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National implementation of a trigger tool and a review of 65 000 hospital admissions in Sweden from 2013–2016.

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Abstract

Objectives: To describe the implementation of a trigger tool in Sweden and present the national incidence of adverse events (AEs) over a 4-year period during which an ongoing national patient safety initiative was terminated.

Design: Cohort study using retrospective record review based on a trigger tool methodology.

Setting and participants: Patients ≥18 years admitted to all somatic acute care hospitals in Sweden from 2013–2016 were randomised into the study.

Primary and secondary outcome measures: Primary outcome measure was the incidence of AEs, and secondary measures were type of injury, severity of harm, preventability of AEs, estimated healthcare cost of AEs and incidence of AEs in patients cared for in another type of unit than the one specialised for their medical needs ('off-site').

Results: In a review of 64 917 admissions, the average AE rates in 2014 (11.6%), 2015 (10.9%) and 2016 (11.4%) were significantly lower than in 2013 (13.1%). The decrease in the AE rates was seen in different age groups, in both genders and for preventable and non-preventable AEs. The decrease comprised only the least severe AEs. The types of AEs that decreased were hospital-acquired infections, urinary bladder distention and compromised vital signs. Patients cared for 'off-site' had 84% more preventable AEs than patients cared for in the appropriate units. The cost of increased length of stay associated with preventable AEs corresponded to 13–14% of the total cost of somatic hospital care in Sweden.

Conclusions: The rate of AEs in Swedish somatic hospitals has decreased from 2013 to 2016. Retrospective record review can be used to monitor patient safety over time, to assess the effects of national patient safety interventions and analyse challenges to patient safety such as the increasing care of patients 'off-site'. It was found that the economic burden of preventable AEs is high.

Keywords: Adverse event, Patient harm, Patient safety, Trigger tool

Strengths and limitations of this study

- The study includes all somatic acute care hospitals in Sweden, except for paediatric units.
- This is a longitudinal study over a 4-year period during which an ongoing national patient safety initiative was terminated.
- An estimation of the economic cost for prolonged hospital stay due to preventable AEs was undertaken.
- The trigger tool and the national database were adaptive to new triggers and trends in healthcare, thus showing the ability to evaluate new patient safety risks.
- Inherent weaknesses in a retrospective record review are poor documentation quality and the risk of hindsight bias.

Funding statement

This work was supported by the Swedish Association of Local Authorities and Regions by creating and hosting a national database for the reporting of data from the record reviews.

Competing interests

The authors declare that they have no competing interests.

Author's contribution

LN, MB-R, MS, UN, CÅ and HR designed and conducted the study. MB-R statistically analysed the data. HR, UN and CÅ undertook the initial interpretation of the data, which was followed by discussions with all the authors. LN and HR drafted the initial version of the manuscript, which was followed by a critical revision process of the intellectual content involving all the authors. All the authors agreed to the final version of the manuscript before submission. All authors agreed to be accountable for the accuracy of any part of the work.

Data sharing statement

No additional data are available.

Introduction

Retrospective medical record review (RRR) is an established and validated method to identify adverse events (AEs).[1-4] The method gives an overview of the incidence, nature, preventability and consequences of AEs. This information can be used in systematic quality improvement work to reduce the incidence of AEs. RRR is superior to clinical incident reporting systems for detecting AEs.[3] A list of criteria (triggers) that indicate a higher probability of AEs may be used to identify details in the record that indicate the presence of AEs. The Institute for Healthcare Improvement (IHI) in the US combined topic- and location-specific trigger tools into one Global Trigger Tool (GTT),[5] which is one of the most commonly used trigger tools. Translated and adapted versions of the GTT are available in, for example, Sweden, Denmark, Norway, Germany, Italy and the UK. Although GTT is considered relevant for measuring AEs at the national level, to the best of our knowledge, only Norway and Sweden have used the methodology for this purpose.[6,7]

The present study describes the implementation of a trigger tool in Sweden, including the development of a national database that covers reviews from all acute care hospitals save for paediatric and psychiatric care. We also present the national yearly incidence of AEs over a 4-year period (2013–2016) and estimate the cost of preventable AEs.

Methods

Implementation of the Swedish trigger tool

The first national handbook for record review was published in 2008. It was based on the IHI-GTT version 2007, which was translated and adapted to a Swedish context. The Swedish handbook included a six-graded preventability scale used in a national survey on AEs initiated by The National Board of Health and Welfare.[8] The trigger tool methodology gradually spread over the country, and in 2011, hospitals in approximately half of the country's 21 regions used the method.

In 2012, a national group of experienced reviewers, in collaboration with a reference group of reviewers, patient safety experts and researchers in the trigger tool field, revised the national handbook.[9] The work was initiated and financed by the Swedish Association of Local Authorities and Regions (SALAR) as part of a national patient safety initiative. The number of triggers was reduced from 53 to 44 based on the fact that the removed triggers seldom pointed to AEs or were not possible to identify in the review. Others were merged together

and renamed. Ten new triggers were added based on local review teams' findings and research pointing to these common AEs. An example of a new trigger added was urinary bladder distension.[10,11] Review teams were educated in all regions in a coordinated effort within a national patient safety initiative, which promoted and financially rewarded record review. This contributed to the rapid use of the method by all somatic acute care hospitals.

National patient safety initiative and database

Launched by the Swedish government and SALAR, a national initiative to increase patient safety took place from 2011–2014. The initiative involved financial incentives and included, among other things, safer use of drugs, prevention of resistance to antibiotics, reduction of hospital-acquired infections and measurement of the patient safety culture. As a result of the national initiative, by 2013, all somatic hospitals involved in acute care (n=63) undertook monthly reviews of patient records to determine the rate and nature of AEs. A database was developed by SALAR in 2012, and in this database, the review results from each hospital were entered. These included hospital type, medical speciality, the patient's gender, age and length of hospital stay and the type, severity and preventability of AEs. The monthly reviews continued after the termination of the national patient safety initiative in December 2014, and by December 2016, the database included almost 65 000 admissions.

The database was expanded in 2015 to include information on risk factors for AEs, such as acute admission, surgical intervention and care provided in another type of unit other than the one specialised for the patient's medical needs ('off-site').

Inclusion criteria and sampling

From 2013–2014, the minimum monthly number of randomly selected admissions reviewed was 40 for university hospitals, 30 for the central county council hospitals and 20 for the county hospitals. In 2015, the number of reviewed records was reduced by 50%. Somatic hospital admissions from patients aged 18 years or older with a hospital stay of at least 24 hours were eligible for inclusion. All records from the whole period of hospitalisation were reviewed, which sometimes included more than one type of department.

Review process

Each hospital had its own review team. The review teams consisted of one or two nurses and at least one physician. All team members were senior level, 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.

A nurse first screened the records for the presence of triggers and possible AEs. In the second review stage, the team assessed the occurrence of AEs. All AEs were categorised according to type, severity and preventability using the national handbook. The physician made the final decisions. There was no assessment of interrater reliability.

Categorisation of adverse events

An AE was defined as an unintended physical injury resulting from or contributed to by medical care that required additional monitoring, treatment or hospitalisation or that resulted in death. An AE was categorised into one of 16 different types (Table 3). A hospital-acquired infection was defined as either an infection associated with previous in-hospital treatment or an infection occurring 48 hours after hospitalisation or within 48 hours after discharge from the hospital. Each AE could only be categorised into one type.

AEs were categorised into one of five severity categories, per 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 within 60 minutes and Category I: contributed to the patient's death.

An AE was categorised as being preventable or not by using a graded scale of four options: 1. The AE was 'not preventable'; 2. 'probably not preventable'; 3. 'probably preventable'; and 4. 'certainly preventable'. The handbook gives detailed instructions concerning the difficult assessment of preventability (Supplementary table S1). AEs categorised as 1 and 2 are denoted as non-preventable, and AEs categorised as 3 and 4 are denoted as preventable in the following text and figures.

Ethics

The study was conducted in compliance of the Declaration of Helsinki (World Medical Association, 2013), and because it was a part of quality improvement initiatives in the hospitals, an approval from an ethical committee was not necessary. The principles published in the national ethical guidelines for research were followed (SFS 2003:460). Names and personal identification numbers were not collected or entered into the database.

Statistics

Data are presented as number (percent), median (range), mean (SD) or mean (95% CI). A comparison of the proportions between two groups was made by chi-squared test. Confidence intervals were calculated using a normal distribution approximation. A p-value <0.05 was considered significant. All statistical calculations were made using SPSS Version 22, IBM, New York, United States.

Results

Results of GTT 2013–2016

A total of 64 917 admissions were reviewed in 59–63 hospitals during the years 2013–2016. The number of hospitals decreased over the period because two of the hospitals stopped reviewing, and two merged with another hospital (Table 1). From the beginning of 2013 to the middle of 2015, there was a continuous decline in the average monthly rates of admissions with AEs and preventable AEs (Figure 1). During the second half of 2015, the rates of AEs increased slightly and subsequently stabilised.

The proportion of admissions with preventable AEs decreased significantly between 2013 and the years 2014, 2015 and 2016, respectively. No significant differences were seen between the other years (Table 1).

The decrease in the AE rate can largely be attributed to a reduction in the least severe AEs (Category E) (Table 2). The types of AEs that decreased significantly were hospital-acquired infections, urinary bladder distention, compromised vital signs and ‘other’ (Table 3). The latter group included allergic reaction, haemorrhage not related to surgery, venous thrombosis or pulmonary embolus, superficial blood vessel or skin harm, anaesthetic-related AE and any other AE. Among the hospital-acquired infections, there were significant reductions in the rate of admissions with pneumonia, ventilator-associated pneumonia and ‘other infections’.

When aggregating data for the years 2013–2016, 11.4% of the AEs were categorised as 'not preventable', 27.2% as 'probably not preventable', 39.4% as 'probably preventable', and 22.0% as 'certainly preventable'. Consequently, 66.6% of the AEs were judged to be preventable (probably and certainly preventable). The types of AEs considered most preventable were pressure ulcer (91%) and urinary bladder distention (88%). The corresponding preventability rates were for hospital-acquired infections (60%), fall injuries (60%), AEs caused by surgery or invasive procedures (56%), 'other' (54%), drug-related AE (46%), compromised vital signs (41%), neurological AE (38%) and postpartum or obstetric AE (41%).

AEs were more common in patients aged 65 years or older than in patients 18–64 years of age (p=0.00). The number of admissions with AEs decreased between 2013 and 2016 in the younger (P=0.02) and older patient groups (p=0.00) (Figure 2). The reductions were significant also for the 'preventable AEs' (younger p=0.05, older p=0.00).

When aggregating data for the years 2013–2016, men had a significantly higher rate of admissions with AEs than women (12.5% vs. 11.5%, p=0.00). Men had significantly higher rates of hospital-acquired infections and urinary bladder distention.

Aggregated data for 2015–2016 showed that the incidence of preventable AEs was almost 100% higher in patients who had undergone surgery or another invasive procedure (n=9584; p=0.00) and approximately 84% higher in patients treated in another unit than the unit specialised to their medical needs ('off-site') (n=984; p=0.00). No difference in AE rates was found between acute and planned admissions (p=0.72) (Figure 3).

Acute admissions were more common in males compared to women (80.5% vs. 78.5%, p=0.001) and in patients aged 65 years or older compared to patients under 65 years of age (82.2% vs. 73.7%, p=0.00). The proportion of admissions where the patient underwent surgery or another invasive procedure did not differ between the genders. In patients who had surgery, the rate of AEs was higher in acute admissions than in planned admissions (19.1% vs. 13.1%, p=0.00).

The proportion of patients cared for 'off-site' increased from 3.1% in 2015 to 4.5% in 2016 (p=0.00). Patients aged 65 years or older were more often treated 'off-site' than younger patients (4.1% vs. 3.1%, p=0.00). No differences related to gender were observed. The most common type of AEs in patients cared for 'off-site' were hospital-acquired infections (36.0%) and 'other' (19.8%), which includes skin injury, superficial vessel injury and vein thrombosis or pulmonary embolism.

The mean (SD) length of hospital stay (LOS) in aggregated data for 2013–2016 was 7.1 (8.1) days. LOS for the admissions without AEs was 6.2 (6.6) days while admissions with preventable AEs was 14.2 (14.5) days. A significantly longer LOS in patients with AEs was seen in both age groups of both men and women (Figure 4). The LOS was significantly longer in older patients (≥65 years) than in younger (18–64 years) both for patients with and without AEs.

The mean difference in LOS between hospital stays without AEs and those with preventable AEs was 8 days. The average incidence of preventable AEs (2013–2016) was 8%, and the average number of hospital admissions per year was almost 1.4 million. Accordingly, it can be estimated that preventable AEs affected some 110 000 hospital admissions per year and were associated with 880 000 extra days of hospitalisation. With the mean cost for 1 day of hospitalisation being approximately 10 000 SEK, the annual cost for preventable AEs can be estimated at 880 million euros. This corresponds to approximately 13–14% of the total cost of adult somatic hospital care in Sweden. During 2015 and 2016, approximately 13 000 records were reviewed yearly. The estimated annual total cost for record review was 0.4–0.5 million euros.

National feedback of the results based on GTT

Regular yearly reports from SALAR described the development of AE rates on an aggregated national level. Also, specific reports for surgical care,[12] orthopaedic care,[13] obstetrics and gynaecology[14] and hospital-acquired infections[15] were published. The mapping of AEs is an important basis for improvement work. In 2016, SALAR published an inventory of all patient safety initiatives undertaken by hospitals or departments based on the record review findings. The prominent areas for the 268 different improvement initiatives were pressure ulcers, education of patient safety experts, falls, healthcare-associated infections, urinary bladder distension, surgical harm and compromised vital signs.

Discussion

From our nationwide review of almost 65 000 randomly selected admissions to acute care hospitals, we have shown there was a reduction in the rate of AEs between 2013 and 2014, 2015 and 2016, respectively. However, a gradual decrease in the rate of admissions with AEs was seen from 2013 until mid-2015; thereafter, the AE rate rose to, and stabilised at, a slightly higher level. The initial gradual decrease in AE rate could reflect the focus on patient safety promoted by the national patient safety initiative. The decrease in the rate of AEs continued 6 months after the termination of the initiative (2014), which may indicate that the effect of the 4-year long initiative persisted for a short period after it was terminated. The subsequent broken trend after the termination of the patient safety initiative may reflect the hospital leadership shifting their focus and a subsequent decrease in the efforts to reduce the rate of AEs. Conceivably, other factors not related to the initiative may have influenced the trends seen in the AE rates. The higher proportion of patients treated 'off-site' 2016 compared to 2015 might explain to some extent the increase in the rates of AEs.

The study has some strengths. To our knowledge, the current study is the largest published trigger tool study, including all somatic acute hospitals in Sweden, save for paediatric and psychiatric care. Also, the current study covers a substantial period of time. The revision of the trigger tool made it possible to add triggers found to indicate AEs that were not included in the initial IHI tool, for example, urinary bladder distension, and the national database enabled a continuous systematic, but also flexible, collection of data because we were able to add administrative data that enabled the detection of safety risks connected to trends in healthcare, for example, increasing 'off-site' care. The trigger tool has high specificity, high reliability, is more sensitive than other methods,[16,17] and large-scale implementations of the GTT including modifications have been successful in other studies.[6,18,19]

In retrospective record review studies, a potential weakness is poor documentation quality, which means only documented AEs can be identified. Another weakness is the risk of hindsight bias when assessing the preventability of AEs. Two-thirds of the AEs were classified as 'probably preventable' or 'probably not preventable', which illustrates the difficulty in determining for certain if the AEs could have been prevented. The number of reviewed admissions from university hospitals, central county council hospitals and small hospitals does not fully reflect the true proportion of admissions to these hospital categories. Because the rates of AEs differ between hospital types, this must be taken into account when estimating the true national average rate of AEs. When doing so, the national rates of AEs presented in this paper increase by approximately 10%.

We have demonstrated an increased rate of AEs in patients cared for in another type of unit other than the one specialised for their medical needs. The main reason why patients are cared for ‘off-site’ is a shortage of available beds due to lack of nurses. Actions need to be taken to reduce the number of ‘off-site’ patients.

As shown earlier,[20] a hospital-acquired infection is the most common type of AE, and its incidence fell during the study period. Evidence-based programs to prevent central venous catheter-associated infections, postoperative wound infections and urinary tract infections were promoted nationally during the study period. This was carried out by conducting a continuous follow-up on compliance to basic hygiene rules and dress code on a department level. Conceivably, the promotion of measures to reduce the incidence of hospital-acquired infections during the patient safety initiative was successful and resulted in a reduction of infection rates.

Urinary bladder distention was most often regarded as preventable, and the rates decreased over time. This could in part be because of the use of a stricter definition after 2013, but this problem was extensively addressed by physicians as well as nursing organisations. The decrease in the rates of compromised vital signs could reflect an increased use of vital sign checks, such as the modified early warning score (MEWS)[21] and rapid response teams.[22]

The higher incidence of AEs found among men can partly be attributed to their higher rates of hospital-acquired infections and urinary bladder distension. The reason behind the former remains to be explained. Another explanation is that the present study included gynaecology and obstetrics, where AE rates are lower than in other medical disciplines.[23]

The suffering associated with patient harm for the patients, relatives and involved personnel is high but cannot easily be quantified. There is also an economic burden associated with patient harm, both on healthcare and society. The golden standard to estimate the financial cost of AEs for healthcare is considered to be retrospective record review.[24] Our estimate, based solely on the costs of prolonged LOS, is in line with a recent report that suggested that 15% of hospital expenditures in Organisation for Economic Co-operation and Development (OECD) countries relate to AEs.[25] These entail additional treatment and diagnostic procedures, (re)admission to hospital and a prolonged hospital stay. In line with our finding, the OECD report estimated that 6–8 additional days are spent in the hospital for patients having an AE.[23] With a longer LOS, it is probable that patients are more exposed to AEs. However, our group has previously shown that AEs most often occur early during the hospital stay or cause the hospitalisation.[26] The OECD report[25] emphasises that the costs for preventive actions are substantially lower than the costs of AEs.

To our knowledge, Norway is the only country that so forth has evaluated the effect of a national patient safety initiative using monthly assessments of AE rates based on GTT. Accordingly, some 40 000 hospital admissions were reviewed during the Norwegian patient safety campaign, and AE rates decreased from 16.1% (2011) to 13.0% (2013).[6] The rates and types of AEs in Norway and Sweden in 2013 have been shown to be similar.[7]

In conclusion, AE rates in Swedish somatic acute care hospitals decreased between 2013 and 2014, 2015 and 2016, respectively. Retrospective record review is a useful method to monitor patient safety over time and to assess the effects of national patient safety interventions. Off-site care of patients is becoming more common. This increases the incidence of AEs and is a challenge to patient safety. The economic burden of preventable AEs is high.

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Table 1. The number of hospitals and admissions, demographics and the proportion of admissions with adverse events and preventable adverse events

	2013	2014	2015	2016
Number of hospitals	63	63	62	59
Number of admissions	19 927	18 629	13 771	12 590
Age (median (range)), years	71 (18-105)	71 (18-109)	71 (18-108)	72 (18-105)
Men, percent	46,8	46,0	47,1	48,0
Admissions with AEs, percent (95%CI)	13.1 (12.7-13.6)[a]	11.6 (11.2-12.1)[a]	10.9 (10.4-11.4)[a]	11.4 (10.9-12.0)[a]
Admissions with preventable AEs, percent (95%CI)	8.7 (8.3-9.1)[a]	7.4 (7.1-7.8)[a]	7.0 (6.6-7.4)[a]	7.2 (6.7-7.6)[a]

AE: adverse event; CI: 95% confidence interval; [a]significant differences compared to 2013

Table 2. Proportion (percent (95%CI)) of admissions with adverse events classified according to severity

	2013	2014	2015	2016
Severity				
E: contributed to or resulted in temporary harm and required intervention	7.4 (7.0-7.8)	6.1 (5.7-6.4)[a]	5.5 (5.1-5.9)[a]	6.0 (5.6-6.4)[a]
F: contributed to or resulted in temporary harm requiring outpatient care, readmission or prolonged hospital care	6.1 (5.8-6.5)	5.8 (5.5-6.2)	5.7 (5.4-6.1)	5.8 (5.4-6.2)
G: contributed to or caused permanent patient harm	0.4 (0.3-0.5)	0.3 (0.2-0.4)	0.3 (0.2-0.4)	0.4 (0.3-0.5)
H: event that required lifesaving intervention required within 60 minutes	0.1 (0.1-0.1)	0.1 (0.0-0.1)	0.1 (0.1-0.2)	0.1 (0.0-0.2)
I: contributed to the patient's death	0.3 (0.2-0.4)	0.2 (0.2-0.3)	0.2 (0.2-0.3)	0.2 (0.2-0.3)

AE: adverse event; CI: 95% confidence interval; [a]significant differences compared to 2013.

Table 3. Proportion (percent (95 % CI)) of admissions with adverse events classified according to type

	2013	2014	2015	2016
Type				
Hospital-acquired infection	5.2 (4.9-5.5)	4.6 (4.3-4.9)[a]	4.5 (4.1-4.8)[a]	4.3 (4.0-4.7)[a]
Infection other	1.4 (1.2-1.6)	1.0 (0.8-1.1)[a]	1.1 (0.9-1.3)	0.9 (0.8-1.1)[a]
Urinary tract infection	1.4 (1.3-1.6)	1.5 (1.4-1.7)	1.3 (1.1-1.5)	1.3 (1.1-1.5)
Postoperative wound infection	1.2 (1.1-1.4)	1.2 (1.0-1.3)	1.1 (0.9-1.2)	1.1 (0.9-1.3)
Pneumonia	0.7 (0.6-0.8)	0.5 (0.4-0.6)[a]	0.5 (0.4-0.6)[a]	0.5 (0.4-0.6)[a]
Sepsis	0.5 (0.4-0.6)	0.3 (0.3-0.4)[a]	0.4 (0.3-0.6)	0.5 (0.4-0.6)
Central venous line infection	0.2 (0.1-0.2)	0.1 (0.0-0.1)	0.1 (0.0-0.1)	0.1 (0.0-0.2)
Ventilator associated pneumonia	0.1 (0.1-0.2)	0.0 (0.0-0.1)[a]	0.1 (0.0-0.1)	0,1 (0,0-0.1)[a]
Clostridium difficile infection	-	0.3 (0.2-0.3)	0.3 (0.2-0.3)	0.3 (0.2-0.3)
Other	2.7 (2.5-3.0)	2.4 (2.2-2.7)	2.0 (1.8-2.3)[a]	2.2 (2.0-2.5)[a]
AEs caused by surgery/invasive procedures	1.9 (1.7-2.1)	1.8 (1.6-2.0)	1.8 (1.6-2.0)	1.6 (1.4-1.8)
Urinary bladder distention	1.7 (1.5-1.9)	1.0 (0.9-1.2)[a]	1.0 (0.9-1.2)[a]	1.1 (0.9-1.3)[a]
Drug-related AE	1.4 (1.3-1.6)	1.4 (1.2-1.6)	1.3 (1.1-1.5)	1.5 (1.3-1.7)
Pressure ulcer (grade 2-4)	1.1 (1.0-1.3)	1.0 (0.9-1.1)	1.2 (1.0-1.4)	1.3 (1.1-1.5)
Fall injury	0.8 (0.7-0.9)	0.9 (0.7-1.0)	0.7 (0.5-0.8)	0.7 (0.6-0.9)
Compromised vital signs	0.5 (0.4-0.6)	0.3 (0.2-0.3)[a]	0.3 (0.2-0.4)	0.2 (0.1-0.2)[a]
Postpartum or obstetric AE*	0.2 (0.2-0.3)	0.2 (0.2-0.3)	0.1 (0.1-0.2)[a]	0.3 (0.2-0.4)
Neurological AE	0.1 (0.1-0.2)	0.0 (0.0-0.1)	0.1 (0.0-0.1)	0.1 (0.1-0.2)

AE: adverse event; CI: 95% confidence interval; *not corrected for the proportion of women in the studied population; [a]significant differences compared to 2013.

Figure 1. The proportion of admissions with adverse events (AEs) every month from 2013–2016.

Figure 2. Proportion of admissions with preventable and non-preventable adverse events (AEs) in younger and older patients from 2013–2016.

Figure 3. The proportion of admissions with preventable and non-preventable adverse events (AEs) in patients with acute admissions, patients who underwent surgery and patients treated 'off-site' from 2015–2016

Figure 4. Length of stay (mean, 95% CI) in two age groups of men and women for admissions without adverse events, with non-preventable adverse events and with preventable adverse events from 2013–2016.

Table S1. Example of a trigger, its definition and clarifying text.

Deep vein thrombosis or pulmonary embolism

Definition	**Deep vein thrombosis or pulmonary embolism diagnosed during hospital care and not apparent on admission**
Check for	Venous catheter (central venous catheter, subcutaneous venous port, etc.), recent surgery, immobilisation, obesity, cancer or cancer treatment increases the risk. Has thrombosis prophylaxis been given according to routines?
Harm that can be found	Transient or permanent reduction of cardiac or pulmonary function, reduced venous circulation in the lower extremities with oedema and reduced function
Preventability	Deep vein thrombosis should be regarded as preventable if: Prophylaxis against thrombosis has not been given according to routines. Increased risk following immobilisation has not been considered, for example, after surgery. Anticoagulation therapy (e.g., warfarin) has not been adequately controlled. Pulmonary embolus should also be regarded as avoidable if signs of deep vein thrombosis have not been adequately observed and treated.
Relevant codes for diagnosis, treatment and medication	ICD-10-code: I82 (Embolus and thrombosis) I26 (Pulmonary embolus) O88.2 (Obstetric embolus due to thrombosis)
Results associated to this trigger	Results from investigation with ultrasound, CT or phlebography. Results from pulmonary scintigraphy (ventilation and perfusion scintigraphy).

Figure 1. The proportion of admissions with adverse events (AEs) every month from 2013–2016.

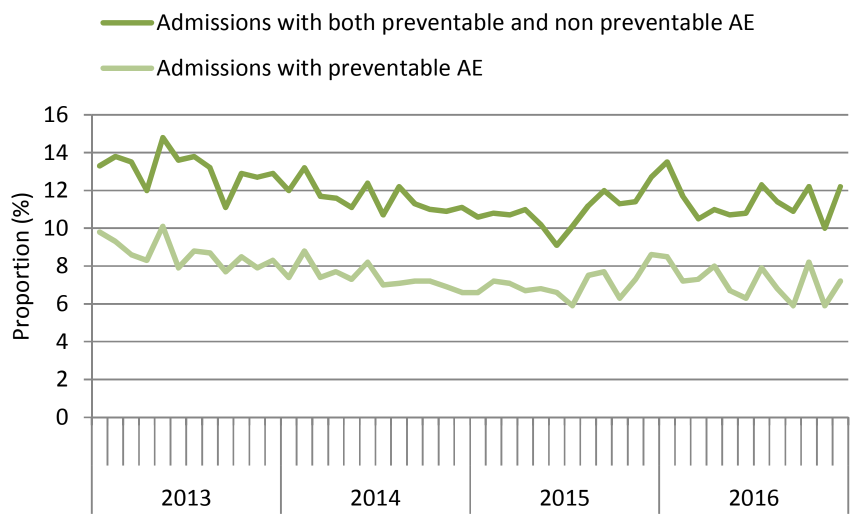

Figure 2. Proportion of admissions with preventable and non-preventable adverse events (AEs) in younger and older patients from 2013–2016.

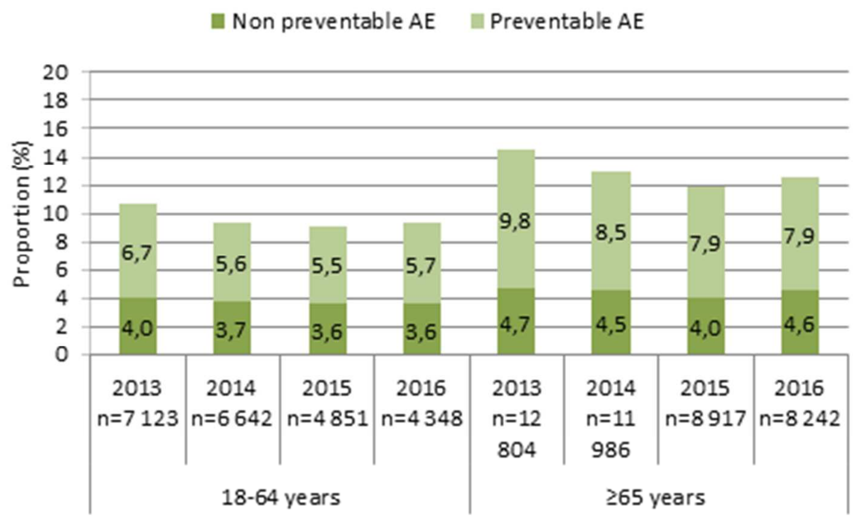

Figure 3. The proportion of admissions with preventable and non-preventable adverse events (AEs) in patients with acute admissions, patients who underwent surgery and patients treated 'off-site' from 2015–2016

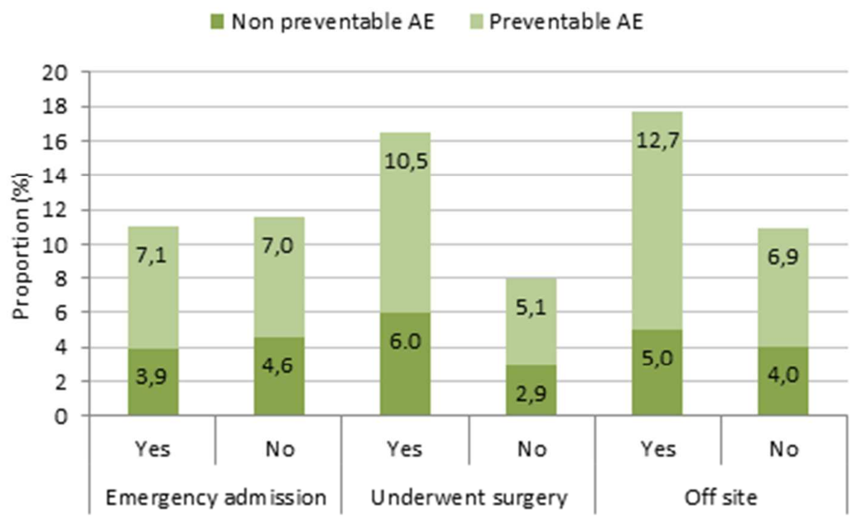

Figure 4. Length of stay (mean, 95% CI) in two age groups of men and women for admissions without adverse events, with non-preventable adverse events and with preventable adverse events from 2013–2016.

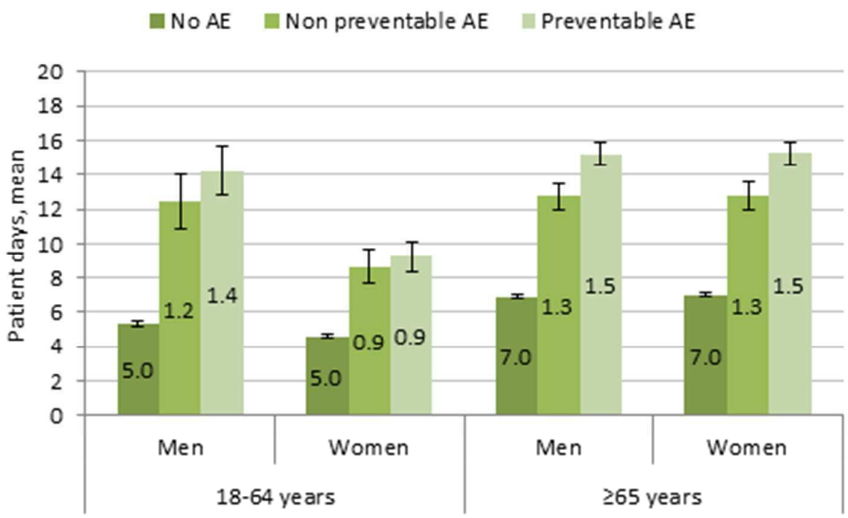

Table S1. Example of a trigger, its definition and clarifying text.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	#1, #2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	#2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	#4
Objectives	3	State specific objectives, including any prespecified hypotheses	#4
Methods			
Study design	4	Present key elements of study design early in the paper	#5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	#4-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	#5-6
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	#6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	#6
Bias	9	Describe any efforts to address potential sources of bias	#6
Study size	10	Explain how the study size was arrived at	#5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	#7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	#7
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) If applicable, explain how loss to follow-up was addressed	NA
		(*e*) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	#7
		(c) Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	Report numbers of outcome events or summary measures over time	NA
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	#7-9
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	#9
Discussion			
Key results	18	Summarise key results with reference to study objectives	#10
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	#10-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	#12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	#3

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Adverse events in Sweden during 2013–2016 - implementation of a national trigger tool and a review of 65 000 hospital admissions.

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Secondary Subject Heading:	Epidemiology
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Adverse events in Sweden during 2013–2016 - implementation of a national trigger tool and a review of 65 000 hospital admissions.

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Word count: 3211

Abstract

Objectives: To describe the implementation of a trigger tool in Sweden and present the national incidence of adverse events (AEs) over a 4-year period during which an ongoing national patient safety initiative was terminated.

Design: Cohort study using retrospective record review based on a trigger tool methodology.

Setting and participants: Patients ≥18 years admitted to all somatic acute care hospitals in Sweden from 2013–2016 were randomised into the study.

Primary and secondary outcome measures: Primary outcome measure was the incidence of AEs, and secondary measures were type of injury, severity of harm, preventability of AEs, estimated healthcare cost of AEs and incidence of AEs in patients cared for in another type of unit than the one specialised for their medical needs ('off-site').

Results: In a review of 64 917 admissions, the average AE rates in 2014 (11.6%), 2015 (10.9%) and 2016 (11.4%) were significantly lower than in 2013 (13.1%). The decrease in the AE rates was seen in different age groups, in both genders and for preventable and non-preventable AEs. The decrease comprised only the least severe AEs. The types of AEs that decreased were hospital-acquired infections, urinary bladder distention and compromised vital signs. Patients cared for 'off-site' had 84% more preventable AEs than patients cared for in the appropriate units. The cost of increased length of stay associated with preventable AEs corresponded to 13–14% of the total cost of somatic hospital care in Sweden.

Conclusions: The rate of AEs in Swedish somatic hospitals has decreased from 2013 to 2016. Retrospective record review can be used to monitor patient safety over time, to assess the effects of national patient safety interventions and analyse challenges to patient safety such as the increasing care of patients 'off-site'. It was found that the economic burden of preventable AEs is high.

Keywords: Adverse event, Patient harm, Patient safety, Trigger tool

Strengths and limitations of this study

- The study includes all somatic acute care hospitals in Sweden, except for paediatric units.
- This is a longitudinal study over a 4-year period during which an ongoing national patient safety initiative was terminated.
- An estimation of the economic cost for prolonged hospital stay due to preventable AEs was undertaken.
- The trigger tool and the national database were adaptive to new triggers and trends in healthcare, thus showing the ability to evaluate new patient safety risks.
- Inherent weaknesses in a retrospective record review are poor documentation quality and the risk of hindsight bias.

Funding statement

This work was supported by the Swedish Association of Local Authorities and Regions by creating and hosting a national database for the reporting of data from the record reviews.

Competing interests

The authors declare that they have no competing interests.

Author's contribution

LN, MB-R, MS, UN, CÅ and HR designed and conducted the study. MB-R statistically analysed the data. HR, UN and CÅ undertook the initial interpretation of the data, which was followed by discussions with all the authors. LN and HR drafted the initial version of the manuscript, which was followed by a critical revision process of the intellectual content involving all the authors. All the authors agreed to the final version of the manuscript before submission. All authors agreed to be accountable for the accuracy of any part of the work.

Data sharing statement

No additional data are available.

Introduction

Retrospective medical record review (RRR) is an established and validated method to identify adverse events (AEs).[1-4] The method gives an overview of the incidence, nature, preventability and consequences of AEs. This information can be used in systematic quality improvement work to reduce the incidence of AEs. RRR is superior to clinical incident reporting systems for detecting AEs.[3] A list of criteria (triggers) that indicate a higher probability of AEs may be used to identify details in the record that indicate the presence of AEs. The Institute for Healthcare Improvement (IHI) in the US combined topic- and location-specific trigger tools into one Global Trigger Tool (GTT),[5] which is one of the most commonly used trigger tools. Translated and adapted versions of the GTT are available in, for example, Sweden, Denmark, Norway, Germany, Italy and the UK. Although GTT is considered relevant for measuring AEs at the national level, to the best of our knowledge, only Norway and Sweden have used the methodology for this purpose.[6,7]

The present study describes the implementation of a trigger tool in Sweden, including the development of a national database that covers reviews from all acute care hospitals save for paediatric and psychiatric care. We also present the national yearly incidence of AEs over a 4-year period (2013–2016) and estimate the cost of preventable AEs.

Methods

Implementation of the Swedish trigger tool

The first national handbook for record review was published in 2008. It was based on the IHI-GTT version 2007, which was translated and adapted to a Swedish context. The Swedish handbook included a six-graded preventability scale used in a national survey on AEs initiated by The National Board of Health and Welfare.[8] The trigger tool methodology gradually spread over the country, and in 2011, hospitals in approximately half of the country's 21 regions used the method.

In 2012, a national group of experienced reviewers, in collaboration with a reference group of reviewers, patient safety experts and researchers in the trigger tool field, revised the national handbook.[9] The work was initiated and financed by the Swedish Association of Local Authorities and Regions (SALAR) as part of a national patient safety initiative. The number of triggers was reduced from 53 to 44 based on the fact that the removed triggers seldom pointed to AEs or were not possible to identify in the review. Others were merged together

and renamed. Ten new triggers were added based on local review teams' findings and research pointing to these common AEs. An example of a new trigger added was urinary bladder distension.[10,11] Review teams were educated in all regions in a coordinated effort within a national patient safety initiative, which promoted and financially rewarded record review. This contributed to the rapid use of the method by all somatic acute care hospitals.

National patient safety initiative and database

Launched by the Swedish government and SALAR, a national initiative to increase patient safety took place from 2011–2014. The initiative involved financial incentives and included, among other things, safer use of drugs, prevention of resistance to antibiotics, reduction of hospital-acquired infections and measurement of the patient safety culture. As a result of the national initiative, by 2013, all somatic hospitals involved in acute care (n=63) undertook monthly reviews of patient records to determine the rate and nature of AEs. A database was developed by SALAR in 2012, and in this database, the review results from each hospital were entered. These included hospital type, medical speciality, the patient's gender, age and length of hospital stay and the type, severity and preventability of AEs. The monthly reviews continued after the termination of the national patient safety initiative in December 2014, and by December 2016, the database included almost 65 000 admissions.

The database was expanded in 2015 to include information on risk factors for AEs, such as acute admission, surgical intervention and care provided in another type of unit other than the one specialised for the patient's medical needs ('off-site').

Inclusion criteria and sampling

From 2013–2014, the minimum monthly number of randomly selected admissions reviewed was 40 for university hospitals, 30 for the central county council hospitals and 20 for the county hospitals.[5] From 2015 and onward, the number of reviewed records was reduced by 50%. Somatic hospital admissions from patients aged 18 years or older with a hospital stay of at least 24 hours were eligible for inclusion. All records from the whole period of hospitalisation were reviewed, which sometimes included more than one type of department.

Review process

Each hospital had its own review team. The review teams consisted of one or two nurses and at least one physician. All team members were senior level, 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.

A nurse first screened the records for the presence of triggers and possible AEs. In the second review stage, the team assessed the occurrence of AEs. All AEs were categorised according to type, severity and preventability using the national handbook. The physician made the final decisions. There was no assessment of interrater reliability.

Categorisation of adverse events

An AE was defined as an unintended physical injury resulting from or contributed to by medical care that required additional monitoring, treatment or hospitalisation or that resulted in death. An AE was categorised into one of 16 different types (see results). A hospital-acquired infection was defined as either an infection associated with previous in-hospital treatment or an infection occurring 48 hours after hospitalisation or within 48 hours after discharge from the hospital. Each AE could only be categorised into one type.

AEs were categorised into one of five severity categories, per 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 within 60 minutes and Category I: contributed to the patient's death.

An AE was categorised as being preventable or not by using a graded scale of four options: 1. The AE was 'not preventable'; 2. 'probably not preventable'; 3. 'probably preventable'; and 4. 'certainly preventable'. The handbook gives detailed instructions concerning the difficult assessment of preventability (Supplementary table S1). AEs categorised as 1 and 2 are denoted as non-preventable, and AEs categorised as 3 and 4 are denoted as preventable in the following text and figures.

Statistics

Data are presented as number (percent), median (range), mean (SD) or mean (95% CI). Comparison of the proportions between two groups was made by chi-squared test and between more than two groups by Z-test with Bonferroni adjustment. Confidence intervals were calculated using a normal distribution approximation. A p-value <0.05 was considered significant. All statistical calculations were made using SPSS Version 22, IBM, New York, United States.

Ethics

The study was conducted in compliance with the Declaration of Helsinki (World Medical Association, 2013), and because it was a part of quality improvement initiatives in the hospitals, an approval from an ethical committee was not necessary. The principles published in the national ethical guidelines for research were followed (SFS 2003:460). Names and personal identification numbers were not collected or entered into the database.

Results

Results of GTT 2013–2016

A total of 64 917 admissions were reviewed in 59–63 hospitals during the years 2013–2016. The number of hospitals decreased over the period because two of the minor hospitals stopped reviewing, and two merged with another hospital (Table 1). From the beginning of 2013 to the middle of 2015, there was a continuous decline in the average monthly rates of admissions with AEs and preventable AEs (Figure 1). During the second half of 2015, the rates of AEs increased slightly and subsequently stabilised.

The proportion of admissions with preventable AEs decreased significantly between 2013 and the years 2014, 2015 and 2016, respectively. No significant differences were seen between the other years (Table 1).

The decrease in the AE rate can largely be attributed to a reduction in the least severe AEs (Category E) (Table 2). The types of AEs that decreased significantly were hospital-acquired infections, urinary bladder distention, compromised vital signs and 'other' (Table 3). The latter group included allergic reaction, haemorrhage not related to surgery, venous thrombosis or pulmonary embolus, superficial blood vessel or skin harm, anaesthetic-related AE and any other AE. Among the hospital-acquired infections, there were significant reductions in the rate of admissions with pneumonia, ventilator-associated pneumonia and ‘other infections’.

When aggregating data for the years 2013–2016, 11.4% of the AEs were categorised as ‘not preventable’, 27.2% as ‘probably not preventable’, 39.4% as ‘probably preventable’, and 22.0% as ‘certainly preventable’. Consequently, 61.4% of the AEs were judged to be preventable (probably and certainly preventable). The types of AEs considered most preventable were pressure ulcer (91%) and urinary bladder distention (88%). The corresponding preventability rates were for hospital-acquired infections (60%), fall injuries (60%), AEs caused by surgery or invasive procedures (56%), ‘other’ (54%), drug-related AE (46%), compromised vital signs (41%), neurological AE (38%) and postpartum or obstetric AE (41%).

AEs were more common in patients aged 65 years or older than in patients 18–64 years of age ($p<0.001$). The number of admissions with AEs decreased between 2013 and 2016 in the younger ($P=0.02$) and older patient groups ($p<0.001$) (Figure 2). The reductions were significant also for the ‘preventable AEs’ (younger $p=0.05$, older $p<0.001$).

When aggregating data for the years 2013–2016, men had a significantly higher rate of admissions with AEs than women (12.5% vs. 11.5%, $p<0.001$). Men had significantly higher rates of hospital-acquired infections and urinary bladder distention. From aggregated data 2013-2016,when stratifying the older age group into three groups (65-74, 75-84 and ≥ 85 years) the rate of AEs were 12.0%, 13.2% and 14,3%, respectively. The difference was significant between the group 65-74 years and the two older age groups ($p=0.02$ and $p<0.0001$, respectively).

Aggregated data for 2015–2016 showed that the incidence of preventable AEs was almost 100% higher in patients who had undergone surgery or another invasive procedure (n=9584; $p<0.001$) and approximately 84% higher in patients treated in another unit than the unit specialised to their medical needs (‘off-site’) (n=984; $p<0.001$). No difference in AE rates was found between acute and planned admissions ($p=0.72$) (Figure 3).

Acute admissions were more common in males compared to women (80.5% vs. 78.5%, p=0.001) and in patients aged 65 years or older compared to patients under 65 years of age (82.2% vs. 73.7%, p<0.001). The proportion of admissions where the patient underwent surgery or another invasive procedure did not differ between the genders. In patients who had surgery, the rate of AEs was higher in acute admissions than in planned admissions (19.1% vs. 13.1%, p<0.001).

The proportion of patients cared for 'off-site' increased from 3.1% in 2015 to 4.5% in 2016 (p<0.001). Patients aged 65 years or older were more often treated 'off-site' than younger patients (4.1% vs. 3.1%, p<0.001). No differences related to gender were observed. The most common type of AEs in patients cared for 'off-site' were hospital-acquired infections (36.0%) and 'other' (19.8%), which includes skin injury, superficial vessel injury and vein thrombosis or pulmonary embolism.

The mean (SD) length of hospital stay (LOS) in aggregated data for 2013–2016 was 7.1 (8.1) days. LOS for the admissions without AEs was 6.2 (6.6) days while admissions with preventable AEs was 14.2 (14.5) days. A significantly longer LOS in patients with AEs was seen in both age groups of both men and women (Figure 4). The LOS was significantly longer in older patients (≥65 years) than in younger (18–64 years) both for patients with and without AEs. When stratifying the older age group into three groups (65-74, 75-84 and ≥ 85 years) no difference was seen between these three groups in LOS among patients with preventable AEs.

The mean difference in LOS between hospital stays without AEs and those with preventable AEs was 8 days. The average incidence of preventable AEs (2013–2016) was 8%, and the average number of hospital admissions per year was almost 1.4 million. Accordingly, it can be estimated that preventable AEs affected some 110 000 hospital admissions per year and were associated with 880 000 extra days of hospitalisation. With the mean cost for 1 day of hospitalisation being approximately 10 000 SEK, the annual cost for preventable AEs can be estimated at 880 million euros. This corresponds to approximately 13–14% of the total cost of adult somatic hospital care in Sweden. During 2015 and 2016, approximately 13 000 records were reviewed yearly. The estimated annual total cost for record review was 0.4–0.5 million euros.

National feedback of the results based on GTT

Regular yearly reports from SALAR described the development of AE rates on an aggregated national level. Also, specific reports for surgical care,[12] orthopaedic care,[13] obstetrics and gynaecology[14] and hospital-acquired infections[15] were published. The mapping of AEs is an important basis for improvement work. In 2016, SALAR published an inventory of all patient safety initiatives undertaken by hospitals or departments based on the record review findings. The prominent areas for the 268 different improvement initiatives were pressure ulcers, education of patient safety experts, falls, healthcare-associated infections, urinary bladder distension, surgical harm and compromised vital signs.

Discussion

From our nationwide review of almost 65 000 randomly selected admissions to acute care hospitals, we have shown there was a reduction in the rate of AEs between 2013 and 2014, 2015 and 2016, respectively. However, a gradual decrease in the rate of admissions with AEs was seen from 2013 until mid-2015; thereafter, the AE rate rose to, and stabilised at, a slightly higher level. The initial gradual decrease in AE rate could reflect the focus on patient safety promoted by the national patient safety initiative. The decrease in the rate of AEs continued 6 months after the termination of the initiative (2014), which may indicate that the effect of the 4-year long initiative persisted for a short period after it was terminated. The subsequent broken trend after the termination of the patient safety initiative may reflect the hospital leadership shifting their focus and a subsequent decrease in the efforts to reduce the rate of AEs. Conceivably, other factors not related to the initiative may have influenced the trends seen in the AE rates. The higher proportion of patients treated 'off-site' 2016 compared to 2015 might explain to some extent the increase in the rates of AEs.

The study has some strengths. To our knowledge, the current study is the largest published trigger tool study, including all somatic acute hospitals in Sweden, save for paediatric and psychiatric care. Also, the current study covers a substantial period of time. The revision of the trigger tool made it possible to add triggers found to indicate AEs that were not included in the initial IHI tool, for example, urinary bladder distension, and the national database enabled a continuous systematic, but also flexible, collection of data because we were able to add administrative data that enabled the detection of safety risks connected to trends in healthcare, for example, increasing 'off-site' care. The trigger tool has high specificity, high reliability, is more sensitive than other methods,[16,17] and large-scale implementations of the GTT including modifications have been successful in other studies.[6,18,19]

In retrospective record review studies, a potential weakness is poor documentation quality, which means only documented AEs can be identified. The true number of AEs and even premature death is thus probably higher than found only by RRR.[20] Postdischarge patient interviews have shown that even serious AEs are not documented in the record and that AEs that not occur in close proximity to hospital stay might go unnoticed.[21] An example is a forgotten vaccination against pneumococcal infection in connection with splenectomy that may give a serious infection decades later. Direct observation of care is another way of detecting AEs not captured by a record review.[22] Another weakness is the risk of hindsight bias when assessing the preventability of AEs. Two-thirds of the AEs were classified as 'probably preventable' or 'probably not preventable', which illustrates the difficulty in determining preventabiity with certainty. A further limitation is that we did not assess inter-rater reliability. The reason is that as the record reviews were part of a national patient safety initiative with the primary focus on changes in AE rates of individual hospitals and not for comparisons inbetween hospitals. The number of reviewed admissions from university hospitals, central county council hospitals and small hospitals does not fully reflect the true proportion of admissions to these hospital categories. Because the rates of AEs differ between hospital types, this must be taken into account when estimating the true national average rate of AEs. When doing so, the national rates of AEs presented in this paper increase by approximately 10%.

We have demonstrated an increased rate of AEs in patients cared for in another type of unit other than the one specialised for their medical needs. The main reason why patients are cared for 'off-site' is a shortage of available beds due to lack of nurses. Actions need to be taken to reduce the number of 'off-site' patients.

As shown earlier,[23] a hospital-acquired infection is the most common type of AE, and its incidence fell during the study period. Evidence-based programs to prevent central venous catheter-associated infections, postoperative wound infections and urinary tract infections were promoted nationally during the study period. This was carried out by conducting a continuous follow-up on compliance to basic hygiene rules and dress code on a department level. Conceivably, the promotion of measures to reduce the incidence of hospital-acquired infections during the patient safety initiative was successful and resulted in a reduction of infection rates.

Urinary bladder distention was most often regarded as preventable, and the rates decreased over time. This could in part be because of the use of a stricter definition after 2013, but this problem was extensively addressed by physicians as well as nursing organisations. The decrease in the rates of compromised vital signs could reflect an increased use of vital sign checks, such as the modified early warning score (MEWS)[24] and rapid response teams.[25]

The higher incidence of AEs found among men can partly be attributed to their higher rates of hospital-acquired infections and urinary bladder distension. The reason behind the former remains to be explained. Another explanation is that the present study included gynaecology and obstetrics, where AE rates are lower than in other medical disciplines.[26]

The suffering associated with patient harm for the patients, relatives and involved personnel is high but cannot easily be quantified. There is also an economic burden associated with patient harm, both on healthcare and society. The golden standard to estimate the financial cost of AEs for healthcare is considered to be retrospective record review.[27] Our estimate, based solely on the costs of prolonged LOS, is in line with a recent report that suggested that 15% of hospital expenditures in Organisation for Economic Co-operation and Development (OECD) countries relate to AEs.[28] These entail additional treatment and diagnostic procedures, (re)admission to hospital and a prolonged hospital stay. In line with our finding, the OECD report estimated that 6–8 additional days are spent in the hospital for patients having an AE.[26] With a longer LOS, it is probable that patients are more exposed to AEs. Regrettably, we did not collect data on day of occurrence of AEs. However, our group has previously shown that AEs most often occur early during the hospital stay or cause the hospitalisation.[29] The OECD report[28] emphasises that the costs for preventive actions are substantially lower than the costs of AEs.

To our knowledge, Norway and Sweden are the only countries so far that has evaluated the effect of a national patient safety initiative using monthly assessments of AE rates based on GTT. Accordingly, some 40 000 hospital admissions were reviewed during the Norwegian patient safety campaign, and AE rates decreased from 16.1% (2011) to 13.0% (2013).[6] The rates and types of AEs in Norway and Sweden in 2013 have been shown to be similar.[7]

In conclusion, AE rates in Swedish somatic acute care hospitals decreased between 2013 and 2014, 2015 and 2016, respectively. Retrospective record review is a useful method to monitor patient safety over time and to assess the effects of national patient safety interventions. Off-site care of patients is becoming more common. This increases the incidence of AEs and is a challenge to patient safety. The economic burden of preventable AEs is high.

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Table 1. The number of hospitals and admissions, demographics and the proportion of admissions with adverse events and preventable adverse events

	2013	2014	2015	2016
Number of hospitals	63	63	62	59
Number of admissions	19 927	18 629	13 771	12 590
Age (median (range)), years	71 (18-105)	71 (18-109)	71 (18-108)	72 (18-105)
Men, percent	46,8	46,0	47,1	48,0
Admissions with AEs, percent (95%CI)	13.1 (12.7-13.6)[a]	11.6 (11.2-12.1)[a]	10.9 (10.4-11.4)[a]	11.4 (10.9-12.0)[a]
Admissions with preventable AEs, percent (95%CI)	8.7 (8.3-9.1)[a]	7.4 (7.1-7.8)[a]	7.0 (6.6-7.4)[a]	7.2 (6.7-7.6)[a]

AE: adverse event; CI: 95% confidence interval; [a]significant differences compared to 2013

Table 2. Proportion (percent (95%CI)) of admissions with adverse events classified according to severity

	2013	2014	2015	2016
Severity				
E: contributed to or resulted in temporary harm and required intervention	7.40 (7.03-7.77)	6.08 (5.73-6.42)[a]	5.50 (5.12-5.89)[a]	5.99 (5.57-6.40)[a]
F: contributed to or resulted in temporary harm requiring outpatient care, readmission or prolonged hospital care	6.15 (5.81-6.48)	5.84 (5.50-6.18)	5.74 (5.36-6.13)	5.76 (5.35-6.17)
G: contributed to or caused permanent patient harm	0.41 (0.32-0.50)	0.27 (0.20-0.35)	0.29 (0.20-0.38)	0.38 (0.27-0.49)
H: event that required lifesaving intervention required within 60 minutes	0.09 (0.05-0.13)	0.08 (0.04-0.12)	0.12 (0.06-0.17)	0.10 (0.04-0.15)
I: contributed to the patient's death	0.31 (0.23-0.38)	0.23 (0.16-0.29)	0.23 (0.15-0.31)	0.24 (0.15-0.32)

AE: adverse event; CI: 95% confidence interval; [a]significant differences compared to 2013.

Table 3. Proportion (percent (95 % CI)) of admissions with adverse events classified according to type

	2013	2014	2015	2016
Type				
Hospital-acquired infection	5.2 (4.9-5.5)	4.6 (4.3-4.9)[a]	4.5 (4.1-4.8)[a]	4.3 (4.0-4.7)[a]
Infection other	1.4 (1.2-1.6)	1.0 (0.8-1.1)[a]	1.1 (0.9-1.3)	0.9 (0.8-1.1)[a]
Urinary tract infection	1.4 (1.3-1.6)	1.5 (1.4-1.7)	1.3 (1.1-1.5)	1.3 (1.1-1.5)
Postoperative wound infection	1.2 (1.1-1.4)	1.2 (1.0-1.3)	1.1 (0.9-1.2)	1.1 (0.9-1.3)
Pneumonia	0.7 (0.6-0.8)	0.5 (0.4-0.6)[a]	0.5 (0.4-0.6)[a]	0.5 (0.4-0.6)[a]
Sepsis	0.5 (0.4-0.6)	0.3 (0.3-0.4)[a]	0.4 (0.3-0.6)	0.5 (0.4-0.6)
Central venous line infection	0.2 (0.1-0.2)	0.1 (0.0-0.1)	0.1 (0.0-0.1)	0.1 (0.0-0.2)
Ventilator associated pneumonia	0.1 (0.1-0.2)	0.0 (0.0-0.1)[a]	0.1 (0.0-0.1)	0,1 (0,0-0.1)[a]
Clostridium difficile infection	-	0.3 (0.2-0.3)	0.3 (0.2-0.3)	0.3 (0.2-0.3)
Other	2.7 (2.5-3.0)	2.4 (2.2-2.7)	2.0 (1.8-2.3)[a]	2.2 (2.0-2.5)[a]
AEs caused by surgery/invasive procedures	1.9 (1.7-2.1)	1.8 (1.6-2.0)	1.8 (1.6-2.0)	1.6 (1.4-1.8)
Urinary bladder distention	1.7 (1.5-1.9)	1.0 (0.9-1.2)[a]	1.0 (0.9-1.2)[a]	1.1 (0.9-1.3)[a]
Drug-related AE	1.4 (1.3-1.6)	1.4 (1.2-1.6)	1.3 (1.1-1.5)	1.5 (1.3-1.7)
Pressure ulcer (grade 2-4)	1.1 (1.0-1.3)	1.0 (0.9-1.1)	1.2 (1.0-1.4)	1.3 (1.1-1.5)
Fall injury	0.8 (0.7-0.9)	0.9 (0.7-1.0)	0.7 (0.5-0.8)	0.7 (0.6-0.9)
Compromised vital signs	0.5 (0.4-0.6)	0.3 (0.2-0.3)[a]	0.3 (0.2-0.4)	0.2 (0.1-0.2)[a]
Postpartum or obstetric AE*	0.2 (0.2-0.3)	0.2 (0.2-0.3)	0.1 (0.1-0.2)[a]	0.3 (0.2-0.4)
Neurological AE	0.1 (0.1-0.2)	0.0 (0.0-0.1)	0.1 (0.0-0.1)	0.1 (0.1-0.2)

AE: adverse event; CI: 95% confidence interval; *not corrected for the proportion of women in the studied population; [a]significant differences compared to 2013.

Figure 1. The proportion of admissions with adverse events (AEs) every month from 2013–2016.

Figure 2. Proportion of admissions with preventable and non-preventable adverse events (AEs) in younger and older patients from 2013–2016.

Figure 3. The proportion of admissions with preventable and non-preventable adverse events (AEs) in patients with acute admissions, patients who underwent surgery and patients treated 'off-site' from 2015–2016

Figure 4. Length of stay (mean, 95% CI) in two age groups of men and women for admissions without adverse events, with non-preventable adverse events and with preventable adverse events from 2013–2016.

Table S1. Example of a trigger, its definition and clarifying text.

Deep vein thrombosis or pulmonary embolism

Definition	**Deep vein thrombosis or pulmonary embolism diagnosed during hospital care and not apparent on admission**
Check for	Venous catheter (central venous catheter, subcutaneous venous port, etc.), recent surgery, immobilisation, obesity, cancer or cancer treatment increases the risk. Has thrombosis prophylaxis been given according to routines?
Harm that can be found	Transient or permanent reduction of cardiac or pulmonary function, reduced venous circulation in the lower extremities with oedema and reduced function
Preventability	Deep vein thrombosis should be regarded as preventable if: Prophylaxis against thrombosis has not been given according to routines. Increased risk following immobilisation has not been considered, for example, after surgery. Anticoagulation therapy (e.g., warfarin) has not been adequately controlled. Pulmonary embolus should also be regarded as avoidable if signs of deep vein thrombosis have not been adequately observed and treated.
Relevant codes for diagnosis, treatment and medication	ICD-10-code: I82 (Embolus and thrombosis) I26 (Pulmonary embolus) O88.2 (Obstetric embolus due to thrombosis)
Results associated to this trigger	Results from investigation with ultrasound, CT or phlebography. Results from pulmonary scintigraphy (ventilation and perfusion scintigraphy).

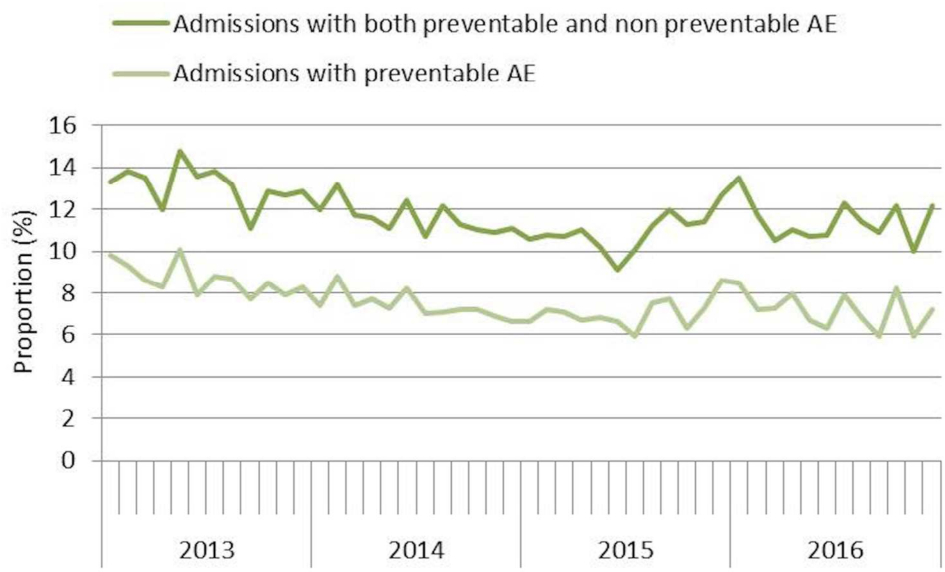


Figure 1. The proportion of admissions with adverse events (AEs) every month from 2013–2016.

127x76mm (300 x 300 DPI)

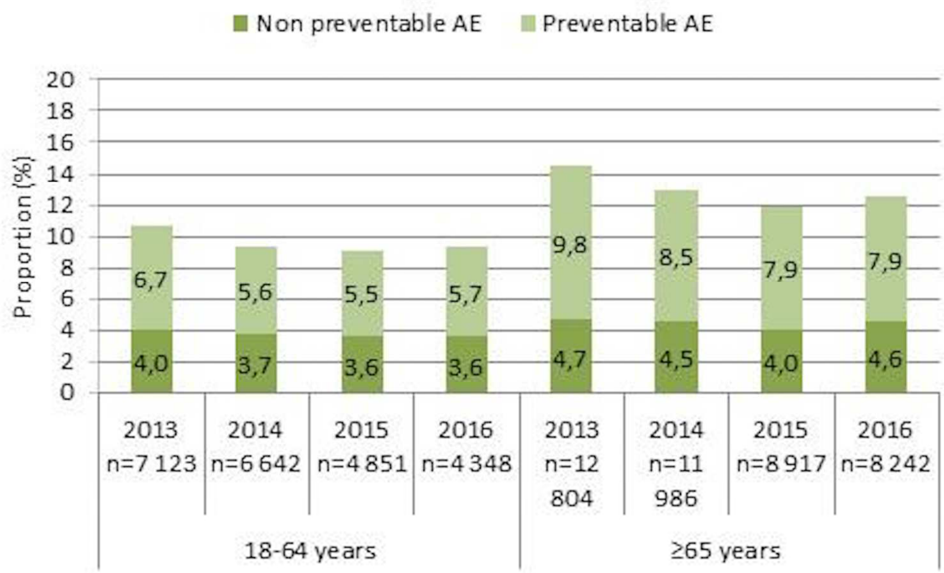


Figure 2. Proportion of admissions with preventable and non-preventable adverse events (AEs) in younger and older patients from 2013–2016.

127x76mm (300 x 300 DPI)

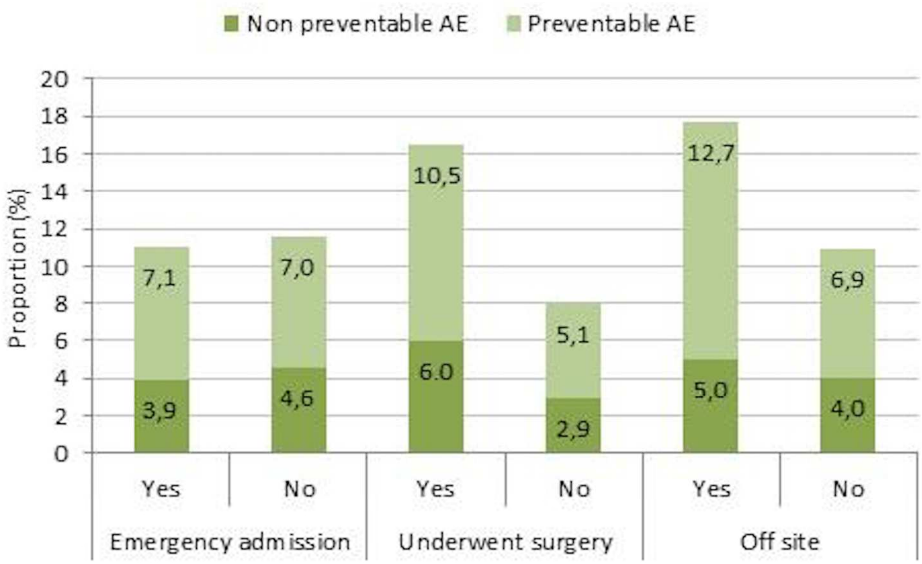
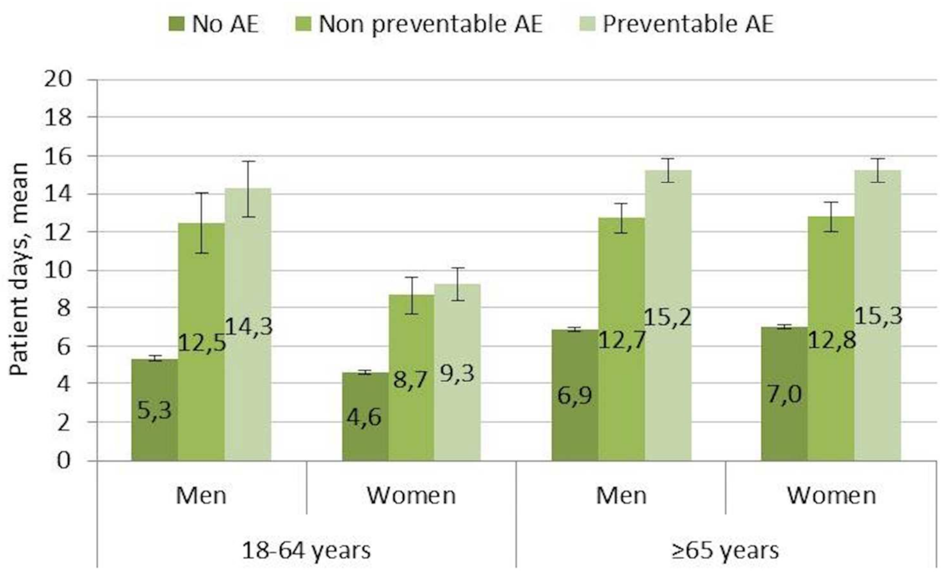


Figure 3. The proportion of admissions with preventable and non-preventable adverse events (AEs) in patients with acute admissions, patients who underwent surgery and patients treated 'off-site' from 2015–2016

129x79mm (300 x 300 DPI)



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Harm that can be found	Transient or permanent reduction of cardiac or pulmonary function, reduced venous circulation in the lower extremities with oedema and reduced function
Preventability	Deep vein thrombosis should be regarded as preventable if: ☐Prophylaxis against thrombosis has not been given according to routines. ☐Increased risk following immobilisation has not been considered, for example, after surgery. ☐ Anticoagulation therapy (e.g, warfarin) has not been adequately controlled. Pulmonary embolus should also be regarded as avoidable if signs of deep vein thrombosis have not been adequately observed and treated.
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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	#1, #2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	#2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	#4
Objectives	3	State specific objectives, including any prespecified hypotheses	#4
Methods			
Study design	4	Present key elements of study design early in the paper	#5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	#4-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	#5-6
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	#6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	#6
Bias	9	Describe any efforts to address potential sources of bias	#6
Study size	10	Explain how the study size was arrived at	#5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	#7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	#7
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) If applicable, explain how loss to follow-up was addressed	NA
		(*e*) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	#7
		(c) Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	Report numbers of outcome events or summary measures over time	NA
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	#7-9
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	#9
Discussion			
Key results	18	Summarise key results with reference to study objectives	#10
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	#10-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	#12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	#3

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Incidence of adverse events in Sweden during 2013–2016: a cohort study describing the implementation of a national trigger tool.

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Incidence of adverse events in Sweden during 2013–2016: a cohort study describing the implementation of a national trigger tool .

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Abstract

Objectives: To describe the implementation of a trigger tool in Sweden and present the national incidence of adverse events (AEs) over a 4-year period during which an ongoing national patient safety initiative was terminated.

Design: Cohort study using retrospective record review based on a trigger tool methodology.

Setting and participants: Patients ≥18 years admitted to all somatic acute care hospitals in Sweden from 2013–2016 were randomised into the study.

Primary and secondary outcome measures: Primary outcome measure was the incidence of AEs, and secondary measures were type of injury, severity of harm, preventability of AEs, estimated healthcare cost of AEs and incidence of AEs in patients cared for in another type of unit than the one specialised for their medical needs ('off-site').

Results: In a review of 64 917 admissions, the average AE rates in 2014 (11.6%), 2015 (10.9%) and 2016 (11.4%) were significantly lower than in 2013 (13.1%). The decrease in the AE rates was seen in different age groups, in both genders and for preventable and non-preventable AEs. The decrease comprised only the least severe AEs. The types of AEs that decreased were hospital-acquired infections, urinary bladder distention and compromised vital signs. Patients cared for 'off-site' had 84% more preventable AEs than patients cared for in the appropriate units. The cost of increased length of stay associated with preventable AEs corresponded to 13–14% of the total cost of somatic hospital care in Sweden.

Conclusions: The rate of AEs in Swedish somatic hospitals has decreased from 2013 to 2016. Retrospective record review can be used to monitor patient safety over time, to assess the effects of national patient safety interventions and analyse challenges to patient safety such as the increasing care of patients 'off-site'. It was found that the economic burden of preventable AEs is high.

Keywords: Adverse event, Patient harm, Patient safety, Trigger tool

Strengths and limitations of this study

- The study includes all somatic acute care hospitals in Sweden, except for paediatric units.
- This is a longitudinal study over a 4-year period during which an ongoing national patient safety initiative was terminated.
- An estimation of the economic cost for prolonged hospital stay due to preventable AEs was undertaken.
- The trigger tool and the national database were adaptive to new triggers and trends in healthcare, thus showing the ability to evaluate new patient safety risks.
- Inherent weaknesses in a retrospective record review are poor documentation quality and the risk of hindsight bias.

Funding statement

This work was supported by the Swedish Association of Local Authorities and Regions by creating and hosting a national database for the reporting of data from the record reviews.

Competing interests

The authors declare that they have no competing interests.

Author's contribution

LN, MB-R, MS, UN, CÅ and HR designed and conducted the study. MB-R statistically analysed the data. HR, UN and CÅ undertook the initial interpretation of the data, which was followed by discussions with all the authors. LN and HR drafted the initial version of the manuscript, which was followed by a critical revision process of the intellectual content involving all the authors. All the authors agreed to the final version of the manuscript before submission. All authors agreed to be accountable for the accuracy of any part of the work.

Data sharing statement

No additional data are available.

Introduction

Retrospective medical record review (RRR) is an established and validated method to identify adverse events (AEs).[1-4] The method gives an overview of the incidence, nature, preventability and consequences of AEs. This information can be used in systematic quality improvement work to reduce the incidence of AEs. RRR is superior to clinical incident reporting systems for detecting AEs.[3] A list of criteria (triggers) that indicate a higher probability of AEs may be used to identify details in the record that indicate the presence of AEs. The Institute for Healthcare Improvement (IHI) in the US combined topic- and location-specific trigger tools into one Global Trigger Tool (GTT),[5] which is one of the most commonly used trigger tools. Translated and adapted versions of the GTT are available in, for example, Sweden, Denmark, Norway, Germany, Italy and the UK. Although GTT is considered relevant for measuring AEs at the national level, to the best of our knowledge, only Norway and Sweden have used the methodology for this purpose.[6,7]

The present study describes the implementation of a trigger tool in Sweden, including the development of a national database that covers reviews from all acute care hospitals save for paediatric and psychiatric care. We also present the national yearly incidence of AEs over a 4-year period (2013–2016) and estimate the cost of preventable AEs.

Methods

Implementation of the Swedish trigger tool

The first national handbook for record review was published in 2008. It was based on the IHI-GTT version 2007, which was translated and adapted to a Swedish context. The Swedish handbook included a six-graded preventability scale used in a national survey on AEs initiated by The National Board of Health and Welfare.[8] The trigger tool methodology gradually spread over the country, and in 2011, hospitals in approximately half of the country's 21 regions used the method.

In 2012, a national group of experienced reviewers, in collaboration with a reference group of reviewers, patient safety experts and researchers in the trigger tool field, revised the national handbook.[9] The work was initiated and financed by the Swedish Association of Local Authorities and Regions (SALAR) as part of a national patient safety initiative. The number of triggers was reduced from 53 to 44 based on the fact that the removed triggers seldom pointed to AEs or were not possible to identify in the review. Others were merged together

and renamed. Ten new triggers were added based on local review teams' findings and research pointing to these common AEs. An example of a new trigger added was urinary bladder distension.[10,11] Review teams were educated in all regions in a coordinated effort within a national patient safety initiative, which promoted and financially rewarded record review. This contributed to the rapid use of the method by all somatic acute care hospitals.

National patient safety initiative and database

Launched by the Swedish government and SALAR, a national initiative to increase patient safety took place from 2011–2014. The initiative involved financial incentives and included, among other things, safer use of drugs, prevention of resistance to antibiotics, reduction of hospital-acquired infections and measurement of the patient safety culture. As a result of the national initiative, by 2013, all somatic hospitals involved in acute care (n=63) undertook monthly reviews of patient records to determine the rate and nature of AEs. A database was developed by SALAR in 2012, and in this database, the review results from each hospital were entered. These included hospital type, medical speciality, the patient's gender, age and length of hospital stay and the type, severity and preventability of AEs. The monthly reviews continued after the termination of the national patient safety initiative in December 2014, and by December 2016, the database included almost 65 000 admissions.

The database was expanded in 2015 to include information on risk factors for AEs, such as acute admission, surgical intervention and care provided in another type of unit other than the one specialised for the patient's medical needs ('off-site').

Inclusion criteria and sampling

From 2013–2014, the minimum monthly number of randomly selected admissions reviewed was 40 for university hospitals, 30 for the central county council hospitals and 20 for the county hospitals.[5] From 2015 and onward, the number of reviewed records was reduced by 50%. Somatic hospital admissions from patients aged 18 years or older with a hospital stay of at least 24 hours were eligible for inclusion. All records from the whole period of hospitalisation were reviewed, which sometimes included more than one type of department.

Review process

Each hospital had its own review team. The review teams consisted of one or two nurses and at least one physician. All team members were senior level, 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.

A nurse first screened the records for the presence of triggers and possible AEs. In the second review stage, the team assessed the occurrence of AEs. All AEs were categorised according to type, severity and preventability using the national handbook. The physician made the final decisions. There was no assessment of interrater reliability.

Categorisation of adverse events

An AE was defined as an unintended physical injury resulting from or contributed to by medical care that required additional monitoring, treatment or hospitalisation or that resulted in death. An AE was categorised into one of 16 different types (see results). A hospital-acquired infection was defined as either an infection associated with previous in-hospital treatment or an infection occurring 48 hours after hospitalisation or within 48 hours after discharge from the hospital. Each AE could only be categorised into one type.

AEs were categorised into one of five severity categories, per 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 within 60 minutes and Category I: contributed to the patient's death.

An AE was categorised as being preventable or not by using a graded scale of four options: 1. The AE was 'not preventable'; 2. 'probably not preventable'; 3. 'probably preventable'; and 4. 'certainly preventable'. The handbook gives detailed instructions concerning the difficult assessment of preventability (Supplementary table S1). AEs categorised as 1 and 2 are denoted as non-preventable, and AEs categorised as 3 and 4 are denoted as preventable in the following text and figures.

Statistics

Data are presented as number (percent), median (range), mean (SD) or mean (95% CI). Comparison of the proportions between two groups was made by chi-squared test and between more than two groups by Z-test with Bonferroni adjustment. Confidence intervals were calculated using a normal distribution approximation. A p-value <0.05 was considered significant. All statistical calculations were made using SPSS Version 22, IBM, New York, United States.

Ethics

The study was conducted in compliance with the Declaration of Helsinki (World Medical Association, 2013), and because it was a part of quality improvement initiatives in the hospitals, an approval from an ethical committee was not necessary. The principles published in the national ethical guidelines for research were followed (SFS 2003:460). Names and personal identification numbers were not collected or entered into the database.

Patient and Public Involvement

Patients were not involved in the study design or the implementation of the national trigger tool. Yearly reports from SALAR of AE rates on an aggregated national level have been publicaly available.

Results

Results of GTT 2013–2016

A total of 64 917 admissions were reviewed in 59–63 hospitals during the years 2013–2016. The number of hospitals decreased over the period because two of the minor hospitals stopped reviewing, and two merged with another hospital (Table 1). From the beginning of 2013 to the middle of 2015, there was a continuous decline in the average monthly rates of admissions with AEs and preventable AEs (Figure 1). During the second half of 2015, the rates of AEs increased slightly and subsequently stabilised.

The proportion of admissions with preventable AEs decreased significantly between 2013 and the years 2014, 2015 and 2016, respectively. No significant differences were seen between the other years (Table 1).

The decrease in the AE rate can largely be attributed to a reduction in the least severe AEs (Category E) (Table 2). The types of AEs that decreased significantly were hospital-acquired infections, urinary bladder distention, compromised vital signs and 'other' (Table 3). The latter group included allergic reaction, haemorrhage not related to surgery, venous thrombosis or pulmonary embolus, superficial blood vessel or skin harm, anaesthetic-related AE and any other AE. Among the hospital-acquired infections, there were significant reductions in the rate of admissions with pneumonia, ventilator-associated pneumonia and 'other infections'.

When aggregating data for the years 2013–2016, 11.4% of the AEs were categorised as 'not preventable', 27.2% as 'probably not preventable', 39.4% as 'probably preventable', and 22.0% as 'certainly preventable'. Consequently, 61.4% of the AEs were judged to be preventable (probably and certainly preventable). The types of AEs considered most preventable were pressure ulcer (91%) and urinary bladder distention (88%). The corresponding preventability rates were for hospital-acquired infections (60%), fall injuries (60%), AEs caused by surgery or invasive procedures (56%), 'other' (54%), drug-related AE (46%), compromised vital signs (41%), neurological AE (38%) and postpartum or obstetric AE (41%).

AEs were more common in patients aged 65 years or older than in patients 18–64 years of age ($p<0.001$). The number of admissions with AEs decreased between 2013 and 2016 in the younger ($P=0.02$) and older patient groups ($p<0.001$) (Figure 2). The reductions were significant also for the 'preventable AEs' (younger $p=0.05$, older $p<0.001$).

When aggregating data for the years 2013–2016, men had a significantly higher rate of admissions with AEs than women (12.5% vs. 11.5%, $p<0.001$). Men had significantly higher rates of hospital-acquired infections and urinary bladder distention. From aggregated data 2013-2016,when stratifying the older age group into three groups (65-74, 75-84 and ≥ 85 years) the rate of AEs were 12.0%, 13.2% and 14,3%, respectively. The difference was significant between the group 65-74 years and the two older age groups ($p=0.02$ and $p<0.0001$, respectively).

Aggregated data for 2015–2016 showed that the incidence of preventable AEs was almost 100% higher in patients who had undergone surgery or another invasive procedure (n=9584;

p<0.001) and approximately 84% higher in patients treated in another unit than the unit specialised to their medical needs ('off-site') (n=984; p<0.001). No difference in AE rates was found between acute and planned admissions (p=0.72) (Figure 3).

Acute admissions were more common in males compared to women (80.5% vs. 78.5%, p=0.001) and in patients aged 65 years or older compared to patients under 65 years of age (82.2% vs. 73.7%, p<0.001). The proportion of admissions where the patient underwent surgery or another invasive procedure did not differ between the genders. In patients who had surgery, the rate of AEs was higher in acute admissions than in planned admissions (19.1% vs. 13.1%, p<0.001).

The proportion of patients cared for 'off-site' increased from 3.1% in 2015 to 4.5% in 2016 (p<0.001). Patients aged 65 years or older were more often treated 'off-site' than younger patients (4.1% vs. 3.1%, p<0.001). No differences related to gender were observed. The most common type of AEs in patients cared for 'off-site' were hospital-acquired infections (36.0%) and 'other' (19.8%), which includes skin injury, superficial vessel injury and vein thrombosis or pulmonary embolism.

The mean (SD) length of hospital stay (LOS) in aggregated data for 2013–2016 was 7.1 (8.1) days. LOS for the admissions without AEs was 6.2 (6.6) days while admissions with preventable AEs was 14.2 (14.5) days. A significantly longer LOS in patients with AEs was seen in both age groups of both men and women (Figure 4). The LOS was significantly longer in older patients (≥65 years) than in younger (18–64 years) both for patients with and without AEs. When stratifying the older age group into three groups (65-74, 75-84 and ≥ 85 years) no difference was seen between these three groups in LOS among patients with preventable AEs.

The mean difference in LOS between hospital stays without AEs and those with preventable AEs was 8 days. The average incidence of preventable AEs (2013–2016) was 8%, and the average number of hospital admissions per year was almost 1.4 million. Accordingly, it can be estimated that preventable AEs affected some 110 000 hospital admissions per year and were associated with 880 000 extra days of hospitalisation. With the mean cost for 1 day of hospitalisation being approximately 10 000 SEK, the annual cost for preventable AEs can be estimated at 880 million euros. This corresponds to approximately 13–14% of the total cost of adult somatic hospital care in Sweden. During 2015 and 2016, approximately 13 000 records were reviewed yearly. The estimated annual total cost for record review was 0.4–0.5 million euros.

National feedback of the results based on GTT

Regular yearly reports from SALAR described the development of AE rates on an aggregated national level. Also, specific reports for surgical care,[12] orthopaedic care,[13] obstetrics and gynaecology[14] and hospital-acquired infections[15] were published. The mapping of AEs is an important basis for improvement work. In 2016, SALAR published an inventory of all patient safety initiatives undertaken by hospitals or departments based on the record review findings. The prominent areas for the 268 different improvement initiatives were pressure ulcers, education of patient safety experts, falls, healthcare-associated infections, urinary bladder distension, surgical harm and compromised vital signs.

Discussion

From our nationwide review of almost 65 000 randomly selected admissions to acute care hospitals, we have shown there was a reduction in the rate of AEs between 2013 and 2014, 2015 and 2016, respectively. However, a gradual decrease in the rate of admissions with AEs was seen from 2013 until mid-2015; thereafter, the AE rate rose to, and stabilised at, a slightly higher level. The initial gradual decrease in AE rate could reflect the focus on patient safety promoted by the national patient safety initiative. The decrease in the rate of AEs continued 6 months after the termination of the initiative (2014), which may indicate that the effect of the 4-year long initiative persisted for a short period after it was terminated. The subsequent broken trend after the termination of the patient safety initiative may reflect the hospital leadership shifting their focus and a subsequent decrease in the efforts to reduce the rate of AEs. Conceivably, other factors not related to the initiative may have influenced the trends seen in the AE rates. The higher proportion of patients treated 'off-site' 2016 compared to 2015 might explain to some extent the increase in the rates of AEs.

The study has some strengths. To our knowledge, the current study is the largest published trigger tool study, including all somatic acute hospitals in Sweden, save for paediatric and psychiatric care. Also, the current study covers a substantial period of time. The revision of the trigger tool made it possible to add triggers found to indicate AEs that were not included in the initial IHI tool, for example, urinary bladder distension, and the national database enabled a continuous systematic, but also flexible, collection of data because we were able to add administrative data that enabled the detection of safety risks connected to trends in healthcare, for example, increasing 'off-site' care. The trigger tool has high specificity, high reliability, is more sensitive than other methods,[16,17] and large-scale implementations of the GTT including modifications have been successful in other studies.[6,18,19]

In retrospective record review studies, a potential weakness is poor documentation quality, which means only documented AEs can be identified. The true number of AEs and even premature death is thus probably higher than found only by RRR.[20] Postdischarge patient interviews have shown that even serious AEs are not documented in the record and that AEs that not occur in close proximity to hospital stay might go unnoticed.[21] An example is a forgotten vaccination against pneumococcal infection in connection with splenectomy that may give a serious infection decades later. Direct observation of care is another way of detecting AEs not captured by a record review.[22] Another weakness is the risk of hindsight bias when assessing the preventability of AEs. Two-thirds of the AEs were classified as 'probably preventable' or 'probably not preventable', which illustrates the difficulty in determining preventabiity with certainty. A further limitation is that we did not assess inter-rater reliability. The reason is that as the record reviews were part of a national patient safety initiative with the primary focus on changes in AE rates of individual hospitals and not for comparisons inbetween hospitals. The number of reviewed admissions from university hospitals, central county council hospitals and small hospitals does not fully reflect the true proportion of admissions to these hospital categories. Because the rates of AEs differ between hospital types, this must be taken into account when estimating the true national average rate of AEs. When doing so, the national rates of AEs presented in this paper increase by approximately 10%.

We have demonstrated an increased rate of AEs in patients cared for in another type of unit other than the one specialised for their medical needs. The main reason why patients are cared for 'off-site' is a shortage of available beds due to lack of nurses. Actions need to be taken to reduce the number of 'off-site' patients.

As shown earlier,[23] a hospital-acquired infection is the most common type of AE, and its incidence fell during the study period. Evidence-based programs to prevent central venous catheter-associated infections, postoperative wound infections and urinary tract infections were promoted nationally during the study period. This was carried out by conducting a continuous follow-up on compliance to basic hygiene rules and dress code on a department level. Conceivably, the promotion of measures to reduce the incidence of hospital-acquired infections during the patient safety initiative was successful and resulted in a reduction of infection rates.

Urinary bladder distention was most often regarded as preventable, and the rates decreased over time. This could in part be because of the use of a stricter definition after 2013, but this problem was extensively addressed by physicians as well as nursing organisations. The decrease in the rates of compromised vital signs could reflect an increased use of vital sign checks, such as the modified early warning score (MEWS)[24] and rapid response teams.[25]

The higher incidence of AEs found among men can partly be attributed to their higher rates of hospital-acquired infections and urinary bladder distension. The reason behind the former remains to be explained. Another explanation is that the present study included gynaecology and obstetrics, where AE rates are lower than in other medical disciplines.[26]

The suffering associated with patient harm for the patients, relatives and involved personnel is high but cannot easily be quantified. There is also an economic burden associated with patient harm, both on healthcare and society. The golden standard to estimate the financial cost of AEs for healthcare is considered to be retrospective record review.[27] Our estimate, based solely on the costs of prolonged LOS, is in line with a recent report that suggested that 15% of hospital expenditures in Organisation for Economic Co-operation and Development (OECD) countries relate to AEs.[28] These entail additional treatment and diagnostic procedures, (re)admission to hospital and a prolonged hospital stay. In line with our finding, the OECD report estimated that 6–8 additional days are spent in the hospital for patients having an AE.[26] With a longer LOS, it is probable that patients are more exposed to AEs. Regrettably, we did not collect data on day of occurrence of AEs. However, our group has previously shown that AEs most often occur early during the hospital stay or cause the hospitalisation.[29] The OECD report[28] emphasises that the costs for preventive actions are substantially lower than the costs of AEs.

To our knowledge, Norway and Sweden are the only countries so far that has have evaluated the effect of a national patient safety initiative using monthly assessments of AE rates based on GTT. Accordingly, some 40 000 hospital admissions were reviewed during the Norwegian patient safety campaign, and AE rates decreased from 16.1% (2011) to 13.0% (2013).[6] The rates and types of AEs in Norway and Sweden in 2013 have been shown to be similar.[7]

In conclusion, AE rates in Swedish somatic acute care hospitals decreased between 2013 and 2014, 2015 and 2016, respectively. Retrospective record review is a useful method to monitor patient safety over time and to assess the effects of national patient safety interventions. Off-site care of patients is becoming more common. This increases the incidence of AEs and is a challenge to patient safety. The economic burden of preventable AEs is high.

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Table 1. The number of hospitals and admissions, demographics and the proportion of admissions with adverse events and preventable adverse events

	2013	2014	2015	2016
Number of hospitals	63	63	62	59
Number of admissions	19 927	18 629	13 771	12 590
Age (median (range)), years	71 (18-105)	71 (18-109)	71 (18-108)	72 (18-105)
Men, percent	46,8	46,0	47,1	48,0
Admissions with AEs, percent (95%CI)	13.1 (12.7-13.6)[a]	11.6 (11.2-12.1)[a]	10.9 (10.4-11.4)[a]	11.4 (10.9-12.0)[a]
Admissions with preventable AEs, percent (95%CI)	8.7 (8.3-9.1)[a]	7.4 (7.1-7.8)[a]	7.0 (6.6-7.4)[a]	7.2 (6.7-7.6)[a]

AE: adverse event; CI: 95% confidence interval; [a]significant differences compared to 2013

Table 2. Proportion (percent (95%CI)) of admissions with adverse events classified according to severity

	2013	2014	2015	2016
Severity				
E: contributed to or resulted in temporary harm and required intervention	7.40 (7.03-7.77)	6.08 (5.73-6.42)[a]	5.50 (5.12-5.89)[a]	5.99 (5.57-6.40)[a]
F: contributed to or resulted in temporary harm requiring outpatient care, readmission or prolonged hospital care	6.15 (5.81-6.48)	5.84 (5.50-6.18)	5.74 (5.36-6.13)	5.76 (5.35-6.17)
G: contributed to or caused permanent patient harm	0.41 (0.32-0.50)	0.27 (0.20-0.35)	0.29 (0.20-0.38)	0.38 (0.27-0.49)
H: event that required lifesaving intervention required within 60 minutes	0.09 (0.05-0.13)	0.08 (0.04-0.12)	0.12 (0.06-0.17)	0.10 (0.04-0.15)
I: contributed to the patient's death	0.31 (0.23-0.38)	0.23 (0.16-0.29)	0.23 (0.15-0.31)	0.24 (0.15-0.32)

AE: adverse event; CI: 95% confidence interval; [a]significant differences compared to 2013.

Table 3. Proportion (percent (95 % CI)) of admissions with adverse events classified according to type

	2013	2014	2015	2016
Type				
Hospital-acquired infection	5.2 (4.9-5.5)	4.6 (4.3-4.9)[a]	4.5 (4.1-4.8)[a]	4.3 (4.0-4.7)[a]
Infection other	1.4 (1.2-1.6)	1.0 (0.8-1.1)[a]	1.1 (0.9-1.3)	0.9 (0.8-1.1)[a]
Urinary tract infection	1.4 (1.3-1.6)	1.5 (1.4-1.7)	1.3 (1.1-1.5)	1.3 (1.1-1.5)
Postoperative wound infection	1.2 (1.1-1.4)	1.2 (1.0-1.3)	1.1 (0.9-1.2)	1.1 (0.9-1.3)
Pneumonia	0.7 (0.6-0.8)	0.5 (0.4-0.6)[a]	0.5 (0.4-0.6)[a]	0.5 (0.4-0.6)[a]
Sepsis	0.5 (0.4-0.6)	0.3 (0.3-0.4)[a]	0.4 (0.3-0.6)	0.5 (0.4-0.6)
Central venous line infection	0.2 (0.1-0.2)	0.1 (0.0-0.1)	0.1 (0.0-0.1)	0.1 (0.0-0.2)
Ventilator associated pneumonia	0.1 (0.1-0.2)	0.0 (0.0-0.1)[a]	0.1 (0.0-0.1)	0,1 (0,0-0.1)[a]
Clostridium difficile infection	-	0.3 (0.2-0.3)	0.3 (0.2-0.3)	0.3 (0.2-0.3)
Other	2.7 (2.5-3.0)	2.4 (2.2-2.7)	2.0 (1.8-2.3)[a]	2.2 (2.0-2.5)[a]
AEs caused by surgery/invasive procedures	1.9 (1.7-2.1)	1.8 (1.6-2.0)	1.8 (1.6-2.0)	1.6 (1.4-1.8)
Urinary bladder distention	1.7 (1.5-1.9)	1.0 (0.9-1.2)[a]	1.0 (0.9-1.2)[a]	1.1 (0.9-1.3)[a]
Drug-related AE	1.4 (1.3-1.6)	1.4 (1.2-1.6)	1.3 (1.1-1.5)	1.5 (1.3-1.7)
Pressure ulcer (grade 2-4)	1.1 (1.0-1.3)	1.0 (0.9-1.1)	1.2 (1.0-1.4)	1.3 (1.1-1.5)
Fall injury	0.8 (0.7-0.9)	0.9 (0.7-1.0)	0.7 (0.5-0.8)	0.7 (0.6-0.9)
Compromised vital signs	0.5 (0.4-0.6)	0.3 (0.2-0.3)[a]	0.3 (0.2-0.4)	0.2 (0.1-0.2)[a]
Postpartum or obstetric AE*	0.2 (0.2-0.3)	0.2 (0.2-0.3)	0.1 (0.1-0.2)[a]	0.3 (0.2-0.4)
Neurological AE	0.1 (0.1-0.2)	0.0 (0.0-0.1)	0.1 (0.0-0.1)	0.1 (0.1-0.2)

AE: adverse event; CI: 95% confidence interval; *not corrected for the proportion of women in the studied population; [a]significant differences compared to 2013.

Figure 1. The proportion of admissions with adverse events (AEs) every month from 2013–2016.

Figure 2. Proportion of admissions with preventable and non-preventable adverse events (AEs) in younger and older patients from 2013–2016.

Figure 3. The proportion of admissions with preventable and non-preventable adverse events (AEs) in patients with acute admissions, patients who underwent surgery and patients treated 'off-site' from 2015–2016

Figure 4. Length of stay (mean, 95% CI) in two age groups of men and women for admissions without adverse events, with non-preventable adverse events and with preventable adverse events from 2013–2016.

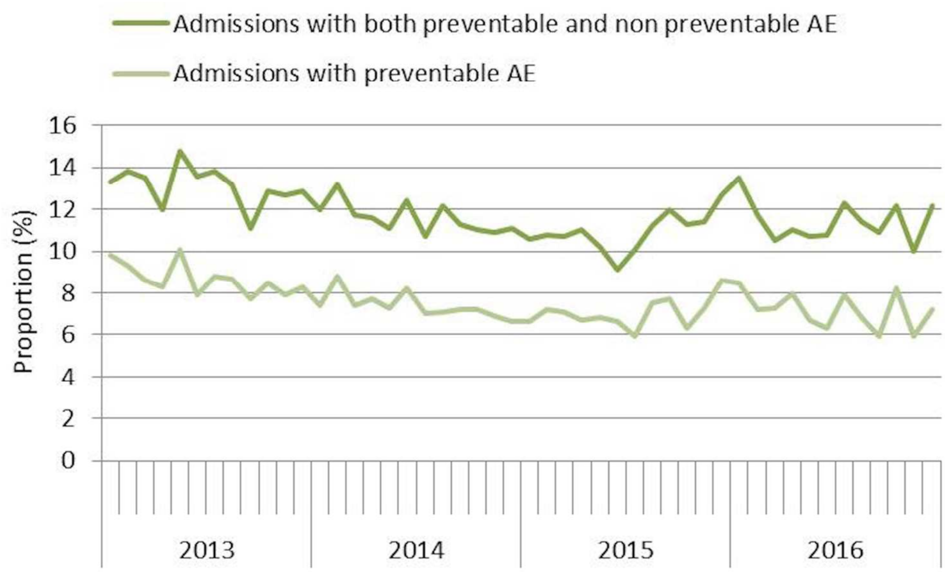

Figure 1. The proportion of admissions with adverse events (AEs) every month from 2013–2016.

127x76mm (300 x 300 DPI)

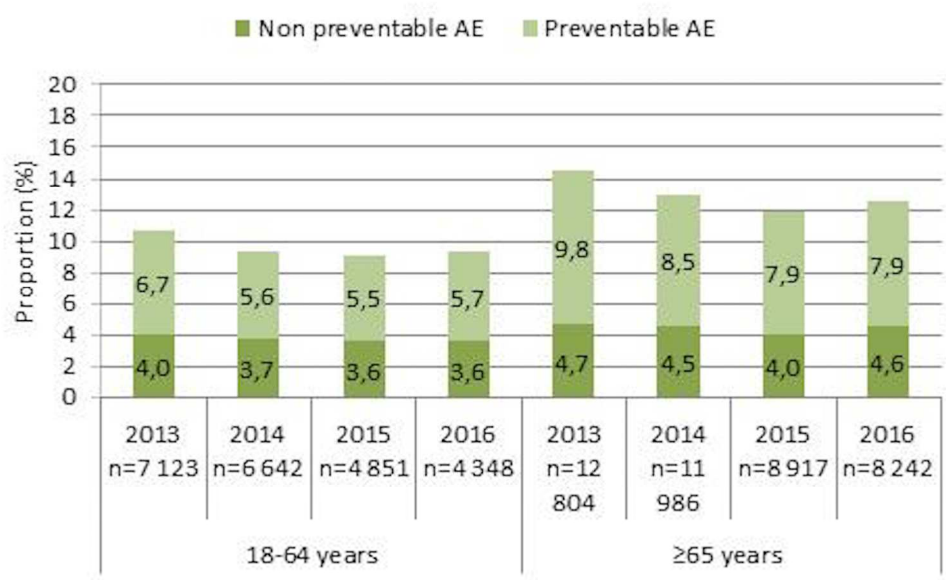

Figure 2. Proportion of admissions with preventable and non-preventable adverse events (AEs) in younger and older patients from 2013–2016.

127x76mm (300 x 300 DPI)

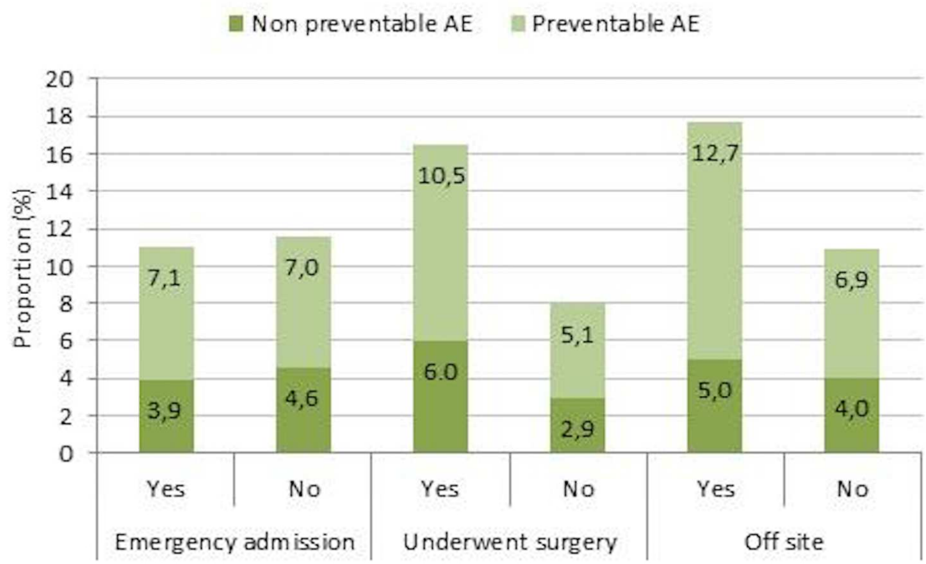

Figure 3. The proportion of admissions with preventable and non-preventable adverse events (AEs) in patients with acute admissions, patients who underwent surgery and patients treated 'off-site' from 2015–2016

129x79mm (300 x 300 DPI)

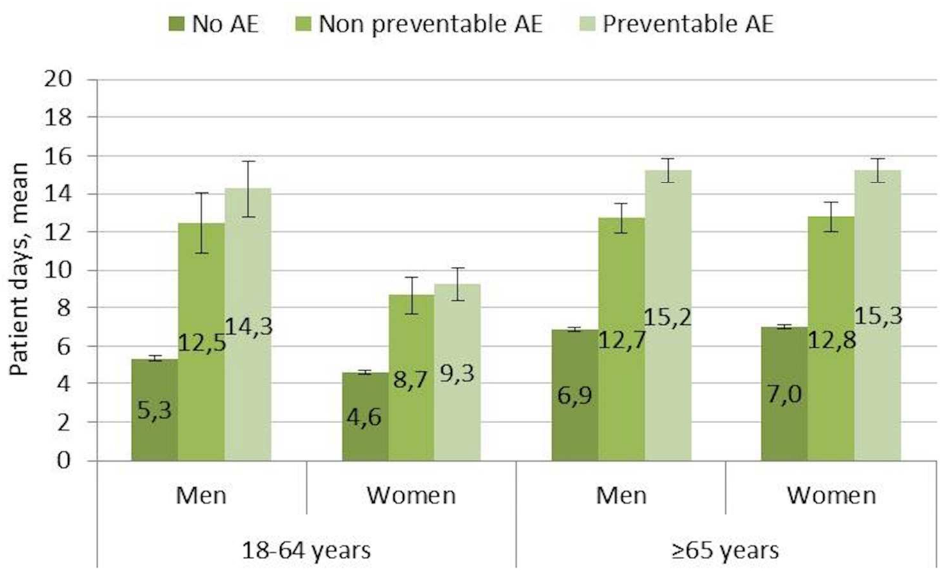

Figure 4. Length of stay (mean, 95% CI) in two age groups of men and women for admissions without adverse events, with non-preventable adverse events and with preventable adverse events from 2013–2016.

127x76mm (300 x 300 DPI)

Table S1. Example of a trigger, its definition and clarifying text.

Deep vein thrombosis or pulmonary embolism

Definition	**Deep vein thrombosis or pulmonary embolism diagnosed during hospital care and not apparent on admission**
Check for	Venous catheter (central venous catheter, subcutaneous venous port, etc.), recent surgery, immobilisation, obesity, cancer or cancer treatment increases the risk. Has thrombosis prophylaxis been given according to routines?
Harm that can be found	Transient or permanent reduction of cardiac or pulmonary function, reduced venous circulation in the lower extremities with oedema and reduced function
Preventability	Deep vein thrombosis should be regarded as preventable if: ☐Prophylaxis against thrombosis has not been given according to routines. ☐Increased risk following immobilisation has not been considered, for example, after surgery. ☐ Anticoagulation therapy (e.g, warfarin) has not been adequately controlled. Pulmonary embolus should also be regarded as avoidable if signs of deep vein thrombosis have not been adequately observed and treated.
Relevant codes for diagnosis, treatment and medication	ICD-10-code: I82 (Embolus and thrombosis) I26 (Pulmonary embolus) O88.2 (Obstetric embolus due to thrombosis)
Results associated to this trigger	Results from investigation with ultrasound, CT or phlebography. Results from pulmonary scintigraphy (ventilation and perfusion scintigraphy).

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	#1, #2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	#2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	#4
Objectives	3	State specific objectives, including any prespecified hypotheses	#4
Methods			
Study design	4	Present key elements of study design early in the paper	#5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	#4-6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	#5-6
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	#6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	#6
Bias	9	Describe any efforts to address potential sources of bias	#6
Study size	10	Explain how the study size was arrived at	#5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	#7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	#7
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) If applicable, explain how loss to follow-up was addressed	NA
		(*e*) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	#7
		(c) Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	Report numbers of outcome events or summary measures over time	NA
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	#7-9
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	#9
Discussion			
Key results	18	Summarise key results with reference to study objectives	#10
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	#10-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	#12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	#3

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.