Five Years of Learning from Analysis of Clinical Occurrences in Pediatric Care Using the London Protocol

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Abstract

A Protocol for the Investigation of Clinical Incidents (1999) was piloted on a Winnipeg high-risk neonatal service in 2001, and was subsequently adopted as the investigative tool of choice at the Winnipeg Regional Health Authority (WRHA). The paper describes the pilot and subsequent experience with the updated London Protocol (2004) in the WRHA Child Health Program.

Themes include: tightly coupled systems; multiplicity of contributory factors; medication safety; predominance of "near misses"; authority gradient; professional accountability; partnerships; and implementation challenges.

The London Protocol is an invaluable tool for review of critical occurrences and near misses. To maximize impact on patient safety, healthcare organizations must involve partners and develop expertise in human factors and change management.

Background

Reason (2001) defined *error* as the "failure of planned actions to achieve their desired goal." He distinguished two types of error: *slips and lapses* and *mistakes*. *Slips and lapses* are failures of execution associated with attention failure; lapses are internal events associated with memory failure. *Mistakes* are failures of intention. Actions go as planned, but the plan is wrong.

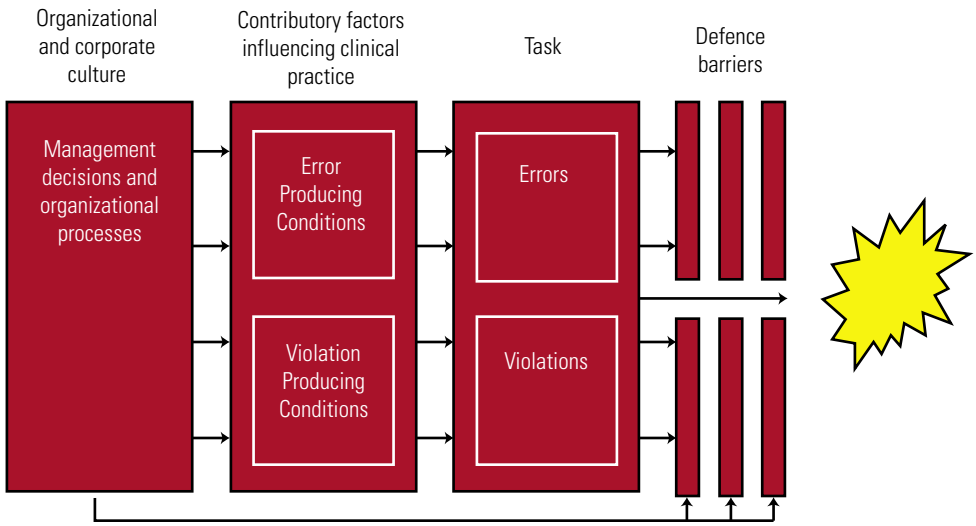
Mistakes may be *rule-based* or *knowledge-based*. *Rule-based mistakes* include failure to apply good rules and application of bad rules; *knowledge-based mistakes* occur when problems must be solved on the spot, without the help of preprogrammed solutions. The operator may be inexperienced, or may use an incorrect mental model (confirmation bias).

Violations are not errors, but deviations from safe operating practices, rules or standards. They include *routine violations* (cutting corners), *optimizing violations* (furthering personal goals) and *necessary or situational violations* (when rules hinder performance).

Active and *latent failures* must be distinguished. Negative outcomes of active failures are often immediate, but adverse consequences of latent failures may not occur for years. In healthcare, *active failures* are unsafe acts (errors or violations) by clinicians at the "sharp end" of the system. *Latent failures* often occur in the boardroom (e.g., budget cuts leading to suboptimal staffing).

Reason's organizational accident model (Figure 1), described in his classic, *Human Error* (Reason 1990), is founded on learning from complex industries. The model is the basis of *A Protocol for the Investigation and Analysis of Clinical Incidents* (Clinical Risk Unit 1999) and the London Protocol (Taylor-Adams and Vincent 2004). The Protocols provide structure for investigating and analyzing clinical incidents: after identifying Care Management Problems (active failures), reviewers consider contributory factors and organizational context. Table 1 itemizes factors that may contribute to error in healthcare.

Figure 1. Organizational accident model



Source: Adapted from Reason (1990).

Goldmann and Kaushal endorsed the Protocol in their discussion of a systematic approach to human factors to medicine (Goldmann and Kaushal 2002).

In this paper I describe five years of experience with these Protocols in the Child Health Program at WRHA.

Phase I: Pilot Study

Methods

The Protocol (Clinical Risk Unit 1999) was piloted between September 2001 and March 2002 on an academic tertiary neonatal service. All nontrivial occurrence reports were reviewed. The author conducted individual private interviews with personnel, based on involvement and fan-out from initial contacts, using the checklist to augment the information.

Results

Eight of twelve reported occurrences were investigated. Up to eight interviews (average 4.75; see Table 2) were required, lasting 20–60 minutes each. No patient harm occurred; there were four "near misses." Occurrence reports were filed within 11 days. Figure 2 shows the distribution of contributory factors. All occurrences had one or more systemic contributory factors. Few occurrences were related to single, individual factors, consistent with the observations of Leape (1994). Five were nocturnal, involving understaffing, delay or difficulty accessing medical staff. In two cases, acuity and poorly planned physical plant contributed to inadequate patient surveillance. Team dysfunction, behavioural issues and lack of respect for colleagues were

Table 1. Framework of factors influencing clinical practice

Factor Types	Influencing Contributory Factors
Institutional context	Economic and regulatory context
Organizational and management factors	Financial constraints Organizational structure Strategic goals Policies and procedures Safety culture
Work environment factors	Staffing and skill mix Workload and shift patterns Design, availability and maintenance of equipment Administrative and managerial support
Team factors	Verbal and written communication Supervision Openness Team leadership and structure
Individual factors	Knowledge and skills Competence Physical and mental health
Task factors	Task design Availability and use of protocols Availability and accuracy of test results
Patient factors	Condition (complexity and seriousness) Language and communication Personality and social factors

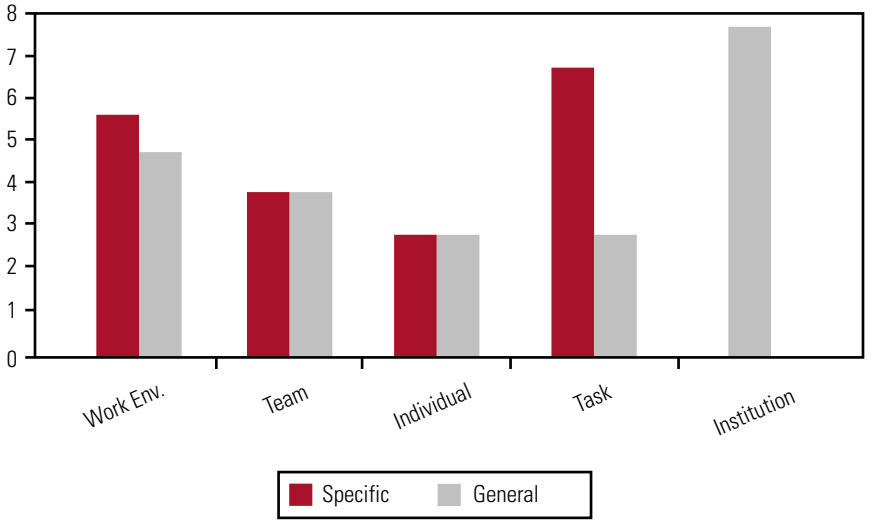
Framework Source: Clinical Risk Unit (1999).

observed in several cases. The interviews validated staff concerns, and made it easier to find and implement solutions.

Table 2. Number of interviews required to determine contributory factors for each occurrence

Occurrence	Number of Interviews
1	2
2	2
3	5
4	3
5	6
6	8
7	4
8	8

Figure 2. Frequency distribution of contributory factors



Source: Clinical Risk Unit (1999).

Phase II: Policy Development and Implementation

Regional policies were developed and implemented on reporting, management and disclosure of occurrences (Winnipeg Regional Health Authority [WRHA] 2002a, b, c). Critical Clinical Occurrences, as defined by policy, include near misses and require formation of a Review Team within 48 hours. An individual designated by the relevant Vice-President chairs the Review Team, which must meet within five days, and conducts a review, using the Protocol, within 30 days. When an in-depth systems analysis is required, a status report is required within 30 days. Rollout of these policies included an educational strategy and development of a Regional Occurrence database.

Concurrently, Manitoba Health developed a congruent policy governing all Manitoba RHAs. It became apparent that lack of legal protection was a significant barrier to openness. WRHA worked with government to address this issue, resulting in new legislation amending the *RHA* and *Manitoba Evidence* acts (*Bill 17* 2005), currently awaiting Royal Assent. Regional policies are currently under revision.

Phase III: Rollout of the Protocol within the Child Health Program, WRHA

The Child Health Program at WRHA, based at Children's Hospital, Winnipeg, provides secondary and tertiary care to the children of Manitoba, Kivalliq, and northwest Ontario. Since 2002, the Child Health Quality Team has led or participated in 30 reviews of critical clinical occurrences and near misses involving children. Review teams are multidisciplinary and may include community partners and families. A database of recommendations and actions is maintained. Reviews are used as learning opportunities and staff debriefings are provided. A synopsis of lessons learned follows.

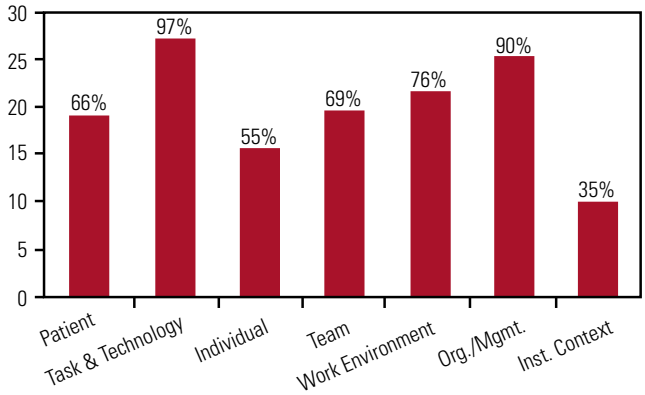
Lesson 1: Acute pediatric care is a tightly coupled system with multiple high-risk processes. All occurrences reviewed occurred in inpatient areas. Eight (27%) occurred in emergency or intensive-care units, in which patient acuity and complexity are high. These environments share many characteristics of high-risk processes, in which failure is likely to jeopardize safety: variable input, complexity, lack of standardization, tight coupling, heavy dependence on human intervention, time constraints and a hierarchical orientation.

Several reviews highlighted tight coupling of different components of patient care. For example, an apparently simple event (a change in the formulation of dopamine), was not perceived as significant by pharmacy staff, but had significant ramifications in PICU (the need to use an unfamiliar IV infusion pump).

> "Tightly coupled systems work best when they operate with well established rules and procedures and when staff work hard to coordinate and adjust their activities through constant two way communication. A downside … is that they can be quite fragile – the consequences of a small, innocuous error, omission, decision or action in one system can be rapidly transferred to the other. Operators in tightly coupled systems must always think in systems terms and must actively consider how a change in their system might affect the other system." (Michael Rodgers, Human Factors Leader, WRHA, personal communication, 2006)

Lesson 2: Critical occurrences usually have multiple contributory factors. We analyzed 30 reviews conducted since program-wide implementation using the taxonomy of the London Protocol (2004), which identifies seven categories of contributory factors but does not distinguish between specific and general factors. Once again, multiple contributory factors were the norm (Figure 3). In 97% of cases, task and technology factors were present. Next-commonest were organizational and management factors. In 66% of cases, patient complexity was a significant factor. Individual (staff) factors contributed to 55% of occurrences. There was *no* occurrence in which the actions of one individual were the only contributing factor.

Figure 3. Frequency distribution of contributory factors, Child Health Program, 2002–2006



Framework Source: Clinical Risk Unit (2004).

> A patient with cancer, fungal and bacterial sepsis and multiple organ dysfunction became hyperkalemic while receiving multiple intravenous infusions including antibiotics and electrolytes. The active failure was administration of excess potassium, due to inadvertent use of the electrolyte solution (intended to correct hypokalemia) as the infusion vehicle for medications. The process involved multiple sequential tasks and complex decisions, magnifying the probability of error. Operator inexperience, coupled with supervisor distraction, contributed to an incorrect decision. Overlying this situation was an unclear understanding of the supervisory role of instructors and mentors.

The London Protocol provides structure for interviews and the collateral search for information, but the complexity of human factors science requires expertise to tease out contributory factors, root causes and the context in which they occurred. Dekker (2002) reminds us to avoid hindsight, always considering the context in which decisions were made.

Medication error was the issue in 50% of occurrences reviewed. Active failures included incorrect medication, incorrect patient, incorrect route, medication preparation and dispensing.

Lesson 3: Medication error is the commonest category of active failure in acute pediatric care. Medication error was the issue in 50% of occurrences reviewed. Active failures included incorrect medication, incorrect patient, incorrect route, medication preparation and dispensing. Latent failures encompassed a broad spectrum of contributing factors, including lack of pharmacy expertise on clinical teams and reliance on paper-based ordering systems. One review led to the first healthcare FMEA investigation in Manitoba, which proved pivotal in identifying and driving change.

Errors related to resuscitation (including failure to rescue in a timely way) were, at 13%, the second-commonest category of active failure. Contributing factors included nighttime, knowledge deficits and an authority gradient. In two cases, existence and use of a rapid response team might have prevented harm.

Patient identification problems accounted for 13% of active failures. One case of wrong patient surgery occurred. In a near miss, an incorrect limb band was placed on a baby's foot; the physical characteristics of the band contributed.

Lesson 4: Most errors that reach the patient do not cause harm. The Canadian Adverse Events Study (Baker et al. 2004) showed a 7.5% incidence of adverse events and a 40.8% incidence of triggers in adult hospitalized patients. *There are no such data for Canadian children.* In this series, 79% of occurrences reached

the patient, but only 35% caused harm. High-reliability systems are characterized by detection and recovery systems for error and by collective preoccupation with the possibility of failure. There is a high awareness of failure in our program (Sinclair 2000), and we are encouraged by the willingness of staff to report occurrences and participate in reviews.

… professionals are accountable for their actions. We found several deliberate rule violations, including "cutting corners" in order to get the job done and occasional "optimizing violations" (self-interest). We discovered no dysfunctional rules.

Lesson 5: The authority gradient is alive and well. "Authority gradient" refers to the balance of decision-making power (Agency for Healthcare Research and Quality [AHRQ] 2006). The term was first used in aviation. Pilots and copilots may not communicate effectively in stressful situations if they differ in perceived experience, expertise or authority. While an authority gradient is necessary for role clarity and decision making, leaders must establish norms appropriate to the training and experience of team members (a responsibility referred to as Crew Resource Management). Cosby and Croskerry (2004) described the contribution of authority gradients to medical error.

This series includes four cases in which an authority gradient played a part. It was observed between nurses and physicians, and between junior and senior physicians. The management of multidisciplinary teams is particularly challenging in an academic environment, in which team members constantly rotate and there is diversity of expertise, training and cultural background. Addressing this issue may require multidisciplinary team learning and simulation beginning at the undergraduate level. The Israel Center for Medical Simulation (www.msr.org.il) has been a leader in this field.

Lesson 6: Accountability matters. Blame is counterproductive in the face of genuine error. Nevertheless, professionals are accountable for their actions. We found several deliberate rule violations, including "cutting corners" in order to get the job done and occasional "optimizing violations" (self-interest). We discovered no dysfunctional rules. Managing rule violations requires performance management, involving education, audit, reinforcement and sometimes discipline.

Lesson 7: The learning organization engages its partners. Healthcare is a complex adaptive system interacting with other systems. Contributory factors may originate outside healthcare and must be addressed at their origin.

> A student nurse erred in a very complex task. The review led to an examination of student supervision and a revised affiliation agreement with educational institutions.

> A case of child abuse led to collaborative work with child welfare agencies on stronger communication protocols and advocacy with Government.

The literature is equivocal on the effects of open-disclosure policies on litigation (Kachalia et al. 2003). Physicians in particular are reluctant to discuss adverse events with patients and quality committees, due to fear of litigation. Insurers counsel that only facts should be disclosed, and only to committees under the umbrella of legal protection (Beilby 2004, 2005). The National Steering Committee on Patient Safety (2002) recommended that *Evidence Acts* and related legislation be reviewed and revised if necessary to ensure that data and opinions associated with patient safety and quality improvement discussions, related documentation and reports are protected from disclosure in legal proceedings. This is now under way in Manitoba.

Lesson 8: Writing recommendations is easy; implementation is challenging. Frequently, important contributing factors to adverse events originate outside the organization and remediation is outside the span of control of the team. The partnerships necessary to address external contributory factors are not formed overnight and require time investment and relationship-building over years.

Challenges occur within organizations too. In a complex adaptive system, every change has the potential to cause problems elsewhere in the system. Experience at WRHA suggests that access to a human factors consultant is invaluable in guiding the team to ask the right questions, to correctly analyze the root causes and contexts uncovered and to craft credible recommendations that will be adopted.

The challenge of obtaining buy-in and action from management has been noted in many industries.

> One investigator described how the writing and inclusion of recommendations is heavily determined by who is … on the committee assessing the recommendations for implementation. Language may be adjusted or changed, some recommendations may be left out in order to increase the chances for others. … [T]he road from investigation to implementation … is largely a political one. … Really good investigations may reveal systemic shortcomings that necessitate fundamental interventions which are too expensive or sensitive to be accepted. (Dekker 2002)

In our experience, reviews leading to successful change are usually conducted within microenvironments, in collaboration with dynamic clinical teams. When there is need for broad systemic change, an individual who has the authority and the will to drive that change must be involved as early as possible. Our organization now involves senior leaders in all critical occurrences within 48 hours, and prior to sign off on the final report. A risk rating is assigned to each recommendation and individuals accountable for implementation and a time frame for action are identified.

Conclusions

The Child Health Program at WRHA has conducted reviews of critical clinical occurrences and near misses since 2001. We have learnt much about human factors, the nature of error in an acute pediatric care environment, organizational culture, interdependencies between organizations, legislative context and change management. The London Protocol has proven a useful platform for structuring the investigations, supplemented by experience, expertise and other management tools.

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