John Abbott

To:

Williams, Bob

Date:

8/9/2005 10:08:25 AM

Subject:

Letters to Patients

Just checking in to see if the letters to the patients respecting re-testing of negative ER/PR test results are being sent. Please advise. Meanwhile, thanks for your continued assistance/advice in this matter.

John G. Abbott Deputy Minister of Health & Community Services (709) 729-3125

CC:

Hennessey, Moira

John Abbott

To:

Hennessey, Moira

Date:

9/2/2005 11:27:28 AM

Subject:

Re: Fw: ER/PR Issue

Noted. I agree with the idea of briefing the Minister at/near Sept. 10th. We also need to know what /when Eastern Health is going to notify patients as part of the briefing. OK.

John G. Abbott Deputy Minister of Health & Community Services (709) 729-3125

>>> "Moira Hennessey" <MHennessey@gov.nl.ca> 9/2/2005 7:21 AM >>> Hi John,

Attached is update from George T. Please let me know whether you want me to arrange for them to come in to update the Minister. I think we should arrange an update post Sept 10 once they have some test results from Mount Sinai.

Moira

----Original Message----

From: "George Tilley" < George. Tilley@hccsj.nl.ca>

Date: Thu, 1 Sep 2005 12:43:43

To:<MHennessey@mobility.blackberry.net>

Cc:<<u>hcc.wilr@hccsj.nf.ca</u>> Subject: RE: ER/PR Issue

Moira,

We have sent out in excess of 200 blocks to Mount Sinai and this represents approximately 50% of the total. They expect to be in a position to provide feedback on these tests on Sept. 10th. We are working to get others from elsewhere in the Province to forward on.

In the meantime we are awaiting the visits of the external experts (physician Sept. 15th and technologist Sept. 20th.) Expecting their reports by mid October.

While all future specimens will be sent out of province on an interim basis, we are doing some fine tuning on the controls of the new Ventanna system, working on the assumption that it is overly sensitive.

Dr. Williams has met with one lady who inquired about this issue.

That it for now.

George

George Tilley President/Chief Executive Officer Eastern Health c/o Corporate Office Waterford Bridge Rd. A1E 4J8

Page 2

Tel: 709-777-1330 Fax: 709-777-1302

----Original Message----

From: Moira Hennessey [mailto:MHennessey@gov.nl.ca]

Sent: Thursday, September 01, 2005 9:56 AM

To: George Tilley Subject: ER/PR Issue

Good Morning George,

The Minister is inquiring when you will be in a position to provide another update on this. Can you let me know.

Thanks, Moira

Moira Hennessey

Assistant Deputy Minister - Regional Health Operations Department of Health and Community Services Government of Newfoundland and Labrador

Phone: 709.729.3127 Fax: 709.729.4009

E-mail: MHennessey@gov.nl.ca

Sent via BlackBerry on the 1X network.

Tansy Mundon

To:

Chaplin, Carolyn; Cheeseman, Josephine; Cooper, Bruce; MacDonald, Sheree;

Date:

Matthews, Elizabeth; Thompson, Robert 9/30/2005 4:59:16 PM

Subject:

Re: Heads up - Eastern Health Issue

Carolyn,

I was just in the process of writing the same email.

Tansy

>>> Carolyn Chaplin 2005-09-30 4:41 PM >>>

Eastern Health Authority has contacted us to advise that an issue that had been on-going throughout the summer concerning ER/PR testing of breast cancer patients is about to hit the media. Late this afternoon, Eastern Health was contacted by the Independent inquiring whether the health authority had an issue with its mammogram screening.

Dr. Carol Lang (oncologist) spoke with the Independent to respond. In addition, NTV (Lynn Burry) contacted the authority at 4:15 this afternoon. Eastern Health will be calling NTV back but given the late hour of the day, it won't be possible for them to get a body for a clip tonight. They are going to offer comment for Monday's news.

Tansy Mundon

To: Date: Chaplin, Carolyn

Subjects

9/30/2005 5:07:40 PM

Subject:

Re: Heads up - Eastern Health Issue

Eastern has prepared a note and it's being revised. I'm a little puzzled about why Susan called you when she already spoke to me?

>>> Carolyn Chaplin 2005-09-30 5:01 PM >>>

Thanks Tansy - are they preparing revised briefing note? It has been a while since they did one (I believe late July).

Carolyn Chaplin Director of Communications Comm and Consultations Branch, Exec Council 729-0329 (Tel) 682-5093 (Cell) 729-5645 (Fax)

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Tansy Mundon

To:

Hennessey, Moira 9/30/2005 5:14:14 PM

Date: Subject:

Re: Heads up - Eastern Health Issue

Moira.

I believe the revised note is being sent to you directly from Eastern. Perhaps you could share it with me.

Tks, Tansy

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From: To: Tansy Mundon Chaplin, Carolyn

Date:

9/30/2005 5:12:55 PM

Subject:

Re: Heads up - Eastern Health Issue

Maybe. I had been talking to Susan earlier but we were playing telephone tag before we touched base on the NTV piece (earlier was just The Independent and before the call back to Claire Gosse).

>>> Carolyn Chaplin 2005-09-30 5:10 PM >>>

George Tilley uses me as a sounding board from time to time. I believe it was before Susan called you because I asked whether Health had been advised and was told that they had been trying to reach Moira.

Carolyn Chaplin
Director of Communications
Comm and Consultations Branch, Exec Council
729-0329 (Tel)
682-5093 (Cell)
729-5645 (Fax)

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729-5645 (Fax)

Tansy Mundon

To: Date: Hennessey, Moira 10/2/2005 2:53:51 PM

Subject:

Briefing Note

Briefing Note ER/PR Testing Results September 30, 2005

In 1997, a Dako semi-automated/manual system was installed for the Immunohistochemistry Service and replaced the bioassay method of testing for ER/PR receptors. This Dako system was replaced in 2004 by an automated Ventana system with onboard antigen retrieval.

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 estrogen and progesterone receptors. Four other patients initially tested as negative in 2002 were also retested, and all tested positive with the Ventana system.

Retesting was expanded 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 has visited the Immunohistochemistry Service 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 our technicians were appropriate and as trained.

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 Immunohistochemistry Service. Debriefing was held after each review and a full report from each is expected within the next few weeks.

Current Activities:

- All negative samples from 1999 to 2004 (with the exception of samples from other regional health authorities) have been collected and sent to Mount Sinai Hospital, Montreal, for retesting. Mount Sinai uses a semi-automated system of testing for ER/PR. Three hundred twenty-three samples reported as weakly positive to negative have been sent to Mt. Sinai for retesting. To date, 153 samples have been reported by Mount Sinai; 73 have been reviewed, and it appears that of those there are 16 – 20 individuals whose treatment could be impacted. Samples for 1997-1998 and for two regional health authorities from outside Eastern Health area will soon be sent for retesting.
- All 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. 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 have just been received.
- Reporting of ER/PR by the Laboratory Medicine Program is currently on hold. All current requests for ER/PR are being forwarded to Mount Sinai for processing, interpretation and reporting.

Tansy Mundon Hynes, Darrell

To: Date:

10/3/2005 8:12:56 AM

Subject:

Briefing Note - ER/PR testing

Darrell,

Here is briefing note provided on issue in the Independent. Moira is back in the office today and I'll discuss with her. I'll also check on the ambulance issue.

Tansy

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From: To: Tansy Mundon Hynes, Darrell

Date:

10/3/2005 11:31:20 AM

Subject:

Update

Darrell,

With respect to the ER/PR issue, Eastern Health will be doing a follow up interview with NTV this afternoon. John, Moira and I discussed this morning and I have left a message for Susan B. suggesting that they now issue a news release (with Frequently Asked Questions attached) to communicate to the public on this issue. An isolated interview may leave people with concerns and will result in inquiries, forcing a reactive response. Some of those inquiries may be addressed with a news release that provides further information about the process and the small number of people that may be affected.

Tansy