From: Dianne Smith

To: "pdawe@nl.cancer.ca";
Subject: FYI From Pat Pilgrim
Date: May-13-08 3:49:48 PM

Attachments: Patient_Apology_Letter_April 30 2008.doc

Clarifying Approach to Hormone Receptor Test - Revised May 2008.doc

Hormonal Therapy Information Sheet (4).doc

Hi Peter,

Pat asked me to forward along on her behalf a copy of the patient apology letter and attachments which were sent from Eastern Health FYI. Please find them attached.

Dianne

Dianne Smith, CPS
Executive Assistant to the COO of
Cancer Care, Quality and Risk Management
Eastern Health
Room 1345, Level I, Health Sciences Centre
St. John's, NL A1B 3V6

Telephone: 709-777-1318 Facsimile: 709-777-1347

E-Mail: dianne.smith@easternhealth.ca

Office of the President and Chief Executive Officer
Eastern Health
Executive Office
Waterford Bridge Road
St. John's, NL
Canada A1E 4J8
T: 709-777-1330
F: 709-777-1302
www.easternhealth.ca

DATE

Address Line Address Line Address Line Address Line

Dear (Name):

As the interim president and CEO of Eastern Health, I feel it necessary to contact you at this time on behalf of Eastern Health. Since the Commission of Inquiry hearings began, it has become increasingly clear that the impact of the ER/PR testing issue is profound. The way we addressed the issue and the decisions we made have had a negative impact on you, our patients, and this is unacceptable. We get calls everyday from patients and families looking for more information and telling us their concerns. We know that every patient deserves to receive the highest standard of care possible from Eastern Health. We wish to say to you that we are sorry that we, as a health care organization, did not provide you the high quality patient care in relation to the ER/PR issue that you deserve and that we expect of ourselves. We deeply regret any stress, pain, and anxiety felt by you and your family because of this issue.

To our knowledge, our decision to go back eight years to retest patient tissue samples for ER/PR is something that had never been done before in Canada. It was a massive undertaking, and its challenges are still being felt. This action was launched without hesitation and for one reason only: to identify patients who might be candidates for additional drug therapies such as tamoxifen.

We have learned many things throughout this process. There are many things we would have done differently if we had known then what we know today about the size and complexity of the task that actually faced us.

We have heard your views on how we communicated with you and the public. Again, there are lessons we have learned. But if there is one thing we want you to know, it is this: those responsible for your care tried to make the best decisions they could at the time. Their main concern was to present you with the most accurate and complete information possible about your own health care as soon as it was available. We know now that there were many cases where you and others like you should have received this information sooner.

To help explain this and give you a better understanding of the events as they unfolded, we have included an information sheet that outlines how we addressed the issues surrounding the hormone receptor retesting and what measures we have taken to improve the care we provide. We have also included some background information on hormone receptor testing and tamoxifen in particular.

We are available to talk to you or your family in person or by telephone to provide further information. If you are unsure of your results or would like to talk about your results please give us a call. In addition, we would welcome any suggestions you might have for further follow-up. If you wish to speak with us, please call 1-866-445-4548 or if you wish to communicate with me personally please email: ceo@easternhealth.ca.

Thank you for taking the time to read this.

Sincerely,

LOUISE JONES
Interim President & Chief Executive Officer

Filename: Patient_Apology_Letter_April 30 2008

Directory: C:\Users\dws\AppData\Local\Microsoft\Windows\Temporary

Internet Files

Template:

C:\Users\dws\AppData\Roaming\Microsoft\Templates\Normal.dot

m

Title: December 7, 2005

Subject:

Author: smith-dia

Keywords: Comments:

Creation Date: 30/04/2008 4:00:00 PM

Change Number: 6

Last Saved On: 13/05/2008 3:48:00 PM

Last Saved By: smith-dia Total Editing Time: 5 Minutes

Last Printed On: 25/08/2008 9:29:00 PM

As of Last Complete Printing

Number of Pages: 2

Number of Words: 505 (approx.) Number of Characters: 2,880 (approx.)

Clarifying Our Approach to the Hormone Receptor Test Issue

Our Review of Hormone Receptor Tests

Doctors and staff at Eastern Health and the other regional health authorities work hard everyday to provide the best patient care possible. This is why we took the unprecedented step of retesting estrogen and progesterone receptor (ER/PR) tests. We wanted to ensure that the tests originally done were correct and that our patients were offered the best treatment options available. We believed that if any patient could benefit from retesting, this needed to be done. Our review involved:

- 1. Identifying patients whose samples required retesting.
- 2. Obtaining the breast tissue samples that had originally been tested.
- 3. Reviewing those samples and choosing the most appropriate for retesting.
- 4. Sending the samples chosen to the Pathology Laboratory, Mount Sinai Hospital in Toronto for retesting.
- 5. If the retest results were returned and did not change, senior nursing staff contacted patients directly by telephone to give them the results.
- 6. If the retest results were returned and changed, a panel of medical experts reviewed them and identified further treatment options if necessary. The recommendations of this review were sent to the patient's doctor in writing.

Eastern Health worked with Western Health, Central Health and Labrador-Grenfell Health to retest patients and to inform them of the results of this process.

Communications with Patients

Our nursing staff and physicians have personally spoken to many of the patients affected by this retesting since July 2005. We also communicated with many other doctors who have requested clarification and assistance in supporting their patients.

Problems Identified with the Process Eastern Health Used

Over the past two years, we have discovered problems with the process that we used to identify and contact patients. In addition, all four Health Authorities have cooperated with the Department of Health and Community Services (DOHCS) in a review of our processes which resulted in the development of a database.

Through all of this we have identified problems with the overall process and the challenges of coordinating a large retesting process between four Health Authorities. In particular, it identified that a greater number of patients were retested than originally reported, patients who had not been retested on a timely basis and patients who had not been contacted with their results.

What We Have Learned

As a result of what we have learned we have made improvements in our pathology laboratory to ensure the public is provided with a quality service. We have made recommendations to government with respect to how to improve our database and decision support systems and we continue to work with government toward implementation of these long-term solutions. We have identified improvements that we would make if we were faced with a similar review in the future. We look forward to all recommendations from the Commission of Inquiry (COI).

Improvements to Our Laboratory

Eastern Health has made the following improvements:

- Eastern Health had external experts visit our pathology laboratory to review the quality of the work done there. These experts provided recommendations for improvement. We have implemented or are in the process of implementing all recommendations from these external reviews.
- We have designated the part of the lab that performs the ER/PR test as a separate division with three (3) designated technologists, a lab medical director and other technical staff.
- Our technologists and pathologists in this division have received additional specialized training in immunohistochemisry.
- We have established a Quality Management Program in this new division.
- We have consolidated all breast cases for examination and reporting to a designated group of pathologists.
- We are working with our provincial government to implement a provincial accreditation program for all laboratories in the province. This program will involve adopting a set of provincial standards and reviewing all laboratories in the province to ensure standards are met.
- We participated in a newly developed national accreditation process for laboratories through the Canadian Council on Health Services Accreditation (CCHSA) program; a recognized program through which national standards are set and institutions compare their services against these standards. We are adopting recommendations made through this review.

Through all of this, Eastern Health is committed to ensuring we offer our patients the best possible service.

Filename: Clarifying Approach to Hormone Receptor Test - Revised May

2008

Directory: C:\Users\dws\AppData\Local\Microsoft\Windows\Temporary

Internet Files

Template:

C:\Users\dws\AppData\Roaming\Microsoft\Templates\Normal.dot

m

Title: Over the past year or two there has been much confusion and

concerns regarding the testimony of hormone receptors in the province

Subject:

Author: dillon-p

Keywords: Comments:

Creation Date: 08/05/2008 4:22:00 PM

Change Number: 4

Last Saved On: 09/05/2008 12:14:00 PM

Last Saved By: smith-dia Total Editing Time: 3 Minutes

Last Printed On: 25/08/2008 9:30:00 PM

As of Last Complete Printing

Number of Pages: 2

Number of Words: 688 (approx.) Number of Characters: 3,923 (approx.)

Hormonal Therapy Information

What are Hormone Receptors?

- The diagnosis of breast cancer is made by taking a biopsy from the patient's breast and then sending the tissue to the pathology lab for testing.
- The cancerous tissue removed from the breast is tested for the presence or absence of hormone receptors, which include the estrogen receptor (ER) and the progesterone receptor (PR).
- The presence or absence of hormone receptors helps to determine the most appropriate treatment of breast cancer.
- If the patient's tumor is ER and/or PR positive, hormonal therapy may be recommended as part of the treatment plan.
- However, there are also several other tumor and patient factors that must be considered to determine the potential risks and benefits of hormonal therapy.

What are the Benefits of Hormonal Therapy?

- Adjuvant therapy for early stage breast cancer includes treatments given after surgery to reduce the risk of cancer recurrence and death from breast cancer.
- Drug treatments used may include chemotherapy, targeted therapy and hormonal therapy.
- Hormonal therapy includes tamoxifen and the aromatase inhibitors, letrozole, anastrazole and exemestane. These drugs may be given for 5 to 10 years.
- Many recent advances have been made in the hormonal therapy of breast cancer and the treatment of breast cancer has changed considerably in last several years.
- Some patients are unable to take hormonal therapy due to side effects or other health conditions.
- Some patients who receive adjuvant hormonal therapy still have recurrence of their breast cancer. Hormonal therapy may still be used to treat recurrent or metastatic breast cancer but eventually the cancer will become resistant to hormonal therapy.

Filename: Hormonal Therapy Information Sheet (4)

Directory: C:\Users\dws\Documents

Template:

m

Title: Hormonal Therapy Information Sheet

Subject:

Author: Dr. Kara Laing

Keywords: Comments:

Creation Date: 02/05/2008 11:20:00 AM

Change Number: 4

Last Saved On: 08/05/2008 4:36:00 PM

Last Saved By: smith-dia Total Editing Time: 3 Minutes

Last Printed On: 25/08/2008 9:31:00 PM

As of Last Complete Printing

Number of Pages: 1

Number of Words: 256 (approx.) Number of Characters: 1,461 (approx.)