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Adverse Events Sustained by Children in The Intensive Care Unit: Guiding local quality improvement

CHRISTOPHER JAMES, CARMEL DELZOPPO, JAMES TIBBALLS, SIVA NAMACHIVAYAM, WARWICK BUTT

Paediatric Intensive Care Unit Melbourne, Victoria, Australia

Correspondence: Christopher.James@rch.org.au

ABSTRACT

Objective: To determine the frequency, nature and consequence of adverse events sustained by children admitted to a combined general and cardiac paediatric intensive care unit (PICU).

Design: Retrospective analysis of data collected between January 1st 2008 and December 31st 2017 from PICU.

Setting: The Royal Children's Hospital, a paediatric tertiary referral centre in Melbourne, Victoria, Australia. The PICU has thirty beds.

Results: During the study period, PICU received 15208 admissions, of which 73% sustained at least one adverse event with a frequency of 67 adverse events per 100 PICU-days and 3 per admission. One adverse event was sustained for every 35 hours of care. The risk of an adverse event was highest in children less than a month of age, or if mechanically ventilated, a high Pediatric Index of Mortality (PIM2) score, longer PICU length of stay, had a pre-existing disability or a high risk adjustment for congenital heart surgery (RACHS) score. Those patients who sustained an adverse event, as compared to those who did not, were mechanically ventilated for longer (80 hrs Vs. 7 hrs, p=<0.001), had a longer PICU length of stay (131 hrs Vs. 35 hrs, p=<0.001), had a longer hospital length of stay (484 hrs Vs. 206 hrs, p=<0.001) and had a higher mortality rate (3% vs. 0.1%, p=<0.001).

Conclusion: Whilst admission to PICU is an essential aspect of care for many patients, the risk of adverse events is high and is associated with significant clinical consequences. Monitoring of adverse events as part of quality improvement enables targeted intervention to improve patient safety.

Keywords: quality improvement, paediatric, intensive care, adverse events

INTRODUCTION

Critically ill children requiring admission to a pediatric intensive care unit (PICU) are at risk of adverse events; from the procedures and technology associated with critical care medicine, and from their underlying disease and its progression.

Adverse events arising as a consequence of care in an intensive care unit (ICU) were first described by Abramson and colleagues [1] in 1980. Despite improved survival and outcome of critically ill children cared for in PICU, adverse event rates remain high [2-4]. Specific data relating to the nature of adverse events

that occur is needed in order to improve the safety of patients and optimise the quality of care delivered in the PICU.

The aim of this study was to analyse the frequency, nature and consequence of adverse events arising during PICU admission at our institution. We report how the frequency of central line associated bloodstream infection (CLABSI), ventilator associated pneumonia (VAP) and accidental extubation rates, key performance indices reported by most ICUs, changed over the study period to highlight progress in patient safety.

The study received ethical approval from the institutions Human Research Ethics Committee (HREC 34221C).

MATERIALS AND METHODS

The Royal Children's Hospital (RCH), Melbourne serves the population of the States of Victoria, Tasmania and southern New South Wales, Australia. The combined general and cardiac PICU has thirty beds and admitted 1719 patients in 2017 (7593 patient days).

Three dedicated data collection nurses from the PICU quality, data and research team prospectively record data on patient admissions, adverse events sustained subsequent to admission and discharges in the 4D database STATIC, an intensive care specific relational database. Data related to PICU admissions and subsequent adverse events was extracted from 1st January 2008 to 31st December 2017 for analysis. Adverse events were recorded as being major or minor in nature and patients grouped by age, pre-existing function, severity of illness on admission (Paediatric Index of Mortality, PIM2), risk adjustment for congenital heart surgery (RACHS) and by length of PICU stay.

Definitions

An adverse event is defined as an injury resulting from a medical intervention [5,6] or an unfavorable consequence of disease. A list of adverse events was compiled by amalgamating hospital and publically available sources [7,8] (Supplemental Table 1). Adverse events were defined as major if they resulted in significant medical or surgical intervention, permanent disability, or unexpected or preventable death, as decided by routine monthly departmental morbidity and mortality review meetings.

A ventilator associated pneumonia (VAP) was identified using a combination of radiologic, clinical and laboratory criteria in a patient intubated and ventilated within 48 hours of onset, as defined in Victorian State guidelines [9]. Our definition of central line associated bloodstream infection (CLABSI) is a laboratory confirmed bloodstream infection in a patient where a central line is in place for greater than 48 hours, as defined by the Australian Commission on Safety and Quality in Healthcare [10]. We define accidental extubation as a premature and unplanned removal of the endotracheal tube by the action of either the patient or a healthcare professional.

Pre-existing function is assessed at admission using the modified Glasgow outcome score (MGOS), a global assessment tool of independent living and social integration for children older than one month of age [11]. The pre-existing function obtained by the MGOS divides children into five categories: normal, functionally normal (physically and intellectually normal) but requiring medication or medical supervision, mild disability but likely to lead an independent existence, moderate

disability and dependent on care, and severe disability and totally dependent on care.

Statistical analysis

Analyses were performed using Stata v13.1 (StataCorp. College Station, TX). Continuous patient outcomes were compared using Mann-Whitney U tests and binary outcomes using Chi-squared tests.

RESULTS

Over the ten-year period, 10417 patients accounted for 15208 admissions to the PICU. Of all admissions, 73% sustained at least one adverse event during their admission at a frequency of 67 adverse events per 100 PICU-days and 3 per admission (Table 1). One adverse event was sustained every 35 hours of care. Thirteen percent of adverse events were major (Table 2). Major adverse events occurred 8 times per 100-PICU days, 0.4 times per admission and for every 288 hours of care.

Of all patients admitted to PICU during the study period, 10028 (66%) required mechanical ventilation and these patients had a higher incidence of adverse events (57%) compared to those not requiring mechanical ventilation (16%). The proportion of patients sustaining an adverse event was highest in those less than a month of age (89%). The likelihood of an adverse event increased as PICU length of stay increased and adverse events were sustained more frequently in patients with higher RACHS and PIM2 scores as well as higher pre-existing disability (Table 3).

Those patients who sustained an adverse event during their PICU admission, as compared to those who did not, had (if ventilated) a longer mean duration of ventilation (80 hrs vs. 7 hrs, p=<0.001), had a longer mean PICU length of stay (131 hrs vs. 35 hrs, p=<0.001), had a longer mean hospital length of stay (484 hrs vs. 206 hrs, p=<0.001) and had a higher mortality rate (3% vs. 0.1%, p=<0.001)(Table 4). Patients who sustained a major adverse event, when compared to those who sustained none, had an even longer mean duration of ventilation (212 hrs vs. 7 hrs, p=<0.001), had a longer mean PICU length of stay (300 hrs vs. 35 hrs, p=<0.001), had a longer mean hospital length of stay (921 hrs vs. 212 hrs, p=<0.001) and had a higher mortality rate (4.4% vs. 0.2%, p=<0.001) (Table 4). The relative risk of death if any adverse event was sustained was 10.7 (95% CI 6.5 – 17.6) and 28.5 (95% CI 17 – 47) if the adverse event was major.

Supplemental Table 1 outlines the specific adverse events by category and whether the adverse event was the result of a medical intervention or an unfavourable consequence of disease. The relative risk of death if an adverse event was the result of a medical intervention was 19 (95% CI 11 – 32) and 11 (95% CI 7 – 18) if the adverse event was an unfavourable consequence of disease (Supplemental Table 2). The frequency of adverse events by RACHS score, PIM2 score, pre-existing patient function, age and PICU length of stay are detailed in Supplemental tables 3-7.

During the first two years of the study period, the central line associated bloodstream infection (CLABSI) rate on our ICU was 2.75 per 1000 central line days. This decreased to 1.9 per 1000 central line days in the last two years of the study period p>0.05). Similarly, the incidence of ventilator associated pneumonia (VAP) was 3.55 per 1000 ventilator days in the first two years of the study, decreasing to 1.2 per 1000 ventilator days in the final two years

(p>0.05). The incidence of accidental extubation was 0.33 per 100 ventilator days at the beginning of the study period and 0.44 per 100 ventilator days by the end (p>0.05).

DISCUSSION

While sick children undoubtedly benefit from having access to a PICU [12], once admitted they are at risk of adverse events arising from both their illness and the care they receive. In this study, patients less than one month of age, those requiring mechanical ventilation and with high RACHS or PIM2 scores, as well as those with pre-existing disabilities were more likely to sustain an adverse event. Patients who sustained adverse events were found to have longer PICU stays, but we are unable to determine whether longer stays are attributable to the consequences of adverse events or whether adverse events are more likely to occur during a longer PICU admission. That adverse events were sustained more frequently in the youngest of patients is not surprising considering that procedures are often more challenging in this population. Similarly, those children whose illness is the most severe, with high PIM2 scores or following more complex cardiac surgery, are more likely to suffer from unfavorable consequences of their disease and are more likely to require multiple procedures. Compared to patients who did not sustain an adverse event, those who did were mechanically ventilated longer, had a longer PICU length of stay, longer hospital length of stay and were at higher risk of death.

The frequency of adverse events that we report is consistent with data from other PICUs. A previous single-center PICU study reported that 59% of their patients suffered at least one adverse event, at a rate of 52.7 per 100 PICU-days and 1.95 per patient [2] and a multicenter PICU study found an adverse event rate of 28.6 per 100 PICU-days and 2.03 per patient [3]. Reported rates from adult ICU literature range from 14% to 31% (4.5 to 10 events per 100 ICU-days) [13-15]. Hooper and Tibballs [16] investigated the incidence of adverse events in our PICU over a three-month period in 2011 by examining 60 randomly selected patient records and identifying adverse events using a Trigger Tool. They found the incidence of adverse events was 59.9 per 100 PICU-days, consistent with our finding of 67 per 100 PICU-days.

Hospital-acquired infections have been highlighted in recent years as a particularly important aspect of patient safety [17] and are used on our PICU as key performance indices. Despite this they were the leading cause of adverse events on our PICU. Deviations from safe practice standards are associated with higher infection rates [18] and in 2011 we put in place teaching programs targeting practices such as hand-hygiene compliance [19] and full sterile barrier precaution during catheter insertions [20,21]. The incidence of CLABSI fell from 2.75 to 1.9 per 1000 central line days and that of VAP from 3.55 to 1.2 per 1000 ventilator days. This highlights progress that has been made in recent years regarding patient safety. Also noteworthy is that in 1992 the rate of accidental extubation on our PICU was 1.26 per 100 ventilator days [22], which was comparable to other PICU reports [23,24]. The rate of accidental extubation over the period of this study was 0.46 per 100 ventilator days.

The occurrence of an adverse event does not necessarily imply medical negligence [25,26]. Brennan and colleagues [27] showed that the occurrence of adverse events does not correlate with the quality of medical care and

that patients in certain specialties, such as intensive care, are at increased risk.

A strength of this study is that the data was collected prospectively from a large PICU over a relatively long period. The study has important implications for safety improvement in the critical care setting. The type and frequency of adverse events sustained can help guide policy making decisions at a local level, as well as for those intensive care units with similar patient mix. Examples of this include targeted interventions based on the assessment of preventable adverse events, and the development of protocols and guidelines to reduce preventable adverse events such as infection, procedure related incidents and pressure sores. Preventable adverse events are often associated with systems-related deficiencies which can be corrected using ICU or hospital-wide changes in practice. This has been shown to be the case in previous studies not restricted to critical care [28,29]. Data on our key performance indices may be useful to other units for comparative purposes.

The study has several limitations. Firstly, we report findings from a single centre. Although the period of study is quite long, our patient mix consisting of general paediatric and cardiac ICU patients, practices and protocols will differ from other institutions making comparison difficult. In addition, our results may not be directly comparable to other institutions due to differing definitions of what constitutes an adverse event. We included complications associated with underlying disease, such as hyperkalemia in a patient with rhabdomyolysis. Whereas some will argue that these are frequently unavoidable, we felt that they still put the patient at risk and should be recorded to aid target intervention. We did not collect data on medication errors which is a weakness of the study. Accurate measurement of medication errors requires the examination of every patient's drug chart each day. Whilst we monitor medication errors in our PICU with regular audits, resources would not allow us to perform this daily.

Future research should concentrate on methods to create a culture in the critical care setting where discussing patient safety and reporting adverse events is encouraged at a unit and hospital level to reduce the incidence of adverse events on PICU and improve outcome.

CONCLUSIONS

Whilst admission to PICU provides life-saving care for patients, adverse events are common and may be associated with significant morbidity and mortality in our PICU. Adverse events decreased in frequency and severity over the study period. Monitoring of adverse events as part of quality improvement enables targeted intervention to improve patient safety.

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Table 1: Adverse events by year

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Total admissions	1213	1273	1352	1360	1392	1682	1721	1758	1738	1719	15208
Total days of care	5388	5182	5888	6243	6347	7195	7862	7436	7799	7593	66933
All adverse events	4215	4502	4323	4051	4100	4166	4474	4492	5195	5520	45038
Major adverse events	539	506	611	528	509	497	567	576	583	616	5532
All adverse events per 100 days of care	78	87	73	65	65	58	57	60	67	73	67
Major adverse events per 100 days of care	10	10	10	8	8	7	7	8	7	8	8
All adverse events per admission	3.5	3.5	3.2	3.0	2.9	2.5	2.6	2.6	3.0	3.2	3.0
Major adverse events per admission	0.4	0.4	0.5	0.4	0.4	0.3	0.3	0.3	0.3	0.4	0.4

Table 2: Adverse events by category

Category	Major	Minor	Total
Abdominal	419	1905	2324
Cardiac arrest	386	0	386
Cardiovascular	610	6057	6667
Central Nervous System	528	147	675
Fluid and electrolyte	1	16628	16629
Haematological	529	7893	8422
Infection	961	1439	2400
Pressure area	286	0	286
Procedure related	229	1653	1882
Respiratory	1596	3784	5380
Surgery related	373	0	373
Total	5918	39506	45038

Table 3: Patient demographics and frequency of adverse events 2008 to 2017

All admissions (n)		No adverse event (per 100 ICU days)	Adverse event (per 100 ICU days)
Admission	Elective (n1903)	12	205
	Emergency (n6105)	49	399
PIM2	< 1 (n1649)	37	112
	1 to 5 (n7409)	20	306
	5 – 15 (n1541)	3	121
	>15 (n698)	0.08	66
RACHS	RACHS 1 (n518)	0.7	10
	RACHS 2 (n1622)	3	48
	RACHS 3 (n1903)	2	89
	RACHS 4 (n655)	0.4	62
	RACHS 5 (n11)	0	2
	RACHS 6 (n163)	0	35
Pre-existing function on admission	Normal (n2918)	16	87
	Functionally normal (n3815)	14	96
	Mild disability (n3669)	11	138
	Moderate disability (n1853)	9	86
	Severe disability (n1006)	7	44
	< 1 month age (n1947)	4	153
Age	< 1 month (n1947)	26	153
	1-12 months (n4442)	24	175
	1-5 years (n3981)	19	114
	>5 years (n4838)	16	162
ICU LOS category	< 7 days (n12926)	57	217
	7-21 days (n1804)	4	200
	>21 days (n478)	0	187
Invasive Ventilation (n10028)		23	537

PIM: Paediatric Index of Mortality (predicted % risk of death); RACHS: Risk Adjustment in Congenital Heart Surgery; ICU: Intensive Care Unit; LOS: Length of Stay

Table 4: Comparison of duration of mechanical ventilation, mean ICU and hospital length of stay and mortality for patients who encountered an adverse event compared with those who did not

	All admissions (n15208)			Major (n6918)			Minor (n12419)		
	Adverse event (n11,066)	No adverse event (n4,142)	P-value	Major (n2776)	None (n4142)	P-value	Minor (n8277)	None (n4142)	P-value
Mean Invasive Ventilation	79	7	<0.001	212	7	<0.001	35	7	<0.001
Mean ICU LOS	131	35	<0.001	300	35	<0.001	75	35	<0.001
Mean Hospital LOS	484	206	<0.001	921	212	<0.001	851	212	<0.001
Patients died	459	16	<0.001	306	16	<0.001	153	16	<0.001

ICU: Intensive Care Unit
LOS: Length of Stay