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Preventable Adverse Events in Surgical Care in Sweden

A Nationwide Review of Patient Notes

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Abstract: Adverse events (AEs) occur in health care and may result in harm to patients especially in the field of surgery. Our objective was to analyze AEs in surgical patient care from a nationwide perspective and to analyze the frequency of AEs that may be preventable.

In total 19,141 randomly selected admissions in 63 Swedish hospitals were reviewed each month during 2013 using a 2-stage record review method based on the identification of predefined triggers. The subgroup of 3301 surgical admissions was analyzed. All AEs were categorized according to site, type, level of severity, and degree of preventability.

We reviewed 3301 patients' records and 507 (15.4%) were associated with AEs. A total of 62.5% of the AEs were considered probably preventable, over half contributed to prolonged hospital care or readmission, and 4.7% to permanent harm or death. Healthcare acquired infections composed of more than one third of AEs. The majority of the most serious AEs composed of healthcare acquired infections and surgical or other invasive AEs. The incidence of AEs was 13% in patients 18 to 64 years old and 17% in ≥ 65 years. Pressure sores and drug-related AEs were more common in patients being ≥ 65 years. Urinary retention and pressure sores showed the highest degree of preventability. Patients with probably preventable AEs had in median 7.1 days longer hospital stay.

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We conclude that AEs are common in surgical care and the majority are probably preventable.

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Abbreviations: AE = adverse event, ERAS = enhanced recovery after surgery, GTT = Global Trigger Tool, ICD = international classification of diseases, LOS = length of stay, RN = registered nurse, SURPASS = SURgical PATient Safety System.

INTRODUCTION

The Harvard Medical Practice study¹ in 1991 first drew attention to the problem of patients being harmed in connection with healthcare, and several nationwide studies have later shown that in-hospital adverse events (AEs) are common, especially in surgical care. In the Harvard Medical Practice study, AEs associated with general surgery were twice as common as in general medical care.¹ In Canada, the most common types of AEs were related to surgical procedures,² and in an Australian study, surgery was shown to account for half of the AEs.³ In a Swedish study (2003–2004), surgery accounted for 62% of all AEs.⁴ In studies focusing on surgical health care, AEs have been reported to occur in 5% to 14% of hospital admissions.^{5–8}

A national initiative to increase patient safety awareness was launched by the Swedish Government and The Swedish Association of Local Authorities and Regions during 2011 to 2014. As a part of this initiative, all Swedish hospitals involved in urgent care, undertook a systematic record review of patient notes to analyze the current status of AEs in healthcare in Sweden. The creation of a national database and the education of review teams were included in this initiative. Approximately, 19,000 admissions were analyzed during 2013.

As surgical healthcare seems to be more afflicted by AEs, and the number of surgical interventions is increasing, it was of interest to focus on the patients from the 19,000 admissions that represented general surgical care. The aim of the present study was to analyze the incidence and severity of AEs, to categorize and to evaluate if the AEs were preventable, and to analyze whether the panorama of AEs in patients ≥ 65 years differed from those of younger age.

METHODS

A Swedish translation and adaptation of the Global Trigger Tool (GTT) method⁹ was introduced in 2008, and is now used all over the country. The Swedish National Manual for Record Reviews¹⁰ gives detailed instructions on judgment of AEs and their preventability. According to Swedish law, every patient that suffers a preventable AE must be informed about this by the medical staff. Therefore, those working in the Swedish health-care system must take action to determine whether or not an AE

could have been prevented by doing things differently. The manual includes specific triggers for surgical care.

Definition of Adverse Events

According to the manual an AE was defined as “an unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment, hospitalization, or that resulted in death”. A hospital-acquired infection was defined as either an infection associated with previous in-hospital treatment, or an infection with an onset 48 h after hospitalization, or within 48 h after discharge from hospital. A postoperative wound infection was defined as a superficial or deep infection at the site of surgery within 30 days after the surgical procedure or within 1 year after implant surgery.

Categorization of Adverse Events

An AE was categorized, as recommended in the Swedish National Manual for Record Review, according to type in 9 main groups; hospital-acquired infection, surgical and other invasive adverse event, urinary retention (≥ 500 mL), failure in vital signs, drug-related adverse event, neurological injury, pressure sore (grade 2–4), fall, and others. The latter group included allergic reaction, hemorrhage not connected to surgery, thrombosis or emboli, skin or superficial vessel adverse event, anesthesia-related adverse event, postpartum or obstetric adverse event, and all other adverse event. An AE could only be categorized in 1 group. The choice was at the discretion of the review team. Severity of the AE was categorized in 5 groups based on the National Coordination Council for Medication Error Reporting and Prevention index.

Category E	contributed to or resulted in temporary harm and required intervention
Category F	contributed to or resulted in temporary harm requiring outpatient care, readmission or prolonged hospital care
Category G	contributed to or caused permanent patient harm
Category H	event that required lifesaving intervention required within 60 minutes
Category I	contributed to patient's death.

An AE was defined as being preventable or not using a 4-graded scale: the AE was “not preventable,” “probably not preventable,” “probably preventable,” and “preventable.”

Inclusion and Exclusions

An AE was defined as being preventable or not using a 4-graded scale: the AE was “not preventable,” “probably not preventable,” “probably preventable,” and “preventable.”

Records from patients of at least 18 years of age, with an in-hospital stay of at least 24 h throughout 2013 from 63 Swedish hospitals were eligible for inclusion in a structured record review based on the GTT method. Throughout 2013, 20 to 40 records at each hospital each month from randomly chosen admissions to various departments were reviewed. A total of 19,141 records were reviewed.

Record Review

Each hospital had its own review teams. Team members, nurses, and physicians, were all seniors, had special training in the record review method, and had an interest and knowledge in the

field of patient safety. The team members often represented different medical specialties, not necessarily including a surgeon or a surgical nurse. Pharmacists were not included in the teams.

In the first stage of the review, a registered nurse (RN) scanned the patient notes for predefined triggers and possible AEs connected to the trigger. Triggers are indicators that might show that an AE has occurred during admission. Reoperation and transfer to the intensive care unit after surgery are examples of a trigger. A maximum of 20 minutes was allowed for each record.

In the second stage, a review team consisting of the RNs, and a physician, closely scrutinized all notes that had a possible AE, to confirm any AE. When an AE was identified, it was categorized according to type and severity. Finally, the team discussed whether or not the AE could have been prevented. The physician was responsible for the final decision of all categorizations. The results from each hospital were entered into a nationwide database. The record review method did not include registration of the international classification of diseases diagnoses and thus comorbidity was not registered. There was no assessment of interrater reliability.

All cases in the national database representing general and vascular surgical care were included in the present analysis. Surgical care was defined as care on or initiated from the surgical ward. All surgical patients in the review did not undergo surgery. Some were, for example, admitted as emergency cases for observation or due to postoperative complications not requiring surgery. Whether or not the patient underwent a surgical procedure was not recorded in the protocol. During 2013, 202,413 of patients ≥ 18 years were admitted to Swedish hospitals for surgical care, of which 108,774 (54%) included a surgical intervention. Corresponding figures for patients ≥ 65 years were 52% of 102,108 admissions. We assumed that our random selection of cases was not different from the total amount of surgical patients in proportion of surgical intervention.

The average length of stay (LOS) for patients with or without AEs was noted.

Statistical Analysis

Demographic data are presented as median (range). Comparison of proportions between groups was made using the Fisher Exact Test. Confidence intervals were calculated using normal distribution approximation. A *P* value < 0.05 was considered significant. All statistical calculations were made using SPSS Version 22.

Ethical Considerations

The study was conducted in compliance of the Declaration of Helsinki (World Medical Association, 2013) and with the approval from all county council directors. The principles published in the national ethical guidelines for research were followed (SFS 2003:460).

RESULTS

Fifty-seven of the 63 hospitals performed surgical care during 2013 and a total of 3301 surgical patient records were reviewed in those hospitals using the modified GTT method (Figure 1). Seven university hospitals reviewed 338 patient records, 22 county hospitals 1643 records, and 28 district hospitals 1320 records. In total, this corresponds to 1.6% of all surgical admissions on a nationwide basis. A total of 49% of the patients were women and 51% men. The median (range) age for women was 67 (18–100) years and 69 (18–98) for men, and

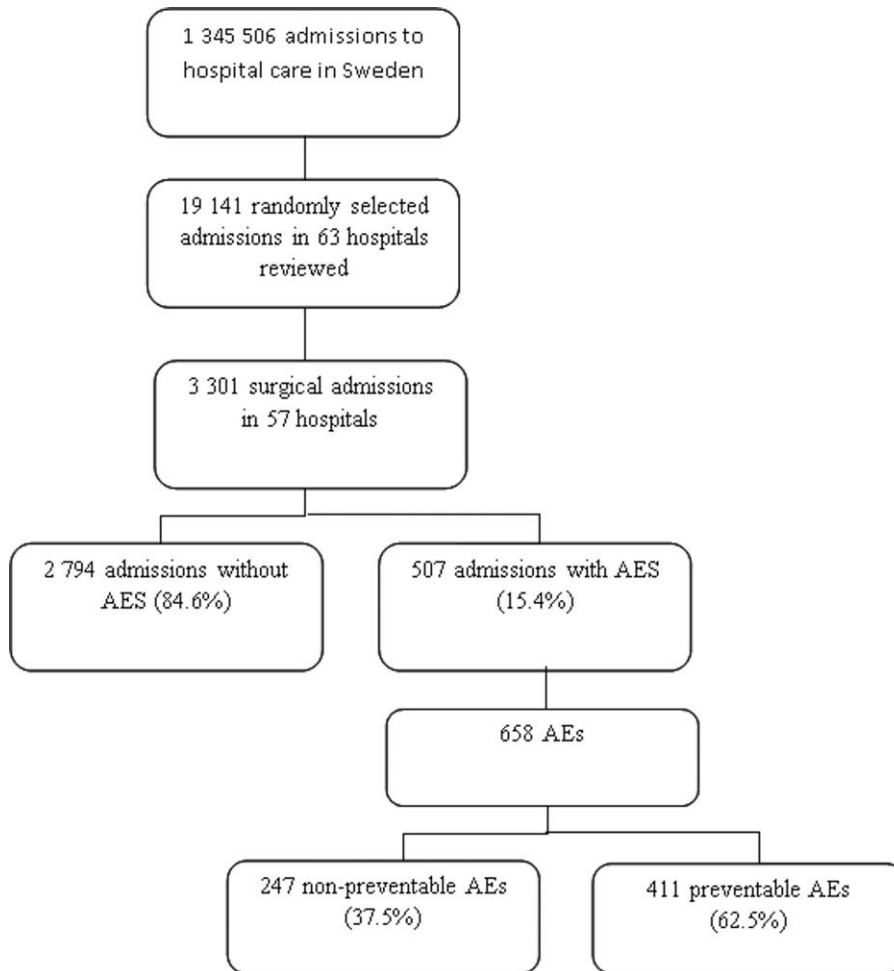


FIGURE 1. Flow chart showing the selection of reviewed records.

887 (55%) of women and 1017 (61%) of men were ≥ 65 years. Among patients < 65 years 53% were women, whereas for patients ≥ 65 years 47% were women.

Frequency of Adverse Events

One or more AEs were identified in 507 out of the 3301 patients' records (15.4%). A total of 658 AEs were identified in these 507 records and 411 of the 658 (62.5%) were classified as "probably preventable" or "preventable". The incidence of AEs was 13% among patients 18 to 64 years and 17% among those aged ≥ 65 years ($P = 0.001$). Men were significantly more often affected by an AE than women, 16.6% and 14.0% respectively ($P = 0.04$). The incidence of AEs was 14.2% among men 18–64 years and 18.25 among men ≥ 65 years ($P = 0.04$). Corresponding figures for women of different age groups were 11.5% and 16.1%, respectively ($P = 0.01$). The incidence of AEs differed between types of hospital ($P = 0.001$), and was 20.1% of patients in university, 16.4% in county, and 12.8% in district hospitals.

Type of Adverse Events

"Hospital-acquired infection" and "surgical and other invasive complication" were the most common AEs in surgical

care accounting for more than half of the admission with AEs (Table 1). Among the patients affected by AEs, patient's ≥ 65 years of age were more often affected by pressure sores and drug-related AEs, and less often by surgical complications. Women were more affected by pressure sores than men ($P = 0.03$). There was no other difference in types of AEs between men and women.

Postoperative wound infections were the most common among hospital-acquired infections (Table 2). Among these, patients < 65 years of age were more often affected by a postoperative wound infection, whereas urinary tract infections were more common in the older age group.

Among specific surgical AEs, reoperation was the most common (32%), followed by organ laceration (18%), postoperative hemorrhage or hematoma not requiring reoperation (16%). There was no difference between patients < 65 years and patients ≥ 65 years. Reoperation and organ laceration were considered to be "probably preventable" or "preventable" in 71% of cases and for postoperative hemorrhage the figure was 54%.

Severity and Preventability of Adverse Events

The least severe AEs (Categories E and F) accounted for 42.6% and 51.7%, respectively, of all AEs. The more severe

TABLE 1. Number of Admissions with Adverse Events Grouped in Types of Adverse Events in Surgical Care in Different Age Cohorts

Type of Adverse Event	All Age Groups n = 507* n (%)	18–64 Years n = 179* n (%)	≥65 Years n = 328* n (%)	P value
Hospital-acquired infection	228 (45.0)	80 (44.7)	148 (45.1)	>0.99
Surgical and other invasive adverse event	131 (25.8)	56 (31.3)	75 (22.9)	0.04
Others	90 (17.8)	30 (16.8)	60 (18.3)	0.72
Urinary retention	68 (13.4)	29 (16.2)	39 (11.9)	0.18
Drug-related adverse event	38 (7.5)	7 (3.9)	31 (9.5)	0.02
Pressure sore (grade 2–4)	31 (6.1)	2 (1.1)	29 (8.8)	<0.001
Fall	12 (2.4)	1 (0.6)	11 (3.4)	0.06
Failure in vital signs	10 (2.0)	6 (3.4)	4 (1.2)	0.18
Neurological injury	1 (0.2)	0 (0.0)	1 (0.3)	>0.99

* The total number of admissions with at least 1 adverse event. Some admissions included more than 1 adverse event.

AEs, (Categories G, H and I) accounted for 2.3%, 1.1%, and 2.4%, respectively, of AEs. Almost half of the AEs that contributed to outpatient care, readmission or prolonged hospital stay (Category F) were hospital-acquired infections. The majority of AEs in Categories G and H were surgical AEs, and in Category I hospital-acquired infections or surgical AEs. There was no difference in distribution of AEs among the Categories E–I between those aged 18 to 64 years and ≥65 years.

The majority of AEs in all severity categories were regarded as “probably preventable” or “preventable”; category E 63%, category F 63%, category G 73%, category H 71%, and category I 38%. Ninety-four percent of the pressure ulcers were regarded as “probably preventable” or “preventable”. The corresponding figure for urinary retention was 85%, for fall 83%, surgical and other invasive complication 63%, and hospital-acquired infection 59%. The number was close to 50% for the remaining AE types. Among all AEs, 8% were regarded “not preventable” and 18% “preventable”. The rest were classified as “probably not preventable” (29%) or “probably preventable” (45%).

Length of Stay

Patients without any AE had an average hospital stay of 5.7 (7.1 SD) days. For patients with non-preventable AE and patients with “probably preventable” or “preventable” AE, the corresponding average LOS was 11.0 (11.2) and 12.8 (13.5) days. The same pattern was seen for the subgroup “hospital-

acquired infection” where the mean LOS for patients with “non-preventable” AEs was 9.1 (7.5 SD) days and for “preventable” AEs 10.9 (9.4 SD) days. LOS was significantly increased in admissions of patients with an AE compared with admissions without an AE regardless of age group (Figure 2). Patient’s ≥65 years of age without an AE had a longer LOS than younger patients, but there was no difference between the 2 age groups in admissions with AEs.

DISCUSSION

This is a survey describing the panorama of AEs in surgical care including all surgical departments in Sweden, and 1 of the largest recent nationwide studies. Fifteen percent of all 3301 patients included were affected by an AE. Of the AEs, 62.5% were regarded as “probably preventable” or “preventable”. More than 50% of the AEs contributed to readmission or prolonged hospital care, 4.7% contributed to permanent harm or contributed to death. The most common AE was hospital-acquired infection, affecting more than 40% of admissions with an AE. Urinary retention and pressure sore were the AEs with the highest degree of preventability. The incidence of AEs was 13% in patients 18–64 years old and 17% in ≥65 years, pressure sores, and drug-related AEs being more common in the elderly.

Comparisons between studies dealing with AEs after surgery must be made carefully, as there are often differences in definitions, methods used to compile data, and classification of AEs. Our review was based on the Global Trigger Tool

TABLE 2. Number of Admissions with Hospital-Acquired Adverse Events Grouped on Types of Infections in Different Age Groups

Type of Hospital-Acquired Infection	All Age Groups n = 228* n (%)	18–64 Years n = 80* n (%)	≥65 Years n = 148* n (%)	P value
Postoperative wound infection	82 (36.0)	39 (48.8)	43 (29.1)	0.004
Urinary tract infection	47 (20.6)	8 (10.0)	39 (26.4)	0.003
Infection other	42 (18.4)	16 (20.0)	26 (17.6)	0.72
Pneumonia	34 (14.9)	11 (13.8)	23 (15.5)	0.85
Sepsis	30 (13.2)	9 (11.3)	21 (14.2)	0.68
Central venous line-associated infection	3 (1.3)	1 (1.3)	2 (1.4)	>0.99
Ventilator-associated pneumonia	2 (0.9)	2 (2.5)	0 (0.0)	0.12

* The total number of admissions with at least 1 adverse event. Some admissions included more than 1 adverse event.

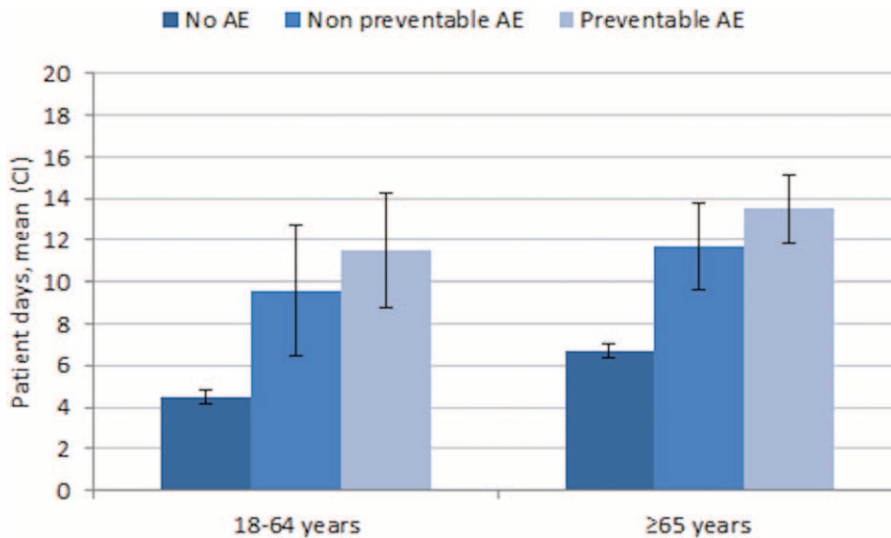


FIGURE 2. Length of stay, in 2 age groups, for admissions without an adverse event, with a “not preventable” AE and with a “preventable” AE.

methodology, and included triggers specific for surgical and intensive care. Every hospital had its own review team, as our intention was to monitor daily clinical practice. We found an AE incidence of 15.4%, which is similar to other studies.^{7,11} Anderson et al⁷ found comparable numbers of minor and fatal outcomes, 52.5% and 3.6%, respectively. Similar figures were reported by Griffin and Classen¹¹ with 14.6% of patients having an AE of which 44% caused temporary harm (Category E) and 2.9% death (Category I).

The rapid development of surgical techniques has stretched indications for surgery, and surgical interventions are increasing also in older and fragile patients. In a recent large study,¹² the frequency of harmful AEs increased with age and the AEs were predominantly infection, renal failure, and deep vein thrombosis. Our study also indicates that older patients are more often affected by AEs, although we did not find any increase in infection rate with age. Postoperative wound infections were even lower in the older age group. Instead, at age ≥ 65 years the incidence of pressure sores and drug-related AEs increased. Patients over 65 years admitted to hospital for any reason, have a 4 times higher risk of drug-related AEs than the general adult population.¹³ From our results, there seems to be an increased risk also among surgical patients. Our results indicate a lower incidence of surgical complications for those aged ≥ 65 years. This might be explained by the fact that a lower proportion of these patients underwent a surgical procedure in connection with hospitalization. A limitation in our study is that we were not able to adjust our findings to important factors like surgical intervention, comorbidities, and ongoing medication.

The most effective strategies to reduce surgical harm identified in a systematic review were the employment of surgical safety checklists and the adherence to care pathways.¹⁴ The World Health Organization “safe surgery checklist” used in the operating theatre can reduce mortality and morbidity after surgery.^{15,16} It was introduced in Sweden 2009 and has become widely spread. SURPASS (SURgical PATient Safety System), a comprehensive checklist that includes the time from decision to operate until outpatient visit after surgery, almost halved the incidence of complications and mortality after surgery.¹⁷ The

translation, adaption, and pilot testing to Swedish conditions started in 2013.

Over 40 Swedish surgical departments have since 2011 participated in the initiative “*Safe abdominal surgery*”. Every step from the decision to operate to the follow-up 3 months after discharge is evaluated, first internally and then by an external revision team that also suggest relevant changes for improvement. After 6 months, a new revision is made to make sure implementation has been successful. The importance of self-evaluation by encouraging a thorough review of objectives, practices, and outcomes for the continuous improvement of an organization has been shown in a similar national project concerning prevention of birth injuries.¹⁸

The principles of enhanced recovery after surgery (ERAS) can reduce overall complications¹⁹ and are embedded in the safe abdominal surgery project. Initiatives to stop smoking before surgery^{20,21} are ongoing and the effects of alcohol cessation²² are gaining interest.

Our study has several limitations. It only presents AEs identified among hospitalized surgical patients. Ambulatory surgical AEs were not included. The results are not risk adjusted. It is most probable that the higher incidence of AEs at the university hospital is influenced by a higher proportion of severely ill patients and another panorama of surgical procedures. The categorization of AEs used in this review followed the recommendation in the Swedish National Manual for Record Review that was intended for all types of hospital admissions using the same method of assessment. In the field of surgery other categorization systems exist that address surgical AEs in general²³ or by subspecialty.²⁴ Not all review teams included a surgeon or surgical nurse. As in all retrospective record review studies, AEs that were not documented in the notes could not be detected, but the ones that led to a consequence will have been detected in this study.

Surgical AEs have a significant negative effect on post-operative quality-of-life and in some cases this effect persists for several years.²⁵ Efforts to improve patient safety must be intensified and target the leading causes of patient harm.

Hospital-acquired infections were those most common in our study. Another recent study identified almost 40% of surgical AEs as being infections.⁸ According to our protocol an infection with onset after 48 hours hospitalization was characterized as a hospital-acquired infection. It can be questioned if, for example, an abscess after emergency surgery for colonic perforation should be characterized as hospital-acquired infection. Anderson et al found that non-operative errors were more frequent than errors in surgical technique.⁷ Non-operative AEs included errors in monitoring, treatment, and diagnostic procedures. In another study, focusing on risk assessment on the surgical ward²⁶ the 5 most hazardous processes were found to be: hand hygiene; isolation of infections; measuring, recording, interpreting and responding to vital signs; medication delivery; and transmission of information when handing over.

We estimated that more than 60% of AEs were “probably preventable” or “preventable”, which is high. This was also found in other recent studies indicating 30% to 40% of AEs as being “preventable”.^{7,8} Seventy percent of the AEs in our study, however, were graded as “probably preventable” or “probably not preventable”, which illustrates the difficulties in strict assessing AEs in a retrospective survey of patients notes. More than 1 of 10 patients affected by an AE suffered from urinary retention. Our definition, ≥ 500 mL, might have been too wide. Joelsson-Alm et al²⁷ found late detection of urinary retention to be the most common AE in orthopedic healthcare. A high number of patients that have suffered bladder distension reported a lifetime of urinary, psychosocial, and emotional problems.²⁸ Actions taken to prevent this very preventable AE must therefore be considered important.

AEs are associated with an increase in LOS and thereby cost.^{29,30} In a prospectively compiled study from a single tertiary hospital in the US, report a shorter LOS for patients with an AE in those over 70-year-of-age.¹² This might be explained by less aggressive care, appropriate and timely end of life decisions, or discharge to other facilities outside the hospital. We found no difference in the increase in LOS in patients affected by an AE between the 2 age groups.

In conclusion, in one of the largest recent nationwide studies covering all surgical departments, we have found that AEs are common in surgical care and the majority of events are probably preventable. Older patients seem more vulnerable and preventing drug-related adverse events is important among these patients.

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