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CANADIAN ROOT CAUSE ANALYSIS FRAMEWORK

A tool for identifying and addressing the root causes of critical incidents in healthcare

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Expert Review Panel

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This publication is provided as information only. All examples are provided as illustrations. This publication is not to be used as a substitute for legal advice. It is not an official interpretation of the law and is not binding on the Canadian Patient Safety Institute.

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Preface

A Collaborative Approach

Patient safety is increasingly recognized as one of the most significant issues facing health systems across the world. In 2002, the Canadian National Steering Committee on Patient Safety issued a comprehensive report, *Building a Safer System*,¹ which recommended a national integrated strategy for improving patient safety in Canadian healthcare. One of its key recommendations was the establishment of a Canadian Patient Safety Institute (CPSI) to promote innovative solutions and facilitate collaboration among governments and stakeholders for the ultimate benefit of patients.

One of the early priorities for CPSI was to develop patient safety tools, including a model for root cause analysis (RCA). A variety of individuals and organizations expressed the need for such a tool. They desired healthcare environments that did not rely entirely on the personal vigilance of healthcare professionals (as is commonly the case) and instead placed the system as also accountable for each intervention and patient outcome.

An example of a situation that required an RCA tool occurred in January 2002. A 76-year-old patient in an Ontario hospital required a sodium chloride 0.9 per cent flush for her peripherally inserted central intravenous catheter, also known as a PICC line. A nurse inadvertently administered 10 milliliters of concentrated potassium chloride, thinking it was the sodium chloride flush and the patient died within minutes. A number of key contributing factors led to this human error, including easy access to vials of concentrated potassium chloride on the nursing unit, and the look-alike, feel-alike packaging and labelling of the two solutions.

Perhaps the most important aspect of this event is that the same fatal human error had previously occurred in many other hospitals in Canada, the United States, the United Kingdom and Australia. The facts and recommendations for improvement from these incidents were not shared publicly and healthcare professionals, hospitals, districts and regions could not learn from one another. By inviting the involved staff and relevant experts to analyze events such as this one, system



changes can be made that will reduce specific hazards or risks to patients.²

In responding to the need for an RCA tool, CPSI identified and approached Saskatchewan Health and the Institute for Safe Medication Practices Canada (ISMP Canada) as two key stakeholders with established credibility and expertise in the RCA process. The collaborative approach to developing a Canadian RCA framework is consistent and complementary to the mandates of all three organizations.^{3,5} They all share the common goal of effectively learning and sharing to improve patient safety. A panel of experts from across Canada was also contacted to review and enhance the content of this document. Their assistance and contributions are gratefully acknowledged (see list on page 2).

The Canadian Root Cause Analysis Framework is designed as a quality improvement tool to help individuals and organizations determine all of the contributing factors and root causes that led to an event (critical incidents are often the focus however, other events such as close calls may also be included). It also provides strategies for developing effective

¹Royal College of Physicians and Surgeons of Canada, National Steering Committee on Patient Safety, *Building a Safer System: A National Strategy for Improving Patient Safety in Canadian Health Care*, 2002, <http://rcpsc.medical.org/publications/building_a_safer_system_e.pdf> (accessed November 28, 2005).

²David U and Sylvia Hyland, "Pharmacists' role in preventing medication errors with potassium chloride," *California Journal of Health Promotion* 55, No. 4 (2002): 278-280, <<http://www.ismp-canada.org/download/cjhp0209.pdf>> (accessed November 28, 2005).

³Canadian Patient Safety Institute, *Canadian Patient Safety Institute - Home*, 2005, <<http://www.patientsafetyinstitute.ca>> (accessed November 28, 2005).

⁴Canada, Saskatchewan, Saskatchewan Health, 2005, <<http://www.health.gov.sk.ca>> (accessed November 28, 2005).

⁵Institute for Safe Medication Practices Canada, *Institute for Safe Medication Practices Canada*, 2005, <<http://ismp-canada.org>> (accessed November 28, 2005).

recommendations and implementing actions for system improvement. The approach is built on the premise that patients, direct care providers, senior management, members of the board, and representatives of key external organizations, all play a role in improving the system. Their roles and terms of participation must be clearly described and supported as the tool is implemented.

Like all tools, this framework should be reviewed to determine what is required for successful implementation and operation in your workplace. The framework is not a substitute for professional legal advice, or professionals with expertise in RCA (either internal or external). The participation of these professionals is therefore required as the process is locally adapted, implemented and operated. Successful local implementation also relies on a broader organizational commitment to moving beyond a culture of blame and building a culture of patient safety. An RCA framework is only one component of this commitment that must also include supportive reporting and disclosure policies, and a quality improvement/risk management infrastructure that enables the applicable processes and activities.

Introduction

The provision of healthcare services occurs in a complex environment with even the simplest of procedures often requiring multiple steps and multiple provider interactions with intricate and ever evolving technology.

Adverse Events in Canada

In May of 2004, the Canadian Medical Association Journal published results from The Canadian Adverse Events Study which was led by Dr. Ross Baker and Dr. Peter Norton.⁹ Adverse events were defined in the study as unintended injuries or complications resulting in death, disability or prolonged hospital stay that arise from healthcare management. The study reviewed 3,745 medical charts across five Canadian provinces and revealed an adverse event rate of approximately 7.5 per cent of medical/surgical admissions in acute care hospitals in the year 2000. The investigators determined that 36.9 per cent of the adverse events were preventable.

A high proportion of adverse events (64.4 per cent) resulted in no injury to patients. Unfortunately, 5.2 per cent of all adverse events resulted in permanent disability and 1.6 per cent were associated with patients who subsequently died.

Definition

The Canadian Patient Safety Dictionary recommends “that adverse events be defined in one of three way[s]:

1. An unexpected and undesired incident directly association with the care or services provided to the patient;
2. An incident that occurs during the process of providing health care and results in patient injury or death;
3. An adverse outcome for a patient, including an injury or complication”¹⁰

“Canadians deserve the safest health system in the world and work is underway across the country and throughout the health sector to realize this goal”

Canadian Patient Safety Institute⁶

“We believe that people come to work to do a good job not to do a bad job. Given the right set of circumstances, any of us can make a mistake. We must force ourselves to look past the easy answer of assigning blame and identify strategies and actions that really help our patients.”

Veterans Affairs NCPS, 2005⁷

“Urging clinicians to be more careful, cautious, or vigilant accomplishes little. Without changes to our approach, we will, like Alexander the Great, continue to slash through the knot instead of carefully untangling it.”

Dr. Pat Croskerry⁸

⁶ Canadian Patient Safety Institute, *Building the Foundation for a Safer Health System: Strategic Business Plan 2004/2005-2007-2008* (Edmonton: Canadian Patient Safety Institute, 2004).

⁷ Department of Veterans Affairs, National Center for Patient Safety, Challenges and Achievements, <http://www.patientsafety.gov/NEWS/NCPSBq/bg_NCPSChallenges_040904.doc>, (accessed February 3, 2006).

⁸ Pat Croskerry, “Cognitive forcing strategies in clinical decision making,” *Annals of Emergency Medicine* 41, No. 1 (2003): 116-120.

⁹ G. Ross Baker et al., “The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada,” *Canadian Medical Association Journal* 170, No. 11 (2004): 1678-86, <<http://www.cmaj.ca/cgi/reprint/170/11/1678>> (accessed November 28, 2005).

¹⁰ Royal College of Physicians and Surgeons of Canada, Jan M. Davies, Philip Charles Hébert and Carolyn Hoffman, *Canadian Patient Safety Dictionary* (Ottawa: The Royal College of Physicians and Surgeons of Canada, 2003), page 40, <http://rcpsc.medical.org/publications/patientsafetydictionary_e.pdf> (accessed November 28, 2005).

All staff, even the most experienced and dedicated professionals can be involved in potentially preventable adverse events. When an adverse event occurs and individuals are singled out and blamed, other healthcare providers may stop providing information about that, and other, adverse events within their organization. The discussion and evaluation of these events will be driven underground, potentially creating a culture of secrecy within the healthcare organization. This approach only serves to jeopardize public safety and, ultimately, undermine confidence in our healthcare systems.

Untangling the knot of patient safety involves accepting the fallibility of humans and investigating potential contributing factors in all areas of the healthcare system.

The Canadian Patient Safety Dictionary defines a system as:

- “1. a grouping of components, such as resources and organizations (Structure),
2. that act together (Process),
3. to achieve a particular result (Outcome).”¹¹

When an adverse event occurs, Slee, Slee and Schmidt¹² describe that there is a:

“tendency on the part of some individuals to take an either - or position, to the effect that one need only be concerned with one of the three dimensions [of a system]. This tendency is not logical; all three must be considered. Clearly certain structure is needed; and equally clearly, there is no way to change outcome except through changing process, since outcome ‘tells on’ process.”

Often the aspect that individuals focus on is the outcome of a situation, such as a medication error or a patient injury. Instead of focusing on the outcome, individuals should seek to understand and address the circumstances in the structure (perhaps the design and location of the medication room) and process (such as pharmacy and nursing workloads). The systems approach to examining adverse events acknowledges the basic premise that humans will make errors but also recognizes that factors in the work environment, such as fatigue, distraction and heavy workload, contribute to the likelihood of these errors.¹³

A Systems Approach

Understanding the complexities and issues within the healthcare system is fundamental to targeting effective analysis and improvement strategies. The point when healthcare services are delivered to the patient can be referred to as the “sharp end” of the system. The “blunt end” of the system represents the broader management, organizational and regulatory factors involved in the system. It includes a wide variety of factors such as policies and procedures, information technology systems, staffing patterns, and the physical structure of the place of care (see Figure 1 below).

To understand why an adverse event occurs in the “sharp end”, it is necessary to examine and analyze the contributing factors in the “blunt end”.

Root cause analysis was first used in engineering and other service sectors, such as the aviation and aerospace industries¹⁴ because they recognized the need to develop strategies to address high-risk activities. The engineering sector benefits from a wealth of hard data to help determine the facts and contributing factors leading to an adverse event. Healthcare is similar to these industries in its reliance on complex interactions and communication. However, healthcare currently does not have hard data to analyze and the dynamic nature of interacting with people and their disease processes varies dramatically, especially compared to an airplane, or any other static piece of equipment.

Individuals and organizations interested in the advancement of patient safety have adapted the RCA process, and in many cases the lessons learned, to the healthcare setting. They accept that RCA has limitations but recognize the enormous benefit that can be derived with thoughtful implementation on a case by case basis.

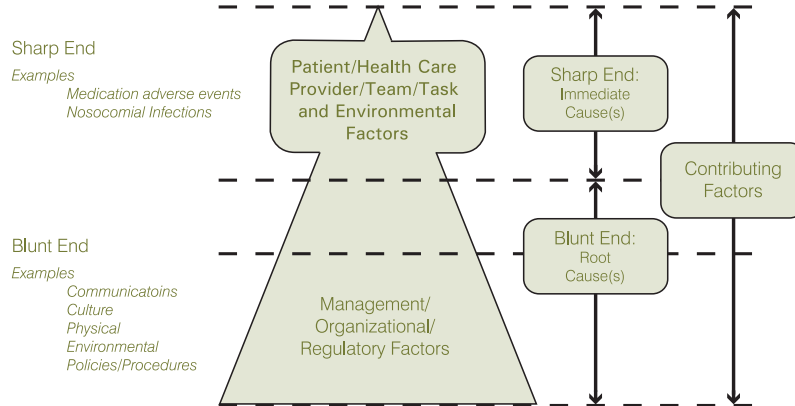
¹¹ Royal College of Physicians and Surgeons of Canada, Jan M. Davies, Philip Charles Hébert and Carolyn Hoffman, Canadian Patient Safety Dictionary (Ottawa: The Royal College of Physicians and Surgeons of Canada, 2003), page 13, <http://rcpsc.medical.org/publications/patientsafetydictionary_e.pdf> (accessed November 28, 2005).

¹² Vergil N. Slee, Debora A. Slee, and H. Joachim Schmidt, *Slee's Health Care Terms, 3rd Edition* (St. Paul: Tringa Press, 1996).

¹³ Department of Veterans Affairs, Veterans Health Administration, National Center for Patient Safety, Root Cause Analysis (RCA), <<http://www.va.gov/ncps/rca.html>> (accessed November 29, 2005).

¹⁴ J.H. Rex et al., “Systemic Root Cause Analysis of Adverse Drug Events in a Tertiary Referral Hospital,” *Joint Commission Journal on Quality Improvement* 26, no.10 (2000): 563-575.

Figure 1: Adapted from the NHS Report - Doing Less Harm, 2001¹⁵



Definition

We define root cause analysis as:

an analytic tool that can be used to perform a comprehensive, system-based review of critical incidents. It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans.

Definition

The Canadian Patient Safety Dictionary defines a critical incident as:

“an incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response”.¹⁶

The investigations into critical incidents and adverse events identify their contributing factors. The responses to these incidents/events include actions to be taken to reduce the likelihood of recurrence. Critical incidents are the most serious subset of adverse events, though not all adverse events are critical incidents. The definition of critical incidents purposely includes potential incidents, or incidents with a significant risk of serious harm, to ensure that close calls will be reviewed and opportunities for improvement can be identified before a patient is significantly harmed.

For the purposes of this framework, the term critical incident will be used to describe events requiring

further investigation through root cause analysis. However, some organizations may choose to describe these incidents using terms such as “sentinel event,” “serious adverse event” or “critical clinical occurrence.”

Though the investigation techniques described in this framework are most commonly applied to critical incidents, it is important to note that they may be applied to incidents of a less serious nature that potentially require system improvements.

The RCA tool can be used in any setting throughout the continuum of healthcare, though it is most commonly associated with acute care environments. In Saskatchewan, mental health, long-term care, emergency medical services, acute care, home care services, and rehabilitation medicine have all benefited from the use of RCA.

Provincial Incident Reporting and Investigation Legislation

Saskatchewan

The government of Saskatchewan passed legislation requiring the reporting and investigation of critical incidents in healthcare as of September 15, 2004. These provincial guidelines define a critical incident as:

“a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service provided by, or a program operated by, a regional health authority (RHA) or a healthcare organization (HCO)”.¹⁷

¹⁵ National Health Service, Department of Health, National Patient Safety Agency, Doing Less Harm: Improving the Safety and Quality of Care Through Reporting, Analyzing and Learning From Adverse Incidents Involving NHS Patients - Key Requirements for Health Care Providers, August 2001 <<http://www.health.vic.gov.au/clinrisk/nhsrisk.pdf>> (accessed November 29, 2005).

¹⁶ Royal College of Physicians and Surgeons of Canada, Jan M. Davies, Philip Charles Hébert and Carolyn Hoffman, Canadian Patient Safety Dictionary (Ottawa: The Royal College of Physicians and Surgeons of Canada, 2003), <http://rcpsc.medical.org/publications/patientsafetydictionary_e.pdf> (accessed November 28, 2005).

¹⁷ Canada, Saskatchewan, Saskatchewan Critical Incident Reporting Guideline, 2004, 2004, <http://www.health.gov.sk.ca/mc_sk_ci_rep_guideline_2004.pdf> (accessed November 28, 2005).

Subsequent to this decision to report and investigate critical incidents, the need to build capacity in local jurisdictions and to ensure that identified issues would be thoroughly addressed, was recognized. The Regina Health District formally implemented RCA in 1998 as a tool to examine critical incidents. Beginning in 2002, RCA was adopted and taught provincially as the preferred method for investigating critical incidents and recommending system improvements in Saskatchewan healthcare.

Manitoba

The Manitoba government passed legislation in 2005 to amend the Regional Health Authorities Act and the Manitoba Evidence Act. The amendments require that critical incidents be reported and define a critical incident as an:

*“unintended event that occurs when health services are provided to an individual and result in a consequence to him/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 service”.*¹⁸

Note that this definition does not include near misses and requires an individual to suffer a serious and undesired consequence to be considered a critical incident.

According to the new provincial legislation, if a critical incident occurs in Manitoba, the regional health authority, health corporation, or prescribed healthcare organization, must ensure that appropriate steps are taken to fully inform the individual of the:

1. facts of what actually occurred;
2. consequences of the critical incident, as they become known; and
3. actions taken, and the actions that will be taken, to address the consequences of the critical incident. A complete record of the critical incident must be made promptly and must be made accessible to the individual(s) involved.¹⁸

This legislation also established requirements for reporting and investigating a critical incident. The health corporation, or prescribed healthcare organization, must:

1. notify the regional health authority, who then must notify the provincial health Minister of the critical incident;
2. consult with the regional health authority and establish a critical incident review committee to investigate and report the critical incident. This committee has the power to compel the production of information, including personal health information; and
3. provide the report of the critical incident review committee to the regional health authority and the provincial health Minister.

Quebec

The Quebec government also has legislation surrounding institutional disclosure and risk management activities related to the provision of safe health services. This legislation, An Act respecting health services and social services¹⁹, was passed in December 2002. It requires disclosure of an accident or incident that occurred during the delivery of healthcare and that could have consequences to the health of an individual. The executive director, or his/her designate, must report all incidents and accidents to the regional board, without identifying a facility, patient, etc. An incident, as defined by the Act¹⁹, is:

“an action or situation that does not have consequences for the state of health or welfare of a user, a personnel member, a professional involved or a third person, but the outcome of which is unusual and could have had consequences under different circumstances.”

The Act further requires the creation of a risk and quality management committee to identify and analyze incident or accident risks, ensure support is provided to the patient, establish a monitoring system for the purpose of analyzing the cause of incidents and accidents, and subsequently prevent such incidents and accidents from recurring.

Reporting and Root Cause Analysis in the United States

The United States Veterans Affairs National Center for Patient Safety (NCPS)²⁰ has worked extensively to develop RCA as an effective tool for systematically identifying

¹⁸ Canada, Manitoba, Manitoba Evidence Act, R.S.M. 1987, c.E150, ss.9, 10 (C.C.S.M., c.E150), <<http://web2.gov.mb.ca/laws/statutes/index.php>> (accessed November 28, 2005).

¹⁹ Canada, Quebec, An Act respecting health services and social services, R.C.Q., c.S-4.2, ss. 183.1, 183.3, 183.4, 190, 213, 214, 218.

²⁰ Department of Veterans Affairs, Veterans Health Administrators, National Center for Patient Safety, VA National Center for Patient Safety, 2005, <<http://www.patientsafety.gov>> (accessed November 28, 2005).

problems and analyzing critical incidents to generate system improvements. A number of the processes and techniques in the Canadian Root Cause Analysis Framework have been made available through the generosity of Dr. James Bagian, Director of the NCPS, and are based on his international experiences in RCA.

Reporting and Root Cause Analysis in the United Kingdom

The National Patient Safety Agency (NPSA) in the United Kingdom was created to co-ordinate the efforts of all those involved in healthcare and, more importantly, to learn from patient safety incidents occurring in the National Health Service (NHS).

The NPSA is committed to finding ways to help NHS healthcare organizations understand the underlying causes of patient safety incidents and to formulate plans for improving safety. Root cause analysis is defined in the NPSA's RCA Model as:

*“a retrospective review of a patient safety incident, undertaken to identify what, how and why it happened. The analysis is then used to identify areas for change, recommendations and sustainable solutions, to help minimise the re-occurrence of the incident type in the future”.*²¹

This RCA Model was used as a reference in the development of the Canadian Root Cause Analysis Framework.

Accreditation and Patient Safety in Canada

The Canadian Council on Health Services Accreditation (CCHSA) has long recognized the importance of patient safety and identified it as a priority for member organizations in its accreditation standards.²² In 2003, patient safety became a key determinant in the accreditation decision process. Subsequent work resulted in the selection of five priority areas and six specific goals for improving patient safety²³:

Culture

1. Create a culture of safety within the organization.

Communication

2. Improve the effectiveness and coordination of communication among care/service providers and with the recipients of care/service across the continuum.

Medication use

3. Ensure the safe use of high-risk medications.
4. Ensure the safe administration of parenteral medications.

Work life/work force

5. Create a work life and physical environment that supports the safe delivery of care/service.

Infection control

6. Reduce the risk of health service organization-acquired infections, and their impact across the continuum of care/service.

Required Organizational Practices (ROPs) were developed for each of these goals.

The CCHSA has also developed a list of sentinel events that are “related to system or process deficiencies, [that can lead] to death or major and enduring loss of function for a recipient of healthcare services”.²⁴

CCHSA expects each member organization to implement a reporting system for adverse events that includes a defined process for reporting sentinel events internally, and to outside organizations, as applicable. Standard 10.0 of the Leadership and Partnerships section states, “The governing body and managers prevent and manage sentinel events.”²⁵ To meet this standard, CCHSA expects an organization to investigate the causes that contributed to a sentinel event, and to make changes to its systems and processes to prevent a similar event in the future. The investigation may be “a root cause analysis or another appropriate form of investigation.”²⁶

²¹ National Health Service, National Patient Safety Agency, Exploring Incidents - Improving Safety: a Guide to Root Cause Analysis From the NPSA, 2005, <<http://www.msnpa.nhs.uk/rcatoolkit/course/index.htm>> (accessed November 28, 2005).

²² Canadian Council on Health Services Accreditation, Canadian Council on Health Services Accreditation Standards.

²³ Canadian Council on Health Services Accreditation, CCHSA Patient Safety Goals and Required Organizational Practices - Communiqué #2: December 2004, December 2004, <<http://www.cchsa-ccas.ca/pdf/PSCommunique2.pdf>> (accessed November 28, 2005).

²⁴ Canadian Council on Health Services Accreditation, Reference Guide for Sentinel Events, <http://www.cchsa.ca/pdf/guideforsentinelevents_e.pdf> (accessed November 28, 2005).

²⁵ Canadian Council on Health Services Accreditation, Canadian Council on Health Services Accreditation Standards, Version 5, Leadership and Partnerships Standard 10.0.

²⁶ Canadian Council on Health Services Accreditation, of the Canadian Council on Health Services Accreditation Standards, Version 5, Leadership and Partnerships criterion 10.2.

Essentials of Root Cause Analysis

Knowing what adverse events occur is only the first step. Most adverse events result from a complex series of behaviours and failures in systems of care. Investigation of the patterns of adverse events requires unearthing the latent conditions and systemic flaws as well as the specific actions that contributed to these outcomes.

Dr. G. Ross Baker & Dr. Peter Norton²⁷

The goals of a root cause analysis are to determine:

- what happened;
- why it happened; and
- what can be done to reduce the likelihood of a recurrence.²⁸

Root cause analysis:

1. is inter-disciplinary, involving experts from the frontline services;
2. involves those who are the most familiar with the situation;
3. continually digs deeper by asking why, why, why at each level of cause and effect;
4. identifies changes that need to be made to systems; and
5. is impartial, in order to make clear the need to be aware of and sensitive to potential conflicts of interest.²⁸

To be thorough, a root cause analysis must involve:

1. an understanding of how humans interact with their environment;
2. identification of potential problems related to processes and systems;
3. analysis of underlying cause and effect systems through a series of why questions;
4. identification of risks and their potential contributions to the event;
5. development of actions aimed at improving processes and systems;

6. measurement and evaluation of implementation of these actions; and
7. documentation of all steps (from the point of identification to the process of evaluation).²⁸

To be credible, a root cause analysis should:

1. include participation by the leadership of the organization and those most closely involved in the processes and systems;
2. be applied consistently according to organizational policy/procedure; and
3. include consideration of relevant literature.²⁸

Root cause analysis is an analytic tool that helps healthcare providers perform a comprehensive, system-based review of significant incidents. An effective foundation for RCA incorporates a strong understanding of relevant legislation and human factors engineering, as well as clear and consistent organizational policies and procedures.

Healthcare Quality Improvement Legislation

Each jurisdiction in Canada has applicable legislative and regulatory frameworks which detail the processes to improve the quality of healthcare services. An overview of legislative protection for quality of care information is provided in Appendix A to highlight its importance and relevance to those individuals and organizations conducting an RCA. The information is accurate as of the date of publication; however, it is subject to change over time. Examples are included only to help explain key concepts.

The information presented in this tool is not intended as a substitute for legal advice. It is imperative that a committee which seeks protection for confidential discussions be established in accordance with all legislative stipulations, to address the risk of being compelled to disclose information. Legal counsel should be consulted to interpret the governing legislation applicable to each jurisdiction.

Root cause analysis is based on an inter-disciplinary approach, with involvement of those closest to the process. It works best in a confidential environment

²⁷ G. Ross Baker and Peter G. Norton, "Next steps for patient safety in Canadian healthcare," *Healthcare Papers* 5, no. 3, (2004): 75-80.

²⁸ Adapted From: Department of Veterans Affairs, Veterans Health Administration, National Center for Patient Safety, Root Cause Analysis (RCA), <<http://www.va.gov/ncps/rca.html>> (accessed November 28, 2005).

where designated persons can collect, analyze, and share information. Quality of care protection is meant to create a confidential environment where discussions and documentation are protected and cannot be disclosed in a legal proceeding. As such, a key step in RCA is to identify the body that will have overall responsibility for the analysis and to determine whether that body should be designated as a quality of care committee.²⁹ Designation as a quality of care committee provides a type of privilege³⁰ for documents and discussions related to the committee process.

The following issues should be considered when establishing committees for root cause analysis.

A. What type of healthcare body is establishing the committee?

Some legislation limits protection to quality of care committees created by hospitals. In others, protection is granted to quality of care committees created by other healthcare bodies. Some jurisdictions permit the provincial health Minister to designate quality of care committees.

For example, under Ontario's Quality of Care Information Protection Act,³¹ hospitals and other health facilities may create quality of care committees. In Alberta, committees may be appointed by a number of different bodies including a regional health authority, the Alberta Cancer Board, the Alberta Mental Health Board, the board of an approved hospital, or the operator of a nursing home. In New Brunswick, the Evidence Act³² provides protection for committees established by hospital corporations.

Both Alberta and British Columbia provide examples of the provincial health Minister designating quality of care committees by regulation. The committees designated in British Columbia are the following:

- a) the Industry Reference Group on Notification or Lookback related to Hepatitis C/HIV (composed of representatives from hospitals, the University of British Columbia, the Centre for Disease Control, and the Ministry of Health);

- b) the Perinatal Mortality Review of the British Columbia Reproductive Care Committee (composed of a wide variety of representatives including hospitals, government, the College of Physicians and Surgeons of British Columbia, and the British Columbia Reproductive Care Program); and
- c) the Critical Incident Report Subcommittee of the Quality Assurance Committee of the British Columbia Anaesthetist's Society.

The provincial health Minister in Alberta has named the following committees as quality of care committees:

- a) the Committee on Reproductive Care established by the Alberta Medical Association;
- b) the Physicians Performance Committee established by the College of Physicians and Surgeons of Alberta;
- c) the Perinatal Morbidity Review Committee established by the Northern and Central Alberta Perinatal Program Advisory Committee; and
- d) the Ambulance Medical Review Committee.

B. Whose communications are protected?

Generally, communications relating to quality of care that do not involve a care committee are not entitled to protection.

For example, Ontario's Quality of Care Information Protection Act³¹ only protects information prepared by, or for, a committee that has been designated as a quality of care committee. Before acting as a quality of care committee, it must be designated as such in writing by the health facility or entity that established, appointed, or approved it. The terms of reference of the committee and its designation must be publicly available.

C. What communications and information are protected?

Protection is generally extended to information, documents and opinions. In some statutes, only documents that have been prepared exclusively or primarily for the quality of care committee will receive protection.

²⁹ There are a variety of terms used in legislation to identify committees that receive protection for confidential discussions. For example, Alberta and Saskatchewan use the term "quality assurance committee" while Ontario uses the term "quality of care committee." In other jurisdictions, there is no definition of "committee" but the functions of the committee are set out in legislation (see, for example, the *Evidence Act*s for New Brunswick and Nova Scotia). For ease of reference, the term quality of care committee will be used throughout this document.

³⁰ Generally, relevant information must be disclosed in the course of a civil action unless it is "privileged." The main classifications of privilege include solicitor-client and litigation privilege. Communications between a lawyer and client are protected from disclosure. Litigation privilege applies when information is generated for the predominate purpose of litigation.

³¹ Canada, Ontario, Quality of Care Information Protection Act, 2004, 2004, S.O. 2004, c.3, Sched. B, <http://www.e-laws.gov.on.ca/dblaws/statutes/english/o4qo3_e.htm> (accessed January 26, 2006).

³² Canada, New Brunswick, Evidence Act, R.S.N.B. 1973, c.E-11, s.43-3, <<http://www.canlii.org/nb/laws/sta/e-11/20051114/whole.html>> (accessed January 27, 2006).

For example, the Saskatchewan Evidence Act³³ does not protect facts, including newly discovered facts not found in the patient record. As well, protection is extended to reports, documents or records that are:

- (i) prepared exclusively for the use of, or made by, a committee; or
- (ii) used exclusively in the course of, or arising out of, any investigation, study or program carried on by a committee.

Nova Scotia's Evidence Act³⁴ does not employ a dominant purpose or exclusivity test. Under Ontario's Quality of Care Information Protection Act,³¹ information that is collected by, or prepared for, a quality of care committee is protected if it was prepared for the "sole or primary purpose" of assisting the committee; or when it relates "solely or primarily to any activity" of the quality of care committee.

D. What committees are protected?

Some statutes identify protected committees according to their purpose, while others only provide protection for particular committees established by statute. The activities of ad hoc committees or individuals acting outside of bylaws or other established parameters are not likely to be protected. In some jurisdictions, official designation is required for a committee's communications to receive protection. To ensure transparency, it is advisable that quality of care committees be designated by resolution of the organization's board or senior management, consistent with the hospital's by-laws and structure on creating committees.

For example, Prince Edward Island's Medical Act³⁵ describes the purpose and composition of, and provides protection for, the Peer Assessment Committee. The Saskatchewan Evidence Act³³ specifically states that the board of governors or the bylaws of a hospital must designate the committee.

E. What is the subject of the communication at issue?

Generally, statutes require that a committee's activity be motivated by the desire to improve healthcare services.

For example, for committees to be established and protected under Ontario's Quality of Care Information Protection Act³¹ they must have a view to improve or maintain: 1) the quality of healthcare, or 2) the level

of skill, knowledge, or competence of the healthcare provider. Under Quebec's Act Respecting Health Services and Social Services¹⁹, an institution must establish a risk and quality management committee that seeks, develops, and promotes ways to identify and analyze incident or accident risks to ensure the safety of users.

F. Who is seeking the quality assurance records?

Some statutes protect quality assurance records from subpoena, discovery, or disclosure in an action, while other laws provide broader protection.

For example, The Alberta Evidence Act³⁶ states that a witness in an action is not liable to be asked, and shall not be permitted to answer, any question before a quality assurance committee. Additionally, the witness is not liable to be asked to produce, and shall not be permitted to produce, any quality assurance record in the committee's possession or under the committee's control. Ontario's Quality of Care Information Protection Act³¹ provides that quality of care information may only be disclosed to management if the committee considers it appropriate for the purposes of improving or maintaining the quality of healthcare provided in the hospital. The information may also be disclosed if it will eliminate or reduce a significant risk to a person or group of persons. Quebec's Act Respecting Health Services and Social Services¹⁹ provides that no person may have access to the minutes of the committee except the committee members, the representatives of accreditation bodies or the representatives of a professional order.

The following steps should be taken after a committee has been established to conduct a root cause analysis (either by the committee itself or by another ad hoc group):

- Once policies for committee records are in place, all personnel involved in committee activities should be educated as to the importance of following those policies meticulously. All participants in a quality of care review should be reminded that it is a privileged and confidential review that is being conducted for quality of care purposes.
- All quality of care committee minutes should be prepared carefully and in accordance with the provincial legislation. Committee minutes should

³³ Canada, Saskatchewan, Saskatchewan Evidence Act, S.S. 1989-90, c. 57, s.35.1, <<http://www.qp.gov.sk.ca/documents/english/statutes/statutes/s16.pdf>> (accessed January 26, 2006).

³⁴ Canada, Nova Scotia, Evidence Act, R.S.N.S. 1989, c. 154, ss.60, 61, <<http://www.canlii.org/NS/laws/sta/r1989c.154/20051216/whole.html>> (accessed January 26, 2006).

³⁵ Canada, Prince Edward Island, Medical Act, R.S.P.E.I. 1998, c.M-5, s.38.7., <<http://www.canlii.org/pe/laws/sta/m-5/20051216/whole.html>> (accessed January 27, 2006).

³⁶ Canada, Alberta, Alberta Evidence Act, R.S.A. 2000, c.A-18, s.9., <<http://www.canlii.org/ab/laws/sta/a-18/20051114/whole.html>> (accessed January 27, 2006).

document conclusions, and not the details of the actual discussion or personal comments made by committee members.

- All documentation that is created should clearly state that it is a privileged and confidential quality of care review document.

Appendix B contains an Administrative Policy and Procedure prepared by Capital Health in Nova Scotia for the Management of Serious Clinical Occurrences. It illustrates how RCA may be conducted within the broader context of quality of care review, and thereby receive legal protection for confidential discussions.

Human Factors Engineering

Human factors engineering is a branch of engineering that specializes in understanding how humans interact with the world around them. It draws upon applied research in many areas, such as biomechanics, kinesiology, physiology and cognitive science, to define the parameters and constraints that influence human performance. This specialized knowledge is used to design efficient, human-centred processes to improve reliability and safety.

Historically, when a critical incident occurred, the tendency was to look for the most obvious explanation of what and why it happened. In most cases, individual human error was identified as the cause, primarily because it was easy to identify and appeared to be easy to fix. This approach ignored the contributing factors that led to the error and thus presented a shallow analysis of the event. The outcome of such an analysis may have included the creation of new policies/procedures, additional training, disciplinary action and/or an expectation of increased personal vigilance. The focus was almost exclusively directed at improving individual performance. This approach was likely not successful in preventing the same or a similar error from occurring again.

Patient safety experts are strongly advocating a new way of thinking that views human error as only the symptom of broader issues within a poorly designed system, such as an adverse physical or organizational environment. Dekker³⁷ has labeled the two views as an old and new view of human error. In the old view, failure is sought and the objective is to find the individual's inaccurate assessments, wrong decisions and bad judgment. In the new view, the objective is not to find where the person went wrong, but instead assesses the individual's actions

within the context of the circumstances at the time. A deeper inquiry into the circumstances will yield system issues.

The RCA process presented in this framework adopts the new view. It recommends the use of human factors engineering to determine what happened, why it happened and what can be done to try to reduce the likelihood of a recurrence. Human factors engineering builds upon the systems approach, which highlights the fact that human performance, and therefore the occurrence of errors, is influenced by many factors in a system. This knowledge can be used to design systems so that they are compatible with human characteristics. When they are not compatible, human performance can be adversely affected, sometimes resulting in an error. In RCA, an understanding of human factors can help to identify incompatibilities, thereby forming a deeper understanding of the root causes of an event. Understanding how these factors influence human performance is critical to identifying effective, long-lasting corrective strategies.

Finding root causes embedded in flawed systems requires targeted strategies. Knowledge of the human factors involved is both useful and important when asking questions during the RCA process and can help the RCA team focus on issues related to systems and not on individual performance.

The RCA model developed by the U.S. Veterans Affairs National Center for Patient Safety¹³ incorporates a number of very useful Triage and Triggering Questions³⁸ on communications, training, and fatigue and work scheduling, which are based on human factors principles. The questions below are examples of pertinent open-ended queries which can help move RCA from immediate, “sharp end” causes, towards “blunt end” root causes and contributing factors.

- **Communication question:** Was information from various patient assessments shared and used by members of the treatment team on a timely basis?
- **Training question:** Had procedures and equipment been reviewed to ensure that there was a good match between people and the tasks they did; or people and the equipment they used?
- **Fatigue/scheduling question:** Was there sufficient staff on-hand for the workload at the time?

Please refer to the Triage and Triggering Questions in Appendix C for other triggering questions.

³⁷ Sidney Dekker, *The Field Guide to Human Error Investigations* (Aldershot: Ashgate Publishing Limited, 2002).

³⁸ Department of Veterans Affairs, Veterans Health Administration, National Center for Patient Safety, “NCPS Triage Cards™ for Root Cause Analysis,” VA National Center for Patient Safety, <<http://www.va.gov/ncps/safetytopics/coaids/triage/index.html>> (accessed November 28, 2005).

Solutions or actions taken to address root causes/ contributing factors should also incorporate human factors engineering. Strong, permanent actions involving physical and system changes should be developed that consider human limitations and capabilities. Forcing functions and constraint functions are at the top of the effectiveness hierarchy when considering system change.

Cohen³⁹ defines a forcing function as “a design feature that makes it impossible to perform a specific erroneous act.” For example, different sizes of line fittings have been designed for each medical gas used in the operating room. The specialized fittings make it impossible to connect the wrong gas line to the equipment that delivers the gas to the patient because each line has a unique coupling that will not connect with another.

A constraint function is defined here as a withholding step where a system process makes it improbable that a specific erroneous act will be performed. An example of a constraint function is removing concentrated potassium chloride from patient care areas. Taking this action, and enforcing the removal, makes it less likely the drug will be administered by direct intravenous injection because the medication is not available for a nurse to select in error.

Forcing and constraint functions are strong and effective measures because they acknowledge the fallibility of human beings. They make it hard to do the wrong thing while making it easier to do the right thing.

We encounter human factors every day in almost everything we do. Recognizing and addressing human limitations in the design of safer systems is essential. An effective RCA always incorporates human factors engineering. To put it in a proper context, human factors engineering is to root cause analysis what microbiology is to infection control. They fit each other well, like a hand in a glove.

Individuals and organizations can develop their human factor engineering expertise by incorporating local experts into the RCA team and/or considering relevant literature on the process being reviewed. Experts may be identified by contacting relevant faculties at universities and related corporate operations.

Organizational Policy and Procedure

Pressure to act can mount quickly when a patient experiences a critical incident. Organizations can best handle the situation if they can initiate a clear sequence of events as soon as possible.

Care for the Patient

Immediately following a serious adverse event or critical incident, staff should take necessary steps to care for the patient, make the situation safe and prevent imminent recurrence of the event.

Secure Articles

Staff should also make sure that any articles related to the event are labelled and secured so that the materials and workplace will be available for RCA team members (or others) to review after the fact. They should place relevant items, including but not limited to: biomedical equipment, IV solutions, bottles, packaging, containers, garments, and sharps, in a designated location, or to a designated person, protect, secure and restrict access to rooms. Photographs of items involved and the workspace may prove helpful. Staff should also record lot numbers or serial numbers in the event that a product recall or further testing is required.

Health records staff should secure the original health record and control access to it immediately following notification of the event. The ward or unit should receive a copy of the chart if the patient is receiving ongoing inpatient care.

Disclosure

The needs of the patient and family for accurate and timely information must be duly considered. Facts should be disclosed to the patient or their designate as soon as reasonably possible after the event, in keeping with legislative requirements as well as local policy. The patient may provide further insight into the critical incident and the system in which it occurred. Including details of the patient’s experience in the RCA process offers yet another valuable perspective on the system.

When conducting a family meeting, it is advisable to provide as many known facts as possible. **Do not speculate about the cause of the event, especially in the early stages of fact gathering.** Ideally, the family should receive all known facts and be engaged in a discussion of how the organization will review the incident.

³⁹ Michael R. Cohen, *Medication Errors* (Washington, D.C.: American Pharmaceutical Association, 1999).

While this manual is not meant to provide detailed discussions of disclosure of harm to patients, this is a broader component of resolving critical incidents and adverse events. Patients, or their designates, should be notified of critical incidents and adverse events related to the provision of healthcare services. Refer to Appendix D for the Saskatchewan Health Disclosure of Harm Guideline as an example of a provincial disclosure framework. A variety of healthcare organizations, including the Canadian Medical Association and the Canadian Nurses Association, have also directed the practice of disclosing adverse events to patients.

Patients, or their designates, may request a follow-up meeting after the initial disclosure meeting occurs. Frequently, they wish to ensure that the critical incident has been thoroughly reviewed and that system changes have been implemented to reduce the likelihood of recurrence.

Each organization, in collaboration with the healthcare professionals involved, must determine what information will be released and what will be considered privileged and therefore protected from disclosure. The organization should seek the advice of legal counsel when making these types of decisions.

Table 1: Notification

The Notification Table is included only as an example. Refer to organizational disclosure policies and applicable provincial guidelines/policy/legislation.

NOTIFICATION TO:	NOTIFICATION BY:	TIMEFRAME
Attending physician	Unit or program manager; in-charge nurse for the unit or service; and/or designated management personnel	As soon as possible after the event
Client/patient and/or designates (and ensure that their needs are being met) *	The attending healthcare professionals should determine who will notify (i.e. physician and in-charge nurse, etc.) and how family members should be involved in the discussions.** Note: it is recommended that notification be made in the presence of two people for medico-legal reasons	As soon as possible after the event
Internal notifications: CEO, chief of staff, senior nurse leader, risk management (and legal counsel where applicable), quality specialist, client advocate, and other notification requirements as per organizational policy or protocols	Unit or program manager and/or designated management personnel	As soon as possible after the event
External notifications as per legislation and/or policy or protocols. Potential reporting includes Provincial Ministry of Health, coroner, legal counsel/ insurer and Health Canada – Therapeutic Products Directorate as applicable	Physician, in-charge nurse and/or designated management personnel	Immediate notification of coroner and others as soon as possible after the event
Health Region/district/facility communications and public affairs department	Quality specialist/risk management office/client advocate or designate	As appropriate

*Please refer to organizational disclosure policies and applicable provincial guidelines/ policy/ legislation.

**Notification to family members should be made only with the consent of the patient, or if the family member has the legal authority to represent and/ or act on behalf of the patient.

Notification

A number of stakeholders will require notification of the event (see Table 1). Depending on how the incident was identified, staff will need to make various care providers and levels of the organization's administration aware of the incident. They need to notify the attending physician as soon as possible and other internal notifications may include the CEO, risk management committee, medical managers, health records staff, and unit or program managers. If the event has been made public, staff may need to notify communications department personnel.

External notifications may include insurers or voluntary reporting structures such as the Canadian Medication Incident Reporting and Prevention System (CMIRPS) which is currently under development. Additionally there may be notifications that are mandated through legislation, such as the Office of the Coroner, Health Canada, and regulatory agencies.

A contact list, prepared in advance, will help ensure that both internal and external partners are appropriately notified about the critical incident as well as provided with the information they require to make decisions and take action.

Staff Discussion

The staff involved in a critical incident should be asked to refrain from discussing the incident outside of quality assurance processes. This is often a challenge, as involvement in this type of event can be traumatic for the healthcare providers and talking about it is a natural coping mechanism. There are appropriate forums for these discussions, including with the organization's critical incident stress management team. The team may involve peers, counselors, social workers or others. It is designed to provide necessary support, as the impact of a critical incident on a healthcare provider may be profound. The role of the critical incident stress management team is not to discuss the facts of the event, but to manage the psychosocial impact of the event on the care team. Alternatively, care providers can be encouraged to enlist the services of an employee assistance or counseling program.

Organizational Reporting

A systematic method of capturing information about adverse events, including the subset of critical incidents, is a key component of organizational risk management and quality improvement processes. Clear and consistent reporting policies and mechanisms assist the organization, and those working within it, to respond quickly and effectively to an event.

The Australian Advanced Incident Management System (AIMS) is one example of an error reporting system. Patient Safety International, a subsidiary of the Australian Patient Safety Foundation, developed the AIMS software tool to consistently capture information on incidents. AIMS captures information including close calls and critical incidents allowing for in-depth analysis of both types of events. AIMS is currently in use in over half the Australian public health system and allows a national comparison of critical incidents and appropriate interventions to reduce the risk of recurrences.

An event severity assessment or stratification step helps determine the appropriate level of response. The method of identifying, stratifying and reporting unusual incidents or occurrences should be widely known at all levels of the organization. Once completed, reports should be reviewed and categorized according to their severity.

There are a variety of methods for stratifying events for the purposes of deciding whether RCA should be undertaken. Below are two examples for consideration.

Example 1: Regina Qu'Appelle Health Region - Incident Classification System

The Regina Qu'Appelle Health Region stratifies incidents according to the following four-code scheme (as below), where some code three incidents, and all code four incidents, receive a RCA. Code one and code two incidents are trended and addressed using aggregate analysis, as appropriate.

Code 1: No known injury/no clinical significance.

Code 2: Minor self-limiting injury requiring basic first aid or short term monitoring. X-ray and lab tests (if performed) remain normal or unchanged. Examples are skin tear, bruise and first-degree burn.

Code 3: Actual adverse outcome occurs with successful intervention, or significant potential for adverse outcome. Examples include major injury such as fracture, major laceration requiring suturing and third degree burn. Additional occurrences of a code three include:

- wandering requiring police protection;
- certified patient who is absent without leave (AWOL);
- breach of confidentiality;
- loss of clinical records; and
- intended self harm (suicide attempt) while under care in a facility.

Code 4: Irreversible complications or death.

Example 2: U.S. Veterans Affairs National Center for Patient Safety - Severity Assessment Code

Another example of a stratification system is the Severity Assessment Code (SAC) Matrix used by U.S. Veterans Affairs.⁴⁰ The assessment table links the severity of the event with the probability of recurrence. An event with an SAC score of three indicates that an RCA is required. Events with an SAC score less than three may be analyzed in an aggregate way (see Table 2).

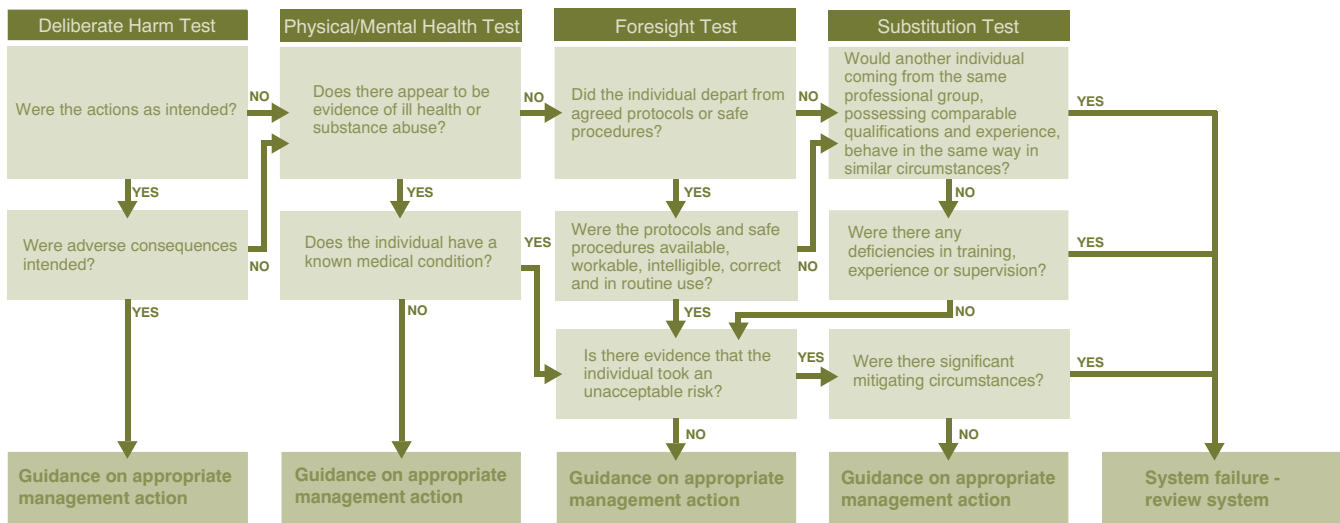
⁴⁰ Department of Veterans Affairs, Veterans Health Administration, National Center for Patient Safety, Patient Safety Improvement/RCA 101 Training, (Ann Arbor, MI: VA National Center for Patient Safety, 2005), 62.

Table 2: United States Veterans Affairs Severity Assessment Code

PROBABILITY	SEVERITY			
	Catastrophic	Major	Moderate	Minor
Frequent	3	3	2	1
Occasional	3	2	1	1
Uncommon	3	2	1	1
Remote	3	2	1	1

The National Patient Safety Agency (NPSA) in the United Kingdom has developed an interactive web-based incident decision tree, based on James Reason’s culpability model.⁴¹ The incident decision tree helps managers determine if an event is appropriate for system analysis.⁴² A sample of a completed incident decision tree is shown in Figure 2.

Figure 2: Incident Decision Tree



Based on James Reason's Culpability Model. © National Patient Safety Agency 2005

It is important to remember that reporting alone does not bring safety into the healthcare system.⁴³ Reporting needs to be coupled with an effective strategy to implement change as well as appropriate measurement tools to ensure that the change achieves the desired outcome.

In 2001, Dr. Ross Baker and Dr. Peter Norton published a conceptual model that outlines the relationship between the three processes (Figure 3).⁴⁴ Only when all three components are in place is there an effective strategy for system change. RCA is one important aspect of the “System Tools and Change Strategies” process. It is beyond the scope of this framework to provide detailed information related to “Culture” and “Measurement”; however, they are important aspects of the systems improvement process. “System Tools and Change Strategies” process.

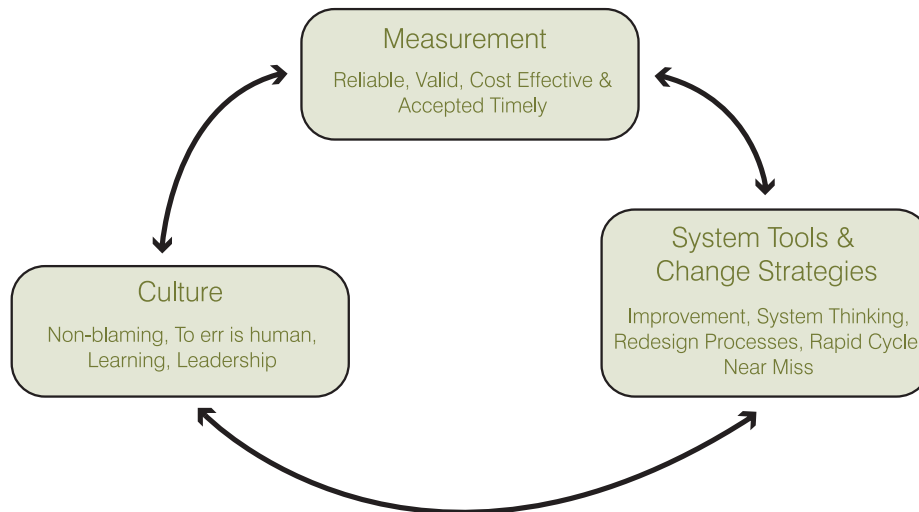
⁴¹ James Reason, *Managing the Risks of Organizational Accidents* (Aldershot: Ashgate Publishing Limited, 1997).

⁴² National Health Service, National Patient Safety Agency, Incident Decision Tree, 2005, <<http://www.msnpsa.nhs.uk/idthz/t330xuehltkez45dvinp245/help.aspx?JS=1>> (accessed November 28, 2005).

⁴³ M. Hume, “Changing hospital culture and systems reduces drug errors and adverse events,” *Quality Letter for Healthcare Leaders* 11, no. 3 (1999): 2-9.

⁴⁴ G. Ross Baker and Peter Norton, “Making Patients Safer: reducing errors in Canadian healthcare,” *Healthcare Papers* 2, no. 1 (2001): 10-31.

Figure 3: Conceptual Model of Effective System Change Strategy



Source: Baker, G.R. & Norton, P.

Improving Safety through Reporting

The Institute of Medicine's report *To Err is Human* (1999)⁴⁵ identified the need for a systematic method of reporting adverse healthcare events. As a result, the U.S. National Quality Forum was asked to develop a list of core events that are considered both serious and preventable in nature. The outcome was the creation of a consensus report that identified 27 serious and reportable events. The list was modified by Saskatchewan Health and is described in *The Saskatchewan Critical Incident Reporting Guideline, 2004*.¹⁷

Saskatchewan is an example of a province currently working to systematically improve reporting and patient safety by provincially sharing lessons learned in local jurisdictions. The process began with the Department of Health who, together with regulatory authorities and healthcare regions, reviewed the available options for sharing the lessons learned from RCA reviews. To make provincial reporting and sharing feasible, it was determined that the action items and recommendations arising from an RCA would require additional legal protection. The findings could then be transmitted to the Department of Health without concerns that the documents and/or discussions would be disclosed in a legal proceeding. To create this additional legal protection, the government decided to legislate the investigation and reporting of critical incidents.

Saskatchewan Health is committed to broadly disseminating applicable system improvement opportunities in a manner which does not identify individuals or individual facilities (known as being "de-identified"). Following the review of a critical incident, any recommendation that may be applicable in other regions is shared province-wide in the form of an Issue Alert. This Alert contains a general, de-identified, description of the circumstances surrounding the incident and the recommendations that are provincially applicable. The Issue Alert does not include any identifying details of the incident or the region in which the incident occurred.

The Institute for Safe Medication Practices Canada (ISMP Canada) collects and analyzes medication error reports and develops recommendations for the enhancement of patient safety. ISMP Canada serves as a national resource for promoting safe medication practices throughout the healthcare community in Canada. It accomplishes this through the dissemination of safety bulletins and promotion of safety tools such as Medication Safety Self-Assessment™, Analyze-ERR®, and educational workshops and consultations. ISMP Canada is a key partner with Health Canada and the Canadian Institute for Health Information (CIHI) in the new Canadian Medication Incident Reporting and Prevention System (CMIRPS).

⁴⁵ Institute of Medicine, Linda T. Kohn, *To Err Is Human*, (Washington, D.C.: National Academy Press, 2000).

Events Not Eligible for Root Cause Analysis

Reviewing critical incidents, and other adverse events, for potential improvement strategies may seem to be a common sense approach to quality improvement. However, in a setting with so many competing demands on services and providers, incidents in healthcare are often discussed but rarely reviewed in detail. Healthcare providers involved in the event may be left with a great sense of grief and frustration about the outcome. Occasionally, valuable and committed healthcare providers leave their profession.

It is paramount that all healthcare providers clearly understand how their organization will approach the review and follow up a critical incident. It is equally important that the organization consistently apply the processes fairly and in the manner they have previously indicated they would. Even one isolated deviation from the agreed upon process has the potential for reporting to be driven underground by caregivers fearing that they will be disadvantaged if they report an incident.

It is important to separate human resource processes, such as discipline, from a quality of care review. If staff involved in the critical incident believe that information provided to RCA facilitators will be used in a disciplinary forum, they are unlikely to be forthcoming with details of the incident. The concept of a “just culture” has been proposed, largely based on an organization “possessing a collective understanding of where the line should be drawn between blameless and blameworthy actions.”⁴⁶ Culture isn’t something that can be implemented solely based on policy or procedure; rather it needs to be consistently fostered over time.

“To promote a culture in which we learn from our mistakes, organizations must re-evaluate just how their disciplinary system fits into the equation. Disciplining employees in response to honest mistakes does little to improve overall system safety.”

David Marx,⁴⁷

Four types of incidents are not recommended for a multidisciplinary root cause analysis forum:⁴⁸

1. events thought to be the result of a criminal act;
2. purposefully unsafe acts (an act where care providers intend to cause harm by their actions);
3. acts related to substance abuse by provider/staff; and
4. events involving suspected patient abuse of any kind.

These types of situations may provide examples for system-based learning. However, the insights will relate to human resource processes (including individual performance management) and security systems. It is important to protect the integrity of the RCA process from a situation where there is probability of dismissal, disciplinary action, or criminal charges. These four specified types of incidents should be referred to a suitable administrative process and, where applicable, to a professional regulatory body for resolution. In circumstances where disciplinary or other administrative action has been taken, it is still possible to run a parallel RCA. However, it is imperative that information not be shared from one process to another and that all participants are aware of the distinction between the two processes.

Preparing for the Root Cause Analysis

A Team Approach

Each organization will determine how to operationalize the RCA framework and ensure consistent application of the methodology. Typically, a facilitator (with expertise in RCA) and a leader (with management responsibility, who understands and supports RCA) share primary responsibility for conducting, coordinating and reporting each RCA process in accordance with applicable organizational policies. See Appendix B for a sample policy provided by the Capital Health Authority in Halifax.

The success of this review depends on the involvement of the attending physician, consulting specialist(s), nurses, pharmacists, therapists and other providers who gave care related to the critical incident, either through the interview process or direct participation in the event analysis (on a voluntary basis). There are two key benefits to involving the healthcare providers in the RCA process.

⁴⁶ James Reason, “Human Error: Models in Management,” *British Medical Journal* 320 (2000): 768-70.

⁴⁷ David Marx, *Patient Safety and the ‘Just Culture’: a Primer for Health Care Executives, Report Prepared for MERS-TM (New York, NY: Columbia University, 2001).*

⁴⁸ Department of Veterans Affairs, Veterans Health Administration, National Center for Patient Safety, *Patient Safety Improvement/RCA 101 Training (Ann Arbor, MI: VA National Center for Patient Safety, 2005), 3.*

1. When the healthcare team comes together for a detailed examination of the events leading up to the incident they may, and often do, discover new information not previously known by all members of the care team.
2. RCA is an invaluable tool that permits healthcare professionals involved in an incident an opportunity to help create solutions to reduce the likelihood of similar incidents in the future. This allows them to impact the system they work in and to take ownership of changes, rather than to feel that senior management is forcing changes upon them.⁴⁹

“Without the strong support of upper management, root cause analyses may be performed in a perfunctory manner...It must be accepted throughout the organization that the results of any given root cause analysis will be for improving situations, not for assigning blame”

Berry and Krizek⁵⁰

Not all team members are required to be involved in and/or conduct all aspects of the RCA. For example, senior leadership representative(s) participate in the review as they have a key responsibility for the blunt end of the system. Their participation can demonstrate a commitment to change at the highest levels of the organization. Additionally, they often are responsible for overseeing the development and implementation of recommendations for system change. It is also useful to involve relevant external experts/consultants with specialized knowledge of the system undergoing review and/or the RCA process. It is important to clearly define the roles and responsibilities of all team members within each organization. See Table 3 for a summary of Team Member Roles and Responsibilities, and Appendix E for a more detailed description of the team membership.

Table 3: Team Member Roles and Responsibilities

ROLES / RESPONSIBILITIES	TEAM MEMBERS				
	Leader	Facilitator	Individuals Knowledgeable about Subject Area	Other Staff or Consultants	Senior Leadership
Knowledge of RCA process and techniques?	required	expertise in RCA*	familiar	familiar	familiar
In depth knowledge of subject area of review?	yes	may or may not	yes	yes	may or may not
Has <u>first hand</u> knowledge of adverse event and internal circumstances surrounding event?	no	no	may or may not	no	no
Authority for decision making and implementing recommendations?	may or may not	no	may or may not	no	yes
Adheres to principles of confidentiality?	required	required	required	required	required

** NOTE: the facilitator is typically an individual who has received education on RCA processes and either practical experience in participating/conducting an RCA or mentoring to the point of confidence in his/her own ability to lead an RCA. We refer to this combination of knowledge and self-confidence as having expertise in RCA.*

Some facilities complete a formal team chartering process to clearly outline the goals of the RCA and the roles of individual team members. Appendix F provides a sample of an RCA team charter memo from the U.S. Veterans Affairs National Center for Patient Safety.

⁴⁹ J. P. Bagian, et al., “Developing and deploying a patient safety program in a large health care delivery system: you can’t fix what you don’t know about,” *Joint Commission Journal on Quality Improvement* 27, no.10 (2001): 522-32.

⁵⁰ K. Berry and B. Krizek, “Root cause analysis in response to a ‘near miss,’” *Journal for Healthcare Quality* 22, No.2 (2000): 16-18.

Meetings

There are two main approaches to conducting a team-based RCA; a single meeting option and a multiple meeting option. The components of the RCA process are the same in both options.

Single Meeting

A facilitator collaborates with the leader and other members of the team to collect the necessary background information in advance of the RCA. At a mutually agreeable date and time, the facilitator (for example, director of quality initiatives, risk manager, other) outlines the meeting objectives and works with the group to:

- review and finalize the sequence of events or flowchart of final understanding;
- explore possible contributing factors; and
- develop contributing factor statements as well as recommendations for improvement.

The meeting is generally two to three hours in duration and a follow up session may be required.

Multiple Meetings

The facilitator and leader work with team members over several meetings (as many as necessary) to establish and complete the RCA process. Duties may be shared among the team members rather than pre-determined.

Setting and Department

All RCA meetings should take place in a comfortable, private room with adequate space for participants. Since the review generally requires a significant time commitment, refreshments are appreciated. A boardroom or a U-shaped table setting best facilitates team discussions.

It is recommended that all documentation provided to the team during the RCA meetings, including the sequence of events, be tracked and returned to the facilitator at the end of the review.

The facilitator sets the meeting tone at the outset by providing clear guidance on the team's mandate. The facilitator should reiterate that the review will address issues related to the system in which the event occurred and not issues related to the competencies of a specific individual. Occasionally, the review team will venture into blaming statements. If this occurs, the facilitator must terminate discussions of blame.

Confidentiality

During an RCA, the principle of confidentiality must be emphasized and maintained at all times. Some organizations require team members to sign



a confidentiality agreement (see Appendix G for an example). This agreement reinforces that information shared within the team is not to be transmitted or disclosed outside of the communication mechanisms stipulated by the Quality of Care Committee, applicable policies and/or legislation.

Ground Rules

A review of ground rules before beginning the RCA process helps outline expectations for the discussions. Suggested ground rules include the following:

- respect for individuals;
- respect for opinions expressed;
- equal participation by all;
- respect for the confidentiality of the discussions;
- ask questions to clarify rather than challenging others; and
- decisions by consensus.

Team Management

An experienced facilitator will be able to anticipate issues likely to arise during discussions. By preparing information in advance (for example, conducting reviews of the relevant literature), the team will be better informed and able to identify relevant leading practices and evidence-based solutions.

The U.S. Joint Commission on the Accreditation of Healthcare Organizations has developed an RCA matrix (see Appendix H). Use of the matrix will help the facilitator ensure that the team considers a variety of potential contributing factors based on the type of event.

Challenges and Strategies

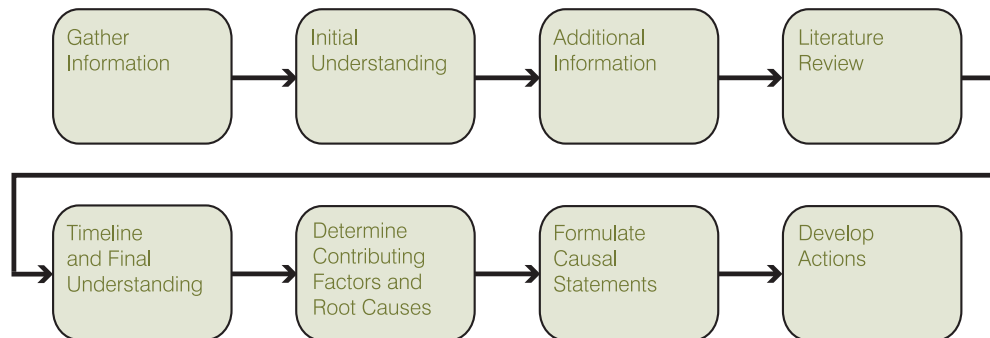
As with all new interventions, a variety of challenges may emerge. The table below (Table 4) outlines some barriers that may affect the implementation of an RCA process and suggests various strategies to consider if these barriers are encountered.

Table 4: Sample Challenges and Strategies

CHALLENGES	STRATEGIES
No organizational RCA policy/ guideline in place	Develop and implement an organizational RCA policy guideline. Use leading practice examples to stimulate and facilitate the process.
Insufficient expertise in RCA within the organization	Approach key risk management and quality improvement individuals in the organization to offer education and support in conducting an RCA (numerous courses and workshops are available in Canada and the United States). Use an external RCA expert to establish a strong foundation of knowledge and skill.
Lack of awareness and understanding of RCA	Develop and implement an education program on the RCA policy/ process. Target several sessions to physician and staff opinion leaders as well as senior leadership and board members.
RCA Team - Group Dynamic Issues <ul style="list-style-type: none"> • Fear • Blaming language (including self blame) • Dominant personalities • Lack of participation • Pre-determination of correct solution or changes 	Provide a copy of the applicable RCA policy to all members of the team prior to the first meeting. Ensure the facilitator, leader or knowledgeable peers are available to clarify questions or concerns. Refer to the ground rules. Do not tolerate the use of blaming language. Do not permit one person or persons to dominate the discussion. Respect that participation is voluntary. As the process becomes established the participation rate will increase. Guide the team to explore alternative solutions (perhaps found in the literature review).
Unwilling to explore specific system improvements/changes	Use examples (such as those provided in this document) to illustrate the process. Support innovative thinking.

Root Cause Analysis Process

Figure 4: A Coordinated Approach to the Process



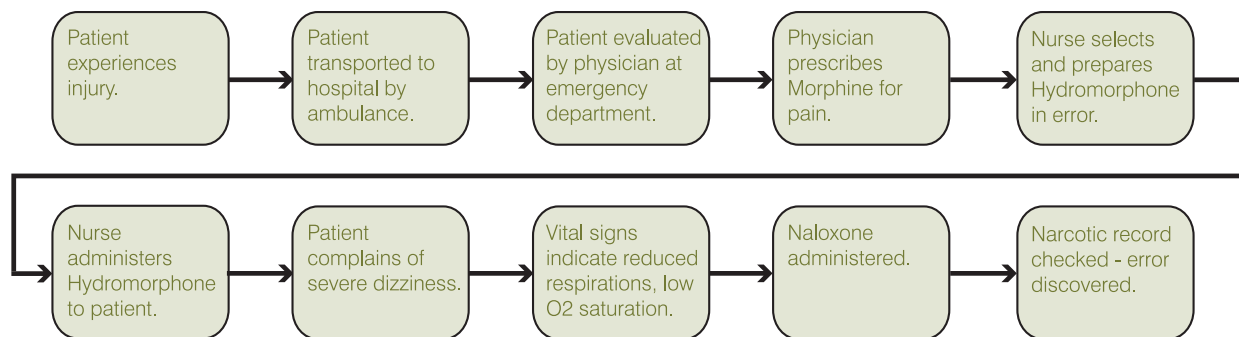
Gather Information

The team's first priority is to gather information relevant to the event. The Canadian Root Cause Analysis Framework provides two approaches to the gathering of information. The first approach is for one or two key individuals to collect and review the information and construct an initial understanding of the event for analysis by the larger group at a specific RCA meeting. Alternatively, the whole team may meet initially to determine information gaps and assign specific duties for completion to several individuals, who then bring the findings back to the team in a series of meetings for further review and refinement. A review of the health record relating to the critical incident will be an early step in determining the sequence of events. Regardless of the approach taken, the standard process components described over the following pages will help to ensure that the analysis is thorough and credible.

Initial Understanding

An initial understanding is prepared based on the facts known at the time. The team reviews the initial understanding to determine where information gaps exist. Effective ways to provide this information may be a flowchart, narrative timeline, or chronological description. A sample flowchart of an initial understanding of a medication error event is shown in Figure 5. The initial timeline is often included in this flowchart or may be provided separately.

Figure 5: Sample Flowchart - Initial Understanding Flowchart Morphine/ Hydromorphone Incident



Additional Information

The team should visit the location where the incident occurred to help establish the physical environment. Photographs and videos are particularly helpful for sharing with team members who may not be familiar with the site and for comparison following implementation of applicable recommendations.

The team should also review organizational policies and procedures that are relevant to the critical incident. These should be made available during team meetings. The policies and procedures help establish the standard of care to which the organization and individual care providers will be held. They may also be the subject of one or more recommendations arising from the RCA.

Members of the team should interview all staff involved in the incident. Their perspective will likely yield additional key information relevant to the RCA. Interviews should occur as soon as possible after the incident to record the sharpest version of the events. Memories can fade and as time lapses recollections can be affected by discussions surrounding the event. A timely interview will increase the probability of obtaining the most accurate sequence of events.

Where possible, two individuals should conduct each interview to provide enhanced recall. They should record the interview in a comfortable way, either by note taking or tape-recording, with the permission of the interviewee. Generally only one individual is interviewed at a time. Interview questions should be broadly determined in advance to assist in keeping the interview sessions on track and ensure that all vital areas of inquiry are covered. The interviewees should initially be asked to establish the sequence of events and allowed the opportunity to provide an uninterrupted description. The interviewers may then ask any clarifying questions, exploring such things as possible contributory factors and suggestions for preventive measures and barriers.

Literature Review

The facilitator should obtain a literature review to determine if there are leading practices or evidence-based guidelines relevant to the critical incident. The facilitator should review any previously reported studies or examinations of relevant processes, procedures, techniques, medications, pieces of equipment, etc. and review the incident reporting system database to identify any similar incidents or close calls. All information discovered during these reviews should be brought to the team meeting and a list of the references reviewed should be included in the RCA report.

An important feature of the literature review is the evaluation of current professional practice standards for all areas of care involved in the event. For example, a literature review could assist in answering whether practice standards were recommended and nationally employed in the event or whether there was some variation. It could also assist in determining whether organizations encountered barriers when implementing the practice standard.

Sometimes, unique safety events have no literature citations available. Consultation with colleagues in the same field may help to determine if the issue in question has been previously observed in everyday practice, but not published.

Timeline and Final Understanding

When all the information is gathered, the team can complete a final understanding and timeline of the event, which is essential for determination of causal factors. Sticky notes are a helpful aid as the team adds new information to the initial understanding to create the final understanding. The final understanding may also include the management of the patient's care after the incident was discovered. As with the initial understanding, some teams will use a flowchart format for the final understanding; others prefer a narrative timeline or chronological description to record the sequence of events. The team will use the final understanding and timeline as a starting point for detecting failure points in the process and identifying the root causes and contributing factors underlying the event.

Figure 6 and Table 5 illustrate a sample final understanding diagram and narrative timeline. Note that for both the initial and final understanding of the event, it is the actual acts or processes that are recorded and not what was supposed to happen. In almost all cases, the final understanding of the event is different from the initial understanding, which illustrates the importance of conducting information gathering activities, including interviews and chart review.

In addition to any steps added to the initial understanding to create the final understanding, the flow diagram can include various references or call out boxes to denote other factors that contributed to the event. Contributing factors such as lighting, staffing levels, noise level and interruptions in the workplace can be gleaned from the interviews or by visiting the event location. The Triage and Triggering Questions (Appendix C) provide a useful checklist at this point, to make sure the team thinks about asking those questions and does not forget to include the results on the final diagram. A flow diagram illustrates what happened leading up to and during the event and can be extremely useful to everyone reviewing the event after the fact. It gives all review participants a common mental model of the event and may tell the story more succinctly than the final understanding narrative.

Figure 6: Sample Final Understanding Diagram:

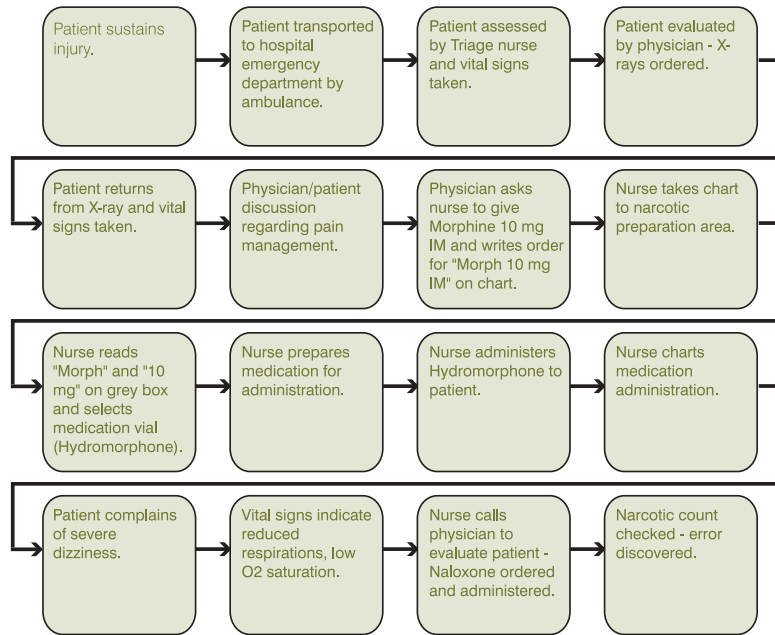


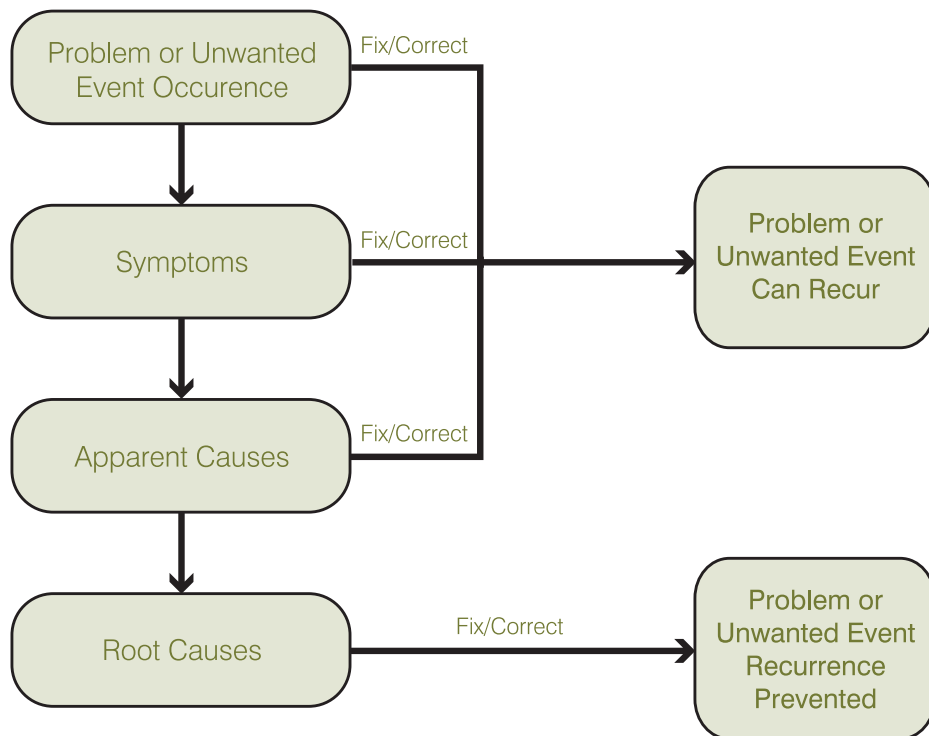
Table 5: Sample Narrative Timeline: Morphine/Hydromorphone Incident

TIME	ITEM	INFORMATION SOURCE
10:00	Patient sustains injury	Ambulance record
10:14	EMS call	Ambulance record
10:58	Arrives hospital emergency department (ED)	Patient chart
11:02	Assessed by triage RN	Patient chart
11:04	Vital signs	Patient chart
11:25	Seen by ED physician	Patient chart
12:15	Patient returns from X-Ray and vital signs taken	Patient chart
12:20 – 12:25	Physician/patient discuss pain management	Physician/nurse/patient interviews
12:30	ED physician note written	Patient chart
	Physician asks nurse to give Morphine 10 mg IM and writes order for "Morph 10 mg IM" on patient chart	Patient chart
	Nurse takes chart to narcotic preparation area	Nurse interview
	Nurse reads "Morph" and "10 mg" on grey box and selects medication vial (Hydromorphone)	Nurse interview
12:35	Nurse documents removal of Morphine on narcotic record and prepares the drug for administration (Hydromorphone)	Nurse interview
	Nurse administers Hydromorphone in error	
12:40	Nurse charts Morphine given on ED record	Patient chart
13:00	Patient complains of severe dizziness	Patient chart; patient interview
13:02	Vital signs indicate reduced respirations, low O ₂ saturation	Patient chart
13:04	Physician evaluates patient	Physician/nurse interview
13:05	Naloxone ordered	Patient chart
13:06	Naloxone administered	Patient chart
13:20	Narcotic count checked; error discovered	Nurse interview

Determine Contributing Factors and Root Causes

At this phase of the RCA process, the focus is on recognizing all system issues that may have contributed to the adverse event. As discussed previously, it is human nature to identify causes at the sharp end, in other words those causes that are apparent, and close to the point of occurrence. It is important to work away from the sharp end towards the blunt end to ensure determination of all underlying causes. If contributing factors and root causes are not properly identified, the recommendations developed by the team may not effectively reduce the likelihood of recurrence of the critical incident (See Figure 7: Cause and Event Relationship).

Figure 7: Cause and Event Relationship⁵¹



In general, RCA teams are highly successful at determining the sequence of events and identifying contributing factors close to the event, but often struggle to identify root causes and create recommendations to prevent the recurrence. A key aspect of the process is understanding how the various contributing factors relate to each other and ensuring that the analysis has progressed far enough into the blunt end of the system so that root causes can be clearly identified. Diagramming techniques can assist teams to better understand these inter-relationships and ensure a thorough review. Visualization of relationships can help the team see where issues arose and identify areas to target for improvement.

The two types of diagrams presented below (Figures 8 and 9), Ishikawa or fishbone diagrams and tree diagrams, are useful tools for visualizing the relationships. These diagrams also may be referred to as

⁵¹ P.F. Wilson, L.D. Dell and G. F. Anderson, *Root Cause Analysis: A Tool for Total Quality Management* (Milwaukee: ASQC Quality Press, 1993) P. 11.

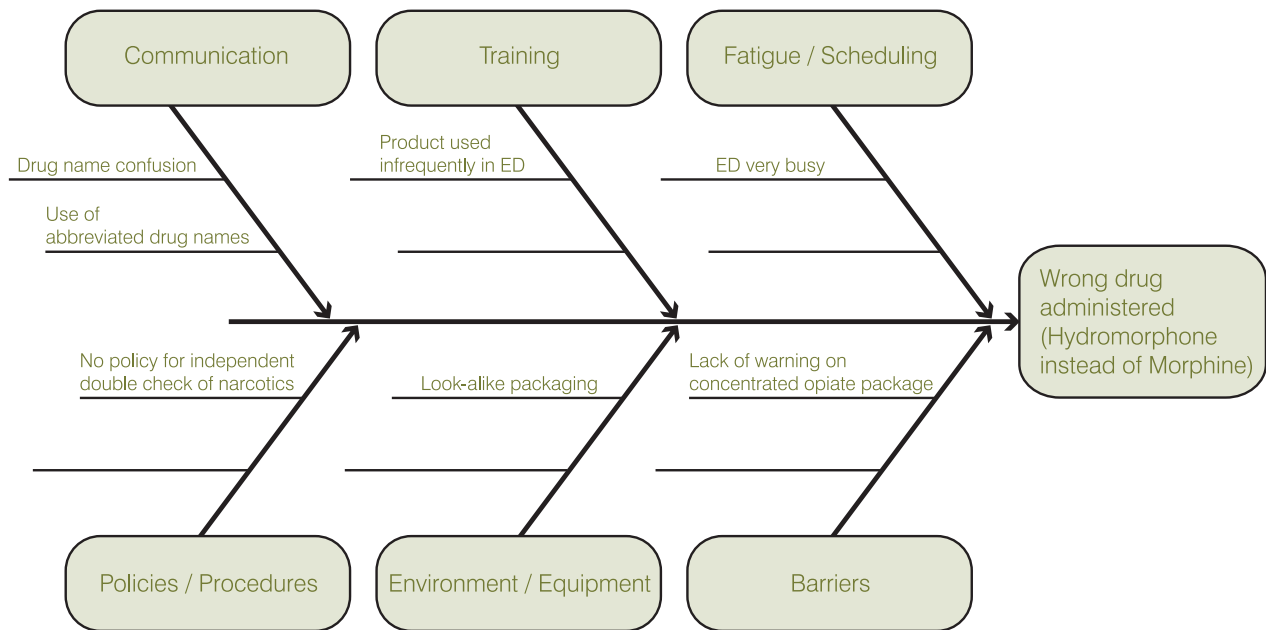
⁵² Adapted From SkyMark, Cause & Effect Diagrams, SkyMark 2005, <<http://www.skymark.com/resources/tools/cause.asp>> (accessed November 29, 2005).

cause and effect diagrams or contributory factor diagrams.⁵² Teams may have expertise in other diagramming techniques, which they may wish to use.

Ishikawa or Fishbone Diagram

The Ishikawa diagram resembles the skeleton of a fish; the main arrow represents the primary outcome of the adverse event and the other bones represent individual contributing factors and root causes (see Figure 8 below for an example of the Ishikawa Diagram). These causes can be clustered in the fishbone diagram according to any number of groups; Figure 8 uses the categories from the Veterans Affairs Triage and Triggering questions (communication, training, fatigue/scheduling, environment/equipment, rules/policies/procedures and barriers). The diagram assists in perception of patterns and provides a record of discussion.

Figure 8. Ishikawa (Fishbone) Diagram: Morphine/Hydromorphone Incident

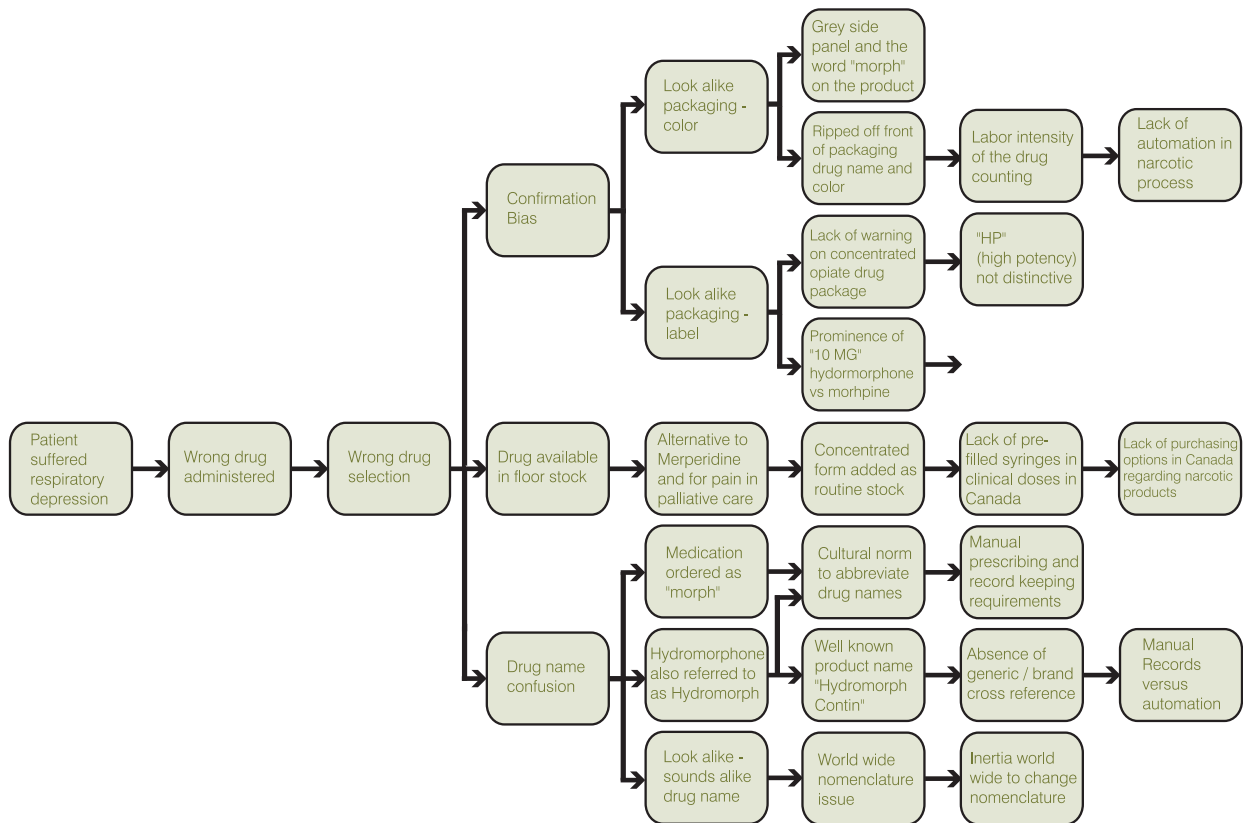


Tree Diagram

A tree diagram is an alternative form of the cause and effect diagram, which resembles a tree turned on its side. The branch arrangement facilitates recording of contributing factors identified by asking a series of “caused by” and “why” questions. Diagramming begins with formulation of the outcome or problem statement. The team can then begin to work away from the “sharp end” of the event. This part of the process can also be assisted by the use of sticky notes because the organization of ideas will be very fluid. Clustering of contributing factors will help to organize thought processes and assist in the analysis or root causes (Figure 9).

The Triage and Triggering Questions (see Appendix C) are again a useful tool for ensuring that all relevant areas are considered. It is crucial to ask “why” at each level of cause and effect until there are no more questions, knowledge becomes limited, or until the issues identified fall outside the scope of the RCA. For example, one root cause pertaining to a medication error may be traced back to an issue of look-alike packaging; however, the RCA team would not be expected to remedy this issue, which falls outside of their control. If such an issue is identified, it is appropriate for the team to refer it to the applicable external organization.

Figure 9. Sample Tree Diagram: Morphine/Hydromorphone Incident



Diagramming is an essential component of the RCA process. Visualization through cause and effect diagramming helps clarify team understanding and shifts the focus away from individual performance towards system performance and underlying factors. It also helps the team avoid the trap of hindsight bias. This awareness helps the team develop causal statements.

The team must agree on the contributing factors and root causes before moving forward in the RCA process. If there is a lack of immediate agreement, it is important to discuss and work through any disagreements to arrive at consensus before proceeding.

Identify Incidental Findings

During a root cause analysis process, the team may uncover other issues, which may not be direct causes to the event, but are relevant to patient safety or to patient care in general. It is recommended that these issues be brought to the attention of the appropriate individuals for follow up. As well, these issues should be documented in the RCA report for future review and action outside the RCA process if needed.

Formulate Causal Statements

When the team has fully discussed all of the potential factors requiring consideration, it should shift its focus towards the development of causal statements that will provide the backbone for development of recommendations and actions. Careful wording is essential to communicate the issues clearly and target systems, not individuals.

Causes can be either actions or conditions. For example, in a motor vehicle collision it could be determined that one cause of the event was the driver speeding, which is an action. If, however, at the time of the accident the road was icy, another cause of the event was the condition of the road. An action is a one-time episode and a condition usually exists over time.

David Marx developed seven rules of causation, five of which are directly applicable to healthcare and have been widely adopted.³⁸ These rules help RCA teams understand the theory of causation as they prepare causal statements, which must accurately reflect the true root causes of the event under analysis to ensure actions are directed appropriately. Using the rules of causation keeps the focus on system issues and the relationship between cause and effect clear and concise.

One way to think about the formulation of causal statements is to use an A, B, C format, where:

A = Antecedent
B = Behaviour
C = Consequences

Thus the set of circumstances (A) increased the likelihood (B) that this set of consequences (C) would occur.

The Five Rules of Causation, summarized below, provide guidance regarding the need to demonstrate a causal link as well as the type of language that should be used in causal statements. The cause and effect diagrams created by the team will help to illustrate the causal links. The use of the five rules as a guideline increases the likelihood that the actions developed will address the true underlying issues. It is important to focus primarily on those issues, which, if rectified, would eliminate or reduce the possibility of the incident recurring. The facilitator takes the RCA team back through the work they have already completed to ask the question: if this factor were eliminated or corrected, would it have prevented the outcome?

Five Rules of Causation:³⁸

1. Root cause statements must clearly show the cause and effect link. (For example, “X increased the likelihood or led to Y”.)
2. Negative descriptions should not be used in root cause statements. (For example, describe specifically why staff did not use an available manual instead of writing “the manual was written poorly”).
3. Each human error must have a preceding cause. (For example, it is not sufficient to say that a physician made a dosing error; the causal statement should identify the underlying conditions that allowed this to happen, e.g. lack of automated dose checking software.)
4. Violations of procedure are not root causes; they must have a preceding cause. Procedures may not be followed for a variety of reasons; failure to follow a procedure is not necessarily a causal factor.
5. Failure to act is only causal when there was a pre-existing duty to act. (For example, failure of a nurse to check charts individually for new orders would not be a causal factor unless this was a clearly defined expectation and standard practice.)

Consider the following example, where a patient commits suicide while receiving care in a local mental health facility. A review identified the following contributing factors:

1. suicide risk assessment was not completed when patient was admitted;
2. staffing levels were lower than usual that day as two staff members called in sick with the flu and replacements could not be found; and
3. the attending physician ordered one-to-one, continuous supervision but this was not in place at the time of death due to the supervising staff member taking a lunch break.

While each of these contributing factors is important, they would not all have prevented the incident if corrected. In other words, while they may have contributed to the event, it cannot be said that they caused the event. In this example, even if the staffing levels were normal that day and even if the suicide assessment were completed when the patient was admitted, the suicide still could have occurred. The only way to eliminate the possibility of the suicide, in this instance, is to have continuous supervision as ordered by the physician. So, in this example, the first statement identified for the purposes of generating recommendations would be based on statement #3.

Causal statements must focus on the root causes and should be specific. For example, issues related to financial and human resources may be readily identifiable but are not specific enough. Instead of focusing simply on the total number of staff available at the time of the incident, discussions should reflect upon training/continuing education requirements, staffing patterns, supervision and patient demands on staff members. The Veterans Affairs Triggering and Triage Questions (Appendix C) can help focus discussions.

The following causal statements have been developed for the sample case used in this framework.

1. Look-alike/sound-alike medication names increased the likelihood that a nurse would select and administer Hydromorphone instead of Morphine as intended.
2. The removal of drug identification information from the Hydromorphone package to facilitate narcotic counts increased the likelihood of a look-alike medication being selected.
3. The routine availability of a high potency, yet infrequently used narcotic in the emergency department increased the likelihood of an incorrect drug selection.

Develop Actions

The ultimate goal of an RCA is the development of actions to reduce the potential for recurrence of a similar event. The team will identify measures to address the root causes they have uncovered. The initial focus is on removal or elimination of the circumstances that allowed the outcome. If there is no action that can be applied to eliminate the cause, the team should seek the most appropriate control to reduce the possibility of recurrence. It is important to note that applying a control means that although checks will be in place, there still is a chance of reproducing the same or related circumstances that led to the original critical incident.

There are circumstances under which a team may choose to accept one or more root causes without further intervention. The frequency and/or severity of the incidents may not be significant. The team may determine that one or more root causes cannot be altered, thus they must be accepted. For example, in reviewing an event related to lack of timely access to tertiary care, the RCA team would have to accept the fact that this level of service will not be made available in remote locations and focus attention on rapid transfer of patients when such services are needed.

When recommending change, many possible categories of options with varying degrees of effectiveness, ranging from most to least effective, are available. The team should be apprised of this range of possibilities (see below, listed in order from most effective to least effective) and encouraged to recommend the most effective solution that is reasonable and/or possible given the circumstances. Note that items such as training and

policy development are necessary components, but do not change the underlying conditions that lead to error.

Recommended Hierarchy of Actions:³⁸

Stronger Actions

- Architectural/physical plant changes
- New device with usability testing before purchasing
- Engineering control or interlock (forcing functions)
- Simplify the process and remove unnecessary steps
- Standardize on equipment or process or caremaps
- Tangible involvement and action by leadership in support of patient safety

Intermediate Actions

- Increase in staffing/decrease in workload
- Software enhancements/modifications
- Eliminate/reduce distractions (sterile medical environment)
- Checklist/cognitive aid
- Eliminate look and sound alike
- Read back
- Enhanced documentation/communication
- Redundancy

Weaker Actions

- Double checks
- Warnings and labels
- New procedure/memorandum/policy
- Training
- Additional study/analysis

Actions should:

- target the elimination of the root causes;
- offer a long term solution to the problem;
- have a greater positive than negative impact on other processes, resources and schedules;
- be objective and measurable; and
- be achievable and reasonable.

From a human factors standpoint, the strongest interventions are “physical rather than procedural and permanent rather than temporary.”⁵³ Examples of preferable actions include architectural or physical changes and forcing functions. An example of an architectural change would be installation of grab bars; a forcing function example would be lack of connectivity of non-related devices, for example blood pressure cuffs and luer lock syringes. Standardization of processes and equipment (for example, limiting the number and type of

⁵³ Caryl Lee and Kierston Howard Hirschler, “How to Make the Most of Actions and Outcome Measures,” NCPS TIPS July/August (2004), <http://www.patientsafety.gov/tips/docs/tips_julaug04.doc> (accessed November 28, 2005).

IV pumps) and simplification of processes to remove unnecessary steps and duplication are also effective. Other human factors interventions include such things as reducing reliance on memory and vigilance, elimination or reduction of distractions, built-in redundancy and use of warnings and labels. **Organizations may find the assistance of human factors engineers helpful in determining if the proposed actions will be effective from a human factors perspective.**

In discussion of potential actions, the RCA team should be encouraged to consider innovative ideas. In the final report, the RCA team should present all actions they consider reasonable to correct the underlying causes of the event. The senior leadership then makes decisions about prioritization and implementation of recommendations and actions and determines the allocation of resources; this is not the responsibility of the RCA team.

For best success, an individual, often at a senior level, leads the implementation of individual actions. As well, a specific time frame for completion of the recommendations should be established and agreed upon by review participants. It is important to note that your organization will want to evaluate how best to summarize the RCA findings so that appropriate protections are provided to the document. Table 6 provides a sample action table.

Table 6: Sample Action Table for Morphine/ Hydromorphone Incident

ROOT CAUSE / CONTRIBUTING FACTOR #	ROOT CAUSE / CONTRIBUTING FACTOR STATEMENTS	ACTION #	RECOMMENDED ACTION(S)	TYPE OF ACTION (CONTROL, ELIMINATE, ACCEPT)	TIME-FRAME	INDIVIDUAL RESPONSIBLE
RC 1	4. Look-alike, sound-alike medication name: Look-alike and sound-alike medication names increased the likelihood that a nurse would select and administer Hydromorphone instead of Morphine as intended.					
Wrong drug selected	Drug available in floor stock	1 A	Remove high potency concentrations of narcotics from ward stock in emergency department.	Eliminate	Immediate	Director of Pharmacy
Wrong drug selected	Medication ordered as "Morph"; cultural norm to abbreviate drug names	1 B	Standardize a list of (error prone) abbreviations, acronyms, symbols and truncated (stem) drug names that are NOT to be used throughout the organization.	Control	Intermediate	P&T Cttee/MAC
RC 2	5. Look-a-like packaging – The removal of drug identification information from the Hydromorphone package to facilitate narcotic counts increased the likelihood of a look-alike medication being selected.					
	Look alike packaging; limited risk assessment of look-alike sound-alike floor stock	2A	Implement a process to evaluate the potential for look-alike sound-alike products which: a) allows purchase of drugs which do not look alike where possible; b) use of auxiliary labeling; c) segregation or separation of products where possible.	Control	Immediate	Director of Pharmacy
RC 3	6. High-alert medications treated as supplies: The routine availability of a high-potency yet uncommonly used narcotic in the emergency department increased the likelihood that a wrong drug selection could occur.					
Wrong drug selected	Drug available in floor stock; undefined process for risk assessment	3A	Institute an interdisciplinary oversight process to review and formally approve the medications that are available via ward stock area by area. Focus on: minimizing the number of units in inventory; the amount of drug per container; and clinical appropriateness for the patient care area.	Control	Intermediate	P&T Cttee

Implementing the Action Plan

The ultimate success of any RCA process depends upon the actions taken by the organization in response to the recommendations of the team. All root cause analyses completed in an organization should be tracked and a designated individual (quality specialist or similar) assigned the responsibility for follow-up of all RCA recommendations. The board of trustees and senior staff should be provided with frequent status updates on implementation of all action plans.

When planning implementation of actions the organization must consider:

- who will be affected by action(s);
- likelihood of success;
- within the organization's capabilities;
- compatibility with the organization's objectives;
- the likelihood of engendering other adverse events;
- receptivity by management, staff and physicians;
- barriers to implementation;
- implementation time, i.e., long term versus short term solution;
- cost; and
- measurability.

The organization should also consider pilot testing or usability testing of interventions prior to broad implementation, especially in situations where substantial changes in process are planned. The use of small cycles of change (e.g. PDSA or Plan/Do/Study/Act cycles) can be beneficial.

Measure and Evaluate the Effectiveness of Actions

The purpose of implementing system changes is to make the system safer. However, the possibility exists that well intentioned and well thought out recommendations may not have the desired effect once put into practice. As with any quality improvement initiative, the effectiveness of the implemented recommendations must be measured to determine if the changes helped make the system safer, there was no effect on the safety of the system, or, in the worst-case scenario, the changes actually made the system less safe. If surveillance indicates that, for whatever reason, the changes did not have the intended effect, the organization needs to revisit the issue to identify alternative solutions. "Rather than being a policing activity, monitoring implements professional

accountability and contributes to rational management by documenting the quality of the product."⁵⁴

There are three general types of measurements: structure measures, process measures and outcome measures. It is important to measure a process when it is stable (i.e., after the variable performance during initial implementation phases) and to know if the measured outcomes match expected ones. Most data analysis will involve comparison of organizational data to a point of reference such as internal comparisons, aggregate external referenced databases, practice guidelines, and/or parameters and performance targets.

Measurement strategies determine the effectiveness of the action and not the completion of the action. For example, a measurement strategy would calculate the percentage of newly admitted patients assessed for fall risk, and not the percentage or number of staff trained to complete falls assessment. Measurement should be quantifiable, with a defined numerator and denominator (if appropriate). The sampling strategy and time frame for measurement must be clearly stated (for example, random sampling of 15 charts per quarter). It is important to set realistic performance thresholds (for example, a target for 100 per cent compliance should not be set unless it can be met).

Measurement may take the form of voluntary reporting, intervention tracking, direct observation of performance, chart review, computerized tracking and surveys.

The organization should consider the following questions when developing performance measures:

- Is there a plan for use of the data? (i.e., don't collect data that will not be used)
- Are the data collected reliable and valid?
- Has data collection been simplified?
- Have key elements required for improvement or change been identified?
- Has a "data rich - information poor" situation been avoided?
- Has a key point for information dissemination been identified?
- How will the measurement be documented?

The improvements/changes are successful when:

- the new processes become the routine/habit; and
- new employees demonstrate proper procedure after orientation.

⁵⁴ A. Donabedian, "Institutional and Professional Responsibilities in Quality Assurance," *Quality Assurance in Health Care* 1, No.1 (1989): 3-11.

Measurement strategies for the actions described in the sample case included in this framework might include periodic audits, to ensure high potency narcotics are not stocked in patient care areas, and chart reviews, to assess continued use of non-approved abbreviations.

Share Results of Improvement

A key part of the completion of the RCA process is the creation of a report of the team's findings. The report may include: a review of the information collected by the team, in the form of the initial and final understandings; the contributing factors and root causes identified; causal statements; and actions and implementation plan developed by the team. The report should reflect only the findings of the team; details of team discussions are not included in the final report. As mentioned earlier, the report should incorporate incidental findings, such as other safety issues identified or information that would be helpful to future teams.

The report is typically submitted to the senior leadership of the organization. Any identifying details such as patient, family and staff identities and location information are protected and not transmitted as the report is disseminated within and outside the organization.

After actions and measurement are completed, the organization should prepare a final report on the results of the improvement. Individual organizations will need to consider how the information can best be disseminated, considering confidentiality, legal requirements and applicability to other areas of the organization or to external organizations.

The organization should broadly distribute de-identified, applicable, system improvement information to further encourage and promote a safety culture and process improvements. Feedback to direct care staff is a critical component of demonstrating a commitment to safety and ensuring that staff members continue to report safety issues. The information can be shared in a variety of ways within an organization, for example, through safety alerts, inservice education sessions, or as part of organizational orientation. A consistent flow of information from senior leadership affirms that every safety initiative is important.

Conclusion

Patient safety is a fundamental aspect of providing quality healthcare services. The Canadian Root Cause Analysis Framework has great potential to improve patient safety in healthcare organizations. It can help these organizations, and the people who provide patient care, perform a comprehensive, system-based review of significant incidents that includes the identification of root and contributory factors, determination of risk reduction strategies and development of action plans along with measurement strategies to evaluate the effectiveness of the plan.

Striving to identify and address the root or underlying causes of critical incidents will lead to a greater understanding of hazards in the system and, ultimately, a safer healthcare system. It is part of moving from a culture of blame to a culture of safety.

“We cannot change the human condition, but we can change the conditions under which humans work.”

James Reason, 2000⁴⁶

“We envision a Canadian health system where patients, providers, governments and others work together to build and advance a safer health system; where providers take pride in their ability to deliver the safest and highest quality of care possible; and where every Canadian in need of healthcare can be confident that the care they receive is the safest in the world.”

Canadian Patient Safety Institute⁶

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Additional Resources List

Selected references have been compiled as a resource for individuals and organizations seeking additional background information on root cause analysis. The list is neither exhaustive nor a substitute for the professional advice and assistance of an expert in the process.

Books and Videos

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Online Resources

Brown-Spath & Associates

Offers healthcare leaders high quality resources on performance improvement topics.

<http://www.brownspace.com/>

Contents

<http://www.brownspace.com/ppinfo.htm>

- PowerPoint presentation entitled “The Basics of Patient Safety.”
- Presentation on proactive risk assessment techniques that can be used to improve the safety of healthcare processes
- Slides from talk on partnering with patients to reduce medical errors, a keynote presentation given by Patrice L. Spath at the conference of the Quality Management Division of the American Society for Quality, March 2004

Institute for Healthcare Improvement

<http://www.ihp.org>

Contents:

- **Systems Analysis of Clinical Incidents: The London Protocol**
<http://www.ihp.org/IHI/Topics/PatientSafety/MedicationSystems/Tools/SystemsAnalysisofClinicalIncidentsTheLondonProtocol.htm>
- **Failure Modes and Effects Analysis (FMEA) Tool (IHI Tool)**
<http://www.ihp.org/IHI/Topics/Improvement/ImprovementMethods/Tools/Failure+Modes+and+Effects+Analysis+%28FMEA%29+Tool+%28IHI+Tool%29.htm>
- **Failure Modes and Effects Analysis (FMEA): Comparison of five medication dispensing scenarios (IHI Tool) [Included in the Failure Modes and Effects Analysis Tool]**
<http://www.ihp.org/IHI/Topics/PatientSafety/MedicationSystems/Tools/Failure+Modes+and+Effects+Analysis+FMEA+Comparison+of+Five+Medication+Dispensing+Scenarios+IHI+Tool.htm>

United States Joint Commission International Center for Patient Safety

<http://www.jcpatientsafety.org/>

Contents

<http://www.jcpatientsafety.org/show.asp?durki=9754&site=165&return=9368>

- Affirmation Statement
- Framework for Conducting a Root Cause Analysis
- Tool to Assist Organizations in the Completion of the Framework for Conducting a Root Cause Analysis
- Process Flow Chart - for event reporting and responses
- Root Cause Analysis Matrix
- Self-Report Form

Joint Commission Resources

<http://www.jcrinc.com/>

United States Veterans Affairs National Center for Patient Safety

<http://www.patientsafety.gov>

Contents:

- **Root Cause Analysis (RCA)**
<http://www.va.gov/ncps/rca.html>
- **Triggering & Triage Questions**
<http://www.va.gov/ncps/SafetyTopics/CogAids/triage/index.html>
- **Five Rules of Causation**
<http://www.va.gov/ncps/SafetyTopics/CogAids/Triage/index.html>
- **Ensuring Correct Patient Surgery**
<http://www.patientsafety.gov/SafetyTopics.html#ECS>
- **MRI Hazard Summary**
<http://www.patientsafety.gov/SafetyTopics/mrihazardsummary.html>
- **Healthcare Failure Mode and Effects Analysis (HFMEATM)**
<http://www.patientsafety.gov/SafetyTopics.html#HFMEA>
- **Falls Prevention Toolkit**
<http://www.patientsafety.gov/SafetyTopics/fallstoolkit/index.html>
- **Patient Safety Curriculum Workshop: How to Teach Medical Residents**
<http://www.patientsafety.gov/PSC/Workshop.html>

Software

- Medical Risk Management Associates, LLC
<http://www.rootcauseanalyst.com/>
- REASON Root Cause Analysis
<http://www.rootcause.com/Welcome.html>
- Reliability Center, Inc.
<http://www.reliability.com/>

Training and Toolkits

- National Health Services (NHS). National Patient Safety Agency. Maureen Baker. NPSA e-learning programme for Root Cause Analysis. United Kingdom, CAPITA Consulting, http://www.aafp.org/PreBuilt/research_baker.pdf.

- National Health Services (NHS). National Patient Safety Agency. RCA Training and RCA toolkit. United Kingdom, National Patient Safety Agency, http://81.144.177.110/health/resources/root_cause_analysis.
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- University of Michigan Health System. University of Michigan Health System Patient Safety Toolkit. Ann Arbor, MI, <http://www.med.umich.edu/patientsafetytoolkit/events.htm>.

Appendix A

Legislative Protection for Quality of Care Information

Alberta

Alberta Evidence Act, R.S.A. 2000, c.A-18, s.9

Quality Assurance Committee Regulation, Alberta Regulation 294/2003

Health Information Act, R.S.A. 2000, c.H-5, ss.35(1)(g), 35(2)-(3)

British Columbia

Evidence Act, R.S.B.C. 1996, c.124, s.51

Designation Regulation, British Columbia Regulation 363/95 as amended

Manitoba

Manitoba Evidence Act, R.S.M. 1987, c.E150, ss.9, 10 (C.C.S.M., c.E150)

Northwest Territories

Evidence Act, R.S.N.W.T. 1988, c.E-8, ss.13, 14, 15

Prince Edward Island

Medical Act, R.S.P.E.I. 1998, c.M-5, s.38.7

New Brunswick

Evidence Act, R.S.N.B. 1973, c.E-11, s.43.3

Newfoundland / Labrador

Evidence Act, R.S.N.L. 1990, c.E-16, s.8.1

Nova Scotia

Evidence Act, R.S.N.S. 1989, c.154, ss.60, 61

Nunavut

Evidence Act, R.S.N.W.T. 1988, c.E-8, ss.13, 14, 15, as duplicated for Nunavut by s.29 of the Nunavut Act, S.C. 1993, c.128

Ontario

Quality of Care Information Protection Act, 2004, S.O. 2004, c.3, Sched. B

Definition of 'Quality of Care Committee' Regulation, Ontario Regulation 297/04

General Regulation, Ontario Regulation 330/04

Quebec

An Act respecting health services and social services, R.C.Q., c.S-4.2, ss. 183.1, 183.3, 183.4, 190, 213, 214, 218

Saskatchewan

Health Information Protection Act, S.S. 1999, c.H-o.021,
s.27(4)(g)

Saskatchewan Evidence Act, S.S. 1989-90, c. 57, s.35.1

Regional Health Services Act, S.S. 2002, c. R-8.2, s.58

Critical Incident Regulations, R-8.2 Reg. 3

Yukon

Evidence Act, R.S.Y. 2002, c.78, s.13

Appendix B

Capital Health (Halifax) Policy

Administrative Policy and Procedure

TITLE:	Management Of Serious Clinical Occurrences	NUMBER:	CH 70-005
Section:	Patient/client Care	Date Approved:	April 2002
Source:	Risk Management & Legal Services	Editorial Revision:	Nov 27th 2002
		Date to be reviewed:	April 2005
Distribution:	All	Approval:	Board of Directors

Policy

As part of the commitment to continuously improve the quality of care and services to Capital Health patients/clients, all Serious Clinical Occurrences (“the Occurrence”) within Capital Health are managed, documented, appropriately communicated and investigated promptly in a consistent and non-accusatory manner.

The management of the Occurrence includes:

- Immediate crisis management; and
- Case Review and Root Cause Analysis.

The immediate crisis management is the responsibility of the involved department(s). If more than one department is involved, the immediate crisis management must be a collaborative effort. Responsibility for the Case Review and Root Cause Analysis lies with the Quality Committee, as part of its routine, ongoing quality assurance activities.

If the Occurrence is solely physician related, the Medical Staff Bylaws and not this policy will direct review of the Occurrence. This decision will be made by the Vice President, Medicine and either the Vice President, Acute Care or the Vice President, Continuing and Community Care, after consultation with the Department Chief/Facility Chief of Staff.

Definitions

A Serious clinical occurrence (“the Occurrence”) is any occurrence that results in a serious, undesirable, and unexpected patient/client outcome that involves the actual or potential loss of life, limb or function.

A **Serious clinical occurrence** may be (but is not limited to):

1. Any patient/client death, paralysis, coma or other major loss of function associated with an adverse drug occurrence or adverse transfusion reaction;
2. Surgically related occurrences, such as wrong side surgery, the wrong patient/client being operated on, or the wrong procedure being performed;
3. Equipment malfunction, unavailability, disconnection or failure that results in loss or potential loss of life, limb or function to a patient/client or visitor;
4. Disruption in power or any other essential service which results, or has the potential to result in patient/client or visitor injury;
5. Lack of appropriate follow-up, such as failure to notify a patient/client of abnormal findings (i.e. Laboratory or Diagnostic Imaging tests);
6. Unexpected deaths, including all suicides in the acute and long term care settings. All suicides and homicides of patients/clients in the Capital Health Mental Health Program will be reviewed as per the existing policy (s);
7. Occurrences where a patient’s/client’s death has been within 72 hours of discharge, including discharge from an Emergency Department;
8. A series of events which, cumulatively, has the potential to become a serious clinical occurrence.

Immediate Crisis Management is the process by which the care team immediately responds to an Occurrence, which includes actions within the first 24 hours of the Occurrence to: attend to the needs of the patient/client and staff involved; secure the area; gather facts and notify all appropriate people.

Root Cause Analysis: A Root Cause Analysis is an intensive assessment conducted to prevent recurrence of an Occurrence by identifying the reason(s) underlying an undesirable condition or problem in the system.

Characteristics of a Root Cause Analysis:

1. The analysis focuses on systems and processes, not individual performance;
2. The analysis starts with the apparent cause(s) of the Occurrence and progresses to identification of reasons for any undesirable conditions or problems with hospital systems/processes;
3. The analysis repeatedly digs deeper by asking why questions until no additional logical answer can be identified; and
4. The analysis identifies changes that could be made in systems and processes - through either redesign or development of new systems or processes - that would improve the level of performance and reduce the risk of a particular serious adverse occurrence occurring in the future.

Procedures

A. Immediate Crisis Management (hour 0 - hour 24).

Proceed directly to section B if the Occurrence does not involve a specific patient/client.

1. **The Care Team: The manager or delegate assigns the following:**
 - 1.1 Addresses immediate needs of the patient/client and family;
 - 1.2 Immediately notifies the:
 - a. Director of the Department;
 - b. Department Chief;
 - c. Attending Physician;
 - d. Patient Representative; and
 - f. Risk Management.

Note: If the Occurrence happens during the evening, night or weekend, the administrative person in charge of the facility is notified. Telephone messages are left for Risk Management and the Patient Representative;

- 1.3 Isolates and secures any medication, supplies or equipment which might have contributed to the Occurrence;
- 1.4 If the Occurrence is related to equipment malfunction, marks with a "Do Not Use" sign and contacts Biomedical Engineering;
- 1.5 Records the clinical aspects of the Occurrence in the patient's/client's health record;

- 1.6 Completes an Occurrence Report Form, and forwards it to Risk Management, as per policy; and
- 1.7 Addresses immediate needs of staff (e.g. Critical Incident Stress Management), other patients/clients, families, or visitors.

2. The Attending Physician or physician designate:

- 2.1 Addresses the immediate needs of the patient/client and family;
- 2.2 Offers ongoing support and information to the patient/client and family;
- 2.3 Notifies the Department or Division Chief or the facility Chief of Staff;
- 2.4 Notifies the Family Physician, if appropriate;
- 2.5 Notifies the Medical Examiner (ME) if:
 - a. There is reasonable cause to suspect that a person died by violence, undue means or culpable negligence; or
 - b. The cause of a patient's/client's death is undetermined;
- 2.6 Documents the notification to the ME in the health record; and
- 2.7 Is a member of the Case Review Team and the Root Cause Analysis Team.

3. Risk Management:

- 3.1 Informs the Executive Management Team of the Occurrence;*
- 3.2 Assists and advises on procedure for management of the Occurrence;
- 3.3 Gathers and secures the following (if relevant) and forwards to the Chairperson of the Case Review:
 - a. Patient/client Care Record (this includes impounding the record)*
 - b. List of staff involved in care/service
 - c. Copies of pertinent protocols and procedures
 - d. Copies of relevant documentation (e.g. Kardex, medication records, etc.)
 - e. Copies of staff rotation, assignments
 - f. Names of other patients/clients, family, visitors in the room
 - g. Equipment, medical devices, labels etc., from the Care Team*
 - h. Copies of any taped or written reports involving patient/client or occurrence*
- 3.4 Receives and compiles all reports for risk, quality and legal purposes; and
- 3.5 Prepares summary reports for the Vice Presidents.

Please note: Activities marked with a "*" are to be done by the administrative person in charge of the facility if the Occurrence occurs during the evening, night or weekend. Please leave a message with Risk Management stating what has been done.

4. Public Affairs

- 4.1 Maintains accurate records of all statements, releases, newspaper articles and broadcast reports; and
- 4.2 If deemed necessary by the Executive Management Team, drafts an immediate written statement for approval by Risk Management Legal Counsel and the CEO and assigns one spokesperson to respond to all media requests.

B. Case Review and Root Cause Analysis (day 2 - day 45)

5. Case Review Team:

- 5.1 Is led by a Chairperson who is appointed by the Chair of the Quality Committee to co-ordinate the review and analysis on behalf of the Committee. This person will not be a stakeholder in the processes and systems being evaluated;
- 5.2 Gathers and reviews:
 - a. all appropriate documentation and chart information;
 - b. all related policies/guidelines; and
 - c. all information gathered from other sources, such as Risk Management;
- 5.3 Compiles all additional information in a Serious Clinical Occurrence Review File. No copies are made;
- 5.4 Inquiry Meeting: A meeting chaired by the Chairperson is convened within 10 working days of recognition of the Occurrence.
 - a. Case Review Members:
 - Case Review Chairperson;
 - A member of the departmental Peer Review Committee, if such a committee exists;
 - The Attending physician;
 - Directors (or delegates) of department(s) involved and
 - A facilitator trained in Root Cause Analysis.
- 5.5 Objectives:
 - a. corroborate all factual information. The individuals directly involved and the manager(s) of the department(s) involved must be interviewed;
 - b. where possible, resolve disputes of fact;
 - c. identify the cause(s) of the Occurrence;
 - d. identify any risk reduction strategies; and
 - e. To perform an assessment of the system(s) with the goal of isolating what, if any hospital systemic/process issues contributed to the Occurrence.
- 5.6 Upon completion of the system(s) assessment, the Chairperson files a report with the Quality Committee within 45 days of the Occurrence with recommendation(s) for improvement. No copies of the report are made.

C. Resolution and Follow-Up

- 6. Quality Committee (day 45 - 60):
 - 6.1 Reviews the report and recommends an action plan for the Executive Management Team.
 - 6.2 Delivers the Serious Clinical Occurrence Review File to Risk Management for filing.
- 7. Executive Management Team (day 60 - year 1)
 - 7.1 Assigns responsibility for implementation of recommendations and accountability for measurement of status at 3, 6 and 12 months;
 - 7.2 Monitors the changes at 3, 6 and 12 months from the time of the assignment at per 8.2;
 - 7.3 Presents a summary of the findings to the Board of Directors;
 - 7.4 Delivers the report to Risk Management for filing with the Serious Clinical Occurrence Review File; and
 - 7.5 Risk Management and Legal Services will provide to the Executive Management Team a quarterly report that outlines the status of all reviews conducted under this policy.
- 8. Documentation
 - 8.1 Documentation should be succinct and factual. No copies are made of any reports prepared as part of this process;
 - 8.2 All documents are clearly marked, “**PRIVILEGED AND CONFIDENTIAL. FOR QUALITY IMPROVEMENT PURPOSES**”;
 - 8.3 A file containing only a summary of factual information pertaining to the Occurrence and recommendations resulting from the Case Review and/or the Root Cause Analysis will be held in secure storage by Risk Management;
 - 8.4 The security of information sent by e-mail cannot be guaranteed. Therefore e-mail will not be used to communicate information about the Occurrence information;
 - 8.5 Reporting outside of the internal review process outlined in this policy is only done on the advice of Risk Management Legal Counsel.
- 9. Process Review (day 60 - 120)
 - 9.1 Under the direction of the Executive Management Team, the process for “Management of Serious Clinical Occurrences” is reviewed by the Director(s) involved to determine what worked and what did not. Consideration is given to: Were needs met? Was the process known and followed? Was the process appropriate and efficient? Were resources adequate? Were desired outcomes achieved?
 - 9.2 Requires input from all participants in the process; and
 - 9.3 Must be completed within 60 days of the Root Cause Analysis final report.

Appendix C

Triage and Triggering Questions for Root Cause Analysis

The United States Veterans Affairs National Center for Patient Safety has developed a list of triage and triggering questions (included below with slight revisions) designed to aid the facilitator in conducting root cause analysis. It is important to note that the questions are not a script for conducting the RCA, therefore not all questions will be explicitly asked in this format. They are, in fact, triggers designed to lead away from the sharp end towards the blunt end of the system, and can help identify potential areas where contributing factors have not yet been considered and/or shared by the review team.

Concept Definitions for Triggering Questions

Concept definitions and examples can help determine contributing factors. Using the questions in a systematic way can lead an RCA team to root causes for an event. The questions often trigger other relevant queries and supplement the natural emergence of factors in the RCA process. A skilled facilitator will ensure that all areas are explored in sufficient depth.

I. Human Factors/Communication:

Questions that help assess issues related to communication, flow of information and availability of information as needed. These questions also reveal the importance of communication in use of equipment and application of policy and procedure, unintended barriers to communication and the organization's culture with regard to sharing information.

For example: A patient without an identifying bracelet is administered medication based on the nurse's memory of the patient's identity. The hospital has a policy requiring that wrist bracelets be checked before every dose of medicine, but because the dose is overdue, the nurse delivers the medicine without confirming the patient's identity.

II. Human Factors/Training:

Questions that help assess issues related to routine job training, special training and continuing education, including the timing of that training. Training issues may concern application of approved procedures, correct use of equipment or appropriate manipulation of protective

barriers. These questions also focus attention on the interfaces between people, workspace and equipment.

For example: A new group of physicians in residency training arrived this week to start a rotation at your facility. They do not receive an orientation to the lab system. A lab error occurs when the wrong form is submitted with a blood vial.

III. Human Factors Fatigue/Scheduling:

Questions that weigh the influence of stress and fatigue that may result from change, scheduling and staffing issues, sleep deprivation or environmental distractions such as noise. These questions also evaluate relationships to training issues, equipment use, and management concern and involvement.

For example: Because of sick calls, a nursing unit normally staffed by two Registered Nurses and four Licensed Practical Nurses is reduced to a staffing level of one RN and three LPNs. During this shift, a patient's nursing call bell goes unanswered and she experiences a fall while trying to use the bathroom unassisted.

IV. Environment/Equipment:

Questions to help evaluate factors related to: use and location of equipment; fire protection and disaster drills; codes, specifications and regulations; the general suitability of the environment; and the possibility of recovery after an error has occurred. These questions show that what appears to be equipment failure may relate to human factors issues, policy and procedure questions, and training needs.

For example: Housekeeping staff is thorough in their care of bedding material. While the patient is in physical therapy they flip a patient's air-filled anti-decubitus mattress, inadvertently reversing the correct alignment of the air chambers.

Renovation is taking place in adjoining space making it difficult for staff to converse and to hear patient call bells.

V. Rules/Policies/Procedure:

Questions that help assess the existence and ready accessibility of directives including technical information for assessing risk, mechanisms for feedback on key processes, effective interventions developed after previous events, compliance with national policies, and the usefulness of and incentives for compliance with codes, standards and regulations. The qualifications of the facility and employees for the level of care provided, orientation, and training for compliance with safety and security measures including handling of hazardous material and emergency preparedness, and the availability of information to all part time, temporary or voluntary workers and students are also considered.

For example: A nurse hired for the day through the local registry is not familiar with your facility's policy against unlocking the door to the balcony in order to smoke while taking a break.

Starting Point

First:

Was this event thought to be the result of a criminal act, a purposefully unsafe act related to alcohol or substance abuse (impaired provider/staff), or events involving alleged or suspected patient abuse of any kind (i.e., those situations which are outside the scope of the patient safety program)? If YES, request that the RCA process be stopped and that an administrative process be started.

Second:

1. Were issues related to patient assessment a factor in this situation? If YES, respond to questions in Human Factors: Communication.
2. Were issues related to staff training or staff competency a factor in this event? If YES, respond to questions in Human Factors: Training.
3. Was equipment involved in this event in any way? If YES, respond to questions in Environment and Equipment.
4. Was the work environment a factor in this event? If YES, respond to questions in Environment and Equipment.
5. Was the lack of information (or misinterpretation of information) a factor in this event? If YES, respond to questions in Human Factors: Communication.
6. Was communication a factor in this event? If YES, respond to questions in Human Factors: Communication.
7. Were appropriate rules/policies/procedures—or the lack thereof—a factor in this event? If YES, refer to Using the Five Rules of Causation.
8. Was the failure of a barrier—designed to protect the patient, staff, equipment or environment—a factor in this event? If Yes, respond to questions in Barriers.
9. Were personnel or personal issues a factor in this event? If YES, respond to all Human Factors questions: Communication, Training, and Fatigue/Scheduling.

Third:

Remember, doing an RCA is an iterative process. So, as you learn more about the big picture for this event, feel free to come back and use the triage questions to get a

clearer idea of what happened and how to prevent it from happening again.

Human Factors: Communication

In this section, address all questions.

1. Was the patient correctly identified?
2. Was information from various patient assessments shared and used by members of the treatment team on a timely basis? If NO -- This could be a Root Cause/Contributing Factor.

Organize your thoughts about the Five Rules of Causation.

3. Did existing documentation provide a clear picture of the work-up, the treatment plan and the patient's response to treatment? Including:
 - assessments
 - consultations
 - orders
 - treatment team notes
 - progress notes
 - medication administration record
 - x-ray
 - lab reports
 - etc.
 If NO -- This could be a Root Cause/Contributing Factor.

Review the Five Rules of Causation.

4. Was communication between management/supervisors and front line staff adequate? Was it:
 - accurate?
 - complete?
 - using standard vocabulary and no jargon?
 - unambiguous?
 If NO -- Describe how management/supervisors and front line communications are not adequate.
5. Was communication between front line team members adequate? If NO -- Describe how communications between team members were not adequate.
6. Were policies and procedures communicated adequately? If NO -- Describe how policies and procedures were not communicated adequately.

If this is an issue, see the **Rules/Policies/Procedures questions**.

7. Was the correct technical information adequately communicated 24 hours a day to the people who needed it? If NO -- Describe how communication about technical information is not adequate.

8. Were there methods for monitoring adequacy of staff communication? Were there methods for:

- “read back”?
- confirmation messages?
- debriefs?
- etc.

If NO -- This could be a Root Cause/Contributing Factor.

9. Was the communication of potential risk factors free from obstacles? If NO -- This could be a Root Cause/Contributing Factor.

Review the Five Rules of Causation.

10. Was there a manufacturer’s recall/alert/bulletin on file for equipment, medication, or transfusion related elements at the time of the event or close call? Were relevant staff members aware of the recall/alert/bulletin? If this is an issue, consider Environment and Equipment questions.

11. If relevant, were the patient and their family/significant others actively included in the assessment and treatment planning?

12. Did management establish adequate methods to provide information to employees who needed it in a manner that was easy to access/use and timely? If NO -- This could be a Root Cause/Contributing Factor.

Organize your thoughts about the Five Rules of Causation.

13. Did the overall culture of the facility encourage or welcome observations, suggestions or early warnings from staff about risky situations and risk reduction? (Also, has this happened before and was anything done to prevent it from happening again?)

14. Did adequate communication across organizational boundaries occur?

Human Factors: Training

In this section, address all questions.

1. Was there a program to identify what is actually needed for training of staff? If NO -- this could be a Root Cause/Contributing Factor.

2. Was training provided prior to the start of the work process? If NO -- this could be a Root Cause/Contributing Factor.

3. Were the results of training monitored over time? If NO -- this could be a Root Cause/Contributing Factor.

Review the Five Rules of Causation.

4. Was the training adequate? If not, consider the following factors:

- supervisory responsibility
- procedure omission
- flawed training
- flawed rules, policy, or procedure

If YES, go to the Rules/Policy/Procedure questions.

5. Were training programs for staff designed up-front with the intent of helping staff perform their tasks without errors? If NO -- this could be a Root Cause/Contributing Factor.

6. Had procedures and equipment been reviewed to ensure that there was a good match between people and the tasks they did, or people and the equipment they used (i.e., human factors engineering)? If procedures were not followed as intended, see the Rules/Policy/Procedure questions.

7. Were all staff trained in the use of relevant barriers and controls? If YES, see the Barriers questions.

8. If equipment was involved, did it work smoothly in the context of:

- staff needs and experience?
- existing procedures, requirements and workload?
- physical space and location?

If equipment was involved, see the Environment and Equipment question.

Human Factors Fatigue/Scheduling

1. Were the levels of vibration, noise or other environmental conditions appropriate?

2. If applicable, were environmental stressors properly anticipated?

- If stressors were anticipated, see the Human Factors/Training questions.
- If stressors were not anticipated, why weren’t they anticipated?

3. Did personnel have adequate sleep?

4. Did scheduling allow personnel adequate sleep?

Review the Five Rules of Causation.

5. Was fatigue properly anticipated?
6. Was the environment free of distractions?
7. Was there sufficient staff on-hand for the workload at the time? (i.e., workload is too high or too low, or wrong mix of staff.) If YES, see the Human Factors/Training questions.
8. Was the level of automation appropriate? (i.e., neither too much nor not enough.) If YES, see the Environment and Equipment questions.

Environment and Equipment

In this section, address all questions.

Environment

1. Was the work area/environment designed to support the function it was being used for?
2. Had there been an environmental risk assessment (i.e., safety audit) of the area? If NO, consider reviewing the **Rules/Policy/Procedures and Barriers questions**,
3. Were the work environment stress levels (either physical or psychological) appropriate (e.g. temperature, space, noise, intra-facility transfers, construction projects.)? If YES, go to the Human Factors/Scheduling/Fatigue questions.
4. Had appropriate safety evaluations and disaster drills been conducted?
5. Did the work area/environment meet current codes, specifications and regulations?

Equipment (If training was an issue go to Human Factors/Training.)
6. Was equipment designed to properly accomplish its intended purpose?
7. Did the equipment involved meet current codes, specifications and regulations?
8. Was there a documented safety review performed on the equipment involved? If relevant, were recommendations for service/recall/maintenance, etc., completed in a timely manner?
9. Was there a maintenance program in place to maintain the equipment involved? If NO, go to Rules/Policy/Procedures.
10. If there was a maintenance program, did the most recent previous inspections indicate that the equipment was working properly?
11. If previous inspections pointed to equipment problems, what corrective actions were implemented and were they effective?
12. Were adequate time and resources allowed for physical plant and equipment upgrades, if problems were identified?
13. Was there adequate equipment to perform the work processes?
14. Were emergency provisions and back-up systems available in case of equipment failure?
15. Had this type of equipment worked correctly and been used appropriately in the past?
16. Was the equipment designed such that usage mistakes would be unlikely to happen?
17. Was the design specification adhered to? If YES, go to the Human Factors/Training questions.
18. Was the equipment produced to specifications and operated in a manner that the design was intended to satisfy?
19. Were personnel trained appropriately to operate the equipment involved in the adverse event/close call? If no, see the Human Factors/Training questions.
20. Did the design of the equipment enable detection of problems and make them obvious to the operator in a timely manner?

Review the Five Rules of Causation.

21. Was the equipment designed so that corrective actions could be accomplished in a manner that minimized/eliminated any undesirable outcome?
22. Were equipment displays and controls working properly and interpreted correctly?
23. Was the medical equipment or device intended to be reused (e.g. not a single use device)?

Rules/Policies/Procedures

In this section, address all questions.

1. Was there an overall management plan for addressing risk and assigning responsibility for risk?
2. Did management have an audit or quality control system to inform them how key processes related to the adverse event are functioning?
3. Had a previous audit been done for a similar event, were the causes identified and were effective interventions developed and implemented on a timely basis?
4. Would this problem have gone unidentified or uncorrected after an audit/review?

5. Was required care for the patient within the scope of the facility's mission, staff expertise and availability, technical and support service resources?
6. Were the staff involved in the adverse event or close call properly qualified and trained to perform their functions?
7. Were all involved staff oriented to the job, facility and unit policies regarding: safety, security, hazardous material management, emergency preparedness, life-safety-management, medical equipment and utilities management?
8. Were there written up-to-date policies and procedures that addressed the work processes related to the adverse event or close call?
9. Were these policies/procedures consistent with relevant federal and VHA policies, standards, and regulations?
10. Were relevant policies/procedures clear, understandable and readily available to all staff? If NO, go to the Human Factors/Communication questions.
11. Were the relevant policies and procedures actually used on a day-to-day basis?
12. If the policies and procedures were not used, what got in the way of their usefulness to the staff?
13. If policies and procedures were not used, what positive and negative incentives were absent?
8. Were the relevant barriers and controls maintained and checked on a routine basis by designated staff? If NO, go to the Rules/Policy/Procedures questions.
9. Would the adverse event have been prevented if the existing barriers and controls had functioned correctly?
10. Were the system or processes tested before they were implemented?
11. Did the audits/reviews related to barriers include evaluation of plans, designs, installation, maintenance and process changes? If YES, go to the Rules/Policy/Procedures questions.
12. Did management have a method for identifying what the results of the system changes would be before implementation? If YES, go to the Rules/Policy/Procedures questions.


Barriers

In this section, address all questions.

1. What barriers and controls were involved in this adverse event or close call?
2. Were these barriers designed to protect patients, staff, equipment, or environment?
3. Was patient risk considered when designing these barriers and controls?
4. Were these barriers and controls in place before the event happened?
5. Had these barriers and controls been evaluated for reliability?
6. Were there other barriers and controls for work processes?
7. Was the concept of "fault tolerance" applied in system design?

Appendix D

Saskatchewan Health Disclosure
of Harm Guideline

 Saskatchewan Health	Cross Ref	None
	Contact	P. Beard/ J White, AESB
	Page	64 of 1
Section:	Risk Management	
Subject:	DISCLOSURE OF HARM GUIDELINE	

Intent: To provide regional health authorities with guidelines concerning the disclosure of harm to patients and/or their families.

Guideline: Disclosure of harm
to patients.

Principles for the disclosure of harm to patients are derived from medical, legal and ethical considerations. Ethically, when done with care, disclosure can bolster public confidence in the health care system. For reasons of autonomy, institutional responsibility, transparency, and because it is the “right thing to do”, it is recommended that disclosure become embedded in the health care culture in Saskatchewan.

Arising out of the duty to obtain informed consent, “patients must be told what may go wrong...it must surely follow that they also have a right to be told what has in fact gone wrong.”

-Robertson 2002

Definitions:

Error - The failure to complete a planned intervention as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim. Errors can result from an act of commission or omission.

Harm - Any injury to the body. The occurrence of a change for the worse.

Patient - Means a patient, client or resident.

Substitute Decision Maker - A proxy or nearest relative as per the Health Care Directives and Substitute Health Care Decision Makers Act, 1997.

Triggers for the disclosure of harm to patients:

Disclosure should be considered when harm has come to the patient as a result of the health care services

provided or omitted. Disclosure may be considered in the presence of any of the following circumstances:

1. The harm should have been anticipated and/or communicated during the process of obtaining informed consent;

Example: Prior to an abdominal surgery, a patient is told that there is a possibility the surgeon will nick the bowel during the procedure. This in fact happens, the bowel is repaired and the patient is given antibiotics to ward off possible infection. In this case, the surgeon should then disclose to the patient that nicking of the bowel did occur.

2. The harm was not anticipated therefore not communicated during the process of obtaining informed consent;

Example: A patient consented to have a left-sided hernia repair performed under general anaesthetic. The surgeon repairs a right-sided hernia, then realizes his error and proceeds to perform the left-sided hernia repair. In this case, the surgeon should disclose to the patient that an unanticipated event occurred during the surgery.

3. The harm may have been caused by human or systemic error (this may not be immediately clear but should not delay disclosure).

Example: A Home Care patient is prescribed 10 units of insulin. The nurse arrives at the patient’s home and accidentally administers 100 units of insulin and as a result the patient becomes hypoglycaemic. An ambulance is called; the patient is treated for

hypoglycaemia, and recovers. In this case, the attending physician and nursing manager for Home Care should disclose to the patient that he unintentionally received ten times the usual dose of insulin, causing his hypoglycaemia.

When should disclosure occur?

Disclosure should occur as soon as possible following to a triggering event. Ideally, disclosure would occur within 24-48 hours of the healthcare team first becoming aware of the event. However, there are some situations that require additional time for the discovery of accurate information to provide to patients, and the coordination of the disclosure process. This circumstance is frequently associated with disclosure involving multiple patients, equipment failure, or the potential for the spread of nosocomial infection.

If the need to disclose is not immediately obvious, consideration should be given to performing a scientific risk assessment (e.g. the probability of disease transmission resulting from exposure to an unsterilized piece of equipment is 1 in 25,000) to determine if harm is present. In the absence of harm, a close call should prompt the organization to review issues associated with the event to ensure future patient safety, however, disclosure is not required, as no harm has been done.

Who should receive disclosure?

The patient or their substitute decision maker should receive disclosure, as appropriate and provided for by statute in the individual circumstances of each case. For the purposes of continuity of care and maintaining trusting relationships between patients and their caregivers it is essential that all appropriate members of the healthcare team are aware of any plans to provide disclosure of harm to patients.

Who should provide disclosure?

A team approach is best utilized for discussing harm with a patient and/or their substitute decision maker, however, there may be circumstances when it is more appropriate for an individual to do so. The team may include the most responsible physician, medical manager, or Chief of Staff. Additionally, a representative for the region (i.e. manager/director for the clinical area(s) involved or any combination that may be appropriate to the situation) may be present. It may also be appropriate to include the organization's Risk Manager. The organization should be mindful that having too many individuals present during a disclosure meeting may be overwhelming to the patient and should be avoided.

Lead for the disclosure discussions should rest with those who have the most knowledge of the event(s) that led to the patient harm. Though not required, consideration should also be given to involving medical

residents or students who were present for the event that caused harm, as the experience will create a basis for their future practice. Regardless of who attends the actual disclosure meeting, all healthcare professionals involved in the provision of services to the patient should be aware that disclosure has been provided.

Finally, the organization should consider what resources the patient might require during and after the disclosure meeting. The Client Representative or Quality of Care Coordinator can assist patients and their families by providing support both during and subsequent to the meeting. There may be additional treatments or procedures that the patient will need to undergo and/or follow-up meetings required to further discuss the event and the QCC will ensure continuity for the patient. Depending on the situation, it may also be beneficial to offer the assistance of a social worker, grief counsellor, chaplain, or similar to the patient following to the disclosure meeting.

How should disclosure be provided?

Ideally, disclosure should be provided in a private, quiet setting. It is further recommended that those involved in the disclosure meeting will invoke other processes as necessary to ensure that the appropriate information is provided to the patient. This may include the need to access, prior to the meeting, the services of an ethics consult, social worker or legal counsel.

Those responsible for the disclosure discussion should establish the tone of the meeting by providing a clear understanding for what will happen during the disclosure. Factual information should be provided professionally, compassionately, truthfully, and in the absence of blaming statements. It is important to understand that disclosure is a separate and distinct process that, for reasons of privilege, should not cross over into critical incident reviews and investigations.

What should be disclosed and how should it be documented?

Discussions should focus on currently known information about the facts surrounding the event. Blame should not be assigned. Opinions should not be discussed. Speculation as to cause, if not yet known, should not occur during the meeting. Disclosure should not be delayed because all facts are not known, but the patient should be made aware if this is the case, and a follow-up discussion should be planned to disclose any new facts that are discovered.

The process the organization plans to use to review the circumstances of the event should be provided to the patient. The discussions should include clarification about what information can be provided to the patient (e.g. information generated in preparation for and during

quality assurance discussions will not be disclosed as per Section 35.1 of the *Evidence Act* and Section 58 of the *Regional Health Services Act*). It may be advantageous to meet with legal counsel prior to disclosure discussions if there is any uncertainty as to what the organization and/ or medical staff is able to share during the meeting.

It will be valuable to have all documentation related to the care provided (with the exception of privileged documents) available during the meeting so that the most accurate information may be given to the patient. In addition to having these documents available during the meeting, patients should be provided with information about how to access their health information and consideration should be given to waiving fees for obtaining copies of patient charts.

A complete entry of all facts related to the disclosure meeting should be entered into the health record, including a reflection of the nature of the disclosure discussion with the patient or their substitute decision maker. The entry should include the date, time, any facts provided and who was present during the discussion. It may also be appropriate to keep a more detailed record of events with the occurrence or incident report and any other relevant documents in an administrative file secured by risk management personnel. These documents should be prepared in such a manner that they would benefit from the protection offered by the *Saskatchewan Evidence Act* or the *Regional Health Services Act* and the distinction between discloseable facts and privileged opinion and peer review discussion should always be borne in mind.

Multi-Patient Disclosure:

It may be appropriate to modify the disclosure process for events that involve more than one patient. Initial contact may include a registered letter, telephone call, or an invitation to an in-person meeting. Regardless of the way in which initial contact is made, an opportunity for an in-person private meeting should be provided to every patient involved. Group meetings set up by the organization are not encouraged for reasons of confidentiality of patient information and protection of the privacy of those involved.

Every attempt should be made to inform all patients involved at approximately the same time and, where possible, in advance of any media attention to the issue.

Multi-Jurisdictional Disclosure:

There may be disclosures that extend beyond jurisdictional borders as follows:

- A patient receives care and harm occurs as a result of the care in the originating jurisdiction but is not disclosed and/ or known prior to the transfer of the patient to another jurisdiction.

or

- A process or event may be common to multiple jurisdictions where the opportunity now exists for variation in the decision to disclose.

In either of the above circumstances, effective communication and cooperation between jurisdictions is key. Ideally, both jurisdictions should be a part of disclosure discussions. The lead will normally fall under the responsibility of the jurisdiction in which the event occurred. If issues become difficult to resolve, Saskatchewan Health may be approached to assist in facilitating the disclosure.

Disclosure Policy:

It is the expectation of Saskatchewan Health that all regional health authorities prepare and implement the use of disclosure policies based on the principles and guidelines outlined in this document.

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Appendix E

Team Membership, Roles and Responsibilities.

1. **Leader:** someone knowledgeable about the general type of event and organizational authority to implement the process.

Attributes:

- analytical in that subject area

Responsibilities:

- keep team focused on event
- provides support for cultural change
- support team members in their analysis
- remove barriers faced by team members

2. **Facilitator:** quality specialist or risk manager

Attributes:

- expert in RCA tools and techniques
- skilled at group dynamics
- skilled at delegation
- skilled at group consensus building

Responsibilities:

- coordination of team meetings
- keep team focused on event
- completion of timelines
- ensuring that RCA process is followed
- participate in interviews
- writing final report (often done by a formal recording secretary for the RCA)

3. **Individuals knowledgeable about subject area:**

Depending on the RCA type, this will vary. Clinical and non-clinical staff members (including those involved in the critical incident and several who were not) provide valuable insight. Suicide events may include physical plant or architecture staff, housekeeping, nursing and security, etc. Medication events may include pharmacists, biomedical engineering, information technologists, physicians, nurses, unit clerks, technicians, etc. Patient falls may include physiotherapists, rehabilitation staff, nursing aids, nurses, etc.

Attributes:

- extensive knowledge of the subject area
- credibility within organization
- analytical, open-minded
- interested

Responsibilities:

- Provide information relevant to the different steps involved in the event
- Provide information on the usual process
- Help identify contributing factors and actions relevant to current practice

4. **Other staff or consultants:**

Include outside agencies as appropriate (home care, EMS, vendors, etc.) They provide information that is not available to members inside the organization.

Attributes:

- Specific knowledge of equipment, technology, etc that may have contributed to event or may be required for actions.

Responsibilities:

- Provide expert opinion and knowledge to facilitate identification of root causes/contributing factors and/or development of action plans.

5. **Senior leadership:**

Attributes:

- Authority for decision-making.
- Drive the safety culture by example.

Responsibilities:

- Ensure that actions are implemented once approved.
- Ensure that staff members are scheduled away from normal duty to participate in RCA.
- Ensure that results of RCA are communicated broadly.

Appendix F

Sample of RCA Team Charter

Date:

From: Director (oo)

Subj: RCA Team Charter Memo

To:

1. This memo confirms that an RCA Team will be convened to determine the root cause and contributing factors for the adverse event(s), close call(s), or aggregated review briefly described below.

Date Event Occurred ___/___/___ Date Facility was Aware of Event ___/___/___

This RCA is for (check one): Individual Case ___ Aggregated Review ___

2. As part of the RCA process, the team will be responsible for developing a final report and recommendations based on their expert analysis. All RCAs are quality assurance, focused review processes, and the team's products (e.g., interviews, preliminary and final reports, etc.) are considered confidential, privileged and protected under 38 USC 5705.

Note: If in the course of conducting the RCA it appears that the event(s) or close call(s) under consideration were the result of an intentional unsafe act or acts (as described in the VHA National Patient Safety Improvement Handbook - Paragraph 5c), the team will contact the facility Director so that other, administrative review processes may occur, instead. At that point, the RCA team will discontinue their work, and the information they have already developed will remain protected as a focused review (38 USC 5705).

3. RCA Participants are listed below. (The respective service chiefs/designees have already been notified of this important commitment, and are in full support.)

RCA Advisor: The advisor's role is to initiate the RCA process, provide an introduction/overview for the team, and provide consultation to the team according to the Advisor's assessment of the process.

Name _____ Title _____ Phone _____

Has the RCA Advisor had formal RCA training? (check one): Yes ___ No ___

(If "no", the RCA Advisor must be provided with "just-in-time" training.)

Team Leader: The team leader's role is to skillfully lead the team through the RCA process and ensure that the best possible product is developed in a timely manner. The team leader is also responsible for estimating time and resources spent on this process.

Name _____ Title _____ Phone _____

Has the Team Leader had formal RCA training? (check one): Yes ___ No ___

(If "no" the Team Leader must be provided with "just-in-time" training.)

Team Members (name/title/phone/training needed): The team member's role is to rigorously conduct the RCA as full and active participants in the process.

Name	Title	Phone	Training? (Yes/No)

(Team members, who have not had training, must receive "just-in-time" training.)

4. List of disciplines and/or services involved in this adverse event(s) or close call(s):

5. List of potential internal (i.e., facility) and external experts or consultants:

6. List of space and equipment currently available to the RCA team (e.g., room number, flip charts, laptop computer, etc.)

7. The RCA team's final report is due to the Risk Manager on: ___/___/___

8. The team may add additional members and go beyond the preliminary listing of disciplines/services and experts/consultants, as needed. In addition, if team members are added, more space or equipment is required, or report due dates require an extension the team leader is requested to contact _____.

9. Thank you for improving patient safety

Director's Signature Block

Appendix G

Confidentiality Agreement

ROOT CAUSE ANALYSIS CONFIDENTIALITY AGREEMENT

(EXAMPLE ONLY)

Name (please print): _____

Affiliation with _____:

(Insert name of organization) (Position)

1. I understand that the organization has custody and control of information, which it must protect for ethical, legal and proprietary reasons. This document represents my commitment to treat any information which is entrusted to me during the root cause analysis (RCA) process in a manner that respects the privacy of practitioners, patients and involved organizations, including information that does not identify individual healthcare practitioners, institutions or patients.
2. I will treat all root cause analysis information related to the incident, as well as any administrative, financial, employee or other information as confidential information. This includes information held in any format, such as fax, email, discussions and other records. This obligation does not apply to information in the public domain.
3. I agree to respect the following rules regarding the treatment of information with which the organization is entrusted.
 - (a) I will not access information related to the incident unless I need to know it to perform my current job duties or to meet my professional responsibilities as part of the RCA process.
 - (b) I will not disclose information related to the RCA process except to perform my job or meet my responsibilities to the organization.
 - (c) I will not engage in discussions about information arising from the RCA process in public or in any area where it is likely to come to the attention of others who are not entitled to receive such information, such as: hallways, elevators, washrooms, cafeteria, locker rooms, lounges, public reception areas, etc.
 - (d) I will not allow another person to use my authorised access (e.g. username and password) to gain access to information regarding the RCA.
 - (e) I will only access, process, and transmit information using authorized hardware, software and other equipment.
4. I understand that the organization reserves the right to conduct audits to ensure information is protected against unauthorized access, use, disclosure, copying, modification, and disposal.
5. I have read this confidentiality agreement and understand that the conditions as described in this agreement will remain in force even if I cease to have an association with the organization.

Signature

Date

(Adapted from the ISMP Canada Organizational Confidentiality Agreement)

Appendix H

Root Cause Analysis Matrix

Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events – October 2005

Detailed inquiry into these is expected when conducting a root cause analysis for the specified type of sentinel event. Inquiry into areas not checked (or listed) should be conducted as appropriate to the specific event under review.

	Suicide (24 ^h care)	Med. Error	Proced. Cmplic.	Wrong site surg.	Treatment delay	Restraint death	Elopement death	Assault/ rape/ hom.	Transfusion death	Patient abduction	Unanticipated death of full term infant	Unintended retention of foreign body	Fall related
Behavioral assessment process ¹	X					X	X	X					
Physical assessment process ²	X	X	X	X	X	X	X				X		X
Patient identification process		X		X					X				
Patient observation procedures	X				X	X	X	X	X		X		X
Care planning process	X		X			X	X				X		X
Continuum of care	X	X			X	X							X
Staffing levels	X	X	X	X	X	X	X	X	X	X		X	X
Orientation & training of staff	X	X	X	X	X	X	X	X	X	X	X	X	X
Competency assessment / credentialing	X	X	X	X	X	X	X	X	X	X	X	X	X
Supervision of staff ³	X	X	X		X	X			X			X	
Communication with patient/family	X	X		X	X	X	X			X			X
Communication among staff members	X	X	X	X	X	X	X	X	X	X	X	X	X
Availability of information	X	X	X	X	X	X			X		X		X
Adequacy of technological support		X	X										
Equipment maintenance / management		X	X		X	X					X		X
Physical environment ⁴	X	X	X	X		X	X	X	X	X			X
Security systems and processes	X						X	X		X			
Medication Management ⁵		X	X		X				X		X		X

1. Includes the process for assessing patient's risk to self (and to others, in cases of assault, rape, or homicide where a patient is the assailant).
2. Includes search for contraband.
3. Includes supervision of physicians-in-training.
4. Includes furnishings; hardware (e.g., bars, hooks, rods); lighting; distractions.
5. Includes selection & procurement, storage, ordering & transporting, preparing & dispensing, administration, and monitoring.

Source: United States Joint Commission on the Accreditation of Healthcare Organizations. <http://www.jcaho.org/accredited+organizations/sentinel+event/se_root_cause_analysis_matrix.pdf>.

NOTE: Provided for information purposes only.



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