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Subject: ER/PR Interim Report

Robert:

Attached is the interim report which outlines the approach used in developing the database, the data dictionary and recommendations for the maintenance and development of the database interface. As noted in my earlier e-mail work continues on adding to the database as new information becomes available, however we are in a position to begin providing you preliminary data analysis. I also have attached a copy of the letter I will be sending to Pat Pilgrim tomorrow - this letter came out of last meeting. It took some time to put together given the number of patients involved. Clearly, once we hear back from Eastern Health on our request there will be further updates to the database.

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**Estrogen and Progesterone Receptor (ER/PR)
Breast Cancer Testing Communication Event Database**

Interim Report

Submitted by:

Research and Evaluation Department
Newfoundland and Labrador Centre for Health Information

September 19, 2007

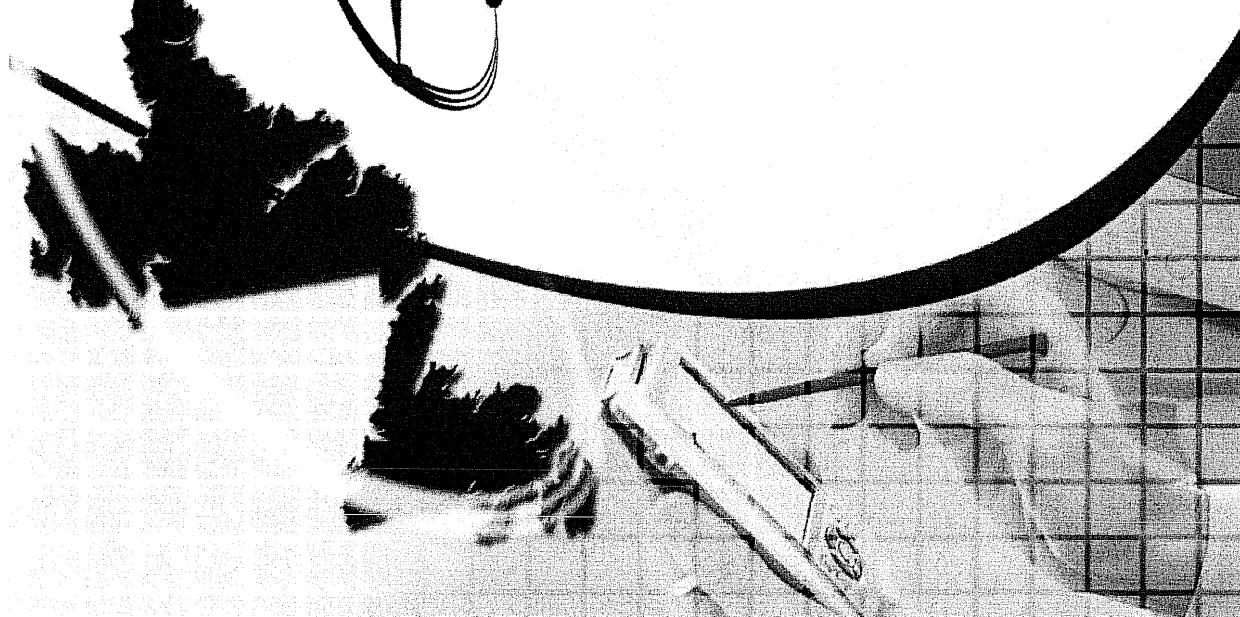
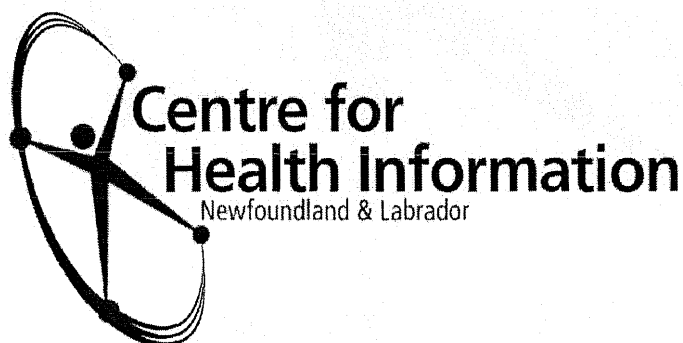


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Project Background

Estrogen and progesterone receptor (ER/PR) testing takes place after a diagnosis of breast cancer and is used to determine whether cancer cells have estrogen and progesterone receptors. Breast cancers that are either ER-positive or PR-positive (or both) may respond to hormone therapy such as Tamoxifen. Hormonal therapy, chemotherapy and radiation are potential treatments given after surgery.

In July 2007, the Department of Health and Community Services requested that the Centre for Health Information develop a database that would identify all breast cancer patients who received ER/PR testing in Newfoundland and Labrador (NL) (prior to August 2005) and were subsequently retested at Mount Sinai Hospital (Toronto). A second phase of this work involved the documentation of relevant communication events related to the retesting. While the main focus of the database is on: 1) when and how patients were contacted to inform them of the retesting, and 2) when and how patients were informed of the subsequent test results, it was recognized early in the process that the foundation of the database would be an accurate patient list. Given this, the approach taken to develop the database had two components, the patient listing and communications events surrounding the patient. For the purpose of this report the resulting database is called the "*ER/PR Patient Listing and Communication Events Database*". The aim of this report is to describe the methodology used to develop the database, and present a description of the variables within the database. It should be noted that this document serves as an interim report as of September 20, 2007. The database will continue to be enhanced as additional information becomes available. .

Selection Criteria

The following criteria were initially used to develop the ER/PR Patient Listing and Communication Events database:

- Both male and female breast cancer patients;
- Original ER testing in NL within time frame: between January 1997 and August 2005;

- Original ER testing (either negative or positive) done in NL **AND** retested at Mount Sinai;
- Include tissue other than breast (e.g., lymph node, chest etc);
- Include DCIS (ductal carcinoma in situ) patients (originally sent for retesting but at Mount Sinai diagnosed as DCIS and were not retested);
- Insufficient tumor for ER testing at Mount Sinai;
- Include deceased patients who have recently been sent for retesting;
- Include all originally negative ER done in NL BUT not retested at Mount Sinai;
- Include all ER tested at Mount Sinai BUT no original ER testing in NL;
- Called in and asked to be tested at Mount Sinai BUT did not meet the eligibility criteria.

On September 11, 2007, a meeting between the Department of Health and Community Services and the Centre resulted in the original criteria being revised.

Revised Criteria

1. Had original ER test in NL;
2. Had original ER test for sample related to breast cancer (e.g., breast, lymph node, chest etc);
3. Had original ER test between January 1997 and August 2005 (inclusive) **OR** had original ER test prior to January 1997 **AND** sent to Mount Sinai for re-testing;
4. Had negative original ER test result **OR** had positive original ER test result **AND** sent to Mount Sinai for re-testing.

OR

1. Had sample taken in NL related to breast cancer (e.g., breast, lymph node, chest etc);
2. Had sample taken between January 1997 and August 2005 (inclusive) **OR** had sample taken prior to January 1997 **AND** sent to Mount Sinai for testing;
3. Had no original ER test in NL **BUT** sample sent to Mount Sinai for testing.

In addition, if an individual met the above criteria, he/she would not be excluded based on any of the following criteria:

1. Sample not retested at Mount Sinai due to DCIS;
2. Sample not retested at Mount Sinai due to insufficient tumor for ER testing;
3. Patient is deceased.

Description of Data Sources

The following data sources (electronic and hard copy) were used in the development of the *ER/PR Patient Listing and Communication Events* database:

I) Patient Clinical/Demographic Data Sources

a) Eastern Health Quality and Risk Management August 1st Excel File

The Centre received this data file in electronic format (Excel) on August 1st, 2007. The data included 1032 records. The data file originally did not contain MCP numbers. An extensive effort was made to capture MCP number for each patient using the MCP registry file (primary source) as well as Meditech (secondary source). As a result, a total number of 924 unique patients were identified in the Eastern Health Quality and Risk Management August 1st file based on MCP number. The data included demographic and clinical information regarding ER/PR scoring and communication events for most patients records. It should be noted that prior to the Centre receiving a copy of this data file on August 1st it was modified over time with no documentation on previous changes.

b) Eastern Health Quality and Risk Management August 3rd Excel File

The Centre received this file in electronic format (Excel) on August 20th, 2007. This file was an updated version of the Eastern Health Quality and Risk Management August 1st Excel file. The data included 1055 records. This database was used only for identifying newly added cases since the August 1st file – the foundation for developing the *ER/PR Patient Listing and Communication Events* database was the August 1st file.

c) *Eastern Health Laboratory Written Lists*

The Centre received a hard copy of the following lists developed by the Laboratory Department at Eastern Health. The lists were electronically entered into SPSS software by the Centre.

- a) A list of breast cancer patients with ER negative and/or weakly positive for the St. John's region - This list included demographic information (name, MCP, Surgical Number) as well as original ER/PR scoring and contained 652 records.
- b) A list of breast cancer patients with ER negative for other Regional Health Authorities (Central, Western, Labrador/Grenfell, Clarenville [former Peninsulas Institutional Board] and Carbonear [former Avalon Institutional Board]) - This included demographic information (name, MCP, Surgical Number, Regional Health Authority) as well as original ER/PR scoring and contained 464 records.
- c) A list of deceased breast cancer patients who were ER negative, as well as those individuals who called (or their family called) inquiring about ER retesting at Mount Sinai - This included demographic information (name, MCP, Surgical Number, Regional Health Authority) as well as original ER/PR scoring and contained 111 of records.

d) *Mount Sinai ER/PR Retesting File*

On July 18, 2007, the Department of Health and Community Services requested from Mount Sinai Hospital a list of all breast cancer patients who had been sent for retesting. This file was received by the Centre on August 17, 2007 and contains demographic information (Name, Surgical number, Block number, Site/Region, MS reference number [RS#]) as well as ER/PR retest scores.

e) *Mount Sinai Pathology Consultations*

In some cases, samples for breast cancer patients were individually sent to Mount Sinai

for ER/PR retesting which resulted in a full pathology report being generated for each patient. Eastern Health's Laboratory provided the Centre with a copy of these pathology consultation reports. In addition, Eastern Health's Quality and Risk Management Division provided the Centre with a number of Mount Sinai consultation reports which were reviewed by Eastern Health's Laboratory staff. Consultations from both the Eastern Health Laboratory and the Health Quality and Risk Management Division were reviewed to identify unique consults that met the inclusion criteria for the database. The resulting data file contained demographic information including Name, Surgical Number and Block Number, as well as ER/PR retest scores.

f) Regional Health Authority Pathology Reports

At the request of the Department of Health and Community Services, the other Regional Health Authorities (Central, Western, Labrador/Grenfell, Clarenville [part of the former Peninsulas Institutional Board] and Carbonear [part of the former Avalon Institutional Board]) provided the Centre with original pathology reports for all breast cancer patients (1997-2005) that had ER/PR testing. These included both original negative and/or positive ER scoring. The reports contained demographic information (Name, MCP, Surgical and Block Number) and, where available, original and retest scores. The name of the pathologist who reported the original ER/PR scores was available from most reports.

g) Meditech System

The pathology module of the Meditech system at Eastern Health was used to obtain demographic (e.g. MCP, Surgical Number, name of the pathologist who reported the original ER/PR etc) and clinical information (ER/PR testing and/or retesting scores) to supplement existing sources.

h) Medical Care Plan (MCP) File

The MCP registry and Meditech were used to obtain the MCP number for each breast cancer patient.

i) Mortality System

Using the mortality system, vital status and date of death were obtained. Causes of death are to be obtained at a later date.

II) Communication Events

a) Eastern Health Sources

The following sources were used to identify and document communication events surrounding the ER/PR testing process:

- i. *Quality and Risk Management Communication Documents* - used to identify whether an individual was initially contacted regarding the ER/PR retesting process. Information includes the name of the employee who placed the call, the employer, and the date of contact. In addition, information on re-contacting the patient regarding the Mount Sinai results were obtained.
- ii. *Panel Letters issued by the Expert Review Panel (Tumor Board)* - The Expert Review Panel consisted of oncologists and pathologists and the Eastern Health's Quality and Risk Management official who reviewed the Mount Sinai ER/PR retest results for those patients whose ER/PR test scores required a clinical review (i.e. changed from negative to positive). The Panel reviewed the results and made recommendations for treatment. A letter was sent to the most responsible physicians (e.g., oncologist, family physician, surgeon) summarizing the Panel's recommendation. The Panel letter includes demographic and clinical information, as well as the date that the Panel reviewed the patients' results and the date that the letter was issued.
- iii. *Patient Relations Database (Quality and Risk Management Division)* - a hard copy list compiled and maintained by the Patient Relations Officer at Eastern

Health. This list includes information on those individuals who contacted Eastern Health regarding the ER/PR recall process. A summary of the conversation, the dates and suggestions were documented. Demographic information on the caller was also collected.

b) Regional Health Authorities Sources

The Western Regional Health Authority provided the Centre with written documentation on communication events surrounding ER/PR retesting for each individual from their region. The Central Regional Health Authority provided the Centre with similar information in an electronic format (Excel) for both Central East and Central West (former Institutional Boards). The Labrador/Grenfell Regional Health Authority provided the Centre with information on communication events through email communication.

Database Development Methodology

In order to develop and create the ER/PR Patient Listing and Communication Events database, data standardization, linkages and cross-referencing between various data sources were carried out:

Step 1: Standardization - All variables in each data source (electronic) were standardized in order to ensure proper data linkages (e.g. name, MCP, etc).

Step 2: Data Linkage and Cross Referencing – Various data sources were linked via MCP number or Name where applicable; discrepancies were investigated using secondary data sources.

Step 2.1: Eastern Health Quality and Risk Management August 1st Data and Mount Sinai Data linkage. Since the Mount Sinai file was considered to be a “core source”, the purpose of this linkage was to identify potential missing cases/records in the Eastern Health Quality and Risk Management August 1st file through cross referencing. Any missing cases/records were investigated and documented.

Step 2.2: Eastern Health Quality and Risk Management August 1st Data and Mount Sinai Consultations File Linkage. The Mount Sinai Consultations file was considered to be the second “core source”; therefore, this linkage was carried out to identify potential missing cases/records in the Eastern Health Quality and Risk Management August 1st file through cross referencing. Any missing cases/records were investigated and documented.

Step 2.3: Eastern Health Quality and Risk Management August 1st Data and Eastern Health Laboratory Written List (A list of deceased breast cancer patients who were ER negative, as well as those individuals who called (or their family called) inquiring about ER retesting at Mount Sinai). This was performed to identify deceased patients who were not on the Eastern Health August 1st Data file and sent to Mount Sinai for retesting. These patients were documented and listed to be added to the final database if they met the inclusion criteria.

Step 2.4: Eastern Health Quality and Risk Management August 1st Data and Eastern Health Laboratory Written List (A list of breast cancer patients with ER negative and/or weakly positive for the St. John’s region; A list of breast cancer patients with ER negative for other Regional Health Authorities). This linkage was carried out to capture those breast cancer patients who were identified by Eastern Health’s Laboratory but were not found in Eastern Health’s August 1st Data. In addition, cross referencing between the above linked data files and the Mount Sinai file and Mount Sinai Consultations file was performed in order to identify those who were in the Eastern Health Laboratory file and were not sent to Mount Sinai. These patients were listed and documented to be added to the final database if they met the inclusion criteria.

Step 2.5: Eastern Health Quality and Risk Management August 1st and August 3rd Files. The purpose of this linkage was to identify any differences in records/cases

between the two files. Any differences were resolved with the use of the other data sources (Meditech, MCP, Mount Sinai File, and Mount Sinai Consultations) and documented to be added to the final database if they met the inclusion criteria.

Step 2.6: Eastern Health Quality and Risk Management August 1st File and Regional Health Authority Pathology Reports. The pathology reports were reviewed and cross-referenced with Eastern Health's Quality and Risk Management August 1st File. Information (e.g., name of the pathologist, original ER/PR scores etc) was added from the reports and any missing/inaccurate information was corrected. Any reports that were received by the Centre from the Regional Health Authorities that were not included in Eastern Health's Quality and Risk Management August 1st File were documented and added to the final database if they met the inclusion criteria.

Step 2.7: Eastern Health Quality and Risk Management August 1st File and Communications Data. The Communication data for each patient was linked to the demographic and clinical data.

Step 2.8: Eastern Health Quality and Risk Management August 1st File and the Centre's Mortality System. This linkage identified the vital status of patients that were in the Centre's Mortality System up to June 2007.

Table 1 presents description of variables in the ER/PR Patient Listing and Communication Events database.

Table 1. Description of the ER/PR Patient Listing and Communication Events database variables

Variable Name	Label	Values
Name	Patient Name	Patient Name
MCP	MCP Number	MCP Number
region	RHA	St. John's; Western Memorial; Carbonear; Grand Falls; St. Anthony; G.B. Cross; Gander
res_con	Results Contact	Variable from the Eastern Health Quality and Risk Management August 1 st file
ori_con	Original Contact	Variable from the Eastern Health Quality and Risk Management August 1 st file
other_is	Other issues	Variable from Eastern Health Quality and Risk Management August 1 st file
Con_retesting	Contact re retesting	Whether the patient was initially contacted regarding the ER/PR retesting process (Yes/No)
Date_Con_Retest	Date patients informed Retesting	The date of contact if the initial contact was made with the patient regarding the ER/PR retesting process
Person_Con_Retest	Person informed patient retesting	Person who made the initial contact with the patient regarding the ER/PR retesting process
Employer	Employer	Employer of the person who made the initial contact with the patient regarding the ER/PR retesting process
Date_panel	Date Panel Review	The date that patient was paneled (note: not all patients were paneled)
Date_panel_letter	Date panel letter sent to physician	The date the panel letter was issued and sent
Date_Con_Pt	Date patients (no conversion) contacted re results	Date patient was contacted regarding the Mount Sinai results (mostly for those whose their ER/PR results were changed)
Comment_Communication	Comments/Notes on Communications	Extra communication information regarding the processing and/or results (e.g., patient/family called in etc)
Verification	Verification	Verification that doctor reviewed results with patient

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vital_stat	Vital status	1 → Deceased 0 → Alive
dod	Date of death	Date of death
specimen	Specimen #	Specimen (surgical) number assigned by the
RE_Num	Referral number	RE# assigned by Eastern Health to each specimen/block from the regions before being sent for retesting at Mt. Sinai
date_ms	Date sample sent Mt. Sinai	Date sample sent Mt. Sinai for retesting
date_ent	Date result Mt. Sinai entered Meditech	Date Mt. Sinai results entered in Meditech
patholog	Name of Pathologist	Name of Pathologist who reported the original ER/PR
Note	Notes	Comments/Notes regarding specimen numbers, ER/PR scores etc
ori_er	Original ER	Original ER reported in NL
ori_er_reg	Original ER Pathology reports regions	Original ER found in the pathology reports from the regions
ori_pr	Original PR	Original PR reported in NL
ori_pr_reg	Original PR Pathology reports regions	Original PR found in the pathology reports from the regions
ms_er	MS ER	Mount Sinai ER score
ms_pr	MS PR	Mount Sinai PR score
blocks	Block	Pathology block # retested at Mount Sinai
rs#	RS #	Mount Sinai research number (assigned number to each specimen submitted for retesting)
OriginalName	Patient Name	Original patient name from the Eastern Health Quality and Risk Management August 1 st file
comm_a	Comment	Comment regarding patient vital status, communication, etc from the Eastern Health Quality and Risk Management August 1 st file
Reason	Reason for adding	Source of and reason for adding each record/patient
comment		Comment regarding paneling from the Eastern Health Quality and Risk Management August 1 st file

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ms_tumor	MS Tumour	Mount Sinai tumor diagnosis : D-ductal, DL-ductal with lobular features, DT-ductal with tubular features, L-lobular, PAP papillary, DCIS-ductal carcinoma in situ, DCIS/M-ductal carcinoma in situ with microinvasion (<1mm), C-colloid, T-tubular, MCA-metastatic CA,EPAP-encysted papillary in situ carcinoma, DA-ductal carcinoma with apocrine features, EIC-extensive DCIS (>25%), M-metaplastic carcinoma, AC-adenoid cystic carcinoma, CaNOS-unclassified carcinoma, PU-pickup with tumour adherent to tissue and NT-no tumour
ic	Internal Control	internal controls with P-present but not stained, PS-present and stained, PSW-present and stained weakly, A-absent
fp	F/P	fixation and processing with A-adequate and P-poor

Action Items

Database Maintenance and Analysis Implications

The Centre is currently maintaining the ER/PR Patient Listing and Communication Events database on behalf of the Department of Health and Community Services. It is recognized that the “*ER/PR Patient Listing and Communication Events Database*” will require ongoing maintenance and updating for several months as more data becomes available. The Centre recommends that until the database is complete, it be maintained and updated by the Centre, given the high level of complexity of the database structure, and the data it contains.

Database Interface

The database needs to be put in a user friendly software package. It is currently in SPSS, which the Centre will use to maintain as the Master File, but this software is provides little value as an information tool. Two options are:

1. Have Eastern Health IMAT Department develop the user interface with the data.

GOGNOS has been mentioned as one possibility.

2. Have the Centre prepare a user interface using ACCESS, or some other public software

Having Eastern prepare the interface has the advantage of having significant resources with expertise in the area of database interface development. The disadvantages are that: 1) Eastern may not be able to access some data in the database may negate them accessing the full database for developing the interface, and 2) having Eastern develop the interface would require that they maintain it. Having one agency responsible for the data and another responsible for the interface is not good database management practice.

Having the Centre develop the interface has the disadvantage that we do not have extensive development resources or expertise compared to that at Eastern Health The Centre has the advantage of keeping all interface, maintenance and update activities located at one source. It is recommended the Centre develop the interface.

Database Access

A protocol will need to be put in place to transfer the database to the Commission of Inquiry and, if possible, to the Eastern Health Authority.