, the more opportunities there are for error
After April 2004: The Ventana system was installed, which automates this process removing as much manipulation as possible In additionally, there a significant advances in the development and use of re-agents


Understanding the ER/PR Test
Eastern Health
Immunohistochemistry:
In order to determine whether a tumor has ER or PR receptors, laboratory technicians must expose cellular constituents so that pathologists can see them and count them to determine the percentage of positivity
Antibodies are used to visualize cellular proteins An antibody is "a molecule that has the property of combining specifically to another molecule, termed an antigen " This process is called fixation
Antibodies are made to specifically match the cellular antigen of interest During the testing, the antibody is exposed to the tissue and binds to the antigen
Using a good antigen in the right level is critical to the success of the test However, there is no perfect fixative



Understanding the ER/PR Test

- There are no standardized immunohistochemistry testing methodologies worldwide
- Currently there is no national laboratory accreditation process for immunohistochemical Labs (However, in 2006 the Canadian Association of Pathologists is piloting an accreditation process and we will be the pilot laboratory)
- "Immunohistochemistry tests are probabilistic, not accurate " *Dr Anthony Magliocco, Associate Professor of Oncology, Pathology and Laboratory Medicine, University of Calgary, at the U of T Pathology Update Course November 2005*
- Internationally, the ER/PR test carries with it a 5% false positive rate

Eastern Health Outcomes

- From 1997 to 2005, Eastern Health conducted 2780 ER/PR tests
- 939 individual samples were sent to Mt Sinai for retesting
- Following an extensive review process including "paneling" by the Tumor Board, 104 individuals had recommended treatment changes
- Other conversions that did not result in treatment recommendations, combined with these 104 individuals, contribute to a xxx% rate of error for the period under review

It is important to note that our first priority was not to conduct a research project but to concentrate on assessing each patient's file and ensuring that they had every treatment opportunity available to them

Where to From Here?

For the last six months, Eastern Health has been focused on completing the disclosure process and a quality review Within the next two months we will be reinstating ER/PR testing at our laboratory

QUALITY ASSURANCES

- All Recommendations from our external reviews have been implemented or are in progress
- Designated IHC Lab as separate department, including 3 designated IHC technologists, IHC Lab director and dedicated cutter
- Our technologists and pathologists have received specialized training in immunohistochemistry
- Consolidated all breast cases for examination and reporting to a designating group of pathologists
- Established a Quality Management Protocol
- Seeking accreditation and proficiency testing

ER/PR Media Briefing
Q & A's

PUBLIC ACCOUNTABILITY

Why didn't you tell the public about the 317? Why did you withhold this critical information from the public?

- It was never our intention to withhold any information from the public.
- In fact, Eastern Health has been completely open with all the patients who have had their tissue samples retested. Disclosure is an important and valued part of the health care system in general and to us in particular.
- Frankly, if we had known the reaction to this we would not have waited until the court proceedings began to release this figure and I apologize for the confusion and concern that has been caused because of this.
- From the beginning, our reason for conducting this retesting and the focus of our efforts has been the patients.
- When we released the results of our review our focus was on individuals whose treatment plans have changed. That number was our focus – not the number of individuals who may have had a change in test result but no change in their recommended treatment plans – and this was the number we reported publicly.

What is the organization trying to hide? Why try to keep this a secret?

- Eastern Health has nothing to hide. There would be no point in trying to hide this information from the public as it would clearly be part of the court case.
- We made a choice in December to inform the public that 117 individuals have had recommended treatment changes as a result of this process. This was the focus of the review in the first place and seemed to us to be the information that the public wanted to know.
- We have contacted all women whose tissue samples were retested, either by phone, letter or in-person meeting. We have informed the physicians of all the patients in the group with changed test results of their original result, their restesting and what recommendations our expert physicians have made for each of these patients.

Was this about the class action lawsuit? Were you trying to diminish liability?

- Make no mistake about it – we are facing legal action. And when any organization or any individual for that matter has to prepare for a trial there are limitations to what can be said outside of the legal system.
- We respect the judicial system and we respect the rights of individuals to take action against us when they feel they have been wronged.
- That does not in any way however diminish our responsibility to the public at large.
- This is why we stopped testing in our laboratory as soon as we knew that we may have an issue and why we did not beginning testing again until we could assure the public that we had taken every step in our power to ensure that this test is being performed here as well as anywhere else in this country.

Do you feel the organization mishandled how it informed the public? In hindsight, would you have handled things differently?

- Yes, in hindsight we would have handled the information differently.
- This situation is a complicated one, but we have always acted in what we determined to be the best interest of our patients.
- In the early days of this discovery, the situation and our understanding of what we were dealing with changed daily. Initially we had no specific information to disclose, only that there appeared to be an issue. We made a determination to wait until we had something specific to tell the public.
- However, this did not stop us from informing individuals as soon as information about their personal situations was available. We have been very upfront and open with our patients in one-on-one settings. We were not surprised when these individual disclosures lead to the public learning of the review and we responded publicly to the best of our ability.

The public has had their trust in Eastern Health shaken? How can they trust that the whole system isn't flawed?

- I deeply regret that some people have had their faith in the system shaken.
- Eastern Health has a team of individuals who are deeply committed to providing safe, effective and quality care.
- Our actions in the case of ERPR speak to our commitment to making the system the best that it can be: we immediately took action as soon as we became aware of a potential issue; we suspended testing; we conducted internal and external reviews; we did cross-country searches to compare our lab and our results nationally; we conducted hundreds of patient disclosures; held briefings for the media and conducted numerous interviews.

What do you say to those women who were left for months wondering if they received the wrong care plan?

- We regret that this may have been stressful period for some of our patients. We were in constant contact with many of these patients and we provided them with their personal information as quickly as possible.

What do you say to these women who have been living with mental distress because of this and who have lost faith in the health care system?

- It is unfortunate is this has caused individuals to loose faith in the system.
- I can certainly appreciate and understand the stress this may have caused some of our patients.
- However, we would hope that individuals can have faith in the fact that we have taken action here that, to our knowledge, no other lab has taken and that Eastern Health did what we felt was in the best interest of our patients despite the consequences for the organization in terms of increased scrutiny and legal action.

Should other cancer patients question their diagnoses?

- ER/PR is not a diagnostic test used to determine if an individual has cancer. A tumor is removed and sent for testing to determine if it is positive for hormone receptors. The test is used to help oncologists determine appropriate therapies.

THE TEST

How do you answer to the fact that you have a 42% rate of error?

- First and foremost, this review took in a 7 year period during which time a lot of things changed in both cancer care and in laboratory medicine – not just here but all across the country. We know things today that we did not know in 1997, 1998 all the way up to 2005 and this new knowledge has been applied to tissue samples and tests conducted all through that time period.
- Secondly, a changed percentage on a test does not necessarily mean a change in the way that a person is treated. For example, many of the patients in this group of 317 were already receiving hormonal therapy, regardless of the fact that they were considered to be ER negative from their original test result.
- Finally, we cannot say with certainty that the reason the numbers changed was because of error. It would certainly make it easier for you, me and everyone involved if we could point a finger at the reason why these changes occurred. We cannot.

If you did 763 tests and 317 of them were wrong how do you account for that?

- I can fully appreciate why people are concerned about the high number of changed test results. It is not acceptable to any of us that we would have a percentage of error higher than nationally accepted anywhere in this organization.
- But as we have stated previously (and will likely be a key point in any litigation) this is not your typical laboratory test.
- We know that this particular test is problematic across the country. There are no nationally accepted standards, as there are in other tests we perform. This is a developing area with new knowledge, new technology, new practices emerging every single day.

176 women have died as a result of this error, and Charles Hutton says that 36 of those women who should have received hormone therapy probably died because of your error. What do you say to those families?

- We know that this issue must be causing incredible anxiety for the families of the women who have passed away and I feel very badly about that.
- There has been some confusion about this matter. Of the 900 patients who originally tested negative from 1997-2005, our officials identified 176 patients who had passed away since 1997 – there has been a concern expressed that these individuals have passed away in the time that we have been conducting the retesting. This is not accurate.
- We simply don't know how many of these patients may have benefited from hormonal therapy.
- While hormonal therapy has been shown to improve outcomes for breast cancer patients, it is also not something that all patients can tolerate. We will never be able to say with any certainty if the individuals who may have been eligible for hormonal therapy would have received it, could have tolerated it and would have had benefits from it.
- We are committed to being responsive to all our patients and their families and if there are family members who want to know the tests results for a loved one that has passed away since 1997 we are more than willing to provide them with that information. In fact, we have provided that information already for a number of individuals.
- More than that I personally commit to providing these individuals with the full resources of this organization.

A MESSAGE to OUR PATIENTS

We have heard all the recent media coverage concerning our testing. We want to make sure that you have the right information.

We have heard from patients who are concerned about their mammograms or worried about breast cancer diagnosis. **These issues are NOT connected in any way with mammography or breast cancer screening.** Estrogen and progesterone (ER/PR) tests help determine treatment options for breast cancer patients.

WE HAVE ALWAYS BEEN UP FRONT AND OPEN WITH OUR PATIENTS

An impression has been left with the public that patients affected by the ER/PR review were not given their own health information. This is not true.

Disclosure is an important and valued part of the health care system in general and to us in particular.

Our first priority is and always has been quality patient care. That's why, in 2005, when these issues came to our attention we acted immediately to put safeguards in place.

- We stopped testing in our lab until a quality review could be completed;
- We called all patients whose samples were being re-tested;
- We talked about the issue in the media;
- We posted information on our website;
- We set-up an inquiries line so every patient's concern could be heard;
- We informed all patients and their doctors of their individual test results; and,
- We invited international experts into our lab to review our processes.

Our pledge to you

Every day, health care professionals conduct reviews to ensure we provide the best quality care to you, our patients.

No health care system is perfect. But when we discover issues or concerns, we take every step possible to address them.

Your doctors, nurses, technicians and health care managers are all committed to earn and keep your trust.

For more information visit
our website: www.easternhealth.ca

Eastern Health

HMQ 20

File
ER/PR

Eastern
Health

MEDIA TECHNICAL BRIEFING

Estrogen and Progesterone Testing Review
Monday, December 11, 2006
11:30 a.m.-1p.m.
Level One, Room 1767, Medicore Boardroom, Health Sciences Centre

Agenda

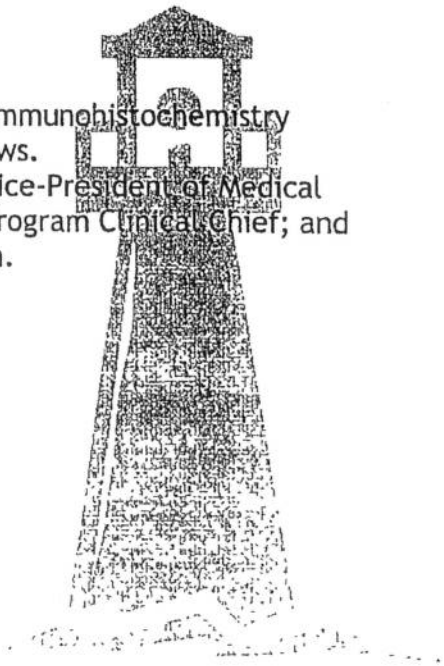
1. Chronology of events
2. Understanding the principles and practice of disclosure
3. Understanding the ER/PR Test
4. Reviewing our outcomes
5. Where to from here?

Materials

1. Chronology
2. CD: charts, graphs and sample slides
3. Press Release

Supplemental

1. Opportunity to visit and videotape/ photograph the immunohistochemistry laboratory and the Ventana System. No staff interviews.
2. Interviews may be arranged with Dr. Oscar Howell, Vice-President of Medical Services for Eastern Health; Dr. Kara Laing, Cancer Program Clinical Chief; and Dr. Nash Denic, Chief Pathologist Laboratory Program.



ER/PR Retesting Key Messages (CONFIDENTIAL)

The Process:
Our first priority was and continues to be to our patients.

From the beginning, our reason for conducting this retrospective review was to ensure that patients had every treatment opportunity available to them.

We take these matters seriously and we regret that this may have been stressful period for some of our patients.

We are committed to ensuring that we provide a quality service in our laboratory.

Eastern Health is committed to disclosure; this is a private matter between patient and care provider which we do not discuss publicly.

Eastern Health has acted through this process with the best intentions for our patients.

The Results:
In the vast majority of cases tested and treated between 1997 and 2005, the patient's treatment was confirmed appropriate.

117 patients have had recommended treatment changes. Some of the changes were related to ER/PR conversion while others were as a result of the Tumor Board reviewing charts.

Error is a matter for the legal system and our quality review processes to determine.

The Test:
Testing for ER/PR is a complicated procedure with multiple steps.

This area of lab testing - immunohistochemistry - does not have standardized methods in this country.

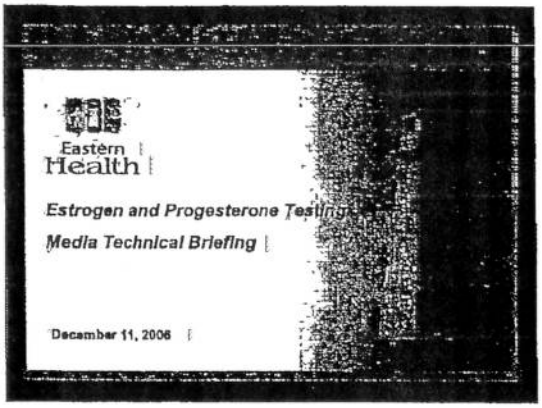
As in many areas of medicine, our understanding of ER/PR, from testing to the impact it has on treatment, has advanced in the last ten years.

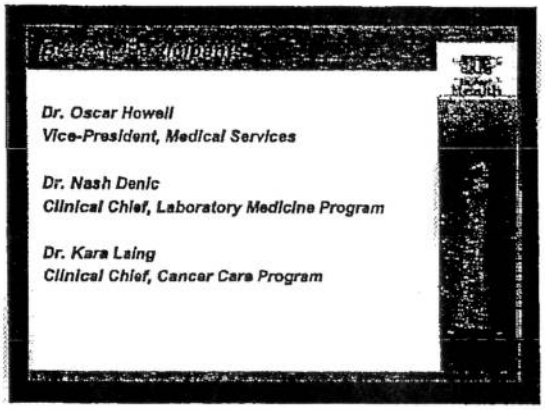
Our organization is one of very few internationally who have conducted a retrospective review of our testing.

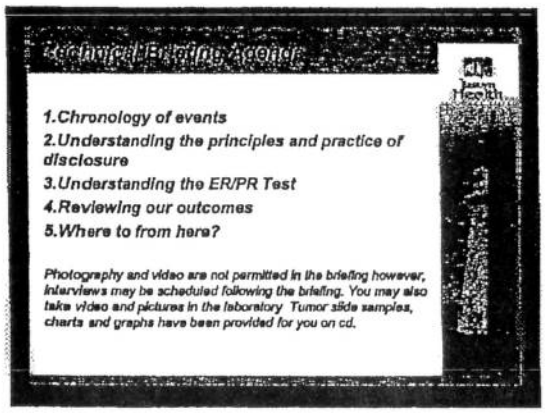
We are amongst the first laboratories in Canada to introduce a new testing system that improves the consistency of results by automating many of the manual steps in the procedure.

The Lawsuit:
Everyone has the right to take whatever action they deem appropriate and we must allow the legal system to address the legal issues.

The outstanding statement of claim restricts our ability to discuss the details.


Eastern Health
Estrogen and Progesterone Testing
Media Technical Briefing
December 11, 2006


Dr. Oscar Howell
Vice-President, Medical Services
Dr. Nash Denic
Clinical Chief, Laboratory Medicine Program
Dr. Kara Laing
Clinical Chief, Cancer Care Program


1. Chronology of events
2. Understanding the principles and practice of disclosure
3. Understanding the ER/PR Test
4. Reviewing our outcomes
5. Where to from here?
Photography and video are not permitted in the briefing however, interviews may be scheduled following the briefing. You may also take video and pictures in the laboratory. Tumor slide samples, charts and graphs have been provided for you on cd.

April 2004: Eastern Health (then the Health Care Corporation of St. John's) installs a new Ventana system

May 2005: Index case

June 2005: 2002 case review

Early July 2005: Decision to retest all ER/PR negatives from 1997-2004 (internally)

Late July 2005: Stop reporting ER/PR in our laboratory; arrange for an independent, external laboratory to complete our retesting

August 2005: Mt. Sinai Hospital agrees to take on project; collecting, packaging and shipping all negative test results.

October 2005: First results come in from Mt. Sinai.
Tumor Board begins reviewing and making treatment recommendations.
Organization conducts media interviews.
Phone contact with all individuals being retested.
External review process begins.

November/ December 2005: Mt. Sinai concerns

Late January 2006: Final samples arrive; forwarded to Mt. Sinai

February 2006: Last test results received

February - May 2006: Tumor Board work continues

June – November 2006: Quality review process; establish centre of excellence for breast cancer pathology; assign head pathologist for immunohistochemistry; prepare for continuation of ER/PR testing

September 2006: Statistical review begins- this work is continuing.

Late November 2006: Quality review completed

"Disclosure is the imparting, by health care workers to patients or their significant others, of information pertaining to any health-care event affecting (or liable to affect) the patient's interests."

The Canadian Patient Safety Dictionary, Davies et. al

Eastern Health is committed to candid and timely disclosure of adverse events, particularly those that may cause risk to a patient.

Our Policy States:

(a) Concentrate on what happened and the possible consequences. Avoid too much detail and technical language.
(b) Remain factual.
(c) Take the lead in disclosure
(d) Outline a plan of care to rectify the harm and prevent recurrence for this patient and others.
(e) Offer to obtain second opinions where appropriate.

·get current policy

The Policy States:

(f) Offer the option of a family meeting.
(g) Document the discussion in the patient's health record.
(h) Determine the need for follow-up meetings and who should attend.
(i) Be prepared for strong emotions and offer personal support and support from others.
(j) Accept responsibility for outcomes
(k) Apologies are appropriate.

- Systems issue
- Oncology practice has changed
- Laboratory technology has changed
- No patient specific information to disclose
- National implications
- Class action lawsuit

- When a breast cancer is removed from the body, tests are used to determine if the cancer cells have estrogen or progesterone receptors.
- If estrogen receptors present on those cells, anti-estrogen therapy such as Tamoxifen is used to treat that cancer.
- Literature suggests about 75% of breast cancers are estrogen-receptor-positive (or "ER-positive"), "positive" meaning that a certain number of cancer cells have receptors present.
- When a cancer shows no estrogen receptors (when it is "ER-negative"), anti-estrogen therapy is not effective.

Tamoxifen and Cancer

Hormonal Therapy is considered to be an adjuvant therapy, which means that it is additional treatment given after potentially curative surgery.

Adjuvant therapies include:

- Radiation Therapy
- Chemotherapy
- Targeted Therapy
- Hormonal Therapy

The aim is to get rid of residual cancer cells in the body.

The goal is to:

- Decrease recurrence rates; and
- Improve overall survival.

However, a significant number of patients with breast cancer have recurrent disease despite advances in adjuvant therapy.

Tamoxifen:
"Gold standard" for years
Optimal duration 5 years
Side effects:

- Vasomotor (hot flashes)
- Uterine cancer
- Thromboembolic (blood clots)

[redacted]

Aromatase Inhibitors:

- Used in post-menopausal patients
- May be given instead of or after Tamoxifen
- Side Effects:
  - Osteoporosis
  - Joint and Muscle Pain

Prior to April 2004: The Dako testing technique was used in our laboratories. This technique required the manual boiling of tissue and precise measuring of mixtures of immunohistochemical reagents.

After April 2004: The Ventana system was installed, which automates some of this process removing as much human manipulation as possible. In addition, there are significant advances in the development and use of reagents (such as antibodies).

Immunohistochemistry:

- In order to determine whether a tumor has ER or PR receptors, laboratory technicians must expose cellular constituents so that pathologists can see them and count them to determine the percentage of positivity.
- Antibodies are used to visualize cellular proteins. An antibody is "a molecule that has the property of combining specifically to another molecule, termed an antigen."
- Antibodies are made to specifically match the cellular antigen of interest. During the testing, the antibody is exposed to the tissue and binds to the antigen.
- Using good antigen retrieval methods are critical to the success of the test.

Understanding Current Issues

- There are no standardized immunohistochemistry testing methodologies worldwide.
- Currently there is no national laboratory accreditation process for immunohistochemical labs.
- "Immunohistochemistry tests are probabilistic, not accurate." *Dr. Anthony Magliocco, Associate Professor of Oncology, Pathology and Laboratory Medicine, University of Calgary, at the U of T Pathology Update Course November 2005*
- In tumors with low expressors it is difficult to retrieve the antigen.

Retrospective Review

- From 1997 to 2005, Eastern Health conducted 2760 ER/PR tests.
- 939 individual samples were sent to Mt. Sinai for retesting
- 117 individuals had recommended treatment changes.
  (Of these 117 individuals, some of the changes were related to ER/PR conversion while others were as a result of the panel reviewing their charts.)

What is Eastern Health Doing?

For the last six months, Eastern Health has been focused on completing the disclosure process and a quality review. Within the next two months we will be reinstating ER/PR testing at our laboratory.

QUALITY ASSURANCES

- All recommendations from our external reviews have been implemented or are in progress
- Designated IHC Lab as separate department, including 3 designated IHC technologists, IHC Lab director and dedicated cutter
- Our technologists and pathologists have received specialized training in immunohistochemistry
- Consolidated all breast cases for examination and reporting to a designating group of pathologists
- Improved Quality Management Program.
- Seeking accreditation for entire laboratory.
- Involved in proficiency testing

ER/PR Media Technical Briefing
Q & A's

Q1. Why has Eastern Health taken more than a year to go public with what went wrong & release the numbers of how many women received false results? Is this acceptable in your view?

A1. Eastern Health takes this matter seriously and we regret that this may have been stressful period for some of our patients. This is the first opportunity that we have had to release numbers and to look retrospectively at our test results. It has taken a significant amount of time to collect, send, retest, review and analyze almost 1000 test results. We also had to allow an opportunity for doctors and clinical teams to act on our recommendations and to ensure that all patients impacted by the review have been contacted.

Q2. Why didn't Eastern Health notify the public right away when the problem was first discovered?

A2. Originally we believed that results would be returned to us much quicker than they actually were. It was our intention to wait for the results so that we could disclose actual information to our patients instead of having to tell them that they may or may not be impacted by this review; that we didn't know what this would mean for them; and to unnecessarily raise alarm for individuals who may not affected.

Q3. Did Eastern Health hold off on going public with this because of legal complications?

A3. No. Eastern Health began disclosing information about the review to the individuals impacted before any legal action was initiated. Individuals have every right to take whatever action they deem appropriate, including legal action. That does not weigh into our decision-making process.

Q4. Do you feel the organization mishandled how it informed the public? In hindsight, would you have handled things differently?

A4. This situation is a complicated one, but we have always acted in what we determined to be the best interest of our patients. In the early days of this discovery, the situation and our understanding of what we were dealing with changed daily. Initially we had no specific information to disclose, only that there appeared to be an issue. We made a determination to wait until we had something specific to tell the public. However, this did not stop us from informing individuals as soon as information about their personal situations was available. We have been very upfront and open with our patients in one-on-one settings. We were not surprised when these individual disclosures lead to the public learning of the review and we responded publicly to the best of our ability.

As to our ability to discuss the retesting publicly today, we are inhibited by the legal process. That is a reality that we hope the Newfoundland and Labrador public can appreciate and understand.

Q5. Were some individuals put in danger do to the delays in retesting?

A5. It is impossible to predict how the impact of this review will impact specific cases into the future. However, the delay in testing was only a matter of weeks or months and is unlikely to be significant. It is also important to remember that, in the vast majority of cases tested and treated between 1997 and 2005, the patient's treatment was confirmed appropriate.

Q6. Were the tests prioritized when sent to Mt. Sinai?

A6. No.

Q7. What do you say to those women who were left for months wondering if they received the wrong care plan?

A7. We regret that this may have been stressful period for some of our patients. We were in constant contact with many of these patients and we provided them with their personal information as quickly as possible.

Q8. How many patients have been impacted by this?

A8. In the vast majority of cases tested and treated between 1997 and 2005, the patient's treatment was confirmed appropriate.

From 1997 to 2005, 2760 individuals had ER/PR tests in our laboratory. 939 of these patients originally received negative results. 117 of these patients have had recommended changes in their treatment plans as a result of review by a panel of experts.

Q9. What is the rate of error? How many people converted?

A9. Up to this point, our focus has been on making treatment changes, where appropriate, and 117 individuals have experienced treatment changes.

Some of these changes are because of a conversion in their ER/PR test result from negative to positive; some because the definition of "negative" has changed; some because of where patients are today with their disease - there are multiple factors involved.

Now that legal proceedings have been initiated, we will have to allow the legal process to determine if in fact error has occurred.

The numbers of individual conversions are not relevant and turn the process into a "numbers game." For example, some people have minor conversions that did not impact upon whether they would be considered suitable for hormonal therapy. Some individuals converted, but upon review of their treatment plan it was discovered that for other clinical reasons they were already receiving tamoxifen.

What is relevant is the number of people whose care may change as a result of the process, and that was 117.

Q10. What caused the conflicting results?

A10. In the vast majority of cases tested and treated between 1997 and 2005, the patient's treatment was confirmed appropriate.

The test used for most of the review period for ER/PR is a complicated one with more than 40 manual steps. Additionally, there has been in this period changes in practice and new understanding about treatment protocols. For example, oncologists once considered a negative test to be less that 30% positive. Today, oncologists believe that a positivity rate of greater than 1% may mean that hormone therapy could be effective.

The reasons for the new numbers will be explored in detail during legal proceedings are we are unable, as a result, to speculate further. However, what is most important is that when we identified what we considered to be a potential problem, we acted immediately to take whatever action we could to ensure that our patients have every treatment opportunity possible.

Q11. Are pathologists to blame for this? Did these errors occur because of the difficultly to recruit pathologists and because some haven't achieved their national examinations? Is this a competence issue?

A11. Our organization employs competent and nationally recognized pathologists, oncologists, surgeons, and technicians who are dedicated to provided the highest quality care possible to our patients. It was our employees and physicians who brought this issue forward and who have been working diligently over the last eighteen months to ensure that the retesting and the quality review process have been conducted as efficiently and as effectively as possible. There has been and there will be no blame assigned within our organization.

Q12. Were there quality checks in place when the error was discovered?

A12. All laboratory testing conducted at Eastern Health uses standard controls.

Q13. What did the medical experts review reveal? What recommendations came out of that review? (Visit from the BC Cancer Institute and Chief tech. Mt. Sinai)

A13. We were pleased to have external experts review our laboratory as part of our quality review. This is common practice. However, quality review materials are kept confidential. The reason for this is that the courts and the legislature recognize that quality review in the health care sector is vital. In order to encourage staff and external reviewers to express their opinions freely, there must be protection from disclosure beyond the quality review. This protection from disclosure is recognized in the Evidence Act, which provides that quality assurance material is not to be disclosed within a legal proceeding. It is also recognized in the Access to Information and Privacy Act, which provides that opinions or recommendations made to an agency do not have to be disclosed. However, it is important to note that there is no protection from disclosure for facts uncovered or disclosed during quality review investigations.

Q14. Could more have been done to prevent this from happening?

A14. This is impossible to answer at this point.

Q15. What's been done to prevent this from happening again?

A15. We have implemented or are in the process of implementing all recommendations from our external reviews.

Because we recognize that testing for ER/PR is a complicated procedure that requires specialized skills, we have designated the lab that performs these tests as a separate department with 3 designated technologists, a Lab medical director, and a dedicated cutter. Additionally, our technologists and pathologists have received specialized training in immunohistochemistry.

As well, we have consolidated all breast cases for examination and reporting to a designating group of pathologists, a centre for excellence in this area.

We have established a Quality Management Program in this new department and we are involved in proficiency testing.

Moreover, we are seeking accreditation for entire laboratory. Unfortunately, there are **no standardized immunohistochemistry testing** methodologies worldwide, and currently there is **no national laboratory accreditation process** for immunohistochemical labs.

Q16. Could this happen again?

A16. If you are asking me if issues may arise in the future with individual ER/PR tests results, or any test results for that matter, I would say that there is a standard deviation in most lab results. No test is absolutely perfect. No lab is absolutely perfect. Medical science is not absolute. However, I would say that we have taken the steps necessary to ensure that the ER/PR tests we will perform and the treatments resulting from them will meet or exceed the standard of care offered anywhere in the country.

Q17. Have individuals died because of this error in testing?

A17. It is not possible to answer this question. In the last 10 years, individuals who were tested for ER/PR have passed away - some because of cancer and others for numerous reasons.

Q18. Did you retest the deceased? Would you retest the deceased?

A18. Our focus has been on addressing those patients who could be helped by additional treatment, so we did not retest individuals who have passed away. However, we would do so upon request of the family members.

Q19. Do those women who have converted now have a shorter life expectancy because of this error?

A19. It is not possible to answer this question. Hormonal and other adjuvant therapies are intended to decrease recurrence and improve overall survival. The hope is to stop or delay the cancer from metastasizing.

Hormonal therapy is most effective 2-4 years post cancer surgery, which is why we were anxious to retest as quickly as possible and to offer the opportunity to any patient who could benefit from it. However, studies indicate that hormonal therapy can be effective up to and even beyond 12 years post-cancer surgery.

Q20. How many women were given extensive treatment (i.e. Surgery, Chemo etc.) that through this retesting you now realize they did not need to be treated so aggressively?

A20. Oncologists use a combination of therapies to treat patients. Hormonal therapy is used in combination with radiation, chemotherapy, surgery and other targeted therapies. Discussing individual patients would breach patient confidentiality.

Q21. What is the survival rate if a patient is prescribed Tamoxifen compared to someone who is not?

A21. How any drug or treatment will impact upon any patient is very individual and can not be predicted universally.

Q22. What do you say to these women who have been living with mental distress because of this and who have lost faith in the health care system?

A22. It is unfortunate is this has caused individuals to loose faith in the system. We certainly appreciate and understand the stress this may have caused some of our patients. However, we would hope that individuals can have faith in the fact that we have taken action here that, to our knowledge, no other lab has taken and that Eastern Health did what we felt was in the best interest of our patients despite the consequences for the organization in terms of increased scrutiny and legal action.

Q23. Should other cancer patients question their diagnoses?

A23. ER/PR is not a diagnostic test used to determine if an individual has cancer. A tumor is removed and sent for testing to determine if it is positive for hormone receptors. The test is used to help oncologists determine appropriate therapies.

Q24. Is there anything patients can do to inform themselves when they're having these tests done?

A24. We encourage our patients to be informed about testing and all aspects of their disease and its treatment. In fact, the program develops literature on testing and on other elements of care for our patients.

Q25. What are the cost implications of this discovery?

A25. As the process continues, we are unable to estimate cost at this time. Certainly, we have dedicated significant human and financial resources to this process.

ER/PR RETESTING CHRONOLOGY

DECEMBER 11, 2006

Eastern Health

April 2004: Eastern Health (then the Health Care Corporation of St. John's) installed a new Ventana system for use in our immunohistochemistry laboratory. This more extensively automated system replaced the Dako System , a complicated, manual and multi-phase procedure with more than 40 steps. The Dako system was an advance from biochemical assay, used prior to 1997.

May 2005: One of our oncologists was treating an individual whose ER/PR was originally tested in 2002 (using the Dako system) and shown to be negative. Given the nature of this woman's cancer, her age and other factors, the oncologist requested that the test be repeated. The second test was conducted on the new Ventana system, and converted to a positive result.

Representatives from the Laboratory Program met with oncologists to discuss this new result and a decision was made to retest five more negative patients, who all converted to positive.

June 2005: It was decided to retest all negative results from 2002 to determine if these were isolated cases or symptomatic of a bigger issue. The chief of pathology wrote to all Laboratory directors in the province to return all negative ER/PR specimens for the year 2002 for retesting on the new, more sensitive Ventana system.

Early July 2005: A meeting was scheduled and the decision was made that all patients who were ER/PR negative from 1997-2004 would be retested internally on the Ventana System with testing to take place over the next number of weeks.

Late July 2005: The decision was made to stop reporting ER/PR in our laboratory and to arrange for an independent and external laboratory to complete our retesting as well as ongoing work.

August 2005: Mt. Sinai Hospital, considered to be a "gold standard" laboratory internationally, agreed to take on the project. Our laboratory began the process of collecting, packaging and shipping all negative* test results from 1997-2005 to Toronto.

** The definition of "negative" has changed within the seven year period in question. Originally, oncologists believed that tumors with less than 30% positivity for ER/PR should be considered negative. With advancing understanding of cancer and treatment, the negative rate has dropped, first to 10% and now to 1%. Today, oncologists believe that any positivity may be worth treating with hormonal therapy.*

Mid October 2005: The organization established a Tumor Board comprised of two (2) oncologists, two (2) surgeons, two (2) pathologists, one (1) representative from the Quality Department and one (1) support person. The Tumor Board was tasked with reviewing the results as they arrived, reviewing charts, and making treatment recommendations for each patient.

The Tumor Board met once a week from October 2005 to May 2006 reviewing individual cases and making recommendations.

Mid October 2005: The organization conducted the first of numerous media interviews, and provided what background information was available at that time. Advertising was also purchased informing the general public of the retesting in general.

October 2005: Patient Relations representatives from Eastern Health telephoned all individuals whose specimens were being sent away for retesting.

The laboratory conducted the first of a number of external review processes. During this period, the laboratory also attempted to gain insight from other laboratories across Canada regarding their experiences with ER/PR testing.

November/ December 2005: The organization expressed concerns to Mt. Sinai about the slow pace of reports. However, they were experiencing unexpected manpower issues and were unable to move the tests through the system any faster.

Late January 2006: The last batch of samples arrived at Eastern Health from the other provincial health authorities. They were forwarded to Mt. Sinai for review.

February 2006: The last test results were received from Mt. Sinai.

February - May 2006: Concentrated effort of the Tumor Board to review test results, write recommendations and conduct disclosures. A six month period *(May to October)* follows to ensure that the organization has completed all the disclosures possible and that every patient has had every opportunity to contact their physicians.

June - November 2006: The new Chief Pathologist and the new Vice-President, Medical Services worked on the results of the quality review process; established a centre of excellence for breast cancer pathology; assigned a head pathologist for immunohistochemistry; and generally prepared for the continuation of ER/PR testing in our laboratory.

September 2006: A statistical review is initiated to examine the numbers and arrive at conclusions. This information will form the basis of the quality review. Analysis is currently continuing.

Late November 2006: The organization completes its quality review.

Eastern Health

NEWS RELEASE

Eastern Health releases outcomes of laboratory review

EMBARGO - 9 a.m., December 12, 2006 - St. John's, Newfoundland and Labrador - Eastern Health today released the outcomes of its review of estrogen and progesterone receptor (ER/PR) testing conducted by the laboratory at the Health Sciences Centre since 1997. Eastern Health has been focused on collecting, sending, retesting and reviewing all test samples and conducting an extensive quality review within the laboratory since October 2005.

"From the beginning, our health care providers have been motivated by a desire to ensure that our patients have every treatment opportunity that may be available to them and to make sure we provide quality services to the public," said Dr. Oscar Howell, Vice-President of Medical Services for Eastern Health. "In the review period, from 1997 to 2005, 2,760 ER/PR tests were conducted by our laboratory. 939 of these test results were originally negative. These test samples were sent to Mount Sinai Laboratory in Toronto for review. In the majority of cases, the patient's treatment was confirmed appropriate. However, 117 patients had been identified as requiring treatment changes by a panel of oncologists, pathologists and surgeons."

Breast tumor samples are tested for estrogen and progesterone receptors to determine if hormonal therapy such as the drug Tamoxifen may be one treatment option for patients.

Patients who have been notified of a change in result have since met with their treating physicians to determine their current treatment options.

Eastern Health's first priority is its patients and the organization is committed to notifying them about issues that may impact upon their diagnosis or treatment. "Our clinical team members have communicated individually with all patients impacted by this review," says Dr. Howell. "We have had many conversations with the patients involved and we are always willing to discuss the details of a patient's care with them. However, patient confidentiality is an important principle in health care so we do not discuss the details of individual cases publicly."

"We have been assured through our review process, which included consultation with national experts in laboratory medicine, that when we reinstate testing we will provide the people of this province with a high standard of estrogen and progesterone receptor testing," added Dr. Howell.

Eastern Health is dedicated to improving the system. As a result of this review the organization has implemented new means of ensuring high standard patient care such as: improving a Quality Management Program; seeking accreditation for the entire laboratory; and ensuring all technologists and pathologists have received specialized training in immunohistochemistry. The organization is expected to reinstate ER/PR testing at the Health Sciences Centre in the coming year.

-30-

MEDIA CONTACT:
Leona Barrington

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T: 709-777-1339 or 728-7935
leona.barrington@easternhealth.ca

A MESSAGE TO BREAST CANCER PATIENTS

Re-testing for estrogen and progesterone (ER and PR) Receptors

WHAT'S IT ALL ABOUT?

You may have heard in the media that Eastern Health is re-testing breast cancer tissue samples.

Recently the lab at the Health Sciences Centre discovered some inconsistent results in breast tumour samples.

To ensure that all patients have every treatment opportunity that may be available to them, Eastern Health has decided to re-test all the negative estrogen receptor results since 1997.

WHAT ARE ER AND PR RECEPTORS?

All patients who have had breast cancer have been tested for the presence or absence of estrogen and progesterone receptors (ER and PR). The presence or absence of ER and PR helps determine the most appropriate treatment of breast cancer.

When you are ER and/ or PR positive, hormonal therapies such as Tamoxifen may be one treatment option open to you. ER and PR are just one of the many things oncologists look at to determine the type of cancer treatment a patient will receive.

Only a small percentage of breast cancer patients may be affected by this re-testing as treatment for breast cancer is based on several factors, not just ER and PR.

WHAT IS HAPPENING NOW?

We are sending previously collected tissue samples to Mount Sinai Laboratory in Toronto to make sure patients are getting the appropriate treatments. Patients are not required to come to hospital or have any additional testing.

All patients who are being re-tested are being contacted.

Our first priority is to notify patients whose results have changed because of the re-testing. If there is a change to your result and your treatment is affected, you will be contacted directly by your oncologist or treating physician. You will also be notified if there is no change in your ER and PR status.

It is important to note that most patients will not experience a change in their earlier test results. About 75% of all breast cancer patients tested positive for ER and PR from 1997 to 2005. These patients are not impacted by this re-testing.

If you had breast cancer and are concerned about your previous test results and treatment, you may wish to contact your oncologist, surgeon or family doctor.

You may also call the Patient Relations Officer at Eastern Health at 777-6500. She will attempt to answer your questions or link you with someone who can help.

Eastern HEALTH

HMQ 38

From: "Jeanette OKeefe" <Jeanette.OKeefe@easternhealth.ca>
To: "Tansy Mundon" <TansyMundon@gov.nl.ca>
Date: 2007-05-23 11:13:38 AM
Subject: ER/PR Advertisement Date

Hi Tansy,

Not sure exactly when this ad ran, but it was sent to The Telegram, Western Star, The Independent and The Express (16 Community Papers) on Thursday, October 20, 2005. I'm assuming the ad ran that following Saturday but can't be certain on that.

Jeanette

Jeanette O'Keefe

Communications Manager

Strategic Communications - Eastern Health

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