ORIGINAL ARTICLES

Detection of Adverse Events in a Scottish Hospital Using a Consensus-based Methodology

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Abstract

Objective

To determine, using a consensus based methodology, the rate and nature of adverse events (AEs) among patients admitted to acute medicine, acute surgery and obstetrics in a large teaching hospital in Scotland.

Methods

Retrospective case-note review of 450 medical, nursing and medication records to identify and classify adverse events.

Results

For 354 patients whose length of stay was greater than 24 hours, the overall adverse event rate was 7.9% which ranged from 0% in obstetrics, 7.2% in acute medicine to 13% in acute surgery. Among all AEs, 43% were deemed preventable by a consensus group and 59% of the AEs contributed to a proportion of the patients' hospital stay or led to hospital readmission. Whilst nurse identification of adverse events was highly specific (94%), its sensitivity was poor (43%). Only 10% of the identified AEs were identified by the hospital's voluntary reporting system for adverse events. The estimated additional cost of adverse events in terms of bed days was £69,189 which if extrapolated Scotland-wide could cost £297 million per annum.

Conclusions

This study supports the need to continue the traditional retrospective record review to identify adverse events. The current hospital-based reporting of adverse events does not provide a complete measure of adverse events and needs to be complemented by other measures.

Introduction

Patient safety is receiving increased attention worldwide with numerous healthcare organisations initiating programmes aimed at improving patient safety and reducing adverse events (AEs).[1,2,3] Adverse events are unintended injuries or complications that are caused by health care management, rather than by the patient's underlying disease, which lead to death, disability at the time of hospital discharge or prolonged hospital stay. International retrospective case note review studies have demonstrated variable rates of AEs of between 3% and 17% among hospitalised patients.[4,5,6,7,8] Whilst some AEs are unavoidable, international studies have estimated that between 37% and 51% of adverse events are judged in retrospect to have been preventable.[4,5,6,7,8,9] A retrospective pilot study from two London hospitals has previously demonstrated an adverse event rate of 10.8%, with 6% of the adverse event cases resulting in permanent impairment and 8% contributing to the patient's death. Of all the identified AEs in this study, 48% were judged to be preventable and it was suggested that the total costs of preventable harm to the NHS in England and Wales could be as high as £1 billion per annum.[8] A recent study of 1006 admissions identified an adverse event rate of 11% with only 5% of these incidents that resulted in patient harm being recorded by the routine reporting system.[10] This heightened awareness concerning patient safety has led to the development of both national and local hospital reporting systems. However, it remains to be determined whether these systems are providing complete records of adverse events. A recent observational study of acute admissions to a Scottish surgical ward recorded an average of 4.8 errors per patient.[11] Kennedy has recently pointed out that "we still do not know with anything like the degree of precision and specificity to allow any sort of targeted response, what the real scale of the problem is….this continued lack of knowledge must be a matter of significant regret".[12]

Retrospective record review has been used in several countries to estimate the national level of adverse events. The traditional methodology however is relatively costly and labour intensive, and it can be difficult to recruit and retain medical reviewers to review large numbers of case notes. Furthermore there has been variability in reviewers' judgements on both the presence

of AEs and their preventability, contributing to doubts about the validity of the methodology.[13,14] In an attempt to explore some of these issues ahead of launching a national study in Scotland, this study introduced some adaptations to the traditional methodology of retrospective record review. We wished to retain traditional screening of all records by nurses but in addition to this a parallel screening method of nurses identifying AE or potential AE directly was employed in order to compare the sensitivity and work load implications of each screening method. The second stage review of AE determination would then be carried out by a consensus group rather than by individual medical reviewers.

Finally, as medication errors contribute to a significant number of AEs and it has been suggested that more than one method of review should be used to detect adverse events,[15] we examined whether a further targeted review of prescription data would identify further events.

Methods

The study was conducted at Aberdeen Royal Infirmary (ARI), a 900-bed teaching hospital providing care for patients in the north east of Scotland, and in Aberdeen Maternity Hospital, a 110 bed regional maternity unit. The following groups were chosen,

- acute medical admissions admitted to the Acute Medical Admission Unit in ARI,
- acute surgical admissions admitted to Acute General Surgical Units in ARI,
- acute obstetric admissions admitted to Aberdeen Maternity Hospital.

These index patient groups were selected due to previous reports of a high prevalence rate for the potential of adverse events and the potential for adverse events to cause serious patient injury.[8]

Assuming that the underlying rate of AEs lay towards the middle of the previously reported range (approximately 13%), we estimated that 450 patients would allow us to estimate the true underlying rate of AEs to within 3% accuracy (with 95% confidence).[16] The sample consisted of 150 consecutive patients admitted to each of the index units over a one month period starting on 1st July 2004 identified by the Information Services Division (ISD) of Scotland. The study protocol was approved by the Caldicott Guardian Privacy Committee of ISD Scotland in full and the requirement for ethical approval was waived by the Grampian Local Research Ethics Committee as it represented an audit of clinical care. Whilst previous studies have excluded patients admitted for less than 24 hours, the pattern of admissions to the NHS has changed in recent times to reflect new targets such as Accident and Emergency four hour waiting targets, whereby patients must have been treated and discharged or transferred to ward care within four hours of arrival. We therefore also wished to include admissions $<$24hrs.[17]

Identification of Adverse Events

An adverse event is defined as an unintended injury or complication which led to temporary or permanent disability and/or increased length of stay or death and which was caused by healthcare management.[8] Adverse events which occurred prior to hospital admission, which were discovered in, or after, hospital admission or were identified following readmission were included in the analysis.

Stage 1a Traditional Screening Phase

This stage consisted of the assessment by one nurse of each file of case notes for the presence of one or more of 15 screening criteria known to be sensitive to the occurrence of an AE (Appendix 1).[18] Cases which were identified as fulfilling one or more criteria present were designated as screen positive and referred for further review by medical reviewers.

Stage 1b Screening by Nurse Identification of Possible Adverse Events

In this stage, for all case notes, the modular review form adapted from Vincent et al, was used by a research nurse to identify adverse events documented in the medical or nursing notes.[19] (The modular form used can be seen in full on http://www.smj.org.uk.) Two research nurses with at least 20 years' clinical experience underwent a period of training in the identification of adverse events by the National Patient Safety Agency (NPSA). They were supervised in this process until it was deemed (by the senior clinicians in the research team and a clinical researcher with expertise in adverse event monitoring) that they were fully familiar with the review process. In cases where the nurses had doubt about the presence of an AE they were encouraged to mark this as present to ensure the case went forward for further review. A random 10% sample of all cases underwent double review by an additional screener with an expertise in risk management.

Summaries of cases screened positive in stage 1a and cases with AEs identified in stage 1b were generated by the research nurses and were reviewed by two of the authors (DW and SO) who determined which potential AEs should be reviewed by the consensus group in stage 2.

Stage 2 Consensus Group Review

Potential adverse events were then presented to a consensus group for further analysis. The expert consensus group comprised consultant clinicians from various acute hospital backgrounds (medicine, surgery, obstetrics and gynaecology, intensive care and anaesthesia), acute sector nursing staff, a clinical risk specialist, an industrial psychologist with expertise in safety research, a psychologist with expertise in communication in health care and a researcher in health services research (Appendix 2). The process of analysis for each case followed that set out by Neale[20] and the findings were recorded on the modular review form 2 (MRF2), previously validated by Woloshynowych et al.[19] This group firstly adjudicated on the potential adverse events identified by the nurse reviewers and two clinicians and then coded them according to their nature, severity, impact on the patient, likelihood of causing harm to the patients or staff involved.[8] The preventability of any event was analysed with regard to patient, staffing and hospital factors which were considered to have contributed to the aetiology, recognition and prevention of the event.[5,8,9]. The costs associated with an AE were calculated on the basis of the extra length of bed days associated with each AE and extrapolated to national data.[8]

Further analysis was performed to compare the incidence of AEs using this methodology with the incidence of events identified using a prospective anonymous reporting system, maintained by the risk management system in ARI.

A clinical pharmacist subsequently reviewed prescription data from 403 records which had complete medication records available to determine the prevalence of medication-related adverse events. The full results of this medication review are reported elsewhere.

Results

Four hundred and fifty cases were analysed initially (M:F, 30:70, median age 42 years, SD 22.4 years, median duration of admission was four days, SD 8.5 days). 96/450 cases whose the length of stay was less than 24 hours had no AE identified. These were excluded for further analysis to make the results comparable with previous findings, leaving a total of 354 admissions (M:F, 35:65, median age 51, SD 22.6 years). Regarding the quality of the medical records for data extraction, 79% of the medical records were judged to be adequate by the researchers, with 14% having some deficiencies and 7% having severe deficiencies.

Stages 1a (Traditional screening) identified 111 cases as screen positive (31%). Stage 1b (screening by nurse identification of AE) identified only 17 cases with adverse events. Four cases selected by stage 1b were not screened positive in stage 1a, and none of these contained an AE as determined by the consensus group.

There was 100% agreement between the additional reviewer and the nurse reviewers in identification of AEs in the 10% sample for double review (kappa= 1).

After final review of cases by the consensus group a total 28 (8% (95% CI 5.6%-11.2%)) AEs were identified of which 12 (43% (95% CI 26.5%-60.9%)) were deemed preventable. Five potential AEs identified by nurse reviewers in stage 1b were found to be false positive and 16 cases were deemed false negative, providing a sensitivity and specificity of 43% and 94% respectively.

The 28 cases where AEs, were identified contained a total of 36 separate AEs. As previous studies have only reported the most significant AE for each case the remaining findings will be presented similarly. The incidence of AEs varied markedly between clinical areas (Table I).

Table I. Number of Adverse Events by Specialty in all Admissions and in Patients Admitted for more than 24 Hours.

Admitting Specialty	Duration of admission	Valid Record	Number of patients with adverse events detected	
			Number (%) of records	Number of preventable (%) events
Acute Medicine	All	150	10 (6.7%)	7 (70%)
	>24 hrs	138	10 (7.2%)	7 (70%)
Acute Surgery	All	150	18 (12%)	5 (27.7%)
	>24 hrs	143	18 (13 %)	5 (27.7%)
Obstetrics	All	150	0 (0%)	N/A
	>24 hrs	73	0 (0%)	N/A
Total	All	450	28 (6.2%)	12 (42.9%)
	> 24 hrs	354	28 (7.9%)	12 (42.9%)

Table II demonstrates the consequences and time to recovery from the adverse events. In 41% of cases there was no increase in hospital stay resulting from the AE, in 38% the AE contributed to a proportion of the hospital stay and in 21% of AEs the event led directly to re-admission to hospital. The average number of extra bed days contributed by each adverse event was 7.5 days (range 0-58 days). Adverse events occurred throughout the patient care pathway and were related to a large variety of interventions (Table III). Three (10%) of the identified adverse events using the retrospective chart review were reported by the existing voluntary anonymous adverse event reporting system.

Following a review of medication records one further adverse event was identified. This involved a patient who was admitted with multiple injuries following a road traffic accident who was prescribed appropriate thromboprophylaxis but did not receive it for three days and subsequently developed a pulmonary embolism.

Table II. The Consequences and Time to Recovery of Adverse Events in Patients who Stayed more than 24 Hours.

Effect of adverse events	Expected time to recovery	Number (%)
No physical impairment	n/a	5 (17.9%)
Minimal physical impairment	One month	10 (35.7%)
Moderate impairment	One year	8 (28.6%)
Permanent impairment	n/a	2 (7.1%)
Contributed to patient's death	n/a	3(10.7%)

Table III. Stage of Care and Nature of Problem Leading to an Adverse Event in Patients Admitted for Greater than 24 Hours.

Stage of Care	Number (%)	Nature of problem	Number (%)
Before admission	6 (21.4%)	Overall assessment	1 (3.6%)
During procedure	4 (14.3%)	Medical and nursing management and monitoring	8 (32.1%)
Post-operative	3 (10.7%)	Infection related	10 (35.7%)
General ward care	11 (39.3%)	Technical procedure related	6 (21.4%)
Admission / discharge planning	4 (14.3%)	Drug / I.V fluid problem	2 (7.1%)
Other	0 (0%)	Other (fall, collapse)	1 (3.6%)
Total	28 (100%)	Total	28 (100%)

Discussion

Our methodology differs from that used in other similar studies by incorporating a consensus group to determine the presence of AEs following the screening process. In this study the number of case records selected by traditional screening (31%) was comparable with previous studies.[4,8] Nurse identification of adverse events however was unsatisfactory selecting only 12/28 cases found to contain AE by the consensus group. The finding of this small feasibility study supports the need to continue the traditional two stage review methodology for retrospective record review. The experience of this methodology was however positive and gave rise to fruitful discussions about a number of controversial cases. It may be that such an approach will be useful to further examine cases where individual stage 2 medical reviewers have found low or borderline confidence scores for the presence of AEs or preventability in a larger study. Finally, we added a subsequent targeted medication review by a pharmacist. However this identified only one further adverse event and is unlikely to be cost effective on a larger scale.

Overall 8% of patients admitted to hospital experienced an AE although the rate varied from 0% in obstetrics to 13% in general surgery. Approximately 40% of these cases overall were deemed preventable with 45% of AEs leading to moderate or greater disability or death. These results are comparable with other international retrospective record review studies which

have demonstrated variable rates of adverse events of between 3% and 17% among hospitalised patients with between 37% and 51% of these events being judged in retrospect to have been preventable.[4,5,6,7,8,9] Furthermore, our results are similar to the only previous retrospective pilot study in the United Kingdom, which demonstrated an adverse event rate of 10.8% of obstetric cases who had a significantly shorter length of stay were removed from the analysis.[8] The estimated additional cost of adverse events in terms of bed days was £69,189 which if extrapolated to the rest of Scotland could cost £297 million per annum.

This work was intended as a feasibility study to explore methodological questions before embarking on a larger national study. However, it was also its intention to obtain an indication of the likely number of AEs which might be found in the wider Scottish study. In terms of the generalisability of the findings, there are a number of important limitations present in this study. One was the relatively small number of patients enrolled and the fact that the study was performed in one teaching hospital. Approximately half of the obstetric cases were removed from the analysis as they were admitted for less than 24 hours and therefore the results in these cases need to be interpreted with caution. Removal of such patients from the analysis would provide an AE rate which is similar to that of the first UK-based study.[8] Furthermore, we did not include patients in other specialties such as psychiatry, geriatric medicine or critical care who may have very different adverse event rates. These factors would need to be addressed in the design or a larger scale study.

Only 10% of the adverse events identified by case-note review were identified by the established voluntary anonymised reporting system in Aberdeen Royal Infirmary. This system is similar to that employed in other hospitals across the UK. This result has been confirmed by another recent study[10] and it has been suggested that a number of different methods are required to detect adverse events.[15] A recent multi-centre study on AEs and near miss reporting in England and Wales demonstrated that voluntary reporting by staff when linked to a multi-centre data collecting system could yield information on a large number of incidents. It also provided support for a national information technology system to collect and analyse incident data.[21]

This study provides an important starting point for the understanding of adverse events and their consequences in the Scottish Healthcare system. A larger investigation, which would explore the types of AEs and their contributing factors, and which is based on the learning from this feasibility study, is required to provide a more representative picture for hospitals in different areas of Scotland. Such an investigation would allow the implementation of specific risk reduction strategies for the principal types of AEs. Given the distribution of AEs in our study, efforts to improve medical and nursing management, infection control and medication safety will play a pivotal role in improving patient safety. Such improvements are also likely to be cost-effective, given the significant costs associated with AEs which were identified in this study.

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Examples of Adverse Events

- A 76 year old man admitted with swelling and pain in scrotal area three weeks after discharge following repair of right inguinal hernia. A testicular ultrasound scan was performed showing a large mass consistent with an organising haematoma.
- A 78 year old lady admitted with abdominal pain and vomiting. She was taken to theatre four days later and had a laparotomy with bilateral salphing-oopherectomy, for removal of torsion of an ovarian tumour. She developed a wound infection which was treated with antibiotics. Her wound clips were removed the day before being transferred to a convalescence ward, following which she developed wound dehissence requiring re-admission to the original surgical ward. The patient was kept in hospital for a further 12 days and required the wound to be dressed by the community nurse on discharge.
- A 70 year old man was admitted to a medical ward due to sudden onset of Bilateral Peripheral Neuropathy + and an infective exacerbation of chronic obstructive airways disease. He developed an infected ulcer on his right ankle which required dressings. His discharge was delayed, and he was eventually transferred to another hospital for convalescence. The ulcer was still present some six weeks after discharge from the medical ward.

Appendix 1

Screening Form
Criteria for Further Assessment

1. Previous admission to any hospital in the past 12 months
2. Length of hospital admission longer than expected
3. Length of admission >10 days
4. Diagnosis significantly delayed at any stage of admission
5. Unplanned event occurred during surgery/procedure/anaesthesia
6. Unplanned visit to operating theatre or elsewhere for procedure
7. Unplanned transfer to other unit or hospital
8. Required period of intensive or high dependency care
9. Hospital acquired infection/sepsis
10. Condition complicated during hospital stay by intervening event (eg heart failure, DVT, PE, MI, pressure sore, neurological episode, cardiorespiratory arrest, etc)
11. Adverse drug reaction or problem arising from infusion of iv fluids/blood (including cellulitis, haematoma)
12. Fall or other accident
13. Death
14. Patient or relative made complaint regarding care (Please Specify)
15. Doctor or Nurse unhappy about any aspect of care (Please Specify)

Appendix 2

Membership of Consensus Group

Professor MK Campbell, Professor of Health Service Research, Health Services Research Unit, University of Aberdeen

Professor BH Cuthbertson, Professor in Critical Care, Health Services Research Unit, University of Aberdeen

Dr V Brace, Clinical Research Fellow, Department of Obstetrics and Gynaecology, University of Aberdeen

Dr P Danielian, Consultant Physician, Department of Obstetrics and Gynaecology, Aberdeen Maternity Hospital

Professor RF Flin, Professor of Applied Psychology, Department of Psychology, University of Aberdeen

Professor Z Krukowski, Consultant Surgeon, Department of Surgery, Aberdeen Royal Infirmary

Dr M-J MacLeod, Clinical Senior Lecturer, Department of Medicine and Therapeutics, University of Aberdeen

Dr S Olsen, Honorary Research Fellow, Department of Biosurgery and Surgical Technology, Imperial College London.

Dr D Williams, Consultant Physician, Department of Clinical Pharmacology, Aberdeen Royal Infirmary

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