BJCP British Journal of Clinical Pharmacology

DOI:10.1111/j.1365-2125.2009.03422.x

Prevention of medication errors: detection and audit

Germana Montesi & Alessandro Lechi

Internal Medicine, University Hospital, Verona, Italy

Correspondence
Dott.ssa Germana Montesi, Medicina Interna C, Policlinico G.B Rossi – P.le L.A. Scuro, 10, 37134 Verona, Italy.
Tel: +39-045-8124414
Fax: +39-045-8027465
E-mail: germanadolores.montesi@univr.it

Keywords
clinical audit, clinical risk management, incident reporting, medication error, patient safety

Received
18 February 2009

Accepted
18 March 2009

1. Medication errors have important implications for patient safety, and their identification is a main target in improving clinical practice errors, in order to prevent adverse events.
2. Error detection is the first crucial step. Approaches to this are likely to be different in research and routine care, and the most suitable must be chosen according to the setting.
3. The major methods for detecting medication errors and associated adverse drug-related events are chart review, computerized monitoring, administrative databases, and claims data, using direct observation, incident reporting, and patient monitoring. All of these methods have both advantages and limitations.
4. Reporting discloses medication errors, can trigger warnings, and encourages the diffusion of a culture of safe practice. Combining and comparing data from various and encourages the diffusion of a culture of safe practice sources increases the reliability of the system.
5. Error prevention can be planned by means of retroactive and proactive tools, such as audit and Failure Mode, Effect, and Criticality Analysis (FMECA). Audit is also an educational activity, which promotes high-quality care; it should be carried out regularly. In an audit cycle we can compare what is actually done against reference standards and put in place corrective actions to improve the performances of individuals and systems.
6. Patient safety must be the first aim in every setting, in order to build safer systems, learning from errors and reducing the human and fiscal costs.

Medication errors and drug-related adverse events have important implications – from increased length of hospitalization and costs to undue discomfort and disability or increased mortality [1, 2]. Reason has proposed two approaches to considering errors and accidents [3]. First, identify individual problems and deficiencies that can lead to error; second, analyse faulty systems design. Problems with both individuals and systems are responsible for most accidents. However, individual problems can also result from defective systems. The frequency and severity of medication errors are not evenly distributed in the population, and there are clusters of patients, drugs, and settings that are associated with higher risks; however, these can generally be attributed to common underlying contributory/latent factors [4, 5].

Detection

In order to build safer systems we must be able to learn from previous errors [6], and detection is the first crucial step. Scientific societies and surveillance agencies, reviews, original studies, and case reports may warn us to be on the alert and promote knowledge of risks and improved performance. For this purpose, reports, alerts and recommendations are available on the web, issued by national and federal healthcare systems, regulatory agencies, and non-profit-making organizations [the Food and Drug Administration (FDA), European Medicines Agency (EMEA), United States Pharmacopeia (USP-MEDMARX), UK – National Health Service (NHS), Veterans Health Administration (VHA), Australian Patient Safety Foundation (APSF), Joint Commission on the Accreditation of Healthcare Organizations (JCAHO)] [7, 8].

The approaches used to detect errors are likely to be different in research and routine care, given the available resources [9]. In order to prevent medication errors and reduce the risks of harm, organizations need tools to detect them [10]. Any system must then be able to analyse errors and identify opportunities for quality improvement and system changes. The major methods for detecting adverse events are chart review, computerized monitoring, incident reporting, and searching claims data. Medication errors are mainly detected by means of direct observation, voluntary reporting (by doctors, pharmacists, nurses, patients, and others) and chart review. Research applies

Table 1
Detection methods used to investigate medication errors and adverse events

Method	Advantages	Limitations	Efficacy	Costs
Chart review	Retroactive; disposable data; commonly used; standardized criteria; poor at capturing latent failures	Difficult; time-consuming; labour intensive; planning criteria/indicators necessary	Gold standard to detect adverse events; less medication errors detected; reviews, papers	Reviewers' training and time (nurses, pharmacists, students, physicians)
Claims data	Local data; captures latent failures	Litigation based; legal implications	Adverse events detected	Reviewers' training and time
Incident reporting (sentinel events)	High-quality data; root cause analysis due; captures active and latent failures	Only detects severe, unexplained events/deaths; underestimated rates (blame and fear of punishment)	Reports and alerts; detects adverse events; less medication errors detected	Root cause analysis
Voluntary reporting	Variety of sources; structured simple form; Captures active and latent failures; promotes a culture of safety	Variable quality; underreporting; blame culture; problem of data integration	Reports and alerts; feedback and corrective actions; medication errors detected	Time for feedback and analysis
Administrative data examination	Disposable and retroactive data; easy; standardized	Absence of clinical data	Statistical	Routine evaluation
Computer monitoring	Multidata source integration; real time; adverse events prevention	Inserted errors; poor software; poor triggers; undetermined future risks	Prescribing faults, prescription errors, and dispensing errors (CPOE)	High costs for software and implementation
Direct care observation	Accurate; captures active errors	Time-consuming; training difficult;	Good quality data about administration errors	Nurse training
Patient monitoring	Data from outpatients; wide impact	Not standardized tools (interviews, questionnaires, focus groups, etc)	Future development	Nurse training

combined methods. The advantages and limits of the main methods are summarized in Table 1; here are notes on the most interesting ones [10, 11].

Chart review

Chart review is retrospective and based on practice sources (medical charts and laboratory data, prescription data, and administrative data) [2, 10, 11, 12]. It can be improved by using computerized data, such as electronic medical records, computerized physician order entry (CPOE), and computer-integrated triggers. Chart review is the most precise approach for detecting adverse events, but is less good at detecting medication errors. Cases are evaluated independently by two or more experts. Good planning is required for definitions, inclusion criteria, and triggers. The downsides of this method are the difficulty in training reviewers (nurses, pharmacists, students, research assistants) and the resources needed, both fiscal and human. Furthermore, the results depend on the quality of documentation and reviewers' abilities to capture triggers.

Computerized monitoring

Computerized monitoring is the modern version of voluntary pharmacist reporting (pharmacy logs) [13]. Pharmacists detect order errors, rectify them, and fill out a report. Medication errors can thus be intercepted before adverse events occur. If CPOE is in use, prescription and dispensing errors may be readily detected [14]. Advanced software implementation supports integration of laboratory and clinical data with Clinical Decision Support Systems (CDSS), providing detection and prevention of adverse events. CPOE systems improve safety, but need to be used in combination with CDSS. Implementation of information technology is costly and necessary for safety, but it can also give rise to new, unknown risks.

Administrative databases

Administrative databases screen International Classification of Diseases, 9th revision codes, for statistical purposes. Patient safety indexes and adverse event-adjusted rates are elaborated from a combination of discharge data. However, adverse events are poorly detected, because of the lack of clinical data.

Claims data

The value of screening of claims data is limited by the underlying reasons for litigation, which are sometimes frivolous, and by the involvement of small numbers of local claims. Events often still need to be confirmed, and about one-third of claims lack evidence of errors. Claims data have a positive predictive value for adverse events of about 50%, of which only about 18% point to a medication source [15].

Direct observation

Direct observation is the only method available for detecting errors of administration of medications. A trained nurse observes drug administration, registers each action, and then compares what was done with the original physician orders. The observer must be trained and visits different units in sequence.

Reporting systems

Reporting systems derive from procedures in high-reliability organizations. However, their application to health systems is quite difficult. Reports submitted to management or legal services can cause misunderstanding and carry a connotation of blame. Furthermore, reports may concern different organizations, according to the field of application, causing multiplication and incorrect analysis.

The Royal College of Anaesthetists was the first to use an incident reporting system in the UK in 1978 [16]. Nowadays, every health system requires reporting, either directly (the VHA in the USA, the Ministero della Salute in Italy), or by specific agencies [Australian Institute of Medical Scientists in Australia, National Report Learning System (NRLS) in the UK]. The Joint Commission in the USA (formerly the Joint Commission on the Accreditation of Healthcare Organizations) analyses reports from accredited care settings, and issues alerts and recommendations based on integrated data analysis. National Patient Safety Goals (NPSGs) are then elaborated, with subsequent practice suggestions and improved standards of quality to be fulfilled. In the UK the National Patient Safety Agency (NPSA) has developed the first comprehensive NRLS and has set up the Patient Safety Observatory to compare and combine data from the NRLS with other sources of information, such as litigation bodies, industry, healthcare organizations, and patients. Drug-related reports are also collected by specific surveillance agencies (USP-MEDMARX, FDA, EMEA, Italian Pharmaceutical Agency (AIFA)). Major organizations are now trying to integrate a wider database, as latent failures and system errors are widespread and often repetitive [6, 7, 12].

There are two safety-oriented levels of reports:

1 *Incident reporting* Where this is in place, it is obligatory and restricted to severe unexpected events/deaths (sentinel event list). A timely narrative report of the incident must be sent, with root cause analysis, to the central organization, which issues regular statistical reports, capturing both adverse events and medication errors and raising concerns about quality improvement.
2 *Voluntary reporting* Voluntary reporting must be anonymous, confidential, and blame-free. A simple structured form is required to help reporting and analysis. Feedback, regular reports, and the implementation of corrective actions are all necessary [17]. Near misses and medication errors are usually reported, but rarely adverse events [18]. An increasing number of reports does not necessarily betoken poor practice, but is related to improved capture of events. The advantages of voluntary reporting are the discovery of active and latent systems failures, evidence of the critical nature of processes, the correction of contributory factors, and the diffusion of a culture of safety [12, 17, 18]. Every experience underlines the existence of common barriers to physician involvement in reporting of errors, in fact this is minimal compared with the nurses' involvement [19]. Although the vast majority of incidents will be reported locally, the existence of another independent and confidential reporting system provides a safety net for staff.

Other methods

Patient monitoring, with interviews, using structured forms, by mail, telephone, or visits, or by satisfaction questionnaires and focus groups, can discover medication errors and associated adverse events in outpatients [12], where many errors arise from poor communication. In future the focus will be on long-term care, primary care, and outpatients.

Audit

In 1854 Florence Nightingale used audit to prevent post-surgical mortality. In 1989, *Working for Patients*, a UK Government white paper, proposed standardization of audit as part of professional healthcare. The paper defined 'medical audit' as 'the systematic critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources, and the resulting outcome and quality of life for the patient.'

In a paper, *Principles for Best Practice in Clinical Audit*, published by the National Institute for Health and Clinical Excellence [20], multidisciplinary 'clinical audit' was proposed and defined as: 'a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change'. The paper went on to say that 'Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery'.

Clinical audit is generally retroactive, caused by the occurrence of near-miss events and adverse or critical events involving a multidisciplinary team. The team's discussion is confidential, anonymous, and blame-free; its aim is to monitor critical events, revisiting care actually provided and learning for the future. Peer review is similar, but is concerned with 'interesting' or 'unusual' cases, rather than problematic ones. Recommendations from these reviewers are often not pursued, as there is no systematic method to follow. Users' views about quality of care, when available, are evaluated.

Audit is also an educational activity, which promotes high-quality care and should be carried out regularly. It is characterized by the Deming cycle (Plan–Do–Check–Act; named after the US philosopher W. Edwards Deming, 1900–1993) and offers a systematic framework for investigating and assessing the work of healthcare professionals and for introducing and monitoring improvements. The audit process involves a characteristic sequence of events, the audit cycle [20]:

1. Planning the audit by identifying the problem, the objectives, the current state of the art, the participants (five to seven multiprofessional, interested people, a leader, a secretary), activities, responsibilities, times, limits, and resources.
2. Defining objectives, standards, or protocols of best practice against which performance can be compared (evidence based medicine and nursing, scientific reviews, guidelines, benchmarking data, leaders' opinions), and developing evaluation criteria for adherence to these standards and indicators; the standards, criteria, and indicators must be clear, written, and agreed [21].
3. Gathering systematic and objective evidence of performance (according to stated criteria).
4. Comparing the results with preset criteria and standards and/or among peers.
5. Identifying deficiencies and solutions and planning implementation actions.
6. Closing the loop by monitoring the results obtained and producing a report.

Clinical audit should be an objective way of measuring and monitoring practice against a set of agreed standards and of detecting mismatches between the written word and actual practice. Audit is not a means for measuring outcomes, but a way of comparing what we do against what research evidence indicates should be done – auditing performance against a reference standard [21]. Audit enables assessment of the appropriateness of specific healthcare decisions, services, and outcomes.

Change is possible when an intervention is well designed, and most quality interventions that have been studied have had some effect (average about 10% for main targets). However, none of them is superior for all changes in all settings. Interventions that are targeted at specific obstacles to change seem to be more effective than those that are not [9].

Audit and feedback seem to be effective when they target the ordering of tests and preventive activities, but the effect size can be modulated by feedback, depending on its source, format, and frequency or intensity of presentation. Feedback is recommended in combination with education, outreach visits, or reminders.

The audit process is better used in the USA, UK and Australia, where it has influenced clinical practice and management, changing the culture of healthcare providers, enabling them to appreciate written guidelines and protocols and to develop a sense of clinical accountability, interprofessional understanding, and sensitivity to patients' needs [6, 17, 18]. However, it has some drawbacks: it takes time and effort, it is resource intensive, and facilitators need to be trained.

Clinical audit can also be used proactively, in the hope of avoiding medication errors or adverse events that have not yet occurred, but have been outlined in surveillance alerts like JCAHO Sentinel Event Alert and National Patient Safety Goals (NPSGs), or in order to pay attention to a known critical step (for example, prescription dispensing forms, discharge therapy, oral anticoagulant prescription) [22].

To conduct proactive risk assessment the use of Failure Mode, Effect, and Criticality Analysis is recommended, in order to survey critical processes (e.g. cancer chemotherapy, potassium chloride infusion) [14]. It analyses all potential failure modes and consequent failure effects inside the system, as perceived by the user. A block diagram gives an overview of the major components of the steps in the process and how they are related. The process is mapped step by step, by subprocesses and activities, with their single possible failures. Risk analysis can be calculated by means of the Risk Priority Number (RPN) = Severity × Occurrence × Detectability. Failures can be prioritized according to the RPN, the highest being given the highest priority for corrective or preventive actions [23].

Conclusion

Prevention of medication errors relies on epidemiological knowledge, detection of errors, and improvements in performance.

Chart review is the gold standard in detecting adverse drug-related events and, in future, computerized monitoring will be the method of capturing adverse events before they occur.

Reporting discloses medication errors, can trigger warnings, and encourages the diffusion of a culture of safe practice.

Audit is a relatively simple tool for evaluating actual performance and in planning corrective actions to reduce the risk of medication errors.

Competing interests

None to declare.

REFERENCES

1 Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D. Incidence of adverse drug events and potential adverse drug events. JAMA 1995; 274: 29–34.

2 deVries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. Qual Saf Health Care 2008; 17: 216–23.

3 Reason JT. Understanding adverse events: human factors. In: Clinical Risk Management: Enhancing Patient Safety, ed. Vincent CA. London: BMJ Publications, 2001; 9–30.

4 Vincent CA. Understanding and responding to adverse events. N Engl J Med 2003; 348: 1051–6.

5 Institute of Medicine of the National Academies. Preventing Medication Errors. Quality Chasm Series. Washington DC: The National Academies Press, 2007.

6 Vincent CA. Patient Safety. Edinburgh: Elsevier Churchill Livingstone, 2006.

7 Vincent CA, Lee ACH, Hanna GB. Patient safety alerts: a balance between evidence and action. Arch Dis Child Fetal Neonatal Ed 2006; 91: 314–5.

8 NHS–NAPS. Building a memory: preventing harm, reducing risks and improving patient safety. The First Report of the National Reporting and Learning System and the Patient Safety Observatory, July 2005.

9 Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. Lancet 2003; 362: 1225–30.

10 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: 306–14.

11 Hogan H, Olsen S, Scobie S, Chapman E, Sachs R, McKee M, Vincent C, Thomson R. What can we learn about patient safety from information sources within an acute hospital: a step on the ladder of integrated risk management? Qual Saf Health Care 2008; 17: 209–15.

12 Tam KWT, Kwok KH, Fan YMC, Tsui KB, Ng KK, Ho KYA, Lau KT, Chan YC, Tse CWC, Lau CM. Detection and prevention of medication misadventures in general practice. Int J Qual Health Care 2008; 20: 192–9.

13 Dean B, Schachter M, Vincent CA, Barber N. Prescribing errors in hospital inpatients: their incidence and clinical significance. Qual Saf Health Care 2002; 11: 340–4.

14 Bonnabry P, Despont-Gros C, Grauser D, Casez P, Despond M, Pugin D, Rivara-Mangeat C, Kock M, Vial M, Iten A, Lovis C. A risk analysis method to evaluate the impact of a computerized provider order entry system on patient safety. J Am Med Inform Assoc 2008; 15: 453–60.

15 Studdert DM, Mello MM, Gawande AA, Gandhi TK, Kachalia A, Yoon C, Puopolo AL, Brennan TA. Claims, errors, and compensation payments in medical malpractice litigation. N Engl J Med 2006; 354: 2024–33.

16 Cooper JB, Newbower RS, Long CD, McPeek B. Preventable anesthesia mishaps: a study of human factors. Anesthesiology 1978; 49: 399–406.

17 Stump S. Re-engineering the medication error-reporting process: removing the blame and improving the system. Am J Health Syst Pharm 2000; 57 (Suppl. 4): S10–7.

18 Pierson S, Hansen R, Green S, Williams C, Akers R, Jansson M, Carey T. Preventing medication errors in long-term care: results and evaluation of a large scale web-based error reporting system. Qual Saf Health Care 2007; 16: 297–302.

19 Kaldjian LC, Jones EW, Rosenthal GE, Tripp-Reimer T, Hillis SL. An empirically derived taxonomy of factors affecting physicians' willingness to disclose medical errors. J Gen Intern Med 2006; 21: 942–8.

20 National Institute for Clinical Excellence (NICE). Principles for Best Practice in Clinical Audit. Oxford: Radcliffe Publishing, 2002.

21 Hearnshaw H, Harker R, Cheater F, Baker R, Grimshaw G. A study of the methods used to select review criteria for clinical audit. Health Technol Assess 2002; 6: 1–78.

22 Gommans J, McIntosh P, Bee S, Allan W. Improving the quality of written prescriptions in a general hospital: the influence of 10 years of serial audits and targeted interventions. Intern Med J 2008; 38: 243–8.

23 Esmail R, Cummings C, Dersch D, Duchscherer G, Glowa J, Liggett G. Using Healthcare Failure Mode and Effect Analysis tool to review the process of ordering and administrating potassium chloride and potassium phosphate. Healthc Q 2005; 8: 73–80.