

Building Safer Systems through Critical Occurrence Reviews: Nine Years of Learning

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At The Hospital for Sick Children (SickKids), the term *critical occurrence* was developed to describe any event that results in an actual or potential serious, undesirable and unexpected patient or staff outcome including death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition. It also includes a breach of legislation including the *Personal Health Information Protection Act* of Ontario. Although broader in its definition, the term aligns closely with *critical incident* as defined within the amendments to Regulation 965, under the *Public Hospitals Act* (Government of Ontario 1990). Critical occurrences may include (but are not limited to) potential or actual adverse outcomes (including death) associated with or resulting from medication errors; a wrong site, patient or procedure performed; contaminated drugs, devices or products; an equipment malfunction; an outbreak or unusual pattern/type of nosocomial infection; employee actual or potentially serious injuries.

SickKids' *Blueprint for Patient Safety* includes the management of critical occurrences and disclosure as one component of a 10-item road map that has guided the hospital in its active transition to a culture of safety (Stevens et al. 2005; Matlow et al. 2008). An essential underpinning of the blueprint is the ongoing need to identify failures, examine their contributing factors and apply lessons learned and system redesign to prevent recurrences.

In 2001, The Hospital for Sick Children formally imple-

mented an innovative, systematic process for reviewing critical occurrences. This process was implemented following a series of inquests and in response to the Institute of Medicine's report challenging healthcare to learn from sentinel events in an effort to prevent harm (Kohn and Donaldson 2000). The review process was largely influenced by the work of the Clinical Risk Unit and the Association of Litigation and Risk Management (1999), which described a formal, practical protocol for investigating and analyzing clinical incidents. Subsequently, the London Protocol (Taylor-Adams and Vincent 2004) provided further support for a "systems analysis" that would identify a variety of contributing factors leading up to the eventual incident as well as taking into account all aspects of the healthcare system in question.

A systems approach to incident reviews recognizes that human performance is greatly influenced by environmental (or system) factors. These include factors related to the patient and family (e.g., complexity, ability to communicate), the task and technology (e.g., availability and use of protocols, decision-making aids), the individual (e.g., training, fatigue), the team (e.g., communication), the workplace (e.g., working conditions), the organization (e.g., priority setting) and regulatory and government agencies (e.g., rules, laws, regulations) (Reason 1995). When problems are identified, these broader aspects of the system are explored to determine whether they had an influence on the actions of caregivers and to decide what changes can be made to prevent similar events from occurring in the future.

At SickKids, critical occurrences are managed, documented and investigated promptly and consistently using a defined approach. The critical occurrence review (CO review) process is innovative in terms of the characteristics of the review team, which consists of a leadership “triad” of a senior administrator, senior physician (often a division head) and a representative from the Department of Quality and Risk Management (QRM). As well, the broad definition of a critical occurrence within our process is unique in that the definition goes beyond the criteria of actual patient harm to include potential-for-harm events with broader hospital systems issues.

CO Review Process

Despite our best efforts, unexpected harm as the result of care provided in hospital does occur, resulting in a significant impact on the patient, family, healthcare provider and institution. The first step in our CO review process is ensuring the needs of patients and families have been met as well as providing support for staff involved in events. Appendix 1 and 2 outline immediate priorities for the patient/family and staff as well as the investigation process for the management of critical occurrences at SickKids.

Reporting of an event leads to executive notification and agreement to launch a CO review, at which time the review team, the leadership triad, is established. The review team includes, at minimum, the administrative director for the area involved, the division head or department chief (a physician from within the area) and a representative from QRM. Other members may be added such as a senior staff member from another area also involved in the event. At this time, the decision is made whether to conduct the review under the guidelines of the *Quality of Care Information Protection Act (QCIPA)*, which would protect the information from disclosure in legal and disciplinary proceedings (Government of Ontario 2004).

The review process begins with the creation of a chronological timeline of events to answer, “What happened?” This typically involves a review of the health record and any related documents (e.g., resuscitation records and staffing schedules). Review teams also interview individuals who may provide relevant facts or pertinent background information. The review determines “what was supposed to happen” (e.g., reference to relevant policies, procedures and/or protocols) as well as “what typically happens” (e.g., chart audit of similar cases, interviews with staff). The review process investigates why the event happened, determines recommendations to prevent recurrence and assigns responsibilities and establishes timelines for implementation to try and prevent it from happening again.

Recommendations are selected based on Eldridge’s Hierarchy of Interventions framework (N. Eldridge, personal communication, June 6, 2008), which ranks interventions from weak to strong in terms of their effectiveness on impacting change and improvement (Table 1). Recommendations are specific,

Table 1. Hierarchy of effective interventions

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

Courtesy of N. Eldridge, Department of Veterans Affairs.

actionable and measurable (e.g., via an audit) with associated timelines. If personal performance issues are identified within the review process, these are dealt with separately by the appropriate supervisor.

A summary report describing the facts of the case and the proposed recommendations to prevent a similar occurrence are presented for approval to the hospital’s Quality Management Council (whose mandate is to ensure and promote a culture of quality improvement at SickKids). Following approval, the recommendations are presented to the Quality Committee of the SickKids Board.

The results of the review and, in particular, the recommendations for improvement are shared more broadly throughout the organization and with the patient and family. In the case of a QCIPA review, the hospital discloses to the patient and family the systemic steps, if any, that the hospital is taking or has taken in order to avoid or reduce the risk of similar critical incidents (Ontario Hospital Association 2008). Steps to the management of critical occurrences are outlined in Appendix 1 (Immediate Priorities) and Appendix 2 (Investigation).

Follow-up reports are prepared by QRM at appropriate intervals to assess progress toward the implementation of the endorsed recommendations.

Rationale

Best practices in highly reliable organizations support the investigation of critical occurrences. They can also be a strong impetus for change and are essential for the full and frank disclosure of harm related to adverse events to patients and families. The focus

of our work was to reflect on our methods for reviewing critical occurrences, evaluating their effectiveness and determining opportunities for improvement. Woloshynowych et al. (2005) completed a review of published and unpublished “techniques” on the investigation and analysis of critical incidents and adverse events in healthcare. Although much valuable work was identified in their review, the authors acknowledged that “there is considerable potential for further development of techniques, the utilization of a wider range of techniques and a need for validation and evaluation of existing methods which would make incident investigation more versatile and use limited resources more effectively” (Woloshynowych et al. 2005: 85).

Methods

In 2009, a retrospective analysis of all CO reviews completed over a nine-year period was undertaken by QRM. A database of all critical occurrence events was created and reviewed with the intention of identifying and trending these events. A “harm index” (Table 2) was used to identify events in terms of the extent and severity of harm occurring. Severity codes are often applied to safety and incident reports as a measure of the potential or actual outcome of the event and are used to highlight the event’s seriousness and assist in the prioritization of system improvements. Events were analyzed and scored with respect to contributory factors using a “theme index” (Table 3). This index was created for and used in our safety reporting systems but is similar in nature to other “human error taxonomies” that have

been produced to categorize error (Taylor-Adams 1996; Taylor-Adams and Vincent 2004).

This process was also an opportunity to update the “recommendations logbook” to identify changes that occurred as a result of the review process and to review the recommendations made by review teams. Recommendations are selected based on the Hierarchy of Interventions framework (see Table 1).

Descriptive statistics were used to analyze the findings.

Results

Between 2001 and 2009, 93 CO reviews were completed. Results of the study are summarized in Figures 1–5.

Discussion

Our results identified several changes that occurred over the nine years since the implementation of the process for critical occurrences management. Increased reporting of critical occurrences and, subsequently, an increase in the number of CO reviews

Figure 1. Number of annual reviews over nine years (n = 93)

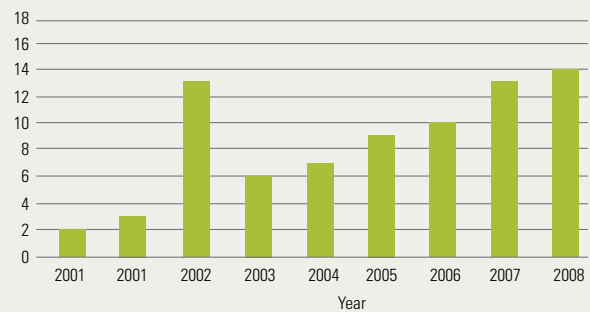
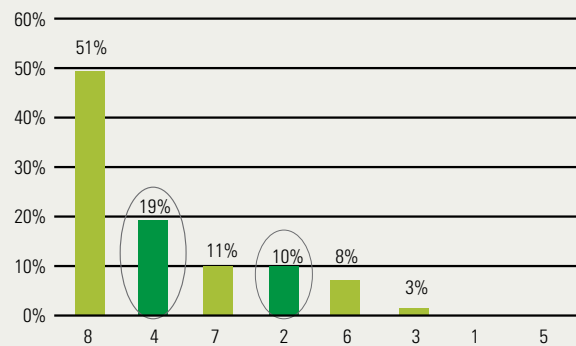


Figure 2. Percentage reviews by severity*



*See Table 2 for entry on harm index that corresponds with numbering along x-axis.

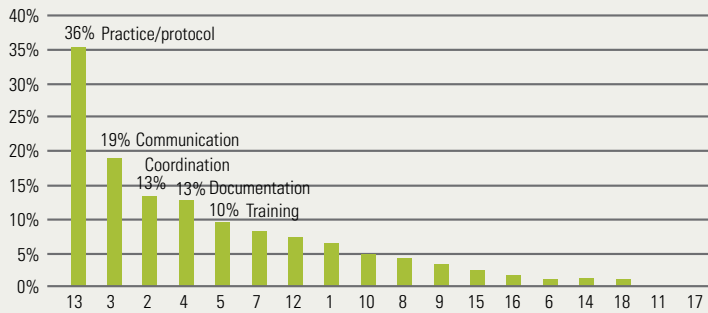
Table 2. Harm index

1. Event did not reach anyone; potential minor harm
2. Event did not reach anyone; potential major harm
3. Event reached the person; minor or no harm resulted
4. Minor or no harm resulted; potential major harm
5. Event resulted in extra observation; monitoring
6. Event resulted in treatment or intervention
7. Event resulted in increased length of stay
8. Event may have contributed to permanent disability or death

Table 3. Theme index

- | | |
|-----------------------|----------------------------|
| 1. Access | 10. Information technology |
| 2. Care coordination | 11. Leadership/culture |
| 3. Communication | 12. Medication management |
| 4. Documentation | 13. Practice/protocol |
| 5. Education/training | 14. Privacy |
| 6. Environment | 15. Transfer of care |
| 7. Equipment | 16. Workflow |
| 8. Human resources | 17. Evaluate/audit |
| 9. Infection control | 18. Other |

Figure 3. Percentage reviews by theme



*See Table 3 for entry on theme index that corresponds with numbering along x-axis.

Figure 4. Average number of recommendations per review by year

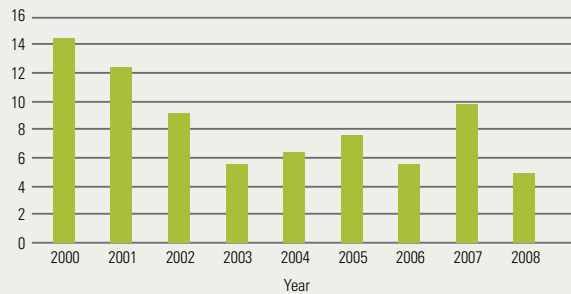
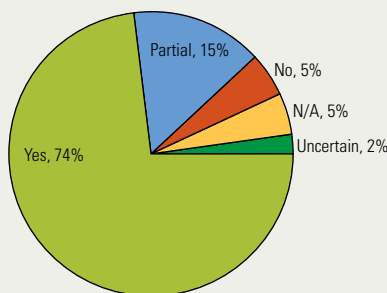


Figure 5. Percentage of recommendations completed (n = 528)



undertaken annually were noted. Similar trends can be found in the literature, where a rise in the number of critical incidents being reported was attributed to an increased awareness among clinicians of the need to report, and a greater willingness to do so, rather than to any underlying change in the quality of care (Walshe and Dinneen 2001).

Thirty percent of these events were classified as potential-for-harm events with respect to the severity index (see Figure 2), suggesting a proactive approach to the prevention and mitigation of harm. Increased reporting and CO reviews are considered a positive trend in our facility, resulting from a trust that the process will lead to improvements.

Overarching themes contributing to critical occurrences were identified as practice and protocol, communication, coordination and documentation issues (See Table 3 for entry on theme index that corresponds with numbering along x-axis.). These findings are consistent with the patient safety literature (Joint Commission on Accreditation of Health Care Organizations

2004; Sutcliffe et al. 2004; Wilson et al. 1995). In the Lingard et al. study (2004) on communication failures in the operating room, communication failures occurred in approximately 30% of team exchanges. Communication breakdowns have long been cited as a root cause in almost every sentinel event reported to the Joint Commission’s Sentinel Event Database and as the leading root cause in a majority of cases studied since 1996. Hierarchy differences, conflicting roles, ambiguity in responsibilities and power struggles can all lead to communication failures that compromise patient safety and quality of care.

Woloshynowych et al.’s report (2005) suggests that both researchers and investigation teams need to give more attention to recommendations for change and the implementation of changes. In our retrospective review, we identified a change in the number of recommendations from the review teams over the years (see Figure 4). Recommendations became increasingly focused and streamlined, with increased emphasis on the Hierarchy of Interventions framework (see Table 1), ranking weakest to strongest interventions in terms of their impact on “making it hard for people to do the wrong thing and easy for people to do the right thing.”

Our analysis indicated that of 528 total recommendations over the nine years, 74% of recommendations were fully completed and 15% were partially completed (see Figure 5), resulting in significant system changes aimed at mitigating patient harm. The challenge of obtaining buy-in and action from management has been noted in many industries (Cronin 2006). Involvement of the leadership triad in our CO review process was thought to have a positive impact in terms of accountability with respect to following-up on recommendations.

Table 4 provides a summary of selected improvements that were implemented as a result of the CO review process over the years.

The absence of an inquest involving our facility was an additional unanticipated but significant outcome following

Table 4. Selected improvements as a result of critical occurrence reviews over nine years

Helicopter landing protocols
Quality control for rare laboratory tests
Pre-procedure safety checklists
Air-flow monitoring
Ambulatory referral system
Safe environment initiative
Communication of critical test results
Self-harm prevention (checklist)
Redesign of TPN order sheet
Osteopenia risk assessments
Widespread use of CCRT*
Improved documentation tools
Privacy and security practices
Building contractor sign-off/roof surveillance processes

CCRT = Critical Care Response Team; TPN = total parenteral nutrition.
 *CCRTs are otherwise known as Medical Emergency Team or Rapid Response Team. CCRTs are composed of critical care specialists whose mandate is to provide rapid assistance to patients on the ward who have been identified as potentially at risk for deterioration.

the implementation of the CO review process. This suggests that our internal processes for the investigation and analysis of critical incidents are seen as effective in identifying and implementing changes that will reduce and potentially eliminate recurrences of similar events.

In recent years, new legislation has been enacted related to critical occurrences in our province. Amendments to Regulation 965 of the *Public Hospitals Act* (Ontario Regulation 423/07), which came into enforcement July 1, 2008, mandate the disclosure of critical incidents to the patient or substitute decision-maker. Hospitals are required to disclose material facts of what occurred; consequences for the patient; and actions taken to address the consequences and systemic steps, if any, that the hospital is taking or has taken in order to avoid or reduce the risk of further similar critical incidents. Despite this new legislation, there has been relatively minimal impact to our facility as it has always been our practice to provide full and frank disclosure of events to patients and families, even for lower-risk events.

QCIPA has had an influence on our CO review process. QCIPA was enacted in 2004 as Schedule B of the *Health Information Protection Act* to encourage healthcare professionals to share information and hold open discussions to improve patient care without fear that the information will be used against them in legal proceedings (Government of Ontario 2004). Following a QCIPA review, a patient can be informed only of new facts identified in the review and system changes that have been made since the completion of the review.

Lessons Learned and Next Steps

In other high-risk industries, learning from accidents and near-misses is a long-established practice. However, learning within healthcare has been described as “fragmentary, uncertain and usually confined to individuals or teams” (Woloshynowych et al. 2005: ix). Our review of critical occurrences over the past nine years has highlighted many positive changes that have resulted. It has also reinforced the need for continued efforts to improve the sharing of lessons learned and recommendations from critical incident reviews at an organizational level. Recently, pediatric grand rounds presentations have been introduced as a pilot initiative used to share organization-wide learnings from our CO reviews. Other opportunities exist, such as the Safety Learning Summaries circulated by the Winnipeg Regional Health Authorities to promote and share learnings from reviews of critical incidents (http://www.wrha.mb.ca/healthinfo/patientsafety/criticalincidents/sls_all.php).

Although our findings suggest that the majority of recommendations from reviews were completed, it would be of value to enhance testing of their efficacy and to validate whether the suggested changes have led to the desired effect(s) on the system. This would help ensure that identified systemic problems have been addressed; recurrences have been reduced or eliminated; lessons have been learned and communicated; barriers to change have been unfrozen; and the “loop” has been closed to ensure organizational learning (Woloshynowych et al. 2005).

A variety of methods and approaches can and are being used to test the efficacy and sustainability of recommendations and improvement strategies. The observation of a ward/unit and auditing of a component of practice (e.g., removal of 0.3 NaCl with 3.3% dextrose intravenous solution from units) are effective checking mechanisms. Small research projects can also be implemented to assist in validating the success of improvement strategies.

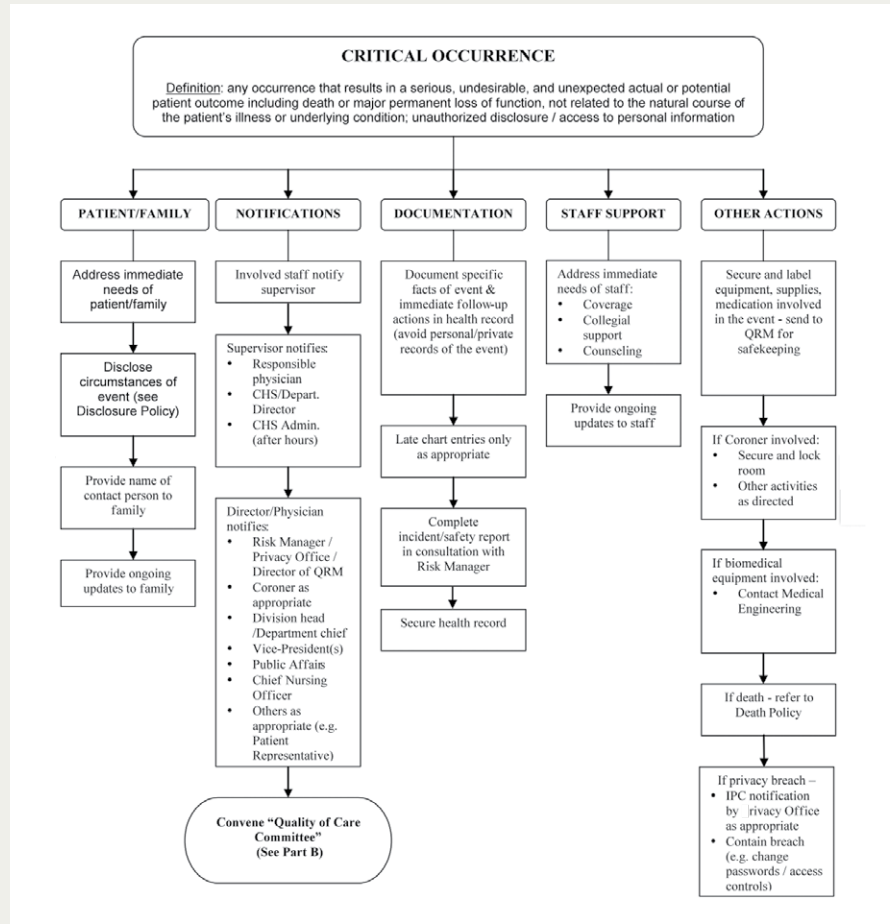
Qualitative research (presently under way) aimed at exploring the experiences and perceptions of staff involved in these reviews will further inform the evaluation of our innovative “systems approach” to the management of critical occurrences. Regardless of the methods used, the presence of additional evaluation will ensure that learning from critical occurrences as well as near-misses will continue to be a cornerstone of safety analysis and improvement in our organization. **HQ**

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Appendix 1. Management of critical occurrences, part A: immediate priorities



S = Child Health Services; IPC = Information and Privacy Commission; QRM = Department of Quality and Risk Management.

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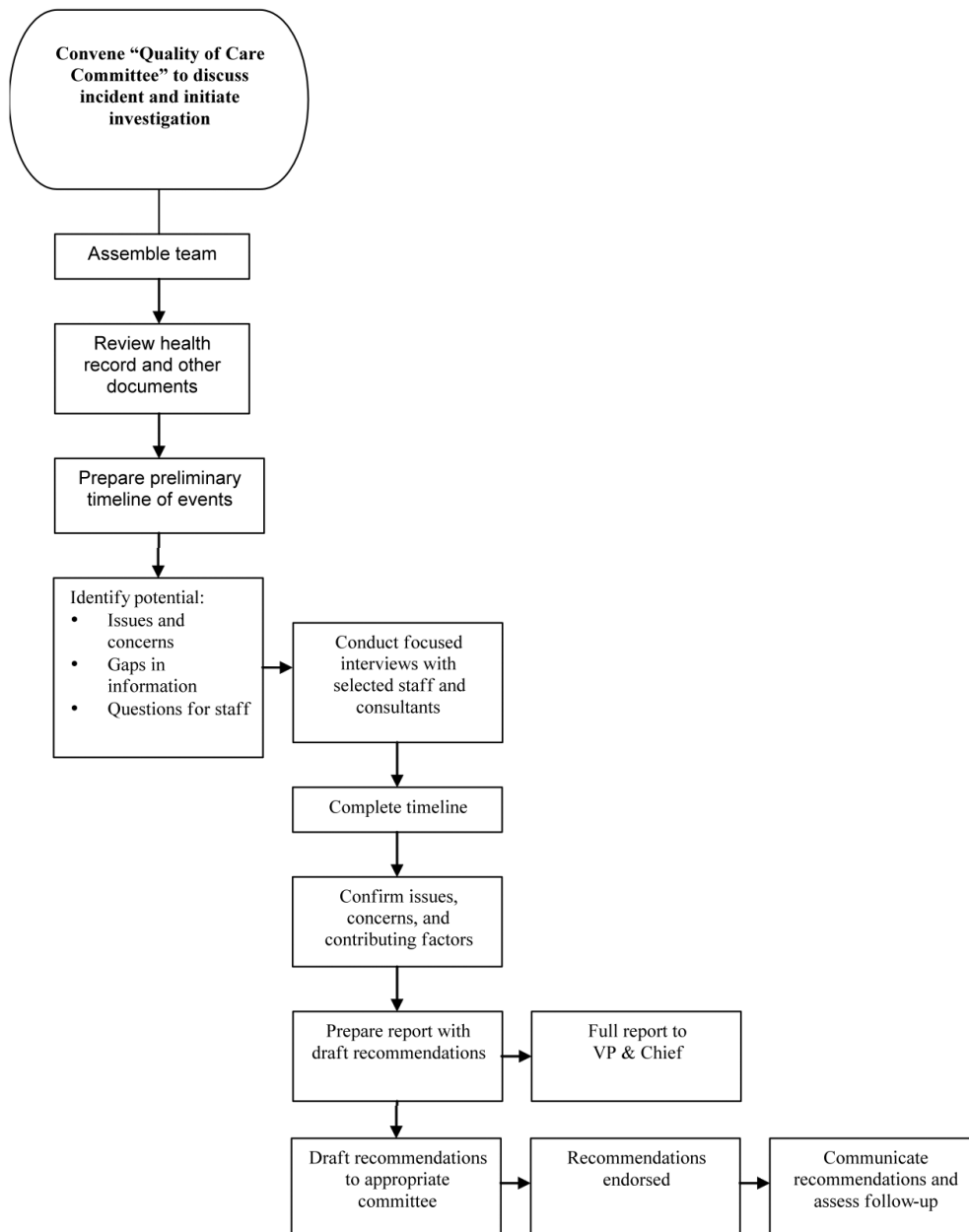
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Appendix 2. Management of critical occurrences, part B: investigation



VP = vice-president.