

The assessment of adverse events in hospitals in Brazil

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Abstract

Objective. To evaluate the incidence of adverse events in Brazilian hospitals.

Design. Retrospective cohort study based on patient record review.

Setting. Three teaching hospitals in the State of Rio de Janeiro, Brazil.

Participants. Random sample (1103) of 27 350 adult patients admitted in 2003. Patients under 18 years old, psychiatric patients and patients whose length of stay was less than 24 hr were excluded, and obstetric cases were included.

Main Outcome Measure(s). Incidence of patients with adverse events; proportion of preventable adverse events; number of adverse events per 100 patients and incidence density of adverse events per 100 patient-days.

Results. The incidence of patients with adverse events was 7.6% (84 of 1103 patients). The overall proportion of preventable adverse events was 66.7% (56 of 84 patients). The incidence density was 0.8 adverse events per 100 patient-days (103 of 13 563 patient-days). The patient's ward was the most frequent location of adverse events (48.5%). In regard to classification, surgical adverse events were the most frequent ones (35.2%).

Conclusions. The incidence of patients with adverse events at the three hospitals was similar to that in international studies. However, the proportion of preventable adverse events was much higher in the Brazilian hospitals.

Keywords: adverse events, retrospective patient record review, patient safety, quality in health care

Introduction

The Harvard Medical Practice Study, conducted in New York State in 1984, drew attention to the occurrence of adverse events in hospitals, as a severe and little-known problem [1]. Several other studies were published subsequently in developed countries, using a similar methodology based on retrospective patient record reviews: in the USA [2], Canada [3], Denmark [4], France [5], Australia [6], New Zealand [7], UK [8] and more recently Spain [9].

The retrospective patient record review method, considered the 'gold standard' for the identification of adverse events, has been criticized due to its cost and limitations for monitoring the occurrence of adverse events in health services [10]. However, the measurement of frequency of adverse events and the identification of the most common causes have been important stages adopted by several countries to draw attention to the seriousness of the problem and to guide the development of policies for patient safety. A recent review indicates that prospective or retrospective studies do not explain the differences observed in adverse outcome rates between studies. However, study methodology

is an important factor, which can influence the mortality differences [11].

In Brazil, as in other developing countries, research on adverse events has focused on the frequency of adverse events associated with specific causes, e.g. medication use [12] and emergency care [13]. Still, it is important to know the overall incidence of patients with adverse events during hospital stay in order to understand the problem's magnitude in Brazilian hospitals and to encourage and orient the development of policies to improve quality. This study aims to evaluate the incidence of adverse events in Brazilian hospitals based on a retrospective patient record review.

Methods

Adverse event was defined as an unintended injury or harm resulting in death, temporary or permanent disability or dysfunction, or prolonged hospital stay that arises from health care. The study design was a retrospective patient record review, based on the assessment tools developed by the Canadian Adverse Event Study [3]. At our request, the

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Canadian Study team authorized us to use their assessment instruments. The study was performed in three public teaching hospitals in the State of Rio de Janeiro that provide acute care and emergency care. Obstetric care is provided by two of them. Teaching hospitals were selected because of their willingness to participate and the comparatively higher quality of their patient records.

The study population consisted of 27 350 patients admitted in the year 2003. A random sample of patients was selected. The sample frame excluded patients under 18 years old, patients who stayed in the hospital less than 24 hr and cases with psychiatric diagnoses. Unlike the Canadian study, obstetric cases were included in the sample due to the persistently high maternal mortality rate in Brazil (73 maternal deaths per 100 000 live births in 2003). It must be noted that the great majority of deliveries in Brazil occur in hospitals (97%). The parameters used to define the sample size were based on the Canadian study: a 10% expected incidence of patients with adverse events (maximum absolute error 3%) and a 50% proportion of potential adverse events and, with a significance level of 5%. The loss rate was estimated at 10%. The rate of ineligible patients was estimated at 20%. The final sample size was 1628 patients, with 1103 eligible for the study.

Assessment of adverse events involved two phases. Phase 1 was an explicit patient record review by nurses to screen for patients potentially with adverse events based on screening criteria (trigger tools). At least one screening criterion determined that the record should be included in the second phase review. Phase 2 was an implicit structured review by physicians.

Reviewers were trained using standard patient records specially selected for this purpose. Reviewers were only authorized to perform fieldwork after reaching at least 80% agreement with these patient records. All the physicians and nurses had more than 20 years of professional experience.

The phases 1 and 2 review forms, developed by the Canadian study, were translated and adapted to the context of Brazilian hospitals. The forms were translated from English to Portuguese by two different translators, followed by a comparison of the two versions. An expert panel decided by consensus on the best translation of key terminology. The expert panel consisted of nine physicians with clinical, surgical, intensive-care, epidemiological and pharmaceutical backgrounds.

The expert panel also decided on the list of screening criteria to be used, based on the Canadian study list of screening criteria. The expert panel suggested the exclusion of two, the addition of one and the modification of five screening criteria. Excluded criteria were: Criterion 1, 'Unplanned hospitalization (including readmission) as a result of any health care provided during the 12 months prior to the index admission', and Criterion 2, 'Unplanned admission to any hospital during the 12 months following discharge from the index admission'. These were judged inappropriate in the Brazilian context, because of lack of systematic documentation in the patient records about details of previous admissions to the same hospital or to other hospitals. The added criterion refers to increases in creatinine level during hospital

stay. This criterion was included to identify patients who developed acute renal failure while in hospital. Other modifications were based on the writing for accuracy of understanding. The adapted forms were pre-tested and back-translated [14]. Software was developed for data collection.

The exclusion of the two screening criteria suggested by the expert panel had an impact on both the incidence of patients with adverse events and the proportion of preventable adverse events, but these differences were not statistically significant ($P > 0.05$). The new criterion of 'starting from a normal creatinine in admission, the value increased to twice the admission value during hospital stay' was identified 17 times but did not change either the incidence or the proportion of preventable adverse events. For purposes of comparison, the results presented in this article adhered strictly to the Canadian list of screening criteria.

In the phase 2 review, the physicians first identified the occurrence of unintentional injuries or harm. Then, they analyzed injuries or harm for any association with temporary or permanent disability and/or prolonged hospital stay or death. Finally, using the six-point scale from the Canadian study, they determined whether the injury or harm was caused by the care provided to the patient. This scale ranges from (1) 'virtually no evidence' to (6) 'virtually certain evidence'. An injury or harm is classified as an adverse event when it is rated as 4 or more. The preventability of the adverse events is also judged according to a six-point scale, with an adverse event classified as preventable when rated as 4 or more.

The target patient safety measures included: incidence of patients with adverse events (number of patients with at least one adverse event/total number of patients); proportion of preventable adverse events (number of patients with preventable adverse events/total number of patients with adverse events), number of adverse events per 100 patients and incidence density of adverse events per 100 patient-days (number of adverse events/sum of hospital days across all study patients).

Descriptive analysis included patient characteristics: sex and age (age group: 18–20; 21–30; 31–40; 41–50; 51–60; 61–70 years; and 70 years and older); adverse event classification—diagnostic error, surgical procedure, orthopedic care (fractures), medication, anesthesia, obstetrics, clinical procedure, system (organization); type of error—omission and commission; location of the adverse event—inside the hospital (ward, surgery room, intensive care unit, emergency room, delivery room, procedure room, service area and out-patient service) and outside the hospital (home and other places)—and time of occurrence and detection of the adverse event.

Reliability in screening criteria between nurse reviewers was measured at a significance level of 5%, using simple agreement statistics given the small number of comparisons. After each 10 cases reviewed, the following case was also reviewed by a second reviewer, previously assigned as the first reviewer's pair for purposes of comparison. Cases for testing inter-rater agreement were automatically selected by the software. Simple agreement between nurse reviewers in

assessing potential adverse events was judged as good, although it was better between nurses A and B (80.6%; 95% CI: 74.0–92.0) than between nurses C and D (77.8%; 95% CI: 64.7–93.2). Inter-rater reliability was not tested in the phase 2 review, because the assessment was performed by a single physician.

The software generated a Microsoft Software Access database, which was exported to Microsoft Software Excel format, and the data were analyzed using Stata 10.0.

Results

A total of 1103 patients were considered eligible cases. Of these, 888 (80.5%) were non-obstetric patients. Of the total cases, 676 (61.3%) were female. Even excluding obstetric cases, the majority of cases were women: 462 (52%). The mean age of patients was 46.9 years (standard deviation 19.1) with a median age of 46 years. The most frequent age group was 18–30 years old: 292 (26.5%). When excluded the obstetric cases, the predominant age group turned to be 51–60 years old: 160 (18.0%). Inpatient mortality rate was 8.5% (94 of 1103) (95% CI: 6.9–10.2), and there were no cases of maternal death.

Of all the patients, 452 (41.0%; 95% CI: 38.1–43.9) had at least one potential adverse event, i.e. met at least one positive screening criterion. When obstetric patients were excluded, 395 patients had at least one potential adverse event (44.5%; 95% CI: 41.2–47.8).

The total number of positive screening criteria was 834 (Table 1). The two predominant positive screening criteria were: Criterion 18, 'Any unwanted events not mentioned above' and Criterion 1, 'Unplanned hospitalization (including readmission) as a result of any health care provided during the 12 months prior to the index admission'. Screening Criterion 17, 'Documentation or correspondence indicating litigation, whether merely intent to sue or actual lawsuit' was not detected in any case (Table 1).

Of all the patients, 84 had at least one adverse event. The total number of positive screening criteria among those 84 patients was 349. The three most frequent positive screening criteria in adverse events were: Criterion 3, 'Occurrence of injury or harm to patients during hospitalization', Criterion 15, 'Hospital infections/septicemia' and Criterion 9, 'Other unexpected complications during index admission which are NOT a normal development of patient's disease or expected result of treatment' (Table 1).

The incidence of patients with adverse event was 7.6% (84 of 1103 patients) (95% CI: 6.0–9.2). The proportion of preventable adverse event was 66.7% (56 of 84 patients) (95% CI: 56.4–77.0). In the 84 patients, 103 adverse events were identified. Number of adverse events per 100 patients was 9.3 (103 of 1103) (95% CI: 7.6–11.1) and the incidence density of adverse events was 0.80 adverse events per 100 patient-days (103 of 13 563 patient-days) (95% CI: 0.60–0.90). Among patients with adverse events, 17.9% have had more than one adverse event. On average, among patients with adverse event, it was observed 1.2 events per patient.

Incidence of non-obstetric patients with adverse events was 8.6% (76 of 888 patients) (95% CI: 6.7–10.4), and the proportion of preventable adverse events was 65.8% (50 of 76 patients) (95% CI: 54.9–76.7). Among obstetric patients, eight experienced one or more adverse events or a 3.7% (8 of 215 patients) incidence of obstetric patients with adverse events (95% CI: 1.2–6.3). The proportion of preventable adverse events in these patients was 75.0% (6 of 8) (95% CI: 36.3–113.7).

Among the 94 deaths in the study population, 32 (34.0%) had an adverse event, and 25 (78.1%) of these were classified as having experienced a preventable adverse event. The most frequent class of adverse events was surgical procedures (35.2% of all cases). Second in frequency were medical procedures (30.6%) (Table 2). The proportion of errors by omission was 35.0% (36 of 103), and that of errors due to the care provided (commission) was 65.0% (67 of 103). The highest frequency of adverse events was observed in the wards (48.5%), followed by the operating room (34.7%) and intensive care unit (11.9%) (Table 3). The most frequent times of occurrence (85.4%; 88 of 103) and detection (91.3%; 94 of 103) of adverse events were during admission.

Discussion

The incidence of patients with adverse events was 7.6%, and 66.7% of the adverse events were preventable. Excluding obstetric cases, the incidence of patients with adverse events was 8.6%. Studies focusing on health care quality improvement have shown incidence similar to this study: New Zealand (11.3%), Australia (16.6%), UK (10.8%), Denmark (9.0%), France (14.5%), Spain (9.3%) and Canada (7.5%) [3–9].

However, the proportion of preventable adverse events (66.7%) observed in this Brazilian study was higher than that observed in other studies: New Zealand (61.6%), Australia (50%), UK (52%), Denmark (40.4%), France (27.6%) and Spain (42.6%) [4–9]. The Canadian adverse event study [3] showed a proportion of preventable adverse events of 36.9% (95% CI: 32.0–41.8). The contrast between the proportion of preventable adverse events in Brazil and these other countries suggests that patient safety problems may be more frequent in Brazil than in developed countries. Moreover, the proportion of preventable adverse events was higher among patients who died in hospital compared with those who survived.

Assessment of the preventable nature of unwanted outcomes poses a major challenge, due mainly to the inherent complexity of health care processes. There is no valid instrument to unequivocally judge whether an event could have been prevented. In general, other factors can have synergistic or antagonistic effects. Outcome assessment is usually based on subjective (or implicit) criteria and standards, backed by the expertise, practical experience and clinical decision-making of specialists [15].

As observed in other studies [3, 8, 9], 17.9% of patients with adverse events had more than one event. However, the

Table 1 Distribution of screen-positive criteria for potential adverse events and adverse events

Screening criteria ^a	Potential adverse events, N (%)	Adverse events, N (%)
1. Unplanned admission (including readmission) as a result of any health care provided during the 12 months prior to the index admission	124 (14.9)	20 (5.7)
2. Unplanned admission to any hospital during the 12 months following discharge from the index admission	334 (4.0)	4 (1.1)
3. Occurrence of injury or harm to patient during hospitalization (including any harm, injury, or trauma occurring during index admission)	87 (10.4)	53 (15.2)
4. Adverse drug reaction	24 (2.9)	11 (3.2)
5. Unplanned transfer to intensive or semi-intensive care unit ^a	24 (2.9)	17 (4.0)
6. Unplanned transfer from or to another acute care hospital (excluding transfers for specialized exams, procedures, or care not available in the original hospital) ^a	18 (2.1)	3 (0.9)
7. Unplanned return to surgery room	20 (2.4)	17 (4.9)
8. Unplanned removal, injury, or repair of an organ or structure during surgery, invasive procedure, or vaginal delivery	6 (0.7)	3 (0.9)
9. Other unexpected complications during index admission which are NOT a normal development of the patient's disease or an expected result of the treatment	109 (13.1)	50 (14.3)
10. Development of a neurological alteration absent at admission, but present at the time of discharge from the index admission (includes neurological alterations related to procedures, treatments, or investigations) ^a	16 (1.9)	14 (4.0)
11. Death ^a	94 (11.3)	46 (13.2)
12. Inappropriate hospital discharge/inadequate discharge plan from index admission (excludes unauthorized discharge)	15 (1.8)	4 (1.1)
13. Reversed cardio-respiratory arrest ^a	19 (2.3)	10 (2.9)
14. Injury related to abortion or labor and delivery	6 (0.7)	2 (0.6)
15. Hospital infection/septicemia (excludes infections/septicemia occurring fewer than 72 hr after admission)	76 (9.1)	51 (14.6)
16. Dissatisfaction with care received as documented on patient record, or evidence of complaint lodged (includes documents, documented complaint, conflicts between patient/family and health care professionals, and unauthorized discharge)	22 (2.6)	4 (1.1)
17. Documentation or correspondence indicating litigation, whether merely intent to sue or actual lawsuit	0 (0.0)	0 (0.0)
18. Any unwanted events not mentioned above	141 (16.9)	40 (11.5)
Total	834 (100.0)	349 (100.0)

^aModified criteria: Criterion 5, the word 'semi-intensive' was included; Criterion 6, the word 'from' was included (this matches the definition of the criteria in the Canadian study); Criterion 9, the word 'unexpected' was included (this matches the definition of the criteria in the Canadian study); Criterion 10, neurological deficit was changed to neurological alteration; and Criterion 11, the word 'unexpected' was excluded (this match the criteria in the Harvard Medical Practice study).

incidence density of adverse events per 100 patient-days in this Brazilian study was lower (0.80 adverse events 95% CI: 0.60–0.90) than the one observed for all hospital in the Spanish study (1.2 adverse events), but near to the one observed for medium-sized hospitals (0.99 adverse events 95% CI: 0.85–1.12). Possibly these differences are related to variations in hospitals characteristics, as the length of stay that was 12.3 days for all patients in this Brazilian study. Extended length of stay has previously been shown to be associated with increased adverse events [6].

The modifications suggested by the expert panel in the list of screening criteria did not produce statistically significant changes in the outcome measures. This finding corroborates that it is more important to focus on the comprehensiveness

of the group of screening criteria (i.e., criteria are not mutually exclusive) than on a single criterion's inclusion/exclusion. Still, non-specific criterion, such as Criterion 18, 'Any unwanted events not mentioned above', showed high frequency in the study, despite representing fewer cases with adverse events. Possible causes for the high percentage of cases selected on the bases of unspecified criterion might be the recurrent problem of lack of medication in hospitals in the study and other problems related to the hospital's structure/system.

The fact that six out of eight cases (75%) with a principal diagnosis related to obstetrics were preventable adverse events highlights the relevance of including obstetric admissions in studies on adverse events in Brazilian hospitals.

Table 2 Classification of adverse events

Classification	Adverse event, N (%)
Surgical	38 (35.2)
Medical procedures	33 (30.6)
Diagnosis	11 (10.2)
Obstetric	9 (8.3)
Medication	6 (5.6)
Fractures	2 (1.9)
Anesthetic	1 (0.9)
System events	7 (6.5)
Others	1 (0.9)
Total	108 (100.0) ^a

^aIn five adverse events, two were classified in two classes.

Table 3 Percentage distribution of adverse events by location

Location	Adverse event, N (%)
Inside the hospital	
Room or ward	49 (48.5)
Surgery room	35 (34.7)
ICU	12 (11.9)
Emergency room	1 (1.0)
Delivery room	1 (1.0)
Procedures room	1 (1.0)
Service area	1 (1.0)
Ambulatory	1 (1.0)
Sub total	101 (100.0)
Out of hospital	
Home	2 (50.0)
Other place	2 (50.0)
Sub-total	2 (100.0)
Total	105 (100.0) ^b

ICU, intensive care unit.

^aIn two adverse events, two locations were identified.

In Brazilian hospitals, more adverse events were due to commission (65%) than omission (35%) of care. This differs from the proportion observed in the Canadian study, adverse events due to omission was 57.1% for medicine and 50.8% for surgery services [3].

Several methodological limitations should be mentioned. The quality of data in the patients' records has still not been systematically assessed. Quality problems can cause underestimation of the incidence of adverse events. The preliminary results of phase 1 predictive validity comparing trigger assessment performed by physicians (gold standard) to nurse assessment showed a sensitivity of 69%, suggesting that the incidence of patients with adverse events in this study was underestimated. Importantly, the validity of the implicit evaluation (phase 2) depends on the physician reviewer's experience and knowledge.

Conclusion

The study analyzed only three hospitals, representing a limited sample of all the hospitals in Rio de Janeiro State, Brazil. In addition, the criteria used led to selection of the best hospitals. Teaching hospitals can be expected to have better patient records and better quality-of-care than the average non-teaching hospital. However, the hospitals included here could have a higher incidence of patients with adverse events, because they are teaching hospitals with higher patient acuity. The reported incidence of patients with adverse events in teaching hospitals in other studies was higher than in non-teaching hospitals [3]. Finally, the high volume of obstetric cases decreased the relative proportion of non-obstetric cases, a point to be considered in future studies. However, this study's findings clearly support the inclusion of obstetric cases in countries with low-quality maternal care.

The study showed a high proportion of preventable adverse events in Brazilian teaching hospitals, thus emphasizing the magnitude and characteristics of patient safety problems in Brazilian hospitals in general. The adverse events assessment tools adopted in this study can provide the basis for the development of monitoring strategies and can be applied in association with methods to evaluate adverse events of specific origins. These are approaches for creating learning opportunities and the potential for change in the development of safer health care.

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References

1. Kohn LT, Corrigan JM, Donaldson MS *et al.* *To Err Is Human*. Washington, DC: National Academic Press, 2000.
2. Thomas EJ, Studdert DM, Burstin HR *et al.* Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care* 2000;**38**:261–71.
3. Baker GR, Norton PG, Flintoft V *et al.* The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *Canadian Med Assoc J* 2004;**170**:1678–86.

4. Schioler T, Lipczak H, Pedersen BL *et al.* Danish Adverse Event Study, incidence of adverse events in hospitals. A retrospective study of medical records. *Ugeskr Laeger* 2002;**164**: 4377–9.
5. Michel P, Quenon JL, Sarasqueta AM *et al.* Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *Br Med J* 2004;**328**:199–202.
6. Wilson RM, Runciman WB, Gibbert RW *et al.* The quality in Australian health care study. *Med J Aust* 1995;**163**:458–71.
7. Davis P, Lay-Yee R, Schug S *et al.* Adverse events regional feasibility study: indicative findings. *N Z Med J* 2001;**114**: 203–5.
8. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *Br Med J* 2001;**322**:517–9.
9. Aranaz-Andrés JM, Aibar-Remón C, Vitaller-Murillo J *et al.* Incidence of adverse events related to health care in Spain: results of the Spanish National Study of Adverse Events. *J Epidemiol Community Health* 2008;**62**:1022–9.
10. Murff HJ, Patel VL, Hripcsak G *et al.* Detecting adverse events for patient safety research: a review of current methodologies. *J Am Med Assoc* 2003;**36**:131–43.
11. Marang-van de Mheen PJ, Hollander EJ, Kievit J. Effects of study methodology on adverse outcome occurrence and mortality. *Int J Qual Health Care* 2007;**19**:399–406.
12. Rozenfeld S. Agravos provocados por medicamentos em hospitais do Estado do Rio de Janeiro, Brasil. *Rev Saúde Pública* 2007;**41**:108–15.
13. Daud-Gallotti R, Dutilh Novaes HM, Lorenzi MC *et al.* Adverse events and death in stroke patients admitted to the emergency department of a tertiary university hospital. *Eur J Emerg Med* 2005;**12**:63–71.
14. Mendes W, Travassos C, Martins M *et al.* Adaptação dos instrumentos de avaliação de eventos adversos para uso em hospitais brasileiros. *Braz J Epidemiol* 2008;**11**:55–66.
15. Donabedian A. *An Introduction to Quality Assurance in Health Care*. Oxford: Oxford University Press, 2003.

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