attached info to go to Brenda Boyle

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ber 07, 2005 4:18 PM

To: 'susangillam@hcsw.nf.ca';

Cc: Dr. Robert Williams; George Tilley; Patricia Pilgrim

Subject: Information Requested

Importance: High

Attached information is forwarded on behalf of Patricia Pilgram for your perusal and in preparation of meeting scheduled by Mr. TIlley's office for this coming Tuesday, October 12th, at 12:30 p.m.

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Dr. D.) Susan
Good idea y/o
Jackie Stapleton-Simms
Kim
Dr. Jenkins V.P. Medical Services

Letter to Medical Directors
- had gotten a verbal overview.

Did not set up a "hot line"

Overview of Estrogen progesterone receptor testing

Once an individual is diagnosed with breast cancer, the tumor is tested for the presence of estrogen and progesterone receptors (ER/PR). Since 1997 this test is conducted as an immunohistochemistry test, before that date it was done in a bio-assay method.

The Dako semi-automated method of ER/PR testing, used at the Health Care Corporation of St. John's Laboratory from 1997 to April 2004, involved boiling or microwaving the specimen for a specific length of time (between 15 and 20 minutes). This would allow the receptors to be released and receptive to staining. Under or over processing would affect the results. After this stage technologists would stain and prepare the slides to be read by a pathologist. The entire process contained more than 40 steps, each just as critical as the next. For example, the length of time the sample was placed in formalin following surgical removal could have a major effect on staining.

In 2004, when new technology became available, a Ventana system with on-board antigen retrieval was purchased and installed. This technology eliminated some of the variable manual steps in the process.

The presence or absence of hormone receptors contributes to the decision of the type of therapy available to patients. A positive ER/PR would allow for the consideration of hormonal treatment (for example, Tamoxifen).

In 2005, a patient, initially tested in 2002 with the Dako system and reported as ER/PR negative, was retested with the Ventana system and was positive for estrogen and progesterone receptors. Four other patients initially tested as negative in 2002 were also retested, and all tested positive with the Ventana system.

Retesting was expanded to include all samples initially tested as negative in 2002 on the Dako system. Of these samples, a majority showed positive results. This high conversion rate then placed the sensitivity of the Ventana System in question. All negative samples from 1999 to 2004 have been collected and sent to Mount Sinai Hospital, Montreal, for retesting.

Reporting of ER/PR by the Laboratory Medicine Program is currently on hold. All current requests for ER/PR are being forwarded to Mount Sinai for processing, interpretation and reporting.

Consumer Feedback

The following questions and answers are posted on our website and form the basis of our response to individuals when they inquire.

What is ER/PR?

All patients who have had breast cancer have been tested for the presence or absence of estrogen and progesterone receptors (ER and PR). The presence or absence of ER and PR helps determine the most appropriate treatment of breast cancer.

When your ER and PR are positive, hormone therapy is one treatment option open to you. ER and PR are just one of the many things oncologists look at to determine the type of cancer treatment a patient will receive.

What is happening now? Why are some test results different?

Eastern Health has begun retesting a select group of breast cancer patients – those whose results indicated that they were negative for ER and PR. In 2004, the lab at the Health Sciences that does all of the ER and PR testing for the province introduced a new piece of technology and we discovered some inconsistent results from the old system.

This has prompted Eastern Health to re-test all the negative ER and PR receptors results since 1997 to ensure that all patients have every treatment opportunity that may be available to them.

We are using previously collected tissue samples, so patients are not required to come to hospital or have any additional testing.

Only a small percentage of breast cancer patients may be affected by this retesting.

I haven't been contacted, what should I do?

The laboratory is continuing to test results and patients are being contacted if there is a change to their result and their treatment may be affected. If you had breast cancer and are concerned about your previous test results and treatment, you may wish to contact your oncologist, surgeon or family doctor.

You may also call the Patient Relations Officer at Eastern Health at 777-6500. She will attempt to answer your questions or link you with someone who can help.

Synopsis of Feedback received to date

As of October 7, 2005, 11 calls have been received regarding ER/PR. All were a patient, family member or friend calling to inquire about the status

of an individual i.e.: if the individual was being retested and when the results will be known.

- A lady whose mother was diagnosed with breast cancer in 2003 and has since passed away, called to inquire what her mother's status had been and whether she will be retested. She was told that everyone who requires retesting will be retested but our focus at the present is on patients who are living. She would be contacted sometime in the future if there was a discrepancy in her mother's test results.
- A lady called from the west coast, and as her sample was collected and interpreted there, we have no information to share with her at this time.
- One lady was upset with how this was handled and that she learned of this situation in the media.

All inquiries concerning patients currently actively being followed by the Cancer Clinic, were forwarded to the Cancer Clinic for follow-up.

Retesting Process for Samples Outside the St. John's area