Anderson, Mike S

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To: Tansy Mundon
Cc: Susan Bonnell
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As requested, Tansy.

Deborah ☺

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"In a perfect world, every dog would have a home and every home would have a dog."

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?

The minister was informed in early July as soon as Eastern Health became aware that this was not an isolated issue. He reaffirmed Eastern Health's decision to retest all of the samples in the best interests of patients. The minister has been updated regularly on this issue.

- 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 to defer advising affected patients until the results of the retesting was available was made by a team including medical oncologists, surgeons, pathologists and administrative staff. The advice that swayed the decision was that it would cause excessive anxiety on patients, while waiting for the latest results, recognizing that they were already under a great deal of stress.

It was recognized that there would be differing views regarding this decision however it was felt that this approach was putting the patient's interest in the forefront.

It was regrettable that many patients found out through the media. When this happened and recognizing the sensitivity of this issue, Eastern Health set up a process to make a personal contact with each patient, respond to all media inquiries and place a full page ad in the print media.

- 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?

Eastern Health decided to use an independent laboratory, Mount Sinai, to retest the samples. Mount Sinai is considered to have one of the best laboratories in the country. Unfortunately, we anticipated that the process of obtaining test results would be faster. However, Mount Sinai has agreed to do this retesting in addition to their own workload and the timeliness of the tests results is dependant on their capacity. Officials from Eastern Health are in contact with those at Mount Sinai on

a regular basis and recently learned that they are acquiring more technology which will allow for greater capacity.

Notification of results, once obtained, is 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 forwards clinical follow up recommendations to the attending physician, who then notifies the patient.

- 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 into this situation however there is amble literature to suggest that these tests have limitations and are not guided by national standards. In the meantime until all the results from retesting are obtained it is impossible to determine the exact details of the 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.

With respect to disciplinary action, to date there is no evidence of a deliberate break down of procedures on any person's part. Furthermore the current focus of the Canadian patient safety movement is to create work environments where mistakes are acknowledged to promote disclosure and follow up as quickly as possible. To that end disciplinary action is discouraged.

- 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?

Eastern Health responds successfully to the needs of thousands of patients in any one year. Furthermore, it has quality monitoring programs in place and has highly qualified professional on staff. While regrettable, the fact that this situation was identified in the first place is reflective of the importance of quality in the organization. I am confident that this is not reflective of the services provided.

Across the country, laboratories are looking at their testing procedures in light of the findings in Newfoundland and Labrador. Eastern Health has shared it's learnings with other centres and has asked the Association of Canadian Pathologists to investigate the need to develop national standards for this testing process. .