From: Heather Predham
To: "pelliott@nl.rogers.com";
Subject: briefing note
Date: August-10-06 1:14:38 PM
Attachments: Briefing Note August 10.doc

Hi Pam,

Find the note attached. I made the changes to the first part.....I have qualms about the concern section and the factors affecting the timelines...but I'll let you decide.

How do you want me to adress it at the beginning? Also, I didn't include the inofmration about the reviews....I think we can tell them that, but I don't want to write it down.....

I'm here all afternoon

Heather

To:

Re: Update on Estrogen and Progesterone Receptor Testing

Based on this information, the total number of patients that were sent for retesting was 939. The numbers below include 9 patients from St. Pierre.

Confirmed negative

These are patients who were retested and the original results were verified by the Mount Sinai retesting. These patients did not require review by the panel and there was no change in the patient's treatment plan.

Region	Number
St. John's	186
Corner Brook	71
Carbonear	14
Clarenville	3
St. Anthony	3
Gander	19
Grand Falls	40
St. Pierre	5
Total	**341**

Patients that required review by the panel.

This panel consists of representatives from medical oncology, pathology, surgery and quality.

Category	Number	Comments
Patient ER/PR status has changed from negative to positive but there are no treatment recommendations	208	This category includes: • Patients who are deemed to be at a low risk for recurrence or previously could not tolerate or did not want Tamoxifen (60) • People who have been previously treated with Tamoxifen or another aromitase inhibitor (148) ○ This group of patients include those not placed on Tamoxifen for their original disease, but for subsequent metastatic disease (13)
Patient ER/PR status has changed from negative to positive and there are treatment recommendations	109	These patients are recommended to be placed on Tamoxifen or another Aromitase inhibitor. This group includes: • Patients who have been impacted by the delay in receiving Tamoxifen: i.e. their disease has progressed (9) • Patients whose results have not changed significantly, but the clinical definition of positive and negative has changed since the time of diagnosis. (13)
Confirmed negative	28	These patients' original results were considered to be negative by the treating clinician and treated appropriately. There was a slight change in the patient's ER/PR status but review by the panel confirmed the ER/PR status as still being negative. No action other than notification was required.

Category	Number	Comments
Confirmed positive	12	These patients' original results were considered to be positive by the treating clinician and treated appropriately. There was a slight change in the patient's ER/PR status but review by the panel confirmed the ER/PR status as still being positive. No action other than notification is required.
DCIS	56	Confirmed DCIS (39) Outstanding (14) Follow-up required (3) **For further information see note below**
Required assessment prior to recommendation	5	The panel could not make a recommendation for these patients without seeing the patient. The combination of the time since diagnosis and the original presentation of the disease places the patient near the borderline between treatment and not. This information was communicated to the patient through the most responsible physician with the offer of follow-up through the Cancer care program of Eastern Health.
Retro Convertors	4	**See note below**
Total	**422**	

Patients who are deceased (176):

176 patients are identified as being deceased either through chart review or direct contact with a family member.
Of these 176, 101 that were retested and results received. In June, an ethics review was conducted regarding notification to the families of the deceased. The recommendation was that upon conclusion of the ER/PR review, a public statement be made stating that if the next of kin of a deceased patient would like the results, that they contact Eastern Health.

Ductal Carcinoma In Situ (DCIS):

DCIS is a diagnosis made by the pathologist when the cancer cells grow inside the ducts of the breast. DCIS means that there is no, or only a very limited amount of, invasive component of the disease and this diagnosis would form the basis of the plan of treatment. As I understand it, from our specialists, Tamoxifen is not recommended for DCIS. There is, therefore, no reason to test the ER/PR status.

Of the results returned from Mount Sinai, there were ones that Mount Sinai did not retest as they diagnosed them as being DCIS. Initially, the panel reviewed the original pathology report and if that report diagnosed the person as having DCIS, then there was no further action required; the patient is confirmed DCIS and does not have to be retested for ER/PR.

If the panel could not do this initial step, then two pathologists reviewed the original blocks and slides. This has led to the identification of other "confirmed DCIS". In total, there have been 39 confirmed DCIS.

However, our review has also revealed patients who were incorrectly diagnosed in their original pathology report, which may have led them to being treated with Tamoxifen or chemotherapy. At this time, there are three women who fall in this category:

- One patient was diagnosed with invasive carcinoma when review indicates that it was DCIS
- Two patients were diagnosed with DCIS with a large amount of invasive component. Upon review the invasive component is much less.

Representatives of Eastern Health and the Clinical Chiefs of Pathology and Cancer Care have disclosed this information to those affected.

There are **14** more DCIS patients throughout Newfoundland and Labrador that require further review by pathology.

Retro Convertors

All patients who were negative for ER were included in the retesting process. As the clinical definition of negative changed over the years, all patients with an ER of 30% or less were retested.

That means that in the group retested there are women who, although their ER level met this definition of negative, were considered positive at the time and received hormonal treatment. However, in **4** cases, retesting by Mount Sinai identified that women in this category now have an ER/PR status of 0% that has been confirmed by subsequent retesting at Mount Sinai.

Representatives of Eastern Health and the Clinical Chiefs of Pathology and Cancer Care will meet with them in the near future to disclose this information.

Pam…I'm not sure about these two sections as we still don't know how Ches Crosbie found out his information…..also, DOH has already released our briefing notes in that ATIPP request last time……what do you think?

Concerns

- Of the patients who were originally ER/PR negative but are now ER/PR positive, there is greatest concern for those patients who:
  - Were originally ER/PR negative and were not prescribed Tamoxifen at that time but are now receiving Tamoxifen because of metastatic disease.
  - Were originally ER/PR negative and were not prescribed Tamoxifen at that time but were at high risk for metastatic disease. Now that they have converted they are started on Tamoxifen.
- Patients who were originally ER/PR positive but are now ER/PR negative and they have received Tamoxifen for a period of time (retro convertors). Tamoxifen is linked with an increased risk of uterine cancer and stroke.
- Patients who it was discovered during this intensive chart review had a previously unknown adverse event. This is unrelated to the ER/PR review.

Factors contributing to review timeline

- Identification of an appropriate referral hospital to conduct retesting.
- Identification of patients requiring retesting. This includes verification with the cancer registry, HCCSJ Meditech laboratory module and the other region lab records.

- Collection and coordination of the lab slides and blocks for retesting. This includes communicating with the other regions to receive their specimens and slides.
- Creating a database of the patients being retested and their results upon return
- Developing and implementing the process of informing patients directly within Eastern Health that their samples were to be retested and coordinating this communication process with the other regions.
- Developing and implementing the appropriate handling of the returned results.
- Developing and implementing the process of informing patients directly within Eastern Health that their results were returned and indicated that they were either confirmed negative or confirmed positive and coordinating this communication process within the other regions.
- Developing the review panel process, including scheduling of meetings and obtaining pertinent clinical records.
- Pathology review of select cases to verify results.