From: Heather Predham
To: Dr. Robert Williams; Dr. Donald Cook; Terry Gulliver;
cc: Denise Dunn;
Subject: Update for Mr. Tilley
Date: July-18-05 8:56:32 AM
Attachments: Update on ERpr.doc

Hi,

Here's the update for Mr. Tilley. Please review it and add anything you feel necessary. I'm not sure who this should go from, so I left it blank.

I didn't include any information re: Dr. Ejeckam's memos.....should we?

Thanks

Heather

To: Mr. George Tilley

From:

Re: Update on ER/PR receptor testing

The following activity has taken place since the memo of Dr. D. Cook to Dr. R. Williams dated May 24, 2005:

- Samples collected from 25 women, initially tested as negative in 2002, were retested. 16 of these came back positive. Testing is currently being done on 33 more patients. Five of these patients have been informed by their oncologists. (*Is this accurate or have all 16 been informed?)*

- June 13, 2005, Dr. Cook wrote to all Laboratory directors in the province to submit all negative ER and PR cases for the year 2002 for retesting with the new, more sensitive Ventana system. So far, no samples have been received, so Dr. Cook will contact all Laboratory Directors again requesting samples from 1997 to 2004.

- The Dako test was implemented in 1997 to replace an entirely different and much less sensitive assay test. All samples which initially tested as negative from 1997 until the implementation of the Ventana system in April 2004 will be retested. As the test results can affect future treatment, patients that are still living will have the testing done first, before it is done on those that are deceased.
  Extra resources have been identified within the HCCSJ lab to undertake identification and retesting. The list of patients will be double-checked with the names on the Cancer Registry to ensure none have been missed.
  Timelines required to do the retesting internally will be determined as soon as possible. If it is determined to be too time-consuming, options to utilize external laboratories will be explored.

- It has been determined that positive controls were conducted everyday, as part of the quality assurance process within the lab. The results were read and documented daily by a pathologist. Also

the processes used by HCCSJ technicians were those outlined in the Dako procedure manual.

- Other laboratories are being contacted to identify their ER/PR positive rate for infiltrating lobular and ductal cancer for comparison to the rate for the HCCSJ.

- The current testing standards (Ventana system) are being assessed by cross-referencing our results with another laboratory.

- The public will have to be informed. Corporate Communications have been involved and, as at least five patients are aware of this information already, disclosure has to be made quickly. After meeting with the surgeons and oncologists, it was decided to wait until we were able to get more information regarding retesting, the anticipated timelines and a support line established. This support line for patients will be coordinated through QSI. Legal counsel will review the proposed media release before it is distributed.

- Once the magnitude of the problem and the relevant time frames has been determined, an external technical consultation will need to be undertaken to assess standards and quality of service.

- HIROC will be contacted to determine if they are aware of any other issues with the Dako testing system.