

Briefing Note
Department of Health and Community Services

Title: Testing of Breast Cancer Patients at St. John's Hospitals

Issue: Media coverage regarding potential breast cancer diagnostic errors within ERIHA.

Background:

- In 1997, a Dako semi automated/manual system for testing ER/PR receptors in breast cancer patients was installed in 1997. Based on patient-specific test results, a patient's course of treatment is then determined by the attending physician. The Dako system was replaced in 2004 by an automated Ventana system.
- 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 ER/PR receptors. Four other patients initially tested as negative in 2002 were also retested, and all tested positive with the Ventana system.
- Retesting was then expanded at the Health Sciences Centre 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.
- A representative from Ventana visited the laboratory in July to review use and practices of the Ventana system. In their written report, they stated that they found the system to be operating as expected and that the procedures used by technicians were appropriate and as trained.
- An article on the retesting of tissue samples taken from breast cancer patients as far back as 1997 appeared in the Independent on Sunday, October 2. NTV has also been in contact with Eastern Health and aired a story on October 3, 2005. CBC's Website is also carrying this story.

Current Status:

- Eastern Health has collected and sent all negative samples from 1999 to 2004 for the St. John's hospitals for retesting to Mount Sinai Hospital. Three hundred twenty-three samples reported as weakly positive to negative have been sent. To date 73 of the samples have been reviewed, and it appears that of those there are 16 – 20 individuals whose treatment could be impacted. Samples for 1997-1998 from the St. John's hospitals will soon be sent for retesting.
- Laboratory directors in the province were contacted over the past few months to submit all negative ER and PR reports and samples for this same time period for

retesting to Eastern Health. This process is underway. Seventy-eight samples from 1997 – 2004 from Gander and Carbonear are in the process of being submitted. Specimens from Grand Falls-Windsor have just been received and will also be sent to Mount Sinai.

- All current requests for ER/PR testing on breast cancer patients in NL are being forwarded to Mount Sinai for processing, interpretation and reporting at this time until the current problem with test results is corrected.
- Eastern Health is also sending letters to the surgeons and other attending physicians on the 16-20 individuals whose treatment could be impacted, based on the Mount Sinai testing results. The physicians will then determine the follow up action for these patients. The focus is on notifying physicians of living patients regarding the findings. This process will continue as test reports are received from Mount Sinai.
- There could be some potential litigation issues for the families of deceased patients once the families are notified.
- Eastern Health is setting up a consumer telephone line where patients can obtain additional information on the ER/PR receptor issue.
- An external peer review, by the Chief Pathologist of the British Columbia Cancer Institute and the Chief Technologist from Mount Sinai Hospital, was conducted September 15 - 22, 2005, to review current practices and procedures within the laboratory service. Debriefing was held after each review and a full report from each is expected within the next few weeks.
- Dr. R. Williams, VP-Medical Affairs – Eastern Health has done an interview with NTV today.

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October 5, 2005

