From: Pat Pilgrim
To: Heather Predham;
Subject: FW: Today
Date: February-20-08 9:10:31 AM
Attachments: Technical Briefing.ppt

Patricia Pilgrim
Chief Operating Officer
Cancer Care, Quality and Risk Management
Eastern Health
c/o Room 1345, Level I, Health Sciences Centre
Prince Philip Drive
St. John's, NL A1B 3V6

Telephone - 709-777-1306
Fax - 709-777-1347
E-mail - Pat.Pilgrim@easternhealth.ca

Eastern Health

From: Thompson, Robert [mailto:rthompson@gov.nl.ca]
Sent: Wednesday, February 20, 2008 9:03 AM
To: Pat Pilgrim
Subject: Today

Pat:

Received some feedback from Debbie on yesterday's meeting. Important that we receive further feedback from you today. Can we meet late morning? Will you have additional feedback then?

We also need to coordinate on the "deceased" messages and figure out how tomorrow will unfold. Therefore, perhaps we should include our com people so everyone is on same page. Does 12 noon sound good??

In the meantime, I am sending you the slide deck which would form the basis of the media technical briefing tomorrow. We also have a draft press release and backgrounder which I will send you in an

hour or so. And we have a backgrounder on lessons learned/budget initiatives which will be announced alongside, to be sent to you in an hour or so.

Lots of detail here.

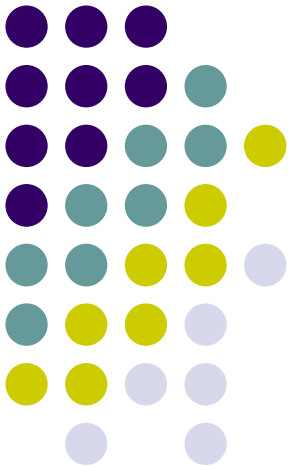
Please advise.

Robert

Technical Briefing
ER/PR Database

February 19, 2008

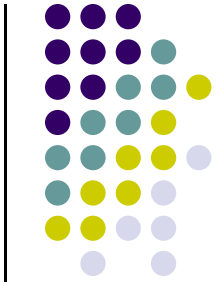
DRAFT



Background

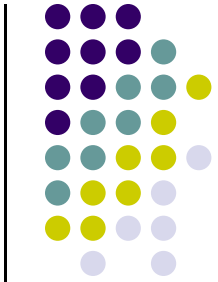
- June 2007 – questions asked about patient contact. Was it complete?
- Department asked NLCHI to prepare database on communications and clinical information. Eastern Health endorses and provides full cooperation.
- Additional value for work of Commission.
- July 2007 – work commences (2 full time staff)

Content and Methodology



- Content
  - Original scores/Mount Sinai scores
  - Dates of testing
  - Region/gender
  - Type of contact/Date of Contact
- Methodology
  - Data linked to source documents where available
  - Multiple sources cross-checked
  - All four RHAs involved
  - Cooperation was excellent

Database Limitations

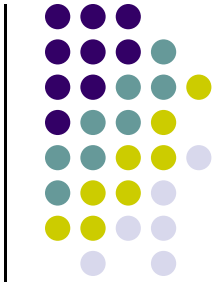


- Due to multiple RHAs and multiple information systems, not certain that every patient captured (though much higher degree of certainty than before).
- Some retests were done on different samples, thus may affect comparability
- The Eastern Health retest process was not a research project – it was patient care.

Number of Patients

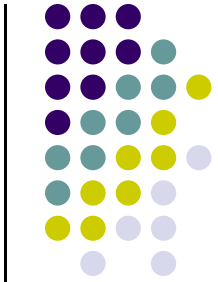
- 06-11-23 – Easter Health reported 939 patients were retested.
- 07-11-02 – Minister announces actual number about 1000.
- Result – 1013 people had original ER/PR tests and were rested at Mount Sinai.

Number of Negative ER Patients



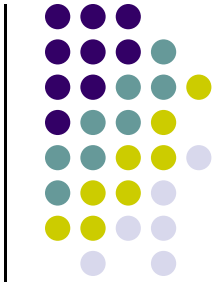
- 06-11-23 – Easter Health reports 12 people were confirmed positive, which means a total of 927 ER-negative patients were retested.
- Database confirms that 18 people were originally positive, which means the actual number of ER-negative patients retested at Mount Sinai was 995.

Number of Deceased ER-negative Patients



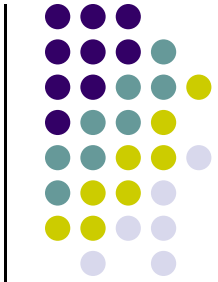
- 06-11-23 (and 07-05-17) Eastern Health reported 176 deceased out of the 939 patients sent to Mount Sinai.
- Did not use mortality database to identify deceased patients.
- Database includes 294 patients who were deceased on 06-11-23 (323 one year later)
- This issue is one of data; not patient care or treatment.

Contact with Families of Deceased



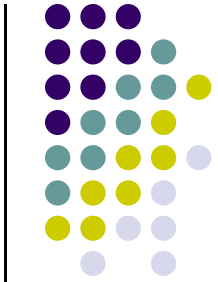
- Some families of deceased have already obtained results.
- In May 2007 Eastern committed to test all deceased and make results available.
- Will announce that data is now ready and provide contact information for families to identify themselves.
- This method is preferred over proactive contact given time elapsed and sensitivity of such information.

Total Tests at Eastern Health Positive and Negative



- As database focuses on ER-negative group, it was necessary to have the number of “total tests” in order to calculate positivity rates.
- This count was done by Eastern Health, monitored by NLCHI.
- Uncertainty about total for 1998.
- Small bias given inclusion of non-breast samples in total outside St. John’s.

Usage of ER and PR



- Separate tests, but always performed and reported together.
- Both indicate pathways for receptivity, but not equally. ER stronger.
- Oncologists use both in making treatment decisions (even ER-/PR+)
- Even though all ER-negative samples were retested, some were PR+ and may have been treated with tamoxifen originally. Raises question why these were retested.

Cutoff Points

- Clinical context:
  - 1997-2000: less than 30% staining is negative; greater than 30% is positive.
  - 2001-2005: less than 10% staining is negative; greater than 10% is positive
- Technical Context:
  - Any staining is positive (e.g., 1% or greater)

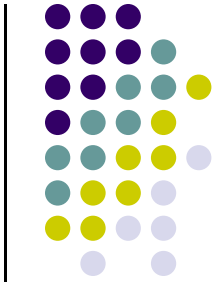
Expected Incidence of ER-/PR- and ER-/PR+

Year of Publication	ER-/PR- (%)	ER-/PR+ (%)
*Harvey et al (1999)	29.5%	
Rhodes et al (2000)	22.1	3.2
Anderson (2001)	18.6	3.4
Dako Manual **N.D.	15	4.0
Huang (2005)	17.3	1.6
Killeen (2006)	19.3	1.3
Francis et al (2006a)	17.4	2.5
Francis et al (2006b)	22.7	2.4
Collins et al (2008)	Any positivity 18.7 10% positivity 19.0	Any positivity 5.1 10% positivity 4.8

Incidence of ER-/PR- and ER-/PR+, 1997-2005 Average

Cutoff Point	Original		Retest	
	ER-/PR- % of Total Tests (HR Adjusted)	ER-/PR+ % of Total Tests (HR Adjusted)	ER-/PR- % of Total Tests (HR Adjusted)	ER-/PR+ % of Total Tests (HR Adjusted)
30/10	34.5	8.2	23.7	1.6
10	31.9	8.6	21.8	1.0
1	23.4	8.5	19.3	0.4

What is a Positivity Rate?

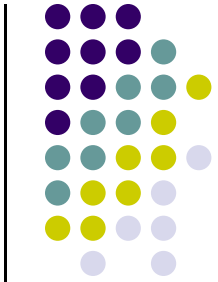


- Indicates the percentage of total tests which are hormone receptor positive, by cutoff point.
- If positivity is below a benchmark, or the expectations found in the literature, it may indicate the need for optimizing lab performance.

Expected Positivity Rate

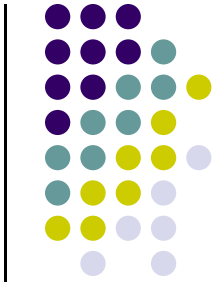
Year of Publication	ER Positivity rate	HR Positivity rate (excludes ER-PR-)
*Harvey et al (1999)	70.5%	---
Rhodes et al (2000)	74.6%	77.8%
Anderson (2001)	78.5%	81.9%
Dako Manual **N.D.	81.0%	85.0%
Huang (2005)	81.1%	82.7%
Killeen (2006)	79.3%	80.6%
Francis et al (2006a)	80.1%	82.6%
Francis et al (2006b)	74.9%	77.3%
Collins et al (2008)	Any positivity 76.2% 10% positivity 76.2%	Any positivity 81.3% 10% positivity 81%

Database "Original Positivity Rate", 1997-2005



Cutoff Point (%)	ER-	ER Positivity Rate	ER-/PR-	ER-/PR+	HR Positivity Rate
30/10	1089	57.0	871	207	65.5
10	1030	59.2	803	215	68.1
1	815	68.1	597	217	76.6

What is a Change Rate?



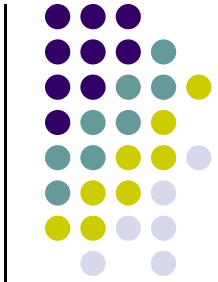
- The proportion of ER or HR negative tests that changed to positive after retesting
- E.g., false negatives

Expected Change Rate

Database Change Rate

Cutoff Points (%)	ER Negative Change Rate	ER-/PR- Change Rate	ER-/PR+ Change Rate
30/10	42.8	33.0	81.2
10	45.6	33.4	88.4
1	39.8	19.6	94.9

Contact with Patients

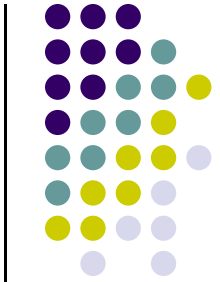


- Data was difficult to collect
- Actual contact process was dynamic, hectic, changing as results came in, and required coordination between four regions.

Method of Initial Contact with Patients

Method of communications	Total	
	No. of patients	%
Patient/Family initiated contact	46	4.5
Patient was contacted before results back	267	26
Patient was contacted after results were back	168	16.3
Patient was deceased before contact was made	233	22.7
Unable to contact	24	2.3
No Contact Made	53	5.2
Unsure if contact was made	9	0.9
Physician was informed by Health Authority of the results	10	1
Panel letter sent to the most responsible physicians*	145	14.1
Panel letter sent to the most responsible physicians also patient was contacted by physician*	26	2.5
Family of patient was contacted before results back	5	0.5
Family of patient was contacted after results back	2	0.2
Family of deceased was contacted	7	0.7
Direct consultation with Mount Sinai – Unable to confirm contact made	8	0.8
Other (outstanding information - require further clarifications)	4	0.4
Outstanding information	21	2
Total**	1028	100

Follow-up contact process



- Each RHA is being asked to verify non-contact. All non-contacts will be followed by with current contact to ensure completion.

Questions