received
at
from Dalia Thomas-Pennell
5/12/17.
Commission Office

Briefing Note – ER/PR Receptors

Background:

On May 11th, Dr. Joy McCarthy contacted Dr. Don Cook to retest a patient who previously tested negative for Estrogen and Progesterone Receptors in 2002. Using new technology for immunoperoxidase staining installed at the General Hospital Histology Lab in April of 2004, this woman sample was retested and discovered to be positive for ER and PR.

On May 17th, representatives from the Laboratory Program met with Drs. McCarthy and Kara Laing to discuss this new result and a decision was made to retest five more negative patients, who all retested positive.

It was decided to retest all negative results from 2002 to determine is this was a few isolated cases or a bigger issue. 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. Approximately 12 of these patients have been informed by their oncologists.

On 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.

Actions:

- On Thursday, July 14th, the decision was that all patients who were ER and PR negative from 1997-2004 will be retested, beginning with the 2002 patients. This testing will take place over the next number of weeks.

- To date, no samples have been received from the Provincial Laboratory Directors. Dr. Cook will contact all Laboratory Directors again requesting samples from 1997 to 2004.

- As a precautionary measure and to back-up the validity of the new technology, the current testing standards (Ventana system) are being assessed by cross-referencing our results with another laboratory. (Mount Sinai)

- 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.

- HIROC have been contacted to determine if they are aware of any other issues with the Dako testing system

- Women who have to have their treatment altered because of this result will be contacted by her family doctor or oncologist.

- 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.

Notes:

- We do expect a higher number of positives due to the sensitivity of the newer equipment

- 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.

- Estimates are that 50 – 85 per cent of all breast cancers exhibit estrogen receptors and that such tumours are commonly found in post-menopausal women.

- A high percentage of tumours with estrogen receptors may regress after hormonal manipulation whereas only a small number (about 5 per cent) of those that are negative respond. The highest response rates are in patients with tumours exhibiting both ER and PR receptors. Breast cancer patients with high level hormone receptors have a slightly better prognosis than those without receptors.

- The Dako test was implemented in 1997 to replace an a bioassey method for ER/PR receptors. 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.

Eastern
HEALTH

MEDIA RELEASE

FOR IMMEDIATE RELEASE

Breast Cancer tests being re-examined

July 18, 2005, St. John's, Newfoundland and Labrador – Eastern Health would like to inform the public about a situation affecting some breast cancer patients in the province.

Earlier this year a breast cancer patient was retested for her level of estrogen and progesterone receptors. This test resulted in a conflicting result than her initial sample. This information prompted health care officials to question the original tests validity. To be certain, Eastern Health has begun retesting a select group of breast cancer patient samples, many of which yielded a similar result which conflicted with the original tests. Many of the first tests were showing a negative result, however, on retesting some results were positive.

Because of this discovery, as many as 300 tissue samples will be retested in the coming weeks. Testing for estrogen and progesterone receptor levels help to determine what type of treatment a patient will receive and at what stage.

Estimates are that 50 – 85 per cent of all breast cancers exhibit estrogen receptors and that such tumours are commonly found in post-menopausal women. A high percentage of tumours with estrogen receptors may regress after hormonal manipulation whereas only a small number (about 5 per cent) of those that are negative respond. The highest response rates are in patients with tumours exhibiting both ER and PR receptors. Breast cancer patients with high level hormone receptors have a slightly better prognosis than those without receptors.

"We are investigating where this process may have broken down and have acted quickly to reduce any additional risks," said Dr. Robert Williams, M.D., Vice President Quality, Diagnostic and Medical Services.

Retesting will be conducted with existing tissue samples. Women are not required to have any additional testing and are not required to come to the hospital.

Women who have to have their treatment altered because of this result will be contacted by her family doctor or oncologist.

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For information, contact:

EASTERN REGIONAL INTEGRATED HEALTH AUTHORITY
CORPORATE COMMUNICATIONS DEPARTMENT, CORPORATE OFFICE
WATERFORD BRIDGE ROAD, ST. JOHN'S, NEWFOUNDLAND AND LABRADOR, A1E 4J8

Deborah Thomas, Corporate Communications, 777-1339/685-7697

Briefing Note – ER/PR Receptors

Background:

As a last ditch effort and as a favour to a friend, Oncologist Cara Laing contacted a colleague in the U.S. earlier this Spring about a patient of hers who was suffering with Breast Cancer. The woman was terminal. The American Oncologist found it odd that the woman in question was ER/PR negative considering her illness type. He suggested she be retested.
Her tissue was retested and her status was confirmed to be ER/PR POSITIVE.
Although too late for this woman, it prompted Oncologists here to order five more tests of previous ER/PR Neg. tests; which all came back positive.

Current Status:

- 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. Approximately 12 of these patients have been informed by their oncologists.

- All patients who were ER/PR negative from 1997-2004 will be retested, beginning with 2002 patients. This testing will take place over the next number of weeks. Any change in the result or treatment options, and the patient will be contacted by her oncologist.

- We do expect a higher number of positives due to the sensitivity of the newer equipment

- Lab results are being double checked by Mount Sinai Hospital

- 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 a bioassey method for ER/PR receptors. 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.

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

- 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

- Estimates are that 50 – 85 per cent of all breast cancers exhibit estrogen receptors and that such tumours are commonly found in post-menopausal women.

- A high percentage of tumours with estrogen receptors may regress after hormonal manipulation whereas only a small number (about 5 per cent) of those that are negative respond. The highest response rates are in patients with tumours exhibiting both ER and PR receptors. Breast cancer patients with high level hormone receptors have a slightly better prognosis than those without receptors.

- Retesting will be conducted with existing tissue samples. Women are not required to have any additional testing and are not required to come to the hospital.
- Women who have to have their treatment altered because of this result will be contacted by her family doctor or oncologist.
- Hotline is being set up for concerned patients to call, leave a message, and have their call returned within an hour or so

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HEALTH

MEDIA RELEASE

FOR IMMEDIATE RELEASE

Re-testing due to improved technology

July XX, 2005, St. John's, Newfoundland and Labrador – Some former and current breast cancer patients will have some existing breast tissue specimens re-examined on newer technology to ensure accuracy, Eastern Health announced today.

The decision to retest some specimens comes after a second test of a tissue sample obtained in 2002 on an older piece of technology yielded a different result on the newer system, installed last year.

The public need not be concerned about this retesting. It is precautionary and patients will be contacted by their oncologists if any further treatment is required.

"We believe we have a responsibility to our patients to do a double-check in this situation" said Dr. Robert Williams, M.D., Vice President Quality, Diagnostic and Medical Services. "Our patients are always our first priority and we want them to know we have given them the best options for their care."

These specimens are being retested for estrogen and progesterone receptors (ER/PR). These tests have a positive or negative result which affects treatment type and options for breast cancer patients.

Common text book literature suggest that 50 – 85 per cent of all breast cancers exhibit estrogen receptors and that such tumours are commonly found in post-menopausal women. A high percentage of tumours with estrogen receptors may regress after hormonal manipulation whereas only a small number (about 5 per cent) of those that are negative respond. The highest response rates are in patients with tumours exhibiting both ER and PR receptors. Breast cancer patients with high level hormone receptors have a slightly better prognosis than those without receptors.

Approximately XXX of specimens will be retested. Patients do not need to visit a hospital. The retesting is being completed on existing lab specimens.

If a patient needs to have his or her treatment altered because of this result they will be contacted by her family doctor or oncologist or can call HOTLINE NUMBER and leave a message. Someone will call back asap.

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For information, contact: Deborah Thomas, Corporate Communications, 777-1339/685-7697

Eastern
HEALTH

MEDIA RELEASE

FOR IMMEDIATE RELEASE

Eastern Health reviews ER and PR test results

July XX, 2005, St. John's, Newfoundland and Labrador – The General Hospital Laboratory will be retesting breast tissue specimens collected prior to 2004 that tested negative for estrogen and progesterone receptors, Eastern Health announced today.

The decision to retest these specimens comes after a review of specimens revealed that a high percentage of previously negative tests have changed to positive using a new, more sensitive, type of testing technology. The retesting may provide new opportunities for patients with breast cancer.

ER/PR positive tumours are more likely to respond to hormone therapy. Although not a cure for breast cancer, hormone drugs such as Tamoxifen can affect the progression of these tumours.

"We believe we have a responsibility to our patients to do a double-check in this situation" said Dr. Robert Williams, M.D., Vice President Quality, Diagnostic and Medical Services. "Our patients are always our first priority and we want them to know we have given them the best options for their care."

Patients who may be impacted have been contacted by letter and all patients will be contacted by their oncologist or physician if any treatment changes are required.

Approximately XXX of specimens will be retested. Patients do not need to visit a hospital. The retesting is being completed on existing lab specimens.

Patients with questions about this process can contact the Patient Relations Officer at 777- XXX or toll free 1-800 XXXXX.

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Media contact:
Deborah Thomas,
Corporate Communications 777-1339/685-7697

Key Messages

- We have reacted quickly to investigate this issue so as to identify any inconsistencies with our procedures; however, we are certain that, at least in part, these conversions are due to new, more sensitive, technology.

- Laboratory technicians have been working around the clock to complete re-testing of samples to ensure proper treatment has been and will be administered. A second specimen sample is being retested by Mount Sinai to ensure accuracy.

- Our former technology, the DAKO system, is a widely accepted form of immunoperoxidase staining method in North America which many hospital laboratories are still using today.

- We replaced the DAKO system in 2004 to keep current with technology and were among one of the first in Eastern Canada to install the Ventana system.

- We have an independent consultant coming to our organization in the fall to further review our immunoperoxidase staining system and methods now and previously.

- Laboratory directors across the province have been asked to comply and return tissue samples so they, too, can be retested.

- We are retesting hundreds of tissue samples from the past several years to ensure accuracy.

- Positive controls were conducted daily as part of the immunoperoxidase staining methodology.

- Literature suggests that 50-85 per cent of all breast cancers exhibit estrogen and progesterone receptors; however newer technologies are seeing that number increase with some American laboratories not testing for ER/PR but treating all patients as positive.

- Very few laboratories/hospitals keep track of ER/PR rates.

- If patients have questions they can call the Patient Relations Officer.

Eastern
HEALTH

MEDIA RELEASE

FOR IMMEDIATE RELEASE

Laboratory testing review to be completed by outside consultant

July XX, 2005, St. John's, Newfoundland and Labrador – Changes in technology and a commitment to quality control has prompted Eastern Health to examine its pathology system at the General Hospital in St. John's.

Eastern Health has hired an outside consultant to review existing laboratory procedures and equipment, as well as provide expertise on the past several years of laboratory activity.

"We are thrilled to have someone of this calibre to study our operations," said Dr. Robert Williams, M.D., Vice President Quality, Diagnostic and Medical Services. "It's imperative to us and to the safety of our patients that we are always looking at ways to be better and this is an example of that."

In 2003, significant changes were made to improve the accuracy of immuno testing, and in 2004 the purchase of the Ventana system further improved processes. However, in 2005 some test results from prior to 2004 were reviewed prompting a more extensive review of procedures, leading ot the external review being conducted this month.

XXXX XXXX from Mount Sinai, a graduate of XXXX, will be visiting the provincial laboratory on Sept. whatever. He/she will have the full cooperation of the entire department and access to all pertinent areas.

A report is expected in XXX of this year.

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For information, contact: Deborah Thomas, Corporate Communications, 777-1339/685-7697

Eastern Health would like to advise you of a situation which has led to the retesting of your breast tissue sample.

This is just an advisory notice; you do not have to do anything.

Due to improved technology and the finding of some earlier, inconsistent results, Eastern Health has begun retesting a select group of breast cancer patient samples to check for estrogen and progesterone receptors.

The presence of these receptors helps determine the most appropriate treatment of breast cancer.

Although we are retesting your tissue, this does not mean your treatment has, or will change. Retesting will be conducted with existing tissue samples. Women are not required to have any additional testing and are not required to come to the hospital.

Women who do have to have their treatment altered because of this result will be contacted by her family doctor or oncologist. If you are not contacted, your result did not change.

If you have any questions about this process please call 1-800 and leave a message. Someone will get back to you promptly.

Thank-you.