From: Heather Predham
To: Deborah Thomas-Pennell;
Subject: questions
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Attachments: Questions_ERPR1.doc

Hi,

Here's the latest...call me

Heather

ER/PR Questions

- When did the HCS Minister find out about the inaccurate cancer test results and what direction did he give to Eastern Health on how to handle this situation?

- Why weren't patients immediately notified that the samples were being retested and were forced to find out through the media? Would the minister not acknowledge that this has created anxiety for all patients who had been tested in the last number of years?

The decision whether or not to notify patients about the retesting of samples was very difficult to make and caused much debate within Eastern Health and HCS. Eastern Health has made the commitment to candid and timely disclosure to every patient any knowledge of an adverse event. However, a critical component of this situation was that this is still an ongoing investigation; until all the results from retesting are obtained; it is impossible to determine the scope and cause of the problem or the impact on the individuals.

It was always the intent to inform each individual and to disclose the information regarding the problem publicly when the retesting results were done. There was no ill intent in the delay, but it was felt that not being able to give the results or an accurate timeline as to when the results would be obtained would cause even greater anxiety in those affected.

- How many patients are affected? How many have been notified to date?

Province-wide, there are 835 individuals whose samples require retesting at present. Notification is still ongoing, but all individuals will be contacted and informed that their sample has been retested.

- Why is the notification process taking so long and when do you expect to have all testing completed?

Notification of results, once obtained, is very rapid. The results are reviewed internally and the notification route is determined. If the results are unchanged the patient is contacted directly. If their results have changed, a panel, consisting of oncologists, surgeons and pathologists reviews the patient's clinical information and forward recommendations to the attending physician.

Unfortunately, we anticipated that the results of the retesting would be completed by now. Mount Sinai has agreed to do this retesting in addition to their own workload. Timeliness of tests results is dependant on their resources.

- Has a review occurred to determine how this could have happened – how could there be inaccurate tests for a period of five years without being detected? Will there be disciplinary action taken?

This is still an ongoing investigation; until all the results from retesting are obtained; it is impossible to determine the exact details of the scope and cause of the problem. Three reviews have taken place; of our current testing procedure, our pathology services and our technical services. Recommendations have been made and are being acted upon which will immediately ensure the quality and reproducibility of results.

<u>These are details supplied by the lab:</u>
It was found there were problems with interpretation and quality of specimens used for interpretation. There was no Q.A. program in place being monitored by one individual. Too many individuals were involved without delegated responsibility and required individuals may be unfamiliar with standards required for interpretation.
Actions:
Implementation of a subspecialty sign out, so only a few individuals will be responsible for overseeing the performance and interpretation and will also allow for individuals to maintain expertise in subspecialty area.
CME will be provided for interpretation.
Labs will undergo accreditation

- Has any legal action been taken toward Eastern Health for how this situation has been handled?

As of this date, there has been no legal action taken against Eastern Health

- Can the Minister ensure the public that this is not reflective of other unreliable methods of testing in the province. Is our health system safe?

All laboratories across the province This incident has raised the awareness within Eastern Health of the need of focused resources for the Immunohistochemistry service for dedicated subspecialty sign out of pathology cases. Also dedicated technologists to be assigned to performance of highly specialized tests. We are now also subscribing to external proficiency testing.