International Journal for Quality in Health Care 2005; Volume 17, Number 1: pp. 1–3 10.1093/intqhc/mzi014

Editorial

Investigating safety incidents: more epidemiology please

Learning from errors has become the core of policies to improve safety in health care. For instance, the World Alliance for Patient Safety lists 'reporting and learning to improve patient safety' as one of six key action areas [1]. Health care personnel are encouraged to report incidents, errors, and near-misses. These events are then analysed to uncover the underlying causes of the incidents and to propose corrective actions. The analysis is often based on the framework proposed by James Reason and Charles Vincent [2], which explores in a systematic fashion how factors related to the patient, the professional, the task or activity, teamwork, medical devices, procedures, information systems, etc. relate to the occurrence of an incident.

The causal attribution model

In such investigations, the investigator has a role similar to that of a clinician who seeks to identify the underlying cause, or causes, of a patient's ailment. Does this patient have renal failure because of diabetes—or has he been exposed to heavy metals or organic solvents at his workplace? And this patient who has lung cancer—of course, he is a smoker of cigarettes. The idea is that possible causes are known, that the clinician is able to recognize a possible cause with good reliability, and that a limited number of causes—sometimes just one—is at the root of the patient's problem. Let us call this approach the causal attribution model (Table 1). To each case of the disease its cause. To each safety incident its set of contributing factors. This is how clinical medicine has operated for decades, with good success. The application of this method has also yielded important insights into safety incidents. A particularly rich analysis of weaknesses in the health care system that led to serious incidents can be found in the paper by Ternov and Axelsson in this issue of the Journal [3].

But all methods have limitations. The obvious limitation of the causal attribution model is its reliance on expert opinion during the analysis of an incident. Experts are prone to biases, and tend to disagree among themselves [4]. Virtually nothing is known today about the reliability of expert assessments of root causes of incidents, but evidence from other fields suggests that it cannot be very high.

The epidemiological risk factor model

A viable alternative to the causal attribution model is the epidemiological risk factor model (Table 1). This model does not attempt to assign a cause to any specific event, but seeks to uncover statistical associations, at the population level, between putative risk factors or causes and outcomes of interest. Male sex, older age, high blood pressure, smoking, and high cholesterol level are associated with coronary heart disease in the general population, but we do not know exactly what caused a heart attack in Mr Smith. This approach is not inherently superior to the causal attribution model—each model has advantages and drawbacks (Table 1). But the epidemiological model avoids the main weakness of the causal attribution model: it does not require human judgment of causality for individual events.

One type of epidemiological study design that is particularly useful for exploring multiple risk factors for a disease is the case–control study, where people with and without the disease of interest, drawn from the same population, are compared in terms of their past exposure to risk factors. This type of design can be applied not only to people, but also to 'events'. This has been successfully done for some time in research on injuries. For instance, McCarroll and Haddon [5] have conducted more than 40 years ago a case–control study of alcohol consumption in relation to accidental death among New York City automobile drivers. Cases were drivers who were fatally injured in traffic accidents. For each case, six control drivers were identified from the location of the crash, on the same day of the week, and the same time of day, by stopping randomly selected cars. This study demonstrated a 20-fold increase in the risk of a fatal crash for drivers whose alcohol levels exceeded 1.0%. The innovative feature of this study was the careful selection of controls, which afforded an adjustment for exposure to driving and to traffic conditions, so that results were interpretable despite the complexity of the system in which traffic collisions occur.

In the area of patient safety, a more recent but conceptually similar study was conducted by Gawande *et al.* [6] to examine risk factors for retained instruments and sponges after surgery. Cases were operations where an instrument or a sponge was left inside the patient's body, controls were operations of the same type where this did not happen. Information was collected on the patient, the surgical team, and the context. Retained sponges or instruments were more likely when the operation was an emergency procedure, when an unexpected change occurred in the procedure, and if the patient's body mass index was high. Only the latter is a traditional patient-related risk factor, the other two are related to the health care process. All three could be considered as contributing causes within the Reason–Vincent

Table 1 Comparison of two models for the analysis of patient safety incidents

	Causal attribution model	Epidemiological risk factor model
Core disciplines	Psychology Organization science System analysis	Epidemiology Statistics Public health
Typical outcome of interest	(i) Human error (ii) Incident/event	(i) Health problem (ii) Incident/event
Unit of analysis	Single event	Population or sample of events
Design of investigation	Single case analysis	Case–control study Prospective study Randomized trial
Assessment of causes	Expert investigation	Standardized measurement of risk factors
Attribution of causality	Expert understanding of the chain of events	Statistical association between risk factor and outcome
Threats to validity	Perception biases (+++)	Selection bias (+) Information bias (+) Confounding (+) Random error (+)
Key advantages	Flexibility and insight Sensitivity to context Understanding of causal mechanism	Generalizability Capacity to examine joint effects of several risk factors Quantification of the strength of risk factors

framework. Just as importantly, performing counts of sponges and instruments did not have a statistically significant protective effect. In a traditional root cause analysis of such incidents, it is likely that the failure to perform such a count would have been identified as having a key causal contribution.

The case–control study is not the only epidemiological study design that deserves consideration for research into the causation of incidents. Other designs include cross-sectional studies such as that reported by Lisby *et al.* in this issue [7], large database analyses [8], community surveys [9], randomized trials [10], and before–after studies [11].

The way forward

The unsettling question is why so few epidemiological analytic studies are done today on what is clearly a major public health issue. One possible explanation is that the field of patient safety research lacks standardized case definitions and reliable measurement tools for risk factors. The concepts of incident, error, adverse event, near-miss, avoidable harm, misadventure, etc. are not clearly and consensually defined [12,13]. Until we agree on what constitutes an 'event', research on its causes will be difficult. Similarly, it is far from certain that all investigators of incidents would agree on definitions of contributing factors, such as 'teamwork problems'. The current project led by the World Health Organization to develop a taxonomy of patient safety is therefore most welcome, and should greatly facilitate future research on patient safety [1].

Another problem is the cultural divide between the patient safety community and the more traditional public health community. The former leans heavily on the human factors psychology and organization science, and has not yet embraced epidemiology as a basic science. Cross-disciplinary collaboration and training in epidemiology of safety experts should help broaden the methodological toolbox of incident investigations.

Thomas V. Perneger
Quality of Care Unit, Geneva University Hospitals,
CH-1211 Geneva 14, Switzerland

References

1. World Health Organization. *World Alliance for Patient Safety: Forward Programme 2005*. Geneva: WHO, 2004. Available at: http://www.who.int/patientsafety/en/brochure_final.pdf Accessed 25/11/2004.
2. Vincent C, Taylor-Adams S, Chapman EJ *et al.* How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management Protocol. *Br Med J* 2000; **320**: 777–781.
3. Ternov S, Axelsson R. System weaknesses as contributing causes for accidents in health care. *Int J Qual Health Care* 2005; **17**:
4. Parker D, Lawton R. Psychological contribution to the understanding of adverse events in health care. *Qual Saf Health Care* 2003; **12**: 453–457.
5. McCarroll JR, Haddon W. A controlled study of fatal automobile accidents in New York City. *J Chron Dis* 1962; **15**: 811–826.

6. Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk factors for retained instruments and sponges after surgery. *N Engl J Med* 2003; **348**: 229–235.

7. Lisby M, Nielsen LP, Mainz J. Errors in the medication process—frequency, type, and potential clinical consequences. *Int J Qual Health Care* 2005; **17**:

8. Lau DT, Kasper JD, Potter DE, Lyles A. Potentially inappropriate medication prescriptions among elderly nursing home residents: their scope and associated resident and facility characteristics. *Health Serv Res* 2004; **39**: 1257–1276.

9. Adams RE, Boscarino JA. A community survey of medical errors in New York. *Int J Qual Health Care* 2004; **16**: 353–362.

10. Landrigan CP, Rothschild JM, Cronin JW *et al*. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med* 2004; **351**: 1838–1848.

11. Potts AL, Barr FE, Gregory DF, Wright L, Patel NR. Computerized physician order entry and medication errors in a pediatric critical care unit. *Pediatrics* 2004; **113**: 59–63.

12. Classen DC, Metzger J. Improving medication safety: the measurement conundrum and where to start. *Int J Qual Health Care* 2003; **15(Suppl. 1)**: i41–i47.

13. Morimoto T, Gandhi TK, Seger AC, Hsieh TC, Bates DW. Adverse drug events and medication errors: detection and classification methods. *Qual Saf Health Care* 2004; **13**: 306–314.