ER - PR numbers.

2760 ER/PR tests
- 939 reported negative (34%) → Mt. Sinai
- 763 reviewed
- 176 not reviewed (deceased)

763 reviewed
- 433 no change and no Δ Rx
- 317 had change in test results (41.5%)
  - 104 required a Δ Rx
  - 213 did not require a Δ Rx
- 176 patients deceased

? 117 required Rx Δ

Key messages:

① our first responsibility is the care of our patients
- patients diagnosed c̄ cancer and already under Rx all contacted → best Rx
- new patients → D/C our labs → best labs

② ER-PR test
- tech review
- professional review
  > acted on recommendations
- IHC a separate dept c̄ specialized training
- consolidated services to fewer more specialized teams
- proficiency testing < UK AFPA
- seeking accreditation for entire lab

- test reliability
  - results changed at Mount Sinai
- connected w pts
- supports are put in place for people
- ethical decision to go back knowing full well the consequences
- treat as system is important
  cancer increases every stress
- briefings of Peter Dewe & gov
- professional conduct
  Pt safety org
  Pathology Assoc
  Oncology Assoc

Oscar Howell

From: Susan Bonnell
Sent: Wednesday, May 16, 2007 4:25 PM
To: George Tilley; Stephen Dodge; Oscar Howell
Subject: ER/PR: Private and Confidential

Why should we speak publicly?

- Our credibility as an organization and our ability to provide quality care are being maligned.
- When you don't speak, the story continues - with or with you – and the media look for less credible spokespeople who will speak to them. Hence, Peter Dawe, Geri Rogers, Ches Crosbie...
- Two things happen when you don't stand up to bad press: (1) the public automatically assumes that there is a good reason why you are being quiet and there must be something to the allegations; and (2) just like the school-yard bullies, an individual with an axe to grind feels uninhibited and will keep digging and digging.
- Moreover, a gang-mentality develops. I'm already seeing this amongst the press themselves who automatically assuming that the organization is lying to hide the true facts. "If they won't defend themselves then they must be a back of liars."
- Bad stories come and bad stories go. I don't suggest for a minute that we should jump to react on every bad story – that would not be responsible, ethical or sensible. However, this issue is not just any issue. We've been dealing with this one for two years. And we have been acting in good faith, in the best interests of patients, knowing the full consequences, and we're letting the media beat us up on the wrong issue!
- If they want to criticize us for negatively impacting 117 people – so be it. We should be held accountable. However, we shouldn't allow the media to unfairly criticize us for (a) admitting we negatively impacted patients publicly but (b) refusing to play a numbers game and (c) respecting the legal system once action was initiated.
- We are also allowing the Canadian Cancer Society to leave the general public with the impression that there are a "new" group of women. This is causing confusion and we are getting calls asking about this. There's a new level of fear and anxiety that Peter Dawe is creating and then blaming us for.

What could we possibly say to the media?

- From the beginning, we have been upfront with the public at large and with the patients impacted by this review in particular.
- In December when we issued an assessment of the review to the public, we did so because we felt that the public deserved to know as much as we could tell them about the results of the review.
- When this all began in 2006, we took this on because we felt that if there was even the possibility that we had made a mistake or that new technologies and new approaches in testing could mean that even one women may benefit from retesting, we had an obligation to retest all women.
- Since that time some of the individuals impacted by this review have decided to take legal action against the organization. This is entirely within their rights and we respect the law, respect the judicial system, and must allow the legal matters of this issue to be tried in a court of law.
- No one from our organization is disputing that there are numbers in the public today, obtained from public court documents – affidavits signed by our officials – that were not released to the public in December. However, in December we told the press that we could not (a) release all the numbers or (b) assign a rate of error for this test. The total number of individuals impacted by this retesting is a key part of the legal case and needs to be dealt with in court – not in the press. Secondly, we cannot assign a "rate of error" for this test. Error will need to be determined by the courts. We have said repeatedly in the media that we do not know with certainty what caused there to be new or differing results.
- From the beginning, our focus was on answering the question – whose treatment plan may require a change? That question has been asked and answered and every single individual impacted has been

contacted through their physician.

These were our key messages in December:

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.

Some of the Q and A from December:

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.

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.

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.

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.

Eastern
Health

Susan Bonnell
Director, Strategic Communications
709-777-1426 (1338)

ER/PR Retesting Key Messages (CONFIDENTIAL)

The Process:
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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.

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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. ? No

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.

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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 … ?

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.

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.