Clin Chem Lab Med 2006;44(6):694–698 © 2006 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2006.127

Review

Clinical Governance: from clinical risk management to continuous quality improvement

Maria Laura Chiozza[1,*] and Mario Plebani[2]

[1] Quality Department,
[2] Department of Laboratory Medicine,
University-Hospital of Padova, Padova, Italy

Abstract

Reducing medical errors has become an international concern. Population-based studies from a number of nations around the world have consistently demonstrated unacceptably high rates of medical injury and preventable deaths. The introduction of effective reporting systems is a cornerstone of safe practice within hospitals and other healthcare organisations. Reporting can help to identify hazards and risks. However, reporting in itself does not improve safety. It is the response to reports that leads to change. Clinical teams must feel empowered to change the way in which they deliver their services, promoting effective clinical risk management. Process analysis, implementation of evidence-based practices, and a clear accountability system are effective tools not only for decreasing error rates, but also for improving effectiveness. Clinical Governance represents the context in which effective clinical risk management should be promoted and continuously improved. It should not be regarded as a separate activity, but should form part of the everyday practice of all healthcare professionals. It requires good multidisciplinary working and a willingness to reflect on and learn from errors to achieve a patient-centred and safer system.

Keywords: adverse event reporting; Clinical Governance; clinical risk management; continuous quality improvement; error prevention; healthcare system; patient safety.

Introduction

The report of the Institute of Medicine (IOM), ''*To Err is Human: Building a Safer Health System*'' (1), galvanised a dramatically expanded level of debate and concern about patient injuries in healthcare. This report has recently been characterised as the most influential healthcare publication in the past two decades (2). Patient safety, a topic that had been little understood and even less discussed in care systems, in hospitals, and in academic training of physicians and nurses, became a frequent focus for journalists, healthcare leaders, politicians and concerned citizens. According to the Bion and Heffner forecast, ''*Patients' safety has come to characterise the first decade of the third millennium just as managed care and cost-containment did the 1990s*'' (3).

Clinical Governance emerged at the end of the 1990s as a response to several episodes of poor clinical performance and patient deaths, such as paediatric cardiac surgery in Bristol, the activities of a general practitioner-turned-murderer, Harold Shipman, and failures in screening programmes (4). Clinical risk management, therefore, plays a central role in developing a systematic approach to create the right sort of organisation that allows the implementation and development of Clinical Governance (5).

Adverse event reporting

The IOM estimated there are 44,000–98,000 preventable hospital deaths per year and although some clinicians and the lay public continue to doubt that injury and mortality rates are as high as the IOM claimed (6–8), subsequent data from various sources suggest that the IOM may have substantially underestimated the magnitude of the problem. Nosocomial infections alone, most of which are preventable, account for more than 90,000 deaths per year, and hospital-acquired bloodstream infections alone may rank as the eighth leading cause of death in the US (9, 10). Reducing medical errors has become an international concern. The World Alliance for Patient safety has been launched by the World Health Organization (WHO) to galvanise and facilitate efforts by all Member States to make healthcare safer (11). This organisation has produced a draft guideline to introduce adverse event reporting and focus on reporting and learning to improve the safety of patient care. The primary purpose of patient safety reporting systems is to learn from experience. It is important to underline that reporting in itself does not improve safety. It is the response to reports that leads to change. However, an effective reporting system is a cornerstone of safe practice and, within a hospital or other healthcare organisation, a measure of progress towards achieving a safety culture. The main issues that should be addressed by a reporting system are shown in Table 1.

Some conditions for successful implementation of a reporting system should be assured. In particular, the following issues should be addressed: a) clear objectives; b) clarity about who should report and what gets reported; c) mechanisms for receiving

*Corresponding author: Maria Laura Chiozza, MD, Servizio Qualità, Azienda Ospedaliera-Università di Padova, Via Giustiniani 2, 35128 Padova, Italy
Phone: +39-049-8218338,
E-mail: marialaura.chiozza@sanita.padova.it

Table 1 Components of a reporting system.

a)	**Aim:** It should be specified if the reporting system focuses on learning and contributing to system redesign (voluntary) or is specifically developed by external regulatory or legal agencies to ensure accountability (mandatory)
b)	**Confidentiality and public access to data**: According to the main objectives of the reporting system, it should be designed as a document to be used within the institution, or to be accessible to external agencies or to the public
c)	**Content:** Types of events, such as adverse events, errors, near misses, hazard and unsafe conditions
d)	**Form:** It should be written in a structured form, or narrative text, and should be released by e-mail, fax, Internet, or mail
e)	**Type of analysis:** Data should be analysed on the basis of hazard identification, trend and cluster analysis, risk analysis, and causal analysis

reports and managing data; d) expertise in analysis; e) capacity to respond to reports and a method for classifying and making sense of reported events; f) the capacity to disseminate findings; and g) technical infrastructure and data security.

The ultimate aim of reporting is to lead to system improvements by understanding the system failures that may cause error or risk of errors and can translate into adverse events and patient injuries. Therefore, the reporting system should be viewed as a part of a broader safety programme, which should use the evidence of the reporting system as a guide and input for improvement initiatives. However, a general consensus has been reached to demonstrate that moving away from a focus on merely reporting on errors to the implementation of evidence-based practices will generally yield better clinical outcomes (12). The fundamental shift is to move from error description and a focus on saving lives solely by avoiding error perpetuation, to a systematic approach to describe and document all activities, responsibilities and related procedures involved in delivering care processes. In this way, it should be possible to identify the most critical steps for which latent failures and errors may remain and accumulate, making the system more prone to future possible errors and adverse events. Discovering latent failures and modifying the processes in which they grow are likely to have a greater effect on building safer systems than efforts to minimise active errors at the point at which they occur. In fact, the main thrust of the safety movement, one of the most important learnings during the past decade, is that safety is primarily a systems problem (1). This, in turn, has two fundamental implications: a) better systems must be developed to prevent errors; and b) better systems must be developed to ensure that clinicians provide the effective care they intend to provide.

Towards a proactive approach to error minimisation

Preventing errors and improving safety for patients require a system approach to modify the conditions that contribute to error. Despite the widely disseminated message from the IOM that systems failures cause most injuries, many managers of healthcare systems still believe that the major cause of poor care is poor physicians and nurses, and that if miscreant clinicians and nurses were removed, everything would be all right. Only recently, the concept that bad systems, not bad people, lead to the majority of errors and injuries, which is a crucial scientific foundation for improvement of safety in all successful high-hazard industries, has also become a mantra in healthcare (13). High reliability theory believes that accidents can be prevented through good organisational design and management. The more complex any system is, the more chances it has to fail. According to the Dean of Safety Researchers, James Reason, healthcare is more complex than any other industry in terms of relationships, with more than 50 different types of medical specialties and subspecialties interacting with each other (14). Currently, however, physicians and nurses are not equipped to consider the full range of clinical, organisational and interpersonal processes that are entailed in delivering care. This has been described by Degeling in a seminal paper as the ''old flawed model'' in which the operations of the standalone ''silos'' are oriented to ensure that a hospital's senior management can satisfy its accountability on centrally determined generic performance measures. By divorcing issues of risk and safety from the specifics of providing care to a nominated patient group, this model encourages clinicians to view risk management and Clinical Governance as a management-driven exercise that has exploded their paperwork to the detriment of patient care (15).

An effective risk management approach has to be based on the systematisation of clinical work and in particular on the description and continuous improvement of integrated clinical care pathways. These pathways describe the diagnostic and therapeutic events that will appreciably affect the quality, outcomes and costs of care, and, eventually, possible related adverse events. Clinical pathways, in turn, generate organisational, technological, training and educational needs that have to be described and recorded. The deployment of processes, procedures and related responsibilities that constitute the backbone of clinical pathways should be focused on to recognise the most critical steps and phases in which latent errors can survive and eventually generate adverse events. In this way, it should be possible to move from simply recognising errors and eventually avoiding their persistence over time (corrective actions) to a proactive approach by identifying potential errors and non-conformities through planned review of processes (preventive actions).

Strategies to improve safety

On the basis of a planned review of processes and procedures, some strategies should be implemented to decrease errors and adverse events and to improve patient safety. These strategies can be summarised

Table 2 Strategies for improving safety: error prevention.

Strategy	Activities
Error prevention through: • Clinical pathways and diagnostic/therapeutic processes • Working facilities • Personnel and team work	Quality system Process analysis Chain of power Organisational rules: • Physician duties • Nurses and support staff: • job description Preventive activities Emergency issues: • Working team • Checklist (drugs)

Table 3 Strategies for improving safety: learning from adverse events and reducing impact of errors.

Strategy	Activities
1. Learning from errors	Non-conformities
• Transparency and error reporting	Identification of operators involved in drug prescription (physician) and administration (nurse) Double checking Information technology for system monitoring and individual activities
2. Reducing error impact	Implementation of a procedure for drug administration: antidotes

as: 1) error prevention; 2) learning from incidents; 3) reducing error impact; 4) decreasing complexity; 5) optimising interactive and communication activities; 6) using information technology to support human activities; 7) introducing ''alert values'' into instrumentation; and 8) reducing errors when introducing innovation.

Tables 2–6 describe strategies and related activities to improve safety and decrease errors that have been implemented in the University Hospital of Padova for promoting an effective risk management approach. In particular, as detailed in Table 2, a strategy for error prevention has been initiated through three main projects that are related to: a) recognition and characterisation of all clinical pathways and diagnostic/therapeutic processes performed within the trusts; b) recognition of working facilities; and c) recognition of existing personnel and needs for team working.

The activities related to these issues are better defined in the right-hand column of Table 2, and are represented as related to the quality system, process analysis, chain of power, etc.

Table 3 shows what has been carried out to improve safety through the strategies ''learning from incidents'' and ''reducing error impact''.

The background of this strategy is that if accidents are inevitable in certain systems, the same mistakes should not occur repeatedly in the same setting, and that all efforts should be made to reduce the eventual impact of these errors to patients. In this sense, for example, the immediate availability of antidotes to reduce the impact of drug-related adverse events is not a remedy, but an effective tool for minimising patient injuries.

Table 4 describes another strategy to reduce complexity in the delivery of care. Simplification, by reducing steps that are not really necessary and do not create value in the system, reduces the possibility of errors inherently related to each step.

Table 5 stresses the essential nature of communication and interaction between professionals within each institution. From a strategic point of view, the overall quality of care greatly depends on the collaborative and communicative links that exist between different activities. Safety, in fact, does not reside in one person, device or department, but emerges from interaction of the components of a system. Frequently, errors do not arise within one department, but in the boundaries between different departments and processes. This is the reason why teamwork, involving a multidisciplinary and multiprofessional approa-

Table 4 Strategies for improving safety: decreasing errors and adverse events.

Strategy	Activities
Decreasing the complexity/simplification: • Number of steps • Number of alternatives in each step • Avoiding careless mistakes (slips)	Clinical pathways Medical procedures Nurse procedures Organisational procedures SOP (standard operating procedures) Unified (physician-nurse) system for recording/reporting Automatic administrative system (or patient identification and recording)

Table 5 Strategies for improving safety: communication.

Strategy	Activities
Optimising interactive and communication activities • ''Hand-over'' • Avoiding memory-based information through protocols, checklists, written orders, codes and coloured stick-ons	Organisational procedures for describing specific activity steps Reporting, e.g., laboratory requests, drugs, written briefings

Table 6 Strategies for improving safety: technology assessment and proper utilisation.

Strategy	Activities
1. Using information technology to support human activities	Automatic implementation and validation of triage Accessibility to clinical pathways and related procedures (Acrobat Reader and Intranet) Barcode identification
2. Introducing ''alert values'' (through calibration and maintenance) into the instrumentation	Automatic alarm signals and related SOP
3. Reducing adverse events when introducing innovation (drug, technology, personnel)	Identification of skills and related training needs: courses and other educational initiatives

ch, is essential. Sadly, this is not the norm in many hospitals.

Finally, Table 6 shows three additional strategies, decreasing errors using information technology, introducing ''alert values'' into instrumentation, and creating a policy for the introduction of innovation.

Towards a widespread culture of clinical risk management

To improve patient safety and decrease errors, it is necessary to change the culture and introduce an effective knowledge management system. An integrated system of remedial and proactive activities should be based on: a) understanding the way in which errors and organisational failures have been identified; b) investigating and understanding error causes; c) mechanisms to use that understanding to bring about changes to make future recurrence less likely (16); and d) initiatives for changing processes and procedures to make the system safer. This cannot be achieved through a top-down strategy, but must involve the creation of a culture of a genuine learning organisation.

This requires a focused approach to knowledge management, so that the organisation is clear about the knowledge it takes in, how that knowledge is used within the organisation, and what knowledge and what quality of knowledge are provided for patients (17). To reach this goal, in the University Hospital of Padova, a series of courses devoted to both physicians and nurses have been initiated to create:

a) A ''critical mass'' of physicians and nurses who are convinced that each clinical practice has to be evidence-based;
b) A culture that promotes a multidimensional approach to quality in healthcare based on patient safety, effectiveness, appropriateness, equity, patient involvement, and efficiency;
c) Knowledge and skills to search for, critically evaluate, integrate and update clinical practice guidelines;
d) Techniques to achieve a consensus in the ''grey areas'', which means procedures and processes that are not covered by the evidence;
e) Local adaptation of internationally or nationally recognised clinical guidelines to achieve compliance by potentially all professionals involved; and
f) A system that evaluates the impact of clinical guidelines on process and outcome indicators through clinical audit.

Conclusions

The IOM Quality Committee has defined safety and distinguished it from what it termed ''effectiveness'' (18). The distinction is critical in order to implement a valuable clinical risk management programme. Safety is freedom from accidental injury. Effectiveness, on the other hand, ''*refers to care that is based on systematically acquired evidence to determine whether an intervention such as a preventive service, diagnostic test, or therapy, produces better outcomes than alternatives*'' (18). Measures of effectiveness should be evidence-based and broad, and go beyond an analysis of accidental injury. Achieving safer care, therefore, has three agendas: identifying what works (efficacy), ensuring that patients receive it (appropriateness), and delivering it flawlessly (no errors). Thus, moving away from a focus on saving lives solely by avoiding error repetition and instead emphasising the implementation of evidence-based practices to improve the quality of care, so preventing errors, will generally yield better long-term results, and better clinical outcomes.

References

1. Kohn LT, Corrigan JM, Donaldson MS. To Err is Human: building a safer health system. Washington, DC: National Academy Press, 1999.
2. Altman DE, Clancy C, Blendon RJ. Improving patient safety – five years after the IOM report. N Engl J Med 2004;351:2041–3.
3. Bion JF, Heffner JE. Challenges in the care of the acutely ill. Lancet 2004;363:970–7.
4. Mohammed MA, Cheng KK, Rouse A, Marshall T. Bristol, Shipman, and clinical governance: Shewhart's forgotten lessons. Lancet 2001;357:463–7.
5. Scally G, Donaldson LJ. Clinical governance and the drive for quality improvement in the new NHS in England. Br Med J 1998;317:61–5.
6. Blendon RJ, DesRoches CM, Brodie M, Benson JM, Rosen AB, Schneider E, et al. Views of practising physicians and the public on medical errors. N Engl J Med 2002; 347:1933–40.
7. McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in Institute of Medicine Report. J Am Med Assoc 2000;284:93–4.

8. Leape LL. Institute of Medicine medical errors figures are not exaggerated. J Am Med Assoc 2000;284:95–7.
9. Centers for Disease Control and Prevention. Monitoring hospital-acquired infections to promote patient safety – United States, 1990–1999. MMWR Morb Mortal Wkly Rep 2000;49:149–53.
10. Wenzel R, Edmond M. The impact of hospital-acquired bloodstream infections. Emerg Infect Dis 2001; 7:174–7.
11. World Alliance for Patient Safety. WHO draft guidelines for adverse events reporting and learning systems. www.who.int/patientsafety.
12. Brennan TA, Gawande A, Thomas E, Studdert D. Accidental deaths, saved lives, and improved quality. N Engl J Med 2005;353:1405–9.
13. Leape LL, Berwick DM. Five years after To Err is Human. What have we learned? J Am Med Assoc 2005;293: 2384–90.
14. Reason J. Human error. Cambridge: Cambridge University Press, 1990.
15. Degeling PJ, Maxwell S, Iedema R, Hunter DJ. Making clinical governance work. Br Med J 2004;329:679–81.
16. Walshe K. Understanding and learning from organisational failure. Qual Saf Health Care 2003;12:81–2.
17. Donaldson LJ, Muir Gray JA. Clinical governance: a quality duty for health organisations. Qual Health Care 1998;7:S37–44.
18. Adams K, Corrigan JM, editors. Priority areas for national action. Washington, DC: National Academy Press, 2003.