



Critical Incidents & Multi-Patient Events

Risk Resource Guide
April 2015



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This document will be updated as new information and insights arise. We are very interested in receiving questions, suggestions and feedback regarding this work. Please direct your comments to:

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Critical Incidents & Multi-Patient Events

Contents

- Introduction**..... 1
 - Challenges 1
 - Defining Critical Incidents 2
 - Purpose of the Guide 3
- Leadership** 4
 - Crisis Management 4
 - Crisis Communications..... 5
 - General Principles 5
 - Managing the Media 5
 - Key Messages 5
 - Internal Communication 6
 - Organizational Policy and Procedure 6
- Patients and Families** 7
 - General Principles 7
 - Immediate Response and Initial Disclosure 7
 - Ongoing Communications 8
 - Input Into Incident Analysis..... 8
 - Post Analysis Disclosure 8
 - Disclosure Resources 9
- Staff** 10
 - Second Victim 10
 - Just Culture 11
 - Privilege Protection 12
- Key Concepts**..... 14
 - Systems 14
 - Systems Thinking/Approach..... 14
 - Human/Active/Sharp-end Errors..... 15
 - Systems/Latent/Blunt-end Errors, Contributing Factors 16
 - Human Factors..... 17
 - Complexity Theory and Complex Adaptive Systems 17
 - High Reliability 18
 - Risk Management 18
 - Medical Malpractice..... 19
 - Quality Improvement 20
 - Reviewer Biases 21
- Analysis**..... 22
 - Purpose and Process 22
 - Triggering an Analysis..... 22
 - Review Team 23
 - Information Gathering..... 24
 - Chronology of Events/Timeline 25
 - Interviews 25

Critical Incidents & Multi-Patient Events

- General Principles 26
- Pre Interviews 26
- Setting 26
- Interview 26
- Closure 27
- Note Taking 27
- Post Interviews 27
- Identification of Issues and Contributing Factors 28
- Recommendations Development..... 29
 - Prioritization 30
- Report 31
 - Report Confidentiality 31
- Implementation and Follow up..... 32
 - Recommendations Tracking 32
 - Sharing Results 33
 - Results Trending..... 33
- Multi-Patient Events..... 35**
 - ALERT – Early Involvement of HIROC 35
 - Types of Events 35
 - Infectious Disease Outbreaks 35
 - Sterilization Failures 36
 - Diagnostic Errors 36
 - Privacy Breaches..... 36
 - Identifying Patients and Assessing Impact 37
 - Notification of Patients..... 38
 - What to Disclose..... 38
 - Methods..... 39
 - Timing..... 39
 - Managing the Media 40
 - Organizational Policy..... 40
 - Class Action Lawsuits 41
- Conclusion 41**
- References 42**
- Appendix 1: Crisis Communications Key Messages 46
- Appendix 2: Elements of a Critical Incident Management Policy, Procedure, Guideline 47
- Appendix 3: Key National and International Resources..... 48
- Appendix 4: Frameworks for Developing Effective Recommendations..... 51
- Appendix 5: Checklist for Managing Multi-Patient Events 55

Introduction

A serious clinical adverse event is a crisis for everyone involved. Governing bodies and executive leadership carry the burden of these events forever, but carrying the burden isn't enough. They also have a responsibility to ensure that everything possible is done to understand what happened and why it happened, and to prevent it from ever happening again. These crises have the power to be used to transform the organization to a dramatically better one. We have the responsibility to meet the patient, family, staff, organization, and community where they are with the elements of empathy, disclosure, support, assessment, resolution, learning, and improvement. (Conway et al 2011, p.28).

In healthcare, adverse outcomes are common. Most relate to the patient's underlying disease process or known complications of medical care and are generally not avoidable (Wachter 2012). Unfortunately, adverse outcomes can also result from the mistakes of healthcare providers and weaknesses in the systems that contribute to them. The most critical of these incidents involve serious injury, permanent disability or death, and while the rate of critical incidents is low as a proportion of all healthcare encounters, in aggregate, the number of impacted patients is significant (Baker et al 2004).

Challenges

The risks of not responding to critical incidents in a timely and effective manner include further suffering for the patients, families and staff involved, reputational harm, lost learning opportunities and the growth of fear which, in turn, introduces more failures into the system. If done well, however, the management of critical incidents can be the most important activity an organization does to improve patient safety (Vincent 2004, Watcher 2012).

Ensuring an appropriate response to critical incidents is challenging and issues associated with the subsequent review of events have been reported in the literature (Wu, Lipshutz and Pronovost 2008, ECRI 2011, Robson 2012, ISMP 2010, CPSI 2012, Boyd 2014). These include:

- Lack of upper management support;
- Lack of a defined organizational approach/policy/guideline;
- Lack of awareness about the approach/policy/guideline if it exists;
- Lack of consensus on what constitutes a critical incident;
- Lack of support for impacted patients, families, and staff;
- Poor communication with stakeholders;
- Insufficient expertise to perform analysis;
- Lack of time to perform analysis;
- Unjust punitive responses to staff involved;
- Incorrect or incomplete analyses including:
 - Skipping key steps such as development of a chronology;
 - Too broad or too narrow a focus;
 - Biases leading to premature closure of analysis;
 - Pre-determination of issues and solutions;
 - Truncated/incomplete/reluctant input from those involved;
 - Failure to identify deep-seated systems failures;
 - Failure to explore the goal conflicts that encourage cutting corners and lack of compliance with established policies and protocols;
- Poorly developed, weak risk-reduction strategies;
- Resistance to change and unwillingness to consider necessary system improvements;
- Failure to implement and monitor recommendations;
- Detrimental unanticipated outcomes resulting from changes.

Defining Critical Incidents

Harm as a hospital-induced patient outcome has not been well defined in healthcare. The lack of a standard definition of patient harm leads organizations to use disparate, subjective determination that requires significant interpretation. (HPI 2009, p.1).

Most jurisdictions across Canada define critical incidents (also called serious safety events, sentinel events, or serious adverse events) through application of inclusion and exclusion criteria; specifically they are incidents that:

1. Are unintended;
2. Are care related;
3. Result in serious harm, disability, or death;
4. Are not the result of an underlying disease process;
5. Nor the result of known complications.

The element of preventability is implied, underscored in some instances by a pre-defined list of highly preventable or “never” events (Saskatchewan 2004). It is important to note that this definition does not stipulate that the event result from an unsafe act or human error as is the case elsewhere (Reason 2000, Taylor-Adams and Vincent 2004, HPI 2009).

One issue with this definition is that there is considerable variability within and across organizations in terms of what constitutes “serious” harm. The following sources may provide guidance to leaders as they establish thresholds for serious/critical incidents within their organizations:

1. World Health Organization (2009).
 - Moderate harm – Patient outcome is symptomatic, requiring intervention (e.g. operative procedure, therapeutic treatment), increased length of stay, or causing permanent or long term harm or loss of function;
 - Severe harm – Patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function;
 - Death – On a balance of probabilities, death was caused or brought forward in the short term by the incident.
2. National Coordinating Council for Medication Error Reporting (2001) Serious Safety Events (SSE).
 - G – An error occurred that may have contributed to or resulted in permanent patient harm;
 - H – An error occurred that required intervention necessary to sustain life;
 - I – An error occurred that may have contributed to or resulted in the patient’s death.
3. Healthcare Performance Improvement (2009) Serious Safety Event (SSE).
 - Deviations (human or equipment failures) from generally accepted performance standards that reach the patient and result in moderate to severe harm or death including:
 - SSE 1 – Death;
 - SSE 2 – Severe Permanent Harm (e.g. wrong site procedure resulting in removal of healthy limb; missed diagnosis resulting in permanent impairment; anoxic brain injury resulting in permanent brain damage);
 - SSE 3 – Moderate Permanent Harm (e.g. incorrect dosing resulting in reduced renal function; inadvertent injury to an organ during surgery requiring removal);
 - SSE 4 – Severe Temporary Harm (e.g. induced condition that requires resuscitation);

- unrecognized fluid overload that progresses to pulmonary edema requiring transfer to the ICU; failure to diagnose respiratory insufficiency resulting in temporary intubation; preventable fall with hip fracture that requires surgical repair; retained object that requires return to the operating room);
- SSE 5 – Moderate Temporary Harm (e.g. failure to treat a low potassium level that results in an arrhythmia requiring administration of intravenous anti-arrhythmic drug and requiring extended monitoring; incorrect dose of narcotic for pain resulting in over-sedation and requiring transfer to ICU; failure to routinely assess IV site resulting in an infection at IV site requiring extensive surgical incision and drainage to resolve; incision made on one side versus the other).
4. Joint Commission (2014) Sentinel Event.
- A patient safety event, not primarily related to the natural course of the patient’s illness or underlying condition, that reaches the patient and results in:
 - Death;
 - Permanent harm;
 - Severe temporary harm and intervention required to sustain life.
5. Institute for Healthcare Improvement (Conway et al 2011).
- A (usually) preventable clinical adverse event with an impact of permanent psychological and/or physical harm (or death) on one patient or many.

Another challenge related to defining critical incidents relates to the fact that some events result from a combination of underlying disease processes, known complications of care and unintended healthcare problems. Additionally, the full impact of some incidents (e.g. chronic pain or disability) may not be apparent for some time after the event.

Purpose of the Guide

This guide pulls together evidence-informed practical advice for managing critical incidents including:

- Ensuring an effective organizational response to the crisis;
- Ensuring patients, families and staff are supported; and
- Ensuring impactful incident analyses through application of key concepts and processes.

Particular attention will also be paid to managing complex incidents involving multiple patients.

Incorporating best practices from the literature, tacit and experiential knowledge in managing critical incidents, and thoughtful risk management advice, this guide will inform organizational leaders and board members and help to build capacity in the healthcare system for carrying out high-quality incident analyses which will in turn lead to effective change and improved patient safety.^{1, 2}

¹ While the focus is on critical incidents, the concepts and methods discussed in the guide are appropriate and scalable to less serious events as well.

² The terms “incident” and “event”; “analysis” and “review”; and “disclosure” and “notification” are used interchangeably in this guide.

Leadership

Every day, clinical adverse events occur within our health care system, causing physical and psychological harm to one or more patients, their families, staff, the community, and the organization. In the crisis that often emerges, what differentiates organizations, positively or negatively, is their culture of safety; the role of the board of trustees and executive leadership; advance planning for such an event; the balanced prioritization of the needs of the patient and family, staff, and organization; and how actions immediately and over time address the integrated elements of empathy, disclosure, support, assessment, resolution, learning, and improvement. (Conway et al 2011, p.4).

As with all important organizational endeavours, an effective response to critical incidents requires careful forethought, effective planning, and strong leadership. Leaders must manage the emerging crisis, support patients, families and staff, communicate with key stakeholders, and initiate a process to analyze and learn from the event.

Crisis Management

Few things are more destructive to public trust and staff morale than the failure to respond positively to the patients and staff involved in adverse events. (Vincent 2003, p.1056).

Concurrently with attending to the immediate clinical needs of the patient, the most important task for staff involved in a critical incident is to communicate what happened to their immediate manager and most responsible practitioner (MRP). Occasionally, however, critical incidents may be identified through routine surveillance of incident reports, mortality and morbidity reviews, or safety huddles. Awareness of a critical incident should trigger an institutional response that will result in the ethical and respectful care of those involved and effective learning to help prevent the recurrence of such events in the future.

Following the initial alert, notification should cascade through to risk management, senior management and the board. The risk manager will help to ensure that other notifications (e.g. the coroner, the insurer, legal counsel) and processes (e.g. management of the health record, sequestering of biomedical supplies and devices) are carried out. An early assessment will be carried out to ensure no other patients are at risk, and in due course, a decision will be made as to whether a formal review will be triggered and if so, who will lead it.

The hours after a critical incident can be chaotic and important steps, considerations and communications may be missed. Conway et al (2011) recommend that “in the spirit of ‘never worry alone,’ organizations should establish a standing Crisis Management Team (CMT) that can assemble immediately in response to a serious clinical event. The role of the CMT is to ensure that the priorities of the patients and families, staff, and organization are met, as well as to ensure enhanced communication, support, assessment, resolution, learning, and improvement following the event” (p.11).

Modeled after the Incident Management System (IMS) (OHA 2008) which supports effective management of low frequency/high severity events, the organization would develop an incident response plan with pre-identified key roles, responsibilities, and processes that would be activated immediately after a critical clinical incident occurs. These roles would include the incident manager (e.g. senior operations leader or risk manager), senior executive (responsible for keeping the board informed), communications, human resources, patient representative, pastoral care, etc. Depending on staff and resources available, one person could assume more than one role. The team would check in at defined intervals (more frequently initially) to ensure key activities are carried out, receive updates,

and review crisis communications. This plan could be tested with periodic drills or table-top exercises. A helpful checklist to support effective crisis management after a critical incident is included in Conway et al (2011). A sample “Incident Management System Framework for the Critical Incident Management Team” has been prepared by HIROC under separate cover.

Crisis Communications

It is difficult to find hospitals or health systems as energized to improve safety as those that have been the subject of widespread media coverage after a major error. (Wachter 2012, p. 353).

Effective communications that reflect the organization’s values of caring, honesty, and integrity and that demonstrate concern for those involved and a commitment to doing the right thing are essential for maintaining the confidence of internal and external stakeholders. Conversely, poor communications can lead to long-term reputational risk and degradation (Conway et al 2011).

Leaders often struggle with determining an overall approach to communications, dealing with the media, and deciding on when, how, and what to say. This underscores the need for an effective crisis response plan and communications protocols. Conway et al (2011) and Dykeman and Dewhirst (2011) provide helpful advice on this, which is summarized below:

General Principles

- Remember the adage: “Whoever informs the first story informs the overall story”; in the absence of an organizational response, misinformation will fill the vacuum which will be very hard to correct;
- Recognize most stakeholders want and need to believe in the organization – make that possible;
- Ensure core stakeholders never learn anything from the media first;
- While an organization is restricted for privacy/legal reasons from disclosing certain details, recognize that patients, families, and friends are under no such obligation; consider obtaining their consent to comment on details they have released;
- “Even where consent of the patient or appropriate substitute decision maker is sought for the organization to release information to the public (and specifically to the media), extreme care should be taken to limit the message, while remaining responsive, empathetic and neutral” (Dykeman and Dewhirst 2011, p. 23).

Managing the Media

- Establish credibility and cultivate key media relationships long before an event occurs;
- Pre-identify effective organizational spokespersons and ensure they have formal media training;
- Assume the situation will go public; be prepared for calls from the media at any time;
- Don’t stonewall; return requests for information in a timely manner, and be attentive to reporters’ deadlines;
- Provide available facts and explain related clinical concepts in plain language;
- Place appropriate restrictions on media access; healthcare organizations are not public buildings;
- Assume that in interviews, nothing will be off the record.

Key Messages

- Define essential messages clearly and concisely;
- Be honest, show remorse, and don’t make excuses;
- Convey caring and compassion;

- Respect the privacy of the patient, family, and staff;
- Don't speculate about causes or long-term effects;
- Talk about how the organization typically addresses similar incidents, and policies (past and future) designed to minimize harm;
- Briefly respond to questions; providing essential information only;
- Use all available tools to provide regular updates, including personal calls, email, websites, letters, social media.

Helpful language and potential talking points are included in Appendix 1.

Internal Communication

- Recognize all staff will be impacted and that they want and need to understand what's going on;
- Recognize other patients and families will be asking questions; staff need to be able to answer them;
- Ensure staff know to direct all outside inquiries to communications/public relations.

Organizational Policy and Procedure

A values-driven policy/procedure/guideline should be developed outlining key aspects of the organization's approach to critical incident management (Accreditation Canada 2015 – patient safety incident management required organizational practice). This needs to be communicated to all staff and leaders, consistently applied, tested, evaluated, and modified as required (CPSI 2012). The standard elements of such a policy are included in Appendix 2.

A list of national and international English language resources which could be helpful to organizations as they develop and enhance their processes for effective management of critical incidents is included in Appendix 3.

Patients and Families

Patients are often in a vulnerable psychological state, even when the diagnosis is clear and the treatment goes according to plan. Even routine procedures and normal childbirth may produce posttraumatic symptoms. Therefore, when patients experience harm or an unexpected event, their reaction is likely to be particularly severe. Patients and relatives may suffer in two distinct ways after an adverse outcome: they may suffer first from the incident itself and second from the manner in which the incident is subsequently handled. (Vincent 2003, p.1054).

The needs of patients and families come first in the aftermath of a critical incident. Depending on the circumstances of the event, additional testing, treatment and hospitalization may be required. The most responsible practitioner (MRP) plays a central role in ensuring effective management of the patient and, along with the unit/area manager, for maintaining communication with the patient and family.

Disclosure of facts to patients and families is an ongoing process that starts immediately after an event and continues through to the end of the review process. The initial disclosure should include expressions of regret and empathy, any facts that are known, immediate care plans, and an overview of the review process including the opportunity for patients and families to provide input and to hear back on what happened and what steps will be taken to try to prevent it from happening again. Speculation as to why the event occurred should be avoided as early perceptions can be, and often are, wrong. This initial disclosure discussion, as with all subsequent discussions, should be documented in the health record.

Numerous and various elements involved in an appropriate response to and support of patients and families after critical incidents have been described in the literature (Taylor-Adams and Vincent 2004, Massachusetts Coalition 2006, NPSA 2008a, ISMP 2008, Zimmerman and Amori 2007, Conway et al 2011, CPSI 2011, CPSI 2012) and are summarized below:

General Principles

- Strive for openness, honesty, respect, sincerity, empathy, the recovery of trust, and the promotion of healing;
- Avoid the phenomenon of “second harm”, i.e. trauma resulting from insensitive and inadequate handling of the incident;
- Avoid isolating the patient and family and ensure ongoing communication and engagement through to resolution of the case;
- Ensure all communications are culturally and linguistically appropriate;
- Address any patient and family needs as soon as possible;
- Offer practical support (e.g. reimbursement for any out-of-pocket expenses);
- Consider development/use of an information sheet for patients and families outlining key elements of the critical incident management process (see Manitoba 2014).

Immediate Response and Initial Disclosure

- Wherever possible, ensure immediate response and disclosure is led/co-led by the MRP or attending clinician with a pre-established care relationship;
- Ensure a full clinical assessment;
- Address immediate clinical, psychological and emotional needs including offering support from psychologist/social worker/pastoral care as appropriate;
- As soon as practical, communicate the facts of what occurred, the consequences for the patient,

and treatment and follow up to address these consequences;

- Express remorse, empathy and compassion (e.g. I am truly sorry this happened) even if the etiology/causes of the event are not yet known;
- Acknowledge the pain and distress caused;
- Avoid speculation, jumping to conclusions, and assigning blame;
- Appoint a staff member (e.g. unit/area manager) to act as key contact and liaison for the patient and family if different from the MRP;
- Discuss the organization's commitment to finding out what happened, why, and what can be done to prevent it from happening again;
- Provide an overview of the incident analysis process and potential timelines;
- Identify questions the patient and family hope the analysis will address;
- Discuss the opportunity for the patient and family to provide input into the analysis and explore how and when they might prefer to do this;
- Establish the frequency with which the patient and family want to be updated on the progress of the analysis (e.g. set times or as new information becomes available).

Ongoing Communications

- Provide updates to the patient and family as promised;
- If a delay in reporting back is encountered, apprise them of the situation and apologize.

The MRP and/or previously identified key contact staff member will likely provide these updates.

Input Into Incident Analysis

- Appreciate that the patient and family have an important and unique perspective on how the event unfolded and what might be done to improve care in the future;
- Appreciate that the patient and/or family may not be ready or able to provide input into the analysis due to acute stress and grief, a reluctance to relive the event, dealing with new medical needs, or managing details of life following the event;
- Consider development of a screening process to determine if patients are psychologically and emotionally ready to participate (Zimmerman and Amori 2007);
- Schedule and carry out an interview with the patient and/or family with members of the review team; generally this will entail an uninterrupted narrative of the event and their suggestions on how care might be improved in the future (see advice on Interviews later in this guide);
- If the patient and/or family is unable to participate, maintain communication and provide an opportunity to provide input at a later date if they choose.

Post Analysis Disclosure

Depending on the incident and with advanced preparation and planning, post analysis disclosure could be carried out by the MRP and/or previously identified key contact and/or member(s) of the review team and/or other senior administrator:

- Apologize (e.g. We deeply regret this occurred);
- Provide an overview of what happened, highlighting any new facts uncovered in the analysis (ensure these are also recorded in the health record);
- Outline recommendations for improvement; the steps (taken and planned) to reduce the risk of similar incidents in the future;
- Identify a key contact (if different from the one previously identified) if the patient/family want to receive periodic updates on recommendations implementation;
- Record this discussion (including apology) in the health record or patient relations file.

Note that in order to maintain the confidentiality of the review process and ensure staff willingness to participate in future reviews, the patient and/or family would generally not be provided with a copy of the incident analysis report (see advice on Report Confidentiality later in this guide). The patient and/or family could be provided a copy of the written summary of the post analysis discussion that is recorded in the health record or patient relations file.

Disclosure Resources

Helpful resources related to disclosure are listed below:

- Canadian Incident Analysis Framework (CPSI 2012) – Checklist for effective meetings with patients/families (Appendix F);
- Canadian Disclosure Guidelines (CPSI 2011) – Checklist for disclosure process (Appendix D); recommended elements of a disclosure policy (Appendix C);
- Canadian Medical Protective Association (2008) – Checklist for disclosure (Tab 6);
- Accreditation Canada (2015) – Patient safety incident disclosure required organizational practice;
- Massachusetts Coalition (2006) – The words for communicating with the patient (Appendix A);
- Manitoba Patient Safety Institute (2014) – A guide to a critical incident and disclosure: information for patients and families.

Staff

The understandable human need to identify one or more people to be held to account means that whenever something goes wrong a hunt starts, and the larger the disaster the more pressure there is... To place too much emphasis on individual blame is to risk perpetuating the illusion that removal of particular individuals is all that is necessary. That is certainly not the case here. To focus, therefore, on blame will perpetuate the cycle of defensiveness, concealment, lessons not being identified and further harm. (Francis 2012, Vol 1 p.41).

The last thing a healthcare provider expects to happen as a result of the care they deliver is serious patient harm. When the unthinkable happens and a critical incident occurs, staff experience significant emotional and physical effects. Leaders and colleagues play an important role in either helping them cope or compounding their isolation and suffering (Wu and Steckelberg 2012). If appropriate support is not provided, long-term negative impacts can develop both for the individual (e.g. emotional disability and physical harm) and the organization (e.g. lack of trust and fear of reporting).

Second Victim

Healthcare workers are often impacted by medical errors as 'second victims', and experience many of the same emotions and/or feelings that the 'first victims' the patient and family members experience. Signs and symptoms are similar to those in acute stress disorder, including initial numbness, detachment, and even depersonalisation, confusion, anxiety, grief and depression, withdrawal or agitation, and re-experiencing of the event. Added symptoms related to medical errors include shame, guilt, anger and self-doubt. (Wu and Steckelberg 2012, p.267).

Healthcare providers involved in critical incidents typically feel extreme guilt; they may suffer emotional trauma, and are at high risk for burnout, leaving the profession, and self-harm. This can be especially severe if the patient-provider relationship was long-term. The term "second victim" was coined to draw attention to this problem and highlight the need for better support for staff in the immediate aftermath of events. (Wu and Steckelberg 2012).

It has been suggested that leaders establish an organizational expectation that "anything less than a supportive response is unacceptable" (Wu and Steckelberg 2012, p. 268). This support could include:

- Expressing empathy and delivering emotional "first-aid" (e.g. I'm sorry this happened to you, we'll figure this out together);
- Ensuring access to counselling (e.g. an employee assistance program or trained peer supports – see comments later in this section on what is appropriate to discuss with staff outside of a confidential review process);
- Ensuring access to formal interventions to address emotional or physical deterioration;
- Identifying and addressing unsupportive or critical colleagues;
- Coaching on how to interact with and disclose the event to the patient and family;
- Providing information on next steps and how staff will be able to contribute to the incident analysis;
- Providing information on potential legal processes that might surround the event, as requested;
- Ensuring respectful interactions and discussions with staff in the course of incident analysis (see Interviews section later in this guide for best practices for conducting interviews);
- Providing support to resume/continue practice.

Just Culture

No one can afford to offer a ‘blame-free system’ in which any conduct can be reported with impunity – as society rightly requires that some actions warrant disciplinary or enforcement action. It is the balancing of the need to learn from our mistakes and the need to take disciplinary action (that must be addressed). (Marx 2001, p.3).

Leaders must ensure a consistent, fair, and just process for assessing accountability and dealing with potential staff performance issues related to a critical incident. This requires an understanding of human error theory, systems thinking, and complex adaptive systems (see Concepts later in this guide). Two leadership decision models incorporating these concepts have been developed to guide the assessment of staff actions: the “Incident Decision Tree” developed for use in the National Health Service (NHS) in the U.K. (NPSA 2003e), and Marx’s “Just Culture” framework (2001).

The NHS’s incident decision tree, modeled after Reason’s “culpability tree” was developed to help managers move away from asking ‘Who was to blame?’ to asking ‘Why did the individual act in this way?’ (NPSA 2008a). It is comprised of four sequential tests and structured questions about staff actions, motives, and behaviour at the time of the incident. Recommended options are provided for each stage. The further along the sequence, the more likely the underlying cause will be found to be a systems failure. The four tests include:

1. **Deliberate** – Were the individual’s actions intended? Was the outcome intended? If harm was intended, immediate suspension, referral to the police and/or relevant disciplinary/regulatory authorities would be indicated.
2. **Incapacity** – Was the staff member aware of their condition at the time (e.g. ill health or substance abuse)? Did they realize the implications of their condition? Did they take proper safeguards to protect patients?
3. **Foresight** – Was there an agreed protocol/practice? Was it workable and in routine use? Was it ignored? If it was ignored, other contextual factors would be assessed including information availability and urgency of the situation.
4. **Substitution** – How would a peer have acted in a similar situation? Deficiencies in training, experience, or supervision would also be explored. (NPSA 2003e).

To provide further clarity in especially egregious situations, managers would be required to refer any of the following incidents to the appropriate authorities:

1. Events thought to be the result of a criminal act;
2. Purposefully unsafe or malicious acts intending to cause harm;
3. Acts related to substance abuse;
4. Events involving suspected patient abuse of any kind. (NPSA 2008a).

It should be noted that the model was not intended for use in determining “negligence” (NPSA 2003e), a complex legal determination (see Medical Malpractice later in this guide).

In Marx’s “Just Culture” framework, a manager’s response is dictated by the type of behaviour exhibited by staff as per below:

1. **Human Error** – An inadvertent action, slip, lapse, mistake. Response – empathy and support.
2. **At-risk Behaviour** – Rationalizing and taking shortcuts that lead to increased patient risk. Response – coaching, mentoring, systems redesign.

3. **Reckless Behaviour** – Intentionally putting patients in harm's way. Response – punishment. (Wachter 2007).

While recognizing that “most errors are committed by good, hardworking people trying to do the right thing” (p.1401), Wachter and Pronovost (2009) also support the concept of proportional and just discipline for certain types of actions, whether or not they lead to harm. “Once a reasonable safety rule is implemented and vetted (since some rules create unanticipated consequences or work-arounds and need to be reworked after initial implementation), failure to adhere leaves the world of “no blame” and enters the domain of accountability” (p.1402).

Privilege Protection

Nobody will be honest unless they feel they are in a safe place. You have to create an environment where people can speculate, sometimes offer wild ideas about what happened. (Boothman cited in Clark 2014, p.4).

An ongoing challenge in critical incident management is how to reconcile the need for staff to feel safe reporting incidents and participating in reviews with a commitment to transparency and full disclosure to patients and families. In healthcare, if staff do not report incidents, these would largely remain hidden and important improvements in care would not be made. One of the ways to encourage reporting and candid discussion is to provide staff with legal assurances that their input into incident analysis would not be used against them or their colleagues for any other purpose, including disciplinary actions, lawsuits or other proceedings (OHA 2004). This assurance is provided through “privilege” protection. “Privilege” is a legal term used to denote information which, although relevant, is protected from disclosure in a legal proceeding. The four key types of legal privilege and their relevance to management of critical incidents are outlined below (OHA 2004, Nova Scotia 2006, Morris and Clarke 2011):

1. **Solicitor-Client** – For reviews undertaken at the direction of a lawyer; strong protection, but intended to be used in limited circumstances (e.g. not as a matter of course for critical incident /quality improvement reviews);
2. **Litigation** – For reviews undertaken in contemplation of or for the predominant purpose of litigation; not as broadly protected as solicitor-client privilege and limited utility for most critical incident reviews (too soon to determine the likelihood of litigation) but could be very helpful in management and investigation of multi-patient events (see Multi-patient Events section later in this guide);
3. **Quality Assurance/Common Law** – For reviews that meet the four “Wigmore” criteria (i.e. confidentiality is promised to review participants, confidentiality is required to ensure participation, participation is important to improving care, and the benefits of improving care outweigh the benefits of disclosure). This does not provide automatic or blanket protection and must be argued on a case by case basis if challenged;
4. **Legislative** – Privilege conferred by a piece of legislation (e.g. the *Evidence Act* in most provinces and territories or the *Quality of Care Information Protection Act* in Ontario) – Reflecting the public policy objective of encouraging healthcare providers to participate in reviews, legislation has been enacted in most provinces and territories to facilitate an environment of open sharing of opinions (CMPA 2010). This provides strong protection if specific requirements are met (e.g. review takes place under the direction of an established

quality assurance/improvement/of care committee). Legislation can pose some challenges, however, particularly related to sharing incident analysis findings with patients, families, and stakeholders outside the organization (Laupacis and Morin 2014).

It should be noted while privilege covers the subjective interpretations of staff on what *should* have happened, *could* have happened or what they *wished* had happened, it does not extend to the facts of the case which should always be disclosed and documented in the health record. Parallel reviews may take place for different purposes (e.g. critical incident analysis and medical-legal investigation); see Medical Malpractice section later in this guide.

The principle of confidentiality must be emphasized and maintained at all times during an analysis. (CPSI 2012 p.34).

Inherent in these privilege protections is the concept of confidentiality. For staff and managers, important elements related to this in the immediate aftermath of events are outlined below:

- While it is appropriate to obtain preliminary facts and discuss how staff are feeling and coping, detailed discussions about the critical incident including (potentially erroneous) assumptions about cause should be avoided outside of a formal, confidential analysis process or at the direction of assigned defense counsel if appropriate;
- Health records play a critical role in post-event analysis and other legal processes that may follow. Sometimes when a critical incident is unfolding, clinical documentation is delayed, however, it is important for staff to record relevant patient care facts as soon as practically possible. If the delay is lengthy, appropriate “late entry” notation is required. On occasion, in response to stress, worry, or poor counsel, staff may attempt to change previous chart entries or make independent, personal notes about an event. Such practices should be strongly discouraged (OHA 2004). Records that have been tampered with will call into question the integrity of staff involved. Personal records, often distorted by emotion and bias, are not protected from disclosure in the event of a legal proceeding and have generally been found to be more harmful than helpful. All relevant facts related to the event should be entered into the health record;
- While most organizations have incident reporting policies and systems that promote the recording of facts only, using defined fields and drop down menus, others allow for considerable free text and narrative description of events. For the latter, staff should get advice on completing the incident report from the organization’s risk manager on a case by case basis (OHA 2004).

Key Concepts

Effective management and analysis of critical incidents requires thorough knowledge of a number of concepts from a range of disciplines including health science, management, engineering, epidemiology, cognitive psychology, sociology, risk management, health law, and improvement science. Such knowledge helps to ensure a deep understanding of how incidents occur and how improvement strategies can be focused (CPSI 2012).

Key concepts important in the **immediate post-incident response** that have been previously discussed include:

- Disclosure;
- Second victim;
- Just culture;
- Privilege protection.

Key concepts related to the **incident analysis** process include:

- Systems;
- Systems thinking/approach;
- Human/active/"sharp-end" errors;
- Systems/latent/"blunt-end" errors, contributing factors;
- Human factors;
- Complexity and complex adaptive systems;
- High reliability;
- Risk management;
- Medical malpractice;
- Change management and quality improvement;
- Reviewer biases.

A high-level overview of each of these concepts is provided below.

Systems

A system, such as a hospital, is a dynamic and complex whole, interacting as a structured functional unit to achieve goals (e.g., treating patients). One system may be nested within another system—for example, a hospital is nested within a larger healthcare system; an intensive care unit exists inside a hospital. The behaviour of a system reflects the linkages and interactions among the components that make up the entire system. All medicine is practised within a system. (Dekker and Leveson 2015, p.1).

Healthcare organizations are systems with many components and various levels (e.g. micro, meso, macro). Knowledge of systems will help reviewers better identify contributing factors and recommendations for improvement (CPSI 2012).

Systems Thinking/Approach

The basic premise in the system approach is that humans are fallible and errors are to be expected, even in the best organisations. Errors are seen as consequences rather than causes, having their origins not so much in the perversity of human nature as in "upstream" systemic factors... All hazardous technologies possess barriers and safeguards. When an adverse event occurs, the important issue is not who blundered, but how and why the defences failed. (Reason 2000, p.768).

The systems approach is seen as one of the most important advances in our approach to patient safety (Reason 2000, Vincent 2003, Wachter and Pronovost 2009, Dekker and Leveson 2015). It distinguishes between active failures (“sharp-end”, human errors) and latent failures (“blunt-end”, systems errors). Latent failures are seen to pose the greatest risk for accidents due to their impact on system defenses, which make human errors more likely (ECRI 2011). Reason’s iconic “Swiss Cheese Model of System Accidents” depicts the major tenets of this approach and has been a foundational element of effective incident investigations for over a decade. Vincent’s “London Protocol” (modeled after Reason and modified for healthcare) and the ubiquitous “root cause analysis” promoted by the Joint Commission in the U.S. are other well-known examples of incident analysis models based on the systems approach.

It is important to note, the term “root cause analysis” is not considered an accurate depiction of an effective incident analysis. “It is misleading in a number of respects. To begin with, it implies that there is a single root cause, or at least a small number. Typically, however, the picture that emerges is much more fluid and the notion of a root cause is a gross oversimplification. Usually there is a chain of events and a wide variety of contributory factors leading up to the eventual incident” (Taylor-Adams and Vincent 2004, p.1).

One criticism of the systems approach is that it does not hold providers to account for their actions or incompetence. Dekker and Leveson (2015) argue, however, that “the management of (in)competence can be seen as a system issue, by carefully looking at training, selection, continuing development, and life-long competency checking. In aviation, individual competence is taken as a system responsibility – too important to leave the retaining, refreshing and checking of it to an individual professional” (p.8).

Another criticism of this approach is that it may promote an overly simplified, linear picture of systems that are in fact, much more complex (Robson 2012). This is addressed through appreciation and application of complexity and complex adaptive systems concepts.

Human/Active/Sharp-end Errors

The proximate cause is often an act committed (or neglected, or performed incorrectly) by a caregiver. (Wachter 2012, p.22).

Unfortunately, healthcare has typically responded to all errors as if they were mistakes, with remedial education and/or added layers of supervision. In point of fact, most errors are actually slips, which are failures of schematic behavior that occur due to fatigue, stress, or emotional distractions, and are prevented through sharply different mechanisms. (Wachter 2012, p.438).

Humans are the most critical component of the healthcare system and are constantly interacting with one another and other system components (ECRI 2011). Humans have limitations and are fallible, making human error predictable, inevitable and frequent. Fortunately, most human errors have no negative impact, however, when combined with flaws in the system (latent errors), harm can occur. Reviewers need to understand the nature and types of human errors, not in a futile attempt to perfect human performance (Wachter 2012), but to ensure a complete understanding of how an event unfolded and how it might be prevented or mitigated in the future.

In general terms, an error involves either doing something wrong (commission) or failing to do the right thing (omission). Various taxonomies describe human error in more detail (NPSA 2003a, ECRI 2011, Wachter 2012, HPI 2012). A summary is provided below:

- **Unintended actions**
 - **Lapses** – memory failures (e.g. losing place, skipping steps)
 - **Slips** – attentional failures (e.g. intrusions, omissions, misordering)
 - Caused by distractions, interruptions, fatigue, stress
 - Difficult to eliminate; reduce their likelihood through work, device, or environmental redesign
- **Intended actions**
 - **Mistakes**
 - Insufficient knowledge
 - Application of the wrong rule or heuristic*
 - Caused by lack of experience or insufficient training
 - Reduce likelihood through training, supervision, and interventions to improve diagnostic reasoning
 - **Violations** (of accepted, appropriate, expected practices and protocols)
 - **Routine** – tacit acceptance over time; generally due to poorly designed processes
 - **Situational/optimizing/reasoned** – risks and benefits assessed, decision to violate protocol often made to prevent or mitigate harm
 - **Reckless** – deliberate disregard for protocols, harm foreseeable but not intended**
 - **Sabotage** – intention to cause harm**
 - Risk reduction efforts are based on the type of violation and may include systems redesign, protocol revisions, or proportionate discipline.

* This includes errors made as a result of cognitive biases, particularly in diagnostic processes, including confirmation and availability biases.

** If found, these types of violations would be addressed outside of the incident analysis process (see previous discussion on Just Culture in this guide).

Systems/Latent/Blunt-end Errors, Contributing Factors

The behavior of the components or entities that exist within that system is influenced by the system design and structure, such as the remuneration schemes, time and financial pressures, the accuracy of available information about the patient or the procedure being performed, and much more. These system design factors can help or hinder medical professionals from doing their job. While it is laudable that professionals accept responsibility for their actions, it is unrealistic to believe that their behavior is not affected by the context in which it occurs. (Dekker and Leveson 2015, p.7).

Systems/latent errors refer to the many layers of the healthcare system that are not in direct contact with the patient (the “blunt-end”), but which influence those that are (Wachter 2012). Latent failures arise primarily from flawed management decisions, influenced by wider goals or limited by regulatory or financial constraints. These decisions can weaken defenses while also influencing the working conditions of healthcare staff, creating error and violation provoking conditions (NPSA 2003a). Latent failures can lie dormant for long periods of time, combining with active failures in particular circumstances to cause accidents. Latent factors are also called contributing (or contributory) factors.

Numerous frameworks and taxonomies exist for contributing factors (Taylor-Adams and Vincent 2004, NPSA 2009, CPSI 2012, Duchscher and Davies 2012, HPI 2012, and Joint Commission 2013). The categories included in the Canadian Incident Analysis Framework (CIAF) (CPSI 2012) include: Task;

Equipment; Work environment; Patient; Team (caregivers and supporting staff); and Organizational.

Human Factors

Human factors science 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. (CPSI 2012, p.20).

Human factors looks at how humans interact with devices and their work environments and seeks to minimize the risk of error by making these devices and environments more human-centered; more compatible with how humans think and work (Wachter 2012). Human factors may play a role in understanding events and the development of effective recommendations for improvement (e.g. usability testing, heuristic analysis, and device standardization) (CPSI 2012). ISMP's (2006) well known hierarchy of error prevention measures is based on human factors principles.

Complexity Theory and Complex Adaptive Systems

Complexity theory, rather than Newtonian reductionism, is where healthcare should look for answers. With the introduction of each new part or layer of defense, technology, procedure, or specialization, there is an explosion of new relationships between parts, layers, and components that spreads out through the system. Complexity theory explains how accidents emerge from these relationships, even from perfectly "normal" relationships, where nothing (not even a part) is seen as broken. The drive to make systems reliable, then, also makes them very complex – which, paradoxically, can in turn make them less safe. (Dekker 2010, p. 148).

Complexity theory holds that large organizations do not operate like predictable and static machines, rather as complex adaptive systems, with elements of unpredictability, codependency, and nonlinearity (Wachter 2012). It divides decisions and problems (based on the degree of predictability of outcomes and agreement of strategies to achieve these outcomes) into three categories: simple, complicated and complex. When a process is simple, outcomes are predictable and there is widespread agreement on how things should function. Simple processes can be fixed through straight forward process improvement and development of new standard operating procedures. When aspects of care are complicated, outcomes are generally seen as predictable but there is general but not complete agreement as to approach. Improvements to complicated processes require careful analysis and development of "if/then" decision trees and protocols. Complex processes are non-linear, outcomes are uncertain and there is no agreement as to approach. Typical improvement initiatives may not work, however, "simple rules" and a focus on improving relationships may be effective (Wachter 2012). The key for reviewers is to try to match recommendations with the types of problems encountered.

In contrast to the systems thinking/Swiss cheese model, which some suggest promotes an understanding of accident causation as a chain of events, complexity theory sees accidents arising from an interrelated web of factors (Boyd, 2014). In complex adaptive systems, events unfold in unpredictable ways, contributing factors are influenced by a number of other factors, and even small changes in one area of the system can lead to big and unintended effects elsewhere (CIAF 2012). There is an appreciation that actions of staff that result in safe, efficient care one day may result in an adverse event the next. As a result, reviewers should focus on: developing a multi-faceted and nuanced narrative of the event; understanding how things usually go right; identifying goal conflicts (e.g. tradeoffs between efficiency and safety; between what should happen (e.g. policies) and what typically happens; and the cautious application of recommendations that will (hopefully) improve care for future patients (Robson 2012).

High Reliability

Some researchers estimate that most people under work and time pressures make errors at the rate of 10^{-2} even when doing their best work. To be highly reliable, systems must be designed to compensate for the limits of human ability. (Nolan et al 2004).

High reliability organisations – which have less than their fair share of accidents – recognise that human variability is a force to harness in averting errors, but they work hard to focus that variability and are constantly preoccupied with the possibility of failure. (Reason 2000, p.768).

Reliability principles are used in other industries to help evaluate, calculate, and improve the overall reliability of complex systems. Reliability is measured as the number of defects per attempts. Thus, 10^{-1} means one defect per 10 attempts, 10^{-2} is one defect per 100, and 10^{-3} is one defect per 1,000 and so on. Nolan et al (2004) note that the average performance of healthcare organizations is considered to be 10^{-1} and they outline specific design features that can be used to advance to higher levels of reliability (see Appendix 4).

“High reliability organizations” (HROs) is a term used to describe organizations in high risk industries with disproportionately fewer catastrophes. A key feature of HROs is their heightened sense of mindfulness, their “preoccupation with failure” and their focus on both prevention and containment of risks (AHRQ 2008). Staff are constantly on the lookout for things that went (or almost went) wrong; analyzing each event to identify opportunities to improve the system. There is a low threshold for initiating incident reviews, however different types of events would be dealt with differently. In healthcare, this could entail minor incidents being reviewed at a unit level, outcomes/complications reviewed at morbidity and mortality meetings, concise analysis for more serious incidents, and comprehensive analysis for critical incidents and multi-patient events (CPSI 2012).

HROs recognize that even in the best systems, incidents will occur. As a result, they exert considerable effort to contain incidents before the impact (e.g. patient or staff harm, damage to equipment or reputation) worsens. For reviewers, this would mean that they would consider when and how the incident was detected and whether recommendations targeted at mitigating the effects of inevitable incidents would be indicated (e.g. mechanisms for early detection of patient deterioration).

Nolan et al (2004) propose a three-step model for high reliability in healthcare including:

1. Prevent failure (a breakdown in operations or functions).
2. Identify and Mitigate failure: Identify failure when it occurs and intercede before harm is caused, or mitigate the harm caused by failures that are not detected and intercepted.
3. Redesign the process based on the critical failures identified. (p.1).

Risk Management

After defining the critical event, participants are asked to think of all possible risk factors and threats. A threat is defined as an event that solely could cause the critical event and can also be theoretical or very uncommon. Threats are on the left side in the bow-tie diagram. In a similar way consequences are determined and placed on the right side of the bow-tie diagram. Consequences are potential events resulting from the occurrence of a critical event, also described as the negative effects that should be avoided. (Kerckoffs 2013, p.155).

Risks in healthcare (e.g. events that shouldn't happen that do and events that should happen that don't) are assessed in terms of both the probability of an event occurring and the impact of the

event (harm) should it occur. Risks can have multiple causes and multiple effects. Risk management methods, therefore, focus on putting in place controls and barriers to both prevent an event occurring and limiting harm if it does. Event reviewers should try to understand breakdowns related to both aspects – why did the event occur, and why, when it occurred, were the effects not better mitigated. Recommendations focused on better risk management will include, for example, strategies to improve early detection of patient deterioration.

Risk management also recognizes that the assessment of the likelihood or impact of a risk and decisions made as a result of this are influenced by a number of cognitive biases including the availability and effect heuristics (HIROC 2014). This explains how after an event, there is often great motivation to change as the perception of that event recurring is high.

Medical Malpractice

It is well documented that a lawsuit can be among the most emotionally damaging experiences a clinician can experience. (Wu and Steckelberg 2012, p.268).

Negligence/fault occurs when harm to the patient is caused by the failure to exercise a reasonable and acceptable standard of care. The standard of care is not perfection. (CMPA 2008, p.32).

In the aftermath of a critical incident, one of the legal proceedings most concerning for staff and influencing their willingness to disclose the incident to patients/families and participate in reviews, is the medical malpractice lawsuit. It should be noted that disclosure of a critical incident is the right thing to do professionally and ethically (CPSI 2011) and must always be carried out regardless of whether it may (Kraman and Hamm 1999, Kachalia et al 2010) or may not (Kachalia et al 2003, Studdert et al 2007) decrease the probability of a critical incident proceeding to a medical malpractice claim.

A medical malpractice lawsuit/medical-legal claim is a civil action that provides a means to compensate patients monetarily for harm that results from the delivery of care. Although there are no definitive numbers for Canada, in other jurisdictions it has been found that only a relatively small percentage of adverse events result in claims and only a minor percentage of these succeed (Schmidek and Weeks 2005, Bismark et al 2006, Pukk-Härenstam et al 2008).

There are significant hurdles a medical-legal claim must overcome in order to succeed. To prove negligence, the plaintiff (patient and/or family) must supply clear and expert evidence that a standard of care was not met, demonstrate compensable harm occurred, and demonstrate the harm was caused by the breach in standard of care. The following outlines these components in more detail (Morris 2011):

1. **Duty of Care** – Ordinarily requires an established care relationship with patient.
2. **Breach of Duty of Care** – Whether the care provided failed to meet a reasonable standard in the particular circumstances of the case. What is reasonable is determined by that which would be provided by a normal, prudent practitioner with the same experience and standing. Evidence as to the standard of care is generally determined by expert evidence/witnesses. A breach would not include: misadventures/errors in judgment (if all relevant factors were considered and the patient was appropriately assessed); or failure to act in accordance with improvements or modifications that could be suggested in retrospect.

3. **Harm** – Compensable injury or harm sustained by the patient, which could be remedied monetarily. Damages cannot be recovered for sorrow, grief, embarrassment, hurt feelings, or emotional distress unless it results in a recognized psychiatric illness. Damages can be recovered for: the injury or harm itself and related expenses (e.g. medical equipment, cost to modify home); pain and suffering (capped at around \$350,000 in Canada); lost income; and future care costs.
4. **Causation** – Proof that, on a balance of probabilities, the patient’s injury would not have occurred ‘but for’ the defendant’s (care provider’s) breach of duty/standard of care. The breach need not be the only cause of damages.

Sometimes a case is clearly indefensible (e.g. large opioid overdose or intrathecal injection of the wrong medication) and in these instances, compensation would be expected to flow quickly. However, in most cases, the facts are not clear and a long process to seek and assess expert opinion related to standard of care, harm, and cause ensues (Morris and Clarke 2011).

It is helpful for reviewers to understand the distinction between systems reviews and medical-legal reviews and to know that one cannot be substituted for the other. The table below highlights these key differences.

Element	Systems Review	Medical Legal Review
Premise	Patient safety events are the result of system errors	Negligence is the result of individual errors
Objective	Assess what factors contributed to the event, make recommendations for change	Assess each provider’s culpability, make recommendations about defense of legal action
Question	What systems factors contributed to this outcome (i.e. organization, work environment, equipment, care team, task, patient)?	Did negligence lead to this outcome (i.e. duty of care, breach of duty of care, damages, causation)?
Method	Non-punitive and collaborative	Adversarial process, findings of liability

Table 1: Differences between systems reviews and medical legal reviews (de Wit 2013).

Quality Improvement

Use of a change management or improvement tool can help to facilitate implementation of recommended actions in a way that will support success. The Model for Improvement is one approach that has been used successfully by thousands of healthcare organizations in many countries to improve numerous and different healthcare processes and outcomes. (CPSI 2012, p.64).

Patient safety (the focus of critical incident reviews) is usually considered a subset of the larger issue of quality of care (Wachter 2012) that also includes dimensions such as effectiveness, patient-centredness, timeliness, efficiency, and equity (Nolan et al 2004). There are numerous techniques and frameworks for managing change and improving quality, with the Model for Improvement being the most commonly used (CPSI 2012, Wachter 2012). The Model is comprised of the following:

- Aim – What are we trying to accomplish?
- Measures – How will we know that a change is an improvement?
- Changes – What changes can we make that will result in improvement?
- Rapid Cycle Improvements – Plan-Do-Study-Act (PDSA) cycles to test changes. (HQO 2012).

Effective quality improvements entail a well-defined project charter, strong leadership, and an inclusive team membership (HQO 2012) ongoing assessment using an array of structure, process and/or outcome measures.

Critical incident reviewers must appreciate that while some recommendations they develop may involve relatively straightforward changes (e.g. immediate suspension of an activity), the majority will entail changes to existing processes which are much more challenging to implement. Each of these recommendations would represent, in essence, a stand-alone quality improvement project. An understanding of improvement methods will help reviewers identify effective change concepts, ensure recommended changes are articulated clearly and are measurable (e.g. Establish a standardized tool for..., Develop and implement a system-wide process for..., Standardize devices used to...) and that expectations regarding implementation timelines are realistic. The improvement process may result in the original recommendation evolving into something more effective or being abandoned altogether (CPSI 2012).

Reviewer Biases

It is always difficult to establish what happened historically. Particularly when harm has occurred, our assessments of other people's behavior get coloured negatively by outcome and hindsight biases. Knowledge of outcome affects our evaluation of the quality of decisions, whereas, hindsight increases retrospective estimates of the foreseeability of the outcome. Outcome bias has been demonstrated in healthcare practitioners who make judgments on the appropriateness of care. Besides the harshness of judgments, it is also the sheer willingness to make judgments that increases when there is a severe outcome. (Dekker and Hugh 2014, p.1).

A number of inherent biases influence the reasoning and decision-making of human beings. These play a role not only in the care delivery process but also in the process of incident analysis as well. The two most important ones for reviewers to be aware of outcome and hindsight biases. (NPSA 2008a, CPSI 2012, Dekker and Hugh 2014). These can result in the following:

- Misinterpretation of findings;
- Failing to identify real issues and lessons to be learned;
- Assumptions that actions to prevent the incident were obvious at the time;
- Assumptions the outcome was foreseeable/predictable at the time;
- Overestimation of the likelihood of the outcome;
- Oversimplification of what contributed to the outcome;
- Holding decision makers responsible for events beyond their control;
- Decisions/actions judged by the poor outcome versus the quality of the decisions/actions made at the time;
- Premature completion of analysis;
- Overconfidence in analysis findings.

Reviewers can guard against the effects of biases through awareness and by:

- Avoiding jumping to conclusions;
- Remembering that initial perceptions are often incorrect;
- Using structured frameworks and guiding questions to explore all potential contributing factors;
- Evaluating decisions/actions based on what was known or going on at that time;
- Asking those involved "How did that make sense at the time?" (CPSI 2012, Robson 2012).

Analysis

A more important and fundamental objection to the term root cause analysis relates to the very purpose of the investigation. Surely the purpose is obvious? To find out what happened and what caused it? We believe that this is not the most penetrating perspective. Certainly it is necessary to find out what happened and why in order to explain to the patient and family and others involved. However, if the purpose is to achieve a safer healthcare system, then finding out what happened and why is only a way station in the analysis. The real purpose is to use the incident to reflect on what it reveals about the gaps and inadequacies in the healthcare system. (Taylor-Adams and Vincent 2004, p.2).

Purpose and Process

The goal of critical incident analysis is to yield useful findings and to identify recommendations that will make a difference (Duchscherer and Davies 2012). In order to achieve this, the analysis needs to be fair, balanced, thorough and disciplined and answer the questions: What happened? Why? And what can be done to decrease the probability of future events?

While specific techniques may vary depending of the nature of the case and other contextual factors, Duchscherer and Davies (2012) emphasize that in all cases, “the approach is systematic and systems-focused, looking beyond the contribution of individuals to consider how complex, interacting elements of the entire healthcare system influence care” (p.2).

While the focus of this guide is the management and analysis of the most critical of incidents, the methods proposed can be scaled to analysis of less serious incidents as well. Taylor-Adams and Vincent (2004) note that “the analysis of single incidents – whether or not they have a bad outcome – can be scaled to the time and resource available, be it 10 minutes or 10 days. A single incident – a story – almost always engages a clinical group and can be analysed by an individual risk manager or a whole clinical team” (p. 2-3).

The general steps in incident analysis include:

- Trigger the analysis;
- Identify team members, including facilitator/lead;
- Review health records and other documents, observe processes (if applicable), and analyze previously sequestered physical artifacts (if applicable);
- Draft an event timeline and identify potential gaps and issues for further exploration;
- Obtain feedback from those involved in the event;
- Obtain additional expert opinion (if needed);
- Identify issues and contributing factors;
- Develop recommendations for improvement;
- Prepare a summary report for leadership review and approval.

Following the review:

- Implement, evaluate and sustain recommendations;
- Share lessons learned;
- Trend overall results.

Triggering an Analysis

There are a number of reasons for considering that an incident warrants detailed investigation. Broadly speaking the incident will either be investigated because of its seriousness for the

patient and family, for the staff or the organisation, or because of its potential for learning about the functioning of the department or organisation. (Taylor-Adams and Vincent 2004, p.9).

Determining what triggers a critical incident review requires careful consideration and is often the subject of debate, even where there may be a provincially defined list of incidents requiring a review. As discussed earlier, there is little consistency between organizations as to what constitutes a critical incident. However, it is important to strive for internal consistency as this will help to minimize the impact that stress, politics, or workload may play in deciding whether to launch a critical incident analysis or not. It is also important to ensure reviews are coordinated across the organization or region so that separate (and potentially conflicting) analysis of the same incident does not take place.

Generally speaking, the severity of the outcome dictates whether a review will take place but other important contextual factors that might impact the decision include (Taylor-Adams and Vincent 2004, CPSI 2012):

- Potentially critical incident/near miss event – note which ones are actual versus potential in trend analyses and reports to senior leaders and the board (see Critical Incidents Rate Reporting later in this guide);
- Significant gaps in the timeline of events and particularly troubling questions and concerns;
- Evidence of acrimony and finger pointing between individuals and/or services;
- Alignment with other significant incidents and reports (e.g. patient complaints, accreditation findings);
- External pressure;
- Legal mandates;
- Alignment with short and long-term strategic priorities;
- Opportunity for organizational learning.

Other considerations related to the initiation of an analysis include:

- Follow processes to invoke legislative protections as necessary (e.g. formal decision by quality of care committee);
- Begin as soon as practically possible after an incident and take into account mandated timeframes for review completion, if applicable;
- Reviews can take up to 90 person-hours or more to complete (Wu, Lipshutz and Pronovost 2008), therefore consider whether for the most serious incidents, review team members could be relieved of some of their usual duties in order to focus on the review.

Review Team

The person or role charged with leading and/or facilitating critical incident analyses is not consistent across healthcare organizations. Very often it will be the risk manager, but it could also be a patient safety officer, quality leader or operational manager. Regardless of the title, considerable knowledge and skill is required to help staff and the organization navigate the various challenges related to the review process. In other high risk industries, event investigators are experienced industry professionals with extensive additional training in incident analysis and accident causation. In healthcare, most individuals who carry out reviews have years of clinical experience but (often) less formal training in patient safety and incident analysis. These skills are generally obtained through on-the-job experience and periodic professional development opportunities.

A diverse skill-set is required for those leading/facilitating reviews in healthcare (Taylor-Adams and Vincent 2004, Vincent 2004, CPSI 2012, ECRI 2011, ECRI 2013), including:

- Good understanding of healthcare, the organization and the broader healthcare system;

- Good understanding of patient safety and quality improvement concepts (see Concepts section earlier in this guide) including the relative effectiveness of different types of interventions;
- Good understanding of staff/“second victim” needs and concerns;
- Good understanding of health law and the legal processes which often surround critical incidents;
- “Soft skills” including political acumen, conflict resolution, stress management, group facilitation and oral and written communication skills;
- Clinical training and expertise is an asset – a healthcare background helps to ensure that a reviewer is able to understand medical processes, navigate the health record, and establish credibility and trust with front-line staff involved in events.

The CIAF (CPSI 2012) proposes that for less complex reviews in which there is limited patient harm, a single facilitator may undertake a review. For more complex reviews, and events resulting in significant harm, a multi-disciplinary team is recommended. Some organizations have reported success with a small team or reviewer triad including a skilled facilitator, practice/physician leader (if not involved in the incident) and operations leader (Taylor-Adams and Vincent 2004, Stevens et al 2010). The benefits to engaging medical and operational leadership in reviews include: expertise in context, capacity building in patient safety, and enhanced accountability for outcomes and recommendations arising from reviews. The more people on the review team, however, the more challenging it may be to schedule meetings and interviews. On occasion, joint reviews with other organizations (e.g. a transferring organization, home care, or emergency medical services) may be beneficial and could be carried out with careful consideration of the legal implications and confidentiality requirements.

Review teams should have access to previous critical incident report findings and recommendations, incident reporting data, external subject matter experts as required, and to senior leaders for assistance in removing barriers to successful reviews (e.g. lack of cooperation of participants).

Information Gathering

(Analysis) begins with data collection and reconstruction of the event through record review and participant interviews. Many techniques exist, but in all, a multidisciplinary team analyses the sequence of events leading to the adverse outcome in order to identify how the event occurred (through identification of active errors) and why the event occurred (through identification of latent errors). (Boyd 2014, p.1).

Information gathering will likely begin prior to an analysis being formally triggered. This would include a high-level overview of facts that will be used to identify any obvious care issues and problematic processes which will in turn be used to help determine the type, scope and scale of the review (CPSI 2012). It should be noted that all reviews must strike a balance between thoroughness (ensuring the most comprehensive analysis possible) and efficiency (ensuring the analysis is carried out in a timely manner).

The types of information required to help answer key review questions are outlined below:

1. *What happened?*

- Health record, clinical data from physiological monitors and other biomedical devices
- Other records (e.g. paging, staffing and census records)
- Physical artifacts, equipment, maintenance records
- Audio/visual tapes or photographs
- Interviews with involved individuals including patients, families, and staff

2. *What was supposed to happen?*
 - Policies, procedures, and guidelines related to key processes under review
 - Literature and other related external reports (as required)
3. *What typically happens?*
 - Retrospective chart audits (as required) to help determine if actions that weren't supposed to happen in the case in question were "one-off" or typical for other cases as well
 - Direct observation of key processes and tasks (as required)
 - Incident reporting data and findings from previous, related reviews
4. *Why was there a gap between what happened and what was supposed to happen?*

Note: the final question will be addressed in the Identification of Issues and Contributing Factors section, later in this guide.

Chronology of Events/Timeline

The next step in the investigation is to establish a clear and reasonably detailed chronology of the incident. Interviews, statements from those involved in the incident, and a review of the medical records identify what happened and when. The investigation team will need to ensure that this information is integrated and that any disagreements or discrepancies are clearly identified. (Taylor-Adams and Vincent, 2004, p.13).

Development of a timeline or chronology is thought to be one of the most useful and important activities of the review team (Duchscher and Davies 2012). The CIAF (CPSI 2012) describes in detail the development and use of timelines. The initial timeline will be developed based on facts contained in the health record and will be supplemented with other information, such as interviews, as the analysis continues. Challenges associated with development of timelines include determining how far back to go and the level of detail to include. Both can be adjusted, as required, as the analysis unfolds.

Interviews

Interviews lie at the heart of effective investigation. While a considerable amount of information can be gleaned from written records and other sources, interviews with those involved are the most important route to identifying the range of background contributory factors to an incident. (Taylor-Adams and Vincent 2004, p.11).

...The investigation itself holds the potential to cause additional harm. (Wu and Steckelberg 2012, p.268).

Reviewers require skills to empathetically and effectively interact with staff involved in events. As with patients and families, emotions can run high and feelings of guilt and shame may cloud perspectives. Staff often report that anticipation of and participation in interviews is very stressful (Wu and Steckelberg 2012).

There are different approaches for obtaining input from staff: everyone together, small groups, and one at a time. Sometimes a decision on how staff are interviewed depends on logistics (e.g. geography) and personal issues (e.g. availability, health). Individual interviews are recommended wherever possible, particularly for the most serious events, to ensure that each perspective about the incident is well understood, and to guard against issues related to interpersonal team dynamics and reluctance to speak up in front of others (NPSA 2008a, CPSI 2012, Duchscher and Davies 2012, ECRI 2013).

A number of resources provide helpful advice on the interview process (NPSA 2003b, 2008a, 2008b, Taylor-Adams and Vincent 2004, Duchscher and Davies 2012, ECRI 2013) with key points summarized below:

General Principles

- Convey compassion, empathy, and respect;
- Appreciate that supportive discussion can help staff come to terms with what has happened; conversely, confrontational and judgmental comments may lead to demoralization and defensiveness (Taylor-Adams and Vincent 2004);
- Keep an open mind; there is a natural tendency to accept the first account as accurate and to weigh subsequent versions accordingly;
- Recognize that due to stress, participants may have a poor concept of the passage of time and may confuse the sequence of events;
- Use reflective listening skills (e.g. head nodding, remaining silent if the interviewee stops speaking, etc.).

Pre Interviews

- Plan to conduct interviews as soon as possible while memories are fresh and before discussions with others distorts recollections;
- Plan to interview each individual involved, if possible;
- Plan to interview each individual one at a time, if possible; small groups if not (e.g. 2-3 nurses working the same shift);
- Plan to conduct interviews in person, if possible;
- Plan to have all members of the review team present for all interviews, if possible;
- Provide an verbal (e.g. via manager) or written invitation including:
 - The purpose of the interview;
 - What to expect;
 - What preparation they need to do (if any), reiterating the caution against personal notes;
 - The time, place and estimated length of the interview (e.g. one hour);
 - Interviewer(s);
 - What documents will be available to them during the interview;
 - The fact that they can bring a friend or colleague for support;
- Work with area manager to schedule during work time, if possible;
- Consider development/use of an information sheet for staff outlining key elements of critical incident management, including the interview process (see Manitoba 2011).

Setting

- Ensure the location for the interviews is quiet, free from distraction, private and away from the normal work area;
- Provide a copy of the health record;
- Provide a working timeline of events;
- Provide refreshments, tissues, etc.

Interview

- Establish early rapport to help reduce anxiety and stress;
- Provide opening statements which:
 - Reiterate the purpose (fact finding, learning and improvement, fill in any gaps, obtain suggestions for improvement)
 - Express empathy and concern (This must be very difficult for you., How are you doing?)
 - Emphasize expectations related to confidentiality

- Adopt a supportive and understanding demeanor, refrain from judgmental or confrontational comments;
- Start with neutral, easy questions (e.g. How long have you been at the organization? What is your role at the organization?);
- Promote free narrative/story telling (e.g. Tell us what happened? Start at the beginning? Tell us about the shift);
- Avoid interruptions as they may reduce memory recall;
- Ask open-ended questions (What happened next? How did that make sense at the time? What else was going on that impacted the teams' assessment of the situation?) rather than leading questions (e.g. Did you call the doctor then?);
- Explore goal-conflicts (Why was there a gap between what happened and what was supposed to happen?) (Robson 2012);
- Later, explore specific factors that they think might have contributed to the incident (e.g. use CIAF (CPSI 2012) guiding questions);
- Explore factors that they feel helped mitigate the outcome (e.g. What went well?);
- Explore the timeline and identify any discrepancies and/or new information;
- Acknowledge that staff are a great source for improvement ideas; ask if they have any suggestions;
- Try to ask follow-up questions in the order that the event unfolded to aid information retrieval.

Closure

- Gradually return to neutral topics;
- Ask the staff member if they have any other comments to make or questions to ask;
- Attempt to leave the interviewee in a positive frame of mind – reiterate the purpose – fact-finding and identifying opportunities for improvement;
- Outline next steps;
- Avoid making promises about a specific timeline, final recommendations, and the ability for them to access the final report (refer to Report Confidentiality section later in this guide);
- Thank the interviewee for their time and cooperation;
- Provide contact information if they think of anything else they want to add at a later date;
- Have information available on staff support/counselling as depending on the nature of the case or the interviewee's personal involvement, they may find the process of recounting events upsetting (Taylor-Adams and Vincent 2004).

Note Taking

- Given the potential for subsequent legal proceedings, establish the usual practice of:
 - Limiting note taking to one person (e.g. facilitator);
 - Limiting note taking to those elements that will help in preparation of the final report (e.g. new facts about the case, issues identified and suggestions for improvement);
 - Retaining the written notes only until the final report is completed, then shredding them as they were working documents;
- Note taking may make some interviewees uneasy; explain the purpose, make only essential notes and maintain as much eye contact as possible;
- Verbatim transcripts or voice recordings are neither necessary nor recommended.

Post Interviews

- Look for consistent themes;
- Follow up on any discrepancies;
- Ensure any new facts identified are recorded in the health record.

Identification of Issues and Contributing Factors

The final question to be answered by the review team (after *What happened/What was supposed to happen/What typically happens*) is *Why was there a gap between what happened and what was supposed to happen?* This entails the identification of issues and systems-related contributing factors that influenced the outcome.

Some incident analysis frameworks specify that reviewers identify the things that happened that shouldn't have happened and the things that should have happened that didn't – the human errors that had a direct or indirect effect on the eventual adverse outcome (NPSA 2008a). Reason calls these “unsafe acts” (2000), the London Protocol calls these “care management problems” (Taylor-Adams and Vincent 2004), and Healthcare Performance Improvement (HPI 2009) group calls these “deviations from generally accepted performance standards” which also include equipment failures.

Examples of human errors/care management issues that might be identified include:

- Failure to monitor, observe, or act;
- Delay in diagnosis;
- Incorrect risk assessment (e.g. suicide or self-harm);
- Inadequate handover;
- Failure to note faulty equipment;
- Failure to carry out pre-procedure checks;
- Not following an agreed protocol (without clinical justification);
- Not seeking help when necessary;
- Failure to adequately supervise a junior staff member;
- Incorrect protocol applied;
- Wrong patient/site/procedure (Vincent 2000, p.799).

Others incident analysis frameworks suggest that human errors need not be specifically articulated and/or reported, opting instead to move on to identifying the latent/systems factors that influenced them (CPSI 2012, Duchscher and Davies 2012). As mentioned previously, numerous frameworks and taxonomies exist for contributing factors (Taylor-Adams and Vincent 2004, NPSA 2009, CPSI 2012, Duchscher and Davies 2012, HPI 2012, Joint Commission 2013).

The contributing factors outlined in the CIAF guiding questions (CPSI 2012) are summarized below:

- Task (care/work processes);
- Equipment (including information and communication systems);
- Work environment (noise, lighting, space, layout, accessibility of resources);
- Patient (age, diagnosis, language, information, social/cultural factors);
- Team – caregivers (education, experience, fatigue, stress, health, workload);
- Team – supporting (clear roles, communication, morale);
- Organizational (policies and priorities, culture, capacity/resources).

Techniques that may help review teams understand and depict key contributing factors/findings and their interrelationships include:

- **The Ishikawa/Fishbone/Cause and Effect Diagram** – Consisting of a “head” (the event), “spines” off the main backbone (each category of contributory factors), and small “bones” off of these (each specific factor identified) (NPSA 2003d, CPSI 2012, HQO 2012);
- **Five Whys** – For each contributing factor identified, asking why it happened and repeating the question until a key finding/endpoint is reached (NPSA 2003c, HQO 2012);

- **Causal Tree Diagrams** – Articulating contributing factors as branches coming off the event, and continuing to expand along each branch until a key finding/endpoint is reached (CPSI 2012);
- **Constellation Diagram** – Developed by CIAF (CPSI 2012); combines the fishbone and causal tree diagrams, enabling linkages between contributing factors in different categories to be identified;
- **SAFER Matrix** – Promoted by Duchscher and Davies (2012); includes horizontal rows of contributing factor categories (i.e. patients, personnel, environment/equipment, organization, regulatory agencies) and vertical columns for findings related structure, process, and outcome.

Examples of contributing factors/key findings include:

- Lack of standardized patient risk assessment protocol;
- Lack of standardized devices/equipment;
- Patient's cognitive impairment;
- Lack of effective team hand-over process;
- Ineffective team communication;
- Lack of formal process to report close calls;
- Lack of regular "mock" codes / drills. (CPSI 2012, case studies)

The CIAF (CPSI 2012) suggests that the following types of contributing factors be identified:

- Key findings – Contributing factors that, if corrected, would likely have prevented the incident or mitigated the harm – These would become the focus of recommendations;
- Other learnings – Contributing factors that, if corrected, would not have prevented the incident, but are important for safe patient care in the future. These could be brought to the attention of the appropriate leaders for follow-up;
- Good catches – Factors that helped to mitigate harm; that prevented the incident from becoming more serious.

Note that there may be occasions when incident analysis reveals no key findings or issues; that all reasonable actions were taken and that there are no recommendations for improvement.

Recommendations Development

Investigations of what happened can identify the many detailed explanatory factors behind a particular outcome – including the actions and assessments of individual caregivers. These, however, do not necessarily constitute the change variables for preventing recurrence, as those might lie elsewhere in the governance of a complex system. And neither says much about the nature and apparent randomness of suffering in the particular circumstances. (Dekker and Hugh 2014, p.1).

Developing appropriate and effective recommendations is one of the most challenging aspects of the incident analysis process. When a contributing factor is noted, it is tempting to follow up with a recommendation to address it. But recommendations can be ineffective, costly or result in more complex processes and more systems vulnerabilities. Studies have shown that all too often, recommendations focus on sharp-end interventions (e.g. training and vigilance) and are not effective in making care safer (Wu, Lipshutz and Pronovost 2008). Even if appropriately developed, recommendations may not be adequately planned and follow-up may be limited.

Many organizations develop recommendations considering a widely known hierarchy of error reduction

measures (ISMP 2006), and the SMART (specific, measureable, agreed, realistic/reasonable, timely/time-bound) mnemonic. As helpful as these are, they may not take into account the concept of complex systems and the socio-political contexts in which the interventions are to be applied.

Various frameworks for identifying effective recommendations are included in Appendix 4 and summarized below. Specifically, recommendations should focus on blunt-end system factors, taking into account:

- Human factors principles;
- Evidence of impact elsewhere;
- Complexity and potential unintended impacts;
- Cost and other resource implications;
- Other hospital priorities.

Robson (2012) suggests that recommendations could include:

- Short-term locally actionable improvements directly linked to one or more of the findings of the review;
- Longer-term proposals which make good sense, are connected to the contributing factors identified during the investigation and that would take a long time to implement, usually due to resource constraints;
- Reflective consideration or “good questions” for which there are no immediate answers or “quick fixes”.

Mills et al (2008) demonstrate that recommendations developed with the input and support of front-line staff and middle and senior management are also more likely to be implemented. Therefore before the review is completed, there should be a formal process for key stakeholders to accept or reject the proposed recommendations.

Prioritization

Inevitably there is a trade-off with all recommendations. While recommendations at the highest level are the most effective, they are also the most difficult to implement because of their complexity. They are also likely to be more costly, more resource intensive, and take longer to implement. In contrast, lower-level recommendations can usually be implemented relatively quickly and easily, often with minimal impact on resources, but are less effective in contributing to long term improvements to patient safety. Thus, you will be faced with the challenge of developing recommendations that will have the greatest impact on safety and that will also be acceptable to operational leaders. (Duchscher and Davies 2012, p.55).

An organization may find that as their experience with critical incident analysis matures, they become more focused on identifying fewer and more impactful recommendations for improvement (Stevens et al 2010). Given the complexity of healthcare systems, even well-intentioned recommendations may result in negative, unintended consequences elsewhere in the system (CPSI 2012, Robson 2012). Recommendations should be kept to a minimum wherever possible, and designed to significantly reduce the likelihood of recurrence and/or severity of outcome (NPSA 2008a). Reviewers can do this by addressing only those contributing factors that had the most impact on the outcome and that are most likely to be a factor in future events.

Using concepts related to the philosophy of causation and explanation, Boyd (2014) provides a unique perspective on prioritizing contributing factors and addressing the gaps they represent, including:

- Address the most important contributing factors only – those that when present, will guarantee that the event will occur;

- Remove contributing factors with only a small degree of influence;
- Remove contributing factors over which there is no control/that cannot be eliminated (e.g. human error);
- Assess the current “function” (beneficial role) and “evolution” (sequential changes that led to its present format) of the flawed latent failures/contributing factors – any planned recommendations must address these.

The CIAF (CPSI 2012) proposes the development of a prioritization table, indicating for each recommendation the risk, hierarchy of effectiveness, predictors of success, system level, evidence, validity/feasibility, and suggested implementation timeline.

Report

A recent ethnographic analysis of RCAs in England concluded that the process often failed to meet its goals because much of the focus was on the production of a final report. (Wachter 2012, p.245).

When the analysis is complete, the team will need to prepare a report summarizing the results. There is considerable variation in the size and scope of these reports, however. Helpful templates are available (OHA 2004, CPSI 2012, Duchscher and Davies 2012) setting out basic report elements including:

- A short narrative of the event;
- Issues/key findings/contributing factors;
- Recommendations for improvement;
- Chronology of events (often as an appendix).

Reports may or may not include more detailed action planning related to recommendations implementation. Thorough action planning (including identification of responsible individuals, resources required, project planning and expected dates of completion) may take some time to do effectively and may delay the completion of the incident analysis. Some organizations may have a process for hand-off of report recommendations, following a vetting and approval process by senior leaders, to risk management, quality improvement or project management staff for action planning and implementation support.

Report Confidentiality

Review teams need to balance the need to provide enough evidence to support findings and recommendations with the risks that the report could be disclosed in a subsequent legal proceeding, thereby impacting the willingness of staff to participate in future reviews. Best practices for ensuring report confidentiality and quality assurance privilege include:

- Ensure the rationale, expectations and obligations related to confidentiality are discussed with all review participants (does not apply to patient and family members);
- Ensure reports are concise, factual and focused on systems-related improvements;
- Write reports keeping in mind the (unlikely) possibility that it may be discovered in a legal proceeding;
- Ensure reports do not contain any quotes, opinions, speculations made by participants, nor any reference to staff performance related matters;
- Ensure reports do not contain language regarding breach of standard of care, or negligence as these are legal determinations (CPSI 2011);
- Limit and carefully track the numbers of draft reports that are distributed among review team members and/or to key senior leaders; circulate paper-based versus electronic copies if possible;
- Emphasize report confidentiality by including appropriate language in headers or footers (e.g.

- “privileged and confidential – for patient safety purposes only”);
- Limit the number of final reports and keep them in a secure location (e.g. one kept in the Risk Management department);
- Share report findings/recommendations with those that require the information to make improvements;
- Ensure any new facts uncovered in the course of the review are disclosed to the patient/family and added to the health record;
- Ensure systemic steps taken (and planned to be taken) are disclosed to the patient/family and that documentation of the discussion is included in the health record or patient relations file.

Implementation and Follow up

Implementation can be very challenging if the actions are not focused on the contributing factors, do not have clear objectives, are not communicated (handed over) clearly, and are not visibly supported by the senior team. Capacity to take on new initiatives in healthcare is limited – frontline teams are always busy caring for patients and implementing current improvement efforts, and managers feel inundated with corporate or regional projects that are added to the day-to-day operations. To add to the existing pressures, it is expected that all approved recommended actions will be implemented in a timely manner. (CPSI 2012, p.64).

As discussed previously, most recommendations arising out of incident analyses constitute significant change initiatives. Senior leaders must validate recommendations from a strategic and operational perspective, and delegate and resource their implementation (CPSI 2012). An improvement project approach such as the Model for Improvement should be considered for applicable recommendations to ensure that the change process is systematic and collaborative, and, given that even well-designed recommendations may result in unintended consequences elsewhere in the system, that the change is appropriately evaluated (CPSI, 2012).

Recommendations Tracking

Reporting on implementation of recommendations is a challenge in many organizations. This may be partly the result of limitations with existing tools, distributed accountability, and limited centralized resources for this important function. Recommendations arising from reviews quickly accumulate and are in addition to the many other projects likely underway at an organization. As Mills et al (2008) demonstrate, recommendations implementation is correlated with a well-organized tracking system/database with analytical and/or administrative supports to keep it up to date. Specific data elements in the database could include (Nova Scotia 2006, CPSI 2012):

- Recommendation summary
- Critical incident number
- Event type (e.g. birth, diagnosis, surgical, treatment, medication)
- Contributing factor category
- Contributing factor/finding
- Area, systems level
- Date entered
- Responsible individual
- Target completion date
- Actual completion date
- Status (e.g. considered and rejected, nothing done, under consideration, steps taken toward implementation, partially implemented, implemented as presented, implemented and adapted, CPSI 2012).

Getting updates from responsible individuals can be operationally challenging as they will likely require

reminders as due dates approach. An alternative would be to receive updates on all outstanding recommendations assigned to each individual at regular frequencies (e.g. quarterly or semi-annually).

Given evidence that “up to 70% of all organisational change fails” (NHS 2009, p.6), leaders must consider ways to ensure that improvements resulting from recommendations are sustained. This could entail periodic audits and/or ongoing measurement, at least for the most important initiatives.

Sharing Results

Sharing what was learned is the ultimate objective of the analysis and is represented as the last element of the continuum in the framework. Sharing the learning both within the organization (with patients/families, those involved in the incident, the analysis team and others as needed) and outside the organization is key to preventing additional harm and making care safer. (CPSI 2012, p.68).

Ensuring that the findings and results of critical incident analyses are shared appropriately is also a challenging aspect of the incident management process. As discussed previously, results should be disclosed to patients and families (see Post Analysis Disclosure in the Patients and Families section of this guide). Critical incidents and review results should also be reported as per specific jurisdictional requirements (e.g. provincial ministry of health, health region). Staff involved in events and the unit/program where the incident occurred will also want to hear the results of analyses. If the review was undertaken under specific legislative protection, there are confidentiality provisions that must be met. Generally speaking, the review report cannot be distributed to staff, however, the legislation will typically allow for the sharing of information from reviews to management, and through management to staff for the purposes of improving or maintaining the quality of care. This could be operationalized by having the area manager (who may have been a member of the review team) share findings and recommendations at an area staff/quality committee meeting. Staff may also have an opportunity to participate in quality improvement initiatives arising from the recommendations.

Sharing results outside of the organization is the subject of some debate. Questions arise as to potential legislative restrictions related to this (Laupacis and Morin 2014) and whether such information sharing will result in actual changes elsewhere. As discussed previously in the Recommendations Development section of this guide, information sharing alone is generally considered a weak error reduction strategy (ISMP 2006). In the absence of an actual event and the urgency that brings, organizations would have to develop processes to ensure such external alerts/databases are regularly reviewed and potential improvements identified and prioritized over initiatives already underway.

Results Trending

Many incidents are rare, so monitoring weekly or monthly incidence is uninformative. In this case more advanced strategies such as control charts that monitor time between incidents can be used. In settings where control charts are not available, teams can use measures of processes that identify important preventative measures as substitutes or proxies for outcomes. (CPSI 2012, p.66).

Critical incident data and the results of analyses should roll up into regular organization-wide reports to senior leadership and the board. Some jurisdictions dictate the frequency of such reports (e.g. twice per year) and that critical incident findings inform the organization's annual plan.

Trending and comparing the rate of low-frequency events such as critical incidents is a challenge and differences in the way incidents are classified prevent useful comparisons. Measures such as days between events (actual incidents only), and 12 month rolling averages can be helpful in trending

incidents internally. Healthcare Performance Improvement (HPI 2009) in the U.S. has provided guidance on a more sophisticated coding and measurement system which supports inter-organizational benchmarking. This approach provides clear guidance on identifying and coding serious safety events (SSE) with the rate of SSE's reported monthly as a twelve-month rolling average, volume-adjusted to 10,000 patient days. "The 12-month rolling rate provides two benefits. First, as Serious Safety Events do not occur frequently, it presents a clearer picture of the event rate trend. Second, it rewards sustained improvement, rather than episodic improvement, in preventing Serious Safety Events (HPI 2009, p.8)". Some organizations in the U.S. are even posting their SSE rate on their website (Cincinnati Children's Hospital 2015).

Multi-Patient Events

As complex as serious clinical events are, many special circumstances can make them dramatically more complicated. At the top are adverse events where tens, hundreds, or thousands of patients may have been affected – major failures of the health care system, including cases around poor sterilization practices or contamination of endoscopic devices, hepatitis outbreaks, interpretations of diagnostic studies, pseudomonas outbreaks, overdoses of radiation, and cases where it can't be determined how many patients were impacted. (Conway et al 2011, p.25).

Multi-patient events, or large-scale adverse events, are defined as individual, or a series of related events, that injure or increase the risk that many patients would be injured because of healthcare management. In general, the increased risk is neither anticipated by health care professionals nor recognized at the time of the incident. For multi-patient events that require follow-up testing (e.g. sterilization failures), the subgroup of patients who have been injured generally cannot be distinguished from the group of patients who have not been injured (Dudzinski et al 2010).

Examples of multi-patient incidents include: sterilization failures, infectious disease outbreaks diagnostic errors, and privacy breaches.

While most of the strategies for managing critical incidents apply to management of multi-patient events, there are many unique challenges that they pose including:

- Identifying patients impacted;
- Identifying severity of impact;
- Notifying patients – how and when;
- Managing the media;
- Medical malpractice implications – class action lawsuits.

ALERT – Early Involvement of HIROC

If an organization is considering a lookback or notification for a multi-patient event, HIROC should be informed immediately for two reasons. Firstly, HIROC has considerable experience in this area and will advise on lessons learned from previous cases, and engage and fund independent clinical and legal experts to help ensure the effective and ethical management of the case. Secondly, multi-patient events also have a high probability of proceeding to a multi-million dollar class action lawsuit, and as such, organizations have a duty to promptly notify their insurer of any situation that might give rise to a claim. HIROC and legal counsel will help to ensure the preservation of documentation and memories and provide advice on insurance limitation periods and coverage issues as required.

Types of Events

The most common types of multi-patient events and their special considerations are described below:

Infectious Disease Outbreaks

Examples of infectious disease outbreaks include the transmission of tuberculosis and *C. difficile*. Often the outbreak is not able to be determined without trending cases over time (de Wit and Glaspell 2013). Public Health may be involved in making the decision to notify patients. It is increasingly common to notify the public of outbreaks on hospital websites/through television to increase public awareness and reduce the spread of the outbreak by limiting visitors to the organization.

Sterilization Failures

Examples of sterilization failures include sub-optimally processed equipment for endoscopy, colonoscopy and prostate biopsies. These failures are caused by equipment malfunction and issues related to human factors. This type of multi-patient event is extremely challenging since it is difficult to know whether any harm has occurred and analysis may not take place until decades after exposure (Dudzinski et al 2010).

The literature suggests there is an extremely low risk of infection from a sterilization failure. For example, Dudzinski et al (2010) note that scientists could not calculate the increased risk posed by omitting one cleaning step related to endoscopy but they thought it was remote and indistinguishable from the baseline risk of contracting blood-borne pathogens from an endoscope which is estimated to be 1 in 1.8 million. In *Farkas v. Sunnybrook and Women's College Health Sciences Centre*, 2009 44721 ON SC, there was found to be no risk of disease transmission from poorly disinfected prostate biopsy equipment which was identified through an internal audit of infection control practices. A risk assessment should be undertaken in each case because the risk of infection will vary depending on the nature of the reprocessing failure.

Actual harm can only be determined once patients are tested for exposure to blood-borne pathogens. It is ultimately a medical decision to notify patients (de Wit and Glaspell 2013) if it is felt there is a material risk of harm; as with infectious outbreaks, Public Health may be involved in making this decision. If notification occurs, patients should be offered follow-up testing.

The Centers for Disease Control and Prevention (US) offers six steps for evaluating an infection control breach with potential for risk of blood-borne pathogen transmission: 1) identification of infection control breach; 2) additional data gathering; 3) notify and involve key stakeholders; 4) qualitative assessment of breach – classify as Category A (gross error or demonstrated high-risk practice) or B (breach with lower likelihood of blood exposure); 5) decision regarding patient notification and testing – category A (is warranted) or category B (consider factors before notifying) and; 6) communications and legal issues.

Rutala and Weber (2007) offer a 14-step protocol to assess risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines; the authors suggest that patients should be notified if it is determined that the sterilization failure could result in adverse patient events.

Diagnostic Errors

Large scale diagnostic errors have involved breast cancer hormone receptor testing, reading of mammograms, and breast and prostate cancer biopsies. In undertaking a review for diagnostic errors a healthcare organization must carefully determine how far back to go. These reviews involve judgment of pathology/radiology tests and must take into account baseline error rates and clinical significance. Patients should be notified if clinically significant errors are found (de Wit and Glaspell 2013).

Privacy Breaches

Privacy breaches result from either inadvertent loss of data (e.g. misplaced USB key containing patient information), theft or intentional and inappropriate access of patient records by individuals either inside or outside the organization. Once a privacy breach has been identified, there is an obligation, as defined in applicable legislation, to inform patients that their personal health information has been inappropriately accessed. The sensitivity of the personal health information accessed may determine the best form of notification (e.g. telephone, in writing, at next appointment). When notifying patients who are affected by the breach, details of the extent of the breach and the specifics of the personal health information at issue should be provided and patients should be advised of the steps that have

been taken or will be taken to address the breach, in both the short and long-term (Cavoukian, 2006). It is also important to let patients know the provincial/territorial information and privacy officer has been contacted to meet legislative obligations (if they exist) and to reduce the likelihood that the individual will contact the provincial/territorial information and privacy officer themselves (Cavoukian, 2006).

Identifying Patients and Assessing Impact

A very significant challenge of large-scale patient safety incident disclosure is deciding which patients, of the patients potentially exposed to a patient safety incident, are 'at risk' and require disclosure. Where the likelihood of harm is high, the need to contact all affected patients is clear. As the likelihood of harm decreases, a complex weighing of the clinical probabilities and ethical obligations may be required. Ultimately, the criteria for contacting patients should be established with regard to the assessed risk. (CPSI 2011, p.30).

Multi-patient events typically involve retrospective detection of *potential* harm to multiple patients. Often it is unknown if actual harm occurred; most patients experience no harm or a near miss (de Wit and Glaspell 2013). The group of potentially affected patients may be large and not readily identifiable. The probability of harm and severity vary on a case-by-case basis. Some multi-patient incidents may be urgent and others may not, which means that there is a balance between conducting timely and thorough risk assessment and notification. When there are multiple patients involved, the process of risk assessment and notification can be resource intensive and requires an interdisciplinary approach. Careful consideration needs to be given to examining the harm from potential risk against the harm from inappropriate disclosure.

The process for reviewing the event becomes important in determining the assessed risk and the number of impacted patients. The approach to review multi-patient events can take several forms:

- de Wit and Glaspell (2013) suggest conducting a multidisciplinary risk assessment to ascertain the likelihood and severity of clinical consequences. It is then suggested that a list be created of potentially affected patients with help from relevant parties (e.g. infection control, information technology, facilities). With respect to no harm events and near misses, they suggest consulting broadly (clinical, ethics, legal, patient representative) and asking: Would a reasonable patient in these circumstances want to know? Urgency is determined by the ability to prevent, identify or mitigate future harm through clinical testing or treatment, e.g. where an intervention such as prophylactics is available to mitigate the risk, urgency is highest.
- Chafe et al (2009) suggest six steps to follow when addressing adverse events involving large numbers of patients: 1) identify the error in a timely fashion; 2) conduct a review of an appropriate sample of records or procedures to determine the extent of the error; 3) if a full review is necessary, identify a project team, establish the scope of the review and determine the resources needed for the review; 4) identify patients who may have been affected by the error and include their records in the review; 5) review clinical records; and 6) inform patients and other stakeholders. The authors also note that physicians who were directly involved in the error should not lead the process.
- Case law (*Pittmann Estate v. Bain Pittman Estate v. Bain* (1994), 112 DLR (4th) 257 (Sup. Ct.) supports the practice of a timely lookback, use of medical/scientific knowledge to ascertain risk, and notification in a manner and in a time commensurate with the risk to the affected patients' health (de Wit and Glaspell 2013).

- The CPSI (2011) advocates the use of an interdisciplinary team to establish the criteria for disclosure with regard to the assessed risk. A patient experience expert is suggested to be part of the interdisciplinary team.

Notification of Patients

The basic principle that patients should be informed quickly, fully and respectfully of errors that adversely affect them holds true regardless of the number of patients involved. But timely and complete disclosure is especially complex when dealing with errors affecting large numbers of patients and raises challenges well beyond those of identifying who is affected. (Dudzinski et al 2010, p.1).

The Canadian Patient Safety Institute's Canadian Disclosure Guidelines (2011) provide advice with respect to when to disclose patient safety incidents in single patient events; these guidelines can generally be followed for multi-patient events. The Guidelines assert that when there has been harm to a patient, there is a need to disclose; if the event reached the patient but there was no harm, disclosure should generally occur. If the event did not reach the patient (near miss), disclosure does not need to occur unless there is an ongoing safety risk. As with single patient events, multi-patient disclosure should occur as soon as practical. If the event occurred in the past, it may be difficult to locate patients and reasonable steps should be taken to obtain current contact information (CPSI 2011). It is important the organization notifies patients affected by a multi-patient event before the media does.

As identified above, one of the challenges of multi-patient events is there are often difficulties in determining which patients were impacted – for many, the event may not have reached them or if it did, caused no harm. For others, harm may be considerable although the risk has not yet been assessed or quantified. Dudzinski et al (2010) note definitive evidence of harm can usually be established only after a lookback investigation is well under way and that disclosure of large scale adverse events may be warranted before conclusive determination of the magnitude and scope of harm. This creates a dilemma: Should patients be notified? When should they be notified? And which patients should be notified? An interdisciplinary approach is required to review the event in order to consider ethical and legal obligations related to notification.

What to Disclose

With respect to what is disclosed, patients should receive an apology, be told the facts about what happened, the steps that have been taken or are recommended to minimize the harm and that steps will be taken to prevent recurrence (CPSI 2011). Care should be taken to articulate the risk in a manner that is clear, easy to understand and relevant to the patient. Unless it is necessary or evident given the circumstances, individual clinicians should not be identified and assumptions about the cause of what happened should not be included (Chafe et al 2009). Patients should be told what further information they can expect once a full analysis of the event is completed. Organizations should provide follow-up diagnostic testing and treatment to patients where there is a material risk of harm (e.g. sterilization failure). CPSI (2011) suggests affected patients be given priority over current patients when clinical and emergent priorities permit. It is reasonable to offer to pay out-of-pocket expenses related to the disclosure process.

Dudzinski et al (2010) suggest organizations address anxiety produced by the disclosure. One way to do this is by setting up a hotline for affected patients to call should they have questions or offering support from the organization's Social Work or Pastoral Services departments. Face to face disclosure by a health care provider is helpful where feasible because the patient can ask questions and receive support in real time. Of note, the stress experienced by a patient due to the notification of a multi-patient event is not compensable according to recent case law (*Healey v. Lakeridge Health*

Corporation, 2010 ONSC 725) although if the notification itself is negligent that could still be compensable.

In addition to communicating with the patient, it is important to remember communication needs to occur concurrently with the patient's primary healthcare provider (CPSI 2011).

Methods

The best practice for initial disclosure communication with at-risk patients is that it be done in person, and the more urgent or serious the risk of harm, the stronger the case for in-person initial disclosure. (CPSI 2011, p.30).

The method of notification of a multi-patient event will vary depending on the nature of the event, the urgency and the number of individuals affected. Methods for notification include in person, by telephone and in writing (letter, press release, statement on website). Regardless of the method utilized, it is important to be able to identify all successful and unsuccessful attempts that have been made to contact each of the patients (Chafe et al 2009).

Dudzinski et al (2010) suggest written notification regarding low risk, low harm, multi-patient events may be appropriate whereas verbal notification regarding events involving greater harm may be indicated. Verbal or in-person contact is also recommended by CPSI (2011).

When determining the method of notification, consider the volume of patients affected, urgency, recommended follow-up testing/treatment, and relationship to care providers (de Wit and Glaspell 2013). If there are a low number of patients involved, verbal contact (in-person or by telephone) is preferable; a follow-up letter can confirm the discussion and any required next steps. While letters may become unavoidable if a high number of patients are involved, mass mailings often attract the media and the interest of class action counsel and can cause a higher level of distress given the recipient cannot immediately interact with a health care provider to address concerns that flow from receiving the letter (de Wit and Glaspell 2013). It is also preferable to make one notification to all affected patients instead of multiple notifications; however, this may be unavoidable as more impacted patients become known. Use of registered mail alone should be avoided as it can be viewed as self-identifying and embarrassing to the recipients (de Wit and Glaspell 2013).

Regarding who makes the disclosure, whether verbally or in writing, this is typically the role of a senior healthcare leaders in conjunction with the most responsible practitioner. If the numbers of patients are high, personal contact may not be possible. Risk Management will typically draft the correspondence with HIROC and legal counsel (note HIROC has developed several templates to assist with this). The notification needs to be clear about the details of what happened and the language used must be understandable to the patient.

Timing

Chafe et al (2009) suggest moving quickly to publicly disclose an error has clear benefits even when the cause has not yet been determined and note that "transparency needs to trump concerns about increasing legal liability" (p.1126). Similarly, Dudzinski et al (2010) notes that institutions should proactively disclose all large scale adverse events to affected patients unless a strong, ethically justifiable case can be made not to disclose and suggests that disclosure should be the norm. Dudzinski et al (2010) also find the ethical obligations to disclose are greatest when the events resulted from preventable errors or system failures whereas duties to disclose are more ambiguous when the probability of harm is extremely low but the severity of harm is great and there are no definitive diagnostic tests or effective treatments. Furthermore, while an organization may be harmed by the

disclosure (e.g. reputational risk), the obligations to patient care, transparency and retributive justice far outweigh risks to the organization (Dudzinski et al, 2010). CPSI (2011) also notes the greater the risk of harm to the patient, the more compressed the timeline for review and notification should be.

Managing the Media

The organization itself needs to be the first to present the information to the public. Transparency needs to trump concerns about increasing legal liability. (Chafe et al 2009, p.1126).

Healthcare organizations should assume multi-patient events will be covered by the media. It is important to assure patient and provider privacy while keeping the public aware of what has happened and what steps are being taken to address it. CPSI (2011) agrees it is a challenge to balance demands for privacy against public transparency and external demands for information. Dudzinski et al (2010) also note responses to the media should demonstrate the organization's commitment to honesty and transparency.

There are several strategies for addressing the media which have their own risks and benefits: pre-emptive press release (least favoured approach), press release or statement in response to inquiries, and a website statement. Of the latter two approaches, the preferred approach will vary depending on the unique circumstances of the event. Legal counsel can provide advice on the healthcare organization's media strategy.

The experience of one healthcare organization can impact the decisions that others make regarding what to share with the media. For example, after the Cameron Inquiry into hormone receptor/tamoxifen issues in Newfoundland, hospitals became very proactive and wanting to be out front of media (de Wit and Glaspell 2013).

Organizational Policy

Although large-scale adverse events are less common than adverse events affecting individual patients, they occur frequently enough to warrant thoughtful policies and procedures. (Dudzinski et al 2010, p.979).

Most organizational policies for managing incidents address how to manage and disclose single patient events. Organizational policies seldom address disclosure of large scale events (CPSI 2011). The Veterans Health Affairs Directive 2008-002 is an exception and outlines a clear process including convening a multidisciplinary advisory board to recommend whether or not to disclose and to provide guidance on the manner of disclosure (Dudzinski et al 2010).

It is suggested that organizations include the following in their organizational policy: how to manage the disclosure including prompt initiation of a lookback; notifying patients and the public; coordinating follow-up diagnostic testing and treatment; and responding to regulatory bodies (Dudzinski et al 2010). Chafe et al (2009) add several other considerations: a communications plan should be established that includes mechanisms (e.g. a dedicated phone line or website) for affected patients to gain access to information and ask questions; affected patients should be given priority over current patients when appropriate; an analysis of the event should be conducted and led externally; the results of the analysis should be released publicly with statements of the actions undertaken to address problems identified; and a clear and fair process should be used to evaluate the performance of clinicians involved in the adverse event.

A checklist to help organizations manage multi-patient events is included in Appendix 5.

Class Action Lawsuits

There is a high probability that a multi-patient incident will turn into a class action lawsuit. This is a lawsuit in which one person (usually) sues on behalf of a larger group of persons with the same issue. Class actions are intended to allow large numbers of impacted patients' access to compensation when it would be impracticable or too costly for each of them to advance a claim on their own. While the average payout for each individual member of a class action is often relatively low, in aggregate, the total amounts can reach into the millions of dollars (e.g. \$1,000 x 1,000 patients = \$1 million).

Class action lawsuits are also different from individual medical malpractice cases in that:

- There is greater potential for reputational harm;
- They can be played out on the public stage;
- The organization's handling of the case is under particular scrutiny;
- There is the potential for politicians to get involved;
- The scope of the investigation can be broader and over a longer time;
- There is reduced control over case management (Boone 2013).

Conclusion

A national conversation is needed that is sensitive to the political, economic and demographic complexities of getting healthcare delivery 'right' in a mature democracy, and which understands that the risk of error and failure is the inevitable byproduct of pursuing success in a resource-constrained, goal conflicted world. (Dekker and Hugh 2014, p.3).

Striving to identify and address the underlying reasons why incidents occur will lead to a greater understanding of hazards in the system and, ultimately to a safer healthcare system for all. This is an integral part of moving the culture of the entire healthcare organization from blame to understanding, learning and improvement. (CPSI 2012, p.71).

Critical incidents occur too frequently in healthcare. If handled well, they provide an opportunity for great organizational learning; if handled poorly, they can lead to further suffering for the patients, families and staff involved, the growth of fear, and more failures in the future.

This guide has provided practical guidance on some of the most challenging aspects of critical incident management including ensuring an effective organizational response to the crisis; ensuring patients, families and staff are supported; and ensuring impactful incident analyses through application of key concepts and processes. Particular attention has also been paid to managing complex incidents involving multiple patients.

We trust that this guide will become an invaluable resource for healthcare leaders, building capacity to manage and learn from critical incidents, which in turn will lead to effective change and the achievement of our vision of improved patient safety.

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Appendix 1: Crisis Communications Key Messages

Conway et al (2011)

- The hospital has apologized and regrets that the incident happened
- We have disclosed to the patient and family everything we know, and keeping them informed and supported is a priority.
- The board of trustees and leadership are actively engaged in understanding why our systems failed this patient and family and what steps are needed to prevent a similar occurrence in the future.
- We are an excellent organization and staff, but not perfect, and we come to work every day to provide the best care we can and continuously seek ways to improve it.
- We will use this tragedy to make this organization a better and safer place for our patients, family, staff, and community.

Dykeman and Dewhirst (2011)

- Our first priority is everyone's safety.
- We responded quickly, and are working with others (e.g. police, government) as appropriate
- We believe at this time that the situation is under control (if it is).
- We have taken the following steps to manage the incident...
- The public can assist in the following ways...
- While for privacy/legal reasons we cannot speak to the specifics of this case, we can tell you that:
 - We investigate all events/complaints and respond to the individuals involved
 - We view any incident as an opportunity to improve our services
- We take these cases very seriously
- We are still investigating the crisis
- We will continue to be in touch with (our patients, their families, our staff, the public) and will report back as we have more information.

Appendix 2: Elements of a Critical Incident Management Policy, Procedure, Guideline

1. Policy Statement/Purpose

- Statement regarding the purpose of the policy – to provide direction on the reporting and management of critical incidents
- Affirming the organization's commitment to support all those involved, to be collaborative and fair, to learn from incidents and fulfill responsibilities outlined in applicable legislation.
- Articulating the requirement for participation of all involved staff (including physicians)
- Articulating confidentiality requirements

2. Key Terms

- Critical incident or related term (in alignment applicable provincial/territorial legislation)
- Disclosure
- Multi-patient event
- Quality of Care / Assurance Committee (as per legislation)

3. Responsibilities (articulate what each needs to do, who to notify)

- Staff member(s) involved in event (e.g. attend to needs of patient, report immediately, etc.)
- Clinical leader/manager
- Most responsible practitioner
- Administrator on call
- Risk manager
- Vice-president / responsible senior manager
- CEO/executive director
- Communications

4. Process

- Immediate steps
 - Attend to patient care needs
 - Report incident (verbal, +/- complete normal incident report)
 - Activate crisis management team (if applicable)
 - Attend to staff needs
 - Take actions to reduce the risk of imminent recurrence (if applicable)
 - Secure and complete the health record
 - Sequester involved supplies, medications (including discards/waste if applicable), devices, data
- Incident analysis
 - What will be reviewed (system issues only, practice issues, if any, dealt with outside of review)
 - Who will do the review (including role of facilitator and other team members)
 - How the review will be conducted (general concepts, information gathering including interviews with patient/families/involved staff, confidentiality and expected timeline)
 - Recommendations development, approval and implementation
 - Results reporting (e.g. senior management, quality committee, board) and disclosure
 - Ongoing monitoring and trending of results

5. Related Appendices (e.g. process flow chart, information sheet for staff invited to interviews, etc.)

6. Related Policies and Procedures (e.g. Disclosure, Incident reporting, etc.)

Appendix 3: Key National and International Resources

Canadian national and provincial English language resources that could be helpful to organizations as they develop and enhance their guidelines and processes for effective management of critical incidents include:

National

- Canadian Patient Safety Institute (CPSI). (2011). Canadian disclosure guidelines: being open and honest with patients and families. Available at: <http://www.patientsafetyinstitute.ca/English/toolsResources/disclosure/Documents/CPSI%20Canadian%20Disclosure%20Guidelines.pdf>.
- Canadian Patient Safety Institute (CPSI). (2012). Canadian incident analysis framework (CIAF). Available at: <http://www.patientsafetyinstitute.ca/english/toolsresources/incidentanalysis/documents/canadian%20incident%20analysis%20framework.pdf>
- Canadian Medical Protective Association (CMPA). (2008). Communicating with your patient about harm: disclosure of adverse events. Available at: https://www.cmpa-acpm.ca/cmpapd04/docs/resource_files/ml_guides/disclosure/pdf/com_disclosure_toolkit-e.pdf.
- Canadian Medical Protective Association (CMPA). (2010). Just culture of safety: Why protecting quality improvement reviews is important for everyone. Available at: <https://www.cmpa-acpm.ca/-/just-culture-of-safety-why-protecting-quality-improvement-reviews-is-important-for-everyone>.
- Robson R. (2012). Shifting paradigms in healthcare: event review and evaluation. Healthcare System Safety and Accountability. Available at: <http://www.hssa.ca/media/manual-full.pdf>.
- Accreditation Canada. (2015). Required Organizational Practices: handbook 2016. (See patient safety incident disclosure, management, and quarterly reports). Available at: <http://www.accreditation.ca/sites/default/files/rop-handbook-2016-en.pdf>.

B.C.

- BC Patient Safety and Quality Council. (2013). Culture change toolbox. (See adverse event response team, just culture algorithm, learning from defects). Available at: https://bcpsqc.ca/documents/2014/01/SQAN-Culture-Book_6x8_2013_web-FINAL.pdf.

Alberta

- Duchscher C, Davies F. (2012). Systematic systems analysis: a practical approach to patient safety reviews. Health Quality Council of Alberta. Available at: https://d10k7k7mywg42z.cloudfront.net/assets/5501df86c0d67106cf02ae61/HQCA_SSA_PSR_111913.pdf.

Saskatchewan

- Saskatchewan Critical Incident Reporting Guideline. (2004). Available at: <http://www.health.gov.sk.ca/critical-incident-guidelines>.

Manitoba

- Manitoba Institute for Patient Safety. (2011). The Facts about critical incidents and their disclosure: frequently asked questions for health care providers. Available at: http://mbips.ca/assets/facts_about_critical_incidents-05-14.pdf.
- Manitoba Institute for Patient Safety. (2014). A guide to critical incidents and disclosure: information for patients and families. Available at: http://mbips.ca/assets/guide_to_ci_and_disclosure-web.pdf.

Ontario

- Ontario Hospital Association (OHA). (2004). Quality of Care Information and Protection Act toolkit. Available at: <http://www.oha.com/KnowledgeCentre/Library/Toolkits/Documents/QCIPAToolkit.pdf>.
- Laupacis A, Morin A (co-chairs). (2014). QCIPA Review Committee Recommendations Report. Ontario Ministry of Health and Long Term Care. Available at: http://www.health.gov.on.ca/en/common/legislation/qcipa/docs/qcipa_rcr.pdf.
- Health Quality Ontario. (2012). Quality improvement guide. Available at: <http://www.hqontario.ca/portals/0/Documents/qi/qi-quality-improve-guide-2012-en.pdf>.

Nova Scotia

- Nova Scotia District Health Authorities and IWK Working Group. (2006). DHA/IWK quality review: understanding the legal framework. Available at: <http://www.cdha.nshealth.ca/system/files/sites/5714/documents/quality-review-framework.pdf>.

Other well respected resources include:

U.K.

- Taylor-Adams S, Vincent C. (2004). Systems analysis of clinical incidents: the London protocol. Clinical Safety Research Unit, Imperial College, London. Available at: http://www1.imperial.ac.uk/cpssg/cpssg_publications/resources_tools/the_london_protocol/.
- National Patient Safety Agency (NPSA). (2003a). Root cause analysis tool kit: an introduction to human error theory. NHS. Available at: https://report.npsa.nhs.uk/rcatoolkit/resources/word_docs/guidance/guidance_introduction_to_human_error_theory.doc.
- NPSA. (2003b). Root cause analysis tool kit: undertaking an investigative interview – the cognitive interview. NHS. Available at: https://report.npsa.nhs.uk/rcatoolkit/resources/word_docs/guidance/guidance_undertaking_an_investigative_interview.doc.
- NPSA. (2003e). The Incident Decision Tree: Information and advice on use. NHS Confederation. Available at: <http://www.chpso.org/sites/main/files/file-attachments/idtadvice2003.pdf>.
- NPSA. (2008a). Root cause analysis investigation tools: guide to investigation report writing. NHS. Available at: www.nrls.npsa.nhs.uk/resources/?EntryId45=59847.
- NPSA. (2008b). Root cause analysis investigation tools: investigative interview guidance. NHS. Available at: <http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60182&type=full&servicetype=Attachment>.
- NPSA. (2009). Root cause analysis investigation tools: contributory factors classification framework. NHS. Available at: www.nrls.npsa.nhs.uk/resources/?entryid45=75605.

U.S.

- Massachusetts Coalition for the Prevention of Medical Errors. (2006). When things go wrong: responding to adverse events. A Consensus Statement of the Harvard Hospitals. Available at: <http://www.macoalition.org/documents/respondingToAdverseEvents.pdf>.
- Conway J, Federico F, Stewart K, Campbell M. (2011). Respectful management of serious clinical adverse events (second edition). Institute for Healthcare Improvement. Available at:

<http://www.ihl.org/knowledge/Pages/IHIWhitePapers/RespectfulManagementSeriousClinicalAEsWhitePaper.aspx>

- Nolan T, Resar R, Haraden C, Griffin F. (2004). Improving the reliability of health care. Institute for Healthcare Improvement. Available at: <http://www.ihl.org/resources/Pages/IHIWhitePapers/ImprovingtheReliabilityofHealthCare.aspx>.
- Agency for Healthcare Research and Quality (AHRQ). 2008. Becoming a high reliability organization: operational advice for hospital leaders. Available at: <http://archive.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/hroadvice/hroadvice.pdf>.
- ECRI Institute. (2011). Systems safety analysis.
- ECRI Institute. (2013). Event report interviews.
- Healthcare Performance Improvement (HPI). (2009). The HPI SEC & SSER patient safety measurement system for healthcare. Available at: <http://hpiresults.com/docs/PatientSafetyMeasurementSystem.pdf>.
- Institute for Safe Medication Practices (ISMP). (2006). Hierarchy of error reduction measures. Available at: https://www.ismp.org/newsletters/ambulatory/archives/200602_4.asp
- Joint Commission. (2013). Root cause analysis and action plan framework template. Available at: http://www.jointcommission.org/assets/1/6/RCA_Questions_Framework.docx.
- Joint Commission. (2014). Sentinel event policy and procedures. Available at: http://www.jointcommission.org/Sentinel_Event_Policy_and_Procedures.
- National Coordinating Council for Medication Error Reporting and Prevention. (2001). Index for categorizing medication errors. Available at: <http://www.nccmerp.org/sites/default/files/indexColor2001-06-12.pdf>.

International

- World Health Organization (WHO). (2009). Conceptual framework for the international classification for patient safety. Available at: http://www.who.int/patientsafety/taxonomy/icps_full_report.pdf.

Appendix 4: Frameworks for Developing Effective Recommendations

Institute for Safe Medication Practices (2006).

1. Fail-safes and constraints
2. Forcing functions
3. Automation and computerization
4. Standardization
5. Redundancies
6. Reminders and checklists
7. Rules and policies
8. Education and information

Eldridge (cited in Stevens et al., 2010).

Stronger

- Architectural/physical change
- Engineering control or interlock (forcing functions)
- Simplification of the process
- Standardization
- Tangible involvement and action by leadership

Intermediate

- Redundancy
- Increase in staffing/decrease in workload
- Eliminate/reduce distractions (sterile cockpit)
- Checklist/cognitive aid
- Read-back
- Enhanced documentation/communication

Weaker

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

National Patient Safety Agency (2008a)

- Understand that retraining is not always the right solution
- Intelligent use of checklists, policies and protocols
- Minimal dependency on short-term memory and attention span
- Simplification of tasks and processes
- Standardisation of tasks and processes
- Avoidance of fatigue (review of working hours/patterns)
- Alignment with evidence-based practice
- Alignment with organisational priorities and risk registers

Mills et al (2008) Correlates of successful improvements/recommendations

- Strong senior leadership support
- Strong middle management support
- Strong front-line staff support / asked staff for feedback before implementing the action
- Well-organized tracking system

Shojania (2010). Framework for prioritizing interventions.

- Scope of the problem
- Effectiveness of the intervention
- Implementation issues including costs, complexity, and the possibility of introducing new problems
- The degree to which a given intervention is synergistic with other interests or improvement activities in the hospital

Canadian Incident Analysis Framework (2012). Key features of effective recommendations.

- Address the risk associated with the key findings/contributing factor
- Utilizes the most effective solution possible (see hierarchy)
- Long-term solution
- SMART (specific, measurable, attainable, realistic, timely)
- Targets the right level of the system
- Responsibility assigned
- Greater positive than negative effect
- Based on evidence
- Rationale explained

Canadian Incident Analysis Framework (2012). Hierarchy of effectiveness.

- High Leverage
 - Forcing Functions and Constraints
 - Automation/Computerization
- Medium Leverage
 - Simplification/Standardization
 - Reminders, Checklists, Double Checks
- Low Leverage
 - Rules and Policies
 - Education and Information

Robson (2012). SENSE (versus SMART)

- Specific to the findings – Relevant to the findings and understanding that emerged from the investigation
- Effective – Makes use of the evidence that has been accumulated in complex socio-technical systems concerning what works and what doesn't (e.g. forcing functions versus vigilance)
- Not necessarily time-limited
- Shifting the focus from sharp end individual issues to blunt end challenges; addressing ways to reduce the gap between the tasks or functions as designed (usually at the blunt end of the organization) vs. the work as actually done (usually occurring at the sharp end).
- Exploring systemic and organizational goal conflicts; addressing issues related to competing pressures (e.g. production/through-put versus safety); reality tested with those that have to implement it.

Nolan et al (2004). High reliability design principles.

- 10^{-1} performance – emphasis on training and reminders (e.g. standardized equipment, memory aids, checklists, feedback on compliance with standards, awareness raising and training)
- 10^{-2} performance – processes designed using human factors engineering (e.g. reminders, differentiation, constraints, affordances)
- 10^{-3} or better performance – well-designed system with attention to processes, structure, and their relationship to outcomes.

Appendix 5: Checklist for Managing Multi-Patient Events

Phase	Task	Considerations
Concern Raised	<input type="checkbox"/> Assemble interdisciplinary review team/trigger critical incident response team	<ul style="list-style-type: none"> - Identify incident lead (e.g. risk manager or other leader), include area manager(s), physician leader(s), senior executive, communications - Include relevant representation as per event (e.g. infection control, infectious diseases, laboratory/diagnostic imaging, biomedical, IT/privacy, ethics, health records)
	<input type="checkbox"/> Consider potential immediate needs of patients and families	<ul style="list-style-type: none"> - Determine if ongoing patient risk; address as required - Offer follow-up testing as appropriate - Consider prophylactic and other treatments
	<input type="checkbox"/> Consider potential needs of involved staff	<ul style="list-style-type: none"> - Offer Employee Assistance Program as required
	<input type="checkbox"/> Notify HIROC	<ul style="list-style-type: none"> - HIROC will engage and fund independent clinical and legal expertise as required
	<input type="checkbox"/> Other notifications	<ul style="list-style-type: none"> - Consider other external notifications, e.g. Public Health, Information & Privacy Commissioner as required
Look back / Analysis	<input type="checkbox"/> Identify timeframe (may adjust) <input type="checkbox"/> Conduct review of records/risk assessment in a timely fashion <input type="checkbox"/> Create centralized and secure database to track results and follow up	<ul style="list-style-type: none"> - Determine resources needed for review - Conduct an interdisciplinary risk assessment, most often involving external experts, to clarify likelihood and severity of harm and urgency - Create a list of potentially affected patients indicating what records have been reviewed including findings - Ensure that records are maintained and retained
	<input type="checkbox"/> Determine threshold for patient harm and confirm patients to be notified	<ul style="list-style-type: none"> - Use medical knowledge to ascertain risk - Use threshold criteria to identify patients to be notified and document in database
Patient Notification	<input type="checkbox"/> Determine method of patient notification	<ul style="list-style-type: none"> - Determine if follow up/notification is more urgent for some than others - Consider in person, phone call, letter or media - Draft follow up letters (see HIROC for examples)
	<input type="checkbox"/> Notify patients	<ul style="list-style-type: none"> - Offer follow-up testing if appropriate - Create patient hotline if notification was in writing - Set-up follow-up clinic if appropriate
	<input type="checkbox"/> Track notifications in database	<ul style="list-style-type: none"> - Log number of attempts and responses
Communication Strategy	<input type="checkbox"/> Develop communication strategy	<ul style="list-style-type: none"> - Involve HIROC/legal counsel - Consider risk/benefit analysis of various strategies (pre-emptive press release, reactive press release, website statement) - Ensure patient and staff privacy - Develop strategy for patients and families - Develop strategy for staff and physicians - Develop strategy for community/public



This document will be updated as new information and insights arise. We are very interested in receiving questions, suggestions and feedback regarding this work. Please direct your comments to:

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