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Re: **Update on Estrogen and Progesterone Receptor Testing**

Based on this information, the total number of patients that were sent for retesting was 939.

Confirmed negative

These are patients who were retested and the original results were verified by the Mount Sinai retesting. These patients did not require review by the panel and there was no change in the patient's treatment plan.

Region	Number
St. John's	186
Corner Brook	71
Carbonear	14
Clarenville	3
St. Anthony	3
Gander	19
Grand Falls	40
St. Pierre	5
Total	341

Patients that required review by the panel.

This panel consists of representatives from medical oncology, pathology, surgery and quality.

Category	Number	Comments
Patient ER/PR status has changed from negative to positive but there are no treatment recommendations	208	This category includes: • Patients who are deemed to be at a low risk for recurrence or previously could not tolerate or did not want Tamoxifen (60) • People who have been previously treated with Tamoxifen or another aromitase inhibitor (148) o This group of patients also include those not placed on Tamoxifen for their original disease, but for subsequent metastatic disease (13)
Patient ER/PR status has changed from negative to positive and there are treatment recommendations	109	These patients are recommended to be placed on Tamoxifen or another Aromitase inhibitor. This group includes: • Patients who have been impacted by the delay in receiving Tamoxifen: i.e. their disease has progressed (9) • Patients whose results have not changed significantly, but the clinical definition of positive and negative has changed since the time of diagnosis. (13)
Confirmed negative	28	These patients' original results were considered to be negative by the treating clinician and treated appropriately. There was a slight change in the patient's ER/PR status but review by the panel

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Category	Number	Comments
		confirmed the ER/PR status as still being negative. No action other than notification was required.
Confirmed positive	12	These patients' original results were considered to be positive by the treating clinician and treated appropriately. There was a slight change in the patient's ER/PR status but review by the panel confirmed the ER/PR status as still being positive. No action other than notification is required.
DCIS	56	Confirmed DCIS (39) Awaiting review (14) Follow-up required (3) **For further information see note below**
Required assessment prior to recommendation	5	The panel could not make a recommendation for these patients without seeing the patient. The combination of the time since diagnosis and the original presentation of the disease places the patient near the borderline between treatment and not. This information was communicated to the patient through the most responsible physician with the offer of follow-up through the Cancer care program of Eastern Health.
Retro Convertors	4	**See note below**
Total	**422**	

Ductal Carcinoma In Situ (DCIS):

DCIS is a diagnosis made by the pathologist when the cancer cells grow inside the ducts of the breast. DCIS means that there is no, or only a very limited amount of, invasive component of the disease and this diagnosis would form the basis of the plan of treatment. As I understand it, from our specialists, Tamoxifen is not recommended for DCIS. There is, therefore, no reason to test the ER/PR status.

Of the results returned from Mount Sinai, there were ones that Mount Sinai did not retest as they diagnosed them as being DCIS. Initially, the panel reviewed the original pathology report and if that report diagnosed the person as having DCIS, then there was no further action required; the patient is confirmed DCIS and does not have to be retested for ER/PR.

For the remainder, two pathologists reviewed the original blocks and slides. This has led to the identification of other "confirmed DCIS". In total, there have been 39 confirmed DCIS.

However, our review has also revealed patients who were incorrectly diagnosed in their original pathology report, which may have led them to being treated excessively. At this time, there are three women who fall in this category:

- One patient was diagnosed with invasive carcinoma when review indicates that it was DCIS
- Two patients were diagnosed with DCIS with a large amount of invasive component. Upon review the invasive component is much less.

Representatives of Eastern Health and the Clinical Chiefs of Pathology and Cancer Care have disclosed this information to those affected.

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There are 14 more DCIS patients throughout Newfoundland and Labrador that require further review by pathology.

Retro Convertors

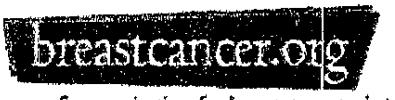
All patients who were negative for ER were included in the retesting process. As the clinical definition of negative changed over the years, all patients with an ER of 30% or less were retested.

That means that in the group retested there are women who, although their ER level met this clinical definition of negative (less than 30%), were considered positive at the time and received hormonal treatment. However, in 4 cases, retesting by Mount Sinai identified that women in this category now have an ER/PR status of 0% that has been confirmed by subsequent retesting at Mount Sinai. It has been noted in the literature that false positive laboratory tests can occur.

Representatives of Eastern Health and the Clinical Chiefs of Pathology and Cancer Care will meet with them in the near future to disclose this information.

Patients who are deceased (176):

176 patients are identified as being deceased either through chart review or direct contact with a family member.
Of these 176, 101 were retested and results received. The remaining 65 will not be retested unless we are approached by the families. In June, an ethics review was conducted regarding notification to the families of the deceased. The recommendation was that upon conclusion of the ER/PR review, a public statement be made stating that if the next of kin of a deceased patient would like the results, that they contact Eastern Health.



A nonprofit organization for breast cancer education

The Basics of DCIS

Ductal carcinoma in situ, or DCIS, is the most common kind of non-invasive breast cancer. The number of cases worldwide isn't known, because most international cancer registries don't keep track of DCIS. But in the United States, according to the American Cancer Society, about 60,000 cases of DCIS are diagnosed each year. There are two main reasons this number is so large and has been increasing over time:

1. Women are living much longer lives. As we grow older, our risk of breast cancer increases.

2. More women are getting mammograms, and the quality of the mammograms has improved. With better screening, more cancers are being spotted early

It's important to know all the basics, so you can discuss them with your doctor and understand your diagnosis, treatment, and follow-up. You'll want to know:

- what DCIS means,
- who's at risk for it,
- how DCIS is diagnosed, and
- how serious it is.

What does DCIS mean?

The name "ductal carcinoma in situ" has three parts:

- "Ductal" means that the cancer started in the milk ducts.
- "Carcinoma" refers to any cancer that begins in the skin or other tissues (including breast tissue) that cover or line the internal organs.
- "In situ" is Latin for "in its original place." This means that the cancer is non-invasive: it hasn't spread into any normal surrounding breast tissue.

Who is at risk for DCIS?

Women at high risk for DCIS are similar to women at high risk for developing invasive cancers. The shared risk factors include:

- never having had a full-term pregnancy,

- having a first full-term pregnancy after age 30,
- menstrual periods starting early,
- late menopause,
- having a parent or sibling with breast cancer,
- more than five years of hormone replacement therapy (HRT), particularly with the therapy that combines estrogen and progestin, and
- having a breast cancer gene abnormality (BRCA1 or BRCA2).

How is DCIS diagnosed?

DCIS generally has no physical signs or symptoms. A small number of women may have a lump in the breast or some discharge coming out of the nipple.

DCIS is usually found by mammography. As the old cancer cells die off and pile up, tiny specks of calcium (called "calcifications" or "microcalcifications") form within the broken-down cells. The mammogram will show the buildup of cancer cells inside the ducts as a cluster of these microcalcifications or as a shadow or lump.

If you do have a suspicious mammogram, your doctor will probably want you to have a breast biopsy. There are two ways to get a biopsy done with only a little bit of surgery. (More invasive biopsies are rarely needed for DCIS):

1. **Fine needle aspiration biopsy:** A very small, hollow needle is inserted into the breast. A sample of cells are removed and examined under the microscope. An aspiration leaves no scars.
2. **Core needle biopsy:** A larger needle is inserted to remove several bigger samples of tissue from the area that looks suspicious. In order to get the core needle through the skin, the surgeon must make a tiny incision. This leaves a very tiny scar that is barely visible after a few weeks. The tissue samples are examined under a microscope. There is usually enough tissue to perform special tests, such as those for hormone receptors and HER2 status.

These tests are done to establish a diagnosis, not to remove the whole cancerous area. More surgery is needed to remove the whole cancer with clear margins.

How serious is DCIS?

DCIS is not life-threatening. It is non-invasive, and is considered the earliest form of cancer—Stage 0. Stage 0 breast cancer (sometimes called pre-cancer) is an uncontrolled growth of breast calls that is stuck inside the milk duct where it started. It has not yet figured out how to spread outside the duct or to other areas of the body.

Although this cancer stays inside the milk ducts, it raises the risk of getting an invasive cancer

in the future. About 25% to 50% of women whose DCIS is treated by surgery ONLY (without radiation) eventually develop an invasive cancer. Most of those cancers (recurrences) happen within the first 5 to 10 years after a DCIS diagnosis.

But a new cancer may turn up 25 years later—or longer. This usually happens in the same area of the breast where the DCIS was. The new cancer can be either non-invasive (not life-threatening) or invasive (potentially serious). The main goal of treating DCIS is to reduce the risk of an invasive cancer later on.

In most cases, the treatment for DCIS is breast-conserving surgery (lumpectomy). The DCIS must be removed with clean margins (also called margins of resection). To substantially lower the risk of developing an invasive cancer, most doctors recommend additional treatment with radiation after surgery for DCIS.

Women with hormone-receptor-positive DCIS may choose to receive hormonal therapy after surgery to reduce the risk of recurrence and to lower the risk of getting a new cancer.

This page was last modified on November 4, 2005