BMJ Open Is researching adverse events in hospital deaths a good way to describe patient safety in hospitals: a retrospective patient record review study

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ABSTRACT

Objective: Adverse event studies often use patient record review as a way to assess patient safety. As this is a time-consuming method, hospitals often study inpatient deaths. In this article we will assess whether this offers a representative view of the occurrence of adverse events in comparison to patients who are discharged while still living.

Design: Retrospective patient record review study. Setting and participants: A total of 11 949 hospital admissions; 50% of inpatient deaths; the other half of patients discharged while alive. The data originated from our two national adverse event studies in 2004 and 2008.

Main outcome measures: Overall adverse events and preventable adverse events in inpatient deaths, and in admissions of patients discharged alive. We looked at size, preventability, clinical process and type of adverse events.

Results: Patients who died in hospital were on an average older, had a longer length of stay, were more often urgently admitted and were less often admitted to a surgical unit. We found twice as many adverse events and preventable adverse events in inpatient deaths than in patients discharged alive. Consistent with the differences in patient characteristics, preventable adverse events in inpatient deaths were proportionally less and were often related to the surgical process. Most types of adverse events and preventable adverse events occur in inpatient deaths as well as in patients discharged alive; however, these occur more often in inpatient deaths and are differently distributed.

Conclusions: Reviewing patient records of inpatient deaths is more efficient in identifying preventable AEs than reviewing records of those discharged alive. Although many of the same types of adverse events are found, it does not offer a representative view of the number or type of adverse events.

INTRODUCTION

Retrospective patient record review is a commonly used method for estimating national incidences, nature and preventability of adverse events (AEs).¹⁻⁵ These studies have

Strengths and limitations of this study

- This study consists of a large representative sample of nearly 12 000 patient admissions, consisting of 50% inpatient deaths and 50% patient admissions discharged alive.
- To our knowledge, no previous study has compared inpatient deaths and hospital admissions discharged alive for number and type of adverse events (AEs).
- To acquire information on as many improvement possibilities as possible, studying inpatient deaths seems to be an efficient manner to identifv preventable AEs.
- It is important to be aware that when studying only inpatient deaths, some problems remain underexposed or unexposed, especially when using the results to prioritise improvement possibilities.
- Limitations of this study can be seen in the standard limitations of retrospective patient record review studies, such as information bias, moderate reliability and hindsight bias. However, these are not likely to have a large effect on the results of the distribution of type of AEs.

data mining, AI training, and similar led to an increased sense of urgency to improve patient safety and to global direchospital safety improvement tions for programmes.

A number of studies have partly or specific-ally focused on inpatient deaths, to estimate of the relationship between an AE and g death.² $^{6-8}$ These studies report considerable numbers of preventable deaths due to hospital care. Previous studies from our group have also shown higher risks of experiencing preventable AEs in this specific subgroup.² This means that through studying inpatient deaths, not only is information on the most serious outcomes of AEs acquired, but also more indications can be found as to where improvements are possible.

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One method will not identify all types of patient safety issues.^{10–12} Retrospective patient record review seems especially useful as a means to assess whether negative patient outcomes are brought on by healthcare or healthcare management. However, it does have certain limitations in, for example, analysis of causes or insight into deviations in processes as captured by incident reports. Despite the downsides, retrospective patient record review does provide the best characterisation of the overall rate of harm at a given time.¹³ It is, however, also a very time-consuming and costly method, and from this point of view efficiency is welcome. In totality, studying inpatient deaths through AE research instigates a sense of urgency which is more than that from studying the total hospital population because of the serious outcome of preventable deaths. However, inpatient deaths are a relatively small proportion of inpatient admissions; in the Netherlands, inpatient deaths in 2008 made up around 3% of the total inpatient admissions (source: Dutch Hospital Data). So the question arises as to whether the same type of patient safety lessons can be learnt from studying inpatient deaths as from studying admissions of patients who are discharged alive with a two-stage review process.

For substantiation of previous research and to direct future research, as well to inform hospitals doing their own research on hospital deaths, it is important to know whether studying inpatient deaths is efficient and offers a representative view of the number and type of AEs in hospitals in comparison to patients who are discharged alive.

METHODS

Study design and population

We used the data from our two previous AE studies.² ⁹ In the Netherlands, we performed AE studies with patient records from 2004 to 2008 to estimate national incidences of AEs and preventable AEs. In both measurements, half of the patient admissions were of inpatient deaths and the other half of admitted patients discharged alive, making it an ideal sample to compare the two groups. The hospital samples were stratified for hospital type: university, tertiary teaching and general hospitals. Within these strata, the hospitals were randomly selected and a proper representation of urban and rural settings in the samples was verified. For the 2004 measurement, 21 hospitals were included, and 20 hospitals for the 2008 measurement. Within the hospitals, half of the sample consisted of patient admissions who were discharged alive from the hospital after a stay of at least 24 h; the other half were inpatient deaths regardless of the length of stay. Within these strata, patient admissions were randomly selected. Patients admitted with an explicit palliative care plan were not excluded, and this information was taken into account during the review process. As is also common in other studies, the psychiatry department, obstetrics AE

admissions and children younger than 1 year were excluded. For the 2004 measurement, in each hospital, 400 randomly chosen patient admissions were reviewed, and 200 patient admissions for the 2008 measurement. In all hospitals, 50% of patient records were from inpatient deaths and the other 50% from patient admissions discharged alive.

Patient record review

Trained external nurses and external physicians reviewed the nursing, medical, and-if available-outpatient records. The method of determining AEs was the same in both groups, and comparable to those of other international studies and based on the Canadian AE study.³ First a nurse screened the records by using 8 triggers indicating potential AEs. One trigger did not apply for deceased patients: "readmission within 12 months after discharge of the index admission". Admissions positive for at least one trigger were further reviewed by a physician. The physicians belonged to the surgery, internal medicine or neurology specialties, and, if needed, could consult with specialties other than their own. Patient records of the index hospital admission were reviewed, as were the patient records of patient admissions a year before and a year after the index admission. Presence and preventability of an AE was determined for all patients based on a standardised procedure and preceded by a number of underlying questions to secure a systematic assessment.⁹ In addition, for the patients who died in hospital, the physician reviewers also assessed whether the preventable AEs had specifically contributed to the patients' death, leading to potentially preventable death.

Assessing AEs

An AE was defined by three criteria:

- 1. An unintended injury
- 2. Resulting in prolongation of hospital stay, temporary or permanent disability or death
- 3. Caused by healthcare management rather than the patient's disease.

An AE was found to be preventable when the care given was not in compliance with existing professional standards and/or due to shortcomings of a healthcare practitioner, management or system. A six-point Likert scale was used to score the likelihood of cause by health-care management as well as the preventability. A score of 4–6 indicated that the reviewer regarded the event as having a greater than 50% chance of being caused by healthcare or being preventable. If a preventable AE had occurred in a deceased patient, the physicians also assessed whether the preventable AE had contributed to the death of that patient. If this was the case, it was marked as a potentially preventable death; 'potentially' because of the multifactorial nature of hospital deaths and the retrospective assessment of the causality. With regard to the timing of AEs, AEs that occurred during the patient's index hospital admission and those that

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were detected during either the index admission or subsequent admissions over the following 12-month period were counted. Also counted were AEs related to patient admissions in the same hospital within the 12 months preceding the index admission but which were not detected until the index admission. If an AE was identified, questions about the clinical process during which the AE occurred were asked, and physicians were able to choose from the following clinical processes: diagnostics: being an incorrect diagnosis or a diagnosis made too late; surgery: during the surgery or within a 30-day postoperative period; drug/fluid; medical procedure; other clinical management, including care given by nurses; discharge and others.

The review process of the 2004 study was slightly modified for the 2008 study. In short, in the 2004 study, pairs of physicians independently assessed all records positive for screening criteria in the first stage review. Disagreement about the presence and/or preventability of an AE prompted a consensus procedure.¹⁴ In the 2008 study, all records positive for screening criteria were reviewed by one physician and standardisation of reviews was supported by regular meetings to discuss inter-rater differences based on double-blind reviews in 10% of all records. As we are not comparing the years, we do not feel this adaptation has a major influence on the results of this article. In 2004, between pairs of specialists for AEs, positive agreement was 54.9% and negative agreement 66.2%. In 2008, for AEs positive agreement was 56.9% and negative agreement 82.9%.

Exploration of type of AEs

Complementary to the analysis of AEs, preventability and related clinical processes, we also wanted to acquire more information on the specific types of AEs. We, therefore, classified the type of AE or preventable AE into more specific subgroups. We based our classification on the classification used by Landrigan *et al*¹⁵ in their study. Based on the information in the structured review and description of the AE, one researcher classified the AEs. In the cases where the researcher was unsure of the chosen classification, a second researcher also assessed the AE and the outcome was compared.

Analysis

The proportions of both samples, the sample of patients discharged alive and the sample of inpatient deaths, were weighted in the same manner for the different proportions of types of hospitals (university, tertiary teaching or general) in the sample in comparison to the total hospital population in our country. All proportions were weighted for the over-representation of university hospitals in the sample frame. After weighting, the estimates were representative of the total Dutch population of hospitalised patients, either discharged alive or inpatient deaths. The sample weight was the inverse of the probability of being included in the sample due to the

sample design. All statistical analyses were performed in SPSS V.20.0.

Summary and descriptive statistics of patient characteristics of inpatient deaths and patients discharged alive were calculated.

Weighted rates of AEs and preventable AEs were calculated with 95% CIs. Preventability of AEs, related clinical process and more specific types of AEs were assessed for both groups.

All differences between patients discharged alive and inpatient deaths, except for the more specific types of rotected AEs due to small numbers, were tested using proportion tests for two independent groups, with corrections for by copyright, includ the binomial distribution and continuity.

RESULTS

In total, 11 949 of the 12 400 sampled patient admissions were reviewed: 5990 inpatient deaths and 5959 patients discharged alive. The 451 patient records that were not reviewed were unavailable or inadequate for review.

AEs and preventable AEs were found more than twice for uses related as often in inpatient deaths than in the patients discharged alive (table 1). In all admissions, 1256 AEs were found in 1130 patients, and 855 AEs in 762 inpatient deaths, of which 375 were found to be preventable (weighted 46.5%). In patients discharged alive, 401 AEs in 368 admissions were found, of which 146 were found ç to be preventable (weighted 37.7%). Of the inpatient e deaths, 5.8% (95% CI 5.2% to 6.5%) experienced a preventable AE; in patients who were discharged alive this was 2.3% (95% CI 1.9% to 2.7%). In 4.5% (95% CI data 4.0% to 5.1%) of the deceased patients, the AE contributed to the death of that patient (table 1).

Patient characteristics differed between inpatient deaths and patients discharged alive. Inpatient deaths ≥ were on average older, the largest group falling into the training '80 years and older' category in contrast with patients discharged alive, who most often fell into the 41-65 years age group. Admission characteristics also differed: patients who died in hospital had on average a longer length of hospital stay and were more often <u>0</u> urgently admitted. The department the patient was admitted to also differed between the two groups: inpatient deaths had more often been admitted to the intensive care unit or the internal medicine, neurology and lung disease departments, but less often admitted to a surgical department such as urology, orthopaedics, **g** ear, nose and throat, and paediatrics (table 2).

We further assessed the clinical process related to preventable AEs in inpatient deaths and patient admissions discharged alive (figure 1). In inpatient deaths, 27.8% of the preventable AEs were related to diagnostics, as opposed to 12.9% of the patients discharged alive (p<0.001). AEs and preventable AEs of patients discharged alive were proportionally more often related to surgery. In 53.7% of the preventable AEs, the related clinical process was surgery in patients discharged alive,

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	Innatient deaths*	Discharged alive*
preventable	AE or preventable death	
	ate of patients, either inpatient death of discharged alive, wh	o experienced at least one adverse event $(A \succeq)$,

	Inpatient	deaths*	Discharg	Discharged alive*		
. <u></u>	N	Weighted (95% CI) %	N	Weighted (95% CI)† %		
AE	762	12.5† (11.7 to 13.4)	368	6.1† (5.5 to 6.8)		
Preventable AE	344	5.8† (5.2 to 6.5)	137	2.3† (1.9 to 2.7)		
Potentially preventable death	265	4.5 (4.0 to 5.1)	_			

*For AEs, preventable AEs and preventable deaths unweighted numbers are given, % are weighted for hospital type.

+Significant differences between inpatient deaths and patients discharged alive (p<0.001).

as opposed to 29.7% of the inpatient deaths (p<0.001). This lower proportion of surgical preventable AEs in inpatient deaths is primarily related to fewer admissions to surgical departments in this group (table 2). When analysing the clinical process related to the preventable AEs for the subgroup of patients who were admitted to a surgical department, these differences disappear to a large extent. For inpatient deaths, 70.7% of the preventable AEs is then related to the surgical process while for patients discharged alive, this is 81.6%.

Looking more closely into specific types of AEs and preventable AEs, two main differences stand out. First, all main types and almost all subtypes of AEs and preventable AEs occur in both groups, but more often in inpatient deaths than in patients discharged alive (table 3). The most pronounced examples of subtypes of AEs occurring more often in inpatients deaths are: heart failure (32 vs 4), pulmonary embolus (23 vs 4), haemorrhage (29 vs 12), ileus (14 vs 6), perforation (17 vs 3) and stroke or intracerebral haemorrhage (30 vs 4) (table 3). Some of these AEs were also found relatively often to be preventable in inpatient deaths; for example, 78% of the 23 pulmonary emboli and 71% of the 14 ileus were preventable. Some AEs are found more often in patients discharged alive:

	Inpatient deaths*		Discharged alive*		
	N	Weighted %	Ν	Weighted %	Significance
Inpatient admissions	5990		5959		
Patient admissions					
University hospital	1179	15.1	993	12.6	<0.001
Tertiary teaching	1748	33.3	1795	34.0	0.215
General†	3063	51.6	3171	53.4	0.013
Male sex	3217	53.7	2924	49.0	<0.001
Age in years, mean (median/SD)	73.7 (76	.0/13.7)	57.4 (61	.0/21.3)	<0.001
Age categories					
1–18	35	0.5	433	7.0	<0.001
19–40	131	2.0	802	13.3	<0.001
41–65	1264	20.7	2253	37.9	<0.001
66–79	2238	37.3	1674	28.2	<0.001
80 and older	2314	39.3	796	13.6	<0.001
Length of hospital stay, days (median/SD)	12.0 (7.0	0/15.3)	7.7 (5.0/9.6)		<0.001
Urgent admission	5172	87.0	3061	52.2	<0.001
Department to which patient was admitted					
Cardiology	717	12.3	730	12.6	0.535
Surgery	726	12.2	1424	23.9	<0.001
Intensive care	563	8.8	62	1.0	<0.001
Paediatrics	12	0.2	209	3.4	<0.001
Internal medicine	1755	29.7	899	15.1	<0.001
Orthopaedics	103	1.7	651	11.3	<0.001
Neurology	706	11.9	430	7.3	<0.001
Lung disease	779	13.2	384	6.5	<0.001
Ear, nose and throat	26	0.4	264	4.3	<0.001
Urology	68	1.1	280	4.7	<0.001
Other‡	535	8.5	626	9.9	0.04
Patient admitted to surgical department	1003	16.5	2976	49.7	<0.001

*For patient characteristics unweighted numbers are given, % are weighted for hospital type.

†Hospital type rates are corrected for the stratified sample.

‡Other: all other departments <3.5%, for example geriatrics, gynaecology, ophthalmology.

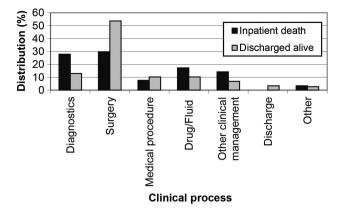


Figure 1 Distribution of clinical process related to preventable adverse event; % are weighted for hospital type.

more surgical site infections, nerve injuries after surgery and failed surgical procedures were found during admission.

Second, as was the case with the clinical process related to the AEs, it appears that the distribution between the groups seems to vary. For the main categories, as a proportion of all AEs, a lower proportion of surgical AEs and a higher proportion of preventable hospital-acquired infections are found in the population of inpatient deaths in comparison with patients discharged alive (table 3). This again is related to differences in departments to which the patient was admitted between the two groups.

There are a number of preventable AE types that occur rarely in patients discharged alive and are found in inpatient deaths, for example, aspiration or sepsis/ bacteraemia.

DISCUSSION

Main findings

Inpatient deaths differ in patient and admission characteristics from patients discharged alive. Patients who died in hospital are on average older, have had a longer length of stay and are more often urgently admitted. Additionally, the department to which the patient was admitted differs between the two groups; for inpatient deaths this is less often a surgical department such as general surgery, orthopaedics, or urology. The number of AEs and preventable AEs differ, occurring at least twice as often in inpatient deaths. There are also differences in distribution of the clinical processes related to the AE and type of AEs. Consistent with fewer admissions to a surgical department, preventable AEs in inpatient deaths were proportionally less often related to the surgical process. A few AEs occur rarely in patients discharged alive: sepsis/bacteraemia and aspiration, and this is most likely because these outcomes often lead to a patient's death. No specific type of preventable AE present in patients discharged alive was absent in deceased patients.

Implications for practice, policy and research

Patient record review used in large national AE studies, or in hospitals as a part of the quality and safety cycle, are often performed, but are also very costly projects. It is important to know if efficiency can be improved by exclusively sampling or oversampling inpatient deaths.

We found that exclusively sampling or oversampling inpatient deaths does seem to be an efficient method: fewer patient records need to be studied to identify where safety improvements are possible; especially when the goal is not specifically the estimation of incidences for the total hospital population, but primarily to obtain as much information as possible on patient safety threats and potential solutions, this seems to be an efficient Å choice as fewer patient records are required to find one preventable AE. This goal is most likely the case for individual hospitals performing chart review as part of their quality and safety improvement cycle. In this case, the results of a structured review of complete patient admissions provide information on improvement possibilities specific for that hospital. The results are often discussed in morbidity and mortality meetings, where additional information on the preventable AEs can be acquired from the involved physicians and nurses. This also may contribute to raising a shared sense of urgency and commitment to improvement. A focus on reviews of deaths is likely to promote interest in the measurement of preventable deaths and perhaps even differences between ç organisations. However, this will be a difficult undertaking given the large samples that are needed to do so and also the low prevalence of preventable deaths and the limited number of inhospital deaths.

Exclusively studying inpatient deaths may underexpose improvement possibilities, especially on wards where patients are proportionally less likely to die. So for some wards it would not suffice to only research hospital deaths. Moreover, through chart review, certain types of problems in healthcare will not be found. Other research has shown that different methods often ŋġ, produce complementary information on patient safety and often have little overlap.¹⁰⁻¹² ¹⁶ Our results also show that types of preventable AEs in the hospitalised population are heterogeneous and spread across many different infrequently occurring specific types. So for one hospital alone it will not necessarily allow an understanding of patterns of harm, even when focusing on all hospital deaths.

For national studies estimating incidence rates of AEs and preventable AEs, reviewing only inpatient deaths will lead to valid information on the number of preventable deaths-these being the most severe kind of AEsbut not to valid information on incidence rates of preventable AEs for the total hospitalised population. This limits the usefulness to prioritise improvement possibilities, as assessing only inpatient deaths can lead to a biased view as to which domain is most important to target. On the other hand, omitting patient records of inpatient deaths in a study also does not seem to be a

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Table 3 Type of harm for all adverse event (AEs) and preventable AEs					
Type of harm	Inpatient death AE, n	Inpatient death Preventable AE, n	Discharged alive AE, n	Discharged alive Preventable AE, n	
Cardiovascular system, total (column %)*	96 (11.2)	41 (11.3)	20 (5.3)	5 (3.4)	
Cardiac arrest	6	1			
Hypotension	3	3	3	1	
Hypertension	1	1			
Shock	7	3			
Arrhythmias or conduction abnormality	9	4	4		
Myocardial ischemia	15	7	4		
Heart failure	32	13	4	2	
Other cardiovascular event	23	9	5	2	
Respiratory system, total (column %)*	110 (13.2)	48 (12.7)	19 (4.8) Г	8 (5.4)	
Pneumothorax	24	3	5	I	
Atelectasis	1	1	2		
Bronchospasm Aspiration	26	11	2		
Pulmonary embolus	23	18	4	4	
Other respiratory event	36	15	6	3	
Renal or endocrine system, total (column %)*	54 (6.0)	32 (7.9)	22 (5.8)	11 (7.5)	
Fluid overload	7	5	2 (3.0)	1	
Dehydration or oliguria	2	2	4	2	
Hyperglycaemia	1	1	3	2	
Hypoglycaemia	7	3	3	1	
Hyperkalemia	5	4			
Renal insufficiency	13	8	4	1	
Other renal or endocrine event	19	9	6	4	
Haematological system, total (column %)*	56 (6.2)	26 (6.6)	19 (5.5)	7 (6.1)	
Haemorrhage	29	14	12	4	
Thromboembolic venous event	12	4	4	2	
Haematoma	4	2	3	1	
Other haematological event	11	6			
Gastrointestinal system, total (column %)*	84 (10.0)	48 (12.7)	27 (6.8)	9 (6.1)	
Nausea or vomiting	1	1	4		
Diarrhoea	2		2		
Pancreatitis		10	2	0	
lleus	14	10	6	2	
Intestinal tract bleeding Perforation	21 17	7 11	3 3	1 2	
Other gastrointestinal event	29	19	3 7	4	
Neurologic system, total (column %)*	52 (6.0)	25 (6.3)	4 (4.5)	4 11 (7.5)	
Over sedation	52 (0.0)	20 (0.0)	1	11 (7.5)	
Delirium or encephalopathy	6	4	2	1	
Seizure	1		1	1	
Stroke or intracerebral haemorrhage	30	11	4	2	
Withdrawal symptoms	3	3			
Other neurologic event	12	7	10	7	
Hospital-acquired infection, total (column %)*	186 (21.7)	58 (16.1)	73 (17.8)	6 (4.8)	
Catheter-related bloodstream infection	19	3	3	1	
Sepsis or bacteraemia unrelated to catheter	88	34	5		
Ventilator-associated pneumonia	3	1			
Nosocomial pneumonia, not ventilator-related	17	6	7	1	
Urinary tract infection	13	4	12	1	
Surgical-site infection	11	2	21	2	
Clostridium difficile colitis	2		1		
Phlebitis	2				
Infected foreign material	7	4	11		
Other hospital-acquired infection	24	4	13	1	
Surgical event, total (column %)*	151 (18.1)	62 (16.9)	142 (34.8)	62 (41.5)	
Postoperative haemorrhage	48	18	30	9	
				Continued	

Type of harm	Inpatient death AE, n	Inpatient death Preventable AE, n	Discharged alive AE, n	Discharged alive Preventable AE, n
Postoperative haematoma	3	1	6	2
Postoperative abscess	5	2	7	1
Laceration or other organ injury	14	4	11	7
Unplanned removal of organ after intra-operative injury	6	3	3	1
Vascular injury	3	1	1	1
Nerve injury	1		8	3
Wound dehiscence	5	2	2	2
Anastomotic leakage	16	7	5	1
Postoperative fistula	2		4	2
Failed procedure	12	10	23	14
Unplanned return to surgery	3	1	7	3
Other event	33	13	35	16
Other types of harm, total (column %)*	66 (7.7)	35 (9.5)	61 (14.8)	27 (17.7)
Fever	9	2	8	
Allergic reaction	2		5	
Pressure ulcer	9	3	5	1
Rash	8	3	6	1
Catheter complication	3			
Fracture	5	2	7	4
Other type of harm	30	25	30	21
Total	855 (100)	375 (100)	401 (100)	146 (100)

good idea, as specific types of severe AEs will be overlooked, for example, sepsis-bacteraemia or aspiration. Given that the incidence of hospital deaths in most hospitals is around 5%, some oversampling of this subgroup will be necessary in most studies.

Strengths and limitations

To our knowledge no previous study has compared inpatient deaths and hospital admissions discharged alive. The strength of our study is the large representative sample of nearly 12 000 patient admissions, consisting of 50% inpatient deaths and 50% patient admissions discharged alive, reviewed in the same years by the same reviewers, thus making it an ideal sample for our research question.

Limitations of this study can be seen in the standard limitations of retrospective patient record review studies. First, information bias could occur in retrospective patient record review. It is likely that not all information on AEs and preventable AEs has been written down in the patient record. We do think that this form of bias is probably the same for the inpatient deaths as well as for patients discharged alive, since during treatment care providers do not know whether the patient will die. As has been recorded in other studies—and is also the case for our own study—retrospective patient record review of AEs is subject to moderate reliability.⁹ ^{17–19} Lastly, hindsight bias is often mentioned as another problem.⁸ ²⁰ Hindsight bias is the influence of knowing the outcome and its severity on the judgement of

causation and preventability.⁸ ²¹ ²² The outcome in inpatient deaths is death and this is more severe than the outcome in the group of patients admitted alive, which is prolongation of hospital stay, temporary or permanent disability. Thus, hindsight bias may be a more serious problem in the sample of inpatient deaths and therefore, may have led to an overestimation of the number of preventable AEs and AEs contributing to the death of a patient (preventable death) in this subgroup. In our study, however, we do not expect the hindsight bias to be of a large influence on the distribution of the types of preventable AEs. This bias can only be fully prevented if the reviewers are blinded for the outcome; this, however, is not possible in large scale retrospective patient record review studies.

In conclusion, studying inpatient deaths with patient record review seems an efficient way to identify preventable AEs in comparison with patients discharged alive: we found more than double the results in the same number of patient records. To acquire information on as many improvement possibilities as possible, this would seem to be an efficient choice. However, when only studying inpatient deaths, awareness of the fact that some problems remain underexposed or unexposed is important. Besides, on certain hospital wards patients rarely die; thus for these wards it would not suffice to only research hospital deaths. When using the results to prioritise where improvement of patient safety is needed, one has to take into account these variations in distribution. Acknowledgements The authors would like to thank everyone who contributed to the study, especially the nurses and doctors who reviewed the patient records, and the 33 hospitals participating in the study, including their staff who facilitated the patient records.

Contributors RJB was involved in the analysis and interpretation of data, drafting of the article; MCdB, ML were involved in the design, interpretation of data, critical revision of its intellectual content; CW was involved in the design, critical revision of its intellectual content, guarantor. All authors approved the final version.

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Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

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