

Shaping policy: the Canadian Cancer Society and the Hormone Receptor Testing Inquiry

M. Mathews PhD,[*] *J. Newbury LLB,*[†] *and E. M. Housser MSc*[‡]

ABSTRACT

Background

In 2007, the Government of Newfoundland and Labrador established the Commission of Inquiry on Hormone Receptor Testing to examine problems with estrogen and progesterone hormone receptor tests conducted in the province between 1997 and 2005. Using the Inquiry as a case study, we examine the knowledge transfer activities used by the Canadian Cancer Society – Newfoundland and Labrador Division (CCS-NL) to shape policy and improve cancer control in the province.

Implementation

CCS-NL established a panel to advise its legal counsel and asked academic researchers to prepare papers to submit to the Commission. CCS-NL also interviewed patients to better inform its legal arguments, used its province-wide networks to raise awareness of the Inquiry, and provided a toll-free number that people could call. It also provided basic information, resources, and contact information for people who were affected by the flawed hormone receptor tests. The effectiveness of CCS-NL's activities is reflected by the inclusion of its key messages in the Commission's recommendations, and the investment in cancer care following the Inquiry.

Discussion

The success of the CCS-NL knowledge transfer efforts stemmed from its reputation as an advocate for cancer patients and its long-standing relationship with researchers, especially at the local level. The case illustrates real-world application of knowledge transfer practices in the development of public policy, and describes how community-based non-government organizations can identify and draw attention to important issues that otherwise might not have been addressed.

KEY WORDS

Knowledge transfer, policy, commission of inquiry, hormone receptor, cancer control

1. BACKGROUND

In 2007, the Government of Newfoundland and Labrador established the Commission of Inquiry on Hormone Receptor Testing (known as the "Cameron Inquiry") to examine problems with estrogen (ER) and progesterone (PR) hormone receptor tests conducted in the province between 1997 and 2005[1]. Investigations into the occurrence and management of adverse events in the health care system are not new. Although inquiries may not be conventionally thought of as knowledge transfer vehicles, they may nonetheless represent an example of the interactive model of knowledge transfer[2]. In this model, those involved in policy development seek information from a variety of sources, including patient advocacy organizations: "All kinds of people involved in an issue area pool their talents, beliefs and understandings to make sense of a problem"[3]. The Inquiry gathered information from multiple sources to understand why the "cancer system" did not incorporate available literature about quality assurance, breast biomarkers, or adverse event disclosure. The Inquiry also created an appetite to identify and implement policies and best practices to prevent similar events in the future.

Using the Cameron Inquiry as a case study, this article examines the knowledge transfer activities used by the Canadian Cancer Society – Newfoundland and Labrador Division (CCS-NL). In this article, we aim to provide a real-world example of activities undertaken by CCS-NL during the Inquiry to shape policy and further improve cancer control in the province. The specific goals of the CCS-NL were to: 1) represent the concerns of patients and ensure that patients' perspectives were heard by the Commission; 2) provide patients and the public with information about the Inquiry, the retesting process,

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and the clinical significance of a changed test result; and 3) gather and submit research evidence to the Commission with the ultimate goal of influencing the policy decisions stemming from the Commission's findings and recommendations. To evaluate the effectiveness of these activities, we consider the response of patients and the Commission to the CCS-NL's key messages.

1.1. Events Leading to the Inquiry

In May 2005, Eastern Health began an internal investigation into ER/PR receptor tests after a number of breast cancer patients' test results changed from clinically negative to positive on retest[1]. The ER/PR tests determine whether a breast cancer patient would benefit from anti-hormonal therapy. Patients with clinically positive results may be offered Tamoxifen or an aromatase inhibitor. The informal internal investigation revealed a number of other patients whose negative ER/PR status changed to positive upon retest. In the summer of 2005, Eastern Health decided to retest all breast cancer patients who were tested between 1997 and 2005 and whose initial ER/PR status was clinically negative. Samples from these patients were sent to Mount Sinai Hospital in Toronto for retesting. However, Eastern Health encountered a number of difficulties identifying all the patients who should have been eligible for retesting. For example, there was no single data source that captured this information.

Eastern Health personnel believed that a change in the equipment used to prepare slides increased the sensitivity of the test and was the cause of the problem[1]. However, both internal and external reviews found serious problems in the preparation and preservation of tissues, the preparation of slides, and the staining of tissues. Among the issues identified was a lack of quality control and quality assurance protocols.

Patients who were initially retested as part of the internal investigation and whose results changed were contacted and followed up by their physician (usually an oncologist)[1]. However, Eastern Health decided to delay informing the patients in the larger group until their retest results were received. It also decided against making a public announcement about the concerns with the test.

Eastern Health had not yet decided upon a plan to communicate with patients when a local newspaper broke the story about the retesting in October 2005[1]. Eastern Health then began to contact patients. Eastern Health suggested that the cause of ER/PR testing problems was due to the change in equipment.

By August 2006, Eastern Health stated that all patients who were impacted by the retest had been contacted[1]. In December 2006, Eastern Health provided a technical briefing to the local media and identified the number of patients whose treatment had changed as a result of the retesting, suggesting an error rate of 12%. Eastern Health again suggested that the cause of the problems was the change in equipment.

In May 2007, a news story, based on an affidavit sworn by an Eastern Health employee, suggested an error rate of 42%[1]. The affidavit was filed as part of a class action suit and included the total number of patients whose results had changed. The renewed publicity about the ER/PR tests led to questions about whether all patients had been contacted. Information from Eastern Health led the Minister of Health and Community Services to declare in the House of Assembly that all patients had been contacted. In May, in a newspaper advertisement Eastern Health stated that it had contacted all patients who had been retested, and that it had notified patients and their doctors of their test results. Despite these assurances, there were media reports that all patients had not been contacted.

Scrutiny of the information provided by Eastern Health led the provincial government to question Eastern Health's handling of the ER/PR retesting. In July 2007 the government established the Inquiry. Justice Margaret Cameron was appointed to lead the Commission of Inquiry.

1.2. The Inquiry

The Inquiry was an investigation conducted pursuant to the Public Inquiries Act, 2006[4]. It consisted of two parts. In part one, the Commission examined the causes of the incorrect ER/PR tests, how the errors were detected, and whether they could have been detected earlier[1]. The Commission also looked at quality assurance and quality control processes. The Commission considered how the ER/PR testing problems were handled, including how Eastern Health communicated to patients, the public, other health authorities, and government.

In part two of the Inquiry, the Commission reviewed the policy and legal issues raised by the terms of reference, such as the obligations of responsible parties to patients, other health authorities, and the public[5]. The Commission also reviewed best practices related to ER/PR testing. The Commission asked six experts to prepare papers on the obligation to disclose medical errors, and organized a public symposium where these six experts discussed their papers.

The Inquiry heard from 93 witnesses between March 19, 2008 and October 31, 2008. The Inquiry was webcast and televised on a local community channel[1].

The Commission submitted its report to the Minister of Health and Community Services on March 1, 2009. In its report, the Commission made 60 recommendations. Notably, the Inquiry, as outlined in its term of reference, did not determine blame. Roughly one year later, the Minster of Health and Community Services reported on the status of the implementation of the recommendations, as outlined in the final recommendation of the Commission[6].

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2. IMPLEMENTATION

The Canadian Cancer Society – Newfoundland and Labrador Division (CCS-NL) was one of the six parties granted standing in Part I and II of the Inquiry. Standing at an Inquiry means that through its legal counsel, the CCS-NL was able to examine witnesses, and submit written arguments to aid the Commission in its work[4,7]. In her decision to grant the CCS-NL standing, Justice Cameron noted the Cancer Society's history of advocating for cancer patients, its partnership with researchers, and its access to expertise relevant to the Inquiry[6]. In addition, the Cancer Society represented the broader public interest unlike any other party with standing at the Inquiry. Other parties may have represented the interests of past patients and their families, but not necessarily those of future patients and their families.

2.1. Advisory Panel and Involvement of Academic Researchers

CCS-NL's legal counsel was assisted by CCS-NL staff and an ad-hoc advisory panel. The panel consisted of volunteers with expertise in cancer control, health administration, health policy, quality assurance, epidemiology, and laboratory operations. The panel included academics and individuals who had worked in senior management positions in the health care system. Although the panel was originally formed as an advisory resource, its members took on a more hands-on role in obtaining and synthesizing evidence. Members of the advisory panel were able to identify important studies and theories to support the CCS-NL's arguments. CCS-NL used this opportunity to highlight aspects of cancer control that were relevant to the Inquiry.

CCS-NL staff contacted experts in Canada to gather background information and best practices. Some of the individuals whom the CCS-NL staff contacted for expertise were reluctant to give their opinion of best practices or the evidence emerging from the Inquiry. This may have stemmed from a variety of reasons. Individuals were hesitant to be seen as "taking sides" and criticizing Eastern Health personnel with whom they may interact on committees, through national organizations, at conferences, etc. The involvement of academic researchers on the CCS-NL advisory panel provided a means to mitigate this obstacle. The academics were able to draw upon their own networks to find experts who were aware of best practice, and were able to comment on the emerging inquiry findings without risk of reprisal. Through these networks, CCS-NL was able to access experts in pathology, immunohistochemistry, patient-centred care, and disclosure of medical errors.

In addition to the information gathered through Parts 1 and 2 of the Inquiry, the Commission also invited written submissions from the public[7]. In these submissions, individuals could provide additional information for the Commission to consider. CSS-NL asked two academic researchers to submit papers to the Inquiry. The first of these papers described the potential of the cancer registry as an important tool in cancer surveillance[8]. It also highlighted how a valid and reliable registry could have aided Eastern Health in identifying eligible breast cancer cases to review, identifying deceased patients, and in providing patients' contact information. The second paper focused on communication in a patient-centred care model[9]. The paper discussed disclosure of information to patients. In addition to calling attention to these issues through her cross-examination of witnesses, CCS-NL's legal counsel also highlighted them in the submission to the Commission[10]. Unlike the submissions of the other parties which emphasized the interests of Eastern Health and physicians, CCS-NL's submission emphasized the interest of patients and their families, and touched upon a wider array of topics than the submission from members of the breast cancer testing class action.

2.2 Media Coverage

From the time that the story was first reported in the local newspaper, CCS-NL regularly commented on it in the media. Through the media, CCS-NL criticized Eastern Health's handling of the problem. It pressed Eastern Health to disclose the causes of the testing problems and the number of patients affected, and for timely disclosure to patients and their families. While comments made by CCS-NL's executive director in the media may have enhanced the CCS-NL's reputation among the public, its critiques were not well received by Eastern Health or the provincial government. In her report, Justice Cameron noted that there was a better understanding of the role of advocacy organizations like the CCS-NL within government than within Eastern Health[1].

CCS-NL also monitored media to ensure that information reported was accurate. For example, when the story first broke, one media source incorrectly stated that the tests were used for diagnosis. CCS-NL contacted the reporter and Eastern Health to correct the story[1].

2.3. Communication with Patients

As part of its knowledge exchange, CCS-NL's communication efforts were aimed at gathering information from patients, as well as providing information to patients and the public. In order for the CCS-NL to better understand the effects from the patient perspective, as one of its first steps, CCS-NL posted a notice in *The Telegram* newspaper asking individuals who had been affected by the retesting to share their experiences with CCS-NL. The information provided by people served to focus CCS-NL on issues that

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were of particular importance to patients, such as the timely notification of results, inclusion in treatment decisions, and the retesting of deceased family members. A number of patients who appeared as witnesses at the Inquiry were identified through this process.

There was confusion among patients and their family members about many issues: the nature of the test, the purpose of the retesting, the implications of a false-negative test, who had been tested, test results, and how to find information. CCS-NL received many inquiries from concerned patients and family members, particularly from individuals who had not been contacted about retesting or their test results. Many of these queries were made following Eastern Health's May 2007 announcement that patients had been retested and test results disclosed to them and their physicians. CCS-NL was concerned that not all patients had been identified and retested, and that patients who had not been contacted would wrongly assume that their samples had not been retested and/or that their results had not changed. During the Inquiry, CCS-NL undertook a number of initiatives to address these concerns.

The CCS-NL raised awareness of the Inquiry using its province-wide network of staff, volunteers, support groups, and partner organizations. It placed notices in local newspapers, church bulletins, and at fundraising events. These notices described the purpose of the Inquiry and gave a toll-free number for the CCS office that people could call with questions. CCS-NL provided these individuals with the contact information of a staff member at Eastern Health who could address their queries.

CCS-NL provided basic information, resources, and contact information for people who were affected or may have been affected by the ER/PR testing errors. Callers were referred to the Cancer Information Service for general information and/or to support groups and the CancerConnect program for emotional support.

There were many questions among patients and their families, and the public in general, about the implications of a false-negative test, particularly if a number of years had elapsed since diagnosis. CCS-NL, in partnership with Eastern Health, planned an information session where a panel of health professionals, including oncologists and pathologists, would answer questions from audience members and callers. The session was to be televised on a local community cable channel. However, the session was ultimately cancelled when the physicians on the panel declined to participate on the advice of their lawyers.

CCS-NL also provided support to a group of affected patients from St. Pierre and Miquelon. The French government contracts Eastern Health to provide health services, including cancer care, to residents of these two islands off the coast of Newfoundland[1]. In November 2008, CCS-NL staff travelled to St. Pierre and Miquelon to meet with a group of affected patients to ensure that the CCS-NL included their perspectives in its ongoing role as patient advocates.

2.4. Evaluation

CCS-NL's efforts to gather the perspectives of patients by raising awareness of the Inquiry through local newspapers and its own network led to the identification of a number of patients who appeared as witnesses at the Inquiry. In addition, CCS-NL staff spoke with close to 100 patients and family members who were unsure of their initial test results, whether they (or their family member) had been retested or were originally tested during the time period in question.

The effectiveness of CCS-NL's activities that were aimed at the Commission itself is best reflected by the inclusion of its key messages in the Commission's recommendations and the investment in cancer care following the Inquiry. For example, the Commission recommended that health authorities should disclose adverse events to patients in an appropriate manner, and that the health system should aid patients in communicating with hospitals through the creation of patient navigators[1]. The CCS-NL was also the primary party who urged a review of the "retro-converters" — that is, cases which changed from clinically negative to positive because of different definitions of clinically positive used between 1997 and 2005. The Commissioner ultimately recommended that a further review and analysis be conducted with respect to these cases for the purpose of patient care and, as well, to obtain as much information as possible about the circumstances giving rise to the ER/PR problem[1]. Moreover, since the Inquiry, Eastern Health has also made substantial efforts to improve the cancer care program, including investment in the Cancer Registry and other information systems[6].

3. DISCUSSION

CCS-NL's actions had many of the characteristics of a knowledge transfer strategy, although it did not label it as such. It was multipronged and tailored to the needs of the different audiences. Its messages incorporated best practices and evidence derived from research. It used an appropriate and credible spokesperson to deliver its messages to different audiences: legal counsel for the Commission, the CCS-NL executive director for the media, and academic researchers for submissions to the Commission.

The success of the CCS-NL efforts to engage the public stemmed from its reputation as an advocate for cancer patients, which was strengthened by its actions in the period leading up to and during the inquiry. CCS-NL's critical commentary in the media and its efforts to reach out to cancer patients during the Inquiry distinguished it from Eastern Health. In her report, Justice Cameron noted that because of

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its credibility with the public, involving organizations like CCS-NL in the management of large scale adverse events could help restore confidence in the health care institution[1].

The ability of the CCS-NL to draw upon researcher expertise stemmed from a long-standing relationship with researchers. In the province, CCS-NL had cultivated a relationship with local researchers to gather local evidence to support its advocacy work[11]. Many of these researchers participated on the advisory panel, gathered and provided information, found out-of-province experts, and/or prepared submissions to the Commission. Because these relationships predated the Inquiry, CCS-NL was able to engage these experts within the relatively short time frame of the Inquiry. At the national level, the Canadian Cancer Society has funded research and researchers for many years. It has also worked closely with researchers to develop best practice in cancer control. The reputation of the national organization likely influenced researchers and clinicians outside the province to assist CCS-NL during the Inquiry. All of the academics, researchers, and clinicians who worked with CCS-NL volunteered their time and expertise. They did not receive payment from the CCS-NL, allowing CCS-NL to operate within its financial resources (CCS-NL received funding from the Commission to cover the costs of its legal counsel; it did not request funding to engage experts[7]). Moreover, the voluntary nature of their involvement lent further credibility to their messages and the CCS-NL activities.

In evaluating the effectiveness of knowledge transfer activities, it should be noted that changes in policy rarely result from the knowledge transfer activities of one organization or one study. Rather, many competing interests influence policy development. These interest groups provide policy decision makers with a sense of important ideas and orientations to consider when considering policy alternatives[2,12]. CCS-NL recognized the opportunity to influence the policy making process through its participation in the Inquiry.

Although this article deals with the single case of ER/PR testing in Newfoundland and Labrador, it highlights lessons for other jurisdictions. Questions have been raised about cancer pathology and ER/PR testing in other provinces[13,14,15]. The responses of cancer advocacy groups, including the Cancer Society in other provinces, have varied. Our case highlights how CCS-NL was able to capitalize on the situation to contribute to the implementation of best practices related to hormone receptor testing, while also furthering cancer control in the province. Our case also highlights how advocacy organizations can shape policy through participation in legal processes such as judicial inquiries. We have described the unique advantages that a non-government organization may harness to engage researchers and promote the use of evidence-informed policy research in these situations.

4. CONCLUSIONS

The Commission of Inquiry on Hormone Receptor Testing in Newfoundland and Labrador presented a unique opportunity to improve the quality of cancer care in the province. Through its efforts to contribute to the legal process, raise awareness, provide information, and contribute to the consideration of best practice, CCS-NL was able to help influence policy discussions and further cancer control. The case illustrates real-world application of knowledge transfer practices in the development of public policy, and describes how community-based non-government organizations can identify and draw attention to important issues that otherwise might not have been addressed. The lessons drawn from this case may be valuable to other organizations trying to achieve similar aims in their own jurisdictions.

5. CONFLICT OF INTEREST DISCLOSURES

The opinions expressed in the article are of the authors alone and not of the Canadian Cancer Society, The Canadian Cancer Society–Newfoundland and Labrador Division, Martin Whalen Hennebury Stamp, or the Newfoundland and Labrador Centre for Health Information.

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Correspondence to: Maria Mathews, Rm 2867, Division of Community Health & Humanities, Health Science Centre, Memorial University, St. John's NL A1B 3V6.
E-mail: mmathews@mun.ca

* Division of Community Health & Humanities, Memorial University, St. John's NL
† Martin Whalen Hennebury Stamp, St. John's NL
‡ Newfoundland and Labrador Centre for Health Information, St. John's NL

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