A Case-control Study to Investigate Variables associated with Incidents and Adverse Events in the Emergency Department

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This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: [10.1111/1742-6723.12736](https://doi.org/10.1111/1742-6723.12736)

Author's contribution to the paper:

J Hendrie: designed the study, reviewed cases, collated the data, assisted with the subset analysis and wrote the paper.

M Yeoh: helped design the study, undertook the ethics submission, reviewed assigned cases to detect incidents and adverse events.

J Richardson: reviewed assigned cases to detect incidents and adverse events.

A Blunt: reviewed assigned cases to detect incidents and adverse events.

P Davey: interrogated the hospital computer system to provide demographic data on patients.

D McD Taylor: helped design the study, undertook the randomization process and allocation of cases, and performed the statistical analysis.

A Ugoni performed the multiple regression analysis.

Word Count of Main Text (excluding tables and boxes): 2490

The work was carried out at: Emergency Department, Austin Health, Burgundy Rd, Heidelberg 3084, Victoria, Australia.

MeSH Key Words:

Drug related side effects and adverse drug reactions

Errors, diagnostic

Errors, medical

Emergency Services, hospital

Human

INTRODUCTION

The Emergency Department (ED) setting is a busy, stressful and challenging work environment. Patients often present with undifferentiated and complicated disease states that need to be managed expeditiously yet competently. Inherent among the responsibilities of ED staff is the accurate monitoring of incidents (Is, no harm sustained) and adverse events (AEs) (see Box 1). These can be used to inform procedural, investigational, education or staff changes in an attempt to minimize these events.

In a previous study of 3,222 ED patients, we reported a Total Event Rate (TER, combined I/AE rate) of 5.1%.^{1,2} This comprised I and AE rates of 1.98% and 3.1%, respectively. The most common events were drug reactions (1.35%), which were usually associated with pre-ED management and were mostly not preventable. I/AEs arising within the ED were most commonly due to diagnostic error (1.2%) and were largely preventable.^{2,3}

Wolff and Burke reviewed a sample of 2.7% of medical records to detect AEs in the ED.⁴ While many studies have simply documented I/AE rates, Wolff and Burke reported a reduction in AE rate following process changes in the ED. These changes reduced AEs from 3.26% to 0.48% over 21 months.

Other studies have reported hospital-wide rates of AEs ranging from 3.7% for the Harvard Medical Practice Study (HMPS) to 16.6% by the Quality in Australian Health Care Study (QAHCS).^{5,6} The ED was the site of the AE in 2.9% and 1.5% in HMPS and QAHCS, respectively.^{6,7}

Sprivulis et al.⁸ used linkage of ambulance, hospital and death registries to calculate citywide mortality rates of patients attending Perth EDs, innovating the term ‘arrival density hazard’ and the ‘overcrowding hazard scale’. Their study demonstrated a linear relationship between the overcrowding hazard scale and 7-day mortality. Richardson and Guttman also reported increased mortality and decline in other parameters with ED overcrowding and prolonged length of stay.^{9,10}

Using pre-specified screening criteria, Klasco et al¹¹ reported an overall incidence of error of 0.13% among all ED patients with an AE rate of

0.11%. They acknowledge that the low rates reported were a function of their highly specific screening criteria.

The objective of this study was to describe and analyze I/AEs in the ED.

We hypothesized that I/AE are associated with patient load and that diagnostic error would have high preventability and would be associated with events that occurred in ED.

METHODS

Study design

This was a case-control study of patients presenting to a tertiary level hospital ED between 1st April 2012 and 31st March 2013. The annual census for the period was 72,386 attendances. The study was approved by the hospital ethics committee.

At the beginning of every month, a random sample of 3% of all patients, who presented during the previous month, was selected using the random number function of the Excel spreadsheet. This was undertaken by one investigator (DT) who did not review the medical records and played no part in determining if I/AEs had occurred.

Cases

Four practicing emergency physicians reviewed an assigned proportion of patient medical records, making a judgment if I/AEs had occurred up until 30 days after presentation to the ED. Each patient's record was reviewed by a single consultant. Cases where a reviewer was in doubt were discussed by all investigators until a determination was made by consensus.

The definitions of I/AEs we used were derived from QAHCS⁶, but modified for the ED (Box 1 for these and other definitions). A 'prior event' is an I/AE that occurred prior to arriving in ED for the index presentation. The definition of diagnostic error was derived from Mosby's dictionary definition of 'diagnose', again modified to the ED setting.¹²

Controls

Unmatched controls were selected on a 2:1 basis. On the randomised patient list, controls were the two patients immediately below an identified case. If one of these two patients was themselves a case, the closest two patients on the list were selected as potential controls. If one potential control was subsequently found to have an I/AE, another control was sought. Given the randomization of the list, there was no time or other relationship between controls and cases.

Study Data

All patient data, including history, examination findings and diagnosis, was retrieved electronically. Times of arrival, seen by doctor, and departure to ward or home are routinely recorded. At the time of the study, MedTrak[®] was the ED operating system. Data was recorded on a

hardcopy data collection instrument that was designed specifically for the study and was trialed and revised before use. It was similar to that used in similar studies.^{1,2} Data on arrival density, ED occupancy and hand-over were extracted from the Hospital Performance Reports by an investigator (PD). The ED has 44 cubicles/treatment areas and a median (range) occupancy of 39.6 (7 - 69).

Data Analysis

Our sample size of 2,300 was based on an expected TER of 6% (found in our previous study) and a 1% expected 95% CI (i.e. 5%-7%). This was achieved by enrolling 3% of all patients who presented during the study period. A post hoc power analysis indicated that the study had a power of 0.91 to demonstrate a difference in TER between the low ED occupancy group (0-35 patients) and all other groups combined (OR 1.8, 95%CI 1.3, 2.5).

I/AEs were analyzed and classified step-wise according to the following criteria: health care management causation, then outcome and finally preventability.⁶ A judgement was made regarding the strength of health care management causation and preventability using a 6-point scale (Box 2).⁶ Events with management causation <50:50 were excluded, following the convention of HMPS.⁵ Events in outcome categories 1 & 2 fell within

the definition of incidents; those with outcomes 3 – 6 were classified as adverse events (Box 3).

Univariate and multivariate regression analysis was undertaken. Odds ratios with 95% confidence intervals (CI) were generated for variables of interest. The level of significance was 0.05. Statistical analysis was performed by SPSS[®] for Windows statistical software (version 22.0, SPSS Inc., Chicago, Illinois, USA).

RESULTS

Of 2,169 patients enrolled, 2 were excluded (one was selected twice, the other for lack of data) leaving 2,167 for review. Two hundred and forty two were judged to have I/AEs. In 25 cases, the outcomes were considered not to be due to health care management. These were excluded, leaving 217 I/AEs for analysis.

One in 10 patients suffered an I/AE, although over half were minor incidents (Table 1). Death and serious AEs were rare (Figure 1).

Approximately one third of I/AEs resulted from events prior to the index attendance, and were largely beyond ED control. Of I/AEs arising from prior care, 4.5% were ED re-attendances. The other 95.5% resulted from health care elsewhere. Most I/AEs were judged preventable (Figure 2).

The regression analysis demonstrates that ED occupancy was significantly associated with I/AEs. Using ED occupancy < 35 as the reference group, if 36-40 or 41-45 patients were in the ED, the odds ratios for sustaining an I/AE was 2.4 and 1.8, respectively (Table 2), but was not significant with e 46 patients (OR 1.7 95%CI 1.0-3.1). An arrival density hazard of more than 14 patients arriving in the hour of attendance

was significant in univariate analysis (OR 1.74), but was not significant on multivariate analysis (OR 1.74, 95%CI 0.93-3.24). Age (51-70 years) was also associated with I/AEs, (OR 1.89), but was not significant over 71 years. Higher hospital occupancy (90-99%) had a lower odd ratio for sustaining an I/AE (OR 0.57, 95%CI 0.35-0.92).

In multivariate analysis, there were no differences between cases and controls with regards to gender, weekend or month of presentation, triage category, time waiting to be seen by doctor or proportion treated within 4 hours, access block occupancy score, or patient hand over at the end of a shift (Table 2). Longer ED length of stay was not significant in multivariate analysis.

Errors of omission accounted for over half of I/AEs (Table 3). Errors of omission were strongly associated with the ED index attendance, errors of commission with prior events (omission: ED/prior 101/10, commission: ED/prior 30/57, $p < 0.001$). Diagnostic error was the most common I/AE, followed by adverse drug reactions, medication errors and postoperative complications.

The diagnostic error rate was 3.7%. Of the 79 cases with diagnostic error, the diagnosis was missed in 44. In 31 cases the diagnosis was considered

in the differential but an alternative was preferred. In four cases the seriousness of the diagnosis was not appreciated. In subgroup analysis of patients with I/AEs, diagnostic error was strongly associated with the ED index attendance and high preventability (Table 4). Compared with other causes of I/AEs, diagnostic error was not associated with worse outcomes. Diagnostic error was attributed to cognitive error alone in 70.9%, 25.3% had both a cognitive and system component, while system error alone contributed only 3.8%.

Adverse drug reactions (ADR) rate was 2.5%. These were strongly associated with prior events (prior/ED: ADR 31/15, no ADR 36/116, $p<0.001$). With 2/3 of these prescribed, or administered elsewhere in the system, or by ambulance, 1.4% (31 of 2167) of the ED presentations results from medications administered elsewhere in the system.

Compared with other events, ADRs were significantly less likely to be judged preventable (low/ high preventability ADR 29/24, no ADR 21/143, $p<0.001$). More serious ADRs included: complete heart block from amiodarone; ventricular tachycardia from adrenaline infusion; haematemesis, malaena, intracranial haemorrhage and epistaxis from warfarin; clostridium difficile enterocolitis from multiple antibiotics; renal failure from cisplatin; and hypoglycemia from insulin. No

patient in the series died from an ADR. Human error in medication delivery occurred in a further 32 cases (Table 3).

The relationship of outcome severity to site of events was investigated. Incidents were strongly associated with ED events, AE with prior events (prior/ ED incidents 26/93, AEs 41/38, $p<0.001$). However, the absolute numbers of AEs were similar in both groups. Thus the difference was due to a substantially higher number of ED events being minor incidents. Incidents were significantly more preventable than adverse events, with 85% judged preventable, compared with 65% of adverse events (incidents/ AEs low preventability 19/31, high preventability 110/57, $p<0.001$).

Post hoc analysis revealed the number of patients reviewed by each consultant was as follows: 501, 644, 482, 540. The TER detected by each consultant was 10.8%, 10.4%, 18.05% and 6.85% respectively ($p<0.001$). However, the AE rate was not significantly different ($p=0.25$). One hundred and ten randomly selected cases were used to measure the level of agreement between the four raters. In 56 (50.9%), all raters were in agreement about whether or not an event had occurred. In 41 (37.3%) cases, one rater disagreed with the other three and in 13 (11.8%) cases, two raters disagreed with the other two.

DISCUSSION

Our study has demonstrated that I/AE are common in the ED setting. Seventy-seven percent were judged preventable. The study demonstrates a complex association between ED occupancy and I/AEs, with I/AEs more likely to occur when there was high patient occupancy, but not highest occupancy. Higher hospital occupancy was protective against I/AEs. One possible explanation is that at low patient occupancy there is time to deal with a patient's problem thoroughly. As patient load increases, there is increasing need to turnover patients rapidly with a rise in error rate. At highest ED occupancy, and with higher hospital occupancy, the department becomes so congested that patient flow slows, again allowing more time to deal with patients in detail.

Our data contrasts with Boden et al in the United Kingdom, who demonstrated reduced inpatient mortality, and improvement in meeting the ED 95% 4-hour target, by lowering in-patient bed occupancy.¹³ A number of other studies have shown an association between ED overcrowding and inpatient mortality and other adverse events measures.^{8,9,10,14}

Age 51 to 70 was also associated with I/AEs, but was not significant over 70, although the subgroup sample size was smaller. In all age groups, the effect sizes do not differ greatly and may not be clinically significant.

We did not show an association between the access block occupancy score and ED I/AEs. Because the overcrowding hazard scale interacted with the access block occupancy score, it was excluded from the multivariate analysis.

While ‘hand-over’ or ‘hand-offs’ are a risk factor in other studies, we were not able to demonstrate this in our study.^{15,16,17} Attendance at weekends, in February-April (when new interns and residents start in the Australian system), waiting time, triage category, and ED length of stay were also not associated with I/AEs.

Diagnostic error was the most common cause of I/AE and was highly preventable. In the Dual Process Theory, proposed by Croskerry, type 1 thinking - fast, intuitive decision making - is thought to be associated with higher diagnostic error rates, while type 2 thinking - slower, analytical decision making - with lower rates.¹⁸ This has been challenged recently. In one study, higher diagnostic accuracy was associated with more rapid responses.²⁰ The two determinants of accuracy are case complexity and

physician experience: complex cases had lower diagnostic accuracy; greater experience was associated with higher accuracy.^{20,21,22} Whatever the underlying neurophysiologic mechanism of decision-making is, reducing diagnostic error is a major challenge for emergency medicine.

Adverse drug reactions are a common cause of AEs in our study, mostly resulting from medications prescribed by doctors or other health workers outside the ED with 45% of ADRs judged preventable. The majority of ADRs, however, arose prior to the ED index attendance. These are not amendable to correction, at least at ED level.

Incidents were judged more preventable than adverse events in this series. More serious AEs have been reported previously as more likely to be preventable or negligent.^{5,6} Most studies have not included incidents and our previous study had a substantially lower proportion of incidents, likely due to the screening methodology. In this study, in which EPs directly reviewed cases without a prior screening process, 59% of events were incidents.

Limitations

This study has important limitations. It was limited to a single centre, and may not be generalizable to other hospitals or health care settings. The

inter-rater agreement in I/AEs was suboptimal. Although the definition of incidents was derived from the literature ('potential to cause patient harm'), this may have allowed excess latitude in interpretation and contributed to the difference in detection rates. Differences of opinion also became apparent, from those critical of any minor deviation from a perceived standard of care, through to those focused on serious errors and their prevention. This warrants further study. Double review was not undertaken due to human resource constraint. We did not analyse the effect of staffing mix and seniority on I/AEs because the data were clouded by overlapping processes, with multiple doctor inputs making the apportioning of responsibility in decision-making difficult in many cases. Finally, incomplete medical records and the use of only the study ED records may have led to an under-estimation of the TER rate.

CONCLUSION

I/AEs are common in the ED and a large proportion is preventable. Our study demonstrates a complex relationship between ED occupancy and I/AEs, which requires further clarification. Strategies for prevention are urgently required.

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Box 1. Definitions

Incident

- an untoward event that had the potential to cause patient harm although harm did not result

Adverse Event (AE)⁶

- an unintended injury or complication which
- resulted in disability, death, prolongation of the hospital stay or natural history of the disease, or change in disposition and is
- caused by health care management rather than the patient's disease

Disability

- temporary or permanent impairment of physical function (including disfigurement) or mental function
- subdivided into little or no disability, disability < 50% and disability ≥ 51% at 30 days

Prior Incident or Adverse Event

- an I/AE that arose from events before the index presentation

ED Incident or Adverse Event

- an I/AE that occurred during the index presentation

Combined Incident or Adverse Event

- an I/AE that had both prior and ED components

Arrival Density Hazard

- the number of patients arriving in the hour of index attendance

ED occupancy

- the number of patients in the ED at the end of the hour of attendance

Access Block Occupancy

- the number of patients waiting more than 8 hours for an inpatient bed, at hour of attendance

Access Block Occupancy Score

- 1<10% of ED beds occupied, 2=10-19%, 3≥20%

Hospital Occupancy Score

- 1<90% acute inpatient beds occupied at midnight, 2=90-99%, 3=100%

Overcrowding Hazard Scale

- = access block occupancy score × hospital occupancy score

Handover

- the thrice daily scheduled times when one shift of doctors hands over care to the next shift of doctors

Diagnostic error

- failure of identification of a disease or condition by a scientific evaluation of physical signs, symptoms, history, laboratory test results and procedures from the information available at the time of attendance in the ED, or might reasonably be expected to be obtainable.

Error of commission

- error undertaking treatment, task, or test

Error of omission

- failure to undertake treatment, task or test; failure to diagnose correctly

Box 2. Levels of evidence for health care management for the two variables of causation (C) and preventability (P)⁶

1. Virtually no evidence
2. Slight to modest evidence
3. <50:50 but close call
4. More likely than not, >50:50 but close call
5. Moderate to strong evidence
6. Virtually certain evidence

Box 3. Classification of Disability Outcome⁶

1. Virtually no influence on patient management
2. Minor influence on patient management
3. Prolongation of the natural history (NH) of illness/injury d 30 days & no/ minimal disability
4. Prolongation of the natural history of illness/injury, with sequelae, lasting > 30 days &/or disability d 50%
5. Prolongation of the natural history of illness/injury, with sequelae, lasting > 30 days &/or resulting in permanent or major disability e 50%
6. Death at 30 days

Box 4. Examples of Outcomes of Incidents and Adverse Events

(See Boxes 2 and 3 for definitions and levels of evidence. C=causality, P=preventability)

1. Index Presentation

Outcome 1: Failure to administer ADT after lacerations in unimmunized patients or record status (C6, P6)

Outcome 2: Failure to refer Salter Harris 2 fracture to orthopaedic outpatients (C5, P5)

Outcome 3: Missed skull fracture and subdural haematoma (C4, P4)

Outcome 4: Tracheal perforation post intubation (C5, P1)

Outcome 5: Presented with constipation. New anaemia, not diagnosed or referred. Colorectal cancer metastatic at time of diagnosis 5 months later. (C5, P6)

Outcome 6: Failure to diagnose bilateral subdural haematomas. Increased confusion attributed to urosepsis. (C5, P4)

2. Resulting from events before the index presentation

Outcome 1: Hypotension from GTN and morphine administered by ambulance (C6, P5)

Outcome 2: Postoperative sternal wound infection (C6, P1)

Outcome 3: Clostridium difficile enterocolitis secondary to multiple antibiotics (C5, P1)

Outcome 4: Bronchopulmonary fistula and sepsis post pneumonectomy (C6, P1)

Outcome 5: None detected

Outcome 6: None detected

Table 1. Incident and Adverse Event Rates[†] (n=2,167)

	n	%	(95% CI)
Total Event Rate	217	10.1	(8.8-11.4)
Incidents (Outcome categories 1,2)	129	6.0	(5.0-7.0)
Adverse Events (Outcome categories 3-6)	88	4.1	(3.3-5)
Serious Adverse Events (Outcome 4,5)	17	0.8	(0.5-1.3)
Mortality (30-day) (Outcome category 6)	2	0.1	(0.01-0.3)
Prior Event Rate	67	3.1	(2.4-3.9)
ED Index Event Rate	131	6.0	(5.1-7.1)
‘Combined’ Event Rate	19	0.9	(0.5-1.4)
Preventable Event Rate	167	7.7	(6.6-8.9)
Diagnostic Error Rate	79	3.7	(2.9-4.5)
Adverse Drug Reactions	53	2.5	(1.8-3.2)

[†]Note-categories are not mutually exclusive

Table 2. Analysis of Variables Potentially Associated with TER[†]

				Univariate Analyses			Multivariate Analyses		
		Controls	Cases	OR	95% CI	p	OR	95% CI	p
Age (Years)	0-25	132	41	1			1		
	26-50	134	50	1.2	0.7-1.9	0.45	1.1	0.7-1.9	0.67
	51-70	121	71	1.9	1.2-3.0	0.01	1.9	1.1-3.2	0.02
	≥71	99	55	1.8	1.1-2.9	0.02	1.7	1.0-2.9	0.07
Gender	Male	233	113	1			1		
	Female	253	104	0.9	0.6-1.2	0.31	0.8	0.6-1.2	0.29
Day of Week	Week day	338	155	1			1		
	Weekend	148	62	0.9	0.6-1.3	0.62	1.2	0.8-1.7	0.47
Month of Presentation	Feb-March	148	71	1			1		
	May-July	99	46	1.0	0.6-1.5	0.89	1.0	0.6-1.7	0.94
	Aug-Oct	100	44	0.9	0.6-1.4	0.71	1.1	0.6-1.8	0.80
	Nov-Jan	139	56	0.8	0.6-1.3	0.42	0.9	0.6-1.4	0.64
Triage Category	1	6	5	1			1		
	2	70	30	0.5	0.2-1.8	0.30	0.5	0.1-1.9	0.29
	3	216	117	0.7	0.2-2.2	0.49	0.7	0.2-2.7	0.63
	4	178	60	0.4	0.1-1.4	0.15	0.5	0.1-1.8	0.26
	5	16	5	0.4	0.1-1.8	0.22	0.7	0.1-3.5	0.62
Time Waiting To Be Seen (Minutes)	0-10	174	72	1			1		
	11-20	85	48	1.4	0.9-2.1	0.17	1.3	0.8-2.1	0.35
	21-50	114	39	0.8	0.5-1.3	0.41	0.7	0.4-1.2	0.15
	≥51	113	58	1.2	0.8-1.9	0.31	1.0	0.6-1.6	0.86
Arrival Density Hazard [†]	0-7	146	50	1			1		
	8-10	116	55	1.4	0.9-2.2	0.16	1.2	0.7-2.0	0.46
	11-13	130	56	1.3	0.8-2.0	0.32	1.2	0.7-2.0	0.63
	≥14	94	56	1.7	1.1-2.8	0.02	1.7	0.9-3.2	0.08
ED Occupancy [†]	0-35	186	56	1			1		
	36-40	78	51	2.2	1.4-3.5	<0.01	2.4	1.4-4.0	<0.01
	41-45	89	46	1.7	1.1-2.7	0.02	1.8	1.0-3.2	0.04
	≥46	133	64	1.6	1.1-2.4	0.03	1.7	1.0-3.1	0.07
No. Pts Discharged	0-10	167	63	1			1		
	11-12	59	29	1.3	0.8-2.2	0.33	1.1	0.6-1.9	0.85

<4 Hours	13-16	147	70	1.3	0.8-1.9	0.26	0.9	0.5-1.6	0.75
	e16	113	55	1.3	0.8-2.0	0.25	0.9	0.5-1.6	0.66
Access									
Block	<10%	127	50	1			1		
Occupancy	10-19%	173	88	1.3	0.9-2.0	0.23	1.2	0.8-1.9	0.37
Score†	e20%	186	79	1.1	0.7-1.6	0.72	1.1	0.6-1.8	0.81
ED Total	0-190	125	66	1			1		
Daily	191-200	96	42	0.8	0.5-1.3	0.43	0.7	0.4-1.2	0.24
Attendance	201-210	138	45	0.6	0.4-1.0	0.04	0.7	0.4-1.1	0.13
(n)	e210	127	64	1.0	0.6-1.5	0.83	0.8	0.5-1.4	0.51
Hospital	<90%	74	46	1			1		
Occupancy†	90-99%	412	171	0.7	0.4-1.0	0.05	0.6	0.4-0.9	0.02
ED Length	0-150	139	42	1			1		
of Stay	151-250	139	72	1.7	1.1-2.7	0.02	1.6	1.0-2.7	0.07
(Minutes)	251-350	86	43	1.7	1.0-2.7	0.05	1.3	0.7-2.5	0.38
	e351	122	60	1.6	1.0-2.6	0.04	1.5	0.8-2.8	0.24
Patient	none	209	89	1			1		
Handed	once	254	115	1.1	0.8-1.5	0.72	0.8	0.5-1.2	0.33
Over†	e2	23	13	1.3	0.6-2.7	0.44	0.9	0.4-2.3	0.88

†see Box 1 for definitions

Table 3. Nature of Incidents and Adverse Events versus Type of Error

Nature of Incidents and Adverse Events	Error of Omission (n)	Error of Commission (n)	Totals
Diagnostic Errors	73	9	82
Adverse Drug Reactions	3	43	46
Post operative complications	0	23	23
Laboratory, other investigative issue/ Test not ordered	15	0	15
No/ wrong medication given	8	6	14
Other medication errors	8	4	12
Post ED procedural complications	1	7	8
Excess medication dose errors	0	6	6
Inadequate physical examination/ observations	5	0	5
Other	5	1	6
Totals	118	99	217

Table 4. Diagnostic Error and associations

	Diagnostic Error (n=79) %	No Diagnostic Error (n=138) %	p
Location of Events			
Prior to ED	6.3	44.9	<0.001
ED events	83.5	47.1	
Preventability			
High [†]	97.5	65.2	<0.001
Low [‡]	2.5	34.8	
Outcome severity			
Adverse event	48.1	36.2	0.09
Incident	51.9	63.8	

[†]levels of evidence 4-6 Box 2

[‡]levels of evidence 1-3 Box 2

Figure 1 Outcome Tiff.tiff

Figure 2 Preventability Tiff.tiff

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Title:

Case-control study to investigate variables associated with incidents and adverse events in the emergency department

Date:

2017-04-01

Citation:

Hendrie, J., Yeoh, M., Richardson, J., Blunt, A., Davey, P., Taylor, D. & Ugoni, A. (2017). Case-control study to investigate variables associated with incidents and adverse events in the emergency department. EMERGENCY MEDICINE AUSTRALASIA, 29 (2), pp.149-157. <https://doi.org/10.1111/1742-6723.12736>.

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