

Background Information on the ER/PR Investigation

Patients who have breast cancer are tested for the presence or absence of estrogen and progesterone receptors (ER/PR). The presence or absence of ER/PR helps determine the most appropriate treatment of breast cancer. Patients who test positive may be candidates for hormone therapy.

Last summer, after introducing a new technology that tests for ER/PR in our laboratory at the Health Sciences Centre, Eastern Health became aware of inconsistencies in test results. Upon careful review, the organization decided to retest all tissue samples collected since 1997 that originally tested negative for ER/ PR.

Because hormone therapy can be beneficial years after the original diagnosis of breast cancer, our clinical leadership felt it was in the best interest of our patients to ensure that the therapy was offered if in fact there was a change in ER/PR status.

Our laboratory suspended testing for ER/PR and began the process of sending previously collected tissue samples to an independent laboratory - Mount Sinai - for review. We also began the process of individually contacting all patients impacted, using the media to inform the public about the review and establishing a communications line for patients through our Patient Relations Officer.

Over 900 samples have been sent to Mount Sinai.

As results have been returned to our laboratory, our clinical team has met to discuss each case and patients whose results have changed have been or are currently being contacted for direct follow-up.

In the vast majority of cases reviewed thus far, there is no change in ER/PR status that requires a change in the ^{Original} treatment plans adopted for patients.

Once we have completed the review of all the individual cases we will be in a better position to assess the reasons why test results changed and will also help us address the factors that led to this issue in the first place.

Although we are aware that experiences, such as those that prompted our review, have occurred in other places, we are unable to find another centre that conducted a retrospective review such as ours.

Research has shown that adverse events do occur in the healthcare system and that we must look at the system to try and prevent them. Baker and Norton in the Canadian Adverse Events Study released in 2004 identified 7.5% of patients

Eastern Health originally began a review of all ER/PR receptor tests conducted by our laboratory since 1997 when we discovered inconsistencies in a small number of results.

Our first priority was and continues to be to our patients.

More than 900 test samples were sent to Mount Sinai Laboratory. Collecting, sending, retesting and reviewing all these test samples has been an extensive process, but most tests have been reviewed and most patients have been notified. In the majority of cases the patient's treatment was confirmed appropriate.

As part of the review we have identified a small number of cases that require further follow-up. We are in the process of reviewing and addressing each of these cases individually.

Eastern Health is committed to disclosure and our clinical team members have communicated individually with all patients impacted by this review. However, patient confidentiality is an important principle in health care, not only in this province but across the country, so we do not discuss the details of individual cases publicly.

As to the statements of claim filed against the organization, every individual has the right to take whatever action they deem appropriate and we must allow the legal system to address the legal issues.

As a health care provider, we will stay focused on ensuring that our patients have every treatment opportunity that may be available to them and on addressing the systems issues that arise.

Eastern Health would like to assure the public that we take these matters seriously, that we have a huge team of clinical and administrative people working tirelessly on this issue, and that we are dedicated to improving the system, learning from our experiences and ensuring quality care.

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admitted to acute care hospitals in 2000 suffered an adverse events; almost 40% of which were identified as being preventable.

The establishment of the Canadian Patient Safety Institute and the Safer Healthcare Now! Initiative are some examples of ways institutions are addressing patient safety.