REVIEW

Medical errors and clinical risk management: state of the art

Errori medici e gestione del rischio clinico: stato dell'arte

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Summary

Medical errors represent a serious public health problem and pose a threat to patient safety. All patients are potentially vulnerable, therefore medical errors are costly from a human, economic, and social viewpoint. The present report aims not only to provide an overview of the problem on the basis of the published literature, but also to stress the importance of adopting standard terminology and classifications, fundamental tools for researchers to obtain valid and reliable methods for error identification and reporting. In fact, agreement on standard definitions allows comparison of data in different contexts. Errors can be classified according to their outcome, the setting where they take place (inpatient, outpatient), the kind of procedure involved (medication, surgery, etc.) or the probability of occurring (high, low). Error categories are analysed taking into consideration their prevalence, avoidance and associated factors as well as the different strategies for detecting medical errors. Incident reporting and documentation of near-misses are described as useful sources of information, and Healthcare Failure Mode Effect Analysis (HFMEA) and Root Cause Analysis (RCA) are seen as powerful methods for process analysis. Furthermore, means to increase patient safety are considered in the broader context of clinical risk management. New approaches in the field of medical errors are aimed at minimizing the recurrence of avoidable patterns associated with higher error rate. A system approach and a blame-free environment, aimed at better organizational performances, lead to much better results than focusing on individuals. Furthermore, use of technology, information accessibility, communication, patient collaboration and multi-professional team-work are successful strategies to reach the goal of patient safety within healthcare organizations.

Riassunto

Gli errori medici rappresentano un problema rilevante di sanità pubblica e pongono una minaccia alla sicurezza del paziente. Tutti i pazienti sono potenzialmente vulnerabili agli effetti degli errori medici, per questo motivo questi sono onerosi dal punto di vista umano, economico e sociale. Il presente lavoro fornisce una panoramica sul problema basandosi sulla letteratura scientifica ad oggi pubblicata. Viene sottolineata l'importanza di utilizzare una terminologia standardizzata e classificazioni riconosciute universalmente. La chiarezza terminologica e la correttezza metodologica consentono infatti la confrontabilità dei dati epidemiologici ottenuti in diverse realtà. Gli errori vengono caratterizzati in base alla gravità degli effetti che provocano sul paziente, al regime di cura (ricovero, day hospital, ambulatoriale), al genere di trattamento che prevedono (terapia farmacologica, intervento chirurgico, ecc.) e alla probabilità di accadimento (alta, bassa). L'errore medico viene valutato per prevalenza, prevenibilità e fattori contribuenti e sono state considerate diverse metodologie di rilevazione. La segnalazione (incident reporting) e la documentazione dei quasi-eventi (near miss) sono descritte come utili fonti di informazione, così come la HFMEA (Healthcare Failure Mode Effect Analysis) e la RCA (Root Cause Analysis) sono considerati efficaci strumenti di analisi dei processi di cura. I suggerimenti proposti per il superamento delle criticità del percorso assistenziale del paziente sono considerati parte integrante della gestione del rischio clinico. L'uso della tecnologia, l'accessibilità delle informazioni, la comunicazione e la collaborazione, la partecipazione del paziente ed il lavoro di gruppo multidisciplinare sono tutte strategie affidabili per raggiungere l'obiettivo del miglioramento della sicurezza del paziente all'interno delle organizzazioni sanitarie. Le iniziative da intraprendere nel campo degli errori medici hanno lo scopo di minimizzare la ricorrenza di pattern evitabili che siano associati ad una più alta quota di errori. Un approccio sistematico mirato all'ottimizzazione dell'organizzazione del lavoro raggiunge infatti risultati migliori rispetto a interventi mirati sui singoli individui.

Introduction

Medical errors represent a serious public health problem and pose a threat to patient safety. Despite a growing body of literature and research on errors in medicine, few studies have directly defined or measured "medical errors".

The problem of patient safety has been repeatedly identified in the medical literature since the mid 1950s, but regular surveys concerning patient deaths and injuries resulting from treatment have had almost no effect on current medical practice. Only very recently has the medical profession made a systematic effort to reduce or eliminate preventable deaths and injuries that occur in hospitals each year. Unnecessary tonsillectomies, for example, have been harshly condemned in the medical literature since the 1950s. However, the profession acted very slowly to limit this common procedure until public scandal, on the avoidable deaths of children, forced the issue in the early 1970s [1].

Definitions

Several definitions of medical errors exist but only the few formulated by valuable sources are worthy of consideration. An error is defined as the failure 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) [2]. Leape defines an error as an "unintended act (either omission or commission) or an act that does not achieve its intended outcome" [3]. Reason defines it as "failure of a planned sequence of mental or physical activities to achieve its intended outcome when these failures cannot be attributed to chance" [4]. The terms "error" and "adverse event" are often used interchangeably but it may be important to distinguish between them because they are conceptually separate. An adverse event is an injury caused by medical management rather than the underlying condition of the patient. An adverse event caused by an error is a preventable adverse event. Nearly all adverse events involve a combination of two sets of factors. Active failures are the unsafe acts committed by people who are in direct contact with the patient or system. Latent conditions are the inevitable "resident pathogens" within the system (Table I) [5]. Unlike active failures, the specific forms of which are often hard to foresee, latent conditions can be identified and remedied before an adverse event occurs and this leads to proactive rather than reactive risk management [6].

Types of errors

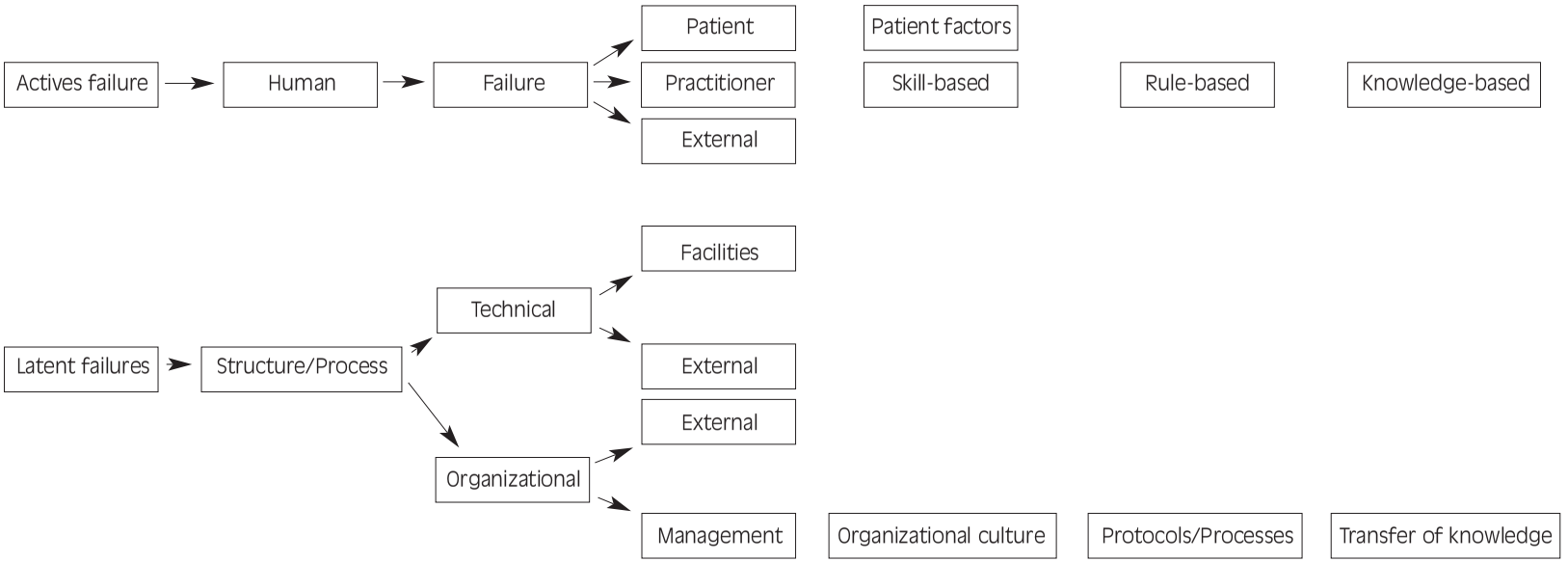
Although many classifications of medical errors have been presented, the most used is that published by the Institute of Medicine in an extensive report "To err is Human: building a safer health system" (Table II) [2]. It is extremely important to adopt standard definitions, throughout the world, on the same topic. In fact, lack of agreement on standard definitions would make it difficult for researchers not only to obtain valid and reliable data, but also to assess the impact of specific organizational interventions.

Some categories of error are more likely to be detected. Treatment-related errors are potentially more detectable than diagnostic and prevention errors, since the associated adverse events may occur quickly and visibly (e.g. inserting a breathing tube incorrectly into a patient's trachea). In fact, if a physician misdiagnoses a patient's condition, or a primary care provider does not regularly arrange for diabetic patients to undergo eye examinations, it might be months or even years before we can recognize that an error has occurred, largely because its recognition is related to an adverse event (e.g., in the case of the diabetic patient, blindness or glaucoma) [7]. We may never recognize that an error occurred in these types of patient care situations, simply because we are not aware of it until a specific adverse event takes place. These problems will be especially difficult to solve in outpatient care settings, where much of the patient care is non-acute and aimed at managing chronic conditions. Furthermore, more and more procedures currently take place in non-hospital settings. New techniques, equipment, and the drugs developed over the past ten years have made outpatient and office surgery more feasible. In general, procedures with a low rate of post-operative complications can be performed also in the day-hospital setting [8].

Errors can also be classified according to their outcome [9], the setting where they take place (inpatient, outpatient), the kind of procedure involved (medication, surgery, etc) or the probability to occur (high, low).

Error classification systems may need to be speciality-specific and reflect each speciality's realm of practice. Different classifications have been drawn up to fit fields such as laboratory medicine [9], anaesthesia [10], general practice [11], otolaryngology [12]. In otolaryngology, for instance, the critical areas that appear to be the more common cause, in order of frequency, are: technical errors (19.3% of all errors), medication errors (13.7%), errors related to testing (10.4%), errors in surgical planning (9.9%), equipment-related errors (9.4%), post-operative errors (8.5%), wrong site surgery (6.1%). These classifications should become familiar to all physicians, within a particular speciality, so that "ad hoc" interventions can be adopted to improve safety [12].

Table I. Classification of causes (JCAHO - Joint Commission on Accreditation of Healthcare Organizations).



Modified from Chang et al., 2005 [5].

Table II. Types of errors following IOM (Institute of Medicine) approach.

Diagnostic
Error or delay in diagnosis
Failure to employ indicated tests
Use of outmoded tests or therapy
Failure to act on results of monitoring or testing
Treatment
Error in 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 or in responding to an abnormal test
Inappropriate care
Preventive
Failure to provide prophylactic treatment
Inadequate monitoring or follow-up of treatment
Other
Failure of communication
Equipment failure
Other system failure

Modified from: Kohn LT et al., 1999 [2].

Epidemiology of medical errors

The largest population studies come from USA and Australia. The Harvard Medical Practice Study is the reference for estimating the extent of medical injuries occurring in hospitals [13]. Brennan et al. reviewed the medical charts of 30,121 patients admitted to 51 acute care hospitals in New York State, in 1984. They reported that preventable adverse events occurred in 3.7% of admissions (69% of injuries were caused by errors) [14]. In a study on the quality of Australian health care, a population based study modelled on the Harvard study, investigators reviewed the medical records of 14,179 admissions to 28 hospitals in New South Wales and South Australia in 1995 [15]. An adverse event occurred in 16.6% of admissions, resulting in permanent disability in 13.7% of patients and death in 4.9%; 51% of adverse events were considered to have been preventable.

A replication of the Harvard study was performed in Colorado and Utah on 15,000 patients. The incidence rate of preventable adverse events was 2.9% in the elderly, of which 3% led to death and 1.6% in the non-elderly, of which 1.9% led to death [16].

Furthermore, again in the US, the national rate of hospital-reported medical errors in hospitalised children was estimated to range from 1.8 to 3.0 per 100 discharges [17].

Medication errors and adverse drug events have been extensively investigated because they are both relevant and preventable. In a study carried out by Bates et al. in two teaching hospitals in Boston, 1% of the events where fatal, 12% were life-threatening, 30% were serious, and 57% were significant. Of the adverse events, 42% classified as life threatening or serious, were preventable. The medication errors were associated with the use of analgesics, antibiotics, sedatives, chemotherapeutic agents, cardiovascular drugs and anticoagulants [18]. In the UK critical care units, the incidence of prescription errors was found to be 15% and the five most common incorrect prescriptions were for potassium chloride, heparin, magnesium sulphate, paracetamol and propofol. Most of the errors were minor, but 19.6% were considered significant, serious or potentially life-threatening [19]. As far as the type of dispensing error is concerned, Rolland reported that wrong drug and wrong patient combined accounted for 67.1% of the reported errors [20].

Medication errors are also a major cause of morbidity and mortality among hospitalised children. Due to small volumes of solution involved, even a large error may occur with an unsuspiciously small dose [21].

Surgical error complications are common in hospitalised surgical patients. The Harvard Medical Practice Study conducted exhaustive reviews of over 30,000 charts and found that 47% of adverse events were associated with an operation, with wound infections and technical complications being the two most common surgery-related adverse events [14]. Healey et al. evaluating the total complication rate for general surgery, vascular surgery, combined general surgery and trauma, and cardio-thoracic surgery

in a University teaching hospital, found, rates respectively, of 30.3%, 42.4%, 32.3% and 26.9%. Almost 50% of these adverse events were judged by peers to be due to avoidable errors [22].

Risk factors such as age, complex care, urgent care and prolonged hospital stay have been associated with a higher rate of errors [13]. Slonim reported that the most seriously ill paediatric patients are also more likely to be subjected to prescription errors [17].

Andersen, collecting nurses and physicians' opinions, identified nine causes or associated factors for medical errors related to handling of medication: insufficient knowledge and uncertainty about procedures, ignorance of sources of error, poorly defined responsibilities, low community spirit, insufficient communication, clinician autonomy and low acceptance of change, strong professional identity, low priority task and logistic problems [23]. Miscommunication appears to play an important role in generating diagnostic and treatment errors. As many as 80% of the errors initiating cascades involve informational or personal miscommunication (among colleagues, between patient and physician, inaccessible medical records, etc.) [24]. Failures in communication sometimes relate directly to poorly written prescriptions. It is, therefore, not surprising that various bodies (the Royal College of Paediatrics and Child Health 1999, the British Medical Association and the Royal Pharmaceutical Society 2001) have made explicit guidelines regarding written prescriptions, i.e., avoid decimal points, use a leading zero before the first point, avoid abbreviations, etc. [25 26].

Even if staff usually report the number of hours worked as a factor affecting the chance of committing errors, Davydov concludes that there is no statistically significant correlation between the number of hours worked and the frequency or significance of the errors [27]. Instead, the prevalence of medical errors related to the discontinuity of care from the inpatient to the outpatient setting is high and may be associated with an increased risk of re-hospitalisation [28].

The individual health professional remains an important contributor to patient safety. Trainees are more likely to commit prescription errors, as a category [29]. Furthermore, a number of individual characteristics and the role they might play in terms of work practices that affect patient safety have been studied. The individual characteristics most likely to affect safety are low risk perception, sensation seeking, Type A behaviour (aggressive, competitive and impatient), high self esteem, psychological ill health, and attitudes concerning safety. More research is needed in this area and psychometrics should be considered as a potential aid in recognizing and addressing potential difficulties [30]. Medical errors are also a result of extreme specialization, as specialists generate more diagnostic hypotheses within their domain than outside, and assign higher probabilities to diagnoses within that domain [31].

Models and management of human error

Two approaches to the problem of human fallibility are possible: the individual and the system approach. The individual approach focuses on the errors of individuals, blaming them for forgetfulness, carelessness or moral weakness. The system approach concentrates on the conditions under which individuals work and tries to build defences to avert errors or mitigate their effects. The basic premise in the system approach is that humans are fallible and errors are to be expected, even in the best organizations. Blaming individuals is emotionally more satisfying for damaged patients than targeting institutions, but the person approach is weak for two main reasons. Firstly, it is often the best people who make the worst mistakes (error is not the monopoly of an unfortunate few). Secondly, far from being random, mishaps tend to fall into recurrent patterns [6].

The system approach, instead, copes with avoidable medical errors through potentially key components' strategies like team working, communication skills, evidence-based practice and further strategies for managing uncertainty [32]. Errors in medicine have to be seen as a dimension of quality of care and organizational performance. An effective response to harm must be based on a reliable risk management policy aimed at minimizing the chances of recurrence of an avoidable medical error.

Intervention in the field of medication errors, such as new hospital information systems for medication ordering, a review process to remove hazardous drugs from wards where they are not needed immediately, and the training of patients on the therapy they are taking, resulted in > 50% reduction of errors reaching the patient [21].

The handling of errors strongly contributes to citizens' choice of actions to be taken. Disclosure of error to patients, families, and hospital colleagues is a difficult process for most physicians, but while the severity of the outcome of errors remains the most important single factor in the choice of actions, the professional's approach to the error is regarded as essential in the overall evaluation of errors and the consideration of consequences. In errors with a severe outcome, an honest, partecipative, and accountable approach to the error decreases the probability of participant's support for strong sanctions against the physician involved by 59% [33].

Detection of medical errors

To analyse and plan to remedy a problem, it is first necessary to collect data about the problem and then

to summarize that data. Collection strategies include: retrospective chart review, performance monitoring, anonymous incident reporting, event audit and analysis of complaints and litigations [34]. Each strategy has unique strengths and none is sufficient by itself.
The analysis of incidents is a powerful method of learning about healthcare organizations and, hopefully, leads to improvements for enhancing patient safety, such as adopting protocols or organizational changes in the field where the error has been found more likely to occur. A non-punitive method of incident reporting is a key strategy that should be considered by health care providers in an attempt to reduce errors. If this is the goal, not only incidents, but also near misses have to be documented, where a near miss is defined as "any action or condition that could have caused an injury or damage". Near misses are useful tools, supporting patient safety, because they give a wider overview of the issue than only those incidents that really occur do.
Incident reporting as a means of identifying the causes of human error in medicine has its limitations: reports are not well distributed across all grades of staff, adverse consequences may only emerge over a matter of days, weeks or months, voluntary reporting is rarely used because the staff are not sure about anonymity, busy personnel do not have enough time to complete reports for small accidents, there are problems concerning classification and analysis, etc. [35].
The need still remains to evaluate the sensitivity and specificity of the various methods of error/near miss reporting.

Strategies to prevent medication errors: HFMEA and RCA

Evaluation of the system for potential causes of error or for errors that have already occurred can be performed using different tools, two of which are presented below.
Failure Mode and Effect Analysis (FMEA) is a systematic process for identifying potential process failures before they occur, with the intent to eliminate them or minimize the risk associated with them. Initiated in the 1940s by the U.S. military, FMEA was further developed by the aerospace and automobile industries. The VA National Center for Patient Safety developed a simplified version of FMEA that better applies to healthcare: HFMEA (Healthcare Failure Mode and Effects Analysis) [36]. This methodology is to prevention and proactive risk management as Root Cause Analysis (RCA) is to occurrence of adverse events. RCA is a structured analytic methodology used primarily to examine the underlying contributors to an adverse event or condition. HFMEA aims to identify, on a "priori" basis, the ways in which that process might potentially fall, the aim being to eliminate or reduce the likelihood and/or severity of the outcome of such a failure. The validity of the methodology is considered a gold standard, therefore organizations accredited by the JCAHO, for example, are required to conduct at least one HFMEA, or similar proactive analysis, annually.
To increase patient safety, one of the major advances, in recent years, has been computerization. Applications of technology in medicine are: order entry systems, especially computerized prescribing, bar-coding for medications, blood, devices and patients, electronic systems to communicate key pieces of asynchronous data, such as markedly abnormal laboratory values and software of clinical decision support [37]. Automation holds substantial promise, for improved safety, but error experts caution that all technology introduces the potential for new and different errors [38]. Staff must be taught the use of sophisticated software or automated systems in order to avoid problems. But medical decision support systems cannot rely exclusively on clinicians' perceptions of their information needs, as such perceptions are frequently incorrect. Clinicians who are overconfident (believe that they are correct when, in fact, they are not) are prone to medical errors [39].
Suggestions for strategies that should be considered by health care providers, in an attempt to reduce errors, are adherence to established policy and procedures, technology use, information accessibility, non-punitive approach to reporting of errors and near misses, teamwork, communication and collaboration, patient compliance, adequate number and range of staff, administrative support for the clinical goal of patient safety, application of HFMEA with team members' involvement, environment and equipment to support patient safety [40]. Healthcare providers must take a leading role in promoting a culture of safety in their organizations.

Final considerations

All patients are potentially vulnerable to the effects of errors. Therefore, medical errors are costly from a human, economic and social viewpoint. Key components in helping tomorrow's doctors to discuss, cope with and commit fewer medical errors are team work, communication skills, evidence-based practice and strategies for managing uncertainty [41].
Reduction of medical error and harm can be put in the broader context of safety and quality of care by providing a framework to assess and evaluate the structure, process and outcomes of care. Healthcare is characterized by a reliance on human operators who work with increasingly complex technology and variable levels of uncertainty. This can lead to error and needs to be managed through a framework where organizations are available for continuously improv-

ing the quality of services and safeguarding high standards of care.

A systematic approach to patient safety should be adopted where responsibility for safety is shared by all members of the healthcare teams [42]. In fact, significant errors occur in all phases of patient care. There is no single area where change will eliminate error. Likewise, a multitude of individuals and services are involved in errors. Although training physicians (or any other single profession) about errors should be beneficial, major strides in safety will likely require educating all those involved in patient care [12].

Efforts to reduce errors should be proportional to their impact on outcome (preventable morbidity, mortality, and patient satisfaction) and the cost of preventing them [43].

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