Reza Alaghehbandan

From: Terry Gulliver [Terry.Gulliver@easternhealth.ca]
Sent: Tuesday, July 24, 2007 11:42 AM
To: Reza Alaghehbandan
Subject: ER/PR CLINICAL CUTOFF POINTS

Reza,

As per your request here is a summary of the guidelines/process used from July 2005 onwards to select patients for possible retest at Mt. Sinai.

1. Barry Dyer and Myself complied by year every ER/PR test performed at the HSC Pathology Lab

2. We then reviewed each pathologist's report and created a manual spreadsheet for each year using the following criteria as decided by the Oncologist's. From 1997 – 2000 every patient that was negative/negative or 0%/0% to be logged on spreadsheet and all patients with staining 30% and less to also be logged. From 2001-2005 every patient that was negative/negative or 0%/0% and all patients with staining 10% or less to be logged. These were the clinical cutoff points provided by the oncologist's as patients with those levels of staining may not have received Tamoxifin.

3. Once Barry and I finished the spreadsheets we then reviewed with Dr. Cook (Laboratory Clinical Chief) to identify the patients that needed to then have their pathology blocks retrieved and sent to Mt. Sinai for retesting. Dr. Cook chose Mt. Sinai as they were still using DAKO reagents/equipment as we were during the period of 1997-2004. Also, Mt. Sinai is an accredited lab and also could handle this huge retesting task.

4. Any patients with staining that was close to the cut off points were then taken by Dr. Cook to the Oncologist to review patient to determine if the patient had already received Hormone therapy. (this was done pretty well a couple times per week for several months until all patients were reviewed and then sent for retesting)

5. After this review by Dr. Cook and Oncologist's Barry and I then cross referenced the retesting spreadsheets with a deceased list given by Heather Predham and removed them from the retesting. (It was decided that we needed to retest the living patients first as were doing all this work to see if we could improve treatment for living patients and we would retest the deceased patients at a later date)

6. We now had a final list of retest's for the St. John's patients. From this the Lab Technologists retrieved the original blocks and slides for each patient. These were reviewed by the pathologist's to ensure that the original testing block was acceptable for retesting. There were cases where it was determined to send a different block from the patient as there may have been very little or no tissue left in the original or a better block was available.

7. We then packed up all the blocks and sent to Mt. Sinai for retesting.

While Barry and I were doing all of this for the ST. John's patient's Dr. Cook had written all the other pathology labs in the province informing them that we were going to retest all the province that had test's performed at the HSC lab. In Dr. Cook's letter he outlined the guidelines used by St. John's to determine if a patient needed to be retested. He asked that the pathologist's/technologist's in each lab review all their ER/PR results and send to Barry Dyer and myself. We received "batches" of patient's and their original blocks/slides and control slides every week for a couple of months.

8. Each batch received by Barry and I we then made a retesting spreadsheet for the referring site (eg. Western Memorial) by year. This was exactly the same as we did for the St. John's patient's. This process of logging and documenting the "out of town" patients took until about the end of October

2005. Remember that Mt. Sinai by then had already received hundreds of blocks for retest and were starting to get result's back from the St. John's patients and still packing up out of town blocks and sending.

9. The out of town patient's were reviewed by the pathologist's from the referring site to determine the clinical cut off result's as provided by the Oncologist's. The blocks/slides were reviewed by our pathologist to ensure we had a good block for retesting. (We discovered after the out of town results started to come back that they did not review their patient list and remove patients that were deceased, hence the reason why we have about 175 deceased patients's retested)

10. Once result's started to come back they were reviewed by our pathologist's and then the new results from Mt Sinai were added to the patients original report in our LIS Meditech system and a new report generated with both the original and new results.

Barry and I had very little involvement after results came back .The pathologist's/oncologists/QI Department/Communications Department handles this phase of the process.

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