HealthManagement
Promoting Management and Leadership

Volume 8, Issue 3 /2006 - Risk Management

The London Protocol

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In most high-risk industries learning from accidents and near misses is a long established practice and a cornerstone of safety analysis and improvement. Aviation accidents, for instance, are exhaustively investigated and the lessons learnt disseminated widely, with important changes made mandatory by the regulatory authorities. In contrast, learning within healthcare, with some notable exceptions, has generally been fragmentary and uncertain.

In the USA the most familiar method of investigation is the root cause analysis approach of the Joint Commission, an intensive process with its origins in Total Quality Management approaches to healthcare improvement. The Veterans Hospital Administration has developed a highly structured system of triage questions. In Britain we have developed the London Protocol, a method based on Reason's model and our framework of contributory factors.

However, the root cause perspective is misleading. First, it implies that the single root cause is oversimplification. Usually there is a chain of events and a wide variety of contributory factors leading up to the eventual incident.We prefer the term "systems analysis" to root cause analysis. Second, the real purpose is not simply to find out what caused this incident, but to use the incident to reflect on what it reveals about the gaps and inadequacies in the healthcare system. The investigation is thus proactive and forward looking.

Conceptual Foundations of the Analysis of Clinical Incidents

The theory underlying the approach described here is based on the organisational accident model of James Reason. His essential insights are that incidents and accidents are usually preceded by some kind of unsafe act, in which a person makes an error or mistake. It is thus necessary to look further back to the "error-producing conditions", which led to the unsafe act, and also to 'latent failures' decisions taken by management.

We have extended and adapted Reason's model for use in healthcare by developing a broad framework of "contributory factors" which can impact on clinical practice and which covers both error-producing conditions and latent failures.

Essential concepts of the investigation of clinical incidents Once the chronology of events is clear, one has to consider:

Care Delivery Problems (CDPs)

The first step in any analysis is to identify the "care delivery problems", namely actions or omissions by staff in the process of care. These may be slips, such as picking up the wrong syringe, lapses of judgement, forgetting to carry out a procedure or, rarely, deliberate departures from safe operating practices, procedures or standards. Basically, one can talk about care deviated beyond safe limits of practice, with a direct or indirect effect on the eventual adverse outcome for the patient.

Clinical Context and Patient Factors

For each care delivery problem identified, the investigator records the salient clinical events or condition of the patient at that time (e.g. bleeding heavily, blood pressure falling) and other patient factors affecting the process of care (e.g. patient very distressed, patient unable to understand instructions).

Contributory Factors

Having identified the CDP, the investigator then considers the conditions in which errors occur and the wider organisational context. These are the contributory factors. For example:

- Individual factors may include lack of knowledge or experience of particular staff.

- Task factors might include the non-availability of test results or protocols.

- Team factors might include inadequate supervision or poor communication between staff.

- Work environment might include heavy workload, inadequate staffing or limited access to vital equipment.

The investigator should differentiate between those contributory factors that are only relevant on that particular occasion, and those which are longstanding or permanent features of the unit. For instance, an unusual failure of communication between management problem may not need to be considered further. A recurrence of this problem, on the other hand, is clearly reflecting a wider systemic problem which needs to be addressed.

The Investigation Process

An investigation team needs to be created for any serious incident investigation. This team should be composed of two to four senior members of the clinic a l /management team. At least one member of the team should be fully trained and proficient in incident investigation and analysis, and be able to coordinate the accident investigation process.

Information is gleaned from a variety of sources. Case records, statements and any other relevant documentation are reviewed. Structured interviews with key members of staff are then undertaken to establish the chronology of events, the main care management problems and their respective contributory factors, as perceived by each member of staff. The key questions are “What happened?” (the outcome and chronology); “How did it happen?” (the care delivery problems) and “Why did it happen?” (the contributory factors).

While a considerable amount of information can be gleaned from written records, interviews with those involved are the most important method of identifying the contributory factors. This is especially so if the interview systematically explores these factors and so allows the member of staff to collaborate in the investigation. In the interview the story and “the facts” are just the first stage. The staff member is also encouraged to identify both the CDPs and the contributory factors, which greatly enriches both the interview and investigation. The incident should also of course be discussed with the patient and family, and they should be informed of the results of the inquiry. The potential contribution of patients to the actual investigation has yet to be properly explored.

For serious incidents, a team of individuals with different skills and backgrounds may be assembled, though often only a risk manager or an individual clinician will be needed. A group approach is useful for teaching, both as an aid to understanding the protocol itself and as a vehicle for introducing systems thinking. While reading about systems thinking is helpful, actually analysing an incident brings systems thinking alive.

Conclusion

The contributory factors that reflect more general problems in a unit are the targets for change and systems improvement. When obvious problems are identified, action may be taken after a single incident, but when more substantial changes are being considered, other incident analyses and sources of data (routine audits and outcome data) should also be taken into account. Recommendations may be made in a formal report, but monitoring of action of outcome as well as assignment of implementation responsibility are essential. Staff affected by the recommendations also need to contribute to the final recommendations, as ownership by the staff is one simple way to achieve sustainable change within our healthcare systems.

The learning and organisational change that can follow the systematic and thoughtful investigation of an incident has not been given sufficient attention in healthcare. While such investigations are only one component of a more general quality and safety strategy, they are a vitally important one. Systems analyses staff should be absolute priorities in any risk management and safety strategy.

Further Information

An overview of the evolution and practice of patient safety can be found in “Patient Safety” by Charles Vincent, Elsevier 2006. The London Protocol can be downloaded from www.csru.org.uk which also describes the work of the Clinical Safety Research Unit.

Published on : Mon, 24 Jul 2006