

THE FREQUENCY OF ADVERSE EVENTS AMONG PEDIATRIC INPATIENTS IN THE MATERNITY AND CHILDREN TEACHING HOSPITAL IN AL-DIWANIYAH

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Abstract: *An important indicator of the pediatric patient safety is the rate of adverse events (AEs) among in-hospital pediatric patients. AEs are an important cause of morbidity and mortality for pediatric inpatients.*

*Population and methods-*A prospective study was performed on admissions to the Maternity and Pediatrics Teaching Hospital in Al-Diwaniyah(Iraq, 180 km south of Baghdad) from January 1st to June 30th, 2019. All patients were followed-up to document the duration of hospitalization, and the degree of harm at discharge. Daily visits to all wards were carried out for recording demographic information and duration of hospitalization, history of chronic conditions, and excluding those out of this study. A total of 3772 were admissions to the hospital during the study period. Data were spread into worksheet of Microsoft Office Excel 2016 for subsequent analysis.

*Results-*In this study, a 356 (9.4%) from 3772 patients found to have AEs. AEs occurred in 16 (4.5%) patients admitted for up to 5 days, 122 (34.3%) patients admitted for 6 - 10 days, and 218 (61.2%) patients admitted for > 10 days (p value = 0.001, significant). Neonates, whether admitted to neonatal intensive care unit or nursery care unit, were more commonly afflicted by AEs. AEs occurred in 115 (32.3%) out of 356 patients with AEs (p value = 0.008). Another statistically significant value (p value = 0.001) was found in the distribution of AEs among patients of specific wards, namely neonatal intensive care unit (NICU), nursery care unit (NCU), PICU, isolation ward, and surgical ward. AEs occurred in 41 (11.5%) patients in neonatal intensive care unit, 67 (18.8%) patients in nursery care unit, 15 (4.2%) patients in pediatric intensive care unit, 23 (6.5%) patients in isolation ward, and 35 (9.8%) patients in surgical ward. No other level of significance was found regarding distribution of adverse events according to sex, residence, provisional diagnosis, and past medical history. Four classes of patients with AEs were identified as a result of the degree of harm: 205 (57.6%) patients who

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required just intervention, 135 (37.9%) patients who required intervention with prolonged hospital stay, 5 (1.4%) patients with disability at time of discharge, and 11 (3.1%) patients who died from AE. Conclusion-The rate of AEs from provision of medical care in our hospital was high and did not seem to be different from that in other studies around the world. AEs incidence rate was common in neonates admitted either to neonatal intensive care unit or to nursery care unit, in patients with longer duration of hospitalization, and in patients from pediatric intensive care unit, and isolation and surgical wards.

Keywords: *Arousal fluid, Vagina cancer, cervical cancer, Slide, Home procedure*

I. INTRODUCTION

Patient safety has received a growing attention in the world and has become a key priority for health care systems. Patient safety is 1 of the 6 domains of quality of health care defined by the Institute of Medicine (IOM),⁽¹⁾ which estimated 44 000 to 98 000 in-hospital patient deaths annually attributable to medical errors (MEs) in the United States of America.⁽²⁾ Patient safety, as defined by IOM, is a “*freedom from accidental injury*” in the health care setting and the prevention of harm.⁽³⁾ A ME is a health care professional’s act of commission (wrong diagnosis or treatment, or poor performance) or omission (failure of diagnosis or treatment) that unreasonably makes the patient at risk of an unwanted outcome. An adverse event (AE) refers to an unintended injury or complication that results from health care management rather than by the patient’s underlying disease process and results in a prolonged hospitalization of at least 24 hours, disability on discharge, or death. A ME that results in harm to the patient becomes preventable AE. A ME with the potential to result in patient harm but does not do so is said to be potential AE or near miss. In many countries, chart reviews of in-hospital patients have disclosed that 2.9% - 16.6% of patients in hospitals of acute care had 1 or more AEs.⁽⁴⁻¹²⁾

AEs are greatly agreed to be a serious issue with severe sequels on the patient safety⁽¹³⁾ and economically they pose a burden on health care system. In addition to the effects on patients and their families, AEs may have a disastrous effect on caregivers, who may experience emotional consequences from both preventable AEs as well as subsequent litigation of care malpractice.⁽¹⁴⁾ According to the IOM the majority of MEs are caused by defects in health care systems rather than by individuals. Many studies in which researchers have detected pediatric patients at high risk for AEs have been emphasized on medical diagnosis or medical complexity.^(15,16) Knowing the differences in the incidence rates of AEs is critical for recognizing patients at high risk of injury during hospitalization. Pediatric inpatients are more liable to AEs, principally because of an increased risk of medication errors, with a frequency of 11%.^(17,18)

Until recently, AEs have largely detected by passive and voluntary reporting systems, which identify only a minority of all AEs.⁽¹⁹⁾ Active tools that detect AEs have been lacking. The Global Trigger Tool (GTT) is said to be the best tool to detect AEs, with a sensitivity and a specificity of 94% and 100%, respectively.⁽²⁰⁾ Despite limitations (dependence on information from the medical records and fair reliability of reviewer’s judgement), retrospective studies remain a commonly used methodology for assessing the nature, incidence rate and burden of AE.^(21,22) Although prospective studies of could offer better and accurate detection of AE, higher efficacy of detecting those preventable, heavy workload and costs make up strong limitations to such studies.⁽²³⁾

Our study was designed to describe the frequency and type of AEs in pediatric patients admitted to the Maternity

and Children Teaching Hospital in AL-Diwaniyah(Iraq, 180 km south of Baghdad) and to compare the rate of these AEs with other hospitals worldwide.

II. PATIENT AND METHOD

An observational prospective study was undertaken on admissions to our hospital from the 1st of January to the 30th of June, 2019. The hospital has 185 beds and provides services for ~ 10000⁽²⁴⁾ pediatric inpatients annually. It contains emergency unit (14 beds), pediatric ward (96 beds), NICU (14 beds), NCU (25 beds), isolation ward (14 beds), PICU (4 beds), and surgical ward (18 beds). The admissions corresponded to the use of all wards. Re-admission of the same patient was considered as two admissions when there is a full recovery between the two admissions. The outcome was detection of AEs. Resident doctors and nurses were all participating in reporting any AE. They were well-informed through lectures about the AEs. A pre-determined list of AEs obtained through extensive online literature search was explained resident doctors and nurses. A questionnaire (appendix 1) was used and distributed on all wards. To judge as an AE, it was > 50% probably to result from health care rather than from the underlying disease process of the patient.⁽²⁵⁾ All patients with AEs were followed-up until they discharged home to document the duration of hospitalization, and the degree of harm at discharge. Daily visits to all wards were carried out for recording demographic information and duration of hospitalization, history of chronic conditions, and excluding those out of this study.

All data from questionnaire (356 patients) and medical records (3416) were then collected (3772) and spread into worksheet of Microsoft Office Excel 2016 for subsequent analysis. The following patients were excluded from our study: Patients who were older than 15 years old, Patients with a planned hospitalization of < 24 h, Patients who were transferred to another hospital within 24 h of admission, Patients who died within 24 h of admission, Patients who were discharged home on the responsibility of their families, Any patient with an adverse event occurring outside our hospital.

All admissions to hospital were 4129 patients during the 6-month period of the study. The eligible population were 3772 patients after exclusion. A total of 357/4129 (8.6%) patients were excluded as follows: 174 (4.2%) admissions were patients who discharged home on the responsibility of their families shortly after admission; 89 (2.1%) were admissions with a planned hospitalization of < 24 h; 52 (1.2%) were patients older than 15 years old; 23 (0.5%) were patients with an adverse event occurring outside our hospital; 14 (0.3%) were patients who died within 24 h of admission; and 5 (0.1%) were patients transferred to another hospital within 24 h of admission. Recording information from medical records of the patients admitted to our hospital required permission from its chairman. Formal approval was granted whenever required. Patients' names are replaced by numbers for ethical purpose, keeping privacy of our patients.

Data were collected and included in a data-based system and analyzed by *Statistical Package for Social sciences* (SPSS, Inc., Chicago, IL, USA) version 20. Discrete variables, presented as number and percentage, were analyzed using chi² test such as comparison between adverse events and age or sex group. Significance was set at the $p \leq 0.05$ level on all analyses.

III. RESULT

The total admissions to hospital were 4129 patients during the study. After exclusion, our study sample consisted of 3772 patients. Of whom, 356 (9.4%) were noticed to have adverse events, as shown below in figure 1.



Figure 1. The percentage of patients with AEs vs. those without AEs.

Patients in our study were divided into 6 predetermined age groups: 0 – 28 days (neonates), 1 month - 1 year, 1 - 3 years old, 3 - 5 years old, 5 - 10 years old, and 10 - 15 years old, figure 2.

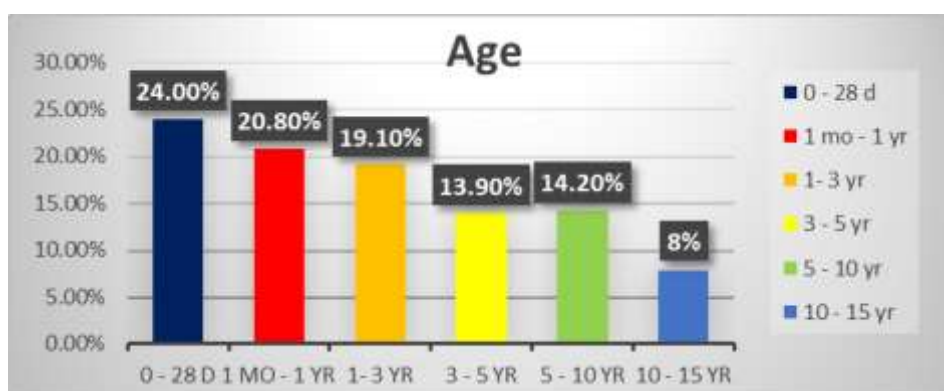


Figure 2. The percent distribution of the study sample by age. Neonates were more commonly afflicted by AEs than any other age group. AEs occurred in 115 (32.3%) neonates from a total of 356 patients with AEs (p value = **0.008, significant**), table 1.

Table 1. The distribution of adverse events by age.		Adverse events				Tot	p-
		Yes		No			
		N	%	N	%		
Age	0 – 28 days	1	3	7	2	905	0.008
	1 month – 1	6	1	7	2	786	
	> 1 - 3 years	6	1	6	1	720	
	> 3 – 5 years	4	1	4	1	524	
	> 5 - 10 years	4	1	4	1	537	
	> 10 -15 years	2	7.	2	8.	300	
Total		3	1	3	1	377	

We found that 1845 (48.9%) patients were male and 1927 (51.1%) patients were female, and 1915 (50.8%) were urban patients while 1857 (49.2%) were rural patients. There was no statistical value of significance in relation to the distribution of AEs according to sex (p value = 0.6, not significant) and address (p value = 0.4, not significant) as shown below in tables 2 and 3, respectively. The diagnosis at presentation of patients was also taken into account and documented in the questionnaire paper. Acute gastroenteritis, pneumonia, respiratory distress syndrome, asthma, prematurity, acute bronchiolitis, congenital heart disease, neonatal jaundice, G6PD deficiency, febrile convulsions, infant of diabetic mother, neonatal sepsis, meningitis, inguinal hernia, acute appendicitis, hypoxic ischemic encephalopathy, encephalitis, measles and transient tachypnea of newborn were the most common reasons for admission of patients with AEs.

History of complex chronic conditions was also questioned for and written down on the questionnaire form. A 223 (5.9%) patients, from all sample, had a positive history of chronic condition. Of whom, 167 (74.9%) had an AE and 56 (25.1%) had no AEs. Congenital heart disease, failure to thrive, asthma, cerebral palsy, diabetes mellitus, epilepsy, Down syndrome, celiac disease and hydrocephalus were the most common chronic conditions. There was no statistical value of significance in the distribution of AEs according to the presence or absence of chronic conditions (p value = 0.6). AEs occurred in patients with or without chronic conditions. AEs occurred in 41 (11.5%) patients in NICU, 67 (18.8%) patients in NCU, 15 (4.2%) patients in PICU, 23 (6.5%) patients in isolation ward, and 35 (9.8%) patients in surgical ward. A statistically significant value (p value = 0.001) was found in the distribution of AEs among patients of specific wards, namely NICU, NCU, PICU, isolation ward, and surgical ward (Table 2).

Type of ward	N	Perce	Adverse events				p-
			Yes		No		
			N	%	N	%	
Neonatal intensive care	3	9.7%	4	1	3	9	0.001
Nursery care unit	5	14.1%	6	1	4	1	
Pediatric medical ward	1	31.2%	7	2	1	3	
Pediatric intensive care	3	0.9%	1	4	1	0	
Isolation ward	9	2.6%	2	6	7	2	
Emergency room	1	32.5%	9	2	1	3	
Pediatric surgical ward	3	9.0%	3	9	3	9	
Total	3	100%	3		3		

Table 3. The distribution of adverse events among patients of different wards.

We also classified the patients according to the *duration of hospitalization* into those admitted for up to 5 days, 6 - 10 days, and > 10 days. We found that 2569 (68.1%) patients admitted for up to 5 days, 810 (21.55%) for 6 - 10 days, and 393 (10.4%) for > 10 days. AEs occurred in 16 (4.5%) patients who were admitted for up to 5 days, 122 (34.3%) patients who were admitted for 6 - 10 days, and 218 (61.2%) patients who were admitted for > 10 days. A statistically

significant difference is present in the rate of AEs among patients admitted for different durations (p value = 0.001). The longer the duration of hospitalization the higher is the risk of adverse events as shown in table 3.

Table 3. The correlation between AEs and duration of		Patients with		Patients		total	p -value
		N	%	No	%		
Duration of hospitalization	Up to 5	16	4.5	25	74.		0.001
	6 – 10	12	34.	68	20.		
	> 10	21	61.	17	5.2		
Total		35	10	34	10		

AEs of our patients were categorized into many types, as shown in table 4.

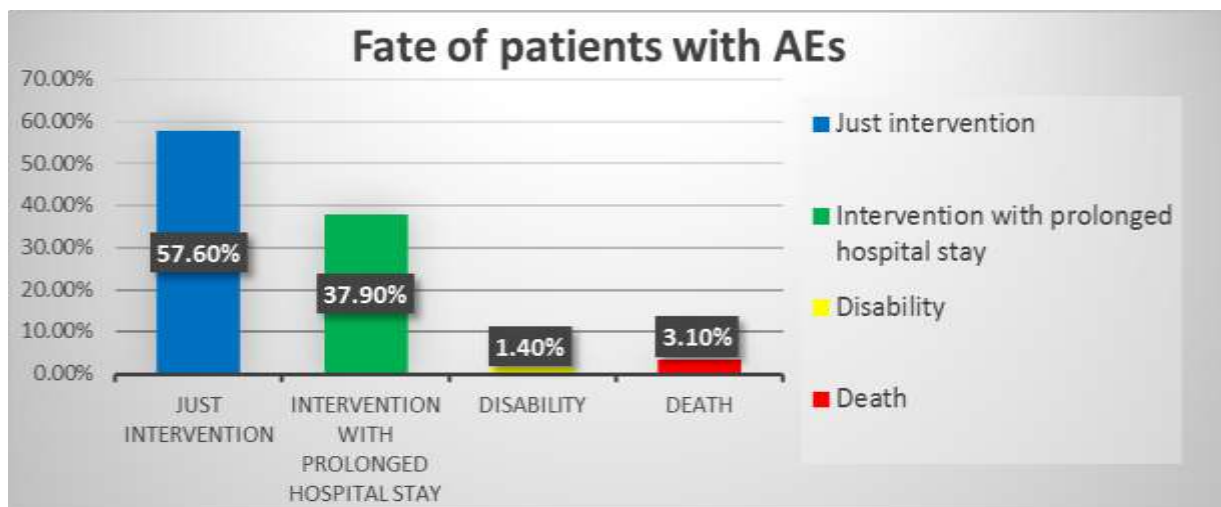
Type of adverse event	No	% from AEs	Type of adverse event	No.	% from AEs
Nosocomial Infections		21.9	Events related to renal, genitourinary or endocrine system		
Total	78				
Nosocomial Diarrhea	7	7.6	Total	8	24.7
IV line infection	20	5.6	Dehydration	31	8.7
Sepsis unrelated to catheter	12	3.4	Fluid overload	28	7.9
Surgical site infection	5	1.4	Hypoglycemia	25	7
Measles	5	1.4	Catheter-associated hematuria	4	1.1
Catheter-associated sepsis	4	1.1	Events related to cardiovascular system		
Pertussis	3	0.9	Total	15	4.2
Ventilator-associated pneumonia	2	0.6	Sinus tachycardia from co-	15	4.2

			administration of positive inotropes		
Events related to respiratory system			Other adverse events		
Total	14	3.9	Total	138	38.8
Tube obstruction	8	2.2	Fluid extravasation	49	13.8
Aspiration pneumonia	4	1.1	Allergic reaction to blood	21	5.9
Unplanned/accidental extubation	2	0.6	Allergic reaction to ceftriaxone	17	4.8
Events related to gastrointestinal system			Allergic reaction to vancomycin	12	3.4
Total	7	1.9	Allergic reaction to penicillin	10	2.8
Ileus	5	1.4	Hypothermia (neonate)	8	2.2
Biliary sludge	2	0.5	Hyperthermia (neonate)	6	1.7
Surgical, obstetrical, or delivery room events			Anaphylaxis to ceftriaxone	6	1.7
Total	16	4.5	Positional head deformity of the neonate	5	1.4
Erb's palsy	5	1.4	Anaphylaxis to snake anti-venin	2	0.6
Wounds during delivery of the newborn	4	1.1	Pressure ulcer (bed sore)	1	0.3
Pneumothorax	4	1.1	Broken bone marrow aspirate needle into the bone	1	0.3
Post-operative hemorrhage	3	0.9	Total	356	

Table 4. Types of adverse events with their frequency and percentage.

Four classes of patients with AEs were identified as a result of the degree of harm by AEs: 205 (57.6%) patients who required just intervention, 135 (37.9%) patients who required intervention with prolonged hospital stay, 5 (1.4%) patients with disability at time of discharge, and 11 (3.1%) patients who died from AEs as shown in figure 4.

Figure 4. The percentage of patients classified according to the degree of harm.



In our study, we found 5 (1.4%) patients to be disabled at time of discharge from the hospital: 4 (1.1%) patients with Erb’s palsy and 1 (0.3%) patient with broken bone marrow biopsy needle inside the iliac bone. Moreover, 11 (3.1%) patients unfortunately died from adverse events in this study: 3 (0.8%) patients died from nosocomial sepsis (unrelated to catheter), 3 (0.8%) patients died from endotracheal tube obstruction, 2 (0.5%) patients died from dehydration, 1 (0.3%) patient died from catheter-associated neonatal sepsis, 1 (0.3%) patient died from aspiration pneumonia, and 1 (0.3%) died from anaphylaxis to ceftriaxone.

IV. DISCUSSION

The current study discussed AEs among pediatric inpatients admitted to Maternity and Pediatrics Teaching Hospital in Al-Diwaniyah and their burden on the life of our patients. It is probably the first study in this city and the country. It described the frequency of AEs to see how close it is to that around the world. It also described percentage of AEs according to parameters such as age, sex, address, past medical history, ward, and duration of hospitalization. We found that 9.4% (356/3772) of inpatients afflicted by AEs. This is consistent with the most recent study about pediatric AEs carried out at 2018 in USA by Stockwell DC, Landrigan CP, Toomey SL, *et al.* where AEs rate was 10.9%.⁽¹⁵⁾ Harvard medical practice study revealed 12.91 AEs per 1000 discharges (about 1.3%) from hospital among patients (birth - 15 years old),⁽⁶⁾ while Colorado and Utah medical practice study revealed 1% of patients had AEs.⁽²⁶⁾ Judging preventability of AEs was made at the time of occurrence after discussing them with senior doctors, with 269 patients (75.6%) having preventable AEs and 87 patients (24.4%) having unpreventable AEs. This contrasts with 210 out of 414 patients (50.7%) having preventable AEs in the most recent study in the USA by Stockwell *et al.*⁽¹⁵⁾ Unpreventable AEs in our study are limited to allergic reactions to blood and drugs (penicillin and ceftriaxone), and anaphylaxis to ceftriaxone and snake anti-venin. Unpreventable AEs from studies around world were high and nearly approaching preventable AEs. This high percentage of unpreventable AEs at the expense of preventable AEs may be due to a number of factors including availability and prescription of variable medications and perfect or near-perfect performance of diagnostic, therapeutic, and nursing issues.

The most significant statistical value in our study was the correlation between AEs and duration of

hospitalization. The longer the duration of hospitalization, the higher is the risk of occurrence of AEs. We found that 16 (4.5%) patients in the study sample who were admitted to the hospital for up to 5 days, 122 (34.3%) admitted for 6 – 10 days, and 218 (61.2%) admitted for > 10 days had AEs (**p value = 0.001**). This significant association between the occurrence of AEs and length of hospital stay may likely be due to a number of factors: the presence of co-morbid condition, history of complex chronic conditions, and use of multiple drugs, as revealed by Härkänen⁽²⁷⁾ and Najjar⁽²⁸⁾ in their studies in 2017.

Studies in the USA by Shareket *al.*⁽²⁹⁾ in 2006 and Agarwal *et al.*⁽³⁰⁾ in 2010 revealed significant correlation between AEs and age and specific types of wards, where higher rates of AEs occurred among neonates in the NICU and patients in the PICU. This could be explained by the use of more invasive diagnostic and therapeutic procedures. This is somewhat consistent with our study, where neonates, either admitted to NICU or nursery care unit, were the commonest age group to be afflicted by the AEs than any other age group (**p value = 0.008**). As regard to type of ward, patients from NICU, NCU, PICU, isolation ward, and surgical ward show the higher percentage of AEs (**p value = 0.001**). The most common AEs were fluid extravasation 49 (13.8%), dehydration 31 (8.7%), fluid overload 28 (7.9%), nosocomial diarrhea 27 (7.6%), iatrogenic hypoglycemia 25 (7%), and allergic reactions to blood 21 (5.9%). In his research in USA at 2018, Stockwell *et al.*⁽¹⁵⁾ described that AEs most frequently occurred as a result of hospital-acquired infections, intravenous line complications, respiratory-related events, and gastrointestinal events.

There was no statistical value of significance in distribution of AEs by presence or absence of chronic conditions (p value = 0.6) despite more patients (167, 46.9%) with chronic conditions had AEs. AEs occurred in patients with or without chronic conditions. This is inconsistent with the study about AEs among children in Canadian hospitals by Matlow AG, Baker GR, Flintoft V, et al.⁽²⁵⁾, where a significant correlation existed between AEs and the history of complex chronic conditions on presentation.

V. CERVICAL FLUID

The rate of adverse events from provision of medical care in our hospital was high and did not seem to be different from that in other studies around the world. AEs incidence rate was significantly common in neonates admitted to NICU or nursery care unit, in patients with longer duration of hospitalization; the longer the duration of hospital stay, the higher is the risk of acquisition of an adverse event, and in patients from PICU, and isolation and surgical wards. No specific gender, address, provisional diagnosis, or past medical history was associated with an increased rate of adverse events.

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