Original Article

The Incidence, Nature and Consequences of Adverse Events in Iranian Hospitals

Ali Akbari Sari MD PhD•[1], Leila Doshmangir PhD[2,3,4], Fereshteh Torabi MD[1], Arash Rashidian MD PhD[1], Mojtaba Sedaghat MD PhD[3], Robabeh Ghomi MSc[4], Nittita Prasopa-plaizier MD[5]

Abstract

Introduction: Adverse events are relatively common in healthcare, leading to extensive harm to patients and a significant drain on healthcare resources. Identifying the extent, nature and consequences of adverse events is an important step in preventing adverse events and their consequences which is the subject of this study.

Methods: This is a retrospective review of medical records randomly selected from patients admitted to4 general hospitals, staying more than 24 hours and discharged between April and September 2012. We randomly selected 1200 records and completed the record review for 1162 of these records. Standard forms (RF1 and RF2) were used to review medical records in two stages by nurses and medical doctors.

Results: Eighty-five (7.3%) of the 1162 records had an adverse event during the admission; and in 43 (3.7%) of the 1162 records, the patient was admitted to the hospital due to an adverse event that occurred before the admission. Therefore, a total of 128 (11.0%) adverse events occurred in 126 (10.9) records as two patients had more than one adverse event. Forty-four (34.3%) of these 128 adverse events were considered preventable.

Conclusions: This study confirms that adverse events, particularly adverse drug reactions, post-operative infections, bedsore and hospital acquired infections are common and potentially preventable sources of harm to patients in Iranian hospitals.

Keywords: Adverse events, hospital, incidence, Iran

Cite this article as: Akbari Sari A, Doshmangir L, Torabi F, Rashidian A, Sedaghat M, Ghomi R, Prasopa-plaizier N. The Incidence, Nature and Consequences of Adverse Events in Iranian Hospitals. *Arch Iran Med*. 2015; **18(12):** 811 – 815.

Introduction

Adverse events are the cause of significant harm to patients needing healthcare. An adverse event is usually defined as any unwanted injury to the patient, which is caused by medical management rather than by the disease process or the patient's own actions.[1] This area (adverse events) has received a significant amount of attention, especially in the last few years. Large-scale U.S. and Australian epidemiological studies of adverse events have estimated that 3%–16% of patients admitted to hospitals suffer some kind of adverse event, of which 30%–70% were considered to be preventable with ordinary standards of care.[2–6] Several other studies have been conducted to explore the extent and nature of adverse events in developed countries,[7–9] but it seems that there is a lack of evidence from developing countries. This is the first epidemiological study in Iranian hospitals to estimate the extent, nature and preventability of adverse events in Iranian general hospitals.

Authors' affiliations: [1]Department of Health Management & Economics, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran. [2]School of Management and Medical Informatics, Tabriz University of Medical sciences, Tabriz, Iran. [3]Iranian Center of Exellence in Health Management, Tabriz University of Medical sciences, Tabriz, Iran. [4]Tabriz Health Services Research Center, Tabriz University of Medical sciences, Tabriz, Iran. [3]Department of Social Sciences, School of Medicine, Tehran University of Medical Sciences, Tehran, Iran. [4]Department of Neonatal Intensive Care Nursing and Midwifery, School of Nursing, Tehran University of Medical Sciences, Tehran, Iran. [5]La Trobe University, World Health Organization, Geneva, Switzerland.

•**Corresponding author and reprints:** Ali Akbari Sari MD PhD, Department of Health Management and Economics, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran. E-mail: akbarisari@tums.ac.ir

Accepted for publication: 7 October 2015

Materials and Methods

Setting

The study was carried out in three large hospitals (hospitals with more than 600 beds) in the capital Tehran and a medium hospital with 250 beds in a city in western Iran. The specialties included were Medicine, General Surgery, Urology, Orthopedics, ICU, CCU, A&E, ENT, Ophthalmology, Pediatrics and Women's Health. We excluded Mental Health and patients that stayed shorter than 24 hours in the hospital. We randomly selected 1200 hospital records from inpatients discharged from each selected hospital between April and September 2012.

Study design

The method we used was a retrospective medical record review using structured data extraction tools - RF1 form for screening and RF2 form for confirmatory reviews (Diagram 1). This is a modification of the methods used by the Harvard, Australia and UK studies.[2,4–5,10–11] This study included two parts. In the first stage, nurses reviewed medical records using RF1 Form. In this stage, identification of one or more positive criteria was considered as an indicator of a potential adverse event and therefore, any record with a positive answer in RF1 was forwarded to the doctor(s) for confirmatory review (RF2). In the second stage, a structured review form (RF2) was completed by medical doctors. Two med-

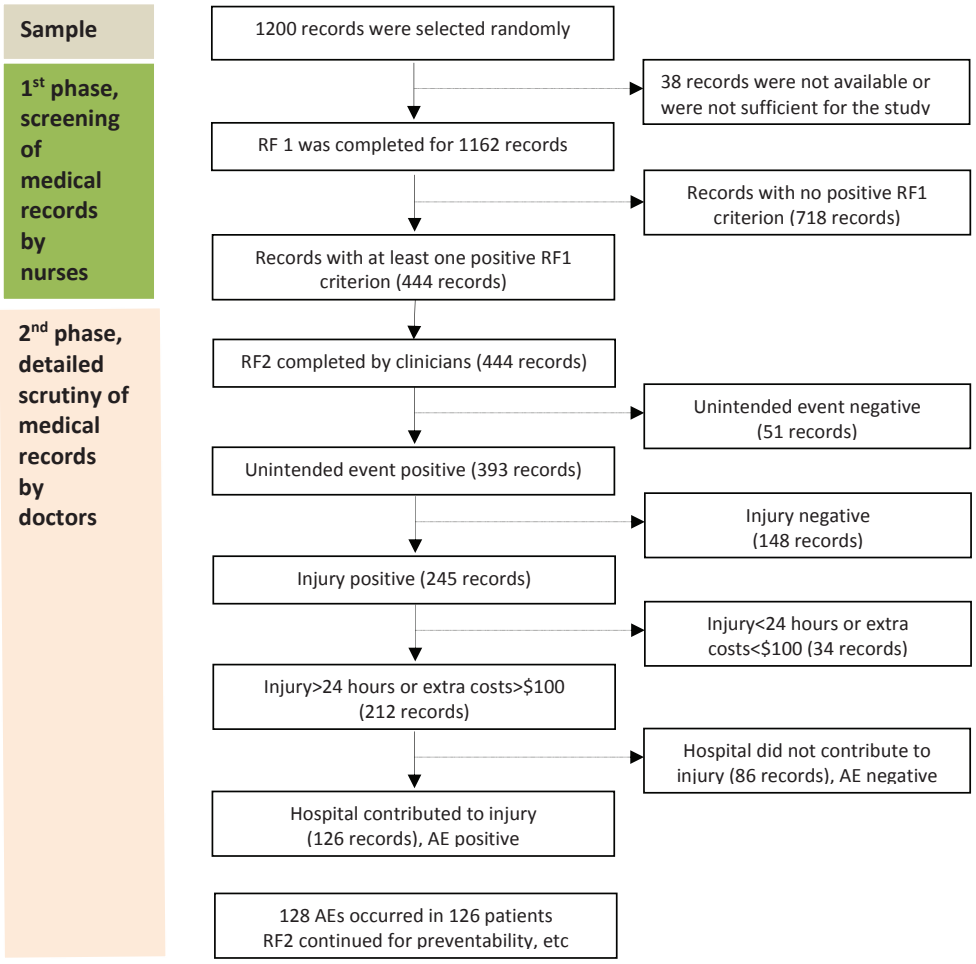

Diagram 1. Summary of the record review process.

ical doctors reviewed the patient notes in the second stage (RF2 review). At this stage, each record was reviewed by a doctor and was checked by a second doctor.

Results

Proportion of adverse events and preventable adverse events

We completed the RF1 form for 1162 records that were available and complete. In stage one, 444 (38.2%) of the 1162 records had at least one positive criterion from the screening criteria (95% CI, 35.4% to 41.0%), (Diagram 1). The RF2 form was completed for these 444 records with RF1 positive criteria, (Diagram 1). The total number of adverse events was 128 (11.0%) when using a causation score of ≥4 (95% CI, 9, and 2% to 12.8). Of all adverse events, 85 (7.3%, 95% CI, 5.9% to 8.9%) were related to the care provided during the index admission and 43 (3.7%; 95% CI, 2.7% to 4.9%) occurred before the patient was admitted to hospital and patients were admitted to hospital due to this adverse event. Using a likelihood of preventable adverse event ≥50% (a preventability score of 4 or more), according to the doctors' judgment, in sum, 44 (34.3) of the 128 adverse events were considered preventable.

Type of adverse events

Adverse drug reaction was the most common type of adverse events (n = 34, 26.56%), followed by post-operative infection (n = 25, 19.5%), pressure ulcer (n = 17, 13.28%), hospital acquired infection (n = 13, 10.2%) and procedural complications (n = 13, 10.2%), (Table 1).

Adverse event and possible risk factors

Adverse events had a statistically significant association with patients' age (OR = 1.012; 95% CI, 1.002 to 1.022; P = 02) and length of hospital stay (OR = 1.066; 95% CI, 1.039 to 1.093; P < 0.0001). An increase of one year in the patient's age increased the odds of an adverse event by 1.2%. An increase of one day in the length of hospital stay increased the odds of adverse events by 6.6% (Table 2).

There was a statistically significant relationship between specialty of admission and the occurrence of adverse events (P = 0.02), but there was no statistically significant relationship between specialty of admission and the occurrence of preventable adverse events or between specialty of admission and the severity of adverse events. Adverse events were most frequent in Medicine and least frequent in Urology.

The proportion of adverse events and preventable adverse events and the severity of adverse events were not statistically different between males and females at a significance level of 0.05.

There was no statistically significant relationship between the admission type (elective or emergency) and the occurrence of adverse events (P = 0.3), admission type or the occurrence of preventable adverse events and admission type and the severity of

Table 1. Number and percent of adverse events by type of adverse event.

Type of adverse event	Frequency	Percentage
Adverse drug reaction (ADR)	34	26.56
Post operative infection	25	19.53
Pressure Ulcer	17	13.28
Hospital aquired infection (HAI)	13	10.16
Post operative/operative complication	12	9.38
Precedure complication	13	10.16
Management of patient	7	5.47
Wrong or delayed diagnosis	6	4.69
Patient fall	1	0.78
Total number of adverse events	128	100

Table 2. Logistic regression for relationship between AE and possible risk factors.

Adverse event	OR	SE	z	P>z	95% CI
Age	1.012	0.005	2.24	0.02	1.002 –1.022
Length of stay	1.066	0.013	5.05	0.000	1.039–1.093
Sex (Male)	1.022	0.230	0.10	0.92	0.657–1.589
Admission type					
Emergency	1.081	0.264	0.32	0.75	0.668–1.748
Specialty					
Surgery	0.944	0.381	-0.14	0.88	0.427–2.085
Medicine	1.192	0.345	0.61	0.54	0.676–2.103
Orthopedics	0.944	0.381	-0.14	0.88	0.427–2.085
Urology	0.482	0.511	-0.69	0.49	0.060–3.852
Other	1.134	0.387	0.37	0.71	0.581–2.213

adverse events.

There was a highly statistically significant relationship between the length of hospital stay and the occurrence of adverse events ($P < 0.0001$), but there was no statistically significant relationship between the length of hospital stay and the occurrence of preventable adverse events ($P = 0.06$) or between the length of hospital stay and severity of adverse events ($P = 0.6$).

Discussion

Prevalence of adverse event

We found that 3.7% of patients were admitted to hospitals because of an adverse event and a further 7.3% of patients developed an adverse event during their admission. The result of this study is comparable to rates found in studies using similar case note review methods in the UK (10.8%),[4] Belgium(7.12%),[12] Canada (7.5%),[13] Tunisia(10%),[14] Sweden (12.3%),[15] and elsewhere (7.5% to 12.5%).[7–9] There are, however, studies reporting a different pattern of results from the USA (3.7%),[5] New Zealand (12.9%),[16,17] and Australia (16.6%).[2] In sum, 44 (34.3%) of these 128 adverse events had a preventability score of 4 or more and were considered preventable. These findings are consistent with several other studies which used similar methods (28% to 70%).[2,5,7–9,17,18] Davis, *et al.*,[17] Forster, *et al.*,[8] and Baker, *et al.*[13] used a confidence score of ≥4 and found that around 37% of adverse events were preventable. Davis, *et al.*[17] found 62% of adverse events to be preventable when using a preventability score of ≥2. Wilson, *et al.*[2] and Vincent, *et al.*[4] found about 50% of adverse events as preventable when using a confidence score of ≥4. Although these studies used similar criteria to assess the preventability of adverse events, they have not necessarily applied them in exactly the same way. Also, Vlayen showed that the preventability of adverse events in ICU admissions varied between 17% and 76.5%.[12]

Adverse drug reaction was the most common type of adverse events (n = 34, 26.56%), followed by post-operative infection (n = 25, 19.5%), pressure ulcer (n = 17, 13.28%), hospital acquired infection (n = 13, 10.2%) and procedural complications (n = 13, 10.2%). As in several previous studies, this research found operative adverse events to be the most common type of adverse events.[4,16,19,20] The majority of admissions in the sampling frame in these studies, and subsequently the majority of study population were in surgical wards, and these admissions would be expected to have more operative, rather than other types of adverse events.[2,4–5,16] This does not necessarily mean that the rate of preventable adverse events was higher in surgical wards than in medical wards. Conversely, virtually all of these studies reported operative adverse events as less preventable than diagnostic and therapeutic adverse events, as confirmed by the research in this study.[2,4–5,17]

Ninety-four (73.4%) of AEs resulted in minimal impairment (recovery in < 1 month), 28 (21.8%) of AEs resulted in moderate impairment (recovery in 1 to 12 months) and the remaining AEs (n = 5, 3.9%) resulted in severe impairment, and one adverse event (0.78% of adverse events) resulted in death. Vincent, *et al.*[4]

reported that in 66% of adverse events, the injury resolved within one month; Baker, *et al.*[9] and Brennan, *et al.*[5] found that in 68% and 70% of adverse events, respectively, the injury resolved within six months; and Wilson, *et al.*[2] found that in 77% of adverse events, the injury resolved within 12 months (These studies did not use the same framework to report the consequences of adverse events). In particular, the majority of studies have found a similar proportion of adverse events contributing to patient death.

Adverse events had a statistically significant association with patients' age (OR = 1.012; 95% CI, 1.002 to 1.022; $P = 02$) and length of hospital stay (OR = 1.066; 95% CI, 1.039 to 1.093; $P < 0.0001$). There was no statistically significant association between patients' sex and admission method and the occurrence of adverse events. There are several possible reasons why patients with a longer hospital stay developed more adverse events. Patients with a longer hospital stay are likely to receive more interventions and consequently more likely to develop adverse events. On the other hand a patient developing an adverse event may have a longer hospital stay. These findings are consistent with several other studies which used similar methods.[2,4–5,9,17] There was no statistically significant independent relationship between adverse events and patients' sex, admission type (elective or emergency) and the specialty of admission.

Patients' disease is more complex in the elderly[5] and they usually have a longer hospital stay, receive multi-drugs or interventions,[21] have less mobility, develop more pressure ulcers,[22] fall more frequently[23] and therefore develop more adverse events.[2,5,17]

The validity and reliability of method of medical record review in identifying adverse events have been supported by the previous research.[2,5,24–26] The reviewers in this study were specifically trained. In addition, the rate and type of adverse events found were comparable to other similar studies from the UK and elsewhere.[2,4,7–9,16]

In conclusion, approximately 11% of patients in Iranian hospitals experience an adverse event, with 34% of these being, to some extent, preventable. Of these patients, 3.7% develop an adverse event before they are admitted to hospital and 7.3% of patients develop an adverse event during their final admission. Adverse drug reactions and operative adverse events are more common and diagnostic adverse events less common. This study made a significant contribution to the understanding of adverse events in Iranian hospitals. This will not automatically result in improvements in patient safety, but may provide important information as to how to move forward to achieve this fundamental aim.

Funding

This project was supported by WHO funding. The study authors were members of staff at Tehran University of Medical Sciences and conducted this study as part of their job.

Competing interests: Not declared.

Ethics approval: The project was approved by Tehran University of Medical Sciences ethics committee.

Acknowledgments

We thank the WHO Patient Safety Research Small Grants for funding and technical support. We also thank Mr. Sorin Banica for his support. We thank deputy for research and his colleagues at Tehran University of Medical Sciences and clinical and administrative staff of the host hospitals for their support.

References

1. Khon LT, Corrigan Janet M, Donaldson MS. To err is Human: Building a Safer Health System. Washington, D.C, National Academy Press, *IOM*; 2001.
2. Sari AA, Doshmangir L, Shedon T. A systematic review of the extent, nature and likely causes of preventable adverse events arising from hospital care. *Iran J Public Health*. 2010; **39(3):** 1 – 15.
3. Gawande AA, Thomas EJ, Zinner MJ, Brennan TA. The incidence and nature of surgical adverse events in Colorado and Utah in 1992. *Surgery.* 1999; **126(1):** 66 – 75.
4. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ.* 2001; **322(7285):** 517 – 519.
5. Brennan TA, Hebert LE, Laird NM, Lawthers A, Thorpe KE, Leape LL, et al. Hospital characteristics associated with adverse events and substandard care. *JAMA.* 1991; **265(24):** 3265 – 3269.
6. Baba-Akbari A, Sheldon TA . Case note review or routine incident reporting system in identifying adverse incidents? ICC, Birmingham; 2006.
7. Schioler T, Lipczak H, Pedersen BL, Mogensen TS, Bech KB, Stockmarr A, et al. Incidence of adverse events in hospitals. A retrospective study of medical records. *Ugeskr Laeger.* 2001; **163(39):** 5370 – 3578.
8. Forster AJ, Asmis TR, Clark HD, Al Saied G, Code CC, Caughey SC, et al. Ottawa Hospital Patient Safety Study: incidence and timing of adverse events in patients admitted to a Canadian teaching hospital. *CMAJ.* 2004; **170(8):** 1235 – 1240.
9. Baker GR, Norton P. Addressing the effects of adverse events: study provides insights into patient safety at Canadian hospitals. *Healthc Q.* 2004; **7(4):** 20 – 21.
10. Sari AB, Sheldon TA, Cracknell A, Turnbull A, Dobson Y, Grant C, Gray W, et al. Extent, nature and consequences of adverse events: results of a retrospective casenote review in a large NHS hospital. *Qual Saf Health Care.* 2007; **16(6):** 434 – 439.
11. Sari AB, Sheldon TA, Cracknell A, Turnbull A. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *BMJ.* 2007; **334(7584):** 79.
12. Vlayen A, Marquet K, Schrooten W, Vleugels A, Hellings J, De Troy E, et al. Design of a medical record review study on the incidence and preventability of adverse events requiring a higher level of care in Belgian hospitals. *BMC Res Notes*. 2012; **5:** 468.
13. Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ.* 2004; **170(11):** 1678 – 1686.
14. Letaief M, El Mhamdi S, El-Asady R, Siddiqi S, Abdullatif A. Adverse events in a Tunisian hospital: results of a retrospective cohort study. *Int J Qual Health Care*. 2010; **22(5):** 380 – 385.
15. Soop M, Fryksmark U, Koster M, Haglund B. The incidence of adverse events in Swedish hospitals: a retrospective medical record review study. *Int J Qual Health Care.* 2009; **21(4):** 285 – 291.
16. Davis P, Lay-Yee R, Briant R, Ali W, Scott A, Schug S. Adverse events in New Zealand public hospitals II: preventability and clinical context. *N Z Med J.* 2003; **116(1183):** U624.
17. Davis P, Lay-Yee R, Briant R, Ali W, Scott A, Schug S. Adverse events in New Zealand public hospitals I: occurrence and impact. *N Z Med J.* 2002; **115(1167):** U271.
18. Hayward RA, Hofer TP. Estimating hospital deaths due to medical errors: preventability is in the eye of the reviewer. *JAMA.* 2001; **286(4):** 415 – 420.
19. Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med.* 1991; **324(6):** 377 – 384.
20. Wilson RM, Harrison BT, Gibberd RW, Hamilton JD . An analysis of the causes of adverse events from the Quality in Australian Health Care Study. *Med J Aust.* 1999; **170(9):** 411 – 415.
21. Thomas EJ, Brennan TA. Incidence and types of preventable adverse events in elderly patients: population based review of medical records. *BMJ.* 2000; **320(7237):** 741 – 744.

22. Pase MN. Pressure relief devices, risk factors, and development of pressure ulcers in elderly patients with limited mobility. *Adv Wound Care*. 1994; **7(2):** 38 – 42.
23. Sattin RW, Lambert Huber DA, DeVito CA, Rodriguez JG, Ros A, Bacchelli S, et al. The incidence of fall injury events among the elderly in a defined population. *Am J Epidemiol*. 1990; **131(6):** 1028 – 1037.
24. Walshe K. Adverse events in health care: issues in measurement. *Qual Health Care*. 2000; **9(1):** 47 – 52.
25. Michel P, Quenon JL, de Sarasqueta AM, Scemama O. Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *BMJ*. 2004; **328(7433):** 199.
26. Woloshynowych M, Neale G, Vincent C. Case record review of adverse events: a new approach. *Qual Saf Health Care*. 2003; **12(6):** 411 – 415.