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 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.

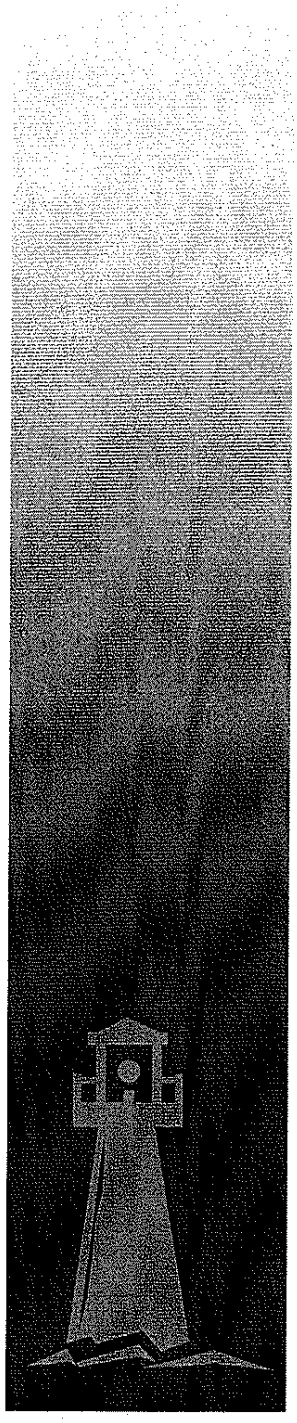
June 2005: It was decided to retest all negative results from 2002 to determine if these were isolated cases or symptomatic of a bigger issue. The chief of pathology wrote to all Laboratory directors in the province to return all negative ER/PR specimens for the year 2002 for retesting on the new, more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

Early July 2005: An emergency 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,*



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.

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Eastern Health

Eastern Health releases outcomes of laboratory review

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.

Dr. Oscar Howell, Vice-President of Medical Services for Eastern Health said, "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."

"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," says Dr. Howell. "We have been assured through our review process, which included consultation with national and international 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."

Eastern Health has learned from this experience and 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: establishing 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.

DRAFT KEY MESSAGES

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 understand that this may have been stressful period for some of our patients; for this we apologize.

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 of the review process.

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 understand that this may have been stressful period for some of our patients; for this we apologize. 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 this review 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. ?

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

A7. We appreciate that this may have been stressful period for some of our patients; for this we apologize. 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 ... ?

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.
We will not be talking about these facts today, as this is a matter that is before the courts.

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 of +or- 5%. 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. Can we answer this?
Can we say: during the course of the review we discovered a very small number (4) of patients with diagnostic complications, but these cases are unrelated to the ER/PR test and we cannot discuss details of these cases as this information is protected by patient confidentiality?

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

Q21. Kara?

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. *Kara? Any suggestions to 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.