 BN0433

Question and Answer Briefing Note
Department of Health and Community Services

Title: Commission of Inquiry on Hormone Receptor Testing

Issue: Current status and key issues related to the Commission of Inquiry.

Anticipated Questions:

1. Do the problems with ER/PR testing point to a larger problem with the health system related to over-sized health authorities and a lack of quality control?
2. Will the Commission be mandated to examine what happened to each patient, as the Minister indicated at his press conference on February 22, 2008?
3. Why didn't government tell Eastern Health to release the two "peer" reviews rather than force the Commission to take Eastern Health to court?
4. What is the number of deceased patients that had faulty tests?
5. Why didn't government force Eastern Health to disclose the number of faulty tests and the number of deceased back in December 2006, before it disclosed these same numbers in a court affidavit?
6. Why did the number of deceased increase from 176 to 322?
7. Would patient outcomes have been better if patients who needed hormonal therapy (like tamoxifen) were treated at the right time?

Key Messages

1. Government created the Commission of Inquiry find out: a) what went wrong with ER/PR testing between 1997 and 2005, b) were all retested patients contacted, c) did officials respond in an appropriate and timely manner, and d) is ER/PR testing today consistent with best practice? The Commission can look at the actions of health authorities as well as government.
2. The problems in the laboratory with ER/PR testing cannot be linked to the re-organization of the regional health authorities. In fact, the laboratory problems occurred before (and were corrected after) the number of authorities was reduced to four.
3. Based on the two quality reviews that were done in 2005, quality control was an issue in the ER/PR laboratory. These issues have since been addressed by Eastern Health, and a new review in December 2007 states that high quality ER/PR testing is occurring. These issues will also be examined by the Commission.
4. The Commission has not been mandated to examine what went wrong with each patient. The Commission's mandate is limited to the questions noted above. The Class Action suit will examine issues at the class and individual level.
5. On February 22, 2008, government announced a new investment of $2.3 million to continue the improvement process in data management and quality control. (details below).

The Province, Eastern Health, Central, Western and Lab–Grenfell Regional Health Authorities, certain doctors at the HSC, the class action, and the Canadian Cancer Society (NL. chapter) all received standing for parts I and II of the Inquiry. HIROC (Eastern Health's insurer), and the NL. Medical Association only received standing for part II of the Inquiry which will focus on legal, ethical and policy issues around disclosure.

Eastern Health filed its defence to the class action on 17 November 2007. The class action was certified earlier in May 2007. The parties now have until 31 May 2008 to commence third party actions without leave of the Court. It is unlikely that there will be any significant developments in this case until the Inquiry concludes.

On February 22, 2008 the Minister of HCS announced $2.3 million to be spent as follows:

- To enhance data management, $2.1 million will be invested for the consolidation of clinical information systems within Eastern Health, a plan for consolidation of similar systems in other regional health authorities, a needs assessment for electronic document tracking systems for each health authority, and funding for five new data management professionals throughout the system. These investments will help improve response times and completeness of data when searching for patient information in the future, and ensure that more tools are available when managing a response to an adverse event.
- $100,000 for planning for a mandatory laboratory accreditation system.
- $175,000 per year for Eastern Health to follow through on education, training and quality assurance activities related to ER/PR testing. In particular, this funding will allow for pathologists and technologists to participate in relevant training programs each year, and allow for external reviewers to visit the Eastern Health laboratory to assess current practice against best practices elsewhere.

Justice Dymond's 14 February 2008 decision in *Eastern Health v. Commission of Inquiry concludes* that external reviews conducted for Eastern Health in 2005 of its Immunohistochemical lab are not protected from disclosure by the *Evidence Act* or the Common Law. Although Eastern Health had previously released these reviews to the Commission of Inquiry on Hormone Receptor Testing, (the Commission), Eastern Health argued in Supreme Court on 23-24 and 28-29 January 2008, that the Commission could not disclose the reviews, or question witnesses respecting the reviews. The Province did not take part in the Application.

The Task Force of Adverse Events was appointed to examine the broader issue of how health authorities respond to adverse events once they are identified. The Task Force will invite written public submission, work with health authority officials, and hold a symposium, prior to completing its report. The report is expected by June 30, 2008.

On February 22, 2008, Eastern Health announced that family members of deceased patients who had ER/PR tests reexamined at Mount Sinai can obtain the results for their deceased by contacting the Provincial Cancer Care Program of Eastern Health.

6. Government did not tell Eastern Health to release the two "peer' reviews because both Eastern Health and the Commission had legal issues that required resolution by a court. In particular, Eastern Health asserted that these documents were peer review protected under the *Evidence Act*.
7. On March 18, 2008, the Minister released the following data: "Of the 1,013 patients whose results were sent for re-testing, 322 are deceased and 691 are living; this information was provided in the last (February 22) update. Additional analysis shows that the number of deceased patients whose test results changed is 108, and the number of living patients whose results changed is 275." (The total number of testing errors is not the same thing as the number of people who would have benefited from tamoxifen, and NLCHI does not have data on the number of people who would have benefited from changed treatment.)
8. The Commission will examine the actions of government and whether it should have disclosed the number of faulty tests and the number of deceased back in December 2006. The public view of Minister Wiseman is that this information should have been disclosed at the time. We look forward to learning from the Commission's findings.
9. The 176 deceased was made public by Eastern Health in May 2007 based on data compiled in mid-2006. Therefore, part of the reason for the higher number of 322 deceased in November 2007 was the passage of time, but even more important was that Eastern Health did not cross-reference its records with the Provincial Mortality Database to determine which of their patients were deceased. It was a data management problem.
10. While there is clear evidence that treatment with Tamoxifen can improve life expectancy for many breast cancer patients, the decision to prescribe Tamoxifen to an individual patient depends upon many factors in addition to the ER/PR test. The benefit, if any, to a particular individual will depend on the stage of their cancer and other individual characteristics.
11. It is essential to remember that a changed ER/PR test result does not necessarily mean that appropriate cancer treatment was delayed, as physicians tell us that this test is one factor among many that help determine course of treatment. Nor do these numbers indicate that there is a relationship between an inaccurate ER/PR test and progression of the disease or death.

Background

The Commission was created in May 2007. The public hearings will start on March 19, 2008 and will last for 16 weeks. This will be followed by a two week period to prepare and present closing submissions. Commissioner Cameron has notified the Minister of Justice that she will be seeking an extension to the July 31, 2008 report date, but has not yet specified by how long.

Prepared by: R. Thompson; R. Pritchard **Approved by:**

Date: March 18, 2008

Reviewed by: _____ **on** _____
Deputy Minister **Date**

Given to Minister by: Pam Bennett **on** Mar 28/08
(Signature) **Date**

Reviewed by: _____ **on** March 28/08
Minister **Date**