+ cc Eator

Sparkes, Hellen

From: Jenkins, Ken
Sent: Wednesday, April 16, 2008 3:46 PM
To: Sparkes, Hellen
Subject: FW: Report and Cover letter attached

Attachments: Louise Jones.doc; Contact Report.doc


Louise Jones.doc
(24 KB)


Contact Report.doc
(175 KB)

ER/PR file

-----Original Message-----
From: Gillam, Susan
Sent: Monday, April 14, 2008 10:07 AM
To: Jenkins, Ken; Hoddinott, Lisa; Payne, Suzanne
Subject: Fw: Report and Cover letter attached

Fyi
Suzanne please print

----- Original Message -----
From: Louise Jones <Louise.Jones@easternhealth.ca>
To: McGrath, Karen <karen.mcgrath@centralhealth.nl.ca>; Gillam, Susan
Sent: Mon Apr 14 08:49:11 2008
Subject: FW: Report and Cover letter attached

Please see this.. I am going to call you immediately about how we move forward today..I am also forwading you another e-mail as of 2105 last night..

From: Thompson, Robert [mailto:rthompson@gov.nl.ca]
Sent: Monday, April 14, 2008 12:05 AM
To: Louise Jones; Pat Pilgrim
Subject: Report and Cover letter attached

Louise:

Given the possibility that the report would be introduced into evidence tomorrow, I have been asked to provide a technical briefing for media on the contact summary report. This will occur at 10:30 tomorrow morning. We will also brief the CCS and the opposition parties in the morning.

I think we have taken into account your major points in the attached report. As noted in my earlier email, the preference for new search strategy to be employed has been maintained.

Thanks

Robert

Louise Jones
Chief Executive Officer
Eastern Regional Health Authority

Re: ER/PR Database – Summary Report on Contact Data

Please find attached the summary report on contact with patients from the ER/PR Database. The report contains statistical tables, assessments of certain aspects of the contact process, and areas for further review. We will be providing this report to the Commission of Inquiry tomorrow, and we are also providing copies to the other CEOs as there are inter-RHA issues identified in the report which can serve as a basis for seeking improved coordination in the future.

We appreciate the assistance of you and your staff in the ER/PR Database project.

Regards,

Robert Thompson
Secretary to Cabinet (Health Issues)

NLCHI ER/PR Database – Notes on Contact Data
April 13, 2008
Office of the Secretary to Cabinet (Health Issues)

Executive Summary

The database project was initiated by the provincial government as a database/information management exercise to determine whether all retested patients were contacted by Eastern Health and other regional health authorities.. The project also enabled the collection of data on the total number of people retested and changes in ER/PR test results. Total counts and test results have already been provided to the Commission. The present report addresses contact and disclosure. The database identified 35 people who may never have been contacted with any information as of February 21, 2008, and 15 people who were informed that they were being retested but may not have been informed about their test results as of March 13, 2008. Since those dates all contacts except one have been made. The database also identifies 4 patients whose retest results were "no tumour" but insufficient information exists to determine if they have been contacted, and 19 living patients who were unable to be contacted after numerous attempts. Remaining contacts will be completed in the week of April 14, 2008. The contact component of the database project has raised a number of additional questions about coordination, data management, and communication of the retesting process.

1. Introduction

The ER/PR database project was initiated to determine whether all retested patients were contacted and to capture original and new test results. The Newfoundland and Labrador Centre for Health Information (NLCHI) was asked by the Department of HCS to carry out this project given their expertise in the development and management of health information systems. It was also hoped the Commission of Inquiry would be able to use this data to assist in its work.

The contact component of the NLCHI ER/PR Database was undertaken to determine whether all patients in the ER/PR retesting initiative were contacted according to the approach outlined by Eastern Health in October 2005. This approach stated that "all patients who are being re-tested are being contacted." As well, all patients would be contacted about their retest results.

The database project started in the summer of 2007. The records on test results and contact within Eastern Health and other RHAs were not organized in an easily transferable format to a new database, so the project was a considerably larger effort than originally anticipated. By November 2, 2007 enough work was completed for the Minister to announce that there were about 1000 patients who had been retested, rather

than the 939 that had been reported by Eastern Health. Furthermore, 15 patients who should have been retested in 2005 had not been sent for retest until the summer or fall of 2007.

On February 22, 2008, the Minister announced that the database project identified a total of 1013 patients who had been retested. He was also provided initial results from the contact component of the ER/PR Database, noting there was no documentation to verify that 35 living patients had ever been contacted about their new ER/PR test. In addition, 9 patients who were alive at the start of the retesting process, but who were since deceased, had never been contacted.

By mid March 2008 the Office of the Secretary to Cabinet (Health Issues) supplied a summary report on the "retest results" component of the database to the Commission. An updated copy of the database was also provided to the Commission. The present report is the summary report on the "contact" component of the database as of April 13, 2008.

After the February 22, 2008 news release, further analysis of the contacts component of the database identified patients who were told that ER/PR retests would occur on their tissue samples, but were not contacted with their results. This finding is explained in section 3(b) below.

The database project by NLCHI, in collaboration with the Office of the Secretary to Cabinet (Health Issues), was designed as a data management, not clinical, project. Nor was it designed to evaluate the quality of the retesting process. It was designed to enable the retesting process to be described. Therefore, throughout the database project any pattern or finding that might indicate a clinical issue was reported to Eastern Health and the other RHAs for follow-up by appropriate clinicians or quality personnel. Sections 3(c) to (f) describe these issues.

2. Methodological Note

For purposes of the contact analysis, another 7 patients have been added to the database, even though they did not meet the criteria for inclusion. These 7 patients are not part of the 1013 Mount Sinai retest group because they were originally ER/PR positive AND they were identified from multiple sources after the database project had started. They have been included in the contact analysis because contact information on all retested patients is important. Consequently, the total number of patients for the contact analysis is 1020.

In addition to determining whether everyone was contacted, certain additional pieces of information were gathered for the database including the type of contact (e.g., to inform that a sample was being retested; or that results had been received), the channel of contact (e.g., phone call from RHA; letter to physician); and the date of each contact.

NLCHI was directed only to include information in the database which could be verified by source documentation, such as phone lists, notations, and spreadsheets. Information was provided by the four regional health authorities, all of whom had a role in the contact process.

The data regarding the date of contact was incomplete and does not permit analysis at the week or month level.

Some categories of contact information do not provide complete certainty that contact was made with the patient. For example, letters to physicians were a standard type of contact for patients who had changed results and, therefore, data is not available on whether follow-up communication occurred between the physician and the patient. This does not suggest that contact did not happen in all cases; however the database cannot be used to verify this point.

3. Results

a. First Contact With Patients (as of February 22, 2008)

Tables 1 and 2 describe the number of patients and the type of first contact they received about the retesting process from regional health authorities or indirectly via physicians. The first contact for some people was about their tissue samples being sent for retesting, and the first contact for some others was about the actual retest results.

Table 1 shows that 270 patients received a first contact to say that tissue samples were sent for retesting. Through various channels, 387 patients were first contacted when their results were available.

The Minister of Health and Community Services advised the public on February 22, 2008 that 35 living patients had either never been contacted or it was unsure if they had ever been contacted. In addition, 9 patients who were alive at the start of the retesting process, but are since deceased, were never contacted or it is unsure if they were ever contacted. As of April 9, 2008, follow-up contact has been completed by RHAs with all but one of the 35 living patients. The tissue sample of the last patient required further pathology assessment, which was completed on April 11, 2008. The disclosure to this patient (no treatment change) will occur in the week of April 14, 2008.

With respect to contact with families of deceased patients, Eastern Health has advertised and issued public notices that next of kin may obtain results by contacting the Eastern Health.

b. Contact with Results (as of March 13, 2008)

Tables 3 and 4 are based on an analysis completed as of March 13, 2008 and describe the type of contact used for communicating the results of retesting. Table 3 shows that the most common type of contact with patients about their results was through a physician. In these cases the physician may have received a panel letter with the results (295), or some other form of communication with the results (128), with an expectation that they would contact the patient directly. The next most common method was for a patient to receive direct contact from a regional health authority that original test results had been confirmed by Mount Sinai (282).

There are 19 living patients who were unable to be contacted after numerous attempts. To extend the possibility of finding these patients, a new strategy will be examined whereby the government would authorize access to MCP records to determine if there are new addresses and phone numbers for these people based on the MCP re-registration completed last year.

It was not expected that anyone would be identified who had received a first contact that their tissue sample would be retested but would not have been followed up with the results. However, on March 13, 2008, 15 living patients were identified with these characteristics. Follow-up contact has been completed by RHAs on all these patients.

On April 11, 2008, further analysis of the database identified 4 living patients who had been originally contacted about the retesting process, but who were returned from Mount Sinai with a test result that indicated "no tumour". There is insufficient documentation to indicate that these patients have been contacted about their results, so this contact will occur if necessary in the week of April 14, 2008.

Contact is also necessary with 19 families of deceased patients because the database shows that a contact process was initiated, but there is no documentation to show that results were provided to the families. These families can be broken into three groups:

- in 4 cases the family initiated the contact with the RHA but was not subsequently contacted with results;
- in 6 cases the patients had been contacted by the RHA about the retesting process but were deceased when the results were back from Mount Sinai, and no subsequent contact with the family was made; and
- in 9 cases, the family of the deceased was contacted in 2007, and may have been provided with results, but the database cannot confirm this with certainty.

c. Follow-up Contact with Living Patients

The following table describes the timeframe in which follow-up contact was made to the 54 living patients noted above who had never been contacted, or who had received initial contact but not their test results, as of April 11, 2008. The 54 patients consist of the 35

living patients from section 3(a) above, the 15 living patients from section 3(b) above, and the 4 "no tumour" patients from section 3(b) above. Some of the contacts pre-date the NLCHI analysis because when the data was compiled NLCHI had not received source documents demonstrating that the prior contact had taken place.

Time Period	February 21 Analysis - Never Contacted	March 13 Analysis – Results Contact Only	April 13 Analysis – "No Tumour" - Results Contact Only	Total
2006	1	-	-	1
December 2007	1	-	-	1
February 2008	2	-	-	2
March 2008	23	10	-	33
April 2008	2	3	-	5
Date Not Identified	5	2	-	7
Not Yet Contacted	1	-	4	5
Total	35	15	4	54

d. Reasons for No Contact

An evaluation of the reasons that contact was not made with some patients was not part of the database project. Discussions with RHAs while collecting the above information have suggested that:

- the original policy that all living patients would be contacted with results was not universally applied when there was no change between the Mount Sinai test results and the original ER/PR test; and
- there was a failure to have a clear protocol between Eastern Health and other RHAs about the types of contacts that were the responsibility of the other RHAs – for example, Eastern Health thought that other RHAs were responsible for contacting "confirmed DCIS" cases, while other RHAs did not have the same understanding.

e. Self-Identified Patients

Between 2005 and 2007, regional health authorities periodically received inquiries from patients who had an ER/PR test but had not been contacted for retesting. Further checking revealed that some of these patients could not have been identified through normal searches in the Meditech Information System because the "order entry" code in the patient record was not filled-in. Despite the absence of this code, the ER/PR test had been performed for these patients.

These patients who self-identified have been retested. However, there remains the question of whether other similar patients exist who have never identified themselves to a regional health authority. This question is reasonable because, even though the attached table identifies 46 patients or families that initiated their own contacts with RHAs, there

are 44 patients where no contact was initiated. Furthermore in late March 2008 another patient who had never been identified in the Meditech system came forward. This person was originally ER/PR negative but had not been identified in Meditech because of the omission of the "order entry" code on her record. She was retested in St. John's and confirmed negative. This person has not been added to the database because she was not retested at Mount Sinai Hospital, but her case is nonetheless important when evaluating detection systems.

These points have caused Eastern Health to examine options for alternative search strategies within Meditech to identify any possible remaining negative ER/PR patients.

f. Revised DCIS Diagnoses and Lack of Contact via Physicians

Revised diagnoses of the extent or severity of cancer is a different issue than ER/PR conversion, but the retesting process has resulted in the identification of a number of these cases. Four changes in original diagnosis were identified by Eastern Health up to May 2007 and disclosed publicly at that time. Since then, as a consequence of the database project, three additional cases with a revised diagnosis have been identified, all of which have been disclosed to patients and families.

Two other cases have been addressed by Eastern Health since April 8, 2008. One case was recorded in the NLCHI database as a valid contact in late 2005 based on information that the patient would be contacted via a physician. Based on further information from Eastern Health, it now appears that contact did not occur. A second case was returned in 2005 from Mount Sinai indicating insufficient tumour for assessment. This information was paneled, along with original patient pathology, with the resulting assessment showing the cancer was not as advanced as originally thought, yet it appears a panel letter was never sent to the attending physician or the patient.

These cases give rise to a specific concern and two general concerns. The specific concern is how the administrative tracking and coordination could have failed in these cases. Eastern Health is documenting these examples under its "critical occurrence" policy as part of the disclosure process. It will also engage with other RHAs to examine the problems encountered with inter-RHA communication.

The two general concerns are: 1) whether there exist other DCIS cases which had different original diagnoses but were not properly identified or disclosed to patients; and 2) how many of the contacts which were supposed to take place by physicians actually occurred? Eastern Health is reviewing both of these concerns. While the likelihood may be low that the DCIS cases were not properly assessed, or the remaining patients did not receive their retest results, it is important to carry out the work necessary to answer these questions. Eastern Health has decided to immediately review all DCIS cases again to determine if there are any outstanding issues and to re-contact patients if there are any undisclosed issues. It is also considering a three-step review of the contacts with patients

that were supposed to occur pursuant to letters sent to physicians: 1) a chart review; 2) contact with physician offices; and 3) if necessary, new contact with patients.

4. Conclusion

The ER/PR Database was a data management exercise initiated by the provincial government to gather data and document the retesting and contact process which occurred between 2005 and 2007. During the analysis of the contact data the identification of patients who were not contacted, or who may not have been contacted, led to new disclosures to patients by regional health authorities. The analysis also brought to light a number of questions on coordination, data management, and communication. Eastern Health has conducted, or is currently conducting, further assessment on these questions.

Table 1 - Method of first contact with breast cancer patients who had original ER tests (either negative or positive) during the course of the ER/PR Recall, as of April 13, 2008

Method of first communications	Deceased	Not deceased	Unknown May be non-NL resident	Total
Patient/Family initiated contact	9	37	0	46
RHA Initiated Contact				
Patient was contacted about retesting before results available§	22	248	0	270
Patient was contacted by RHA with results§	29	199	2	230
Family was contacted before results back	1	3	0	4
Family was contacted after results back	0	1	0	1
Family of deceased was contacted	12	0	0	12
Contact Via Physician				
Results communicated by RHA to physician (no panel letter)	0	9	7	16
Results communicated by panel letter to physician*	17	136	2	155
Panel letter sent to the most responsible physicians (and patient/physician contact confirmed)	0	26	0	26
Deceased prior to contact	225	0	2	227
Unable to contact	5	17	1	23
No Contact Made	9	1	0	10
Total	**329**	**677**	**14**	**1020**

* NLCHI is not able to confirm whether the physicians communicated the ER/PR results with patients.
** The total 1020 excludes those patients who did not have original ER test performed in NL.
§ This includes contacts by RHA, Panel Letter, physicians etc.
† Unable to contact means that RHAs attempted numerous times to reach individual patients but were unsuccessful.
‡ Information on these individuals was not available at the time of the analysis.

Table 2 - Method of first contact with breast cancer patients who had original ER tests (either negative or positive) during the course of the ER/PR Recall by regions, as of April 13, 2008

Method of first communications	St. John's	Carbonear	Clarenville	Grand Falls	Gander	Western	Lab/Grenfell	Total
Patient/Family initiated contact	42	3	0	0	0	1	0	46
RHA Initiated Contact								
Patient was contacted about retesting before results available§	127	18	3	0	0	122	0	270
Patient was contacted by RHA with results§	121	13	3	41	26	10	16	230
Family was contacted before results back	1	0	0	0	0	3	0	4
Family was contacted after results back	0	1	0	0	0	0	0	1
Family of deceased was contacted	1	2	0	0	0	0	9	12
Contact Via Physician								
Results communicated by RHA to physician (no panel letter)	10	0	0	3	0	0	3	16
Results communicated by panel letter to physician*	73	21	7	29	17	4	4	155
Panel letter sent to the most responsible physicians (and patient/physician contact confirmed)	3	0	0	15	8	0	0	26
Deceased prior to contact	124	12	2	26	21	34	8	227
Unable to contact	6	0	0	4	1	12	0	23
No Contact Made	0	1	0	8	1	0	0	10
Total	**508**	**71**	**15**	**126**	**74**	**186**	**40**	**1020**

* NLCHI is not able to confirm whether the physicians communicated the ER/PR results with patients.
** The total 1020 excludes those patients who did not have original ER test performed in NL.
§ This includes contacts by RHA, Panel Letter, physicians etc.

Table 3 - Method of communicating results with breast cancer patients during the course of the ER/PR Recall, as of April 13, 2008

Method of communicating results	Deceased	Not deceased	Unknown May be non-NL resident	Total
RHA				
Patient contacted by RHA	29	261	6	296
Results Communicated by Panel Letter and RHAs	0	8	2	10
Via Physician				
Result Communicated by Panel Letter to physician	23	270	2	295
Result Communicated by Physician	17	64	1	82
Results Communicated by Panel Letter and Physician	2	37	0	39
Results communicated by RHA to physician (not a panel letter)	0	12	0	12
No contact made	6†	1	0	7
Deceased	234	0	2	236
Can't Confirm if contact was made	12†	4	0	16
Other	0	1	0	1
Unable to Contact*	6	19	1	26
Total	**329**	**677**	**14**	**1020**

† These may include deceased patients whose families called in and inquired about the retesting, or patients were contacted initially but were passed away during the course of the ER/PR call.

* Unable to contact means that RHAs attempted numerous times to reach individual patients but were unsuccessful.

Table 4 - Method of communicating results with breast cancer patients who had original ER tests (either negative or positive) during the course of the ER/PR Recall by regions, as of April 13, 2008

Method of communicating results	St. John's	Carbonear	Clarenville	Grand Falls	Gander	Western	Lab/Grenfell	Total
RHA								
Patient contacted by RHA	137	18	4	36	25	63	13	296
Results Communicated by Panel Letter and RHAs	3	0	0	1	0	2	4	10
Via Physician								
Result Communicated by Panel Letter to physician	155	26	9	30	18	57	0	295
Result Communicated by Physician	59	11	0	5	1	4	2	82
Results Communicated by Panel Letter and Physician	15	3	0	13	7	0	1	39
Results communicated by RHA to physician (not a panel letter)	2	0	0	3	0	4	3	12
No contact made	0	0	0	5	0	2	0	7
Deceased	127	13	2	28	22	36	8	236
Can't Confirm if contact was made	2	0	0	1	0	4	9	16
Other	1	0	0	0	0	0	0	1
Unable to Contact†	7	0	0	4	1	14	0	26
Total	**508**	**71**	**15**	**126**	**74**	**186**	**40**	**1020**

† Unable to contact implies that RHAs attempted numerous times to reach individual patients but were unsuccessful.