From: Tansy Mundon
To: Thompson, Robert
Date: 8/7/2007 1:07:47 PM
Subject: Re: Fw: Draft response to MQ re ER/PR results - ATIPP Mark Quinn

Robert,
I have reviewed the attached draft correspondance and provide the following comments:

1. We really need to see the raw data being released before providing any comment on how the data could potentially be interpreted.
2. In my view, the explanatory information does not serve to provide any sort of analysis of interpretation of the raw data and instead reiterates information that has already been provided to media in one form or another. [redacted]
3. With respect to the deadline for the request, while I obviously agree the information needs to be provided on or before the deadline date, I feel we need a complete package of information to review before the information is provided to the requestor, and ultimately to the public.

Tansy

>>> Robert Thompson 8/7/2007 12:42 AM >>>
For review

Sent via Blackberry
Government of Newfoundland and Labrador

August 6, 2007

Mr. Mark Quinn
Canadian Broadcasting Corporation
P.O. Box 12010, Station A
St. John's, NL
A1B 3T8

Dear Mr. Quinn:

Re: Your request to access to information under Part II of the *Access to Information and Protection of Privacy Act.*

This is to confirm that, on February 15, 2007 Eastern Health received your request for access to the following records/information:

- The results of the hormone receptor tests in this province that were sent for retesting from 1997 to the present.
- …the original result of the first test and the result for each re-test…the percentage changes that were found.
- In each case: What percentage of hormone receptor positivity did the original test show? What result did the retest find?
- I am not requesting the names of patients or any information that might identify them.

Eastern Health responded to your request to deny access to the responsive records due to our position that these records are the personal information of the patients. You requested a review of the decision by the Information and Privacy Commissioner of Newfoundland and Labrador.

As recommended by the Information and Privacy Commissioner in his report, received on June 28, 2007, enclosed please find a copy of the responsive records containing the results of laboratory tests and retests for hormone receptors performed for XXX cancer patients of Eastern Health who subsequently had their samples retested by Mount Sinai Hospital.

The interpretation of these data is a complex process and we advise there are a number of important factors to keep in mind:

1. There is a degree of subjectivity involved in ER/PR testing. Any two laboratories or any two pathologists may interpret a slide with slight variations. From 1997 to 2005, a number of different pathologists have been involved in interpreting the ER/PR tests to determine the level of estrogen or progesterone positivity in a tumor. You will also notice that some individuals have two or more results from Mount Sinai. Mount Sinai Hospital advised that the slightly different results obtained for each patient, when the two different tissue sample test results were compared, may be explained by the fact that conducting testing of different portions of a single patient's tissue sample may render different results.

2. Testing to determine whether a tumor is ER-positive or PR-positive is a complicated procedure that involves more than 40 steps. There are no standardized laboratory procedures in Canada for immunohistochemistry testing.

3. Many features of a breast cancer including the size of the tumor, the hormone receptor status of the tumor, the tumor grade, the HER 2 expression, and tumor histology are taken into account to assist medical oncologists in their determination of treatment options and the long-term health of the patient. Simply because a result changed does not always indicate a clinical treatment change.

4. There were two different methods used for testing over the time period. Prior to 2004, the Dako testing technique was used in Eastern Health's laboratories which required the manual boiling of tissue samples and also the measuring of minute mixtures of immunioperoxidase staining. Starting in April 2004, Eastern Health installed the Ventana system for conducting ER/PR testing. This new system automated the process, thereby removing much of the human manipulation of samples. Many independent biochemical variables changed during this time period and may contribute to the preparation and subsequent interpretation of a particular tumor slide. Some examples would be manufacturer recommended pH changes, enhancements to detection 'kits', and 4 antibody changes over the time period.

5. The standard for interpretation of what constituted an ER 'positive' test result changed between the time of original testing and the EH Tumor Board's review (2005-6). You may notice some samples with ER results > 10 as the original result. At the time these were tested, results with ER < 30 were considered negative. After the year 2000, the definition of ER 'positive' changed to a result with 10% or less of positivity. Within this sample, 13 patients saw no change in their ER/PR test results but a change in treatment was recommended as the standard had changed.

6. Mount Sinai follows current clinical guidelines and does not retest patients with a diagnosis was DCIS (ductal carcinoma in –situ).

7. The focus of the Tumor Board and all persons involved with the retesting of breast tumor samples has been on individual patient care and the communication and implementation of personal treatment recommendations.

Please keep in mind that to fully appreciate whether the changes identified for results between the different centres were significant, required a complete review of each patient's medical history by a panel of specialists (pathologists, medical oncologists, surgeons).

If you have any further questions, please feel free to contact the undersigned at 777-8025, or email at marian.crowley@easternhealth.ca

Sincerely,

Marian Crowley
Access and Privacy Coordinator