



**Commission of Inquiry on
Hormone Receptor Testing
The Honourable Madam Justice Margaret A. Cameron, Commissioner**

**Submissions to the Commission of Inquiry on
Hormone Receptor Testing by the
Newfoundland and Labrador Medical Association**

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Summary

The following is a summary of the submissions of the Newfoundland and Labrador Medical Association (“NLMA”) directed to fulfilling the mandate of the Inquiry.

1. Establish a permanent and independent provincial body modeled on the Saskatchewan Health Quality Council to set standards, and assess and report on the quality of medical care performance in an effort to build a better health care system.
2. Within a Health Quality Council (as referred to in Submission Summary #1) establish a formal oversight process to identify and address risk associated with adverse working conditions and concomitant human factors impacting on physicians, including the development of programs to assist with stress, fatigue and burnout.
3. Adopt Canadian Patient Safety Institute (CPSI) Guidelines for patient disclosure through formal documentation within health authority by-laws and policies, with explicit requirements for individual administrators and professionals.
4. Incorporate the CPSI Root Cause Analysis (RCA) as the protocol for health authorities’ investigation of adverse events to improve quality care and patient safety.
5. Establish a Provincial Register to track all RCA findings and recommendations, and produce annual reports with an emphasis on remedial measures for improving the system and monitoring progress.
6. Delegate institutional oversight responsibility for specialty-specific medical quality assurance and patient safety to Clinical Chiefs with clear delineation of roles, responsibilities and dedicated time requirements.

7. Implement protocols to ensure health authorities respond to advice of medical professionals on matters of safety and quality, in accordance with pre-determined criteria. Physicians must be allowed to speak out publicly without fear of intimidation in the event that health authorities fail to follow these protocols.
8. In consultation with representatives of the province's College of Physicians and Surgeons, Medical Association and appropriate external experts, assess the current peer review arrangements to ensure adequate frequency and scope of assessment for all physicians in the province. The peer review process must be educational, not punitive.
9. In conjunction with the expansion to the professional revalidation regime currently under consideration by the College of Physicians and Surgeons, provide adequate resources and support for physicians to be able to meet new compulsory requirements for continuing medical education (CME).
10. Review the current medical school curriculum to determine adequacy of content with respect to patient disclosure, safety and quality assurance practices, and address identified deficiencies.
11. Conduct a comprehensive assessment of the scope and quality of medical information currently available in the province's database(s) to support timely planning and management of services. Determine how efficient and effective the processes are for collecting, storing, organizing and retrieving information in a usable and relevant fashion for effective control and decision-making, and remedy identified deficiencies.

12. Develop and execute a plan to implement a province-wide Electronic Medical Record (EMR) system within the next three years.
13. Put in place the necessary systems to ensure that the results and reports of all diagnostic and treatment services referred to by general practitioners/family physicians to health authority institutions are transmitted back to the referring physicians in a timely and complete fashion so that patients can be safely managed.
14. Recruit professionally-trained industrial engineers to streamline workflow, scheduling and operations of labs, diagnostic facilities and operating rooms to improve efficiency, timeliness and cost-effectiveness.

Background

The Commission of Inquiry on Hormone Receptor Testing was established by order in Council in July of 2007 with the following mandate:

- (a) inquire into why the estrogen and progesterone hormone receptor tests done between 1997 and 2005 in the Newfoundland and Labrador health system resulted in a high rate of conversions when re-tested;
- (b) inquire into why the problem with the estrogen and progesterone hormone receptor tests were not detected until 2005, whether it could have been detected at an earlier date, and whether testing protocols during that period between 1997 and 2005 were reasonable for the first time;

- (c) inquire into whether, once detected, the responsible authorities responded and communicated in a timely manner to those women and men who needed re-tests and those who were being tested for the first time;
- (d) inquiry into whether, once detected, the responsible authorities communicated in an appropriate and timely manner with the general public and internally within the health system about the issues and circumstances surrounding the change in test results and the new testing procedures;
- (e) advise whether the estrogen and progesterone hormone receptor testing systems and processes and quality assurance systems currently in place are reflective of the “best practice”; and
- (f) make the recommendations that the commission of inquiry considers necessary and advisable relating directly to the matters of public concern referred to in paragraphs (a) to (e).

Analysis

1. During the testimony and evidence placed before the Commission of Inquiry on Hormone Receptor Testing (hereinafter referred to as the “Commission”), it became apparent that the heritage authorities responsible for the delivery of health care within the Province of Newfoundland and Labrador in the eastern part of the Province were amalgamated to establish the entity now known as Eastern Health. The management of Eastern Health became preoccupied with the organizational and operational challenges attendant on the reorganization and amalgamation.

2. Throughout the testimony at the hearings held by the Commission, it is evident that one of the shortcomings which lead to the errors in estrogen and progesterone testing came about as a result of the lack of standards required for the performance of this type of test. The NLMA requests that the Commission include as a recommendation in its report to the Government of Newfoundland and Labrador that it:

- Establish a permanent and independent provincial body modeled on the Saskatchewan Health Quality Council to set standards, and assess and report on the quality of medical care performance in an effort to build a better health care system.

3. Human factors are crucial to performance in the rendering of medical care, Consequently, it is crucial that working conditions are organized in a way that reduces risk of error due to human factors. A vital component of any effort to reduce risk due to human error is to monitor the working environment on a regular basis and to maintain standards and practices that make it easy to get things right and difficult to make mistakes. As evidence throughout the hearings indicated, adverse working conditions, stress and fatigue are factors that need to be addressed. It is therefore submitted that:

- Within a Health Quality Council (as referred to in Submission Summary #1) there should be established a formal oversight group to identify and address risk associated with adverse working conditions and concomitant human factors, including the development of programs to assist physicians with stress, fatigue and burnout.

4. The Canadian Patient Safety Institute (CPSI) is a nationally and internationally recognized centre of excellence on medical safety and related issues. The CPSI has established “best practice” guidelines for patient disclosure with explicit requirements for health authorities and those working under their auspices

5. One of the glaring shortcomings expressed throughout the hearings during the testimony of professionals and other health care workers of all levels was the absence of clear direction. This resulted in the inability of these individuals to cope with the peculiar requirements for disclosure to patients of what had taken place in respect of the ER and PR testing errors and, indeed, disclosure of the very fact that retesting of tissue samples taken from the patients was being carried out. It is therefore submitted that the report of this Commission should recommend that the health care authorities in Newfoundland and Labrador:
 - Adopt Canadian Patient Safety Institute (CPSI) Guidelines for patient disclosure through formal documentation within the health authority by-laws and policies, with explicit requirements for individual administrators and professionals

6. As a necessary adjunct to quality control and quality assurance initiatives, CPSI Root Cause Analysis (RCA) is a proven useful tool that should be used in the investigation of adverse events which may occur within the health care system. The RCA method of investigation is widely acknowledged within the health sector to be a highly thorough and constructive means of identifying and correcting deficiencies leading to overall system improvement. The NLMA submits that the Commission recommend that health care authorities:

- Incorporate the CPSI Root Cause Analysis (RCA) as the protocol for health authorities' investigation of adverse events to improve quality care and patient safety.
7. RCA investigations are conducted to identify causes of adverse events and to put in place corrective measures to prevent recurrence. The systematic public recording of RCA findings and recommendations is a necessary means to monitor the extent to which corrective measures are taken and progress is being made over time. This must be done in a transparent manner to restore public trust and confidence in the health care system. It is submitted that the Commission in its recommendations should ask the Government to
- Establish a Provincial Registry to track all RCA findings and recommendations, and produce annual reports with an emphasis on remedial measures for improving the system and monitoring progress.
8. Quality assurance initiatives at Eastern Health during critical times was the responsibility of managers at a senior level in the organization. It was apparent that in many cases these managers were unaware of what was taking place in specific health care delivery programs. It is therefore important that the responsibility and commensurate authority be delegated to those best qualified to oversee and ensure quality assurance and patient safety on a specialty-specific basis, namely clinical chiefs. The Commission should include as part of its recommendations to Government that the Health Authority:
- Delegate institutional oversight responsibility for specialty-specific medical quality assurance and patient safety to Clinical Chiefs with clear delineation of roles, responsibilities and dedicated time requirements.

9. Physicians are the most highly educated and technically trained professionals within the health care setting. They are best qualified to detect the many subtle and intricate procedural and technical risks above and beyond the scope of others. Early detection and prompt response is vital in preventing adverse events and minimizing negative repercussions. It is important, therefore, that doctors not only be involved in the front line delivery of health care – patient contact, but that they have unfettered opportunity to express concern in instances of preventable risk and seek reassurance that appropriate measures are applied. On numerous occasions throughout the testimony before the Commission, it was apparent that highly skilled physicians were working in silos and isolated from other critical components of a system which in the end failed to deliver the quality that is necessary. Physicians, as patient advocates, must be allowed to speak out when they see errors committed or potential hazards that jeopardize patient care. The Commission should therefore recommend that Government and Health Care Authorities:

- Implement protocols to ensure health authorities respond to advice of medical professionals on matters of safety and quality, in accordance with pre-determined criteria. Physicians must be allowed to speak out publicly without fear of intimidation in the event that health authorities fail to address legitimate concerns on a timely and complete basis.

10. The value of the peer review process, its benefits and shortcomings were frequently the subject of discussion by all parties throughout the Commission’s inquiry process. While the legal privilege associated with the peer review process has already been put in place, there is now a need to re-evaluate the mechanisms both inside and outside the health care

system to ensure that the peer review process is educational, non-punitive and, most importantly, works to the benefit of improving patient care and safety.

The groups best equipped to evaluate the efficiencies of this mechanism is the College of Physicians and Surgeons and the Medical Association. This Commission therefore ought to recommend that:

- In consultation with representatives of the province's College of Physicians and Surgeons, Medical Association and appropriate external experts, assess the current peer review arrangements to ensure adequate frequency and scope of assessment for all physicians in the province. The peer review process must be educational, not punitive.

11. The frontiers of science (including medicine) are constantly being pushed back. It was evident throughout the hearings that improvements on fronts such as ER and PR testing were being made in various parts of the world, best practices established and standards set in some settings and not others. In this environment, continuing education of physicians is absolutely critical to the best quality patient care. This Commission should therefore recommend that:

- In conjunction with the expansion of the professional revalidation regime currently under consideration by the College of Physicians and Surgeons, that Government and health care authorities provide adequate resources and support for physicians to be able to meet new compulsory requirements for continuing medical education (CME).

12. Education on matters of patient disclosure, safety and quality assurance practices cannot begin too early. This is not merely an adjunct to formal medical education and training for physicians; it is an imperative for improving and maintaining an improved system that best ensures patient care. This training should be part of formal education in medical school. This Commission should recommend that Government, in conjunction with the Medical School at Memorial University of Newfoundland should:

- Review the current medical school curriculum to determine adequacy of content with respect to patient disclosure, safety and quality assurance practices, and address identified deficiencies.

13. The problems associated with the lack of information gathering at the point when the information is first created and patient contact first made, as well as the subsequent handling, storage and use of that information was readily apparent throughout the inquiry proceedings. No where was this shown to be more inadequate than at the point when patients had to be notified that retesting was taking place or that treatment options had changed. The NLMA therefore requests that the Commission include in its recommendations that Government ensure that the Health Authorities:

- Conduct a comprehensive assessment of the scope and quality of medical information currently available in the province's database(s) to support timely planning and management of services. Determine how efficient and effective the processes are for collecting, storing, organizing and retrieving information in a usable and relevant fashion for effective control and decision-making, and remedy identified deficiencies.

- Develop and execute a plan to implement a province-wide Electronic Medical Record (EMR) system within the next three years.

14. It has long been recognized that the organization of workflow, particularly the scheduling of repetitive operations, can be the subject of expertise. Industrial engineers and planners who have become conversant with the concepts, issues and challenges of the scheduling of repetitive operations and procedures can be of great benefit in the hospital setting. This is particularly so in the operation of laboratories, diagnostic facilities and even the scheduling of operating rooms for the performance of surgical procedures.

The Commission should include as part of its recommendations in the fulfillment of its mandate that hospitals:

- Recruit professionally-trained industrial engineers to streamline workflow, scheduling and operations of labs, diagnostic facilities and operating rooms to improve efficiency, timeliness and cost-effectiveness.

15. The mandate of the Commission is quite specific and focused on the problems with hormone receptor testing and retesting. However, it cannot be overemphasized that the shortcomings and problems in the pathology laboratories were not unique. Chronic under funding, challenges in program delivery including quality control, risk management as well as poor information systems combine with physician stress and burnout are equally applicable to other disciplines in the health care system. As was stated by Mr. Robert Ritter in his testimony before the Commission, the problems with ER/PR testing are not a tempest in a teapot but are the tip of the iceberg and should act as a warning for other parts of our health care system. All of the recommendations made by the Commission to

the Government of Newfoundland and Labrador should include the caveat that the causes and contributing factors to errors in the pathology laboratories and the resulting effect on patients have a valid application to other parts of the health care system. A failure to heed these warnings and to learn from errors in the ER/PR testing program would only serve to invite further problems of equal or greater magnitude.

All of which is submitted on behalf of the NLMA.

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