

SLIDE 1:

May 11, 2005 - notified that a patient originally diagnosed in 2002 with an infiltrating lobular carcinoma and originally ER/PR negative (Dako semi-automated system, implemented in May, 1997) had recently converted following retesting on Ventana Automated System (implemented April, 2004). The retest was recommended following discussion between one of our oncologists and an American oncologist regarding the deteriorating course of the patient.

A request was made to retest four other patients with infiltrating lobular carcinoma, originally reported as ER/PR negative in 2002. All converted on retesting with the Ventana System.

SLIDE 2:

Following a meeting on May 17th, 2005, between Lab and Oncology, it was decided to retest a number of cases with emphasis on the 2002 year.

At the meeting, it was unknown whether we are dealing with a few isolated cases or symptomatic of a bigger issue. It was agreed that if there is a receptor conversion, the patient would be informed.

~~June 13, 2005 - Memo~~ June 13, 2005, Memo sent out to All Laboratories asking to submit all Negative ER & PR cases for the year 2002 for retesting with the Ventana System

SLIDE 3:

Testing completed on 25 cases (June 29, 2005). Case also included years 99, 00, 01, and 03. 12 had converted.

Additional testing on 32 cases (completed July 18, 2005). 25 had converted.

Total conversion rate of 65% (using 10% cut-off point). At this time 12 patients had been informed by Oncology.

Results of 11 cases sent up to Mount Sinai received July 29, 2005, 40% diagnosed 20% major

SLIDE 4:

Following a number of meetings with senior leadership team of Eastern Health, Laboratory Medicine, Surgery, Oncology, Quality Initiatives and Communications, as well as Medical Advisory Committee, a hold was put on the reporting of all ER & PR's on July 29, 2005 (Memo: August 8, 2005). The hold also applied to the Ventana Automated System, as a precautionary measure (concern over high positivity rate of Ventana of 89% from April 2004 to March 2005, as well as high conversion rate).

Corporate
Aug 5, 2005, arrangement made with Mount Sinai to repeat testing of the specimen
Memo: Aug 8, 2005, circulated to all pathologists within the Division of Anatomical Pathology, St. John's Hospital Not to report on ER & PR's,
Considerable discussion and debate over the issue of going public

SLIDE 5:

Decision made to retest all ER negative cases on primary breast lesions independent of PR status from May 1997 to August 8, 2005.

Cut off point of ER at 30% for cases from May 1992 to December 31, 2000, and 10% from January 1, 2001 onward. Memo circulated to all Lab Directors on June 13, 2005 and August 24, 2005 regarding this.

All retesting to be done in Mount Sinai.

Operational status of the Ventana System will not be determined until ER and PR results from Mount Sinai and Montreal General Lab, and review of medical and technical consultants.

SLIDE 6:

Positivity Rates for ER & PR (Total)

1997	1998	1999	2000	2001	2002	2003	Jan - March 2004
73%	75%	76%	62%	77%	68%	83%	88%

Ventana

April, 2004 - March, 2005
89%

7 year Average Positive	1997 - 2004 Dako	=	74%
7 year Average Negative	1997 - 2004 Dako	=	26%

Slide 5

~~Cases referred to~~

Review involved all ER Negative cases on primary breast lesions independent of PR status from May 1997 to Aug 8, 2005

~~Cases from~~

ER Negative defined as 30%^{or less} for cases from May 1992 to December 31, 2001, and 10% or less from January 1, 2001 onward independent of PR status

Slide 6

Aug 18, 2005 - first batch of cases sent off to Mount Sinai
Aug 24, 2005 - memo to all Lab directors requesting asking them to submit ER Negative cases for retesting
Oct 5, 2005 - first set of results arrive from Mount Sinai

Slide 7

- Mid October, 2005
- Tumor board set up to review impact of revised ~~patient~~ results on patients
- Board is composed of
 - 2 Oncologists
 - 2 Surgeons
 - 2 Pathologists
 - 1 Quality Improvement
 - 1 Secretary
- Story broke in local newspaper.

Slide 8 ..

~~During November~~
2005

Nov/Dec, Sharon's concerns expressed by Eastern ~~Health~~ Health over to Mount Sinai over the slow pace of results

Mount Sinai having capacity problems

Slow pace in specimens being referred in from peripheral hospitals

Slide 9:

~~Mount~~

Dec 20, 2005 - receive assurance from Mount Sinai that ~~all~~ all cases will be completed ^{and} by January 2006.

Last Batch of samples from a peripheral hospital arrives in St. John's Jan 25, 2006

Last of Mount Sinai results received Feb 14, 2006

Tumor Board Activities begin to wind ~~down~~ down May, 2006

Slide 4

Following a number of meetings with senior leadership team of Eastern Health, laboratory medicine, Surgery, oncology, Quality Improvement and Communications, as well as MAC, a hold was put on the reporting of all ER6PR's (memo: August 8, 2005). The hold also applied to the Ventana automated system as a precautionary measure. (Concern over high positivity rate of Ventana of 88% and ~~88%~~ from ~~March~~ April 2004 to March 2005 as well as high conversion rate)

Slide 5

Decision made to retest all ER Negative cases on primary breast lesions independent of PR status from May 1997 to ~~March 31, 2004~~ August 8, 2005.

Cut of point of ER at 30% for cases from May 1992 to Dec 31, 2000, and 10% from Jan 1, 2001 onward. Memo circulated to all Lab Directors on June 13, 2005 and August 24, 2005 regarding this.

All retesting to be done in Mount Sinai

Operational status of the Ventana System will not be determined until ER6PR results from Mount Sinai and ~~Mount~~ Montreal General Lab. and ~~Ontario~~ review of medical and technical consultants

Slide 6

Positivity Rates for ER6PR (Total)

1997	1998	1999	2000	2001	2002	2003	Jan-March 2004
73%	75%	76%	62%	77%	68%	83%	88%

10.

Ventana

April 104 - Mar 105

89%

7 year Average Positivity 1997-2004 Data = 74%

7 year Average Negativity 1997-2004 Data = 26%

Oct 12, 2005 Tumor Board Panel Created

- Created meetings on Aug 1

July 29, 2009 - hold put on LRP PR
Reporting

July 29 - 11 ~~cases~~ sent up

11 cases received from Mount Since July 29, 2005
40% disagreement, 20% ~~see~~ major
disagreement

→ Edmonton - Noted an occasional conversion
Winnipeg - 60-70% positive

Monte
Saint John

Vancouver
Mango → 80 to 85%
Sean Kelly → No info
May

- Met July 27
- met July 24

July 21
J

July 14 -

1st Batch submitted to Mount Sinai

Aug 18, 2005

Last batch submitted Jan 25, 2006

For First Sample Results arrived Oct 5, 2005

21 cases MSH

21

{ 4 cases of convert, one block sent up as part of review, second as a stat ~~or~~ or consult
ER PR
{ Column Built Mont first result 1-5% < 1
2E
second 2F 20% }

Oct 27, 2005. Nov 2, 2005

= 11 cases returned same block on different days

Variation anywhere.
ER anywhere.
5% → 40%.

(Variation in 5 cases)

PR variation
anywhere from 4%
up to 40%.

returned cases
26 or $\frac{13}{26}$

Variation in 13
or 50%
Variation

= 5 cases identified 2 blocks sent up and
stayed simultaneously

Variation in ER 13 to 20%

PR 10 to 35%

= 15 cases returned on same block, cleared in Oct and then
returned in Jan. ER variation Variation 8

ER 20% to 30% PR 20% to 40%

