

**DRAFT Note on Database Interpretation**  
**October 22, 2007**  
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**Purpose:**

The purpose of this note is to provide a basic explanation of the contents of the ER/PR database, and identify some of the variances from the data made available to the public (December 2006) and to the Department (August 1, 2007)

**Background**

On November 23, 2006 Eastern Health provided a briefing for the Minister of Health and Community Services entitled “ER/PR Case Analysis”. The data contained in this briefing is largely consistent with the data contained in the August 18, 2006 briefing note prepared by Cabinet Secretariat, and it formed the basis for Eastern Health’s media briefing on December 12, 2006. The data in the “Case Analysis” was highly consistent with the data which remained in the public domain from Eastern Health throughout the winter and spring of 2007. Therefore, the data in the Case Analysis is a good point of comparison for the data in the NLCHI Database.

The NLCHI database project was started in June 2007 at the request of the Department of Health and Community Services. This project was regarded by the Department as essential for objectively understanding the flow of events throughout the ER/PR re-testing process and the subsequent communication process with patients. The Database will be made available to Eastern Health and the Commission of Inquiry.

The NLCHI database is not a direct reflection of the Eastern Health spreadsheets, tally sheets and phone records. While these sources were obtained and used, they did not contain all the data that the Department had requested in its mandate to NLCHI. Therefore, NLCHI built from these and other sources a new database of all cases which were sent to Mount Sinai for re-testing. The inclusion criteria focused on cases where the original test was done between 2005 and August 2007. While the vast majority of cases had negative ER/PR results in the original test, some original positives were also sent to Mount Sinai and were included in both Eastern Health’s reported data and the NLCHI database. The NLCHI database is not a “cleaned up” version of Eastern Health’s spreadsheets; it is a new database that captures information on the same topic. Just as Eastern Health had tried to identify, re-test and contact every patient that had a negative result between 1997 and 2005, NLCHI built a database to include patients that matched Eastern Health’s target patients. Ideally, NLCHI’s results would be exactly the same as Eastern Health’s reported results because the underlying concepts were the same.

## Data

The key data included in the Eastern Health ER/PR Case Analysis was as follows:

- Total cases retested – 939
- Results obtained and reviewed – 763
- Patients who are deceased – 176<sup>1</sup>

Within the 763 “results obtained and reviewed” group, the following key data were provided in the Case Analysis:

- No change in results and subsequently no change in treatment – 433
- No change in results; requires change in treatment as definition of negative has changed – 13
- Change in results but does not require treatment change – 213
- Change in results and requires treatment change – 104

The work undertaken by NLCHI to produce a database for use by the Department does not match the Eastern Health results from November 23, 2006. Nor does it match the results which were contained in the spreadsheets provided by Eastern Health to NLCHI on August 1, 2007. For example, the total numbers of patients who were both tested in NL between 1997 and August 2005, and whose tissue samples were sent to Mount Sinai for re-testing, by source of data, are as follows:

1. November 23, 2006 Eastern Health “Case Analysis”	939
2. August 1, 2007 Eastern Health Datafile	924
3. October 22 NLCHI Database	993

It is not possible to reconstruct why the total changed between November 23, 2006 and August 1, 2007 because the Eastern Health data file was over-written with a series of adjustments and edits. There is no electronic or paper copy of the November 23, 2006 data file at the present time which would allow for case by case comparison. There is only summary data prepared for briefing notes and press releases.

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<sup>1</sup> Given that the last two lines add to 939, it would be natural to infer that the 763 results “obtained and reviewed” were equal to the number of patients still living. However, within the category of 176 deceased, there is a breakdown which states 101 of these patients were retested and results received. This means that 75 of the deceased patients were not initially retested. If correct, and we also take at face value the Eastern Health statement that 939 cases were re-tested, then there were some cases re-tested that were not reported on in the Case Analysis. In other words, by adding the 763 cases “obtained and reviewed” to the 101 deceased cases that were re-tested, the total is just 864 re-tests. If this arithmetic is right, there are 75 extra re-tested cases that were not reported. However, this does not seem likely. Another possible explanation is that 939 cases were not re-tested up to November 23, 2006; rather 939 cases were identified but only 864 cases were re-tested. This ambiguity needs to be examined further.

Similarly, it is not possible to explain why the NLCHI database varies from the November 23, 2006 “Case Analysis” because the case by case file for the earlier date no longer exists.

Analysis can be conducted on the difference between the August 1, 2007 data file and the NLCHI database, but such an analysis may not be completely relevant because the two dates are substantially later than the dates when the events occurred. Nevertheless, a case by case comparison can be undertaken. On this basis, the first difference of note is that the NLCHI total is 69 cases larger than the August 1, 2007 Eastern Health file. There are two general reasons that explain the difference:

1. some cases were found that had negative ER/PR tests between 1997 and 2005 but had not been sent for re-testing;<sup>2</sup> and
2. some cases had been sent to Mount Sinai for re-testing but were not included in the Eastern Health data file.<sup>3</sup>

Comparisons of the three sources above also reveal variances in subdivisions of the data. Using the subdivisions first made public by Eastern Health in December 2006, the following table provides a comparison:

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<sup>2</sup> NLCHI and the Department have informed Eastern Health about these cases and asked that they be tested and that patients be notified.

<sup>3</sup> NLCHI and the Department have also informed Eastern Health about this category. It is unclear from the analysis to date whether these patients were contacted by Eastern Health. It has been recommended that they be called.

Category	Sub-Category	Sub-sub-category	Nov 23 2006	Aug 1 2007	Oct 22 2007
Results Obtained and Reviewed	No Change in Results and Subsequently No Change in Treatment	Confirmed Negative	341	270	
		Confirmed Negative from Panel	28	N/D <sup>4</sup>	
		Confirmed Positive	12	18	
		DCIS	52	36	
		Sub-total	433	324	
	No change in results; requires change in treatment as definition of negative has changed		13	N/D	
	Change in results but does not require treatment change	No recommendation because they are low risk	60	52	
		No recommendation because they are previously treated with Tamoxifen or other aromatase inhibitor	148	150	
		No treatment because they required assessment prior to recommendations	5	7	
		[No recommendation – other]	n/a	5	
		Sub-total	213	214	
	Change in results and requires treatment change	Recommended for treatment with Tamoxifen or aromatase inhibitor	96	101	
		Original diagnosis revised	4	5	
		Originally had a degree of ER positivity but on retesting was negative	4	N/D	
		Sub-total	104	106	
	[Other]		n/a	20	
Deceased			176	184	
Total Retested			939	924	993

As noted above, it is not possible to explain all the variation in the data because a case-level data file for November 23 no longer exists. However, some observations can be made on the data as presented:

1. DCIS: it is unclear why Eastern Health reports any DCIS cases as “no change in results” because none of the original results for any of the cases sent to Mount Sinai were classified as DCIS.
2. Eastern Health used a different system than NLCHI for identifying which patients were deceased. Therefore, Eastern Health did not accurately identify the total number as of November 23, 2006 or August 1, 2007. A case by case comparison is only available for August 1, 2007 vs. October 22, 2007. The deceased variable in the latter database can be manipulated to show how many people were actually deceased as of August 1, 2007. On this basis, the actual number was xxx, or a difference of xx with the number reported by Eastern Health. If the order of magnitude difference also existed for the November 23, 2006 Case Analysis, the actual number of deceased at that time was about xxx.

<sup>4</sup> N/D = No data; n/a = not applicable