

Manitoba Ombudsman

REPORT UNDER

THE OMBUDSMAN ACT

CASE FILE NUMBER 2013-0117

INTERLAKE-EASTERN REGIONAL HEALTH AUTHORITY
(formerly the North Eastman Health Authority)

REPORT ISSUED ON APRIL 8, 2015

CASE SUMMARY

Manitoba Ombudsman received a complaint on February 15, 2013, regarding the North Eastman Health Authority's handling of a critical incident. The complainant was injured during a medical procedure conducted in a health-care facility in September 2010. When he became aware that he had suffered a serious injury as a result of the medical procedure, he reported the injury to the health facility.

The complainant believes the North Eastman Health Authority (NEHA) failed to adequately respond to his report of injury. He alleges that NEHA did not treat him fairly or disclose to him the outcome of the critical incident investigation. Additionally, he maintains that NEHA did not disclose to him any system improvements to prevent similar injuries from happening to other patients.

Based on the evidence we reviewed during the course of this investigation, Manitoba Ombudsman concludes that NEHA did not act in compliance with Manitoba Health's *Critical Incident Reporting and Management Policy*. Further, the evidence indicates NEHA did not act in compliance with its own policy, *Disclosure of Occurrence to Clients and Family*, when responding to this critical incident.

Manitoba Ombudsman has determined that the actions of NEHA resulted in the complainant being treated unfairly, and has identified two administrative improvements that, if implemented, would serve to improve the experience of individuals who suffer unintentional injury while receiving medical treatment.

The North Eastman Health Authority ceased operating in 2012 when 11 existing regional authorities were officially merged into five new regional health authorities. The merger of the North Eastman Health Authority and the Interlake Health Authority took effect on May 30, 2012, formally merging to become the Interlake-Eastern Regional Health Authority. Accordingly, this report is being provided to that authority.

The recommendations in this report are directed to Manitoba Health. While Manitoba Health was not the subject of this complaint, it is the body that provides direction to regional health authorities and provincial organizations with respect to critical incident reporting, investigation, disclosure and recording, and notification to the minister in accordance with the legislation. Revisions to Manitoba Health's *Critical Incident Reporting and Management Policy* would help promote consistency between the five regional health authorities and clarify specific disclosure requirements to patients and families who suffer harm.

Recommendation One:

That Manitoba Health consider revising the *Critical Incident Reporting and Management Policy* to require regional health authorities to develop safety learning summaries for all critical incidents that meet a defined threshold. The safety learning summaries would be similar to those presently posted online by the Winnipeg Regional Health Authority. These summaries would not include any identifying information but would include relevant factual findings and system learnings from critical incident investigations. The goal of said summaries is to promote system-wide improvements in an effort to prevent future harm to patients and to share findings from critical incident investigations with patients and families, health-care workers, facilities, and other stakeholders.

Recommendation Two:

That Manitoba Health consider revising the *Critical Incident Reporting and Management Policy* to provide clear instructions to regional health authorities to advise a patient and or family who suffered harm of any changes that will be made to prevent a reoccurrence of a critical incident and, if a safety learning summary is to be done, to provide a copy of the summary to the patient. The revised policy should also direct regional health authorities to ensure a patient is offered a post-analysis disclosure meeting. Injured patients and their families should be given an opportunity to request a post-analysis disclosure meeting, and the assurance that critical incidents are thoroughly investigated.

OMBUDSMAN JURISDICTION

Manitoba Ombudsman is an independent office of the Legislative Assembly of Manitoba, reporting to the assembly through the Office of the Speaker. The responsibilities and authority of the ombudsman are set out in *The Ombudsman Act*, *The Freedom of Information and Protection of Privacy Act*, *The Personal Health Information Act*, and *The Public Interest Disclosure (Whistleblower Protection) Act*.

Under *The Ombudsman Act*, Manitoba Ombudsman investigates administrative actions and decisions made by government departments and agencies, municipalities, and their officers and employees. Investigations may be undertaken on the basis of a written complaint from a member of the public, or upon the ombudsman's own initiative.

The actions complained about in this matter are of an administrative nature arising from the process by which North Eastman Health Authority responded to a critical incident reported by a patient.

Ombudsman investigations typically assess actions taken or decisions made against a benchmark established by government. Sometimes that benchmark is provincial legislation or municipal by-law. On other occasions it is written policy or established procedures implemented to give effect to legislative purpose. In cases concerning an impact on individual rights or benefits we also examine the fairness of the action or decision. A complaint can raise questions of procedural fairness, substantive fairness or relational fairness. Procedural fairness relates to how decisions are reached including the steps followed before, during and after decisions are made. Substantive fairness relates to the fairness of the decision itself and relational fairness relates to how people are treated during the decision-making process.

While our office has a mandate to investigate complaints, the investigative process we follow is non-adversarial. We carefully and independently consider the information provided by the complainant, the decision maker, and any witnesses we determine to be relevant to the case. Administrative investigations can involve an analysis of statute or by-law provisions, document reviews, interviews and site visits.

The goal of administrative investigations is to determine the validity of complaints and to identify areas requiring improvement. If a complaint is supported by a finding of maladministration, the ombudsman may make recommendations pursuant to section 36 of *The Ombudsman Act*.

Administrative investigations can also identify areas where improvements may be suggested to a government body without a finding of maladministration. Such suggestions are made to support and help government bodies achieve better administration, often through the adoption of best practices. Better administrative practices can improve the relationship between government and the public, and reduce administrative complaints.

THE COMPLAINT

On March 27, 2013, our office received a complaint regarding the North Eastman Health Authority's response to a critical incident. The complainant stated that he was injured during a medical procedure at a health-care facility in September 2010. He became aware of the seriousness of the injury approximately five months later. He subsequently reported the medical event to the health-care facility in February 2011, through the established complaint process.

The complainant alleges that the health-care facility and regional health authority failed to:

- provide him assistance or patient advocacy following him reporting the incident;
- treat him fairly or support him with ongoing medical care;
- disclose to him the results of the critical incident investigation;
- identify any improvements to prevent other patients from being injured in the future.

In short, the complainant feels he was treated unfairly and does not believe NEHA handled the critical incident in an appropriate manner.

KEY ISSUES

- 1. Did the North Eastman Health Authority follow applicable legislation, policies and procedures when conducting this critical incident investigation, including the timelines for reporting to Manitoba Health?**
- 2. Did the North Eastman Health Authority follow the applicable legislation, policies and procedures regarding the provisions for disclosure and communication with the complainant? Was the complainant treated fairly throughout the process by the health-care facility and regional health authority?**

BACKGROUND INFORMATION

Health care is delivered in Canada through a complex system involving patients, health-care providers, facilities and many other entities. Mistakes can occur, whether made by an individual health-care provider, an equipment failure or as a result of some other cause. In Manitoba and throughout the country, there have been increasing efforts to improve both the quality and safety of health care, including new legislation, policies and practices to review unintentional harm and injury to an individual during the provision of health care.

Critical Incident

The Manitoba government introduced mandatory no-blame critical incident reporting across the provincial health system in 2006. *The Regional Health Authorities Act* outlines requirements for the reporting and investigation of critical incidents occurring during the provision of health care by regional health authorities, health corporations, health-care organizations and provincial organizations.

The Manitoba government's purpose of critical incident reporting and investigation is not to lay blame on individuals or determine culpability; rather, it is to examine what can be done differently and what improvements can be made respecting the delivery of health care. This process does not replace disciplinary investigations, complaints to professional regulatory bodies or civil law suits. Instead, critical incident investigations are intended to complement these processes.

Manitoba's legislation defines a critical incident as "an unintended event that occurs when health services are provided to an individual and results in a consequence to him or her that is serious and undesired." This can include death, injury and disability but does not include circumstances resulting from an individual's underlying health condition or from a risk inherent in providing health services. The legislation applies to regional health authorities, hospitals, personal care homes, all licensed land and air ambulances, the Selkirk Mental Health Centre, CancerCare Manitoba, and Diagnostic Services Manitoba.

To encourage reporting and full, open participation in the critical incident investigation process by health-care providers, some parts of the investigation and review – including opinions, speculations and advice – are confidential and privileged under *The Manitoba Evidence Act*. The act protects specific information from being used in subsequent legal or disciplinary proceedings to encourage full participation of health-care providers in the quality improvement review process.

In Manitoba a quality improvement review is performed by a committee struck for the purpose called a critical incident review committee or CIRC. The committee is tasked with investigating the adverse medical event, analyzing their findings, and preparing a report that may include recommendations to correct any system failures. Pursuant to *The Manitoba Evidence Act*, the interviews and report produced by a critical incident review committee are prohibited from being shared with persons other than the minister of health, the regional health authority and the health-care facility in which the incident occurred.

While parts of the critical incident and review are confidential, *The Regional Health Authorities Act* requires certain information be disclosed to a patient. Regional health authority policy may also prescribe that a patient is entitled to receive certain key facts and learn what action has or will be taken to prevent a future recurrence.

POSITION OF COMPLAINANT

The complainant believes that both the health-care facility and regional health authority failed to respond appropriately to his report that a serious medical injury had occurred. He also believes that the health-care facility and regional health authority did not treat him fairly or support him in his on-going medical care. Additionally, the complainant maintains he was not provided with information regarding the outcome of the critical incident investigation or what action had or would be taken to prevent similar injuries in the future.

Although regional health authority representatives were in communication with the complainant between February 2011 and late August 2011, the complainant alleges that NEHA failed to:

- provide him assistance or patient advocacy following him reporting the medical injury;
- treat him fairly or support him with ongoing medical care;
- disclose to him the results of the critical incident investigation;
- identify any improvements to prevent other patients from being injured in the future.

POSITION OF THE NORTH EASTMAN HEALTH AUTHORITY

In 2012, the North Eastman Health Authority merged with the Interlake Regional Health Authority to form the Interlake-Eastern Regional Health Authority. In response to our inquiries, the Interlake-Eastern Regional Health Authority reviewed documentation relating to the complainant's medical event and explained that "with the retirement of almost all involved with this client we have only written records to reference." The regional health authority continued:

The incident of September 24, 2010 did meet the criteria of a critical incident and was reported to Manitoba Health. A Critical Incident Review Committee (CIRC) was established, an investigation of the incident was completed and recommendations were made to prevent the likelihood of a similar incident occurring. The recommendations were accepted and implemented.

Further, the Interlake-Eastern Regional Health Authority provided a chronology of the North Eastman Health Authority's response to the complaint between February 2011, when the medical injury was reported, and August 2011, when direct communication with the complainant was discontinued.

SCOPE OF INVESTIGATION

During the course of our investigation we undertook the following:

- Contacted the Interlake-Eastern Regional Health Authority to obtain information and clarify their understanding of this situation.
- Interviewed the complainant and staff of the Interlake-Eastern Regional Health Authority.
- Reviewed the applicable sections of
 - *The Regional Health Authorities Act*
 - *The Manitoba Evidence Act*
 - *The Apology Act*
 - Manitoba Health - HCS 200.2 – *Critical Incident Reporting and Management Policy*, Version May 20, 2010
 - North Eastman Health Authority Inc. No. 14-3a – *Reporting of Critical Incidents to Manitoba Health*, Effective June 2011
 - North Eastman Health Authority Inc. No. 14-4 – *Disclosure of Occurrence to Clients and Family Policy*, Effective June 2011
 - Interlake-Eastern Regional Health Authority policy – *Critical Incident: Process, Reporting and Management*, GA-8-35 April 2014
 - Canadian Patient Safety Institute (2008): *Canadian Disclosure Guidelines*
 - Pamphlet (2009), *A Guide to a Critical Incident and Disclosure: Information for Patients and Families*, Manitoba Institute for Patient Safety, Regional Health Authorities of Manitoba, Winnipeg Regional Health Authority, Government of Manitoba
 - Pamphlet (2010), *The Facts About Critical Incidents and their Disclosure: Frequently Asked Questions for Health Care Providers*, Manitoba Institute for Patient Safety, Regional Health Authorities of Manitoba, Winnipeg Regional Health Authority, Government of Manitoba
- Reviewed the complainant's chronology of events
- Reviewed the Interlake-Eastern Regional Health Authority's chronology of events
- Reviewed the Critical Incident Report
- Reviewed the Manitoba Health, Healthy Living and Seniors website; the Manitoba Institute on Patient Safety website; the Interlake-Eastern Regional Health Authority website; and the Winnipeg Regional Health Authority website.

ANALYSIS OF ISSUES AND EVIDENCE

1. **Did the North Eastman Health Authority follow applicable legislation, policies and procedures when conducting this critical incident investigation, including the timelines for reporting to Manitoba Health?**

Report and Determination of Critical Incident

The complainant, who was harmed while receiving medical treatment, reported his injury through the health-care facility's complaint process on February 7, 2011. The complainant advised that on September 24, 2010, he was injured during a medical procedure when his artery was punctured and a tourniquet was left on his arm for an extended period of time causing pain, discomfort and resulting nerve damage. He continued to have worsening pain and progressive loss of use of his arm for several months and consulted his family physician who determined there could be serious nerve damage.

Pursuant to section 53.4 of the *Regional Health Authorities Act*, a report by an individual who was harmed should trigger the health facility to determine if the medical event and resulting harm falls under the definition of a critical incident.

Definitions

53.1 *The following definitions apply in this Part.*

"critical incident" means an unintended event that occurs when health services are provided to an individual and results in a consequence to him or her that

(a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of a hospital stay, and

(b) does not result from the individual's underlying health condition or from a risk inherent in providing the health services.

Critical incident: notification by others

53.4.1(1) *Any of the following who believes that a critical incident has occurred in respect of health services provided to an individual may notify the health corporation, prescribed health care organization or regional health authority which provided the health services:*

(a) the individual himself or herself;

(b) a relative of the individual;

(c) an individual working at or for the regional health authority, the health corporation or the prescribed health care organization.

Action where notification received

53.4.1(2) *Promptly upon being notified under subsection (1), the health corporation, prescribed health care organization or regional health authority must determine if a critical incident occurred.*

According to the evidence we reviewed, the health-care facility contacted the complainant on February 9, 2011, two days after the report was made, and explained the incident would be investigated. The health-care facility also offered physiotherapy services which were accepted by the complainant at that time.

In response to our inquiries, the Interlake-Eastern Regional Health Authority explained:

The incident of September 24, 2010 did meet the criteria of a critical incident and was reported to Manitoba Health. A Critical Incident Review Committee (CIRC) was established, an investigation of the incident was completed and recommendations were made to prevent the likelihood of a similar incident occurring. The recommendations were accepted and implemented.

Having determined that the medical injury met the statutory definition of a critical incident, the North-Eastman Health Authority followed the legislation and established a critical incident review committee to investigate the medical incident and prepare a report.

Investigation and reports of review committee

53.3(3) A critical incident review committee established under subsection (1) must, in accordance with the health corporation's or prescribed health care organization's directions,

- (a) investigate the critical incident and, during the investigation, provide information and reports to the corporation or organization as requested; and*
- (b) upon completing the investigation, report its findings and recommendations to the corporation or organization in writing.*

Sections 53.3(4) and 53.3(5) of *The Regional Health Authorities Act* set out reporting requirements for critical incidents – health-care facilities must report a critical incident to their respective regional health authority (RHA), and the RHA must in turn report the critical incident to the minister of Manitoba Health. The RHA is required to notify Manitoba Health of the critical incident, and must provide updates as the critical incident investigation proceeds, and provide the minister with the final critical incident report when completed.

Reports to regional health authority

53.3(4) In accordance with guidelines established by the regional health authority, the health corporation or prescribed health care organization must provide information and reports to the authority about the critical incident and the critical incident review committee's investigation, including a written report upon completion of the investigation.

Reports by regional health authority to minister

53.3(5) The regional health authority must provide information and reports to the minister about the critical incident and the critical incident review committee's investigation, including a written report upon completion of the investigation.

In this case, the health-care facility where the medical event occurred followed the legislation and notified NEHA of the critical incident and undertook to investigate the medical event. A critical incident report was created and provided to the regional health authority and to the minister of Manitoba Health as required by section 53.3(5) of *The Regional Health Authorities Act*.

Policies and Procedures Regarding Critical Incidents

In addition to setting out the definition and reporting requirements of critical incidents, *The Regional Health Authorities Act* also requires that regional health authorities, health corporations, and prescribed health-care organizations must establish written procedures respecting the recording of critical incidents and what information should subsequently be disclosed to affected patients and families.

Manitoba Health also includes a similar directive in the *Critical Incident Reporting and Management Policy*, version May 20, 2010:

5.1 Each RHA and provincial organization shall have written policies and procedures in place to enable compliance with the requirements of The Regional Health Authorities Act for reporting, investigating, disclosing and follow-up of critical incidents.

The North Eastman Health Authority met this legislated requirement and had two critical incident policies in effect in 2011 when the complainant was injured. One policy pertains to the contents and frequency of reporting to Manitoba Health; and the other policy pertains to the contents and frequency of disclosing information to patients who suffer the harm.

Timeline and Reporting of the Critical Incident

While *The Regional Health Authorities Act* requires that health-care facilities report critical incidents to their respective regional health authorities, the regional health authorities must in turn report to Manitoba Health.

Manitoba Health critical incident policy provides further detail regarding the content and timelines of these reports. Section 7.0 of the *Critical Incident Reporting and Management Policy* (version May 20, 2010) states that “within twenty-four (24) hours, the RHA or provincial organization shall provide notification of the critical incident (via telephone or email) to Manitoba Health.”

The policy also provides notification requirements and specifies the follow-up reports that must also be completed. For example, “if the twenty-four (24) hour notification is provided via telephone, then within seven (7) days, the RHA or provincial organization shall provide written documentation on the critical incident to Manitoba Health.” Furthermore, according to this policy, follow-up notifications must also occur within 30 days and 90 days or upon the completion of the critical incident investigation.

While Manitoba Health’s policy provides more specific procedural instructions than found in *The Regional Health Authorities Act*, it should be noted that NEHA also had two written policies at the time of the critical incident investigation regarding reporting and disclosure of critical incidents.

The NEHA policy, *Reporting of Critical Incidents to Manitoba Health*, specifies timelines and information that must be included in critical incident reports sent to the minister of Manitoba Health.

5.1 Manitoba Health will be notified by telephone or email about the critical incident within twenty-four (24) hours of the occurrence by designated NEHA staff i.e. VP Quality and Organizational Development or designate to: criticalincidents@gov.mb.ca using the MH Critical Incident Report. Refer to Manitoba Health CI Reporting template Appendix 2. All information reported will be de-identified.

Within twenty-four (24) hours information required

- *“Name of health authority and facility and/or community program involved*
- *Type of occurrence*
- *Time and date of the CI*
- *Brief description of the CI*
- *Contact person and number where they can be reached”*

5.3 Written follow up continuing to use the initial MH Critical Incident Report. This report is meant to be a cumulative document as the investigation proceeds. Refer to Appendix 2 – Manitoba Health CI Reporting template. Email as per address above.

When our office questioned if NEHA had fully complied with reporting timeframes set out in policy, the Interlake-Eastern Regional Health Authority explained that “the incident occurred September 24, 2010, was first reported to the organization by the client through the complaint process February 7, 2011, the critical incident report form to Manitoba Health is dated November 17, 2011 for both the 7-day and 30-day report.” Further, the Interlake-Eastern Regional Health Authority also explained that “a 90-day report was not filed as the issue had been reviewed. Outcome noted in other documentation....”

Based on the evidence we have reviewed, there is no record of a report having been made – verbal or written – by the regional health authority to Manitoba Health within 24-hours of the determination that the complainant’s injury met the definition of a critical incident. We note that NEHA sent a critical incident form to Manitoba Health dated November 17, 2011 for both the 7- and 30-day reports, over nine months after the complainant reported the medical injury to the health-care facility. As such, it does not appear that NEHA met the previously noted policy requirements of reporting to Manitoba Health at intervals of twenty-four hours, 7 days, 30 days and 90 days.

In our review of *The Regional Health Authorities Act* and applicable policies, we conclude that NEHA did not follow established policies and procedures with respect to the notification timeline and the notification content of the critical incident report to Manitoba Health.

- 2. Did the North Eastman Health Authority follow the applicable legislation, policies and procedures regarding the provisions for disclosure and communication with the complainant? Was the patient treated fairly throughout the process by the health care facility and regional health authority?**

A serious medical event in Manitoba sparks a critical incident investigation, wherein a critical incident review committee is struck to investigate what happened, analyze the findings, and prepare a report for Manitoba Health. Distinct and separate from the critical incident investigation is the process of communicating with the patient and family affected by the medical event, referred to as disclosure. The provisions for disclosure to patients are set out in legislation, policy and procedures, as well as guidelines and brochures to help health-care providers communicate effectively under difficult circumstances.

Duty to inform individual

According to *The Regional Health Authorities Act*, if a medical event falls within the definition of a critical incident, a patient must be informed of the event and the facts as they are known, and any treatment needed. This disclosure process is patient-centered and focused on the medical injury and continuing care.

Duty to inform individual re critical incident

53.2(2) *If a critical incident occurs when a regional health authority, health corporation or prescribed health care organization is providing health services to an individual, the authority, corporation or organization must ensure that*

- (a) appropriate steps are taken to fully inform the individual, as soon as possible, about*
 - (i) the facts of what actually occurred with respect to the critical incident,*
 - (ii) its consequences for the individual as they become known, and*
 - (iii) the actions taken and to be taken to address the consequences of the critical incident, including any health services, care or treatment that are advisable;*
- (b) a complete record is promptly made about the critical incident, which includes*
 - (i) the facts of what actually occurred with respect to the critical incident,*
 - (ii) its consequences for the individual as they become known, and*
 - (iii) the actions taken and to be taken to address the consequences of the critical incident, including any health services, care or treatment that are advisable; and*
- (c) the record described in clause (b) is available to be examined and copied by the individual at no cost.*

Further to *The Regional Health Authorities Act*, Manitoba Health's *Critical Incident Reporting and Management Policy* provides specific direction regarding the information that must be communicated and disclosed to a patient affected by a critical incident. The policy states that each RHA "shall have written policies and procedures in place to enable compliance with the requirements of *The Regional Health Authorities Act* for reporting, investigating, disclosing and follow-up of critical incidents."

The regional health authority at the time of the critical incident met the Manitoba Health requirement for having written policies and procedures in place. NEHA had a policy in place at the time of the incident, *Disclosure of Occurrence to Clients and Family Policy*, which provided direction to staff.

NEHA's disclosure policy makes a clear distinction between what it defines as "disclosure specific to critical incidents" which is defined as the process of providing information to the patient and or family who suffered the harm, and "reporting" which is defined as communication within the health-care system as part of the quality review process or critical incident investigation.

3.0 Definitions

Disclosure

...imparting, by health-care workers to patients [clients, residents] or their significant others, of information pertaining to any health-care event affecting (or liable to affect) the patient's [client's, resident's] interests. The obligation to disclose is proportional to the degree of actual harm to the patient [client, resident] (or the realistic threat of such) arising from an untoward event.

Disclosure specific for CI

The process (verbal and written) of informing the client/family or other individuals authorized by regulation to receive information about critical incidents.

Reporting

Reporting is a different process from disclosure and refers to the communication by health care providers of information about an adverse event (or close call) through appropriate channels inside or outside of health care organizations, for the purpose of reducing the risk of reoccurrence.

Disclosure Policy and Guidelines

NEHA policy, *Disclosure of Occurrence to Clients and Family*, gives practical guidance to staff when communicating with patients who have suffered a critical incident:

4.0 Policy Statements

- *Disclosure is the responsibility of health care providers and the right of every client.*
- *Information communicated to the client or family about the occurrence must come from the information already recorded in the client's medical record and/or from those involved in the event itself and must be factual not speculative.*
- *The most current version of the Canadian Patient Safety Institute's Canadian Disclosure Guidelines at www.patientsafetyinstitute.ca will be used to educate and guide staff when disclosing an occurrence to clients, families and/or significant others.*
- *The manager where the Occurrence Report was initiated will be responsible for coordinating the occurrence, follow up investigation, and ensure client disclosure has occurred if applicable.*

- *Apology in the context of disclosure, does not in itself infer blame or responsibility for an occurrence.*

We note that the above noted NEHA policy states “the most current version of the *Canadian Patient Safety Institute’s Canadian Disclosure Guidelines*” is to be used to educate and guide staff when making a disclosure to patients. Therefore, as part of our investigation it necessitated that we consider the 2008 version of these guidelines which were in effect at the time of this critical incident.

Canadian Patient Safety Institute’s Canadian Disclosure Guidelines (2008)

Disclosure is needed for learning so that improvements to patient safety can be made. We believe the accountability for disclosure, learning and improvements rests at the most senior levels in an organization. We believe disclosure is the responsibility of all health care providers and the right of every patient.

- *The facts of the harm and/or event known at the time.*
- *The steps taken and the recommended options and decisions in the ongoing care of the patient.*
- *An expression of sympathy or regret.*
- *A brief overview of the investigative process that will follow, including appropriate timelines and what the patient can expect to learn from the analysis. (emphasis added)*
- *An offer of future meetings, including key contact information.*

It is clear from the evidence provided by both the complainant and the Interlake-Eastern Regional Health Authority that NEHA representatives had several contacts with the complainant after he reported the medical injury.

The Regional Health Authorities Act and the Canadian Disclosure Guidelines require disclosure be made to the patient and/or family that an incident has occurred; the facts about what happened; and what is being done to address it. This case is somewhat unusual in that the complainant was fully aware of what occurred as a result of the medical procedure, sought medical assistance from his family physician, and subsequently reported his injury to the health-care facility. Additionally, the options respecting continuing care were known to the complainant as he received assistance from his family physician and various specialists both before and after he reported the injury to the health-care facility.

However, the health-care facility and the regional health authority did not provide the complainant with clear information regarding the critical incident review investigative process. It appears that there was a breakdown in communication which resulted in the complainant being unaware that certain parts of the critical incident investigation, and the report itself, are confidential and cannot be shared. It is evident that the complainant had expectations of the critical incident investigation that could have been better managed had NEHA clearly explained the process.

Disclosure Regarding Quality Review Process

Section 5.3 of the NEHA disclosure policy reads:

5.0 Procedure

5.3 Initial Disclosure

- *Disclosure is an ongoing dialogue with the client and their family or significant other(s). Provide the client and family with a copy of the pamphlet: Manitoba Institute for Patient Safety - A Guide to a Critical Incident and Disclosure: Information for Patients and Families.*
 - *Planning the initial disclosure:*
 - *Identify who will do the disclosing.*
 - *Identify who will be present (client, family, health care provider, physician, translator...).*
 - *Determine date of meeting and location.*
 - *Provide facts as known.*
 - *Express regret as appropriate.*
 - *Avoid attribution of blame, opinion or speculation.*
 - *Confirm plan for further clinical care.*
 - *Outline expectations for further information.*
 - *Arrange follow up conversations.*
 - *Identify contact person and process.*
 - *Document the disclosure discussion in the medical record.*

We reviewed the pamphlet that is required to be provided to patients as set out in above noted NEHA policy. The pamphlet, *A Guide to a Critical Incident and Disclosure: Information for Patients and Families*, was produced in conjunction with the Manitoba Institute for Patient Safety, Regional Health Authorities of Manitoba, Winnipeg Regional Health Authority and the Manitoba government. These pamphlets were provided to all health regions in 2009/10 and are available on the Manitoba Institute for Patient Safety website. The pamphlet outlines what the health-care organization will do, what the patient can expect from the health-care system, and how the health-care organization may prevent a similar event in the future.

Pamphlet: A Guide to a Critical Incident and Disclosure: Information for Patients and Families

What will the health care organization/facility do?

- *Register the critical incident with Manitoba Health.*
- *Give you the facts about what actually happened in a clear manner.*
- *Complete a disclosure record that includes:*
 - *the facts of what actually happened as they become known.*
 - *how this event will impact on your health.*
 - *the actions taken or to be taken to deal with the results of the critical incident. This may include any health services, care or treatment advised for the patient.*
- *At your request, provide you with a copy of the disclosure record free-of-charge.*

- *Investigate the event to learn how to prevent the same thing from happening to someone else. Report these findings to Manitoba Health and Healthy Living.*
- *Report the findings to Manitoba Health.*

What can you expect from us?

- *An apology – we are sorry this happened.*
- *To be treated with care, attention and respect.*
- *Open and honest communication so you understand the facts about what happened. This will occur as soon as possible.*
- *Someone will contact you again, if and when new facts become known.*
- *To be told what has been done so far and what will happen next.*

You can expect the organization /facility to review:

- *The how and why of the event.*
- *Recommended changes to improve patient safety to try to prevent the same harm from happening again.*
- *The process to improve the health system, not to assign blame.*

Where may you get a copy of the disclosure record?

Upon request, the organization will provide you with a copy of the disclosure record free-of-charge.

The disclosure records, including the facts of what actually happened with the critical incident and the effects, will be written in the medical record/chart.

[...]

How will the health care organization/facility prevent the same thing from happening to someone else?

A critical incident review committee studies the event and makes recommendations and suggests ways to improve the safety of patient care.

When we inquired if the complainant had been provided with the pamphlet as directed in the NEHA disclosure policy, the Interlake-Eastern Regional Health Authority explained that “Generally, the brochures are provided to clients and families who are involved in a CI, they are not widely available to the public. The pamphlet states ‘You or your family member received this pamphlet to explain what happens now that you have experienced a critical incident.’ I am unaware if this client received a brochure or not.” Conversely, the complainant maintains that he was not provided a copy of the pamphlet and he was not informed that the critical incident review investigation would not be disclosed to him.

The Interlake-Eastern Regional Health Authority provided no evidence to demonstrate, and nor does it assert, that NEHA ever provided the complainant with a copy of the pamphlet. In light of that, and the patient’s assertion that it was not provided, we conclude on a balance of probabilities that the pamphlet was not provided to the complainant as required by NEHA policy. This is unfortunate as the pamphlet

provides information on what an individual can expect from the regional health authority and the option to request a copy of the disclosure record free of charge.

What is evident is that the complainant does not appear to have had a clear understanding of what he could expect from health-care providers and the regional health authority during the critical incident investigation process and what information would remain confidential and be unavailable to him. Lastly, the fee that the complainant was required to pay in order to obtain a copy of the disclosure record appears to have added insult to injury.

Post-Analysis Disclosure

Although some parts of the critical incident investigation process – including opinions, speculations, and the resulting critical incident report itself – are confidential and privileged under *The Manitoba Evidence Act*, both the Manitoba Health and NEHA’s critical incident policies indicate that the patient should have been provided some information regarding the critical incident investigation.

Manitoba Health’s *Critical Incident Reporting and Management Policy* states:

7.1.4 Within ninety (90) days of the Critical Incident or upon completion of the review, the RHA or provincial organization shall submit a written final report on the critical incident to Manitoba Health. The final report shall include:

- *Relevant findings including but not limited to contributing factors*
- *Recommendations including but not limited to follow-up action plans and identification of person(s) responsible for implementation of each activity*
- ***Reference to involvement of the person(s) affected by the critical incident in the critical incident review process and confirmation that final disclosure has occurred and by whom.** (emphasis added)*

Section 5.5 of the NEHA disclosure policy No. 14-4, which was in effect at the time of this critical incident, states:

5.5 Post-Analysis Disclosure

- ***Provide further facts, information and actions taken to prevent another similar occurrence.** (emphasis added)*
- *Document the discussion in the medical record.*
- *Post-Analysis Disclosure: Leadership/management may lead. Provider(s) may be involved.*

Furthermore, both the NEHA disclosure and reporting policies indicate that “the most current *Canadian Disclosure Guidelines* from CPSI will be used to guide disclosure practices.” The Canadian Patient Safety Institute’s *Canadian Disclosure Guidelines* (2008) advises health-care providers that:

When conducting an investigation... in a legally protected quality of care or similar committee, it is important to be aware of the legislation in each province or territory that will impact information exchange. Providers and patients should be made aware that there are explicit limitations to discussing some of the investigative information,

such as opinions and speculations shared, as defined in legislation within each of the provinces or territories quality of care protections.”

Subsequent and post-analysis disclosure discussions with the patient...should include:

- *Continued practical and emotional support as required.*
- *Reinforcement or correction of information provided in previous meetings.*
- *Further factual information as it becomes available.*
- *If applicable, and when all facts are established, a further expression of regret that may include an apology with acknowledgement of responsibility for what has happened as appropriate.*
- *Actions taken as a result of internal analysis that have resulted in system improvements. (emphasis added)*

It is essential during any disclosure discussion that speculation, opinion or attribution of blame does not occur.”

In this case, the disclosure process and discussions with the complainant do not appear to have included clear information regarding the process for investigating the critical incident, nor what the complainant could expect to learn from the process. The meetings and discussions between the complainant and NEHA representatives seem to have focused on the harm he experienced and on-going treatment, including the costs borne by the complainant as a result of the situation. It does not appear that any reference was made to the critical incident investigation process itself, and there was no final disclosure regarding the actions taken, if any, as a result of the critical incident investigation to make improvements to the health-care system.

According to both the complainant and the regional health authority, a meeting occurred on June 29, 2011, wherein the complainant and his spouse met with three representatives from NEHA. The NEHA representatives acknowledged the delay in meeting and apologized. During this meeting the complainant was informed that the health care facility’s insurance company would become involved. As such, the complainant was asked to provide a list of his out-of-pocket expenses which he subsequently submitted on June 30, 2011.

Following the meeting on June 29, 2011, a NEHA representative emailed the complainant on July 4, 2011, advising him that the insurance adjuster had been contacted, a file was being opened, and the insurer would be investigating this situation. This process was confusing for the complainant as he was informed of yet another investigation prior to receiving any information as to what had occurred as part of the critical incident investigation conducted by NEHA.

On July 9, 2011, the complainant emailed NEHA to advise that he would be retaining a lawyer. A NEHA representative replied to the complainant on August 2, 2011, advising that the insurance adjuster, acting on behalf of NEHA, had started an investigation. The following day, the NEHA representative emailed the complainant to notify him that because he obtained the assistance of a lawyer, all future communication between the insurance adjuster and the complainant would have to flow through the complainant’s lawyer. Sadly, communication appears to have completely broken down and no further contact occurred between the complainant and NEHA after this time.

On January 21, 2013, the complainant requested his personal health information from the health-care facility regarding the medical procedure on September 10, 2010, pursuant to *The Freedom of Information and Protection of Privacy Act*, and *The Personal Health Information Act*. He was provided the records a few days later after paying a fee, contrary to NEHA policy, Manitoba Health policy, and *The Regional Health Authorities Act*.

The complainant was concerned that the Critical Incident Report was not provided to him in response to his request for information. However, pursuant to *The Manitoba Evidence Act*, the Critical Incident Report is only provided to Manitoba Health, the regional health authority and the health-care facility at which the critical incident occurred. Unfortunately, due to a lack of communication, the complainant was unaware that he would not be able to examine the Critical Incident Report as he had never been told, and he was never provided a post-analysis disclosure meeting.

Regardless of the fact that the complainant retained a lawyer in 2011, he was entitled to a post-analysis disclosure meeting as per NEHA policy No. 14-4, at which time he should have been provided further facts, including any action taken to prevent another occurrence, and the discussion should have been documented in the medical record to which the patient should have been allowed access free of charge. The critical incident review process is separate from, and is not replaced by, civil legal proceedings. The Manitoba Health website states:

The purpose of reporting is to look at what can be done differently and what improvements can be made to the way health care providers work. This process does not replace other disciplinary investigations such as reviews by employers, complaints to professional regulatory bodies or civil law suits. Instead, investigating critical incidents complements these processes. [emphasis added]

As previously noted, communication stopped between NEHA and the complainant once he retained legal representation. NEHA did not conduct a post-analysis disclosure meeting with the complainant and he was not provided with information on whether any actions were taken to prevent a similar medical incident from happening in the future, in contravention of NEHA Policy No. 14-4 *Disclosure of Occurrence to Clients and Family*.

CONCLUSION

A serious medical event triggers a cascade of responses. In Manitoba, *The Regional Health Authorities Act*, Manitoba Health policy, regional health authority policies and various guidelines prescribe that when a serious medical event occurs and is identified, some distinct processes are put into motion. One process focuses on patient care and includes immediate action to ensure patient safety, prevent further harm, and help with on-going treatment. Various supervisors and health-care professionals must be notified of the incident, and facts pertaining to the incident must be recorded. The medical event is later analyzed to determine if it falls within the legislated definition of a “critical incident” – an unintended event that occurs when health services are provided to an individual and results in consequences that are serious and undesired and do not result from the individual’s underlying health condition or from a risk inherent in providing the health services. If a medical event falls within the definition of a critical incident, a patient must be informed of the event and the facts as they are known, and the treatment needed. This process is patient-centered and is focused on the medical injury and ongoing care. Disclosure of the adverse event and subsequent health care or treatment to patients is required.

Distinct from this process, however, is the analysis of the medical event itself within the framework of quality improvement. While the disclosure to patients that adverse events have occurred is an integral part of patient care, the reporting of adverse events to quality improvement committees is generally part of a much broader initiative aimed at identifying and addressing systemic problems or weaknesses to improve patient care.

In this regard, physicians and health-care professionals need reassurances that the reporting of adverse events and ensuing investigations will not be used or disclosed outside of the quality improvement process, while patients want reassurances that improvements will be made so that these events will not occur again. Most patients want to know that the adverse event created a learning opportunity whereby similar harm might be prevented in the future.

However, quality improvement information can only be disclosed to patients according to the applicable provincial and organizational bylaws. Patients should be informed that quality improvement information such as some of the information pertaining to critical incident review committee investigations, reports, and recommendations are protected by provincial legislation. Patients should be made aware that certain information cannot be disclosed while being notified that a general overview will be shared with the patient once the investigation is complete.

Based on the evidence that we have reviewed, it appears that the complainant was not informed about the distinct processes triggered by his report that a serious medical injury had occurred. Although the health-care facility and NEHA reviewed the medical event and determined that it met the definition of a critical incident, they did not inform the complainant what would happen following the investigation. The complainant was not provided with clear information regarding the processes that would occur as result of him reporting his medical injury.

While NEHA discussed with the complainant the injury he suffered and provided some assistance with ongoing medical care, the complainant was not informed that a critical incident review committee would be struck to perform an internal quality of care investigation. Further, the complainant was not told what information could or could not be shared at the conclusion of the critical incident investigation. To add to the confusion, there was no final disclosure meeting with the complainant and communication ceased after he retained a lawyer for the purpose of litigation, an entirely separate process that should not have ended the critical incident disclosure process.

There is also evidence to conclude that NEHA was not in compliance with *The Regional Health Authorities Act* and with provincial policy with respect to the reporting of the critical incident to Manitoba Health. Timelines for reporting to Manitoba Health were clearly not met.

Although there is sufficient evidence to conclude that NEHA did not follow legislation and policy regarding this critical incident, we are not making any recommendations directed to NEHA at this time as the organization has ceased to exist and the Interlake-Eastern Regional Health Authority now oversees health facilities in the region. Additionally, it is important to note that the Interlake-Eastern Regional Health Authority has recently updated a policy on the reporting and management of a critical incident with clearly delineated roles and responsibilities and timeframes to respond to critical incident reports.

FINDINGS

1. Did the North Eastman Health Authority follow the applicable legislation, policies and procedures when conducting this critical incident investigation, including the timelines for reporting to Manitoba Health?

- The critical incident of September 2010, was not reported to Manitoba Health by NEHA according to the timelines set out in Manitoba Health policy HCS 200.2 nor NEHA policy No. 14-4. The event occurred September 2010 and was reported to the health-care facility by the complainant on February 7, 2011. NEHA submitted the 7-day and 30-day critical incident reports to Manitoba Health in November 2011, nine months after the report was filed with them by the complainant.

2. Did the North Eastman Health Authority follow the applicable legislation, policies and procedures regarding the provisions for disclosure and communication with the complainant? Was the complainant treated fairly throughout the process by the health facility and regional health authority?

- The complainant was not provided with information regarding the separate processes triggered by a report of injury during a medical event: patient care and continuation of treatment on the one hand, and the quality review process on the other hand. He was not advised that a critical incident review committee would be struck to investigate the incident with a view to internal systemic improvements, and that parts of this internal quality review – including the resulting critical incident report itself – are protected by legislation and not shared with patients and families.
- It appears that the complainant was not provided with the pamphlet titled, *A Guide to a Critical Incident and Disclosure: Information for Patients and Families*, as required by the NEHA critical incident disclosure policy. This pamphlet was to be provided at the initial disclosure meeting, and would have helped guide and inform the complainant as to what he could expect during the critical incident process.
- The complainant was not provided with ongoing disclosure meetings after retaining a lawyer. Although there is a pending civil law suit, the disclosure process is reportedly separate and apart from other processes, including civil litigation.
- The complainant was not provided with the required information and actions taken to prevent another similar occurrence.

RECOMMENDATIONS

As a result of this investigation, Manitoba Ombudsman has identified two areas of administrative improvement that would benefit the health-care system in Manitoba as well as patients and their families who have suffered unintentional injury.

Having found pursuant to section 36(1) of *The Ombudsman Act* that the authority acted unreasonably, I make the following recommendations pursuant to section 36 (2) of *The Ombudsman Act*:

Recommendation One:

That Manitoba Health consider revising the *Critical Incident Reporting and Management Policy* to require regional health authorities to develop safety learning summaries for all critical incidents that meet a defined threshold. The safety learning summaries would be similar to those presently posted online by the Winnipeg Regional Health Authority. These summaries would not include any identifying information but would include relevant factual findings and system learnings from critical incident investigations. The goal of said summaries is to promote system-wide improvements in an effort to prevent future harm to patients and to share findings from critical incident investigations with patients and families, health-care workers, facilities, and other stakeholders.

Recommendation Two:

That Manitoba Health consider revising the *Critical Incident Reporting and Management Policy* to provide clear instructions to regional health authorities to advise a patient and or family who suffered harm of any changes that will be made to prevent a reoccurrence of a critical incident and, if a safety learning summary is to be done, to provide a copy of the summary to the patient. The revised policy should also direct regional health authorities to ensure a patient is offered a post-analysis disclosure meeting. Injured patients and their families should be given an opportunity to request a post-analysis disclosure meeting, and the assurance that critical incidents are thoroughly investigated.

The recommendations in this report are directed to Manitoba Health. While Manitoba Health was not the subject of this complaint, it is the body that provides direction to regional health authorities and provincial organizations with respect to critical incident reporting, investigation, disclosure and recording, and notification to the minister in accordance with the legislation. Revisions to Manitoba Health's *Critical Incident Reporting and Management Policy* would help promote consistency between the five regional health authorities and clarify specific disclosure requirements to patients and families who suffer harm.

MANITOBA HEALTH'S RESPONSE TO RECOMMENDATIONS

The ombudsman's report with recommendations was sent to Manitoba Health, Healthy Living and Seniors in April 2015. The department has accepted the recommendations, and their reply is summarized as follows:

Manitoba Health, Healthy Living and Seniors (MHLS) notes and is in agreement with the two recommendations made in the report. Actions that will be undertaken to ensure these recommendations are reflected in day-to-day operations include:

- *consultation with the health regions and provincial organizations (as defined to include CancerCare Manitoba, Diagnostic Services Manitoba, Selkirk Mental Health Centre, and all licensed air ambulance services including LifeFlight)*
- *revision of the MHLS Critical Incident Reporting template*

- *revision of the MHHLS Critical Incident Reporting and Management Policy*
- *communication of the revisions to the health regions and provincial organizations*
- *education and guidance where needed to comply with the new requirements*

We anticipate that these changes will be fully implemented by October 2015.

In light of the department's response to the report and recommendations, the ombudsman considers this matter concluded.

MANITOBA OMBUDSMAN