REVIEW ARTICLE

Errors and adverse events in medical and hospital assistance

Erros e eventos adversos na assistência médico-hospitalar

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ABSTRACT

Currently, one of the biggest challenges in medical and hospital assistance organizations is the implementation of actions to reduce the frequency of human errors and faults in processes and establishment of ways to ensure healthcare security. Therefore, it is necessary to recognize, measure, and evaluate the adverse errors/events and their determinants, and propose actions for better practices. This theme is of great relevance, particularly to critically ill patients, in the face of their significant susceptibility to complications. Errors in assistance processes potentiate risks of complications with consequent increases in morbidity, mortality, and welfare costs. The literature review shows how patients are exposed to a variety of adverse errors/events related to the medical and hospital assistance, which should be tackled as a real public health problem because of its deep impact (often irreversible) on individuals and the collective community, which also becomes a victim of these errors, resulting in sky-high costs related to complications that are shared by the entire society.

Key words: Intensive Care Unit; Medical Errors; Medication Errors; Cross Infection; Hospital Care; Delivery of Health Care; Medical Assistance.

RESUMO

Atualmente, um dos maiores desafios das organizações de assistência médico-hospitalar é implementar ações para reduzir a frequência de erros humanos e de falhas nos processos, e estabelecer formas de garantir a segurança assistencial. Para isso, é necessário reconhecer, dimensionar e avaliar os erros/eventos adversos e seus determinantes e propor ações de melhores práticas. Especialmente em relação aos pacientes criticamente enfermos, este tema se faz de grande relevância diante da expressiva suscetibilidade de complicações dessa faixa da população. Erros nos processos da assistência potencializam os riscos de complicações, com consequentes aumentos da morbimortalidade e dos custos assistenciais. A revisão da literatura mostra como os pacientes estão expostos a uma variedade de erros/eventos adversos relacionados à assistência médico-hospitalar, situação que deveria ser enfrentada como um verdadeiro problema de saúde pública diante dos profundos impactos (muitas vezes irreversíveis) nos indivíduos e na coletividade, esta última também uma vítima desses erros, devido aos altíssimos custos relacionados às complicações, custos estes compartilhados por toda a sociedade.

Palavras-chave: *Terapia Intensiva; Erros Médicos; Erros de Medicação; Infecção Hospitalar; Assistência; Assistência Hospitalar; Assistência Médica.*

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INTRODUCTION

In 1999, the Institute of Medicine (IOM) of the United States published the report "To err is human".[1] This report showed an estimated 44,000 to 98,000 deaths

per year occurring in the United States resulting from flaws in medical assistance. Approximately one million patients admitted to Americans hospitals each year were victims of adverse assistance events, being more than half of them from mistakes that could have been prevented. The deaths resulting from these episodes represent the fourth largest cause of mortality in that country.[2] They exceeded, for example, deaths attributable to car accidents (43,458), breast cancer (42,297), or AIDS (16,516).

The largest study conducted on adverse events was performed by the Harvard Medical Practice Study[3] published in 1991, which showed that adverse assistance events occurred in 3.7% of total admissions, being 69% attributable to errors (i.e. preventable) and 27.6% to negligence. Although 70.5% of events have resulted in disability lasting less than six months, 13.6% resulted in death, and 2.6% caused irreversible sequelae.

Publications from other countries report even more troubling numbers identifying the occurrence of harmful adverse events in 10% of all hospital admissions in Great Britain[4], 16.6% in admissions of adult patients in Australians hospitals, and 12.7% in Canada.[5]

Patients in intensive care units (ICU) constitute a group particularly susceptible to these events. An assessment of assistance failures that combined the methodology of passive reporting of occurrences and direct observation in a British adult medical-surgical unit detected 1.7 error per patient per day.[6] Of these, 29% were potentially harmful or determinants of death. Considering that the average stay in the adult medical-surgical ICU is approximately three days, these data suggest that virtually every patient admitted will have a chance to be exposed, during his hospitalization, to an episode of care failure with potential risk of injury or even death.

Associated with increased morbidity and mortality, hospital adverse events generate significant social costs. In the US, the total national costs related to preventable assistance errors (loss in production, disability, and health care costs) were estimated - at the end of the 90s – between $37.6 billion and 50 billion dollars per year.[1] More recently, the Juran Institute[7] and the National Institute for Healthcare Management[8] reported that 30% of global health costs in the US are determined by failures and errors originated in medical and hospital assistance. This same proportion was found in a study in New Zealand in the public hospital network.[9]

All these studies emphasize that adverse events related to medical and hospital care are common; they are described in reports from various countries and institutions of different characteristics, and possibly are underestimated and under-dimensioned. The issue of adverse events related to medical and hospital assistance is of such magnitude and social impact that it is unleashing a huge mobilization of governmental and non-governmental bodies – especially in the US, Europe, and the World Health Organization – for the control and prevention of these occurrences.

METHOD

The literature review was conducted through an electronic search in the MEDLINE, PubMed, Bireme, and Lilacs databases and specific websites covering the period from 1985 to 2011, using the following descriptors "evento(s)", "adverso(s)", "qualidade", "assistência", "unidade de terapia intensiva", "infecção hospitalar", "adverse", "events", "healthcare", "intensive care unit", "nosocomial infections," and "quality". In addition, theses and dissertations databases from Brazilian universities and national health agencies (National Health Surveillance Agency and National Supplementary Health Agency) were searched for studies in the Brazilian population. Out of the 92 identified articles, 30 were selected based on more relevance.

Terms and definitions for error and adverse events

Despite the safe assistance theme (or patient safety) being one of the most currently covered topics in the literature, the terms used in the various publications show considerable variation creating a difficult factor for synthesis and interpretation of data. The Health Quality Agency from the Department of Health of the United States Government (AHRQ) identified more than 70 correlated terms generating complex and overlapping definitions. To minimize this obstacle it offers recommendations suggested by different authors and organizations for the standardization of terms.[10]

In a report published by the US Institute of Medicine[1], the definitions adopted for "error" and "adverse event" are as follows:

- **error:** failure in a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning);

- **adverse event:** damage caused during the assistance process not determined by the patient's underlying medical conditions. An adverse event attributed to error is a "preventable adverse event."

Provonost et al.[6] use the AHRQ definitions:

- **patient safety:** the absence of damage to the patient related to the assistance process including the absence of "risk" (potential) of damage;
- **assistance errors:** errors that occurred during the healthcare process that result or have the potential to result in damage to the patient. Error includes failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

Thomas and Petersen[11] employ the terms "errors" and "adverse events" in a comprehensive manner. The term "error" includes: faults, almost occurred damage (close call, near misses), effective errors, and potential errors (latent). "Adverse events" include damage to the patient such as injury occurred by the assistive process and damage by iatrogenesis. The authors use the phrase "errors and adverse events" as a general definition contemplating all terms related to patient safety.

RESULTS – LITERATURE REVIEW

The referential study in the area of errors and adverse events related to assistance is the Harvard Medical Practice Study.[3] In this study, conducted in 1984 in New York State (USA), the random review of 30,195 hospital records involving patients of all age groups showed that 3.7% of patients were victims of adverse events, with 13.6% correlated deaths. The events related to drugs (19%), surgical site infection (14%), and technical errors (13%) were the most frequent, with almost half of them (48%) associated with mistakes in carrying out procedures. Other relevant findings of this study are:

- the events that occurred during surgery were less associated to negligence (17%) than those non-surgical (37%);
- the proportion of adverse events related to negligence was greater in noninvasive therapeutic accidents (77%), diagnostics (75%), and events occurring in the emergency room (70%);
- the identification of a high proportion of events associated with errors in processes suggests that many others are potentially preventable;
- the reduction in these events requires the identification of causes and development of methods to prevent errors or minimize their effects.

Later studies conducted in the USA, Australia, and Canada, using methodologies similar to that used by Harvard, identified adverse events that affected 2.9% to 16.6% of patients admitted in hospitals in the public and/or private network.[5, 12, 13] Furthermore, they showed the potential of these events to result in permanent disability (up 13.7% of exposed patients) or death (lethality of 4.9%).[12]

Among the adverse events defined in these studies, the most frequently identified were related to medication errors[5] and unplanned admissions/readmissions.[12]

Potential events against the safety of patients in pediatric ages (age < 19 years) were studied by Miller et al.[14] and Slonin et al.[15] These studies identified assistance errors ranging from 0.2 to 2.96 for every 100 discharges. Children with disabilities or dependent on mechanical technological support were the groups most susceptible to the occurrence of errors.

Hospital adverse events related to medicines are the most frequent and possibly the most underreported. In the study of Aspden[16], each patient hospitalized in the USA is subjected to one medication error per day, generating more than 400,000 preventable events per year.

Mistakes with medicines, despite the wide margin of occurrence variation – 5.75 to 30% of medical prescriptions in Pediatrics[17, 18, 19], appear as one of the most frequent in this age group. Kauschal et al.[17] reported that 20% of these errors are "almost errors", i.e., they are failures detected prior to drug administration; premature newborns are the main victims of failures in the process of medicines administration (91 per 100 admissions in the NICU). Woods et al.[19] identified that drug-related adverse events occur in at least 1% of pediatric patients with 0.6% of those considered preventable. Extrapolating to the American population, it has been estimated that about 70,000 hospitalized children are annually victims of mistakes involving medicines, with 60% likely to be preventable.

When the negative impact of preventable adverse events related to medicines is measured, it becomes relevant that the determinants and the nature of these errors be identified. These errors can occur in various phases of medicine use; however, prescription errors are the most serious and prevalent in hospitalized patients. Rosa[20] shows that prescription errors are events typically derived from mistakes (errors based

on the execution of an action), blackouts (memory-based errors), and errors in the planning of actions whose main predisposing conditions are: readability of the prescription, confusing and incomplete prescriptions, patient identification, date and use of abbreviations, and environmental and latent conditions.

In their evaluation work of incidence of errors in prescriptions containing potentially dangerous drugs in three Brazilian educational public hospitals, before and after the use of educational measures, Rosa[20] analyzed 2,667 prescriptions and found 80.98% of errors, rising to 97.3% when considering only prescriptions with potassium chloride. Errors were found in 75.3% of all prescriptions of non-fractionated heparin. After the implementation of educational measures, a significant reduction in the occurrence of errors ($p < 0.001$) was observed in the control hospital compared to the hospitals where no intervention took place.

Critically ill adult population

With a focus on the critically ill adult population, with more susceptibility to errors and undesirable events in intensive care, the Critical Care Safety Study[21] established the type of incident, its gravity, possibility of prevention, and also failures in process design or individual action. This study showed how frequent the occurrence of errors and adverse events is in this population and its high lethality. A total of 80.5 adverse events and 149.7 errors/1,000 patient-day were identified, being 45% of them preventable and 53% attributed to negligence. More than 10% of adverse events happened with risk of death or led to death.

Assad[22], in a study to identify errors and adverse events in four Brazilian centers for adult intensive care, found an incidence density of non-infectious errors/adverse events of 114.0/1,000 patients-day and infectious events of 25.2/1,000 patient-day. Out of the 2,110 monitored patients, 613 (29.1%) presented non-infectious errors/adverse events and 233 (11.2%) were related with some infectious adverse event. More than 75% of the non-infectious events were related to invasive procedures. VM-related pneumonia, primary laboratory sepsis, arterial or venous infection, and pneumonia unrelated to VM were responsible for about 70% of the total number of infectious events.

A significant data in this study was the finding that, in the final logistic regression model, in addition to the hospitalization time and use of invasive procedures shown as independent risk factors for the occurrence of failures, the degree of processes qualification measured by a score of quality certification (ISO 9001:2008, ISO 14001:2004, ISO 31 000:2009, the Brazilian Accreditation System – SBA/ONA, and the time of each certification) was also an independent risk factor.

The intensive care center with the highest certification degree and longest certification time presented occurrence of errors and adverse events significantly lower than the other centers ($p < 0.001$) suggesting that quality management with continuous improvement of processes and skills development is a critical factor in the prevention and minimization of assistance failures.

Critically ill pediatric population

The occurrence of adverse events in patients in the pediatric intensive care (age: 29 days to 18 years old) is also common, and especially related to invasive procedures with significant lethality. Stambouly et al.[23] found 27 adverse events/1,000 patient-day, being 52% of them related to mechanical ventilation. Approximately 16% of the patients who are victims of these events died.

The complications related to mechanical ventilation (MV) and endotracheal intubation in patients admitted in the pediatric intensive care unit were also studied by Rivera et al.[24] and Sadowiski et al.[25] More than 23% of the followed up patients suffered with complications; the most common being atelectasis, barotrauma, tissue injury, and accidental extubation. Accidental extubation showed an incidence density of 12 episodes/1,000 VM-day leading to a significantly longer time of permanence in VM (six days versus three) and longer time in the pediatric intensive care unit (eight days versus four). Out of these patients, 22% required reintubation.

Critically ill neonatal population

The studies involving exclusively the critically ill neonatal population (age ≤ 28 days old) show that low birth weight, prematurity, and use of invasive procedures are risk factors for the occurrence of assistance adverse events in this population.[26-28]

Kanter et al.[26] using the Health Care Cost and Utilization Project (HCUP) database found 1.2 error/100 newborns discharges, though strongly associated with

birth weight ($p < 0.001$). The most frequent errors were related to complications in invasive procedures (60%).

The study of Sherek et al.[27] aimed at using leads (such as infection, accidental extubation, and use of naloxone among others) to identify errors and adverse events in the NICU. All identified adverse events using the leads were evaluated for severity and possibility of prevention (among other objectives). Results found:

- 2,218 leads were identified or 2.96/patient;
- of these, 554 leads were classified as adverse events – 0.74/patient or 32.4 events/1,000 patient-days;
- the occurrence of adverse events was significantly different ($p < 0.0001$) between different gestational age ranges and birth weight: more occurrence in the range of gestational age ≤ 28 weeks and birth weight ≤ 1,500 grams;
- the most frequent adverse events were related to assistance related infection (27.8%), infiltration by vascular catheter (15.5%), abnormal brain imaging (10.5%), and accidental extubation requiring reintubation (8.3%).

In the work of Ligi[28], 25.6 events/1,000 patients-day were found. Hospital-acquired infections were the most frequent (59%), followed by respiratory events (35%). Low birth weight, prematurity, the average stay in the ICU, central vascular catheter, mechanical ventilation, and continuous positive airways pressure were identified as risk factors for the occurrence of adverse events.

Pedrosa[29] studied the critically ill Brazilian neonatal population in an observational study of a historical cohort of a newborn population consecutively admitted in neonatal intensive care units, between January 2002 and December 2005; the author found that out of the 1,895 monitored patients, 29.5% showed some non-infectious adverse event occurring more frequently in NBs ≤ 1,500 g ($p = 0.001$).

The incidence density of all non-infectious adverse events was 35.19 events/1,000 patient-day, being related for the most part, to CVC and VM invasive procedures. The density of incidence of infectious events was 26.04/1,000 patients-day. Primary bloodstream infection was the most common infection (33% of the total number of events), and more common in RNs ≤ 1,500 g ($p < 0.0001$).

In the Cox regression, the independent variables that were risk factors for the development of bloodstream primary infection until 11 days after exposure were birth weight ≤ 1,500 g ($p = 0.000$) and, a meaningful data, the identification of non-infectious adverse events related to VM as the determinant of risk ($p = 0.037$).

In addition to birth weight ≤ 1,500 g (this factor is already widely known in the literature), non-infectious adverse events related to VM are also important direct determinants of primary bloodstream infection in neonatal populations (up to 11 days after exposure).

This study shows that the prevention of serious infectious events in the neonatal population such as primary bloodstream infection passes not only by the control of microbiological factors but also by the restructuring of assistential processes with a focus on prevention of errors and events that generate episodes of hypoxia in the neonate.

DISCUSSION

The studies selected for this review show that errors/adverse events represent an important and still ill-defined determinant of increased complications and deaths in medical and hospital assistance, generating an impressive consumption of costs to the health system.

These errors and events are most commonly related to planning errors or execution flaws on what was planned in the assistance process, and are expressed particularly as complications associated with invasive procedures and use of medicines.

To get an idea of the magnitude of this problem in Brazil, but in the absence of official data, taking as reference the publications from the Juran Institute and NIHCM[7,8] and epidemiological indicators available on the Datasus and ANS[29] for the years of 2009/2010, more than 6 billion reais are wasted annually in the health system as the result of medical errors/adverse events (Table 1).

Therefore, according to the data in Table 1, it can be inferred that about 79,000 people die annually in Brazil as victims of errors and adverse events related to medical assistance. The 6 billion reais-year wasted in the Brazilian health system is a certainly undersized value because the SUS remunerates hospital procedures based on pre-defined packages, as it is the practice in large operators of the supplemental system to adopt standard or managed procedures. That means that the excess in costs, not covered by contracted values, is being borne by service providers, purchasers of health benefits, and by society.

Table 1 - Estimates of Brazilian costs of hospital errors and adverse events

Total hospital admissions SUS in 2010	11.276.962
Total hospital admissions Health Supplemental System in 2009	4.786.736
Total hospital admissions in the public and private sectors	16.063.68
SUS expenses with hospital admissions in 2010	R$ 10.688.801.568,81
Supplemental System expenses with hospital admissions in 2009	R$ 18.402.271.480,48
Total expenses in the public and private sectors with hospital assistance	R$ 29.091.073.049,29
Number of patients victims of errors and adverse events in Brazilian hospitals (3.7% of all admissions)	578.293
Number of deaths resulting from errors and adverse events (13.6% of all victimized patients)	78.648
Estimates of the contribution of adverse events on total costs (30%)	R$ 8.727.321.914,79
Estimated value of preventable costs (69%)	R$ 6.021.852.121,20

Studies on samples of the Brazilian population in intensive therapy[22, 29] concerning the quality and safety of medical prescriptions[20] confirm the findings in other countries, demonstrating decisively the urgent need of investments in management processes in Brazilian health services with the development of skills and best practices for safe assistential management. This should be one strategic goal of health policies in the country.

REFERENCES

1. Institute of Medicine. To err is human: building a safer health system. Washington DC: National Academy Press; 2000.
2. Bates DW, Spell N, Cullen DJ, Burdick E, Laird N, Petersen LA, *et al*. The costs of adverse events in hospitalized patients. JAMA. 1997; 277:307-11.
3. Brennan TA, Localio AR, Leape LL, Laird NM, Peterson L, Hiatt HH, *et al*. Incidence of adverse events and negligence in hospitalized patients. N Engl J Med. 1991; 324(6):370-6.
4. Stryer D, Clancy C. Patient's safety. BMJ. 2005; 330:553-4.
5. Forster AJ, Asmis TR, Clark HD. Ottawa hospital patient safety study: incidence and timing of adverse events in patients admitted to a Canadian teaching hospital. CMAJ. 2004 Apr; 170(8):1235-40.
6. Pronovost PJ, Thompson DA, Holzmueller CG, Lubomski LH, Morlock LL. Defining and measuring patient safety. Crit Care Med. 2005; 21(1):1-19.
7. Porter ME, Teisberg EO, editors. Redefining health care: creating value-based competition on results. Boston: Harvard Business School Press; 2006. 506 p.
8. National Institute for Healthcare Management. More care is not better care. [Cited 2007 Jul 03]. Available from: http://www.nihcm.org/~nihcmor/pdf/ExpertV7.pdf.
9. Brown P, McArthur C, Newby L, Lay-Yee R, Davis P, Briant R. Cost of medical injury in New Zealand: a retrospective cohort study. J Health Serv Res Policy. 2002; 1(supl 1):29-34.
10. Agency for Healthcare Research and Quality. Implementation planning study for the integration of medical event reporting input and data structure for reporting to AHRQ, CDC, CMS, and FDA. Final Report. Volume 1 - Technical Report. 2002. [Cited 2007 May 10]. Available from: http://www.ahrq.gov/downloads/pub/rfp020015/MERIP.pdf.
11. Thomas EJ, Petersen LA. Measuring errors and adverse events in health care. J Gen Intern Med. 2003; 18:61-7.
12. Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena T, Williams EJ, *et al*. Incidence and types of adverse events and negligent care in Utah and Colorado. Med Care. 2000; 38(261):261-71.
13. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The quality in Australian health care study. Med J Aust. 1995; 163:458-71.
14. Miller MR, Elixhauser A, Zhan C. Patient safety events during pediatric hospitalizations. Pediatrics. 2003; 111(6):1358-66.
15. Slonim AD, LaFleur BJ, Ahmed W, Joseph JG. Hospital-reported medical errors in children. Pediatrics. 2003; 111(3):617-21.
16. Aspden P, Wolcott J, Bootman JL, Cronenwett LR. (editors). Committee on identifying and preventing medication errors. Washington DC: The National Academies Press; 2007. 544 p.
17. Kaushal R, Bates DW, Landrigan C. Medication errors and adverse drugs events in pediatric inpatients. JAMA. 2001; 285:2114-20.
18. Lehmann CU, Kim GR. Prevention of medical errors. Clin Perinatol. 2004; 32:107-23.
19. Woods D, Thomas E, Holl J, Altman S, Brennan T. Adverse events and preventable adverse events in children. Pediatrics. 2005; 115(1):155-60.
20. Rosa MB. Avaliação de intervenções educativas na prescrição de medicamentos potencialmente perigosos em três hospitais de Belo Horizonte [dissertação]. Belo Horizonte (MG): Universidade Federal de Minas Gerais; 2011.
21. Rothschild JM, Landrigan CP, Cronin JW, Kaushal R, Lockley SW, Burdick E, *et al*. The critical care safety study: the incidence and nature of adverse serious medical errors in intensive care. Crit Care Med. 2005; 33(8):1694-700.
22. Assad EC. Erros e eventos adversos não infecciosos relacionados à assistência em terapia intensiva de adultos [dissertação]. Belo Horizonte (MG): Universidade Federal de Minas Gerais; 2011.
23. Stambouly JJ, McLaughlin LL, Mandel FS, Boxer RA. Complications of care in a pediatric intensive care unit: a prospective study. Intensive Care Med. 1996; 22:1098-104.
24. Rivera R, Tibballs J. Complications of endotracheal intubation and mechanical ventilation in infants and children. Crit Care Med. 1992; 20(2):193-9.

25. Sadowski R, Dechert RE, Bandy KP, Juno J, Bhatt-Metha V, Custer JR, *et al*. Continuous quality improvement: reducing unplanned extubation in a pediatric intensive care unit. Pediatrics. 2004; 114(3):628-32.

26. Kanter DE, Turenne W, Slonim AD. Hospital-reported medical errors in premature neonates. Pediatric Crit Care Med. 2004; 5(2):119-23.

27. Sharek PJ, Horbar JD, Mason W, Bisarya H, Thurm CW, Suresh G. Adverse events in the neonatal intensive care unit: development, testing and findings of an NICU-focused trigger tool to identify harm in North American NICUs. Pediatrics. 2006; 118(4):1332-40.

28. Ligi I. Iatrogenic events in admitted neonates: a prospective cohort study. Lancet. 2008; 371(9610):404-10.

29. Pedrosa TMG. Erros e eventos adversos não infecciosos relacionados à assistência em terapia intensiva neonatal: epidemiologia e sua associação com a sepse primária laboratorial [dissertação]. Belo Horizonte (MG): Universidade Federal de Minas Gerais; 2009.