Setting up a database of medical error in general practice: conceptual and methodological considerations

Aziz Sheikh and Brian Hurwitz

SUMMARY

Though common and the cause of much morbidity and health cost, medical error has until recently attracted little attention from primary care workers. A database that logs medical error, operating within the context of clinical governance initiatives at the level of Primary Care Groups, could provide an appropriate framework within which to scrutinise and identify systematic organisational features associated with risk of serious adverse events. This paper discusses some of the key conceptual and methodological issues that need to be resolved before such a database can be implemented in general practice and considers these deliberations in the light of the Chief Medical Officer for England's recent report, An organisation with a memory.

Keywords: medical error; databases.

A Sheikh, MRCP, MRCGP, NHS R&D national primary care training fellow; Brian Hurwitz, MRCGP, professor, Department of Primary Care and General Practice, Imperial College School of Medicine, London.

Submitted: 21 March 2000; Editor's repsonse: 16 August 2000; final acceptance: 2 October 2000.

Address for correspondence:
Dr Aziz Sheikh, Department of Primary Health Care and General Practice, Imperial College School of Medicine, St Dunstan's Road, London W6 8RP. Email: aziz.sheikh@ic.ac.uk

Introduction

PRELIMINARY research into the epidemiology of medical error suggests that it occurs more frequently than hitherto thought,[1-5] poses a considerable economic and social burden, and in an unknown proportion of instances results in patient harm.[6] Reduction of the rate and impact of medical error will depend in part upon creating a professional culture in which errors are encouraged to emerge from the shadowy position they currently occupy.[7] This requires acknowledgement that medical error can result from systemic organisational failure as well as from individual mistakes.[8] A database that logs medical errors, [9,10] such as that set up by the aviation industry over a decade ago,[11] would help to place recognition and study of error on a systematic basis and to nourish development of better health care practices.[9,10] In this paper, we explore some of the conceptual and methodological issues to be resolved to enable such a log to be created and managed in general practice and consider their implications in the context of Department of Health proposals to set up mandatory reporting of adverse health care incidents at national level.[12]

Database objectives: logging risk, error or adverse event?

An essential consideration is whether such a database should aim to focus on clinical risk, clinical error or adverse events, all of which are important and interrelated but not synonymous (Box 1). For example, databases of negligence claims developed by medical defence organisations[13] are likely to reflect only the tip of an iceberg of adverse processes and occurrences. Logs of sentinel events, such as the Reports on Confidential Enquiries into Maternal Death in the UK,[14] have provided valuable insights into practices associated with serious adverse outcomes but their focus is too narrow to shed light on the vast majority of errors. The Committee on the Safety of Medicines database similarly focuses on occurrence of adverse events in which error may or may not have played a role. Though undoubtedly useful, such databases provide little information of relevance to understanding questions arising from the interrelationship of risk and clinical error, active and latent error, and error and adverse events. How frequently do these sorts of occurrences take place; to what may they be correlated; what proportion are the result of personal factors as opposed to organisational ones? To answer questions such as these, different sorts of logs may be required; while some would focus upon adverse events resulting from clinical error, others could be used to collect data relevant to tackling errors of planning and execution, irrespective of adverse outcome.[15]

These objectives require to be influenced by practical considerations, such as costs associated with collecting, analysing, and interpreting the information collected and ensuring helpful and appropriate dissemination of findings. To begin with, the focus of a database in general practice

- **Risk:** factor(s) associated with increasing the likelihood of adverse health outcome.
- **Error:** the failure, for reasons which are preventable, of a planned action to be completed as intended (i.e. error of execution), or the use of a wrong plan to achieve an aim (i.e. error of planning).
- **Adverse event:** an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a preventable adverse event.
- **Negligence:** negligent adverse events represent a subset of preventable adverse events that satisfy legal criteria used in determining negligence.
- **Active error:** failures at the level of the frontline operator, which are felt almost immediately.
- **Latent error:** failures that tend to be removed from the direct control of the operator and include things such as poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organisations.

Box 1. Definitions.[19]

could be upon documenting the range and type of medical errors that most commonly result in, or have the potential to result in, serious adverse outcomes for patients — a log of sentinel events and processes. General practice is an appropriate arena in which to create such a database because the overwhelming majority of clinical encounters in the health service take place in this setting; however, error here is not well characterised.[16-18]

Confidentiality and legal immunity

The notion of error carries technical and moral connotations. Technically, it refers to some action carried out inappropriately according to a faulty plan, opinion, or judgement. But to suggest that someone has 'erred' also implies they may have gone astray morally, and this connotation means reported error may actually or potentially expose one to the moral judgements of others, and consequently to blame. These aspects of error predispose to under-reporting and therefore to under-recognition.[19]

Research into error logs in the USA has suggested that one barrier to clinicians participating in exercises of this sort stems from concerns regarding lack of confidentiality and perceived increased risk of negligence suits.[20] Calls for guarantees have been made to ensure that material submitted or unearthed during any subsequent investigations, cannot be divulged to a third party. In the UK, aggregated data compiled anonymously would be unlikely to be relevant to the facts of a particular case, though such information might be useful to an expert witness in advising a court about the nature and frequency of particular errors in medical practice. But if an error log contained information pertaining to identifiable individuals who had allegedly suffered harm as a result of medical error then this material would probably carry the status of an internal accident report, and be subject to legal discovery (I Dodds-Smith, personal communication, 2000).

Mandatory or voluntary reporting

Both mandatory and voluntary schemes have been shown to suffer from problems of under-reporting, an important finding in the context of studies seeking to ascertain rates of error.[21] Mandatory reporting schemes are useful in holding health care providers accountable for errors that cause serious patient harm. However, they are difficult and expensive to administer and monitor and, because of their remit, afford little insight into errors that do not result in adverse patient outcomes. In contrast, voluntary, confidential reporting schemes are more suited to promoting safety improvement since they are more likely to bring to light incidents — whether or not patients have been harmed — and to include information about latent errors (Box 1). Experience suggests voluntary logs are viewed with less suspicion by prospective contributors and, if accompanied by guarantees of confidentiality, are likely to offer fuller and richer appreciations of medical error for the purposes of clinical governance than would information gained from mandatory reporting schemes (Box 2).[22,23]

Reporting, analysis, and feedback within Primary Care Groups

For the information gathered to be useful and meaningful to primary care teams, such as one or a cluster of Primary Care Groups (PCG), collection, reporting, and analysis would need to be standardised. Collection mechanisms could include use of error-reporting forms (made available confidentially through a local PCG intranet, for example), or telephone-based reporting lines allowing contact with a member of a team of staff, trained to disentangle complex clinical information and to pinpoint where, in a sequence of events, error(s) may have taken place. If a wide range of general practices participated, working definitions of significant, frequent errors specific to general practice could be developed.

Once logged, information will need to be analysed and interpreted, preferably by a multi-disciplinary team including representatives from clinical practice (doctors, nursing, and administrative staff), patient organisations, and from those with expertise in risk management and organisational change. The analysis is likely to be primarily qualitative, using narrative analysis techniques to analyse the material collected for content, associated cause(s) and predisposition(s) to error, and the roles of practice staff involved in the sequence of events under consideration. The overall thematic structure of reported errors could be examined and in

A series of episodes in an inner-city practice involving mostly errors of internal practice procedure, one of which had been associated with the ambulance service breaking down the door of the wrong house (as change of address had not been recorded on a patient's medical record), prompted the whole practice to keep a voluntary error log over five days. Twenty-five errors were recorded; 10 involved the wrong records accompanying patient consultations or a practice procedure, of which one could have led to an adverse health care event. Five concerned errors of repeat prescribing, one of which could have led to an adverse event. The remaining 10 concerned failure to follow established practice procedures, half of which involved the appointments system.

The same practice reviewed its message diary following a complaint by a patient that a request she had made to be contacted by telephone had not been followed-up. The diary was scrutinised over a six-month period for unticked messages. Of 1248 documented requests for GPs to 'phone patients back, 36 (2.9%) remained unticked. Review of patient records showed that whereas 15 (42%) of these had been correctly actioned and represented clerical errors, 16 (44%) had not and represented a failure of follow-up; five of the relevant records were not available to be checked because the patients had left the list. As a result of this review, the message diary was re-designed to allow unticked messages to be more easily identified; a re-audit will take place after six months.

Box 2. Logging errors in one general practice: two examples.

due course a working typology created that is likely to be considerably wider than that compiled by Leape and colleagues, based upon experience in hospital practice (Box 3). If such analysis were accompanied by an anonymised précis of the actual incident report, as happens in aviation databases, clinicians would be able to draw their own inferences and conclusions.[11,25]

Quality assurance mechanisms need to be built into such a scheme, to check the accuracy of the data being collected; for example, by use of investigative 'root-cause analysis',[21] to enquire more thoroughly from staff and patients about error-associated events in a randomly selected sample of reports. Results of analyses could be fed back confidentially to the providers of the information to inform their deliberations and practice; some evidence suggests such reports can lead to changes in behaviour and may also encourage continued reporting.[19] Dissemination of anonymised results to the data suppliers as a whole could take the form of regular bulletins, focusing on different patterns of error and factors latent to their occurrence, that could be considered at PCG level for policy and planning implications.

Involvement in error, particularly where this has resulted in patient harm, can be a deeply painful experience for health care professionals.[26,27] Anonymous sharing of such information with the aim of contributing to a body of knowledge designed to reduce error rate may help to minimise the feelings of blame and guilt that frequently follow in the aftermath of suboptimal care.[28] In the longer term, systematic and detailed study of sensitive information is vital if health care professionals are to play their part in helping discussions move beyond the 'naming and shaming' approach that so often characterises the subject of medical error.[29,30]

Voluntary, confidential reporting schemes operating at local level could feed information to incident databases held regionally or nationally. Development of such a database network underpins Department of Health plans to introduce mandatory reporting of adverse health care events and health care 'near misses' throughout the health service.

Learning from medical errors and remembering their implications

Under the chairmanship of the Chief Medical Officer for England, the Department of Health convened an expert group to examine how the health service can develop structures and an appropriate culture suited to actively and effectively learning from adverse occurrences. Entitled *An organisation with a memory,* the expert group's report surveys the scale and character of such incidents in the National Health Service (NHS), locating their definition, identification, and monitoring within the framework of clinical governance.[12] The report makes clear that the 'best people can make the worst mistakes' and focuses upon the existence of prevalent 'situational error traps', many of which remain uncharacterised organisationally and therefore uncorrected. Adopting high level definitions of adverse health care event (AHCE) and health care near miss (HCNM), the report defines AHCE as: 'an event or omission arising during clinical care which causes physical or psychological injury', and HCNM as: 'a situation in which an event or omission, or a sequence of events or omissions fails to develop further, whether or not as a result of compensating action, thus preventing injury to a patient', and recommends mandatory, confidential (but not anonymous) reporting of both to be introduced in the NHS, a recommendation encompassing general practice and one that has been accepted by ministers.

- Diagnostic: Error or delay in diagnosis, failure to investigate appropriately, failure to act on results of tests.
- Treatment: Error in the performance of an operation, procedure or test; error in administering treatment; error in the dose or method of using a drug; avoidable delay in treatment; inappropriate care.
- Preventive: Failure to provide prophylactic treatment, inadequate monitoring or follow-up of treatment .
- Other: Failure of communication, equipment failure, or other system failure.

Box 3. Typology of errors proposed by Leape, *et al.*[24]

While the expert group clearly accepted that there is much to be gained from voluntary, confidential reporting of AHCEs and HCNMs, especially when combined with feedback and appropriate action, it decided that mandatory reporting was the only way to establish a national system requiring standardisation of reports and analyses capable of picking out trends, including possible 'black spots' of under- or over-reporting. Implementation of such a scheme in general practice will involve rendering the events, omissions, and occurrences of interest — to be subject to reporting — into a specific form applicable to this particular health care setting; this is currently the subject of consultation. Crucially, it will also depend upon gaining the support and backing of multidisciplinary primary care teams.

Conclusions

Systematic study of medical error would enable appropriate typologies of error to be delineated applicable to different health care settings, and should encourage greater professional reflectiveness about the learning opportunities that error detection offers.

In this paper we have presented a brief outline of how error logs in primary care could be set up; clearly, many practical considerations remain to be formulated. A database of error, funded and administered at PCG level within the context of clinical governance initiatives, would enable patterns of error and deficiencies in the service organisation and delivery of health care to be charted, including those that place patients at risk of harm, some of which are avoidable. It remains to be seen how such developments will interact with the system of mandatory, confidential reporting outlined in the Department of Health's recent document, *An organisation with a memory*, which envisages local reporting mechanisms filtering information into a regional and national network of databases for the purposes of logging and learning from adverse health care events and near misses.

References

1. Brennan TA, Leape LL, Laird NM, *et al*. Incidence of adverse events and negligence in hospitalised patients. *N Engl J Med* 1991; **324**: 370-376.
2. Wilson RM, Runciman WB, Gibber RW, *et al*. The quality in Australian health care study. *Med J Aust* 1995; **163**: 458-471.
3. Bates DW, Cullen D, Laird N, *et al*. Incidence of adverse drug events: implications for prevention. *JAMA* 1995; **274**: 29-34.
4. Andrews LB, Stocking C, Krizek T, *et al.* An alternative strategy for studying adverse events in primary care. *Lancet* 1997; **349**: 309-313.
5. Weingart SN, Wilson RM, Gibberd RW, Harrison B. Epidemiology of medical error. *BMJ* 2000; **320**: 774-777.
6. Vincent C. Risk, safety, and the dark side of quality. *BMJ* 1997; **314**: 1775-1777.
7. Sheikh A. Medical errors: a better alternative to naming and shaming. *Update* 1999; **59**: 826-827.
8. Vincent C, Taylor-Adams S, Stanhope N. Framework for analysing risk and safety in medicine. *BMJ* 1998; **316**: 1154-1157.

9. Berwick M, Leape LL. Reducing errors in medicine. *BMJ* 1999; **319**: 136-137.
10. Sheikh A, Hurwitz B. A national database of medical error. *J R Soc Med* 1999; **92**: 554-555.
11. The Federal Aviation Administration Aviation System. http://nasdac.faa.gov/safety_data (Accessed January 2000).
12. Department of Health. *An organisation with a memory.* London: HMSO, 2000. (www.doh.uk/orgmemreport.htm)
13. Anonymous. Can the society help me avoid the possible pitfalls of practice? In: Medical Protection Society. *The Medical Protection Society review 1998*. London: MPS, 1998; 6-7.
14. Drife J, Lewis G. *Why mothers die. Report on confidential enquiries into maternal death in the UK 1994-1996*. London: HMSO, 1998.
15. Reason JT. *Human errors.* Cambridge: Cambridge University Press, 1990.
16. Majeed A. Role of hospitals in NHS must not be undervalued. *BMJ* 1997; **314**: 1653.
17. Watts G. Checkup time for your GP. *The Times Higher Education Supplement,* 14 January 2000, p38.
18. Sheikh A, Hurwitz B. Log of errors is needed. *BMJ* 2000: **321**: 505.
19. Vincent C, Stanhope N, Crowley-Murphy M. Reasons for not reporting adverse incidents: an empirical study. *J Eval Clin Pract* 1999; **5**: 13-21.
20. Bratman RL. A national database of medical error. *J R Soc Med* 2000; **93**: 106.
21. Error reporting systems. In: Kohn LT, Corigan JM, Donaldson MS (eds). *To err is human: building a safer health system.* Washington (DC): National Academy Press, 1999.
22. Barach P, Small SD. Reporting and preventing medical mishaps: lessons from non-medical near-miss reporting systems. *BMJ* 2000; **320**: 759-763.
23. Cohen MR. Why error reporting systems should be voluntary. *BMJ* 2000; **320:** 728-729.
24. Leape L, Lawthers AG, Brennan TA. Preventing medical injury. *Qual Rev Bull* 1993; **19**: 144-1449.
25. Helmreich RL. On error management: lessons from aviation. *BMJ* 2000; **320:** 781-785.
26. Wu WA. Medical error: the second victim. *BMJ* 2000; **320**: 726-727.
27. Murtagh J. *Cautionary tales.* Roseville: McGraw-Hill, 1992.
28. Anonymous. Looking back. *BMJ* 2000; **320**: 812.
29. Horton R. The uses of error. *Lancet* 1999; **353**: 422.
30. Baker R. Learning from complaints about general practitioners. *BMJ* 1999; **318**: 1567-1568.

Acknowledgements

We would like to thank Helen Watson, Berry Beaumont, and Sangeeta Dhami for their constructive comments on earlier drafts of this paper, and the partners and staff of the practice at 2 Mitchison Road, London N1, for allowing us to describe their errors' log (in box 2). Dr Aziz Sheikh is funded by a NHS R&D National Primary Care Development Award.