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To: "Cathi Bradbury" <CathiBradbury@gov.nl.ca>
Date: 5/24/2007 8:00:15 PM
Subject: Re: Departmental Update - ER/PR testing (May 24, 2007)

Thanks Cathi,
It is as we discussed.
Nash

----- Original Message -----

From: "Cathi Bradbury" <CathiBradbury@gov.nl.ca>
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Cc: "Ed Hunt" <EHunt@gov.nl.ca>; "John Abbott" <JohnAbbott@gov.nl.ca>;
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Sent: Thursday, May 24, 2007 2:18 PM
Subject: Departmental Update - ER/PR testing (May 24, 2007)

> Please find attached a briefing that was provided to the Minister in
> follow-up to our teleconference this morning. I don't have the e-mail
> addresses for all participants (other than the CEO's and VP's of
> Medicine). Please forward the document to other teleconference
> participants within your RHA.

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> Thanks
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> Cathi
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Briefing Note – Question Period

Issue: ER/PR testing for Breast cancer

Background:

Eastern Health (St. John's site) suspended the testing of ER/PR specimens for breast cancer patients in August, 2005. Since August 2005, Mount Sinai has been testing new specimens as well as retesting all ER-negative specimen reported between 1997 and 2005.

Anticipated Questions

1. What is the current status of ER/PR testing in the province?

- ER/PR testing has resumed in St. John's as of February 01, 2007 for the St. John's sites only. ER/PR specimens for all other sites outside of St. John's continue to be tested and interpreted by Mount Sinai Hospital.
- At the same time that ER/PR testing was being referred out to Mount Sinai, a new protocol was instituted to do Her-2-neu testing in conjunction with ER/PR testing. The St. John's labs are in the process of validating their testing for HER-2-neu using this new protocol and hope to finalize the validation by the end of the summer. At that time, they plan to reinstate Her-2-neu testing for St. John's sites. In the interim, all Her-2-neu testing for the province is being completed at Mount Sinai.

For ER/Pr and Her-2-neu:

Pre – 2005:

Specimens prepared (fixed) and processed regionally, tested centrally, and sent back to the region for interpretation and reporting.

August 01, 2005 to January 31, 2007:

Specimens prepared regionally and forwarded to Mount Sinai for testing, interpretation and reporting.

February 01, 2007:

For ER/PR testing: Processing, testing, interpretation and reporting reinstituted for St. John's sites. All other specimen outside of St. John's continue to be sent to Mount Sinai.

For Her-2-neu: All specimens continue to be sent to Mount Sinai.

2. What is the province's plan for ER/PR testing on a go-forward basis?

With agreement of the four RHA's and the Department of Health and Community Services it is intended that the testing, interpretation and reporting of all specimens in the province for ER/PR and Her-2-neu will occur at the St. John's site – "center of excellence".

3. What changes have been implemented following the external review of ER/PR testing to ensure quality reporting?

Eastern Health has undergone an extensive external review of its policies and procedures related to ER/PR testing and are in the process of implementing recommendations arising from the review. Examples of these actions include, but are not limited to:

- Development and implementation of a province-wide policy to standardize the sampling and preparation (fixation) of specimens;
- Establishment of a separate Immuno-histochemistry Department for hormone-based testing;
- Recruitment of four Pathology assistants;
- Upgrading of the Vantana system (automated process for the retrieval of hormone markers);
- Dedicated technologists and Pathologists to report on these tests, who have received additional training in this area;
- Implementation of a new Director of Immuno-histochemistry;
- External Quality assurance program for proficiency testing (receive blind samples from the UK for testing here and comparison to international results and the College of American Pathologists)
- Continuing to send current, random samples to Mount Sinai for reconfirmation of interpretation and results (to date there have been 100% concurrence with Mount Sinai results)

Drafted by: Dr. C. Bradbury
May 24, 2007