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The Irish National Adverse Events Study (INAES): the frequency and nature of adverse events in Irish hospitals—a retrospective record review study

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ABSTRACT

Introduction Irish healthcare has undergone extensive change recently with spending cuts and a focus on quality initiatives; however, little is known about adverse event occurrence.

Objective To assess the frequency and nature of adverse events in Irish hospitals.

Methods 1574 (53% women, mean age 54 years) randomly selected adult inpatient admissions from a sample of eight hospitals, stratified by region and size, across the Republic of Ireland in 2009 were reviewed using two-stage (nurse review of patient charts, followed by physician review of triggered charts) retrospective chart review with electronic data capture. Results were weighted to reflect the sampling strategy. The impact on adverse event rate of differing application of international adverse event criteria was also examined.

Results 45% of charts were triggered. The prevalence of adverse events in admissions was 12.2% (95% CI 9.5% to 15.5%), with an incidence of 10.3 events per 100 admissions (95% CI 7.5 to 13.1). Over 70% of events were considered preventable. Two-thirds were rated as having a mild-to-moderate impact on the patient, 9.9% causing permanent impairment and 6.7% contributing to death. A mean of 6.1 added bed days was attributed to events, representing an expenditure of €5550 per event. The adverse event rate varied substantially (8.6%–17.0%) when applying different published adverse event eligibility criteria.

Conclusions This first study of adverse events in Ireland reports similar rates to other countries. In a time of austerity, adverse events in adult inpatients were estimated to cost over €194 million. These results provide important baseline data on the adverse event burden and, alongside web-based chart review, provide an incentive and methodology to monitor future patient-safety initiatives.

INTRODUCTION

Preventable adverse events are an ongoing challenge in healthcare. International studies demonstrate that 3%–17% of admissions are associated with an adverse event (defined as an injury caused by healthcare management resulting in prolonged hospitalisation, disability on discharge or death[1]).[2 3] Approximately half of the adverse events are preventable.[4]

Little is known about adverse events in the Irish healthcare system. Notwithstanding a number of reports into individual incidents,[5 6] there is no comprehensive national collection of adverse event data, and voluntary reporting captures only a small proportion of events.[7] Therefore, recommendations on improving patient safety at a national level are being made on limited information. Additionally, the WHO recommends collecting local data to provide the mandate and commitment for national patient-safety action.[8]

The aim of the Irish National Adverse Events Study (INAES) was to quantify the frequency and nature of adverse events in acute hospitals in the Republic of Ireland for the first time using an internationally recognised retrospective patient chart review methodology. Previous studies have shown a fivefold difference in adverse event frequency, but these differences are difficult to interpret

due to variation in inclusion criteria for eligible events. We therefore also wished to examine how the Irish rate would vary with application of different published adverse event criteria.[3 9 10]

Patient data from 2009 were collected as it predated the establishment of the National Clinical Programmes in Ireland in 2010: the programmes aim to improve and standardise the quality of patient care.[11] INAES was therefore designed to assess the baseline burden of adverse events and enable future evaluation of the effect of these programmes on patient safety. The INAES also employed web-based electronic data capture which has the potential to make the methodology more accessible for organisations to assess and monitor their patient-safety initiatives.

METHODS

To allow international comparison, we based our methods on the Canadian Adverse Events Study which employed a modified protocol of the Harvard Medical Practice Study.[1 12] Similar protocols have been used in other international adverse event studies.[2–4 9 13–26] This involves a two-stage review of patient charts with nurse reviewers screening for triggers that may identify an adverse event (stage 1), followed by physician reviewers determining the presence of adverse event(s) in trigger positive charts (stage 2).

Definitions

An adverse event was defined as an unintended injury or complication resulting in disability at the time of discharge, prolonged hospital stay or death and that was caused by healthcare management rather than by the underlying disease process.[1] Disability was restricted to temporary (lasting up to a year) or permanent impairment of physical function.[12] Healthcare management included the actions of individual hospital staff as well as the broader systems and care processes of healthcare, including both acts of omission (failure to diagnose or treat or manage) and acts of commission (incorrect diagnosis or treatment).[12]

Study sample

The study hospitals were all acute public hospitals in the Republic of Ireland—public hospitals provide approximately 88% of the national acute hospital beds.[27] Thirty hospitals listed in the Irish Health Service Executive (HSE) 2012 hospital Casemix annual budget adjustment were invited to participate (this excluded eight hospitals with a sole clinical specialty focus, ie paediatrics, maternity and orthopaedics).[28] Casemix is a system which groups patient data to compare activity and costs between hospitals.[29]

Hospitals were classified as 'large' if total annual inpatient, day case and emergency department Casemix units were over 100 000 and/or the hospital hosted a National Cancer Centre (ie, where staff with specialist cancer expertise are concentrated[30]); with the remainder classified as 'small'. The approximate number of annual Casemix units (and distribution into inpatient/day case/emergency) for the nine large hospitals was 980 000 (22%/37%/41%), and for the 21 small, it was 860 000 (30%/23%/47%).[28] Eighteen hospitals agreed to participate, six refused and six did not reply despite several contacts. The selection process involved random sampling of participating hospitals, stratified by health system (HSE) region and hospital size, to select eight hospitals: one 'large' and one 'small' from each of the four regions.[31]

After hospital selection, a random sample of 300–400 admissions ('index admissions') for the calendar year 2009 was generated at each site using the hospital's local Hospital Inpatient Enquiry (HIPE) electronic discharge database. HIPE collects demographic, clinical and administrative information on discharges and deaths from acute hospitals in the Republic of Ireland. Discharge diagnoses and procedures are coded using ICD-10 AM/ACHI/ACS 6th edition (International Classification of Diseases 10th revision Australian Modification/Australian Classification Health Interventions/Australian Coding Standards).[32]

The sampling frame included all inpatient admissions for patients aged at least 18 years who had a minimum stay in hospital of 24 h (or died within 24 h) and excluded admissions with a principal diagnosis related to obstetrics or psychiatry (ICD-10 codes F00–F99 and O29–O927[33]). Admissions that were recorded in HIPE as being a transfer from another hospital were excluded as the likelihood was that full clinical information from the transferring hospital would not be available. Nurse reviewers conducted a further eligibility check prior to commencing review of each chart to identify ineligible admissions that were not able to be excluded using our HIPE methodology, that is, inpatients who were discharged within 24 h and obstetric admissions resulting in uncomplicated births with non-obstetric principal diagnosis codes. Early pregnancy (<20 weeks) was included in line with the Canadian Adverse Events Study.[12]

Reviewer training

Six nurse reviewers, each with a minimum of 7 years' nursing experience and all having experience in clinical research, audit, hospital management and/or education and three physician reviewers (two recently retired respiratory physicians and one public health medicine physician) performed the chart reviews.

Researchers from the Canadian adult and paediatric adverse events studies conducted face-to-face training of the reviewer group over 2½ days.[12 17] An operations manual containing the study protocol and instructions for the web-based data collection was adapted from the Canadian manual. The Canadian website data entry forms and database were modified

for the Irish healthcare setting. The web-based data collection tool captured all study data. It had several advantages—prepopulation of admission demographic data, streamlined data entry (compulsory fields, review of each injury with automatic adverse event determination if the definition was satisfied), enhanced data security (direct download to a secure server), central monitoring of site progress, automatic assignment of reliability charts and direct transfer into statistical software. Structured implicit review assisted physician reviewers to assess causation and preventability with the tool guiding reviewers through a series of questions before they made their judgements.

Reviewers independently reviewed 20 training charts immediately following the group training. These were assessed for inter-rater reliability by calculating the κ statistic (nurse κ=0.16, physician κ=0.52). The low κ for the nurses was due to a subset of nurses being oversensitive and triggering nearly all of the charts. The training charts were discussed in the reviewer groups before beginning data collection. The nurses had support on their initial 10 study charts. A 10% sample of patient charts was rereviewed by all nurse or physician reviewers at each site. The κ statistics in the field improved to nurses 0.79 (95% CI 0.68 to 0.88) and physicians 0.59 (95% CI 0.37 to 0.79).

A sample of trigger-negative charts at each site was also reviewed by a physician reviewer for adverse events as part of a sensitivity analysis of the stage 1 trigger methodology. The sensitivity and specificity were calculated as 96% and 64% respectively, with a 1.0% (95% CI 0.1% to 3.7%) prevalence of adverse events in missed charts (2/196 trigger-negative charts contained events).

Data collection

Patient charts were reviewed between December 2013 and January 2015. Stage 1 involved nurse review of each chart using a list of 18 'triggers' (eg, unplanned readmission, hospital-acquired infection, adverse drug reaction; online supplementary appendix 1). Chart reviews centred on the index admission and all documentation 1 year before and after. The majority of patient charts were paper based or scanned paper records. In some sites, reports or correspondence were available electronically but these tended to duplicate documents included in the paper chart. There was no limit on time taken to review charts.

Stage 2 involved physician review of triggered charts to determine whether an adverse event had occurred. One physician reviewed each chart. Adverse events, which occurred within 12 months before, or during, the index admission, which were detected either during the index admission or within 12 months afterwards, were included. The physician reviewer rated the impact of the event, the likelihood that it was caused by healthcare management and its degree of preventability using standard scales (see online supplementary appendix 2). For each event, the physician classified its nature (ie, whether it was related to diagnosis or other clinical management, an operation or non-surgical procedure, a fracture, an anaesthetic, administration of fluids or medication, pregnancy and/or another type of event) and whether a system issue was involved (ie, if failures within the healthcare system contributed to the event). A consultant surgeon was available for advice on surgical cases.

Demographic and administrative data on the index admissions (age, sex, discharge diagnoses and procedures, consultant specialty code, admission and discharge dates) were collected at the time of random selection at each site. National demographic data for equivalent adult inpatients in acute public hospitals during 2009 was provided by the Healthcare Pricing Office and generated using the same HIPE search strategy as employed in the INAES sampling (see online supplementary appendix 3).[34]

Analysis

Power calculation

A sample size of 1500 admissions was calculated using a 20% rate of adverse events and ±2% precision (with precision improving at lower rates).[3] This allowed a precision of ±5% in any subgroup constituting 20% or more of the total sample. Thus, at least 187 eligible admissions were required to be reviewed at each hospital.

Weighting and analyses

The risk (period prevalence) of adverse events in inpatient hospital admissions was calculated as the proportion of admissions associated with one or more adverse events.[12] The incidence density was calculated as the number of adverse events occurring per 100 admissions, excluding events occurring prior to the index admission (to avoid double counting). CIs for binary variables were modelled using logistic regression; CIs for incidence were calculated using Poisson regression with robust variance estimation to account for overdispersion; p values were derived from logistic regression, unless otherwise noted. To maximise the number of adverse events reviewed, the sample was stratified such that half of admissions had undergone a surgical procedure (without stratification, this figure was approximately one quarter[34]). The procedure codes for general anaesthetic, regional and neuroaxial blocks (ACHI 9251400–9251499, 9250800–9251299) were used as proxies to indicate that surgery was likely to have been performed during the admission. Analyses were weighted for this sampling frame (ie, the ratio of admissions with and without the anaesthetic procedure codes in each hospital's eligible study population). Inter-rater reviewer reliability was analysed using Cohen's κ, with CIs calculated using a bootstrap method implemented in the user-

written command kapci.[35] All analyses were performed using Stata release 13.1.

The national cost of adverse events in adult inpatients was estimated as the product of (1) the estimated number of adverse events—using the INAES incidence density of adverse events applied to the number of adult inpatient admissions to acute public hospitals in 2009, excluding those with obstetric and psychiatric principal diagnoses (n=339,844[34]); and (2) the average cost of an event—calculated as the INAES mean number of added bed days attributed to adverse events multiplied by the average cost of an inpatient hospital bed in Ireland in 2009 (€909 per day[36]).

RESULTS

A total of 2600 admissions were randomly selected from the hospitals' HIPE discharge databases. Oversampling was performed to account for missing charts or ineligible admissions. Hospitals were advised to retrieve charts in batches from the top of the randomly generated list. Nurse reviewers were asked to review a target of 190–200 eligible charts at each site, reviewing the top 200 charts first and using the oversample as backup. A total of 1854 charts were screened for eligibility by the nurse reviewers and 1609 (87%) were eligible for the study (figure 1). The majority of ineligible admissions had a hospital stay of under 24 h. After excluding charts with inadequate documentation, 1580 admissions underwent a full stage-1 review (188–201 admissions per hospital), of which 6 were excluded by physician reviewers leaving a total of 1574 fully reviewed charts (figure 1).

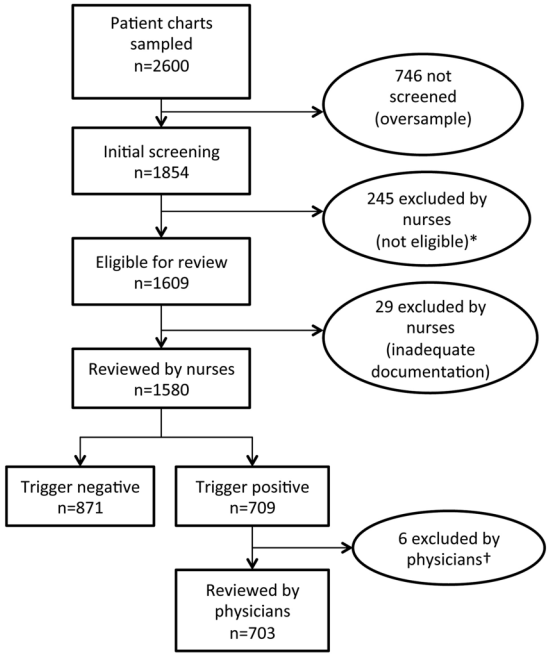

Figure 1 Flow chart of the INAES chart review process. INAES, Irish National Adverse Events Study. *<24 hours (n=216), uncomplicated birth (n=25), transfer (n=2), not admitted (n=1), under 18 years old (n=1). †<24 hours (n=1), uncomplicated birth (n=1), transfer (n=3), unable to locate (n=1).

The reviewed charts were comparable with national acute public hospital admissions in 2009 for age, sex and length of stay (see online supplementary appendix 3). However, a lower proportion of the national admissions compared with the INAES sample died during the admission (2.7% vs 4.8%, respectively). This is likely due to INAES excluding admissions with a hospital stay under 24 h unless the patient died, whereas the national figure includes all short-duration admissions.

A total of 45% of charts reviewed in stage 1 were trigger positive. The triggers of hospital-acquired infection, unplanned return to the operating theatre and unplanned removal/injury during surgery had the highest relative risks for subsequent adverse event determination (5.3, 4.8, 4.7, respectively; online supplementary appendix 1).

In stage 2, physician reviewers identified 247 adverse events in 211 admissions, including 15% with more than one event (see case descriptions in online supplementary appendix 4). Most (72.4%, weighted) of the adverse events occurred during the index admission (table 1). Approximately a quarter of events (23.5%) were detected after the index admission, and in 27.7%, the event occurred prior to the index admission.

The overall adverse event prevalence (ie, the proportion of admissions associated with one or more adverse events) was 12.2% (95% CI 9.5% to 15.5%) after weighting for the sample frame. The weighted incidence density was 10.3 adverse events per 100 admissions (95% Poisson CI 7.5 to 13.1). The mean age of patients was significantly higher among admissions with an adverse event than those without (61.8 years vs 55.4 years; p<0.001 (t test)), and with each 10-year age increment, there was an 18% increase in risk of an adverse event (OR 1.18, 95% CI 1.09 to 1.27). There was no difference in risk between women and men (p=0.683).

Of the 247 adverse events, 179 (72.5%) were judged to be preventable (see online supplementary appendix 2). When these results were adjusted for the sampling strategy, 72.7% (95% CI 58.8% to 83.3%) of events were deemed preventable (table 2), including 74.6% (95% CI 60.2% to 85.1%) of the 187 events occurring during the index admission. There was no difference between large and small hospitals in risk of an adverse event (p=0.918) or in the proportion rated as preventable (p=0.254).

Two-thirds (67.6%, weighted) of adverse events resulted in no physical impairment or disability at discharge or in minimal-to-moderate impairment with recovery within 6 months (see online supplementary appendix 2). Nonetheless, 9.9% of the adverse events resulted in permanent disability, and 6.7% (occurring in 14 patients) were judged to have contributed to the

Table 1 The weighted distribution of adverse events by the timing of occurrence and detection

	Timing of adverse event occurrence (O) and detection (D)		
Weighted distribution (95% CI) of all study adverse events*	**Before index admission**	**Index admission**	**After index admission**
48.9% (40.7% to 57.0%)		O→D	
27.7% (19.9% to 37.0%)	O→	D	
23.5% (18.1% to 29.9%)		O→	D

*Point estimates and CIs were weighted to account for the sampling frame.

patient's death (see online supplementary appendix 2). There was no significant difference in risk of death in admissions that had adverse events compared with admissions without events (p=0.331).

Patients who experienced adverse events had a median length of index admission of 7 days (IQR 3, 17) compared with four days (IQR 2, 8) without adverse events (p<0.001, Wilcoxon–Mann–Whitney). Physician reviewers judged events occurring in the index admission to result in a mean of 6.1 (95% CI 4.8 to 7.7) additional hospital days in that admission or readmission(s). This represents an additional cost of approximately €5550 for each adverse-event-associated admission, which when extrapolated nationally gives an estimated annual cost of hospital-based adverse events to the Irish healthcare system of €194 million.

Adverse event risk was higher in admissions with anaesthetic procedure codes indicating a surgical procedure was likely to have occurred, than in admissions without these codes (17.9% (95% CI 13.5% to 22.3%) versus 10.2% (95% CI 7.2% to 13.1%)). However, when the 1499 admissions with medical or surgical consultant speciality codes were compared, there was no difference in event frequency between the specialities: medical-weighted prevalence 11.9% (95% CI 8.3% to 15.5%), surgical 13.1% (95% CI 9.8% to 16.5%). The type of adverse event varied by speciality, with surgical specialities having a greater proportion of operation-related events (occurring during surgery or within 30 days postoperatively), whereas therapeutic events (inappropriate or delay in treatment or failure to monitor) and medication-related events were the dominant categories for medical specialities (figure 2). When operation-related events were removed, the distribution of remaining event types was similar in medical and surgical specialties (see online supplementary appendix 5). A system issue was identified in 106 events (weighted proportion 46.1% (95% CI 31.5% to 61.4%)). Overall, adverse events resulting from errors of omission were as common as those resulting from errors of commission (data not shown), with no significant difference between medical and surgical specialties (p=0.627).

Adverse event prevalence varied significantly if different criteria were used to identify the events (table 3). For example, exclusion of events occurring in the index admission and discovered subsequently reduced the weighted risk to 9.4% (95% CI 7.4% to 11.9%).[1 9] Similarly exclusion of events prior to the index admission resulted in a risk of 8.6% (95% CI 6.7% to 10.9%).[19] If events caused by healthcare management outside the index hospital were included (eg, occurring in general practice, nursing homes or other healthcare facilities), then the weighted prevalence rose to 14.6% (95% CI 11.6% to 18.3%).[22] Furthermore, using a lower threshold to determine likelihood of causation by healthcare management (a score of ≥2, online supplementary appendix 2) increased the prevalence to 14.5% (95% CI 11.3% to 18.4%),[21] and if events caused by healthcare

Table 2 Adverse event frequency, by hospital type

	Hospital type		
Variable	**Small**	**Large**	**All**
Number of admissions sampled	792	782	1574
Number of admissions associated with an adverse event	108	103	211
Crude adverse event prevalence (95% CI)	13.6% (11.4% to 16.2%)	13.2% (11.0% to 15.7%)	13.4% (11.8% to 15.2%)
Weighted adverse event prevalence (95% CI)*	12.4% (7.7% to 17.1%)	12.1% (8.5% to 15.7%)	12.2% (9.5% to 15.5%)
Number of adverse events	123	124	247
Number of incident adverse events (ie, excluding events occurring prior to the index admission)	89	98	187
Crude incidence of adverse events per 100 admissions (95% CI)	11.2 (9.0 to 13.8)	12.5 (10.2 to 15.3)	11.9 (10.2 to 13.7)
Weighted incidence of adverse events per 100 admissions (95% CI)*	9.5 (7.0 to 11.9)	10.8 (6.0 to 15.6)	10.3 (7.5 to 13.1)
Weighted percentage of adverse events that were preventable (95% CI)*	80.1% (68.7% to 91.5%)	68.1% (52.4% to 83.9%)	72.7% (58.8% to 83.3%)

*Point estimates and CIs were weighted to account for the sampling frame.

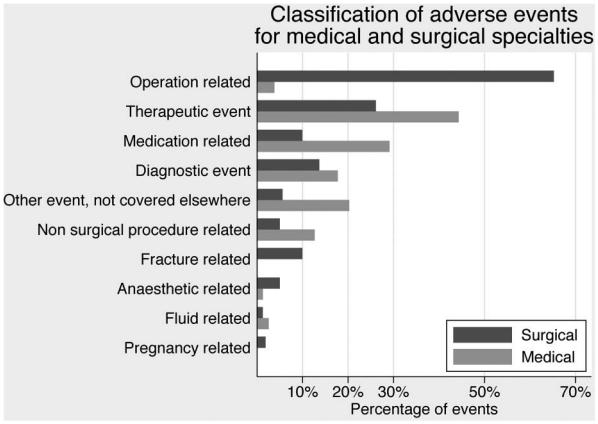

Figure 2 Frequency of adverse event types for medical and surgical specialties.

management outside the index hospital were also included, this became 17.0% (95% CI 13.4% to 21.3%).[3]

DISCUSSION

This is the first national study to report adverse event prevalence in the Republic of Ireland. The major strengths of this research are its standardised methodology and the ability to compare with international studies that have used this method but different adverse event eligibility criteria. Our adverse event prevalence of 12.2% and incidence of 10.3 events per 100 admissions fall at the upper end of the range of other international studies (3%–17%).[3 9] At a national level, this extrapolates to 41 000 admissions associated with one or more adverse events out of approximately 340 000 similar admissions to Irish acute public hospitals in 2009.

In contrast, adverse events were reported in only 1.9% of patient contacts in 2011 to the National Incident Management System (NIMS).[37 38] While not directly comparable (NIMS includes near-misses and community settings), there appears to be significant under-reporting of adverse events in the Irish healthcare system, similar to other research.[7 23] Reasons for this include lack of awareness or belief in the value of reporting, fear of litigation and lack of a supportive culture encouraging reporting.[39 40]

The leading categories of events by frequency in INAES were similar to other studies: operation related, therapeutic, medication related and diagnostic.[9 12 13] Additional analyses will be needed to delineate the nature of events within these categories for prioritisation of future patient-safety initiatives. Unlike the Canadian study, we did not find a difference with hospital size; however, hospital categorisation differs between studies and necessarily relates to local demographic and health service factors.[12] Over 70% of INAES adverse events were considered preventable. This appears high (compared with a previous systematic review aggregate estimate of 43.5%[4]) but preventability is likely to increase over time with advances in surgical techniques, therapeutics, quality initiatives and increased availability of documentation with electronic clinical notes;[41] more recent studies have reported similar rates.[16 18 22] Furthermore, judgement of preventability can only be based on available documentation and will be influenced by reviewers' experience and knowledge.[42 43] In line with other research, undergoing a surgical procedure was associated with a greater risk of an adverse event.[4] However, this finding was not true for the surgical specialities overall. This is probably because a quarter of admissions coded with a

Table 3 Weighted occurrence of Irish National Adverse Events Study (INAES) adverse events with the application of international adverse event eligibility criteria

Adverse event eligibility criteria	Weighted prevalence (95% CI)	Weighted incidence density (95% CI)	Magnitude (%) change in prevalence
Include only events related to the index hospital (exclude events caused by healthcare management outside the index hospital) with healthcare management causation at least more likely (≥4 out of 6, online supplementary appendix 2). INAES prevalence	12.2% (9.5% to 15.5%)	N/A*	Baseline
Exclude adverse events detected after the index admission	9.4% (7.4% to 11.9%)	10.9 events per 100 admissions (8.2 to 13.7)	23% decrease
Exclude adverse events occurring prior to the index admission. INAES incidence	8.6% (6.7% to 10.9%)	10.3 events per 100 admissions (7.5 to 13.1)	30% decrease
Include adverse events in all settings (ie, include events caused by healthcare management outside the index hospital)	14.6% (11.6% to 18.3%)	N/A*	20% increase
Include events with at least slight-to-moderate evidence for healthcare management causation (≥2 out of 6, online supplementary appendix 2)	14.5% (11.3% to 18.4%)	N/A*	19% increase
Include all events with at least slight-to-moderate evidence for healthcare management causation (≥2 out of 6, online supplementary appendix 2) in all settings	17.0% (13.4% to 21.3%)	N/A*	39% increase

*Not applicable: unable to calculate an incidence because including events occurring in admissions prior to the index admission as well as events detected in subsequent admissions will result in double counting.

surgical speciality (ie, under the care of a surgical consultant for their principal diagnosis) did not appear to have had surgery (judged by the absence of a procedure code for an anaesthetic) while approximately 5% of those with a medical code underwent surgery.

Comparison of published adverse event rates is problematic. Results from international studies conducted over a 30-year period present the burden of adverse events at one point in time and may not reflect current practices or quality and patient-safety improvements in that healthcare system. In addition to differences in setting, these studies differed by eligible population, threshold for causation by healthcare management, extent of documentation reviewed and the timing and location of events relative to the index admission. For example, some studies included paediatric and all obstetric patients and had no length-of-stay eligibility criteria,[1 9 13] some had a lower threshold for causation,[3] while others did not include events that were discovered before, or after, the index admission.[1 9 19] When our data were recalculated by applying different adverse event criteria, the INAES prevalence varied from 8.6% to 17.0% (representing a 30% decrease to a 40% increase when compared with the main result of 12.2%). This highlights the challenges inherent in measuring and comparing adverse events. Current variation in methodology and definitions, as well as setting and year, make it difficult to assess whether there are intrinsic differences in adverse event occurrence between healthcare systems.[44]

The cost of adverse events is significant in terms of adverse outcomes for patients and the trauma and consequences for all involved—patients, families and staff.[45] Financially, an annual cost of €194 million represents approximately 4% of the Irish healthcare acute services 2009 budget.[46] This is an underestimate as it does not take into account costs such as escalation of care and litigation. Furthermore, day cases, emergency department assessments, paediatric and the majority of obstetric and psychiatric admissions were not included in our study.

Study limitations

Not all invited hospitals agreed to participate. However, the INAES included large and small hospitals from across the country and was comparable with national demographic data. Our estimate may not have captured all adverse events. For example, the two-stage methodology means that not all charts undergo physician review. However, our trigger screening sensitivity analysis indicates that the adverse event rate would only result in a relative 4% increase (to 12.7%) if physicians had reviewed all charts. Events detected in the index admission that occurred over a year beforehand (estimated to contribute 10% of all events[3]), and events from the index admission that were detected after a year are not included. In addition, retrospective chart review is restricted to chart documentation without direct information from staff involved in patient care. Our reviewers commented that there was significant variability across hospitals in terms of filing practices, recording of information (extent of documentation, handwritten or typed), layout of drug charts, presence of discharge summaries and availability of investigation results. Furthermore, studies comparing prospective and retrospective methodologies have found that although these methods identify similar rates of events, they do not necessarily identify the same adverse events.[47]

In addition, chart review relies on consistency between reviewers, in order for physicians to agree that an adverse event has occurred, all three elements of the definition (injury, resulting disability at discharge/prolonged hospitalisation/ death and causation) must concur. Our κ statistic of 0.59 for physicians is in line with other studies, where κs have ranged from 0.25 to 0.78.[15 19] This need for reviewer consistency across elements of the adverse event definition highlights the problem of rater reliability in detecting adverse events. To enhance reviewer consistency, INAES employed standardised training and structured implicit review, with the data collection tool guiding physicians to informed professional judgements.

Irish healthcare has undergone extensive change due to the economic recession and the growth of the quality movement, including the National Clinical Programmes. Therefore, our study of adverse events in 2009, near the start of these dual influences, provides an important baseline and the opportunity to link safety with subsequent organisational reform.[11] However, while our results describe the burden of adverse events, the retrospective methodology may be viewed as a blunt instrument for monitoring specific quality initiatives, as adverse events are a heterogeneous group.[48] A reduction in one category may be counterbalanced by an increase in others, leading to no overall change in adverse event rates. Thus, interventions to reduce adverse events need to be targeted at specific adverse event categories, and studies monitoring effects tailored accordingly.[41 48]

The INAES web-based tool is now available for use in Irish hospitals, providing an electronic application for chart review that will allow hospitals to conduct their own reviews and monitor patient-safety initiatives. The results from these reviews will be directly comparable with the INAES results. Furthermore, other national studies have spearheaded the development of national patient-safety organisations and policy, and we anticipate that this study will further support patient-safety initiatives in the Irish healthcare setting.[1 12–14]

CONCLUSION

INAES provides the first estimate of adverse event occurrence within the Irish healthcare system and an important measure of the burden and impact of these

events. Our results give an overview of the types of patient-safety issues that will help guide future interventions to reduce specific adverse events and improve safety. We found a significant discrepancy between our rate of adverse events and that reported to the national reporting scheme. Therefore, efforts must be made to encourage a 'reporting culture'. From an international perspective, this most recent large-scale retrospective chart review national study shows broad consistency yet again in the frequency and nature of adverse events. Patient-safety experts should question why, after 30 years, there has been so little evidence of overall improvement.

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Appendix 1 List of triggers applied to eligible charts: percentage of charts positive for each trigger, relative risk (RR) and 95% confidence interval (CI), and diagnostic test criteria (sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV)

Trigger number	Trigger description (ordered by frequency)	% with trigger	RR (95% CI)	Sensitivity	Specificity	PPV	NPV
2	Unplanned readmission after discharge from index admission	18.5%	3.2 (2.5-4.0)	41.7%	85.1%	30.2%	90.4%
1	Unplanned admission before index admission	17.1%	2.5 (1.9-3.2)	33.6%	85.5%	26.4%	89.3%
18	Any other undesirable outcome not covered above	9.3%	2.7 (2.1-3.6)	21.8%	92.7%	31.5%	88.4%
9	Other patient complication (e.g. acute myocardial infarction, stroke, pulmonary embolism, any unexpected complication that is not a natural progression of disease or an expected outcome of treatment)	6.9%	3.7 (2.8-4.8)	21.3%	95.4%	41.7%	88.7%
15	Hospital-acquired infection or sepsis	6.5%	5.3 (4.3-6.7)	27.0%	96.7%	55.9%	89.5%
3	Hospital-incurred patient injury	5.5%	3.4 (2.6-4.6)	16.6%	96.3%	40.7%	88.2%
4	Adverse drug reaction	5.1%	2.7 (2.0-3.8)	12.8%	96.1%	33.8%	87.7%
16	Dissatisfaction with care documented in the medical record	2.5%	2.2 (1.3-3.6)	5.2%	97.9%	28.2%	87.0%
11	Unexpected death	1.3%	4.3 (2.8-6.5)	5.2%	99.3%	55.0%	87.1%
5	Unplanned transfer from general care to intensive care	1.2%	4.5 (3.0-6.7)	5.2%	99.4%	57.9%	87.1%
7	Unplanned return to the operating theatre	1.1%	4.8 (3.2-7.0)	5.2%	99.5%	61.1%	87.1%
12	Inappropriate discharge to home	<1%	4.1 (2.5-6.9)	3.3%	99.6%	53.8%	86.9%

8	Unplanned removal, injury or repair of organ during surgery	<1%	4.7 (3.0-7.4)	3.8%	99.6%	61.5%	87.0%
10	Development of neurological deficit not present on admission	<1%	4.5 (2.7-7.3)	3.3%	99.6%	58.3%	86.9%
13	Cardiac or respiratory arrest	<1%	2.1 (0.7-7.0)	0.9%	99.6%	28.6%	86.7%
6	Unplanned transfer to another acute care hospital	<1%	0	<1%	99.9%	<1%	86.6%
17	Documentation or correspondence indicating litigation	<1%	0	<1%	99.9%	<1%	86.6%
14	Injury related to abortion or labour and delivery	Not triggered	-	-	-	-	-

Appendix 2 Scales used by physician reviewers to classify the impact, causation and preventability of the adverse event; distribution of physical impairment and preventability results

After due consideration of the clinical details of the patient's management, irrespective of preventability, and your responses to the questions above; what level of confidence do you have that the health care management caused the injury? [a score of at least four was required to indicate causation through healthcare management]		
1. Virtually no evidence of management causation		
2. Slight to modest evidence of management causation		
3. Management causation not likely (less than 50/50, but "close call")		
4. Management causation more likely (more than 50/50, but "close call")		
5. Moderate to strong evidence of management causation		
6. Virtually certain evidence of management causation		
Based on the evidence in the medical record, how would you judge the degree of physical impairment attributable to the adverse event on the day of discharge?	**INAES event distribution**	
	Unweighted	**Weighted (95% CI)**
None	12.6%	13.2% (9.2%-18.6%)
Minimal impairment, or recovery in 1 month, or both	32.4%	33.6% (26.2%-41.9%)
Moderate impairment, recovery in 1-6 months	21.9%	20.8% (15.9%-26.7%)
Moderate impairment, recovery in 6-12 months	5.7%	5.0% (2.6%-9.1%)
Permanent impairment, degree of disability ≤ 50%	9.3%	8.8% (5.1%-15.0%)
Permanent impairment, degree of disability > 50%	1.2%	1.1% (0.3%-4.4%)
Death	6.1%	6.7% (3.3%-12.9%)
Unable to determine	10.9%	10.9% (6.2%-18.5%)
Rate on a 6 point scale your confidence in the evidence for preventability [an adverse event was considered 'preventable' if it had a score of four or more]	**INAES event distribution**	
	Unweighted	**Weighted (95% CI)**
1. Virtually no evidence of preventability	8.5%	9.6% (5.0%-17.6%)
2. Slight to modest evidence for preventability	3.6%	3.6% (1.4%-8.7%)
3. Preventability not quite likely; less than 50-50 but close call	15.4%	14.1% (8.8%-22.0%)
4. Preventability more than likely; more than 50-50 but close call	38.5%	39.7% (33.3%-46.4%)
5. Strong evidence for preventability	25.9%	24.8% (17.4%-34.0%)
6. Virtually certain evidence for preventability	8.1%	8.3% (4.2%-15.5%)

Appendix 3 Patient characteristics, INAES sample compared to national acute public hospitals

	National inpatients*	**INAES reviewed charts**
Number of admissions	339,844	1,574
Mean age (years)	55.4	54.2
Female (%)	53.5	53.4
Mean length of stay (days)	7.0	7.4
Died during admission (%)	2.7	4.8‡

*based on INAES HIPE search strategy - adult inpatients in acute public hospitals excluding psychiatric and obstetric principal diagnoses

‡INAES excluded discharges with a hospital stay less than 24 hours but included deaths within 24 hours

Appendix 4 Brief description of clinical details of adverse events occurring in 211 admissions, by corresponding maximum degree of preventability as judged by INAES physician reviewers*

Case	Description of adverse event†
Virtually certain evidence of preventability	
1	New onset atrial fibrillation, no anti-thrombotic therapy prescribed. Readmission with arterial embolism.
2	Pre-cardiac surgery, patient developed diarrhoea and antibiotic-resistant bacteraemia. Intra-operative perforation of ventricular wall. Post-operative sepsis; patient died.
3	Frank haematuria post traumatic catheterisation requiring longer duration of in-dwelling catheterisation. Patient also suffered infectious diarrhoea; norovirus positive.
4	Delayed diagnosis of ureteric calculus; multiple presentations with flank pain.
5	Pneumonia post laparotomy. Readmission with acute renal failure after vomiting and diarrhoea. Delayed diagnosis coeliac disease.
6	Delayed diagnosis bladder tumour; readmission for anaemia and per vaginal bleeding, with history of haematuria and previous ultrasound showing possible bladder tumour.
7	Delayed diagnosis Crohn's disease; multiple admissions with abdominal pain.
8	Delayed diagnosis small bowel obstruction; delay in repeat laparotomy despite persistent gastrointestinal signs and symptoms and abnormal abdominal radiographs.
9	Readmission for repeat surgery on metacarpal. Check radiograph requested after surgery but not performed.
10	Post-operative spinal wound infection and dehiscence requiring readmission and several wound washouts.
11	Missed diagnosis pneumothorax. Patient discharged home from emergency department with severe pleuritic chest pain, dyspnoea and no definitive diagnosis; subsequent review of initial chest radiograph revealed a pneumothorax.
12	Readmission with digoxin toxicity after inadequate monitoring of serum digoxin levels in the community and outpatient clinic.
13	Multiple readmissions with poor diabetic control in the setting of ongoing tooth abscesses and delay in definitive management.
14	Persistent/recurrent *Clostridium difficile* diarrhoea. Multiple admissions.
15	Multiple admissions with unstable angina whilst awaiting coronary artery bypass surgery.
16	Methicillin resistant *Staphylococcus aureus* (MRSA) colonisation during admission for urinary tract infection, no eradication action documented.
17	Delayed diagnosis of uterine adenocarcinoma in a patient with post-menopausal bleeding. Histology at hysteroscopy recommended further investigations which were not carried out.
18	Failure to adequately investigate original presenting symptoms led to readmission and a delayed diagnosis of diverticular disease and unnecessary appendicectomy.
19	Delay in diagnosis of pulmonary emboli. Initial admission with shoulder/back pain and haemoptysis treated as a respiratory tract infection, computerised pulmonary angiogram (CTPA) not performed. Readmitted with severe pleuritic

	shoulder tip pain and haemoptysis – bilateral pulmonary emboli diagnosed on CTPA.
Strong evidence of preventability	
20	Gluteus medius tendon avulsion post total hip joint replacement; readmitted for surgery.
21	Readmission with symptomatic hypertension. No management plan for hypertension discovered during previous admission for surgery.
22	Readmission with pneumonia, acute cholecystitis and congestive cardiac failure after discharge following surgery for hip fracture. Developed diarrhoea (*Clostridium difficile* positive) and pseudo-aneurysm of profunda femoris artery (adjacent to hip screw) requiring embolisation.
23	Diarrhoea after starting ciprofloxacin for urinary tract infection, *Clostridium difficile* negative, previous episode of diarrhoea with ciprofloxacin.
24	Patient developed norovirus infection and *Clostridium difficile* positive diarrhoea during admission for chronic obstructive pulmonary disease (COPD). Patient also found to be MRSA positive.
25	Readmission with pulmonary emboli and septicaemia; patient died. Failure to administer indicated prophylaxis for venous thromboembolism in previous admission.
26	Readmission with acute on chronic subdural haemorrhage after fall; patient died. During previous admission for acute subdural haemorrhage antiplatelet therapy was withheld and then restarted.
27	Readmission with haematuria and urinary tract infection after inappropriate removal of long-term indwelling urinary catheter and untreated urinary tract infection.
28	Delay in application of abduction brace after hip dislocation leading to delayed mobilisation. Delay in treatment of urinary tract infection despite symptoms and positive report.
29	Confusion after surgery, pain relief medication likely cause. Patient also had a post-operative lower respiratory tract infection and was readmitted with pneumonia.
30	Delayed surgery due to rapid atrial fibrillation, poor management of cardiac condition and communication between relevant specialties.
31	Loose stools; infectious diarrhoea. Patient desaturated during physiotherapy; lower lobe collapse. Warfarin stopped during admission. Readmission with stroke in atrial fibrillation; patient died.
32	Readmitted with an upper gastrointestinal bleed secondary to oesophageal varices. Warfarinised in previous admission for deep vein thrombosis despite new diagnosis of oesophageal varices.
33	Readmission with recurrent small bowel obstruction and persistent collapse/consolidation in both lower lobes; patient died. Inadequate follow-up plan from previous admission.
34	Several readmissions with grand mal seizures on background of alcohol abuse, not fully investigated, no anti-convulsant therapy prescribed on previous admission.
35	Hospital-acquired MRSA in the respiratory tract. Several readmissions for exacerbation of COPD with MRSA in sputum.
36	Readmission for treatment of dehydration and hypotension after previous admission for repair of fistula and ileostomy.
37	Septic arthritis post wiring of fracture.
38	Post-operative restlessness treated with haloperidol. Patient also developed

	rapid atrial fibrillation (new onset), wound infections and pleural effusions. Patient was readmitted for aspiration of pleural effusion.
39	Post peripheral vascular surgery, neuropathic pain attributed to nerve damage intra-operatively.
40	Readmission for surgery after unsuccessful manipulation under anaesthetic for fractured wrist. Restricted range of movement and development of carpal tunnel syndrome at follow-up.
41	Recovery post abdominal surgery complicated by a fall and wrist fracture, pulmonary emboli and a sub-acute bowel obstruction.
42	*Escherichia coli* bacteraemia after catheterisation.
43	Delayed diagnosis of appendiceal mass over multiple presentations to hospital.
44	Post-operative wound haematoma and readmission for infection.
45	Delayed cholecystitis diagnosis leading to readmission.
46	MRSA colonisation of supra-pubic catheter.
47	Readmission with unresolved abdominal pain post trauma, not actively investigated during a previous admission and no definitive diagnosis made.
48	Post-operative MRSA wound infection; inappropriate antibiotic therapy resulted in a prolonged hospital stay and contributed to readmission.
49	Post-operative abdominal wound infection.
50	Abdominal surgery complicated by ischaemic necrosis of the anastomosis requiring return to theatre and abdominal wound infection.
51	Multiple readmissions post spinal surgery with wound infection.
52	Delayed diagnosis and management of strangulated hernia. Patient deteriorated after surgery and died of a likely pulmonary embolus.
53	Poor peri-operative management resulted in re-intubation due to respiratory acidosis (abnormal chest radiographs pre- and post-operatively without evidence of anaesthetic review), plus confusion, vomiting and diarrhoea.
54	Peri-operative pulmonary oedema and readmissions for *Clostridium difficile* diarrhoea.
55	Perforated gastric ulcer in a patient with cancer, on prednisone but no gastro-protection prescribed. Patient deteriorated despite surgery and died.
56	Upper gastrointestinal bleed after the patient was started on aspirin and the proton pump inhibitor stopped during admission for ischaemic stroke. Also developed *Clostridium difficile* diarrhoea.
57	Readmission with chest pain whilst awaiting appointment for coronary angiography.
58	Hospital-acquired pneumonia during admission; admission prolonged while waiting for a permanent pacemaker.
59	Readmission with confusion soon after discharge from surgical admission during which intermittent confusion was noted but required further investigation and discharge planning.
60	Readmission with anaemia and collapse soon after discharge from previous admission with similar symptoms.
61	Pulmonary embolism in patient with prior deep vein thrombosis and sub-therapeutic international normalised ratio (INR).
62	Repeat laparotomy for fistula repair and mesh removal (initial injury was small bowel perforation during lower section caesarean section).
63	Subclavian and axillary vein thrombosis likely due to inadequate care of central venous catheter.
64	Premature discharge home post laparotomy with abnormal serum electrolyte results indicating metabolic acidosis. Readmitted with severe sepsis secondary

	to an abscess.
65	Hepatic duct injury during laparoscopic cholecystectomy.
66	Wound infection post hydrocele repair. Scrotal area noted to be inflamed but no antibiotic therapy given. Readmitted with a necrotic wound.
67	Delayed diagnosis colon cancer; symptoms of constipation and rectal bleeding not investigated in previous acute surgical admission. Readmitted with perforated colon cancer and metastases.
68	Unsuccessful laparoscopy for tubal pregnancy; readmission for laparotomy and partial salpingectomy.
69	Chronic ulcer infected with MRSA during admission for ascites.
70	Inadequate discharge planning - ongoing vaginal bleeding in a patient on anticoagulation. Readmitted with further bleeding.
71	Post spinal surgery wound infection requiring wound washouts and a prolonged course of antibiotics.
72	Delayed diagnosis of hip fracture; admitted, no fracture seen, no follow up radiograph, continued pain, readmitted and fracture diagnosed.
73	Inadequate follow-up of renal profile post discharge; readmission with severe dilutional hyponatremia and recurrence of congestive cardiac failure.
74	Readmission in acute pulmonary oedema after chemotherapy admission and intravenous fluids to prevent side effects from tumour lysis.
75	Several episodes of sepsis attributed to central line infection, aspiration pneumonia and diarrhoea secondary to *Clostridium difficile*.
76	Delayed diagnosis of oesophageal candidiasis and benign stricture; inadequate investigation of gastrointestinal symptoms during previous admission, readmission with vomiting, dehydration and acute kidney injury.
77	Dislocation of intravenous access device and *Enterococcus* detected in blood culture.
78	Delay in definitive management of ischaemic heart disease resulted in myocardial infarction and several readmissions with cardiac failure.
79	Delayed diagnosis of hyperparathyroidism; multiple presentations with similar symptoms and admissions for ureteric calculi.
Preventability more than likely; more than 50-50 but close call	
80	Post-surgical upper lobe collapse and antibiotic-resistant bacteraemia. Readmission with high stoma output and acute renal failure.
81	Non-union and elbow stiffness post open reduction and internal fixation.
82	Pain post knee replacement; overhang of plate, requiring revision.
83	Readmission with pre-syncope; hypotensive in previous admission, medications not adjusted.
84	Readmission with recurrent pilonidal sinus.
85	Lobar pneumonia and aspiration post bowel surgery for adenocarcinoma; patient died.
86	Readmission with wound infection post incisional hernia repair.
87	Re-do open reduction and internal fixation fracture; displaced metalwork.
88	Readmission with recurrent pneumonia, no outpatient radiograph performed.
89	Malaena and rectal bleeding whilst on chemotherapy and an inappropriately high dose of heparin.
90	Several readmissions with vomiting and epigastric pain – known oesophagitis on gastro-protection but also receiving multiple gastric irritant drugs.
91	Several readmissions with atrial tachycardia and cardiac failure, eventual successful ablation.
92	Hospital-acquired *Pseudomonas* lower respiratory tract infection during

	admission for acute exacerbation of COPD.
93	Readmission with pneumonia and positive blood cultures. Reduced breath sounds noted on respiratory examination prior to discharge from previous admission.
94	Readmission with pneumonia and cardiac failure following admission for atrial fibrillation and cardiac failure; patient died.
95	Readmission post laparotomy with abdominal wound infection.
96	Pain secondary to screw migration at site of fracture; readmitted for removal of screw.
97	Post-operative fever, diarrhoea and vomiting.
98	Post lumbar puncture headache, admitted for blood patch.
99	*Clostridium difficile* diarrhoea and urinary tract infections during admission for hip fracture.
100	Readmission with infected knee post-operatively.
101	Readmission with colitis post abdominal surgery for ulcerative colitis; inadequate discharge planning - lack of gastroenterology follow-up.
102	In-hospital fall causing groin pain during admission for fall and confusion. Delay in orthopaedic review and access to hip protectors.
103	Readmissions for post-operative hydrocephalus and malfunctioning shunt after previous surgery for brain tumour.
104	Readmissions with abdominal pain and swelling at stoma site (multiple surgeries for Crohn's disease), requiring open drainage of frank pus.
105	Post nephrectomy wound infection and collection.
106	Intra-operative and post-operative blood loss after breast surgery, multiple readmissions for recurrent seroma.
107	Readmission with deep vein thrombosis after surgery for pathological fracture of femur.
108	Seizures (sub-therapeutic phenytoin level and sleep deprivation) and post-operative pleural effusions following cardiac surgery.
109	Recurrent admissions for cellulitis over graft site post coronary artery bypass surgery.
110	Delayed diagnosis and readmission with peripheral neuropathy; no neurology referral during first admission.
111	Post lumbar puncture headache.
112	Readmission post colectomy with nausea and vomiting.
113	Post-operative lower respiratory tract infection and MRSA-infected wound sinus; absence of follow-up MRSA screening caused postponement of the next stage of surgery.
114	Readmission following transurethral resection of the prostate with acute urinary retention and haematuria.
115	Urinary retention requiring intermittent self-catheterisation for a number of months post colorectal surgery.
116	Hypocalcaemia post sub-total thyroidectomy and cellulitis at a pressure point.
117	Post-operative lower respiratory tract infection.
118	Readmission with arterial thrombus post endarterectomy; subsequent bypass surgery complicated by compartment syndrome, ongoing wound healing problems and graft stenosis.
119	Readmission post repair of fractured elbow with wound infection.
120	Readmission with wound infection post anterior resection.
121	Readmission with pneumonia; likely healthcare-associated infection. MRSA acquired in previous admission.

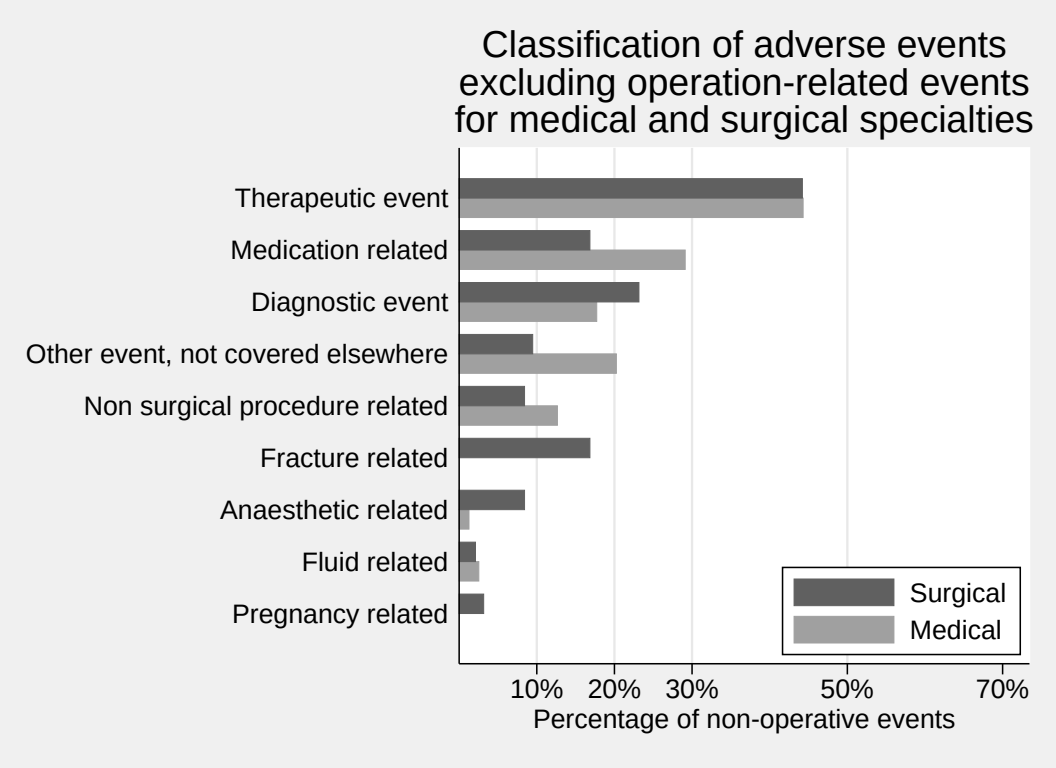
122	MRSA colonisation after multiple previous admissions for ischaemic heart disease.
123	Revision of hip surgery due to displacement during original admission for hip fracture.
124	Urticarial rash secondary to pain relief medication prescribed post-operatively.
125	Pyrexia and generalised skin rash post-operatively; probable adverse drug reaction to antibiotics.
126	Delayed assessment by senior medical staff and delay in transfer to intensive care followed by rapid deterioration; patient died.
127	Acute myocardial infarction a few days after infliximab infusion.
128	Post-operative pneumonia, pulmonary oedema and respiratory failure. Hospital-acquired infection later in admission.
129	*Clostridium difficile* diarrhoea.
130	Post laparotomy wound dehiscence requiring return to theatre. Post-operative pulmonary oedema and ventilator-associated pneumonia.
131	Readmission post pilonidal sinus excision for further surgery.
132	Recurrent inguinal hernia requiring further admissions for surgery after initial repair.
133	Readmission with dizziness following admission with postural hypotension and blood pressure medications not altered.
134	Readmission with pneumonia following hospitalisation for exacerbation of COPD.
135	Readmission with pneumonia following prior admission for head injury.
136	Readmission with *Clostridium difficile* diarrhoea.
137	MRSA colonisation after recurrent hospital admissions.
138	Readmission with sepsis and Clostridium *difficile* diarrhoea after abdominal surgery.
139	Intravenous access device infection resulting in readmission.
140	Uterine perforation during tubal ligation and low blood pressure post-operatively.
141	Readmission with pulmonary oedema and lower respiratory tract infection (healthcare-associated infection).
142	Hospital-acquired pneumonia (?aspiration) during admission for falls and chronic subdural haematoma.
143	Readmissions for caesarean section wound infection and dehiscence.
144	Healthcare-associated pneumonia during admission for urinary sepsis.
145	Recent admission for delirium and dementia; admitted with fracture, developed MRSA septicaemia; patient died.
146	MRSA colonisation during admission for fractured hip.
147	Haematoma, wound infection and subsequent dehiscence at graft site after coronary artery bypass surgery.
148	Readmission after breast reconstruction surgery with wound haematoma.
149	Acute admission for inguinal hernia repair after repeat presentations to the Emergency Department with severe abdominal pain.
150	Femoral artery injury during cardiac surgery requiring laparotomy and blood transfusion; sequelae included anuric acute tubular necrosis and sepsis.
151	Pre-operative traumatic urinary catheterisation, patient required a suprapubic catheter post-operatively.
152	Post-surgery for a fractured hip, patient developed several pressure sores.
153	Prolonged admission for septic shock from severe subcutaneous tissue infection. Complications included healthcare-associated pneumonia, infectious

	diarrhoea, lymphoedema and neuropathic pain after extensive wound debridements.
154	Cardiorespiratory arrest possibly related to benzodiazepine treatment; patient died.
155	Febrile neutropenia secondary to chemotherapy treatment.
156	Readmission with anaemia and raised INR (warfarin continued at previous discharge despite anaemia). Further readmission with methicillin sensitive *Staphylococcus aureus* septicaemia.
157	Lower limb ulcers due to casting of leg in an at-risk patient, also diarrhoea and vomiting due to norovirus.
158	Hospital-acquired lower respiratory tract infection and septicaemia due to MRSA in an immunosuppressed patient; patient died.
159	Admission and readmission for *Clostridium difficile* diarrhoea and abdominal pain.
Preventability not quite likely; less than 50-50 but close call	
160	Recurrent hip prosthesis dislocations. Post-operative discharging hip sinus, glove tip excised from wound, readmissions for sepsis.
161	Peri-operative chest pain, anti-platelet medication stopped pre-operatively.
162	Post-operative bradycardia.
163	Post-operative haemorrhage; arterial bleeding noted in the muscle on the side of the incision.
164	Readmission post appendicectomy for pelvic collection.
165	Readmission post total abdominal hysterectomy with wound abscess.
166	Recurrent admissions for perineal wound infection post abdominoperineal resection.
167	Pneumothorax post bronchoscopy.
168	Post thyroidectomy hypocalcaemia.
169	Urinary retention and haematuria post transobturator tape surgery and cystoscopy.
170	Readmission for infected seroma post breast surgery.
171	Post open cholecystectomy wound collection.
172	Two healthcare-associated pneumonias during admission.
173	Methotrexate-induced pneumonitis in a patient with rheumatoid arthritis.
174	Autoimmune hepatitis and hypotension secondary to chemotherapy.
175	Readmission post tonsillectomy with secondary haemorrhage; bleeding vessel cauterised, aphthous ulcers noted.
176	Post-operative infection after open reduction and internal fixation of fracture; readmission for removal of plate.
177	Incisional hernia post abdominal surgery.
178	Readmission with recurrence of symptoms soon after previous admission for abdominal pain and dysuria.
179	Nausea and vomiting post chemotherapy.
180	Readmission for second hip dislocation (during physiotherapy).
181	Urinary retention post varicose veins surgery.
182	Anaemia and fever post laparoscopic appendicectomy for severe acute appendicitis. Pelvic floor mass noted on ultrasound, either haematoma or abscess.
183	Readmission with wound infection post excision of deep lesion on leg.
184	Drowsy post excision of recurrent pilonidal sinus under general anaesthesia.
185	Urinary retention; unsuccessful removal of indwelling catheter which had been inserted earlier on admission.

186	Intra-operative haemorrhage and bile leak during excision of liver cyst.
187	Cerebrospinal fluid (CSF) leak and blood loss during spinal surgery. Post-operative infected CSF collection, meningitis, revision of surgery (teeth damaged during intubation). Readmission with low pressure headache and antibiotic-related neutropenia and nausea.
Slight to modest evidence for preventability	
188	Post-operative nausea after daycase surgery for inguinal hernia repair under general anaesthetic.
189	Readmission with recurrence of epistaxis. History of raised blood pressure and ischaemic heart disease with stents, on antiplatelet therapy.
190	Multiple readmissions with discharging sinus after surgery for fistula.
191	Post-operative pneumonia and bilateral pleural effusions, and transfused for intra-operative blood loss following emergency surgery for perforated colon cancer.
192	Post-operative urinary tract infection.
193	Multiple episodes of urinary retention requiring catheterisation post vascular surgery, history of prostate cancer.
Virtually no evidence of preventability	
194	Post septoplasty and turbinectomy nasal adhesions requiring further surgery.
195	Persistent post-operative finger numbness after wrist fixation for fracture.
196	Abdominal bleeding due to mesenteric tear during appendicectomy, noted to be secondary to inflammation of appendix to ileum mesentery.
197	Opioid-induced nausea during daycase procedure necessitated an overnight stay.
198	Multiple readmissions with wound infection after surgery on a comminuted fracture in an immuno-suppressed patient.
199	Post-chemotherapy anaemia, fever and transient rash.
200	Post-transrectal ultrasound biopsy leading to bacteraemia despite peri-procedure prophylactic antibiotics.
201	Readmission for polypectomy due to recurrent endometrial polyps on tamoxifen for breast cancer
202	Post cardiac surgery required circulatory support and suffered complications of pneumonia, pleural effusions, antibiotic-resistant bacteraemia; patient died.
203	Post cardiac surgery pleural fluid accumulation requiring readmission and drainage.
204	Readmission post thyroidectomy with minor thyroid cyst accumulation.
205	Neutropenic sepsis during admission for chemotherapy. Patient also developed muscle aches secondary to filgrastim.
206	Pneumothorax after fine needle aspiration of lung mass.
207	Readmission soon after discharge with new upper lobe pneumonia.
208	Post bronchoscopy fever, hypoxia and confusion, likely due to procedure as no organism identified.
209	Readmission with antibiotic-induced nausea.
210	Persistence of abdominal pain at outpatient follow-up after laparotomy and salpingo-oophorectomy
211	Intra-operative transient cardiac arrhythmias during daycase surgery resulted in need for observation overnight.

* Physician reviewers were asked to judge the evidence of preventability of adverse events using a 6-point scale, where 1 = virtually no evidence of preventability and 6 = virtually certain evidence for preventability (see Appendix 2). These judgements are based solely on the documentation contained in the patient chart and do not constitute a full investigation of the clinical scenario.

† An adverse event was defined as an unintended injury or complication resulting in disability at discharge, prolonged hospital stay or death, that was caused by healthcare management.


Classification of adverse events
excluding operation-related events
for medical and surgical specialties
Therapeutic event
Medication related
Diagnostic event
Other event, not covered elsewhere
Non surgical procedure related
Fracture related
Anaesthetic related
Fluid related
Pregnancy related
Surgical
Medical
10%
20%
30%
50%
70%
Percentage of non-operative events

Appendix 1 List of triggers applied to eligible charts: percentage of charts positive for each trigger, relative risk (RR) and 95% confidence interval (CI), and diagnostic test criteria (sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV)

Trigger number	Trigger description (ordered by frequency)	% with trigger	RR (95% CI)	Sensitivity	Specificity	PPV	NPV
2	Unplanned readmission after discharge from index admission	18.5%	3.2 (2.5-4.0)	41.7%	85.1%	30.2%	90.4%
1	Unplanned admission before index admission	17.1%	2.5 (1.9-3.2)	33.6%	85.5%	26.4%	89.3%
18	Any other undesirable outcome not covered above	9.3%	2.7 (2.1-3.6)	21.8%	92.7%	31.5%	88.4%
9	Other patient complication (e.g. acute myocardial infarction, stroke, pulmonary embolism, any unexpected complication that is not a natural progression of disease or an expected outcome of treatment)	6.9%	3.7 (2.8-4.8)	21.3%	95.4%	41.7%	88.7%
15	Hospital-acquired infection or sepsis	6.5%	5.3 (4.3-6.7)	27.0%	96.7%	55.9%	89.5%
3	Hospital-incurred patient injury	5.5%	3.4 (2.6-4.6)	16.6%	96.3%	40.7%	88.2%
4	Adverse drug reaction	5.1%	2.7 (2.0-3.8)	12.8%	96.1%	33.8%	87.7%
16	Dissatisfaction with care documented in the medical record	2.5%	2.2 (1.3-3.6)	5.2%	97.9%	28.2%	87.0%
11	Unexpected death	1.3%	4.3 (2.8-6.5)	5.2%	99.3%	55.0%	87.1%
5	Unplanned transfer from general care to intensive care	1.2%	4.5 (3.0-6.7)	5.2%	99.4%	57.9%	87.1%
7	Unplanned return to the operating theatre	1.1%	4.8 (3.2-7.0)	5.2%	99.5%	61.1%	87.1%
12	Inappropriate discharge to home	<1%	4.1 (2.5-6.9)	3.3%	99.6%	53.8%	86.9%

8	Unplanned removal, injury or repair of organ during surgery	<1%	4.7 (3.0-7.4)	3.8%	99.6%	61.5%	87.0%
10	Development of neurological deficit not present on admission	<1%	4.5 (2.7-7.3)	3.3%	99.6%	58.3%	86.9%
13	Cardiac or respiratory arrest	<1%	2.1 (0.7-7.0)	0.9%	99.6%	28.6%	86.7%
6	Unplanned transfer to another acute care hospital	<1%	0	<1%	99.9%	<1%	86.6%
17	Documentation or correspondence indicating litigation	<1%	0	<1%	99.9%	<1%	86.6%
14	Injury related to abortion or labour and delivery	Not triggered	-	-	-	-	-

Appendix 2 Scales used by physician reviewers to classify the impact, causation and preventability of the adverse event; distribution of physical impairment and preventability results

After due consideration of the clinical details of the patient's management, irrespective of preventability, and your responses to the questions above; what level of confidence do you have that the health care management caused the injury? [a score of at least four was required to indicate causation through healthcare management]		
1. Virtually no evidence of management causation		
2. Slight to modest evidence of management causation		
3. Management causation not likely (less than 50/50, but "close call")		
4. Management causation more likely (more than 50/50, but "close call")		
5. Moderate to strong evidence of management causation		
6. Virtually certain evidence of management causation		
Based on the evidence in the medical record, how would you judge the degree of physical impairment attributable to the adverse event on the day of discharge?	**INAES event distribution**	
	Unweighted	**Weighted (95% CI)**
None	12.6%	13.2% (9.2%-18.6%)
Minimal impairment, or recovery in 1 month, or both	32.4%	33.6% (26.2%-41.9%)
Moderate impairment, recovery in 1-6 months	21.9%	20.8% (15.9%-26.7%)
Moderate impairment, recovery in 6-12 months	5.7%	5.0% (2.6%-9.1%)
Permanent impairment, degree of disability ≤ 50%	9.3%	8.8% (5.1%-15.0%)
Permanent impairment, degree of disability > 50%	1.2%	1.1% (0.3%-4.4%)
Death	6.1%	6.7% (3.3%-12.9%)
Unable to determine	10.9%	10.9% (6.2%-18.5%)
Rate on a 6 point scale your confidence in the evidence for preventability [an adverse event was considered 'preventable' if it had a score of four or more]	**INAES event distribution**	
	Unweighted	**Weighted (95% CI)**
1. Virtually no evidence of preventability	8.5%	9.6% (5.0%-17.6%)
2. Slight to modest evidence for preventability	3.6%	3.6% (1.4%-8.7%)
3. Preventability not quite likely; less than 50-50 but close call	15.4%	14.1% (8.8%-22.0%)
4. Preventability more than likely; more than 50-50 but close call	38.5%	39.7% (33.3%-46.4%)
5. Strong evidence for preventability	25.9%	24.8% (17.4%-34.0%)
6. Virtually certain evidence for preventability	8.1%	8.3% (4.2%-15.5%)

Appendix 3 Patient characteristics, INAES sample compared to national acute public hospitals

	National inpatients*	**INAES reviewed charts**
Number of admissions	339,844	1,574
Mean age (years)	55.4	54.2
Female (%)	53.5	53.4
Mean length of stay (days)	7.0	7.4
Died during admission (%)	2.7	4.8‡

*based on INAES HIPE search strategy - adult inpatients in acute public hospitals excluding psychiatric and obstetric principal diagnoses

‡INAES excluded discharges with a hospital stay less than 24 hours but included deaths within 24 hours

Appendix 4 Brief description of clinical details of adverse events occurring in 211 admissions, by corresponding maximum degree of preventability as judged by INAES physician reviewers*

Case	Description of adverse event†
Virtually certain evidence of preventability	
1	New onset atrial fibrillation, no anti-thrombotic therapy prescribed. Readmission with arterial embolism.
2	Pre-cardiac surgery, patient developed diarrhoea and antibiotic-resistant bacteraemia. Intra-operative perforation of ventricular wall. Post-operative sepsis; patient died.
3	Frank haematuria post traumatic catheterisation requiring longer duration of in-dwelling catheterisation. Patient also suffered infectious diarrhoea; norovirus positive.
4	Delayed diagnosis of ureteric calculus; multiple presentations with flank pain.
5	Pneumonia post laparotomy. Readmission with acute renal failure after vomiting and diarrhoea. Delayed diagnosis coeliac disease.
6	Delayed diagnosis bladder tumour; readmission for anaemia and per vaginal bleeding, with history of haematuria and previous ultrasound showing possible bladder tumour.
7	Delayed diagnosis Crohn's disease; multiple admissions with abdominal pain.
8	Delayed diagnosis small bowel obstruction; delay in repeat laparotomy despite persistent gastrointestinal signs and symptoms and abnormal abdominal radiographs.
9	Readmission for repeat surgery on metacarpal. Check radiograph requested after surgery but not performed.
10	Post-operative spinal wound infection and dehiscence requiring readmission and several wound washouts.
11	Missed diagnosis pneumothorax. Patient discharged home from emergency department with severe pleuritic chest pain, dyspnoea and no definitive diagnosis; subsequent review of initial chest radiograph revealed a pneumothorax.
12	Readmission with digoxin toxicity after inadequate monitoring of serum digoxin levels in the community and outpatient clinic.
13	Multiple readmissions with poor diabetic control in the setting of ongoing tooth abscesses and delay in definitive management.
14	Persistent/recurrent *Clostridium difficile* diarrhoea. Multiple admissions.
15	Multiple admissions with unstable angina whilst awaiting coronary artery bypass surgery.
16	Methicillin resistant *Staphylococcus aureus* (MRSA) colonisation during admission for urinary tract infection, no eradication action documented.
17	Delayed diagnosis of uterine adenocarcinoma in a patient with post-menopausal bleeding. Histology at hysteroscopy recommended further investigations which were not carried out.
18	Failure to adequately investigate original presenting symptoms led to readmission and a delayed diagnosis of diverticular disease and unnecessary appendicectomy.
19	Delay in diagnosis of pulmonary emboli. Initial admission with shoulder/back pain and haemoptysis treated as a respiratory tract infection, computerised pulmonary angiogram (CTPA) not performed. Readmitted with severe pleuritic

	shoulder tip pain and haemoptysis – bilateral pulmonary emboli diagnosed on CTPA.
Strong evidence of preventability	
20	Gluteus medius tendon avulsion post total hip joint replacement; readmitted for surgery.
21	Readmission with symptomatic hypertension. No management plan for hypertension discovered during previous admission for surgery.
22	Readmission with pneumonia, acute cholecystitis and congestive cardiac failure after discharge following surgery for hip fracture. Developed diarrhoea (*Clostridium difficile* positive) and pseudo-aneurysm of profunda femoris artery (adjacent to hip screw) requiring embolisation.
23	Diarrhoea after starting ciprofloxacin for urinary tract infection, *Clostridium difficile* negative, previous episode of diarrhoea with ciprofloxacin.
24	Patient developed norovirus infection and *Clostridium difficile* positive diarrhoea during admission for chronic obstructive pulmonary disease (COPD). Patient also found to be MRSA positive.
25	Readmission with pulmonary emboli and septicaemia; patient died. Failure to administer indicated prophylaxis for venous thromboembolism in previous admission.
26	Readmission with acute on chronic subdural haemorrhage after fall; patient died. During previous admission for acute subdural haemorrhage antiplatelet therapy was withheld and then restarted.
27	Readmission with haematuria and urinary tract infection after inappropriate removal of long-term indwelling urinary catheter and untreated urinary tract infection.
28	Delay in application of abduction brace after hip dislocation leading to delayed mobilisation. Delay in treatment of urinary tract infection despite symptoms and positive report.
29	Confusion after surgery, pain relief medication likely cause. Patient also had a post-operative lower respiratory tract infection and was readmitted with pneumonia.
30	Delayed surgery due to rapid atrial fibrillation, poor management of cardiac condition and communication between relevant specialties.
31	Loose stools; infectious diarrhoea. Patient desaturated during physiotherapy; lower lobe collapse. Warfarin stopped during admission. Readmission with stroke in atrial fibrillation; patient died.
32	Readmitted with an upper gastrointestinal bleed secondary to oesophageal varices. Warfarinised in previous admission for deep vein thrombosis despite new diagnosis of oesophageal varices.
33	Readmission with recurrent small bowel obstruction and persistent collapse/consolidation in both lower lobes; patient died. Inadequate follow-up plan from previous admission.
34	Several readmissions with grand mal seizures on background of alcohol abuse, not fully investigated, no anti-convulsant therapy prescribed on previous admission.
35	Hospital-acquired MRSA in the respiratory tract. Several readmissions for exacerbation of COPD with MRSA in sputum.
36	Readmission for treatment of dehydration and hypotension after previous admission for repair of fistula and ileostomy.
37	Septic arthritis post wiring of fracture.
38	Post-operative restlessness treated with haloperidol. Patient also developed

	rapid atrial fibrillation (new onset), wound infections and pleural effusions. Patient was readmitted for aspiration of pleural effusion.
39	Post peripheral vascular surgery, neuropathic pain attributed to nerve damage intra-operatively.
40	Readmission for surgery after unsuccessful manipulation under anaesthetic for fractured wrist. Restricted range of movement and development of carpal tunnel syndrome at follow-up.
41	Recovery post abdominal surgery complicated by a fall and wrist fracture, pulmonary emboli and a sub-acute bowel obstruction.
42	*Escherichia coli* bacteraemia after catheterisation.
43	Delayed diagnosis of appendiceal mass over multiple presentations to hospital.
44	Post-operative wound haematoma and readmission for infection.
45	Delayed cholecystitis diagnosis leading to readmission.
46	MRSA colonisation of supra-pubic catheter.
47	Readmission with unresolved abdominal pain post trauma, not actively investigated during a previous admission and no definitive diagnosis made.
48	Post-operative MRSA wound infection; inappropriate antibiotic therapy resulted in a prolonged hospital stay and contributed to readmission.
49	Post-operative abdominal wound infection.
50	Abdominal surgery complicated by ischaemic necrosis of the anastomosis requiring return to theatre and abdominal wound infection.
51	Multiple readmissions post spinal surgery with wound infection.
52	Delayed diagnosis and management of strangulated hernia. Patient deteriorated after surgery and died of a likely pulmonary embolus.
53	Poor peri-operative management resulted in re-intubation due to respiratory acidosis (abnormal chest radiographs pre- and post-operatively without evidence of anaesthetic review), plus confusion, vomiting and diarrhoea.
54	Peri-operative pulmonary oedema and readmissions for *Clostridium difficile* diarrhoea.
55	Perforated gastric ulcer in a patient with cancer, on prednisone but no gastro-protection prescribed. Patient deteriorated despite surgery and died.
56	Upper gastrointestinal bleed after the patient was started on aspirin and the proton pump inhibitor stopped during admission for ischaemic stroke. Also developed *Clostridium difficile* diarrhoea.
57	Readmission with chest pain whilst awaiting appointment for coronary angiography.
58	Hospital-acquired pneumonia during admission; admission prolonged while waiting for a permanent pacemaker.
59	Readmission with confusion soon after discharge from surgical admission during which intermittent confusion was noted but required further investigation and discharge planning.
60	Readmission with anaemia and collapse soon after discharge from previous admission with similar symptoms.
61	Pulmonary embolism in patient with prior deep vein thrombosis and sub-therapeutic international normalised ratio (INR).
62	Repeat laparotomy for fistula repair and mesh removal (initial injury was small bowel perforation during lower section caesarean section).
63	Subclavian and axillary vein thrombosis likely due to inadequate care of central venous catheter.
64	Premature discharge home post laparotomy with abnormal serum electrolyte results indicating metabolic acidosis. Readmitted with severe sepsis secondary

	to an abscess.
65	Hepatic duct injury during laparoscopic cholecystectomy.
66	Wound infection post hydrocele repair. Scrotal area noted to be inflamed but no antibiotic therapy given. Readmitted with a necrotic wound.
67	Delayed diagnosis colon cancer; symptoms of constipation and rectal bleeding not investigated in previous acute surgical admission. Readmitted with perforated colon cancer and metastases.
68	Unsuccessful laparoscopy for tubal pregnancy; readmission for laparotomy and partial salpingectomy.
69	Chronic ulcer infected with MRSA during admission for ascites.
70	Inadequate discharge planning - ongoing vaginal bleeding in a patient on anticoagulation. Readmitted with further bleeding.
71	Post spinal surgery wound infection requiring wound washouts and a prolonged course of antibiotics.
72	Delayed diagnosis of hip fracture; admitted, no fracture seen, no follow up radiograph, continued pain, readmitted and fracture diagnosed.
73	Inadequate follow-up of renal profile post discharge; readmission with severe dilutional hyponatremia and recurrence of congestive cardiac failure.
74	Readmission in acute pulmonary oedema after chemotherapy admission and intravenous fluids to prevent side effects from tumour lysis.
75	Several episodes of sepsis attributed to central line infection, aspiration pneumonia and diarrhoea secondary to *Clostridium difficile*.
76	Delayed diagnosis of oesophageal candidiasis and benign stricture; inadequate investigation of gastrointestinal symptoms during previous admission, readmission with vomiting, dehydration and acute kidney injury.
77	Dislocation of intravenous access device and *Enterococcus* detected in blood culture.
78	Delay in definitive management of ischaemic heart disease resulted in myocardial infarction and several readmissions with cardiac failure.
79	Delayed diagnosis of hyperparathyroidism; multiple presentations with similar symptoms and admissions for ureteric calculi.
Preventability more than likely; more than 50-50 but close call	
80	Post-surgical upper lobe collapse and antibiotic-resistant bacteraemia. Readmission with high stoma output and acute renal failure.
81	Non-union and elbow stiffness post open reduction and internal fixation.
82	Pain post knee replacement; overhang of plate, requiring revision.
83	Readmission with pre-syncope; hypotensive in previous admission, medications not adjusted.
84	Readmission with recurrent pilonidal sinus.
85	Lobar pneumonia and aspiration post bowel surgery for adenocarcinoma; patient died.
86	Readmission with wound infection post incisional hernia repair.
87	Re-do open reduction and internal fixation fracture; displaced metalwork.
88	Readmission with recurrent pneumonia, no outpatient radiograph performed.
89	Malaena and rectal bleeding whilst on chemotherapy and an inappropriately high dose of heparin.
90	Several readmissions with vomiting and epigastric pain – known oesophagitis on gastro-protection but also receiving multiple gastric irritant drugs.
91	Several readmissions with atrial tachycardia and cardiac failure, eventual successful ablation.
92	Hospital-acquired *Pseudomonas* lower respiratory tract infection during

	admission for acute exacerbation of COPD.
93	Readmission with pneumonia and positive blood cultures. Reduced breath sounds noted on respiratory examination prior to discharge from previous admission.
94	Readmission with pneumonia and cardiac failure following admission for atrial fibrillation and cardiac failure; patient died.
95	Readmission post laparotomy with abdominal wound infection.
96	Pain secondary to screw migration at site of fracture; readmitted for removal of screw.
97	Post-operative fever, diarrhoea and vomiting.
98	Post lumbar puncture headache, admitted for blood patch.
99	*Clostridium difficile* diarrhoea and urinary tract infections during admission for hip fracture.
100	Readmission with infected knee post-operatively.
101	Readmission with colitis post abdominal surgery for ulcerative colitis; inadequate discharge planning - lack of gastroenterology follow-up.
102	In-hospital fall causing groin pain during admission for fall and confusion. Delay in orthopaedic review and access to hip protectors.
103	Readmissions for post-operative hydrocephalus and malfunctioning shunt after previous surgery for brain tumour.
104	Readmissions with abdominal pain and swelling at stoma site (multiple surgeries for Crohn's disease), requiring open drainage of frank pus.
105	Post nephrectomy wound infection and collection.
106	Intra-operative and post-operative blood loss after breast surgery, multiple readmissions for recurrent seroma.
107	Readmission with deep vein thrombosis after surgery for pathological fracture of femur.
108	Seizures (sub-therapeutic phenytoin level and sleep deprivation) and post-operative pleural effusions following cardiac surgery.
109	Recurrent admissions for cellulitis over graft site post coronary artery bypass surgery.
110	Delayed diagnosis and readmission with peripheral neuropathy; no neurology referral during first admission.
111	Post lumbar puncture headache.
112	Readmission post colectomy with nausea and vomiting.
113	Post-operative lower respiratory tract infection and MRSA-infected wound sinus; absence of follow-up MRSA screening caused postponement of the next stage of surgery.
114	Readmission following transurethral resection of the prostate with acute urinary retention and haematuria.
115	Urinary retention requiring intermittent self-catheterisation for a number of months post colorectal surgery.
116	Hypocalcaemia post sub-total thyroidectomy and cellulitis at a pressure point.
117	Post-operative lower respiratory tract infection.
118	Readmission with arterial thrombus post endarterectomy; subsequent bypass surgery complicated by compartment syndrome, ongoing wound healing problems and graft stenosis.
119	Readmission post repair of fractured elbow with wound infection.
120	Readmission with wound infection post anterior resection.
121	Readmission with pneumonia; likely healthcare-associated infection. MRSA acquired in previous admission.

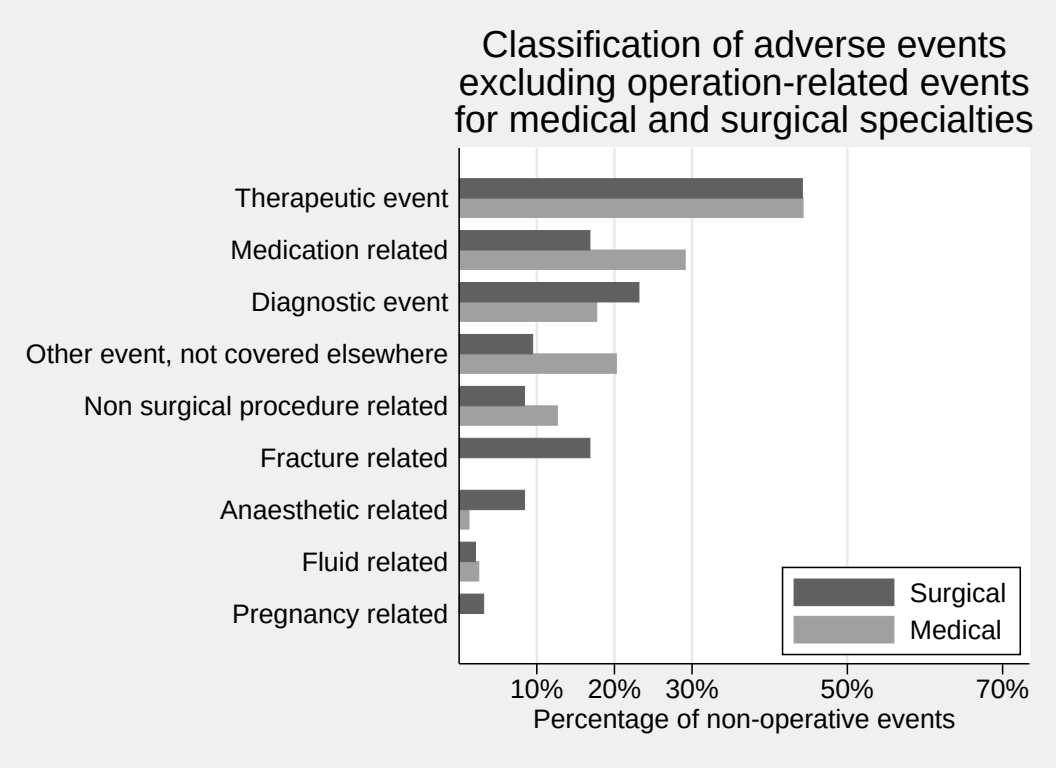
122	MRSA colonisation after multiple previous admissions for ischaemic heart disease.
123	Revision of hip surgery due to displacement during original admission for hip fracture.
124	Urticarial rash secondary to pain relief medication prescribed post-operatively.
125	Pyrexia and generalised skin rash post-operatively; probable adverse drug reaction to antibiotics.
126	Delayed assessment by senior medical staff and delay in transfer to intensive care followed by rapid deterioration; patient died.
127	Acute myocardial infarction a few days after infliximab infusion.
128	Post-operative pneumonia, pulmonary oedema and respiratory failure. Hospital-acquired infection later in admission.
129	*Clostridium difficile* diarrhoea.
130	Post laparotomy wound dehiscence requiring return to theatre. Post-operative pulmonary oedema and ventilator-associated pneumonia.
131	Readmission post pilonidal sinus excision for further surgery.
132	Recurrent inguinal hernia requiring further admissions for surgery after initial repair.
133	Readmission with dizziness following admission with postural hypotension and blood pressure medications not altered.
134	Readmission with pneumonia following hospitalisation for exacerbation of COPD.
135	Readmission with pneumonia following prior admission for head injury.
136	Readmission with *Clostridium difficile* diarrhoea.
137	MRSA colonisation after recurrent hospital admissions.
138	Readmission with sepsis and Clostridium *difficile* diarrhoea after abdominal surgery.
139	Intravenous access device infection resulting in readmission.
140	Uterine perforation during tubal ligation and low blood pressure post-operatively.
141	Readmission with pulmonary oedema and lower respiratory tract infection (healthcare-associated infection).
142	Hospital-acquired pneumonia (?aspiration) during admission for falls and chronic subdural haematoma.
143	Readmissions for caesarean section wound infection and dehiscence.
144	Healthcare-associated pneumonia during admission for urinary sepsis.
145	Recent admission for delirium and dementia; admitted with fracture, developed MRSA septicaemia; patient died.
146	MRSA colonisation during admission for fractured hip.
147	Haematoma, wound infection and subsequent dehiscence at graft site after coronary artery bypass surgery.
148	Readmission after breast reconstruction surgery with wound haematoma.
149	Acute admission for inguinal hernia repair after repeat presentations to the Emergency Department with severe abdominal pain.
150	Femoral artery injury during cardiac surgery requiring laparotomy and blood transfusion; sequelae included anuric acute tubular necrosis and sepsis.
151	Pre-operative traumatic urinary catheterisation, patient required a suprapubic catheter post-operatively.
152	Post-surgery for a fractured hip, patient developed several pressure sores.
153	Prolonged admission for septic shock from severe subcutaneous tissue infection. Complications included healthcare-associated pneumonia, infectious

	diarrhoea, lymphoedema and neuropathic pain after extensive wound debridements.
154	Cardiorespiratory arrest possibly related to benzodiazepine treatment; patient died.
155	Febrile neutropenia secondary to chemotherapy treatment.
156	Readmission with anaemia and raised INR (warfarin continued at previous discharge despite anaemia). Further readmission with methicillin sensitive *Staphylococcus aureus* septicaemia.
157	Lower limb ulcers due to casting of leg in an at-risk patient, also diarrhoea and vomiting due to norovirus.
158	Hospital-acquired lower respiratory tract infection and septicaemia due to MRSA in an immunosuppressed patient; patient died.
159	Admission and readmission for *Clostridium difficile* diarrhoea and abdominal pain.
Preventability not quite likely; less than 50-50 but close call	
160	Recurrent hip prosthesis dislocations. Post-operative discharging hip sinus, glove tip excised from wound, readmissions for sepsis.
161	Peri-operative chest pain, anti-platelet medication stopped pre-operatively.
162	Post-operative bradycardia.
163	Post-operative haemorrhage; arterial bleeding noted in the muscle on the side of the incision.
164	Readmission post appendicectomy for pelvic collection.
165	Readmission post total abdominal hysterectomy with wound abscess.
166	Recurrent admissions for perineal wound infection post abdominoperineal resection.
167	Pneumothorax post bronchoscopy.
168	Post thyroidectomy hypocalcaemia.
169	Urinary retention and haematuria post transobturator tape surgery and cystoscopy.
170	Readmission for infected seroma post breast surgery.
171	Post open cholecystectomy wound collection.
172	Two healthcare-associated pneumonias during admission.
173	Methotrexate-induced pneumonitis in a patient with rheumatoid arthritis.
174	Autoimmune hepatitis and hypotension secondary to chemotherapy.
175	Readmission post tonsillectomy with secondary haemorrhage; bleeding vessel cauterised, aphthous ulcers noted.
176	Post-operative infection after open reduction and internal fixation of fracture; readmission for removal of plate.
177	Incisional hernia post abdominal surgery.
178	Readmission with recurrence of symptoms soon after previous admission for abdominal pain and dysuria.
179	Nausea and vomiting post chemotherapy.
180	Readmission for second hip dislocation (during physiotherapy).
181	Urinary retention post varicose veins surgery.
182	Anaemia and fever post laparoscopic appendicectomy for severe acute appendicitis. Pelvic floor mass noted on ultrasound, either haematoma or abscess.
183	Readmission with wound infection post excision of deep lesion on leg.
184	Drowsy post excision of recurrent pilonidal sinus under general anaesthesia.
185	Urinary retention; unsuccessful removal of indwelling catheter which had been inserted earlier on admission.

186	Intra-operative haemorrhage and bile leak during excision of liver cyst.
187	Cerebrospinal fluid (CSF) leak and blood loss during spinal surgery. Post-operative infected CSF collection, meningitis, revision of surgery (teeth damaged during intubation). Readmission with low pressure headache and antibiotic-related neutropenia and nausea.
Slight to modest evidence for preventability	
188	Post-operative nausea after daycase surgery for inguinal hernia repair under general anaesthetic.
189	Readmission with recurrence of epistaxis. History of raised blood pressure and ischaemic heart disease with stents, on antiplatelet therapy.
190	Multiple readmissions with discharging sinus after surgery for fistula.
191	Post-operative pneumonia and bilateral pleural effusions, and transfused for intra-operative blood loss following emergency surgery for perforated colon cancer.
192	Post-operative urinary tract infection.
193	Multiple episodes of urinary retention requiring catheterisation post vascular surgery, history of prostate cancer.
Virtually no evidence of preventability	
194	Post septoplasty and turbinectomy nasal adhesions requiring further surgery.
195	Persistent post-operative finger numbness after wrist fixation for fracture.
196	Abdominal bleeding due to mesenteric tear during appendicectomy, noted to be secondary to inflammation of appendix to ileum mesentery.
197	Opioid-induced nausea during daycase procedure necessitated an overnight stay.
198	Multiple readmissions with wound infection after surgery on a comminuted fracture in an immuno-suppressed patient.
199	Post-chemotherapy anaemia, fever and transient rash.
200	Post-transrectal ultrasound biopsy leading to bacteraemia despite peri-procedure prophylactic antibiotics.
201	Readmission for polypectomy due to recurrent endometrial polyps on tamoxifen for breast cancer
202	Post cardiac surgery required circulatory support and suffered complications of pneumonia, pleural effusions, antibiotic-resistant bacteraemia; patient died.
203	Post cardiac surgery pleural fluid accumulation requiring readmission and drainage.
204	Readmission post thyroidectomy with minor thyroid cyst accumulation.
205	Neutropenic sepsis during admission for chemotherapy. Patient also developed muscle aches secondary to filgrastim.
206	Pneumothorax after fine needle aspiration of lung mass.
207	Readmission soon after discharge with new upper lobe pneumonia.
208	Post bronchoscopy fever, hypoxia and confusion, likely due to procedure as no organism identified.
209	Readmission with antibiotic-induced nausea.
210	Persistence of abdominal pain at outpatient follow-up after laparotomy and salpingo-oophorectomy
211	Intra-operative transient cardiac arrhythmias during daycase surgery resulted in need for observation overnight.

* Physician reviewers were asked to judge the evidence of preventability of adverse events using a 6-point scale, where 1 = virtually no evidence of preventability and 6 = virtually certain evidence for preventability (see Appendix 2). These judgements are based solely on the documentation contained in the patient chart and do not constitute a full investigation of the clinical scenario.

† An adverse event was defined as an unintended injury or complication resulting in disability at discharge, prolonged hospital stay or death, that was caused by healthcare management.


Classification of adverse events
excluding operation-related events
for medical and surgical specialties
Therapeutic event
Medication related
Diagnostic event
Other event, not covered elsewhere
Non surgical procedure related
Fracture related
Anaesthetic related
Fluid related
Pregnancy related
Surgical
Medical
10%
20%
30%
50%
70%
Percentage of non-operative events