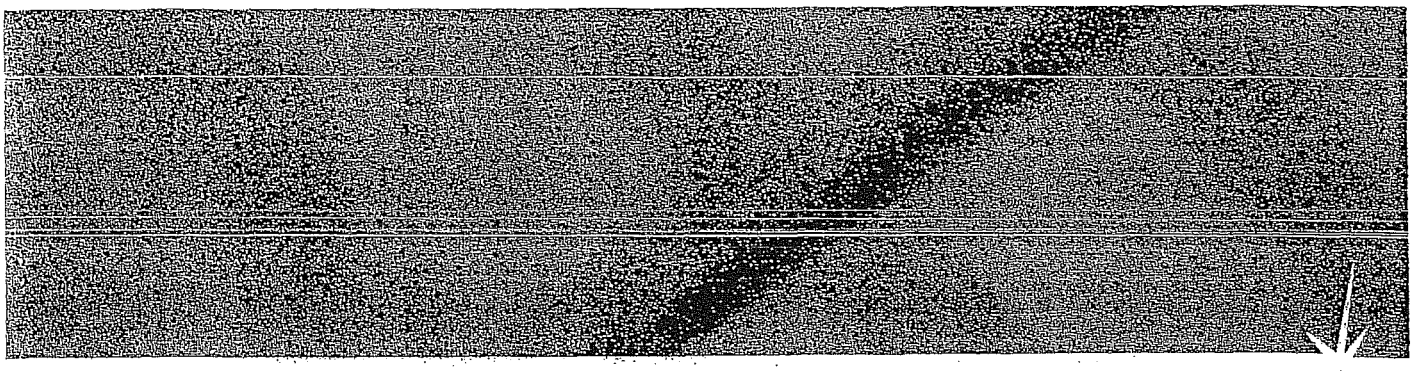

Estrogen and Progesterone Receptor (ER/PR) Breast Cancer Testing Communication Event Database

Scoping Document

Submitted by:

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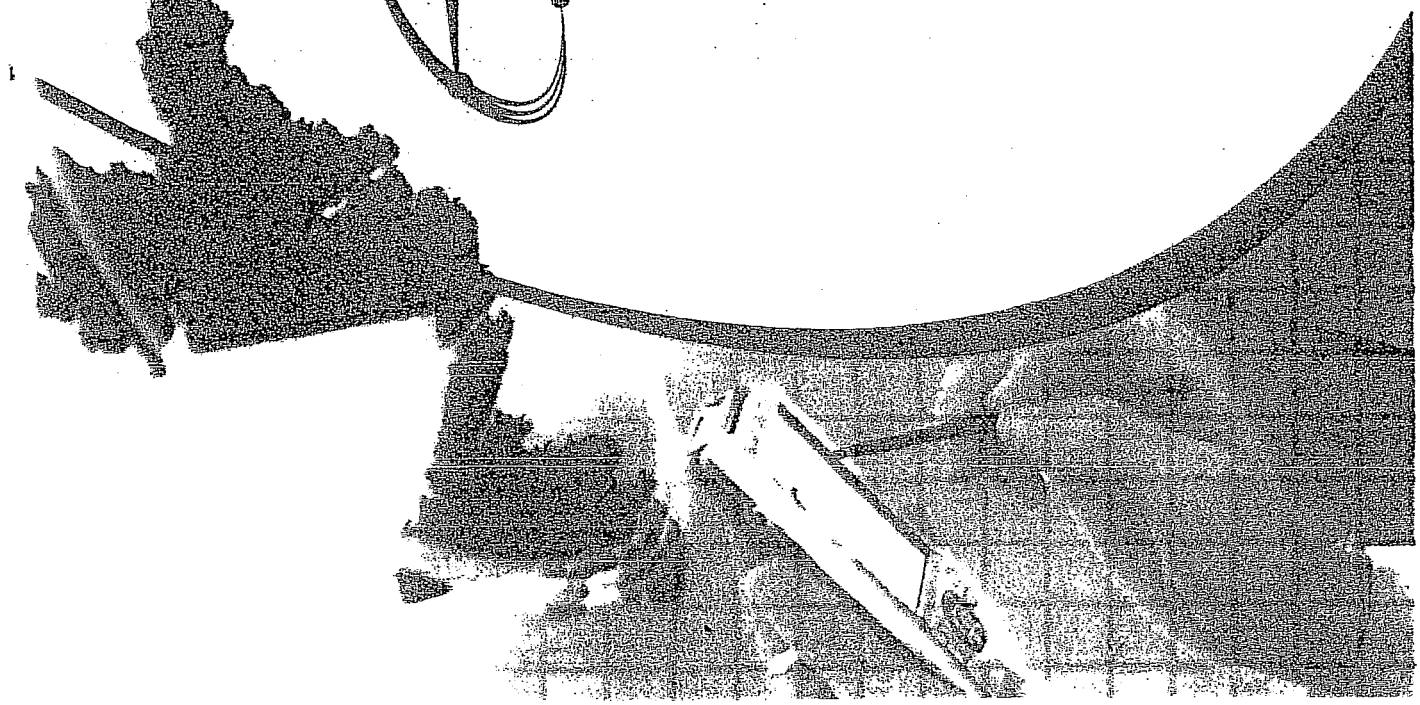
July 6, 2007

Centre for Health Information
Newfoundland & Labrador



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

Estrogen and progesterone receptor (ER/PR) testing takes place after a breast cancer diagnosis 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 additional treatments given after potentially curative surgery.

Given the need identify all patients who received ER/PR breast cancer testing at Eastern Health from 1997-2005, and to document relevant communication events following testing, staff of the Centre for Health Information (NLCHI) met with representatives of Eastern health and the Department of Health and Community Services on June 14 to discuss a framework for a data base management process. The database would focus on when and how patients were contacted to inform them of the retesting, as well as when and how patients were informed of the subsequent test results. It is recognized that the database must identify the source of supporting documentation for any core fields included in the database. The data base is to contain, but not be limited to, the following:

Core Fields

plus: old result
: new result
: living or deceased (date of passing)

1. Health Authority sample originated from
2. Source of original case data (e.g., Meditech) ; phone call from patient;
3. Date that sample was obtained by Eastern Health
4. Date sample sent to Mount Sinai
5. Date of phone call to patient to inform that sample was sent for re-testing
6. Name of person who placed call
7. Employer of person who placed call (i.e., Health Authority)
8. Date that results returned from Mount Sinai
9. Date sample results were reviewed by Tumor Panel
10. Date that sample results and Tumor Panel review were sent to physician

11. Date and means by which Eastern Health contacted patient about results
12. Verification that doctor reviewed results with patient

Following subsequent meetings with Eastern Health officials, and a preliminary review of available documents, it was recognized that the development of the database will be a complex undertaking involving a number of patients' lists and data sources created by various agencies and individuals. While the number of sources adds to the complexity, they also provide a valuable tool for verification and quality checks. There are two main phases to the development of the database: 1) Identifying all patients diagnosed with breast cancer that had ER/PR testing carried out at Eastern Health, and 2) provide all relevant communication event dates for patients tested at Eastern Health. The Centre proposes the following three options for creating a data base of patient interventions and communications specific to Eastern Health's ER/PR breast cancer testing:

careful to note if any new ones were new before part of the database that were never re-tested or called.

PHASE I: Development of Patient List for ER/PR Testing

Option A:

Eastern Health has already identified a list of 2,760 original test cases for the period 1997-2005, with 939 of these having a negative ER/PR result. These negative results were subsequently sent to Mount Sinai for ER/PR retesting. A database of these 939 patients having some of the core fields identified for this initiative is available from Eastern Health. This database (n=939) can be used as the final ER/PR patient list, with additional data fields incorporated to reflect the requirements of Health and Community Services.

Advantages: Builds on work already undertaking by Eastern Health and therefore would be timelier and require significantly less resources to complete.

Disadvantages: The Centre cannot confirm all patients impacted are included in database, as primary source data was not utilized in building client listing.

Option B:

The database be developed completely independent of the work carried out by Eastern Health to create the data base containing n = 939 patients. This new data base would use as it main source a download from Meditech of all ER/PR testing carried out from 1997-2005 from each of the four Health Authorities, identification of those test specific to breast cancer, and confirmation of tests results (positive/negative). This list would then be cross-referenced with Mount Sinai's list of all ER/PR testing/retesting for the province over the period 1997-2005.

Advantages: The Centre can confirm all patients impacted are included in database, as primary source data was utilized in building client listing.

Disadvantages: Would require significant resources and time to complete. It should be noted that ER/PR testing can be either interpreted based on laboratory guidelines, or clinical criteria by an oncologist/pathologist. Thus re-evaluating each ER/PR tests as either positive or negative using Option 'B' needs to be considered in the decision, given the subjectivity of the testing and the resources required to review all ER/PR test results.

Option C:

The database be developed using the hardcopy/electronic data of all (+/-) ER/PR testing results (n=2,760) developed by the Eastern Health Laboratory, ER/PR testing from Central, Western and Labrador-Grenfell, and Mount Sinai's list of all ER/PR testing/retesting for the period 1997-2005. A step-by-step approach is provided below for Option C, although many of these steps are also relevant to Option B.

Step 1:

Obtain a hardcopy/electronic data of all (+/-) ER/PR testing results (n=2,760) carried out at Eastern Health from May 1997 to August 2005. It is recognized that the Central, Western and Labrador-Grenfell Health Authorities routinely sent breast tissue/samples for staining and other laboratory processes to Eastern Health, and that these pathology slides were subsequently sent back to the region of origin for diagnosis.

Step 2:

Medical Directors in each of Central, Western and Labrador-Grenfell Health Authorities to provide NLCHI with a complete list of all ER/PR breast cancer testing in their region from May 1997 to August 2005. This list will be crossed matched with the data obtained from the Eastern Health Meditech System (Step 1). Consideration will be given to the fact that Clarenville (currently under Eastern Health) was the only Centre in the province that directly sent breast samples to Mt. Sinai for ER/PR testing. Thus a list of all ER/PR breast cancer testing from Clarenville will be requested and added to the database.

Step 3:

Obtain a list of all patients diagnosed with breast cancer in the province using the Cancer Registry from May 1997 to August 2005. This cancer registry data will be mapped to patient data created from Step 2, and will be cross-checked to ensure no patients diagnosed with breast cancer are missed.

Step 4:

Obtain list of all breast cancer patients who had ER/PR testing/retesting carried out at Mt. Sinai for years 1997-2005. Map Mt. Sinai patient list to patient database created in Step 3; identify and resolve inconsistencies.

Step 5: Link database from Step 4 to the provincial mortality system in order to identify deceased patients.

Following completion of Step 5 the database will contain:

a) All patients that had ER/PR breast cancer testing carried out at Eastern Health from May 1997 to August 2005

b) All patients that had ER/PR breast cancer testing carried out Mt. Sinai from 1997-2005. Would include samples sent directly to Mt Sinai, bypassing Eastern Health.

c) All patients that had ER/PR breast cancer re-testing carried out at Mt. Sinai from May 1997 to August 2005

d) Patients that are deceased since 1997

e) Data for some core fields, in particular
   - Health Authority sample originated from
   - Source of original case data (e.g., Meditech)
   - Date that sample was obtained by Eastern Health
   - Date sample sent to Mount Sinai
   - Date that results returned from Mount Sinai

Of note, regardless of what option is chosen to develop the Patient List for ER/PR Testing, it will be necessary to identify how best to obtain a complete list of ER/PR testing/retesting conducted at Mount Sinai. It is understood that several lists of ER/PR testing/retesting already exist at Eastern Health, however one of these list has no dates included in the database, while a second has yet to be reviewed. It is possible a new list will need to be obtained from Mt. Sinai.

PHASE II: Data Specific to Communication Event Fields

In Phase II, additional data fields will be incorporated into the databases to reflect the requirements of Health and Community Services. For the purpose of this scoping document the term "communication event" field is used, and is considered a field in the database which

contains data for a specific event that occurred along the patients ER/PR testing time continuum. These would include:

- Date that sample was obtained by Eastern Health
- Date of phone call to patient to inform that sample was sent for re-testing
- Name of person who placed call
- Employer of person who placed call (i.e., Health Authority)
- Date sample results were reviewed by Tumor Panel
- Date that sample results and Tumor Panel review were sent to physician
- Date and means by which Eastern Health contacted patient about results
- Verification that doctor reviewed results with patient

In obtaining data for these event fields several steps, utilizing various data sources, will be investigated.

Step 1: All lab results on ER/PR testing will be reviewed to obtain dates that samples were obtained by Eastern Health.

Step 2: Information on dates of phone calls to patients (to inform that sample was sent for re-testing), name of person who placed call, Employer of person who placed call, will be gathered from documents provided by Eastern Health, as well as other Regional Health Authorities.

Step 3: All correspondences issued by the Tumor Panel will be reviewed to obtain information on dates sample results were reviewed, as well as dates that the results and review were sent to physicians responsible for patient's care (e.g. oncologist, surgeon, family physician).

Step 4. Utilized other data sources to support completion of database (e.g.,, MCP data)

The core field #12 "**Verification that doctor reviewed results with patient**" has been identified as one that may be difficult to obtain supporting documentation. In order to verify that physician

reviewed results with patient, it may be necessary to contact each physician and/or perform a chart audit.

Timelines:

Timelines are estimated based on available information. A major contributor to the length of time to complete the database will be the time required by the data holders in providing data to NLCHI.

PHASE I:	Patient List	PHASE II: Event Fields	Timeline for Each Option
Option A	0 Weeks	4-6 Weeks	4-6 Weeks
Option B	8-10 Weeks	4-6 Weeks	12-16 Weeks
Option C	4-6 Weeks	4-6 Weeks	8-12 Weeks

Costs

The budget to develop the database will be limited to any external costs incurred for: 1) Data from Mt. Sinai (if necessary), costs associated with review all ER/PR test results in Option B, (if necessary), and any costs associated with obtaining documentation for event field "Verification that doctor reviewed results with patient". Given these unknowns, It is not known at this time what, if any, costs will be incurred in securing relevant documentation.