Maurice Dalton Sept 28/05

- ER IPR -ve patients who may be false negatives
- Issue c̄ testing at HSC since 1997
  - processed in St. Johns (this is problem)
  - we would read whether positive or negative

Negative was < 30% - ~~up until~~
Since 2001 < 10% called negative
Across country negative is anything from 0-30%

HCCSJ changed process in 2004 with new system + since July/July 2007 everything St John's ER is sent outside province

I identified that had issue c̄ false negative + trying to get volume of problem.

- 40 mastectomy 1 yr. 30% will be positive ~10 negative.

∴ approximately 70 cases over this time

- ? minister going public soon

- We are sending all negatives as defined by HCCSJ to them which are then sending all of these specimens to mainland. At present suggest the false negative rate is 10-20% ∴ ~7-14 people potentially affected.

- Our % +ve/-ve has stayed within generally accepted reference levels.

- We will be compiling two lists c̄ specimens. of 1997-01 to send to
2002 to 2004. St Johns.

- They will be reviewing all c̄ outside lab as well as tracking patient outcomes. Will have outside laboratory - retest with todays standards

Susan Bonnell Oct 3/05

- Not doing a press release
- <10% of Breast Ca patients would be effected.
- when story broke on Friday was actually thought to mammography related.
- Dr Williams did NTV interview + is doing Telegram. - based on premise that retested one patient who was negative & became positive. This led to further testing
- Info: This has ~~to~~ be individualized because of various treatment options based on no. of factors.

- Media not interested in this story yet.

- Will post on website - ~~few~~ frequently asked questions along c̄ patient liason officer.

- 25% of patients who are negative will change + positive.

Lamy Gallagher	62	150	ER/PR Neg
Maurie Dalton	88		Alive
			Not treated

ER/PR Testing Oct 4/05

- Those who would be positive without any further testing based on changing criteria

- Those who were negative - 0-1% + may now be positive

- 70-80% breast cancer ER/PR positive but also present in normal breast tissue (
- Prior to 2001 need to be > 30% +ve for tamoxifen
- After 2001 > 1% positive
- most labs <1% negative to be considered negative

- Prior 1997 biochemical markers used
  1997 started immuno histochemistry c̄ Dako Semi-Automated System
  - 40 step process

May 2005 Dr Laing - discussed Sloan-Kettering - re: lobular cancer pt who was initially ER/PR Neg (0/0) + retested and found to be positive

- Mt Sinai — old certified Lab in London
  — 25-30% converting

  - Chief Tech - ~~from~~ Mt Sinai has reviewed procedures
  — Pathologist — Also visited
  - Big issue of quality
  - will recommend all slides be read by 2-3 pathologist in St. Johns.

142 specimens back. –

1998/8 < 30% –
2001
~~1997~~ - – cutoff < 10%

– All ER Negative | Independent of PR status
- Pt who were PR positive > 30% were treated

Need pathology assistants to prepare specimens
– Need dedicated lab staff doing this immunohistochemistry
- Regional issues – need to ensure collection / preparation done in a standard procedure across this province
– this would include standardizing formalin

– 60 slides to go out from St. Johns to Toronto from CWHC.

- Will get report through HCCSJ from Mt. Sinai

- 327 sent mid August / 142 reported
- good turn around times with new cases

- 360 – cases / yr. breast 135 – 97 – No out of town
147 – 98
360 – 99 386 – 2004
370 – 2000
374 – 2001
344 – 2002

4) Joy McCarthy Oct 6/07

- Always treated at 10% -
- Letter going out to every family Dr. in Nfld of what to do, from ~~No evidence~~ Paul Gardner.

- Medical oncologists will be available to talk c̄ GP or see patient but will not be immediate - may be within few months which is fine

- Support calling patients + advising them on list + will recall with results. With letter from Dr Gardner + accessibility of oncologists.

- Rx will vary from pt to patient depending on time from original diagnosis, node status at time of surgery, present status, etc.

- There is no change in Rx from 2001 ie 10% or more positive of ER/PR however this was both her and Kara's training. American training may have been different so treatment options not necessarily the same.

Robert Williams telephone call Oct 7 10 r

210 tests sent out so far + returned

41 conversions

- Letter from Dr Williams to GP's
Letter from Dr Gardiner to surgeons

HIROC - didn't want to disclose to patients until we have test results back.
This caused unnecessary worry in Bohrader last yr when pts contacted before results available

- will try to arrange teleconference with CEO's / HIROC to discuss.

Drugs used for Rx

Femara (Letrozole)
Lupron (Leuprolide)
Supprefact (Buserecin acetate)
Zoladex (Goserelin)
Tamoxifen
Arimidex (Anastrozole)
Aromasin (exemestane)

Breast Cancer Pt ER/PR patient Oct 11/05

Teleconference Oct 11/05
- Verbal + written correspondence
- No. of calls to their line (consumer feedback line) - consistent message (QI people are responsible for that line)

- decided not to respond individually - after discussion with oncologists.

- HIROC discussions - ongoing ~~regarding~~ ~~assum~~

George - Each region will identify a contact
- That group will decide re frequency of conference calls
- Use HCCSJ web site + consumer line as point of referral
- Will use global registry
- Need to look nationally at inconsistencies in ER/PR from pathology as well as oncology perspective.

at Pilgrim
~~777~~-1306

777-6500

Nov. 28/05 ERIPR

D/W [redacted] re: FU.

1) - Have no answer to my spreadsheet as to who on our list are actually being retested

2) - Need to know what will be happening with the conversion. my understanding is that a panel consisting of surgical oncologist, medical oncologist x 2 and pathologist will review w/A communication to FD &/or attending

3) Need to know if all patients being retested have been notified of this as my assumption is that ERIHA have taken ownership & would be making this contact.

4) [redacted] will confirm in writing what the process will be

Conference Call re ER/PR Dec 5/05

Heather Predhom, Terry Gulliver & Lorna

- Criteria - For retesting

prior to 2001 ER <30% considered Negative

whatever PR status.

After 2001 ER <10% considered Negative

whatever PR status

St Johns

143 - Central West that have been sent to Toronto

74 - Central East that have been sent to Toronto

- confirmed ~~that~~ we will match lists
- St. Johns will be contacting all pts being retested
- ~~EG cover~~ All will be recontacted once results come back.
- Will be reviewing all converters by panel Dr Joy McCarthy, Kara Laing, Cook, + Kwon.

Asked 2004/05 recently → done on new system.

Heather Predhom 777-6126

570-9703

ER/PR Dr Robert Williams Jan 29/06.

- Want us to notify patients that are negative - they will be provided. (

- being panelled - call

124 - results sent to Mt. Sinai + back 7770 6126

49 - to be panelled (Lamy review 570-9703

40 - Negative - we will

3 - panelled -

10 - (no results yet or ductal-in-situ)

22 - deceased

Heather -

~~71 - Gander~~

124 - 6 Falls

49 - to be panelled (Lamy review -

40 - Negative - (Lamy to call) -

3 panelled already

22 - deceased

10 - DCIS

71 - Gander

27 - panel

19 - Negative

3 - panelled already

20 - deceased

2 - ~~Gand~~ DCIS

1C

ERIPR - Feb 14/04

1 - No change - call with script
- notify FP c̄ script

2) - Panelled — by ERIHA ~~call with script~~
— notify FP c̄ script + surgeon. oncologist
— FIU c̄ physicians to ensure they have gotten letter + have told patient. (wait one month

3) Deceased — what to do.?

Heather Predham — OK with using ERIHA ~~our~~ script.
— Will send to us.

— If being panelled ERIHA will call

— Heather will send out list of all patients being panelled

— GFW - 53/57 being panelled are Ca Clinic Pts
- Gander - 29/31 being panelled are Ca Clinic Pts

IIROC — will talk c̄ Belky re calling

File

ER/PR Tests Teleconference March 17/06

1. – Heather Predham – Letter to ~~patients~~ physicians for patients being panelled – by Eastern Health

– some were brought to panelling group however ~~cannot~~ find were deferred based on not having

- Progress note
- full pathology report
- consult report on breast pathology
- current status

All negatives which are still negative we will be sent script by Eastern Health + we will call patients

Deceased will be reviewed + panel deceased converted patients

Teleconference - CEO's, medical Directors May 24/07
+ DOHCS - John Abbott, John Rumbolt, Mona Hennessey
Eastern Health - Dr. Howell, Dr Denic, Heather Peckham
Western - Terry Gulliver, Ken Jenkins, Paul Neal, RM communical
Labrador - Boyd, Dr Darkwa

Issue - All ER/PR Testing was presumed to be done in St. Johns since St. Johns restarted however apparently this is not the case. Outside St Johns, apparently all still being sent to Mt Sinai

(John Abbott)

Terry Gulliver - Only specimens being done in St Johns are those from St Johns
- rest are being sent to ~~by~~ Mt Sinai for ER/PR/HER-II (all Breast Cancer pt).
- 300 - 350 patients being diagnosed ~~by~~ each year in Nfld.

Nasi Denic - doing St Johns pts, trying to ensure quality assurance is in place & standards are met.
- Mt Sinai would like St Johns to take over ER/PR for all province + may have to send out for HER-II - as not up to standard yet with new antibodies.
- need to ensure with all regions that frozen process for preparation of sample is at same standard

across the province. Have drafted a recommendation for proper fixation on such tissue & ensure reproducability
- needs to be fixed c̄ in 8-24 hrs
- have package prepared for each region so that each region understands protocol & ensures that this will be followed.
- went through validation process for a year by working c̄ facilities in UK and USA to ensure standards ~~agree~~ met. By Feb 1/07 were OK with this & started processing their own samples again.
- Eastern Health are ready to take over ERIPR testing c̄ in next month & will send HER-2-new for all province to Mt. Sinai until their ~~testing~~ is validated. Also suggest that review all DCIS for province.
- Nash got into issue of remuneration of pathologists for taking on extra workload (screening breast Ca diagnostics for the province)

Terry - in past St John's would do preparation & then send back to region for interpretation. In future would suggest that we send ~~slides~~ specimens to St. John's after fixing for ER/PR preparation & would also be read in St. John's

(3)

Maurice Dalton - MD issue that we are aware of related to fixation

Nash Denic - Fixation was a problem at all sites after review

Larry - Why wasn't this identified before

Terry - If tissue was overfixed may cause issues c̄ antigen / antibody & there is new information (? what year) around this that will be shared. (This is part of quality improvement)

- technological advances have helped c̄ over/under fixation issues.

Nash - New studies have suggested that maybe fixation with new technologies is not as much an issue. We however have recommendations from world renowned pathologist in this area who suggest we need to improve fixating / processing

Oscar There is a standardization - with a package - around fixation that has come as part of quality improvement around this ~~issue~~ review.

(4)

Terry – When a pathologist who was responsible for this left, the reporting of the slides were decentralized
– wish to centralize ~~that~~ processing and interpretation again.

Oscar – Data analysis was not done on a regional basis.
– Other than fixation & subsequent reading all other processes were done at HCCSJ.
–

Paul I Nash – Dec. 2000 changed from 30% to 10% however 1-10% were called low expressors. In USA also 0% people were treating ~~at~~ 10%. Others may treat 1-10% depending on other factors.

= Technology has changed.
– What is positive has changed.
- There are process issues which we need to improve
– Issues around fixation – new studies

[redacted]

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