From: Moira Hennessey
To: Abbott, John; Barnes, Sandra; Burrage, Don; Cheeseman, Josephine; Mundon, Tansy ; Stone, Karen; Thompson, Robert
Date: Fri, May 18, 2007 5:39 PM
Subject: Re: New Draft

Robert,

I have reviewed the attached and it reflects our discussion this afternoon. I have one comment-the issue should reference ER/PR testing as I don't believe the intent is to broaden the review beyond this specific testing.

A couple of minor edits-the last two items should be followed by a period.

Moira

[redacted]

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>>> Robert Thompson 18/05/2007 4:41 pm >>>
New draft. Please advise if there are any corrections needed. It was hard to blend the other questions here, but this draft allows for the full scope of the other questions to be addressed.

Moira, please pass on to Ed.

Robert

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DRAFT

Title: Options to Conduct a Review

Issue: What options are available should Government wish to commission a review of the Testing for Breast Cancer System in Eastern Health?

There are four options for consideration, two legislated and two non-legislated:

Legislated:

A legislated review would be authorized by the Lieutenant Governor in Council (LGIC) under the Public Inquiries Act, 2006. This Act provides two methods for undertaking a legislated review:

1. Commission of Inquiry: This is triggered by a "matter of public concern"

    a. Established by the LGIC: appoints the Commissioner(s), sets the Terms of Reference for the inquiry and authorizes the budget (which would be significant).
    b. The Commission can compel evidence
    c. The Commission then essentially runs itself, deciding who will participate, how it will receive information, etc.
    d. The Commission reports to the Minister designated by the LGIC to receive the report.
    e. Report must be released publicly.

2. A "Part II" Inquiry: This is also triggered by a matter of public concern. It is essentially the same as a Commission of Inquiry, except that the LGIC defines the procedures for the conduct of the inquiry, including whether it can compel evidence.

Justice advises that the Fatalities Investigation Act also provides for an inquiry under section 25 of that Act (see below); however Justice is of the view that this is not appropriate for the current circumstance:

Where the Chief Medical Examiner is of the view that it is necessary for the protection of the public interest or in the interest of public safety that an inquiry be held regarding one or more deaths that occurred under a circumstance referred to in section 5, 6, 7 or 8, he or she may recommend to the minister that a public inquiry be held.

Non-Legislated:

Non-legislated reviews could take two forms.

1. Independent Review conducted by an expert(s) or eminent person(s)

    a. Established by the LGIC, including appointment of experts
    b. No power to compel evidence
    c. LGIC would decide whether to publicly release report
    d. Budget could be expected to be substantial

2. Consultant Review:

    a. Authorized through LGIC following a proposal call for professional services

b. No power to compel evidence
c. LGIC would decide whether to publicly release report
d. Budget could be moderate

Questions that could be posed in a terms of reference for a review:

Whatever form the review may take, a core set of questions must be defined for the terms of reference.

Systemic Review

1. What went wrong with the estrogen and progesterone testing that resulted in a high rate of errors?

2. Why was the problem not detected until 2005?

3. Once detected, were appropriate, effective and timely actions implemented to ensure the best possible treatment for people who needed re-tests and for people who were being tested for the first time?

4. Once detected, did the responsible authorities communicate in an appropriate and timely manner with all categories of people who needed re-tests?

5. Once detected, did the responsible authorities communicate in an appropriate and timely manner with the general public about the issues and circumstances surrounding the testing errors and the new testing procedures?

6. Are the testing systems and processes currently in place reflective of "best practice"?

7. Does Eastern Health currently employ an effective quality assurance system to provide maximum probability that the testing problems will not reoccur?

8. Provide recommendations as necessary and appropriate to address the aforementioned issues and provide a system in which testing errors will not reoccur.

Clinical Review - Part One

(Note: It is recognized that the following questions will require the use of probabilistic estimates based on existing medical research and standards.)

9. Given that people certain people who would have required re-testing died before the errors were detected, can it be determined whether, and to what extent, accurate testing would have resulted in treatment that would have prolonged their lives?

10. Given that certain people required new treatment protocols after re-testing, can it be determined whether, and to what extent, the delay in appropriate treatment has had a negative effect on the quality of their lives and their life expectancy?

Clinical review - Part Two

(Note: The following question will only be addressed by the Review only if the answers to questions 9 and 10 are affirmative with a reasonable degree of confidence.)

11. Given that people certain people who would have required re-testing died before the errors were detected, determine whether, and to what extent, accurate testing would have resulted in treatment that would have prolonged their lives?

10. Given that certain people required new treatment protocols after re-testing, determine whether, and to what extent, the delay in appropriate treatment has had a negative effect on the quality of their lives and their life expectancy?