Eastern
HEALTH

MEMO

RE: ER and PR Testing Public Disclosure
DATE: July 21, 2005
TO: George Tilley
FROM: Susan Bonnell

I certainly have some concerns following the meeting this morning re: public disclosure:

- While I am a strong advocate for public disclosure – I was certainly one of the first voices out there when we thought this was our error saying that we need to disclose a.s.a.p. – I'm not convinced that we can serve the "greater good" and still maintain the reputation of the lab which, in my opinion, is in the best interests of the public to maintain.

- In terms of maintaining the quality and professional reputation of our laboratory, it would be better in one way if we could focus on issues with this one test rather than looking at this from the perspective of retesting everyone because the technology has improved. Where does this end?

- We have to protect the integrity of the system at large. Many tests are done using immuno staining and other manual processes. We have to be careful that we don't portray those methods – some of which are still in use in our labs – as somehow inferior. We also have to be careful that we don't set ourselves up to have to redo every single test done in the past where new technology improves our outcomes.

- We need to consider what implications a public announcement will have on a variety of impacted stakeholders:

    - will all breast cancer patients hear and understand the message and will they understand how to handle it?
    - will we reach our intended target?
    - what impact will this announcement have on the family members of deceased breast cancer patients?
    - do we have the potential to ignite breast cancer advocacy groups?
    - are we potentially affecting others who have ER/PR testing? This test is not used exclusively for breast cancer.
    - could the very nature of our disclosure be a factor in litigation, as it was in the Labrador case?
    - what impact is this going to have on oncologists and what support will they need to ensure that patient issues are dealt with promptly? Are they going to be willing or able to make this a priority when they may have patients that are more acutely ill and deserving of priority care?
    - what will be the impact on other serves we offer, particularly in lab and d.i. where testing methods and technologies are ever changing and improving?
    - what impact will this announcement have nationally? Will we be forcing labs across the country to redo all their tests?

- A full public disclosure with a press conference, 1-800 information line, letters to all impacted patients and supportive Ministerial comment would not be my choice in this case.

- Press conferences can be beneficial in that they bring all the media and all the spokespeople together at one time and one message is received. However, reporters can adopt a mob mentality and the issue can be sidetracked in all the media by one stray comment or idea. Besides which, we do not plan to "take blame" for something we did wrong so we do not need to line up the players as if we are taking blame.

- When we were under the impression that our laboratory had greater culpability than we now suspect, I was advocating for direct contact with all impacted patients, providing them with an opportunity to contact our organization directly through a toll-free information line.

- The difference today is that we cannot with certainty say that our lab erred in testing. While there may or may not be an issue with one or more years, we do know that (a) there are some concerns with the lab process that we must address and that (b) new and more sensitive technology is picking up on some false negative test results.

- I'm not sure what it is exactly that we are disclosing publicly. Are we announcing that we have a new technology and that recently we have become aware of its ability to more sensitively assess ER and PR levels? If so, is this not better coming directly from our organization to the patients and their oncologists who make the determinations on care options?

- I'm worried that this will be portrayed in a "black and white" way – just because you tested negative in 2001 for ER/PR but your 4-year old sample now tests positive does not automatically mean that you will now get hormonal therapy and that we avoid the potential for litigation. The media and the public cannot be expected to understand the nuances of cancer diagnosis and the many variables that determine treatment.

- I'm also concerned that the public approach (a) will open a pandora's box and (b) will cause unnecessary and undo stress on cancer patients, their families and the families of cancer victims.

- My preferred approach would be to work directly with the medical community to quickly address each individual case that converts from a negative to a positive ER/PR.
    - (A) We move fast to identify and retest these individuals.
    - (B) We contact their oncologists/ surgeons immediately with their new tests results.
    - (C) In the event that there is no physician, we act immediately to identify a physician who can review the file and take on the case
    - (D) We ensure that every patient is aware of their new tests results, either by follow-up with the physician or possibly by letter directly to the patient, providing our Patient Relations Officer as a contact for information and we establish a toll-free number for provincial patients that links to the PRO's office.
    - (E) No public announcement is necessary.

- If we look at what the Department calls "worst case scenario" – that a patient goes to the media with the fact their cancer care has changed because their lab results were wrong – what can we say to defend our organization?
    - We are actively addressing the issue.
    - We have better technology now that is more sensitive.
    - We have begun the process of identifying and retesting all previous negative results.
    - We are working with the medical teams to notify and change patients' treatments where it is appropriate.
    - Quality assurance is a matter of course in a hospital setting. We are always reviewing our processes and updating our technology.

Susan

Eastern HEALTH

MEMO

RE: ER and PR Testing Public Disclosure
DATE: July 22, 2005
TO: George Tilley
CC: Dr. Bob Williams
FROM: Susan Bonnell

From a communications perspective there are two separate yet connected issues emerging; our obligation to ensure that all breast cancer patients receive the best possible care and our desire to ensure that our laboratory is functioning at the highest level possible.

While I am a strong advocate for public disclosure, I do not believe that it is in the best interests of the public to make a formal announcement regarding ER and PR tests:

- As it stands today, we do not know why we are achieving a high rate of conversions in those specimens that have been retested. Is this a case of increased sensitivity due to the new technology that exposes the limitations of the former manual process, or were the tests performed incorrectly? We cannot answer this question, so we risk confusing and upsetting patients and their families and unnecessarily calling into question the professionalism of the lab.

- We cannot say that we have a new piece of technology that is more sensitive and therefore we are retesting old negatives because if we are retesting in this case, why wouldn't we do it every circumstance where new technology improves our ability to diagnose and treat illness? Furthermore, to state that this is about technology would be only partially truthful as the organization feels that there is a *possibility* of error that must be investigated. If asked the question, "How did this come to your attention?" then it would appear that our actions were obfuscatory rather than open and honest.

- We have an identifiable group of individuals that we can contact directly. In similar circumstances where, for example, we have lost a batch of specimens or made a quality improvement that impacted upon a group of patients, we have contacted those individuals directly. Regardless of the fact that this is a larger group than we have normally dealt with we must treat these patients with the same regard. In the Health Labrador OB/GYN case, plaintiffs in the class action lawsuit have identified the manner in which they were notified and the loss of anonymity as major militating factors in their decision to sue.

- We need to consider what implications a public announcement will have on a variety of impacted stakeholders:

    - Will all breast cancer patients hear and understand the message? Will they understand how to handle it? Will we reach our intended target?
    - What impact will this announcement have on the families of breast cancer victims?
    - Do we have the potential to ignite breast cancer advocacy groups?
    - Are we potentially affecting others who have ER/PR testing? This test is not used exclusively for breast cancer.
    - What impact is this going to have on oncologists and what support will they need to ensure that patient issues are dealt with promptly? Are they going to be willing or able to make this a priority when they may have patients that are more acutely ill and deserving of priority care?
    - What will be the impact on other services we offer, particularly in lab and d.i. where testing methods and technologies are ever changing and improving?
    - What impact will this announcement have nationally? Will we be forcing labs across the country to redo all their tests?

On the second issue – quality issues in the laboratory - there is a need for both an internal plan to address the problems immediately as well as an external strategy to inform the public at large. If it is our firm belief that there are issues that must be addressed relating to our immunoperoxidase staining and other related tests, we must be in a position to acknowledge this publicly and to deal with the consequences.

It is important, however, that we not allow any potential issues with the laboratory and the manner in which we disclose to the public to cause any further damage to these particular breast cancer patients. Although this particular test has led us to this potentially critical discovery about the lab, we must ensure that these patients are not caught up in something else that causes them unnecessary stress.

A. It is critical that we consult with the oncologists to get their expert advice on how to inform the impacted individuals that their specimens can be retested. In all cases, the administration defers to the physician decisions about patient care. For example, we have publicly stated numerous times that decisions about priority, wait lists, and appropriate treatment are the decisions of the medical community – not the hospital administration. We need to be consistent – the decision to retest old negatives must be made by the physician group with their patient. The discussion about this is decision should probably take place in the privacy of a consultation room, not in the public forum.

B. We should be concerned that this could be portrayed in a "black and white" way, particularly if the media are involved. Just because a patient tested negative for ER/PR previously but now tests positive does not automatically mean that the patient will get hormonal therapy. The media and the public cannot be expected to understand the nuances of cancer diagnosis and the many variables that determine treatment.

A full public disclosure with a press conference, 1-800 information line, letters to all impacted patients and supportive Ministerial comment is not recommended. Legal counsel and risk management advise against such a disclosure, particularly before the impacted patients have had the opportunity to hear about this from us.

I recommend that we work directly with the medical community to quickly address each individual case that converts from a negative to a positive ER/PR.

1. We notify patients of the retesting, either through formal letter or by some other means deemed appropriate by the oncologists.
2. We move fast to identify and retest these individuals.
3. We contact oncologists and surgeons immediately with new tests results.
4. In the event that there is no physician, we act immediately to identify a physician who can review the file and take on the case
5. We ensure that every patient is aware of their new tests results, either by follow-up with the physician or possibly by letter directly to the patient, providing our Patient Relations Officer as a contact for information and we establish a toll-free number for provincial patients that links to the PRO's office.

If we are contacted by the media about one or more of these cases, we can confidently address the issues, knowing that we are disclosing the information to the correct individuals:

- We are actively addressing the issue and have been contacting the patients affected.
- We have begun the process of identifying and retesting all previous negative results.
- We have better technology now that is more sensitive.
- We are working with the medical teams to notify and change patients' treatments where it is appropriate.
- Quality assurance is a matter of course in a hospital setting. We are planning an external review in September.

Susan Bonnell
Director, Corporate Communications