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The incidence of adverse events in Swedish hospitals: a retrospective medical record review study

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Abstract

Objectives. To estimate the incidence, nature and consequences of adverse events and preventable adverse events in Swedish hospitals.

Design. A three-stage structured retrospective medical record review based on the use of 18 screening criteria.

Setting. Twenty-eight Swedish hospitals.

Population. A representative sample ($n = 1967$) of the 1.2 million Swedish hospital admissions between October 2003 and September 2004.

Main Outcome Measures. Proportion of admissions with adverse events, the proportion of preventable adverse events and the types and consequences of adverse events.

Results. In total, 12.3% ($n = 241$) of the 1967 admissions had adverse events (95% CI, 10.8–13.7), of which 70% ($n = 169$) were preventable. Fifty-five percent of the preventable events led to impairment or disability, which was resolved during the admission or within 1 month from discharge, another 33% were resolved within 1 year, 9% of the preventable events led to permanent disability and 3% of the adverse events contributed to patient death. Preventable adverse events led to a mean increased length of stay of 6 days. Ten of the 18 screening criteria were sufficient to detect 90% of the preventable adverse events. When extrapolated to the 1.2 million annual admissions, the results correspond to 105 000 preventable adverse events (95% CI, 90 000–120 000) and 630 000 days of hospitalization (95% CI, 430 000–830 000).

Conclusions. This study confirms that preventable adverse events were common, and that they caused extensive human suffering and consumed a significant amount of the available hospital resources.

Keywords: adverse events, medical record review, patient safety, risk management

Introduction

Several previous nationwide studies have demonstrated that adverse events occur frequently in hospitals [1–5]. Denmark was the first Nordic country that studied the incidence of adverse events in hospitals [3]. Although there are large similarities between Danish and Swedish hospital care, the results of the Danish study had little impact in Sweden. Experiences from Denmark and other countries indicate that results from their own national studies were needed to put patient safety issues into focus and significantly enhance patient safety activities. Consequently, the National Board of Health and Welfare undertook the present study, in order to estimate the incidence, nature and consequences of adverse events, and preventable adverse events, in Swedish hospitals. Some of the results have been reported in the *Journal of the Swedish Medical Association* [6].

Methods

Setting and sampling

We carried out a national study based on the 1.2 million hospital admissions from October 2003 to September 2004.

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Admissions to psychiatric clinics, rehabilitation, palliative care and day-only admissions were not included.

We assumed that preventable adverse events would occur in approximately 5% of the admissions, and calculated that a sample of 2000 admissions would be sufficient to estimate the prevalence of preventable adverse events with a 95% CI of $\pm$1%. Twenty-eight acute care hospitals were selected to represent the 72 hospitals in Sweden. All large hospitals (>38 000 admissions), and a random selection of medium (>14 500–38 000 admissions) and small (1800–14 500 admissions) hospitals, were included. The selection was representative for the regional distribution and size of hospitals in Sweden. A random selection of medical records, which was representative for hospital size distribution, was performed with the aid of the Swedish National Patient Register. Oversampling was carried out with the expectation that 10% of the medical records would not be available or would be incomplete. The review comprised all hospital medical records from the selected index admission, the 12 months preceding the index admission and the 12 months after the index admission.

Eighteen trained nurses and 17 experienced physicians participated in a 3-day education programme. The majority were employed by the Department for Supervision of Healthcare Services of the National Board of Health and Welfare.

Process of medical record review

The methods adopted in this study were based on a protocol used in the Harvard Medical Practice Study I [7], with modifications as introduced in subsequent studies in Australia, New Zealand and Denmark [1–3].

Data collection involved a three-stage medical record review. In the first stage, the nurses assessed each record for the presence of at least one of 18 criteria, indicating a potential adverse event (Table 1). To assess inter-rater reliability, 10% of the medical records were screened by two nurses.

In Stage 2, each record that was positive for one or more criteria was reviewed, independently, by two physicians. In accordance with definitions used previously [1], an adverse event was defined as (1) an unintended injury or complication, which results in (2) disability at discharge, death or prolongation of hospital stay, and (3) is caused by healthcare management (including omissions) rather than the patient's disease.

The assessment of causation was performed using a scale from 1 to 6 [1]. At ratings of at least 4 (i.e. more than 50% likelihood), unintended injuries or complications that fulfilled criteria 2, were classified as adverse events. Similarly, preventability of an adverse event was assessed using a scale from 1 to 6. At ratings of at least 4 (i.e. more than 50% likelihood), adverse events were classified as preventable [1].

Table 1 Screening criteria ordered by sensitivity and positive predicted value

	Screening criteria	Sensitivity	PPV[a]	Additional number of prev AE[b]	Cum Number	Cum%
1	The index admission was an unplanned admission related to previous healthcare management	37.9	30.6	64	64	37.9
2	Unplanned readmission after discharge from index admission	37.9	28.6	45	109	64.5
3	Hospital-incurred patient injury	16.0	42.9	14	123	72.8
8	Unplanned removal, injury or repair of an organ during surgery	11.8	50.0	8	131	77.5
15	Hospital-acquired infection or sepsis	17.2	31.2	6	137	81.1
4	Adverse drug reaction	18.9	25.8	6	143	84.6
10	Development of neurological deficit not present on admission	5.3	32.1	3	146	86.4
14	Injury related to abortion or delivery	5.9	30.3	3	149	88.2
7	Unplanned return to the operating room	3.6	40.0	2	151	89.3
11	Unexpected death	3.0	18.5	2	153	90.5
5	Unplanned transfer from general care to intensive care	6.5	18.6	1	154	91.1
12	Inappropriate discharge to home	7.1	28.6	0	154	91.1
17	Documentation or correspondence indicating litigation	4.1	50.0	0	154	91.1
16	Dissatisfaction with care documented in the patient's medical record	3.6	18.2	0	154	91.1
13	Cardiac or respiratory arrest	1.2	11.1	0	154	91.1
6	Unplanned transfer to another acute care hospital	0.6	7.1	0	154	91.1
18	Any other undesirable outcome not covered above	10.7	38.3	10	164	97.0
9	Other patient complication	9.5	28.1	5	169	100.0

[a]Positive predicted value, [b]Preventable adverse events.

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The timing of the occurrence and detection of the adverse event, relative to the index admission, was recorded [1]. The reviewers estimated the extent of disability at discharge and the number of additional hospital days and outpatient visits directly attributable to the adverse event.

A panel of specialists was available for consultation when needed. After having performed independent assessments and completing the case report forms, the physicians discussed their findings with the aim of verifying complete and correct retrieval and interpretation of the information in the medical records. The focus of the discussion was on the assessment of causation and preventability. The physicians were instructed to indicate clearly any change in their original judgment, subsequent to their discussion, in the case report forms.

When the physicians had different opinions concerning the presence of an adverse event or its preventability, an independent assessment was performed by a member of the Scientific Council of the National Board of Health and Welfare (Stage 3).

Statistics

When judging the degree of agreement between reviewers, kappa coefficients (κ) were calculated. Odds ratios were calculated with logistic regression. Proportions, odds ratios and kappa-coefficients are presented with 95% CI. For all statistical analysis and data processing, the SAS package, version 9.1, was used.

Results

Process of medical record review

Eight medical records could not be retrieved, and 14 records were excluded before Stage 1 because of insufficient documentation.

Stage 1. The nurses screened 1997 medical records. Twenty-three records were excluded because of inadequacies in documentation or data registration. Of the remaining 1974 medical records, 648 (33%) were assessed as positive for at least one criterion, on average 1.8 (range 1–9) per record. Double screening was performed on 191 medical records. In 79% of the records, the nurses agreed as to the presence or absence of criterion ($\kappa = 0.53$).

Stage 2. The physicians assessed 648 medical records. Six records were excluded because of inadequacies in documentation or data registration. Before the physicians discussed their findings, their initial assessments corresponded upon the presence of an adverse event in 91% of the cases ($\kappa = 0.80$) and upon preventability in 91% of the cases ($\kappa = 0.76$). When there was initial disagreement concerning the presence of an adverse event, 56% of the physicians' discussions entailed agreement upon the presence of an adverse event, and, correspondingly, when there was disagreement concerning preventability, 62% were judged preventable.

Stage 3. In 12 medical records, disagreement concerning the presence of adverse events and preventability prevailed after Stage 2. Each of these records underwent a new and independent review, by a member of the Scientific Council. The reviews resulted in nine adverse events, of which five were preventable. One record was excluded because of inadequate documentation.

After the medical record review process and data registration, a total of 1967 medical records were available for analysis.

The ability of screening criteria to detect preventable adverse events

The sensitivity of a screening criterion was defined as the proportion of preventable adverse events detected by the criteria, while the positive predictive value was defined as the proportion of preventable adverse events among the criteria. In many cases, more than one criterion was positive during a screening procedure. We therefore ranked the criteria by sensitivity regardless of whether the criterion was present in combination with other criteria or not. The ranking table was repeatedly recalculated after excluding those events where the criterion with the highest sensitivity was present. In this way we calculated the number of additional preventable adverse events detected by each criterion. At the end of this process, we added the two unspecified criteria (numbers 9 and 18, Table 1). More than 80% of the preventable adverse events were detected by five criteria, and 10 criteria were enough to detect 90% of the preventable adverse events, while 5 criteria did not add any preventable adverse events at all (Table 1). 'Bleeding' was the most common complication reported under the criterion 'Other patient complication'.

Adverse events and preventable adverse events

The results are based on 1967 medical records where complete data from the process of medical record review were obtained. The reviewers identified 241 patients with adverse events. Of these adverse events, 169 (70%) were judged to be preventable, corresponding to 8.6% of the 1 967 medical records (Table 2). When excluding preventable adverse events caused in primary healthcare, the figure was 8.1%.

Seventy of the preventable adverse events were a result of insufficient healthcare management during the 12 months preceding the index admission but were not detected until the index admission (situation A, Table 2). Of these, 61 were caused by hospital care and 9 by primary healthcare. Fifty-six of the preventable adverse events occurred during the index admission and were detected during the index admission (situation B). Another 43 adverse events occurred during the index admission but were detected during the following 12 months after discharge (situation C).

The prevalence of preventable adverse events (the sum of preventable adverse events in situation A and B, Table 2) was 6.4%. The risk for a preventable adverse event during the index admission (the sum of situations B and C) was 5.0%.

The 169 preventable adverse events resulted in a total of 1010 additional days in hospital, on average 6 days (0–119)

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Table 2 Number of adverse events and preventable adverse events caused and detected in three different situations in relation to the index admission

	Situation			Total	Events per 100	95% CI
	A[a]	B[b]	C[c]			
Adverse events	107	75	59	241	12.3	10.8–13.7
Prevalence	107	75	–	182	9.3	8.0–10.5
Risk	–	75	59	134	6.8	5.7–7.9
Preventable adverse events	70	56	43	169	8.6	7.4–9.8
Prevalence	70	56	–	126	6.4	5.3–7.5
Risk	–	56	43	99	5.0	4.1–6.0

[a]Caused before the index admission and detected before or under the index admission, [b]Caused and detected under the index admission, [c]Caused under the index admission but detected after the index admission.

Table 3 Number of patients and proportions of adverse events and preventable adverse events by age and sex

	Patients		Adverse events per 100	Preventable adverse events per 100
	n	%		
Age				
0–14	159	8.1	5.0	4.4
15–29	197	10.0	11.7	8.1
30–44	248	12.6	12.5	8.9
45–64	417	21.2	12.0	7.2
65 +	946	48.1	13.6	9.9
Sex				
Male	893	45.4	11.6	8.0
Female	1074	54.6	12.8	9.1
Total	1967	100.0	12.3	8.6

per preventable adverse event. Half of the preventable adverse events led to one or more outpatient visits.

Preventable adverse events were more common among patients 65 years and older, than among those younger (OR 1.3; 95% CI, 1.0–1.9). No statistically significant differences were observed between men and women when taking into account age and hospital size (Table 3). The most common types of injuries were injuries to various organs and infections. Many patients experienced more than one type of injury (Table 4).

Most (55%) of the preventable adverse events led to impairment or disability, which was resolved during the admission or within 1 month from discharge, another 33% were resolved within 1 year. Nine percent of the preventable

Table 4 Types of adverse events and preventable adverse events

	Adverse events ($n = 241$)		Preventable adverse events ($n = 169$)	
	n	%	*n*	%
Bleeding	42	17.4	31	18.3
Thrombosis	10	4.1	8	4.7
Organ injury	95	39.4	70	41.4
Allergic or immunological reaction	8	3.3	1	0.6
Mental suffering or pain	38	15.8	32	18.9
Infection	69	28.6	50	29.6
Fracture	8	3.3	5	3.0
Other	74	30.7	53	31.4

adverse events led to permanent impairment and 3% of the adverse events contributed to patient death. Patients with permanent impairment (disability >50%) had more extra days of hospitalization than patients with lower degrees of impairment (Table 5).

The surgical disciplines accounted for approximately 62% of the adverse events and preventable adverse events, internal medicine for 33% and primary healthcare for 5%. The most common cause of preventable adverse events was inappropriately performed invasive procedures (e.g. surgical operations, catheterizations and endoscopies), including measures to prevent subsequent infections (Table 6). In the field of drug treatment, the most frequent cause of preventable adverse events was failure or delay of drug treatment. In the field of diagnostic procedures, the most frequent cause of preventable adverse events was failure or delay of diagnosis (Table 6).

Discussion

The results show that, during the period October 2003 to September 2004, 8.6% of the patients in Swedish hospitals had experienced preventable adverse events during the index admission, or during the proceeding 12 months.

In order to facilitate comparisons with previous studies, we followed a protocol which is well established [1–3, 7]. Our evaluation of the screening criteria shows that the list of criteria could be reduced, without any major loss of detection of preventable adverse events. Although all criteria were associated with preventable adverse events, five of the criteria did not contribute on their own, only together with other criteria with a stronger association with preventable adverse events. On the other hand, 'bleeding' was a common complication in the unspecified criterion for patient complications. For future investigations of adverse events in healthcare, and, in particular, when the method is used 'clinically' for the purpose of improving patient safety, a revision of the list of criteria may be considered.

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Table 5 Degree of physical impairment or disability at discharge and extra days of hospitalization

	Adverse events			Preventable adverse events		
	n	%	Average extra days	*n*	%	Average extra days
Minimal impairment, recovery within 1 month	129	53.5	4.1	93	55.0	4.1
Moderate impairment, recovery within 1 to 6 months	50	20.7	6.7	39	23.1	5.9
Moderate impairment, recovery within 6 to 12 months	22	9.1	7.1	16	9.5	6.6
Permanent impairment, degree of disability <50%,	19	7.9	7.6	11	6.5	6.4
Permanent impairment, degree of disability >50%	7	2.9	36.9	5	3.0	43.8
Death	10	4.1	9.9	5	3.0	3.0
Unable to determine	4	1.7	3.0	0	0	
Total	241	100.0	6.3	169	100.0	6.0

Table 6 Causes of adverse events ($n = 241$) and preventable adverse events ($n = 169$)

	Adverse events, %	Preventable adverse events, %
Diagnostic procedures		
Wrong diagnosis	0.8	0.6
Failure or delay of diagnosis	7.1	8.3
Incomplete diagnosis	0.4	0.6
The diagnostic procedure	2.9	2.4
Total	11.3	11.9
Drug treatment		
Wrong medication	2.1	3.0
Failure or delay of drug treatment	7.1	8.9
Wrong dose	6.7	6.5
Adverse drug reaction	14.2	8.3
Total	30.1	26.8
Invasive procedures including surgical operations		
Unnecessary invasive procedure	2.5	3.6
Failure or delay of invasive procedure	3.8	4.2
Incomplete invasive procedure	4.2	5.4
Inappropriately performed invasive procedure	38.9	38.7
Total	49.4	51.8
Other procedures		
Unnecessary procedure	0.0	0.0
Failure or delay of procedure	4.6	5.4
Incomplete procedure	7.9	8.3
Inappropriately performed procedure	1.7	1.2
Total	14.2	14.9

Previous and more extensive studies have compared the rate of adverse events and preventable adverse events between different types of hospitals and specialities [1, 4, 8, 9]. The aim of the present study was to obtain a national estimate of the occurrence of adverse events and in particular preventable adverse events. Consequently, the study is too small to allow subgroup analysis of the occurrence of adverse events depending on size of hospitals and specialities [10].

As shown in previous studies, the current method overestimates the number of deaths that are directly attributable to preventable adverse events [5, 11, 12]. In our study, all patients who deceased despite active therapy were elderly or critically ill due to an underlying disease. In view of the inherent risk for death due to age and underlying disease, it was difficult to evaluate the extent to which a preventable adverse event contributed to a fatal outcome.

The occurrence of adverse events in the present study (12.3%, Table 2) is within the upper range of previously published results (2.9–16.6%) [1–7, 13]. Seventy percent of the adverse events were classified as preventable, which is higher than reported in previous national studies (37–51%) [1, 3–5]. The relatively high occurrence of adverse events and

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preventable adverse events may be attributable to several differences between the present study and previous studies. The assessment of adverse events and preventability is sensitive to the knowledge and attitude of the reviewer [1–3, 10]. Previous studies were carried out by physicians and nurses who were employed in hospitals. In contrast, the majority of reviewers in the present study were employed by the Department for Supervision of Healthcare Services of the National Board of Health and Welfare, and trained to supervise the actions of healthcare personnel and healthcare services from a patient safety perspective. It is most probable that they were less prone to view complications and injuries as inherent features of diseases and healthcare management, than reviewers recruited directly from hospitals.

Adverse events and preventable adverse events have been reported to be more common in patients aged 65 years and older, than in patients aged less than 65 years [1–3, 5, 7, 13, 14]. In our study, the proportion of patients 65 years and older was 48%, compared with the Australian study, 28% [1], the New Zealand study, 30% [2], the Harvard Medical Practice Study, 17% [7] and the Danish study, 32% (Thomas Schioler, personal communication, 2008). The higher proportion of elderly patients in our study may be expected to increase the rate of adverse events.

The proportion of severe adverse events, i.e. adverse events that resulted in permanent disability or were a contributing factor to death, was lower than previously reported [1, 3, 4, 7]. This may indicate that we included minor adverse events to a larger extent than in previous studies.

Another difference in comparison with previous results is the higher proportion of adverse events that were detected after discharge from the index admission (situation C, Table 2), in our study 24%, compared with slightly more than 11% [1, 4, 5, 7] and, the highest figure, 20% [3] in previous studies. This may reflect that the duration of stay in acute care hospitals in Western countries has decreased substantially over the past 15 years and that Denmark and Sweden have the shortest average length of stays [15]. It is conceivable that the high proportion of adverse events detected after discharge in our study reflects that some events, e.g. postoperative infection, require some time to be manifested.

The concordance in the physicians' initial independent assessments of adverse events ($\kappa = 0.80$) and preventable adverse events ($\kappa = 0.76$) was slightly higher than reported in most previous studies [1, 2, 4, 9]. In contrast to many previous studies, the physicians subsequently compared their reviews and were at liberty to revise their assessments. In the opinion of the physicians, the comparison of findings contributed to a more complete retrieval and better interpretation of the information in the medical records [10]. This procedure *per se* appeared to slightly increase the proportion of adverse events classified as preventable.

Also, other differences, e.g. in education, planning, conduct and methods for analysis, may have contributed to the differences in results between the present study and previous studies [10, 16].

Taking into account the various differences between the present study and previous studies, it is unlikely that the differences in the rates of adverse events and preventable adverse events between our study and other studies reflect true differences in patient safety [10].

Studies based on retrospective assessment of information in medical records may underestimate the true rate of adverse events, and, in particular, preventable adverse events [1, 4, 10, 17]. Some adverse events, e.g. those related to pharmaceutical therapy, may be difficult to detect, as side effects from drugs may be very similar to the symptoms of diseases. Furthermore, errors in the dosage and dispensation of drugs are not always recognized by the hospital staff, and, when recognized, not always noted in the medical records. Adverse events related to invasive procedures and operations are easier to identify and, conceivably, more consistently documented in the medical records than other types of adverse events.

For practical reasons, we could only assess medical records from the index hospital. Consequently, some of the adverse events that occurred during the index admission, but were not detected until after discharge from the index admission (situation C, Table 2), may have been detected by other facilities and not included in this study. Previous studies have shown that some adverse events are missed during the screening process, which also results in an underestimation of adverse events [1, 3]. Furthermore, some patients experienced more than one adverse event, but only the most significant adverse event was registered and analysed in our study.

Consequently, several circumstances inherent with the present method may lead to an underestimation of adverse events and preventable adverse events. On the other hand, retrospective assessment of adverse events is sensitive to 'hindsight bias', which may have led to overestimation when assessing preventability.

The results show that preventable adverse events occurred frequently in Swedish hospitals and consumed a substantial amount of the available hospital resources. When extrapolated to the 1.2 million index admissions during the 1-year study period, the results would indicate that approximately 105 000 patients suffered preventable adverse events (95% CI 90 000–120 000). In 58 000 cases, the patients had recovered at the time of discharge or within one month of discharge. In another 38 000 cases, the patients' recovery occurred within 1 year, but some 10 000 patients suffered permanent disability. In approximately 3000 cases, preventable adverse events may have contributed to a fatal outcome.

Correspondingly, preventable adverse events entailed 630 000 additional days in hospital (95% CI 430 000–830 000). This is equivalent to almost 10% of all hospital days during the 1-year study period. Half of the preventable adverse events required at least one outpatient visit, which corresponds to more than 50 000 visits.

The results of this study reflect the situation just a few years ago. Since then, initiatives and actions to improve patient safety have been introduced in Sweden, as in many other countries. However, there is still a considerable potential for sparing human suffering and costs in Swedish hospitals. Similar conditions may prevail in other countries. We hope the results of this study may further promote actions to

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improve patient safety, in our country, as well as in other countries.

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