

Identification of Adverse Events in Inpatients: Results of a Preliminary Survey in Japan

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Abstract

To examine the feasibility of detecting adverse events (AEs). A two-stage retrospective review of medical records. Seven hundred cases discharged during fiscal year 2002 were randomly selected from among inpatients, excluding psychiatric ward patients, hospitalized at seven acute-care hospitals. In the first stage of the review, trained nurse reviewers examined the medical records using 18 screening criteria to identify potential AEs. A nurse supervisor then reviewed all the cases judged as being criteria-negative by the first set of nurse reviewers and corrected the judgements as necessary. During the second stage of the review, a physician review team confirmed the occurrence, and categorized the AEs. Of the 700 cases, 79 (11.3%) cases were judged to have had AEs. Of the 79 cases, the AEs were the reason for the index admission in 26 cases, and the AEs occurred during the index admission in 53 cases. It was also judged that the AEs were highly preventable in 21 cases. Our judgement was consistent with that in the Australian survey. We confirmed the feasibility of the two-stage review process to detect AEs. To improve patient safety in Japanese hospitals, a nationwide survey, using this methodology, is necessary to fully understand the epidemiology of AEs, including the types of AEs and the contributory factors.

Key words: adverse event, medical record, retrospective review

❖ Introduction

Large-scale surveys to determine the incidence of adverse events (AEs) in inpatients have been conducted in several countries through retrospective

reviews of medical records performed by outside investigators. One such model survey was the survey conducted by Brennan and his colleagues on a sample of 31,429 medical records of patients from New York State¹⁾, based on the California Medical Insurance Feasibility Study²⁾. Later, Brennan's group conducted a repeat survey employing the same procedure on a sample consisting of 15,000 medical records from patients in the states of Utah and Colorado³⁾. Besides in the United States, a survey has been conducted in Australia using a sample of 14,655 medical records⁴⁾,

Received: September 19, 2011

Accepted: November 9, 2011

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and similar surveys, each involving thousands of medical records, have subsequently been carried out in other countries, including the United Kingdom, New Zealand, Denmark and Canada⁵⁻⁸).

The epidemiology of AEs has not yet been studied in Japan. Thus, we planned a preliminary survey to examine the feasibility of detecting AEs through a retrospective review of medical records using methods similar to those employed in the above-mentioned studies conducted overseas.

❖ Methods

Survey methods

The present study was conducted with the participation of seven acute-care hospitals (one university hospital, 2 public hospitals, and 4 private hospitals) that agreed with the aims of the study. One hundred medical records were randomly selected from among the inpatient records excluding those of psychiatric ward patients, at each hospital. All of the patients had been discharged during fiscal year 2002 (between April 2002 and March 2003). We defined the index admission as the admission sampled in this study.

In the previous studies, an AE was defined as an unintended injury or complication that resulted in disability persisting until the time of discharge, death or prolonged hospital stay, that is caused by health care management rather than by the patient's underlying disease process⁵⁻⁸. In other words, AEs as detected in the previous studies were essentially limited to those that 1) hastened the patients' death, 2) resulted in disability in the patient which persisted until the time of discharge, 3) prolonged the length of stay (LOS) at the hospital or 4) necessitated an additional admission. However, for our survey, we attempted to additionally include cases in which 5) "a major procedure or treatment that was not originally planned for became necessary", even if they did not match with the above four categories, in order to achieve conformity with the guidelines laid down in the "Categories of Medical Accidents to be Reported" issued by the Japanese Ministry of Health, Labor and Welfare in 2003.

The survey method comprised a two-stage review of medical records. In the first stage of the review, trained nurse reviewers examined the medical records using 18 screening criteria to identify potential AEs.

The 18 criteria were based on those used in the Australian study⁴, but some of the definitions of the criteria were modified to enable "instances in which a major procedure or treatment that was not originally planned for was required" to be identified as an AE. A nurse supervisor then reviewed all the cases judged as being criteria-negative by the first nurse reviewers and corrected the judgements as necessary. As a quality check for this first stage of the review, a lead medical assessor read all of the medical records from the first four hospitals and verified the accuracy of the nurse supervisor's judgements.

In the second stage of the review, a physician review team assessed the criteria-positive medical records to determine whether an AE had actually occurred and to classify the causation and preventability of the AEs. If the occurrence or type of AE was difficult to determine, a meeting of an expert panel of specialist physicians recommended by medical societies was convened and the team was requested to discuss the case and convey its decision. A detailed description of the second-stage review can be found elsewhere⁹.

International comparison

The rate of AEs differed substantially among previous studies. Five important methodological differences were revealed by a collaboration between the groups that conducted the U.S. and Australian studies¹⁰. In order to conduct meaningful international comparisons of our data, we invited an investigator of the Australian survey team and organized a training session for the Japanese team before starting the survey in order to understand in detail the methodologies used by the team in Australia. We also conducted an on-site inquiry in Australia with our preliminary results to calculate the AE rates so as to obtain conformity with the context of the Australian survey.

Ethical considerations

This study was conducted with the approval of the ethics committee of each of the participating hospitals. The physicians, nurses, and research assistants involved in the survey submitted written pledges to maintain the confidentiality of all the patient information.

Table 1 The 18 screening criteria

1.	Unplanned admission (including or prior to the index admission)
2.	Unplanned readmission after discharge from the index admission
3.	Hospital-acquired patient injury
4.	Adverse drug reactions
5.	Unplanned transfer from a general to the intensive care unit
6.	Unplanned transfer to another acute-care hospital
7.	Unplanned return to the operating theatre
8.	Unplanned removal, injury or repair of organ during surgery
9.	Other patient complications
10.	Development of neurological deficit not present on admission
11.	Unexpected death
12.	Inappropriate discharge from the hospital to home
13.	Cardiac/respiratory arrest, low Apgar score
14.	Injury related to abortion or delivery
15.	Hospital-acquired infection/sepsis
16.	Dissatisfaction with care documented in the medical record
17.	Documentation or correspondence indicating litigation
18.	Any other undesirable outcomes not covered above

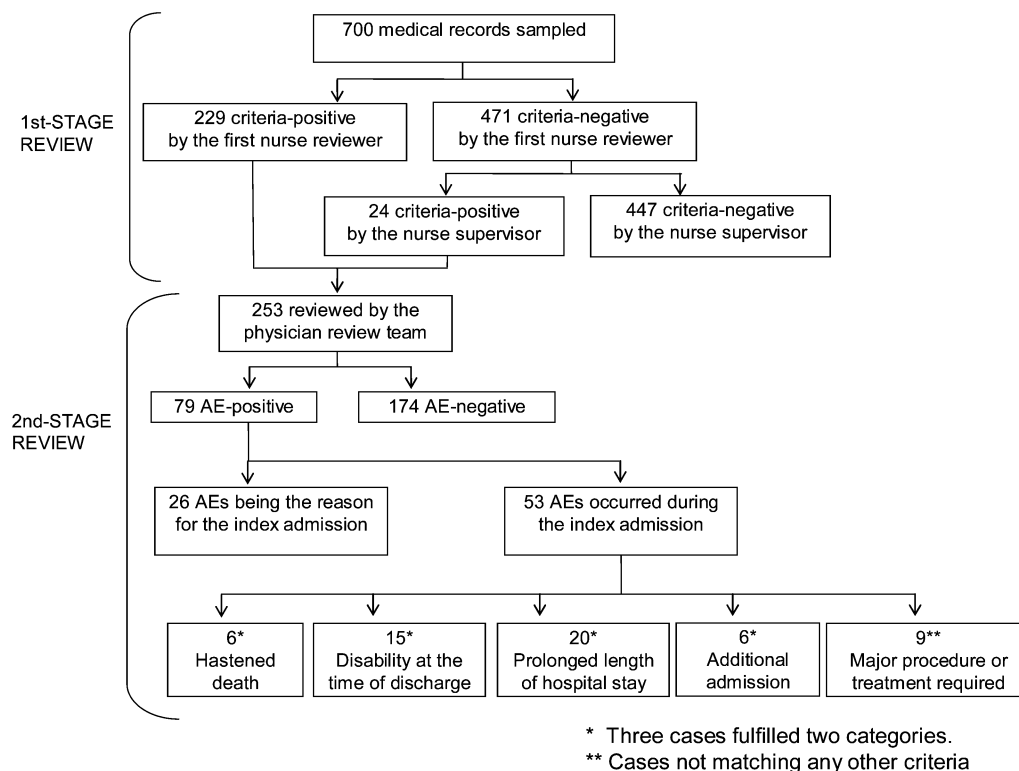


Figure 1 Review Process

Results

Patient characteristics

The characteristics of the 700 patients whose medical records were surveyed are outlined in Table 1. The mean patient age was 53.1 yr, and the mean

LOS was 20.1 d. More than half (56.1%) of the patients were men. Patients hospitalized in the medical departments (at the time of their discharge) accounted for the largest patient group (38.6%). Most of the patients (87.3%) were discharged to their home.

Table 2 Patient characteristics

Average age	53.1 yr
Male	56.1%
Female	43.9%
Discharged to home	87.3%
Transferred to other institutions	5.9%
Died during the index admission	6.1%
Average length of hospital stay	20.1 d
Medical department	38.6%
Surgical department	23.0%
Obstetrics and Gynecology	9.4%
Other departments	29.0%

Table 3 Category, causation and preventability of AEs

Category	(1) AEs that occurred during the index admission: 53 (67.1%)
	1) Hastened death of the patient*: 6 (7.1%)
	2) Disability at the time of discharge*: 15 (19.0%)
	< 1 month: 5 (6.3%)
	1–6 months: 3 (3.8%)
	6–12 months: 2 (2.5%)
	> 1 yr, < 50% disability: 3 (3.8%)
	> 1 yr, > 50% disability: 1 (1.3%)
	unable to determine: 1 (1.3%)
	3) Prolonged length of hospital stay*: 20 (25.3%)
	4) Additional admission*: 6 (7.6%)
	5) Major procedure or treatment required**: 9 (11.4%)
(2) AEs that were the reason for the index admission: 26 (32.9%)	
Causation	Certain evidence for management causation: 48 (60.8%)
	Management causation likely ($\geq 50\%$): 24 (30.4%)
	Management causation unlikely ($< 50\%$): 7 (8.9%)
Preventability	High preventability ($\geq 50\%$): 21 (26.6%)
	Low preventability ($< 50\%$): 22 (27.8%)
	Virtually no preventability: 36 (45.6%)

* Three cases fulfilled two criteria.

** Cases not matching any other criteria.

Review process

The numbers of medical records that was screened and reviewed is shown in Figure 1. The accuracy of the nurse supervisor's judgements was verified for the first four hospitals by a lead medical assessor. Of the 79 cases that were judged to have had AEs, the AEs occurred prior to the index admission and constituted the reason for the admission in 26 cases, and occurred during the index admission in 53 cases. Our final judgement was confirmed to be consistent with that in the Australian survey by the Austrian survey team.

Types of AEs

The most common category of AE that was fulfilled during the index admission was "event that prolonged the length of hospital stay" (20 cases), followed by "event that resulted in a disability in the patient persisting until the time of discharge" (15 cases; five of the 15 cases recovered within one month after the AE). Three cases satisfied two categories. Nine cases (11.4%) matched only the additional cate-

gory of "requiring a major procedure or treatment that was not originally planned for." Therefore, the rate of AEs, adjusted for use of only the Australian criteria and excluding the cases fulfilling our additional criterion of "requiring a major procedure or treatment that was not originally planned for", was 10.0% (70 cases).

Certain evidence of management causation was judged to be present for 48 AEs (60.8%). In terms of preventability, it was judged that the AE was highly preventable (by a 50% or greater chance) in 21 cases (26.6%), while for 36 cases (45.6%), it was judged that prevention would have been virtually impossible (Table 3).

Discussion

In this pilot study, we attempted to determine the frequency of AEs in Japanese hospitals by conducting a retrospective review of medical records. We confirmed the feasibility of the two-stage review process through collaboration with an Australian survey team.

The rate of AEs according to our survey, adjusted

for use of only the Australian criteria (10.0%), was lower than those reported by the Australian (16.6%) and New Zealand (12.9%) studies^{4, 6}). When comparing rates of AEs among countries, it would be important to take cultural differences in the health care delivery systems, such as different thresholds for admission and discharge, into consideration¹⁰). In particular, since the average duration of hospitalization is longer in Japan than in other developed countries (the average LOS in Japan was 20.2 d in 2002), the rate of AEs in Japan may be relatively high, since the additional hospital stay would increase the chances of occurrence of AEs. On the other hand, this factor (prolonged hospital stay) could underestimate the rate as compared with that in other countries, because it would exclude patients with unintended injuries or complications who might recover before discharge from the hospital. Further studies to better clarify the international disparities in the rates of AE in hospitalized patients are needed.

This study was small and based on only seven hospitals which agreed to participate. Therefore, the AE rate obtained from this survey cannot be considered as the representative rate of AEs in hospitals nationwide. The rate reported in this study might be lower than the national average, because the standard of care at the seven participating hospitals is quite high. Alternatively, the rate might be higher because the medical record documentation is accurate and detailed. It is worthy of note that, only about a quarter of the AEs were judged to have been highly preventable, probably because safety is accorded high priority in all of the seven participating hospitals.

Although we cannot extrapolate the results from this pilot study with any precision, our findings suggest that the occurrence of AEs is as serious a problem in Japan as it is in other countries. To improve patient safety in Japanese acute-care hospitals, a nationwide survey, using this methodology, is needed to fully understand the epidemiology of AEs, including the types of AEs and the contributory factors.

◆ Acknowledgements

We are indebted to the staff members of the seven participating hospitals for their cooperation. This study was supported by a scientific research grant from the Japanese Ministry of Health, Labor and Welfare.

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