

Article

The application of Iberoamerican study of adverse events (IBEAS) methodology in Brazilian hospitals

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Abstract

Objective: To assess the prevalence of adverse events (AE) and to investigate its association with factors related to the patient and to hospital admission.

Design: Cross-sectional study.

Setting: Four general hospitals located in the southeastern region of Brazil.

Participants: All patients admitted to the participating hospitals at the time of the study were surveyed.

Intervention: The methodology was based on the Iberoamerican study of adverse events, a two-stage medical record review.

Main Outcome Measure: Medical records were screened for AE only in the day (24-h) immediately before the review process, independently of the admission date.

Results: A total of 695 admissions were examined. Prevalence was 12.8%. Almost 43% of AE were preventable. More than 60% of patients with an event prolonged hospital stay. In final regression model, urgent admission (OR: 2.68; Confidence Interval (CI) 95%: 1.53–4.69), submission to a procedure (odds ratio (OR): 2.41; CI 95%: 1.33–4.39), presence of central venous catheter (OR: 2.25; CI 95%: 1.14–4.41) and immunosuppressive therapy (OR: 3.41; CI 95%: 1.57–7.40) were statistically associated with AE.

Conclusions: Our results indicate that around 1.3 AE happen in each 10 hospital admissions in Brazil. As patient safety continues to be a Public Health concern worldwide and mainly in developing countries, this would indicate the potential use of prevalence measures for monitoring patient safety in Brazilian context.

Key words: patient safety, adverse events, epidemiology and detection, healthcare quality improvement, hospital medicine

Introduction

Patient safety has gained prominence in the international debate about quality of healthcare since the 1999 Institute of Medicine report 'To Err Is Human' [1]. Despite the debate [2], a recent study states that medical errors are the third leading cause of death in the

USA [3]. At the same time, sizeable efforts and initiatives have been developed to reverse this situation [4].

The concept of adverse event (AE) is essential to the analysis in the Patient Safety domain. Since the Harvard Medical Practice Study in 1990 [5], several studies have been conducted to evaluate the

frequency of AE in the USA, Australia, New Zealand, UK, Canada, Denmark, France, Brazil, Spain, Tunisia, the Netherlands, Portugal, Italy, countries around the Mediterranean Sea and recently, Ireland [6–20]. Most of them were based on the retrospective review of medical records methodology and reported AE incidence rates ranging from 2.9% to 16.6% of all hospital admissions and preventable AE proportion rates ranging from 27% to 83%.

Considering the importance of Patient Safety and the impact of AE in terms of morbidity and mortality, studies that evaluate magnitude and methods of detection remain relevant, especially in developing countries.

Brazil is the largest country in Latin America, with a total population of 206 million inhabitants [21]. Brazilian Health System is public and universal but around 25% of its population has private health insurance. In 2009, a retrospective cohort study based on patient charts review was conducted, evaluating AE incidence and proportion of preventable AE [13].

Although prevalence studies can be useful strategies for monitoring the occurrence of AE, few studies reporting prevalence measures of AE have been done worldwide. The methodology used in such studies is similar to that used in the retrospective ones but unlike incidence's study, in the former patients were screened for AE only in the 24-h immediately prior to the review process [22]. A French study compared three methods for estimating rates of AE, including the cross-sectional design [12], showing dependency between the study design and measure/magnitude of the safety problems. The Iberoamerican study of adverse events (IBEAS) is the largest published study of prevalence of AE, conducted in five Latin American countries (Argentina, Colombia, Costa Rica, Mexico and Peru). This was mainly a sectional study, but also a concurring follow-up study was performed to estimate AE incidence from a sample of patients from the prevalence study [22].

In Brazil, following the incidence study [13], the research team engaged in a prevalence study to determine the prevalence of AE, as well as to investigate its association with factors related to the patient and to hospital admission.

Methods

This is a cross-sectional study based on the review of medical records in four general hospitals located in the Southeastern Region of Brazil. These are three public hospitals and one private general hospital.

The methodology applied in this study was based on the IBEAS, a prevalence study developed in five Spanish spoken countries, which estimated the point prevalence of patients showing an AE. According to this methodology, a prevalent AE is the AE that is present on the day of observation [22]. The nomenclature used in this study was based on the Harvard Medical Practice Study, according to which an AE is 'an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge or both' [6].

Regarding inclusion and exclusion criteria, all hospital admissions were included, regardless of their diagnosis or the hospitalization area or medical specialty. Even if the patient was not present at the moment of the study screening, but his/her medical record was present, the data collection was normally performed. All patients admitted to the participating hospitals at the time of the study were surveyed. Medical records were screened for AE only in the day (24-h) immediately before the review process, independently of the admission date. Data collection took place between 2010 and 2011.

Medical record review was conducted according to two stages: during stage 1, the screening for AEs was performed by nurses with clinical experience using the Screening Form; during stage 2, AE identification was performed by doctors (clinicians or medical residents) using the Modular Form (MRF-2). In stage 1, 19 criteria were used for screening AEs. The presence of at least one criterion caused the case to be selected for completing module A of the MRF-2 form. In this module, physicians had to describe patient comorbidities, hospital admission information, probability of an AE occurrence and AE characteristics (such as AE preventability and type: if related to general care, medication, hospital-acquired infection, related to diagnosis or to a procedure and others). AE related to a procedure included surgery, anesthesia, chemotherapy, radiotherapy, fracture treatment and other invasive procedures. Therefore, in stage 2, a structured implicit review was used to identify the AE based on completion of the MRF-2 form. The two electronic forms were adapted and translated to Portuguese by the research team with the participation of a linguistic specialist. No validity testing was applied in the translation process.

Four evaluators were selected in each hospital (two nurses and two physicians). They were previously trained for two consecutive days and at the end agreement among nurses were found to be 100%.

Before considering an AE, the physician needed to fill out the causality assessment module of MRF-2 form which consists on a six-point scale on chance of an AE occurrence. A score >3 means that the analyzed event was an AE. Also, the physician reviewer had to complete the MRF-2 form by assessing the AE preventability scale (six-point scale on chance of a preventable AE). A score >3 in this scale means that the AE was preventable.

A total of 695 admissions were examined in this study. Figure 1 below shows the number of screened admissions, number of AE detected and also the number of preventable AE, based on the two-steps methodology applied.

Exposure variables considered in this study were social and demographic characteristics, type of admission, patient intrinsic and extrinsic factors, presence and types of comorbidities and submission to a procedure during the admission. The outcome was AE occurrence.

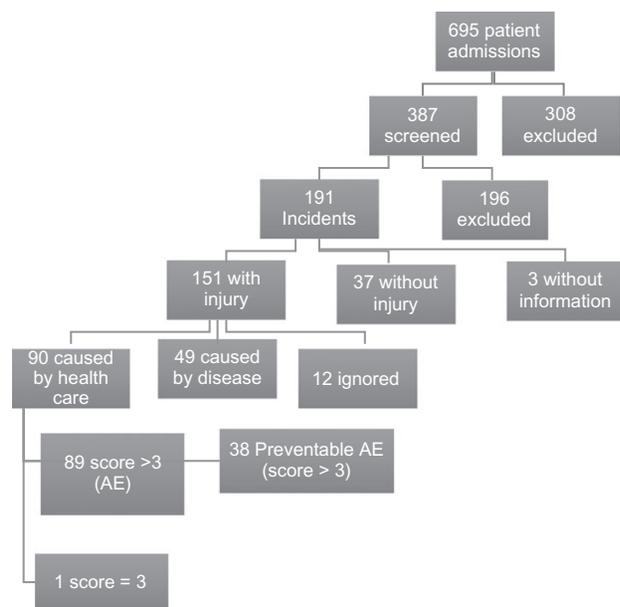


Figure 1 Medical records review and screened cases.

Regarding intrinsic and extrinsic factors, these were risk factors potentially associated with an AE occurrence, collected during stage 1 (Screening Form). Intrinsic factors were considered exposure variables related to the patient or case severity, such as, coma, renal insufficiency, diabetes, cancer, immunodeficiency/AIDS, chronic pulmonary disease, leukopenia, chronic hepatopathy, obesity, hypoalbuminemia/malnutrition, pressure ulcer, congenital malformations, cardiac insufficiency, coronary artery disease, arterial hypertension, hypercholesterolemia and alcoholism. Extrinsic factors were exposure variables related to hospital care, such as, closed urinary catheter system, peripheral venous catheter, arterial catheter, peripherally inserted central catheter, central venous catheter, parenteral nutrition, enteral nutrition, nasogastric/nasoenteral tube, tracheostomy, mechanical ventilation, tracheal intubation, immunosuppressive therapy, infusion pump, hemodialysis and peritoneal dialysis.

Chi-squared tests were conducted to test the association between variables. A final logistic regression model was built to analyze the association between exposure and outcome. The software IBEAS-Brazil System was developed for the study purpose to allow electronic data collection and to avoid double entries in the process of screening and assessment of AEs. Data were analyzed using Stata/IC software version 11 (Stata Corporation, College Station, USA). The study was approved by the Ethics Committee of Oswaldo Cruz Foundation (No. 549/10).

Results

Most patients were male (52.7%), with a median age of 63 years (Interquartile range—IQR: 45–77). Almost 90% of patients had comorbidities (88.6%). Among them, arterial hypertension was the most prevalent (56.8%), followed by diabetes (27.9%), other endocrine disorders (26.3), coronary disease (25.5%) and cardiac insufficiency (25.2). Urgent admissions were the most frequent type of admissions (57.4%) and 66% of patient underwent a procedure during the admission (Table 1).

Table 1 Characteristics of the study population regarding social and demographic factors, comorbidities and hospital admission factors (695 inpatients)

Variables	n	%
Social and demographic		
Men	366	52.7
70 years of age or older	271	39.0
White	299	95.2
College degree	117	33.7
Comorbidities		
Hypertension	214	56.8
Diabetes	105	27.9
Endocrine disorders ^a	99	26.3
Coronary disease	96	25.5
Cardiac insufficiency	95	25.2
Anemia	79	21.0
Cancer	73	19.4
Allergies	63	16.7
Chronic kidney disease	53	14.1
Hospital admission		
Type of admission (urgent)	397	57.4
Procedure during admission	454	65.7
Total	695	100.0

^aFor example: thyroid and adrenal disorders.

Regarding risk factors, collected during stage 1, the most frequent intrinsic factors among patients were arterial hypertension (47.6%), mellitus diabetes (21.7%) and cancer (20.3%). The most frequent extrinsic factor found was peripheral venous catheter (74.4%), infusion pump (34.1%) and closed urinary catheter system (24.6%). In binary analysis of intrinsic factors, renal insufficiency and arterial hypertension were statistically associated with an AE ($P < 0.05$). Among extrinsic factors, closed urinary catheter system, central venous catheter, enteral nutrition, nasogastric/nasoenteral tube, tracheostomy, mechanical ventilation, tracheal intubation, immunosuppressive therapy, infusion pump and hemodialysis were statistically associated with AE occurrence ($P < 0.05$) (Table 2).

About 89 patients had an AE prevalence of 12.8%. Thirty-eight of them (42.7%) were evaluated as preventable. Additional hospitalization days due to AE were almost 40 days and 11.6 additional days in ICU hospitalizations. The severity of the event was mild in 13.3% of cases, which means that the AE did not increase the

Table 2 Frequency of intrinsic factors (factors associated with the patient) and extrinsic factors (factors related to hospital care) and their association with AE occurrence

	n	%	P-value
Intrinsic risk factors			
Coma	26	3.8	0.324
Renal insufficiency	63	9.1	<0.001
Mellitus diabetes	150	21.7	0.930
Cancer	140	20.3	0.262
Immunodeficiency/AIDS	13	1.9	0.573
Chronic pulmonary disease	55	8.0	0.421
Leukopenia	11	1.6	0.705
Chronic hepatopathy	32	4.6	0.120
Drug abuse	2	0.3	0.586
Obesity	27	3.9	0.139
Hypoalbuminemia/malnutrition	16	2.3	0.423
Pressure ulcer	36	5.2	0.086
Congenital malformations	21	3.0	0.259
Cardiac insufficiency	52	7.5	0.111
Coronary artery disease	124	18.0	0.370
Arterial hypertension	329	47.6	0.029
Hypercholesterolemia	70	10.1	0.995
Prematurity	4	0.6	0.441
Alcoholism	16	2.3	0.963
Extrinsic risk factors			
Open urinary catheter system	12	1.7	0.179
Closed urinary catheter system	170	24.6	<0.001
Peripheral venous catheter	513	74.4	0.129
Arterial catheter	88	12.8	0.214
Peripherally inserted central catheter	4	0.58	0.469
Central venous catheter	157	22.8	<0.001
Umbilical venous catheter	3	0.43	0.504
Umbilical arterial catheter	1	0.14	0.700
Parenteral nutrition	9	1.3	0.066
Enteral nutrition	97	14.1	<0.001
Nasogastric/nasoenteral tube	98	14.2	<0.001
Tracheostomy	42	6.1	0.008
Mechanical ventilation	97	14.1	<0.001
Tracheal intubation	86	12.5	<0.001
Immunosuppressive therapy	44	6.4	0.001
Infusion pump	235	34.1	0.010
Hemodialysis	30	4.4	<0.001
Peritoneal dialysis	5	0.7	0.634

Bold: P-values less than 0.05 considered statistically significant.

hospital stay; moderate in 60.2% of cases, that is, prolonged hospital stay for at least 1 day; and severe in 26.5% of cases, which means that the AE caused death, disability at hospital discharge or required surgery. The most frequent types of AE were general care and related to procedure (27.6% each), followed by infection (19.4%), medication (18.4%) and diagnosis (2.0%), the less frequent in this study (Table 3).

In binary analysis, no association was found between AE occurrence and social and demographic variables (gender, age and education). Type of admission (urgent) was statistically associated with AE ($P < 0.001$). The variables admission sector and presence of comorbidity were not associated with AE occurrence in this study. On the other hand, submission to a diagnostic or a treatment procedure during the admission was statistically associated with AE ($P = 0.001$).

In the final model of logistic regression (Table 4), including the exposure variables which showed statistical significance with AE prevalence in binary analysis, only type of admission, submission to a diagnostic or a treatment procedure, central venous catheter and immunosuppressive therapy remained associated with AE. Urgent admission and submission

to a procedure during admission increased more than two times the chance of having an AE (OR: 2.68; CI 95%: 1.53–4.69, and OR: 2.41; CI 95%: 1.33–4.39, respectively). In this phase, no patient factors presented statistical significance. However, presence of central venous catheter nearly doubled the chance of having an AE (OR: 2.25; CI 95%: 1.14–4.41), possibly due to patient severity condition. Submission to immunosuppressive therapy increased more than three times the chance of having an AE (OR: 3.41; CI 95%: 1.57–7.40). This extrinsic factor was strongly related to medication AE ($P = 0.001$). Among the 12 cases that referred immunosuppressive therapy as an extrinsic factor, eight of them (66.7%) had one medication AE.

Discussion

In the present study, we found a prevalence of 12.8% of AE in four Brazilian hospitals, higher to the prevalence found in IBEAS study (10.5%). This is probably due to the similar nature of hospitals selection and the same methodology applied. As in IBEAS study, in this study the selection of hospitals was voluntary and based on feasibility, which tends to include services more engaged in patient safety actions or concerns [22]. However, we found a lower proportion of preventable AE (42.7%) compared with IBEAS study (60%) and to our previous incidence study (66.7%) [13], which may be explained by the specificity of our sample: patients with higher education levels, coming from better quality hospitals.

Although Michel *et al.* [12], when comparing three methods for AE detection, found similar AE rates between the prospective and retrospective methods (15.4% and 14.5%, respectively), and the lowest rate when using the cross-sectional method (9.8%), our study found a higher AE rate compared with the previous incidence study (7.6%) [13]. This finding is also probably related to the nature of our sample and its size, comparatively to incidence study: better quality hospitals, with better healthcare, greater patient safety concerns and better hospital documentation.

In this study, urgent admission, submission to a surgical or invasive procedure, presence of central venous catheter and submission to immunosuppressive therapy were factors with the greatest contribution to AE occurrence. Gender, age and presence of comorbidity, and the intrinsic factors did not show effect on the chance of having an AE. We suspect that may be comorbidities registration in patient records is affected by underestimation [23], or may be, due to the characteristics of the prevalence design, with 24-h evaluation, the

Table 3 Adverse events characteristics: prevalence, preventability, severity, types and impact

	<i>n</i>	%
Adverse events		
AE Prevalence	89	12.8
Preventable AE	38	42.7
AE severity		
Mild	13	13.3
Moderate	59	60.2
Severe	26	26.5
Types of AE		
General care	27	27.6
Procedure	27	27.6
Hospital-acquired infection	19	19.4
Medication	18	18.4
Diagnosis	2	2.0
AE impact	Mean	SD
Additional hospitalization days due to AE	39.9	34.9
Additional ICU days due to AE	11.6	18.9

SD, standard deviation; ICU, intensive care unit.

Table 4 Final logistic regression model of the association between AE occurrence and hospital admission factors

Variables	Odds ratio	CI 95%	<i>P</i> -value
Urgent admission	2.68	1.53–4.69	0.001
Submission to a procedure during the admission	2.41	1.33–4.39	0.004
Renal insufficiency	1.61	0.71–3.62	0.251
Arterial hypertension	1.53	0.94–2.48	0.087
Closed urinary catheter system	1.08	0.57–2.05	0.812
Central venous catheter	2.25	1.14–4.41	0.019
Enteral nutrition	1.32	0.45–3.83	0.612
Nasogastric/nasoenteral tube	1.12	0.39–3.25	0.835
Tracheostomy	0.75	0.25–2.27	0.614
Mechanical ventilation	1.08	0.29–4.04	0.912
Tracheal intubation	1.12	0.35–3.64	0.848
Immunosuppressive therapy	3.41	1.57–7.40	0.002
Infusion pump	0.68	0.35–1.29	0.238
Hemodialysis	1.57	0.55–4.48	0.398

Bold: *P*-values less than 0.05 considered statistically significant. CI: Confidence interval.

information related to patient factors was underrepresented, comparatively to admission factors. In a previous study, conducted by the research group using an incidence design, comorbidity was associated both with AE and death [24]. In this study, admission factors seem to be representative of patient severity.

Therefore, although variables measuring patient comorbidity factors have not shown statistical significance, the association of AE with type of admission (urgent) and also with presence of central venous catheter seems to indicate case severity. Central venous catheter could also indicate AE due to central line infection. Patients submitted to immunosuppressive therapy had three times more chance of having an AE and most of them are medication AE, which indicates an important area of AE prevention. According to our results, 60.2% of patients had moderate AE and had a prolonged hospital stay for at least 1 day. This finding is alarming considering that prolongation of hospitalization time increases the chance hospital-acquired infections, as well as increases the cost for the healthcare system.

Generally, emergency admissions are more severe compared with elective and scheduled admissions. In IBEAS original study, urgent admissions also increased the risk of having an AE (OR: 1.34; CI 95%: 1.12–1.61). Thereby, these results showed that more attention should be given in urgent admissions, especially in the emergency department, with health team continual training to detect and avoid such problems. The performance of diagnostic and therapeutical procedures during admission should follow checklists and guidelines to avoid AE occurrence, as well as patients submitted to tracheal intubation deserve more attention by the caregiver. These results suggest that quality of care initiatives should focus on those high-risk patients in order to reduce the risk of AE and also reduce mortality, such as the ongoing initiatives for reducing the risk of postoperative respiratory complications, including death, in major abdominal surgeries [25].

The limitations of this study are related to the characteristics of our sample size. First, interpretation of results should take into consideration that this is not a random sample representative from all the Brazilian hospitals and that the hospitals were chosen by convenience. The frequency of AE may vary as the hospitals characteristics vary. Some statistical analyses were impaired due to our limited sample size. We performed analysis according to AE preventability and severity, but did not show statistical significance. Also, the quality of collected data (for example, case severity) must have been affected by the poor quality of medical records. Besides, it is important to note that, as this is a cross-sectional design, no causality has been established between exposure and outcome, but on the other hand, the intention is to create a hypothesis that should be tested in longitudinal studies.

Regarding research instruments, we observed that, in some cases, pressure ulcer was both classified as an AE and an intrinsic factor for the same patient. We considered these cases inconsistencies and we proceeded to reclassify them as adverse events. Future research using the same instrument should consider to intensify evaluators training in the identification of the presence of pressure ulcer before admission comparatively to its development during the hospitalization to avoid misclassification.

Despite the limitations, this is the first prevalence study of AE conducted in Brazilian hospitals and it adapted and translated to Portuguese a methodology used in a previous published Latin American study [22]. Although the methodological differences, drew attention the rates obtained by the incidence and prevalence studies have been close. Our results indicate that around 1.3 AE happen in each 10 hospital admissions in Brazil. This is alarming considering the specificity of our sample size.

As patient safety continues to be a Public Health concern worldwide and mainly in developing countries, this would indicate the potential use of prevalence measures for monitoring patient safety in Brazilian context. Considering the convenience regarding costs and methodology, prevalence designs, rather than incidence ones, can be a useful tool for monitoring AE rates in hospitals.

Supplementary material

Supplementary material is available at *International Journal for Quality in Health Care* online.

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References

1. Kohn LT, Corrigan JM, Donaldson MS. (Institute of Medicine). *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press, 2000.
2. Shojania KG, Dixon-Woods M. Estimating deaths due to medical error: the ongoing controversy and why it matters. *BMJ Qual Saf* 2017;**26**: 423–8. doi:10.1136/bmjqs-2016-006144.
3. Makary MA, Daniel M. Medical error—the third leading cause of death in the US. *BMJ* 2016;**353**:i2139.
4. Shekelle PG, Pronovost PJ, Wachter RM *et al.* The top patient safety strategies that can be encouraged for adoption now. *Ann Intern Med* 2013;**158**:365–8.
5. Brennan TA, Leape LL, Laird NM *et al.* Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med* 1991;**324**:370–6.
6. 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.
7. Wilson RM, Runciman WB, Gibberd RW *et al.* The quality in Australian health care study. *Med J Aust* 1995;**163**:458–71.
8. Davis P, Lay-Yee R, Briant R *et al.* Adverse events in New Zealand public hospitals I: occurrence and impact. *NZ Med J* 2002;**115**:U271.
9. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001;**322**:517–9.
10. Baker GR, Norton PG, Flintoft V *et al.* The Canadian adverse events study: the incidence of adverse events among hospital patients in Canada. *CMAJ* 2004;**170**:1678–86.
11. 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.
12. Michel P, Quenon JL, de Sarasqueta AM *et al.* Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *BMJ* 2004;**328**:199–202.
13. Mendes W, Martins M, Rozenfeld S *et al.* The assessment of adverse events in hospitals in Brazil. *Int J Qual Health Care* 2009;**22**:1–6.
14. Aranaz-Andrés JM, Aibar-Remón C, Vítaller-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**:1022–29.

15. Letaief M, Mhamdi SE, El-Asady R *et al.* Adverse events in a Tunisian hospital: results of a retrospective cohort study. *Int J Qual Health Care* 2010;**22**:380–85.
16. Zegers M, Bruijne MC, Wagner C *et al.* Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. *Qual Saf Health Care* 2009;**18**:297–302.
17. Sousa P, Uva AS, Serranheira F *et al.* *Segurança do doente: eventos adversos em hospitais portugueses: estudo piloto de incidência, impacte e evitabilidade*. Lisboa: Editora Escola Nacional de Saúde Pública, 2011. ISBN 978-989-97342-0-3.
18. Sommella L, de Waure C, Ferriero AM *et al.* The incidence of adverse events in an Italian acute care hospital: findings of a two-stage method in a retrospective cohort study. *BMC Health Serv Res* 2014;**14**:358.
19. Wilson RM, Michel P, Olsen S *et al.* Patient safety in developing countries: retrospective estimation of scale and nature of harm to patients in hospital. *BMJ* 2012;**344**:e832.
20. Rafter N, Hickey A, Conroy RM *et al.* The Irish National Adverse Events Study (INAEs): the frequency and nature of adverse events in Irish hospitals—a retrospective record review study. *BMJ Qual Saf* 2017;**26**:111–19.
21. Brazilian Institute of Geography and Statistics. <http://www.ibge.gov.br/apps/populacao/projecao/> (June 2016, date last accessed).
22. Aranaz-Andrés JM, Aibar-Remón C, Limón-Ramírez R *et al.* Prevalence of adverse events in the hospitals of five Latin American countries: results of the Iberoamerican study of adverse events (IBEAS). *BMJ Qual Saf* 2011;**20**:1043–51.
23. Pavão AL, Andrade D, Mendes W *et al.* Incidence of in-hospital adverse events in the State of Rio de Janeiro, Brazil: evaluation of patient medical record. *Rev Bras Epidemiol* 2011;**14**:651–61.
24. Martins M, Travassos C, Mendes W *et al.* Hospital deaths and adverse events in Brazil. *BMC Health Serv Res* 2011;**11**:223.
25. Pearse RM, Abbott TE, Haslop R *et al.* The Prevention of Respiratory Insufficiency after Surgical Management (PRISM) Trial. Report of the protocol for a pragmatic randomised controlled trial of CPAP to prevent respiratory complications and improve survival following major abdominal surgery. *Minerva Anesthesiol* 2017;**83**:175–82. doi:10.23736/S0375-9393.16.11502-0.