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Measuring Adverse Events in the Neonatal Intensive Care Units in Mit-Ghamr Central Hospital

Mohamed Ibrahim EL-Kalioby[1], Shaimaa Ismail Sahmoud[1], Enas El-Said Metwally Helal[2]
[1]Pediatrics Department, Faculty of Medicine - Suez Canal University, Egypt
[2]Pediatrics and Neonatology Department, Mit-Ghamr Central Hospital, Egypt
Corresponding author: Enas El-Said Metwally Helal, **E-mail: Enaselsaid929@gmail.com, Mobile: +201032644043**

ABSTRACT

Background: Children in neonatal intensive care units (ICU) are more susceptible to medical errors. Measuring adverse events is a very important issue for patient safety and using trigger tool methodology as a different strategy is beneficial to both more focused as well as rapid chart review to establish whether or not an adverse event occurred.

Aim: For evaluation the prevalence of adverse events (AEs) in Mit-Ghamr Neonatal ICU using the trigger tool and to evaluate the prevalence of adverse events in Mit-Ghamr neonatal Intensive Care Unit with other hospitals in Egypt and abroad.

Subjects and Methods: A cross sectional analytic study using medical record review and charts study was done including 511 medical records, it consisted of all neonates admitted to Mit-Ghamr neonatal ICU between 1st January to 31 December 2017.

Results: a total of 465 adverse events with incidence rate of 0.91 adverse event/patient and 1.16 trigger/patient. The most common adverse event was nosocomial infections with more than half of the overall adverse events (n=282; 55.2%), followed by catheter infiltration (n=64; 12.5%), hypotension was 5.5%, respiratory arrest 4.7%, accidental extubation 4.1%, death 3.5%, renal insufficiency 2%, and seizures was 0.6%. Category (F) was the most prevalent harm category among the occurred adverse events (45.7%) followed by category (E) (28.8%). Only a minority (3.1%) had a permanent harm (category G) and category H was 22.4%.

Conclusion: Nosocomial infections constitute the majority of all adverse events, followed by catheter infiltration and hypotension.

Keywords: Patient Safety, Trigger Tool

INTRODUCTION

Patient safety is a priority for health care providers. However, some undesirable incidents can occur even with the goal of providing a good care to the patient. These undesirable incidents can lead to injury to the patient. In this case it is defined as an adverse event like (nosocomial infection, catheter infiltration, burn, medication error or respiratory arrest) [(1)].

Childrens in neonatal intensive care units are more at risk for medical errors due to their low weight, physiological immaturity, their limited compensating abilities, and the chance that they may be admitted for long lengths of time as well as exposed to multiple therapies that may lead to injury. Additionally, because of the likelihood that they may be admitted for long periods of time, they are subjected to several interventions that may lead to harm [(2)].

When a patient experiences a medical error, there should be an investigation conducted to uncover the variables that contributed to the incident, regardless of whether or not the patient was harmed by the error (referred to as an adverse event or a near miss) [(3)].

Adverse events can be identified by triggers that may occur in NICU. For example, nosocomial infection could be identified by the trigger antibiotic use, the interventricular hemorrhage could be identified by abnormal cranial imaging; acute renal failure could be identified by the trigger increased creatinine [(4)].

Measuring adverse events is a very important issue for patient safety and using trigger tool methodology as a different strategy in order to facilitate a more targeted and time-saving chart review, it is beneficial to determine whether or not an adverse event occurred [(5)].

The Institute for Healthcare Improvement Global Trigger Tool has been proposed a retrospective chart review as a good method to detect adverse events [(6)].

It was discovered that the glucose tolerance test (GTT) may be utilized in the neonatal ICU to assess adverse events, as well as to detect a two to three times larger harm rate than was previously discovered with the use of alternative methodologies [(7)]. It is proved to be a flexible tool that can be used in different environments and it can accurately identify different types of adverse events at low cost [(8)].

As patient safety is of particular concern to health authorities, the health care sector in Egypt should identify and collect information on adverse events to know their incidence and prevent their recurrence, in addition there is lack of studies and information about adverse events in NICUs, such information is essential for improving the quality and accuracy of the care provided in NICUs in Egypt.

This study used The Global Trigger Tool to retrospectively identify the neonatal adverse events in Mit-Ghamr neonatal ICU.

SUBJECTS AND METHODS

This was a cross sectional analytic study using medical record review and charts of Mit-Ghamr Central

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Hospital's NICU. 20 incubators, 4 mechanical ventilators, 4 continuous positive airway pressure (CPAP) machines, and 2 resuscitators are available.
The time needed for this study was as follow: 1st-2nd month for preparing the protocol, 3rd-6th month for data collection and field work, 7th-9th month for data management and 10th-12th month for editing.

Study population: 511 medical records of all neonates admitted to Mit-Ghamr neonatal ICU between 1st January to 31 December 2017.

Inclusion criteria: All neonates admitted in Mit-Ghamr neonatal Intensive Care Unit for at least two days [(9)] and were either released from the Neonatal Intensive Care Unit, transferred to another facility, or passed away while being treated there.

Exclusion criteria: Patients were excluded if their medical records were not completed.

Methods:

Record review of the study sample was done; all triggers and adverse events like (nosocomial infection, catheter infiltration, burn, respiratory arrest, etc.) were recorded according to The IHI Global Trigger Tool check list. Inter-rater reliability was advantageous, with the mean Kappa varying from 0.53 to 0.73; the technique's accuracy to detect individuals who had at least one adverse event being 94.9% as well as its specificity to detect those with no incidents being one hundred percent [(10)].

The National Coordinating Council for Medication Error Reporting and Prevention's error classification system was employed to describe adverse events to: Category E: caused or helped bring about temporary injury to the sufferer, necessitating treatment. Category F: caused or exacerbated the patient's condition to the point where they needed to be hospitalized initially or for an extended period of time. Category G: resulted in or contributed to the individual's irreversible harm. Category H: caused or played a role in an injury that necessitated medical attention. Category I: Lead to the patient death [(11)]. Adverse events cause temporary harm (E and F) while that causes permanent harm (G through I).

Ethical Approval:

The study was approved by the Ethics Board of Suez Canal University. An informed written consent was taken from the caregivers of the participants in the study to use their data in research. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

SPSS version 20.0 (IBM Corp., Armonk, New York) was utilized in the process of data analysis. The terms used to describe qualitative data were number and percentage. The range (minimum & maximum), standard deviation, mean, median, as well as interquartile range were the statistical measures that were used to characterize the quantitative data. The significance of the findings was established at the five percent level. The chi-square test was used to compare outcomes for categorical variables among several groups. The student t-test was applied in order to normally distribute quantitative data to contrast and compare two separate study groups. The Mann Whitney test was used on quantitative data with asymmetric distributions to compare two examined groups. The ANOVA test was employed to evaluate multiple groups against one another for quantitative variables with a normally distributed distribution.

RESULTS

Baseline features for the trial sample, of the 511 taking part in incubators, are recorded in table 1. The mean gestational age of the neonates was35.25 ± 5.86 days. Females represented about 59% of the patients. The average birth weight of the neonates was 2567.53 ± 728.53 grams. The mean duration of stay at NICU was 6.91 ± 6.07.

Table (1): Baseline characteristics of the studied sample

Variables	n = 511
Gestational age (weeks), mean ± SD	35.25 ± 5.86
Gender	
Male	209 (40.9)
Female	302 (59.1)
Birth weight (grams), mean ± SD	2567.53 ± 728.53
Length of stay in NICU (days)	
mean ± SD	6.91 ± 6.07
≤5 days	297 (58.1)
6-10 days	120 (23.5)
11-15 days	41 (8)
≥16 days	53 (10.4)
Data are presented as number (%) or mean ± SD	

Figure 1 shows that triggers were reported in 58.9% of the cases. To illustrate, a total of 591 triggers were detected among 301 cases out of 511 neonates who were admitted in NICU, resulting in incidence rate of 1.16 triggers per patient; meanwhile, a total of 465 AEs were noticed resulting in an incidence rate of 0.91 adverse events per patient.

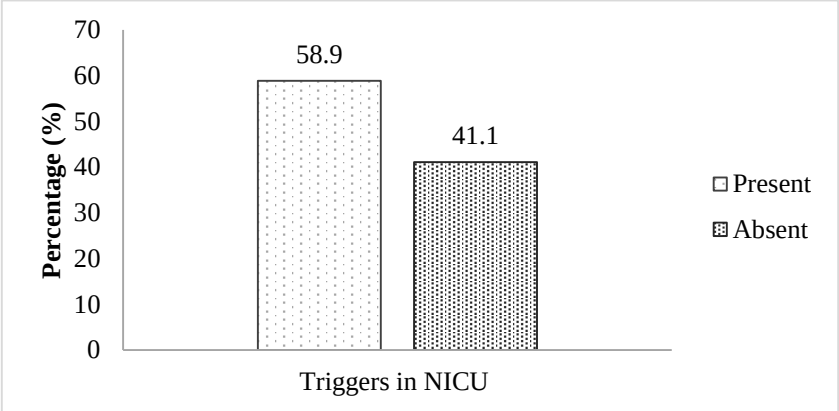

Figure (1): Frequency of triggers in NICU at Mit-Ghamr Central Hospital

Figure 2 displays the determined adverse event frequencies. The most common adverse event was hospitals acquired infections with more than half of the overall adverse events (n=282; 55.2%), followed by catheter infiltration (n=64; 12.5%) with a difference of more than 40% than the former.

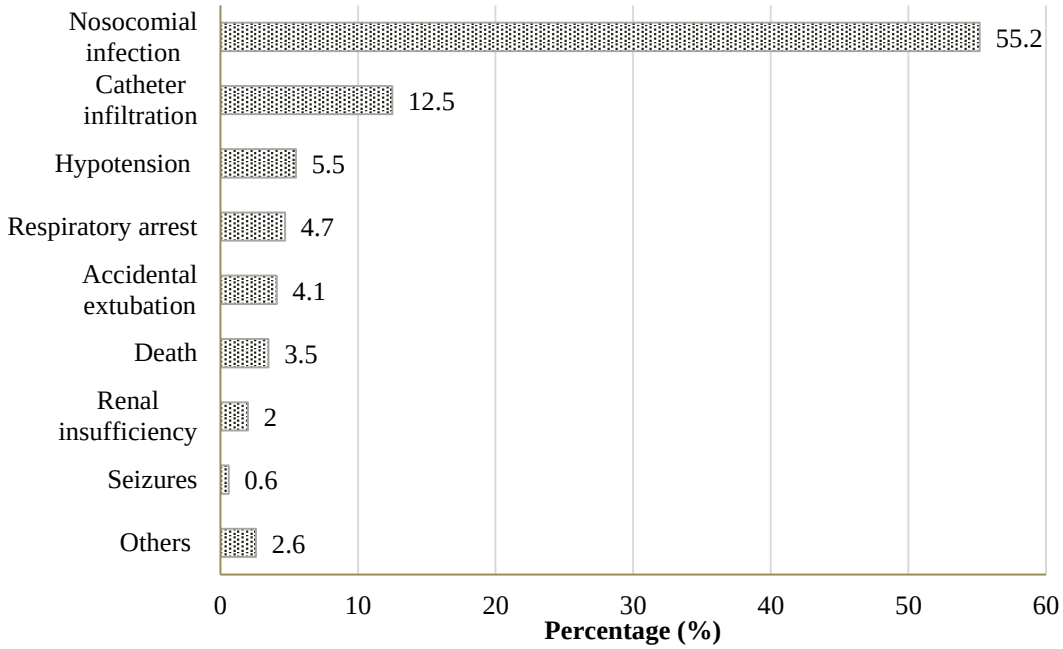

Figure (2): Frequency of adverse event in NICU at Mit-Ghamr Central Hospital

As shown in figure (3), category (F) was the most prevalent harm category among the occurred adverse events.

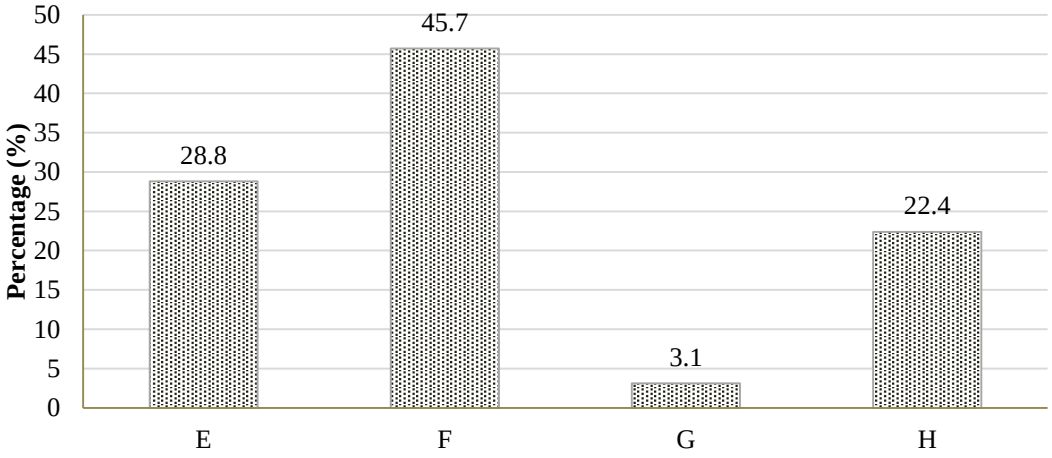

Figure (3): Adverse events harm category

Table (2) shows the relationship between harm category of AE at NICU and baseline characteristics of the examined sample. It was detected that neonates with permanent harm had significantly decreased birth weight and longer time spent in NICU than those with temporal harm.

Table (2): Association between harm category of adverse event at NICU and baseline characteristics of the studied sample (n=301).

Variables	Harm category of adverse event		P-value
	Permanent (n= 6)	Temporal (n=295)	
Gestational age (weeks), mean ± SD	30.50 ± 5.50	33.88 ± 7.24	0.055 [a]
Gender			
Male	3 (50)	125 (42.4)	0.7 [b]
Female	3 (50)	170 (57.6)	
Birth weight, mean ± SD	1691.67 ± 836.3	2375.48 ± 789.1	**0.024**[a]
Length of stay in NICU			
mean ± SD	18.33 ± 9.11	8.96 ± 6.83	**0.008**[a]
≤5 days	0	108 (36.6)	**0.01**[b]
6-10 days	2 (33.3)	97 (32.9)	
11-15 days	0	41 (13.9)	
≥16 days	4 (66.7)	49 (16.6)	
Data are presented as number (%) or mean ± SD			

[a] p-values are based on Mann-Whitney U test.
[b]p-values are based on Fisher Exact test.

Table 3 shows the relationship between trigger occurrence at NICU and baseline features of the research population. The results demonstrated that triggers took place more frequently among neonates with lower gestational age, lower birth weight and with longer stay in NICU.

Table (3): Association between trigger at NICU and baseline characteristics of the studied sample

Variables	Trigger n (%)		P-value
	Absent (n= 210)	Present (n= 301)	
Gestational age (weeks), mean ± SD	37.33 ± 1.40	33.81 ± 7.22	**<0.001** [a]
Gender			
Male	81 (38.6)	128 (42.5)	0.37 [b]
Female	129 (61.4)	173 (57.5)	
Birth weight (grams), mean ± SD	2861.4 ± 492.1	2361.8 ± 794.4	**<0.001** [a]
Length of stay in NICU* (days), mean ± SD	3.70 ± 1.43	9.15 ± 6.99	**<0.001** [a]
≤5 days	189 (90)	108 (35.9)	**<0.001** [b]
6-10 days	21 (10)	99 (32.9)	
11-15 days	0	41 (13.6)	
≥16 days	0	53 (17.6)	

[a] p-values are based on Mann-Whitney test, [b]p- values are based on Mann-Whitney test
*__NICU__=neonatal intensive care unit

Table 4 displays the characteristics of the first eight triggers used by the Global Trigger Tool checklist. Each trigger of them was characterized by its own associated adverse event. Nosocomial infection was the most prominent adverse event that occurred with the first and second trigger. Moreover, accidental extubation, hypotension, respiratory arrest and catheter infiltration were the most prevalent adverse events associated with trigger three, trigger four, trigger five, trigger six and trigger seven, respectively. Trigger eight (Naloxone) was not reported in any case. Each trigger of them was characterized by its own associated adverse event. Seizure was the most prominent adverse event that occurred with the seizures and phenobarbital triggers. Moreover, rising serum creatinine trigger was associated by renal insufficiency in 10 cases. Trigger 11 "Necrotizing enterocolitis (NEC) "was not reported in any case.

Table (4): Characteristics of the first eight triggers by the Global Trigger Tool checklist at NICU (1-16)

Variables	Trigger 1	Trigger 2	Trigger 3	Trigger 4	Trigger 5	Trigger 6	Trigger 7	Trigger 8	Trigger 9	Trigger 10	Trigger 11	Trigger 12	Trigger 13	Trigger 14	Trigger 15	Trigger 16
Trigger occurrence	91 (17.8)	278 (54.4)	21 (4.1)	29 (5.7)	24 (4.7)	17 (3.3)	66 (12.9)	0 (0)	2 (0.4)	12 (2.3)	0 (0)	3 (0.6)	3 (0.6)	6 (1.2)	2 (0.4)	3 (0.6)
Associated adverse event																
Nosocomial infection	91 (100)	278 (54.4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	-	0 (0)	0 (0)	-	0 (0)	0 (0)	0 (0)	0 (0)	2 (66.7)
Catheter infiltration	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	64 (96.9)	-	0 (0)	0 (0)	-	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Hypotension	0 (0)	0 (0)	0 (0)	28 (96.6)	0 (0)	0 (0)	0 (0)	-	0 (0)	0 (0)	-	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory arrest	0 (0)	0 (0)	0 (0)	1 (3.4)	23 (95.8)	0 (0)	0 (0)	-	0 (0)	0 (0)	-	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Accidental extubation	0 (0)	0 (0)	21 (100)	0 (0)	0 (0)	0 (0)	0 (0)	-	0 (0)	0 (0)	-	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Death	0 (0)	0 (0)	0 (0)	0 (0)	1 (4.2)	17 (100)	0 (0)	-	0 (0)	0 (0)	-	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal insufficiency	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	-	0 (0)	10 (83.3)	-	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Seizures	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	-	0 (0)	0 (0)	-	3 (100)	3 (0.6)	0 (0)	0 (0)	0 (0)
Others									2 (100)	2 (16.7)	-	0 (0)	0 (0)	6 (100)	2 (100)	1 (33.3)
Adverse event category																
Temporal harm	91 (100)	278 (100)	21 (100)	29 (100)	24 (100)	17 (100)	61 (92.4)	-	1 (50)	11 (91.7)	-	3 (100)	3 (100)	6 (100)	2 (100)	2 (66.7)
Permeant harm	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	5 (7.6)	-	1 (50)	1 (8.3)	-	0 (0)	0 (0)	0 (0)	0 (0)	1 (33.3)
Adverse event preventable																
Yes	87 (95.6)	71 (25.5)	19 (20.5)	9 (31.1)	4 (16.7)	2 (11.8)	66 (100)	-	1 (50)	10 (83.3)	-	0 (0)	0 (0)	0 (0)	1 (50)	2 (66.7)
No	4 (4.4)	0 (0)	0 (0)	20 (68.9)	20 (83.3)	15 (88.2)	0 (0)	-	1 (50)	2 (16.7)	-	3 (100)	3 (0.6)	6 (100)	1 (50)	1 (33.3)
Occurrence of adverse event in NICU																
Yes	86 (94.5)	79 (28.4)	20 (95.2)	29 (100)	20 (83.3)	14 (82.4)	66 (100)	-	1 (50)	12 (100)	-	3 (100)	3 (0.6)	4 (66.7)	1 (50)	1 (33.3)
No	5 (5.5)		1 (4.8)	0 (0)	4 (16.7)	3 (17.6)	0 (0)	-	1 (50)	0 (0)	-	0 (0)	0 (0)	2 (33.3)	1 (50)	2 (66.7)

DISCUSSION

Patient safety is described as freedom from unintended injury; it is an issue of international concern, but now looks to get excessive precedence on the healthcare quality agenda worldwide [12].

Neonatal intensive care units, as a place that's both delicate and intricate and because of the special characteristics of its patients, there is a significant possibility that AEs will occur in this region [13].

The occurrence of adverse events is a problem impacting the quality of healthcare and causing increasing social expenses, causing patients and their families to suffer. Newborns (NBs) prematurely or with extremely low birth weights, especially those in critical condition as well as hospitalized in neonatal intensive care units, appear to be at greater risk for severe illness [14]. Adverse events symbolize a significant burden to the healthcare system in both adults besides pediatric populations. It has been linked with increased morbidity and mortality, prolonged time of stay in hospital, and extra healthcare costs, so detection of adverse events is very important issue and will offer information for achieving the target safety in NICU setting by finding strategies that help protect against adverse events or reduce it [1].

Detection of adverse events will offer information for achieving the target safety in NICU setting. The Institute for Healthcare Improvement had recommended the trigger tool method to identify adverse events rates as a transition from measuring errors to that of measuring harm, it is an effective method to identify harm but one tool does not function in all contexts [15].

The present study is reviewing 511 charts, the females constituted 59% and males constituted 41%. The mean gestational age was 35.25±5.86 weeks and the mean weight on delivery was 2567.53 ± 728.53 gm. NICU stay for newborns was 6.91±6.07 days.

Frequency of triggers in NICU in the present study was reported in 58.9% of the cases out of 511 neonates who were admitted in NICU resulting in incidence rate of 1.16 triggers per patient. Triggers took place more frequently in neonates with lower gestational age less than 33.81±7.22 and did not occur in neonates with gestational age above 37.33±1.40 week. Triggers took place more frequently in neonates with low birth weight <2361.84±794.4 gm and absent in neonates above 2816.4±492.1 gm and took place more frequently in neonates with longer stay in NICU more than 9.15±6.99 days and absent in neonates with short stay in NICU 3.70±1.43 days.

The present data using the trigger tool method identified a total of 465 adverse events with incidence rate of 0.91 adverse event/ patient. Adverse events in literature were relatively common. In a study done by **Sharek *et al.*** [4] using trigger tool in NICU population, 749 charts were reviewed randomly selected from 15 NICU, revealed 2218 triggers and identified 554 unique adverse events, an adverse event rate of 0.74 adverse event/ patient and 2.96 trigger/ patient. The same study showed that adverse events were higher for cases under 28 weeks gestation and below 1500-gram birth weight.

Another trial by **Lanzillotti *et al.*** [1] using 12.471 reports showed that only 4.380 of events were adverse events and 62.94% occurred in NICU. A study by **Kugelman *et al.*** [16] in 2018 stated that incidence of adverse events was 0.4 adverse events per patient and 18.8 infant per 100 hospitalized infant and the adverse events were associated with infants with less gestational age in addition low birth weight and longer length of stay. Research by **ELMeneza *et al.*** [17] displayed that 43.20% of total 2724 medical errors in NICUs were adverse events and 51.7% of reported incidents were among males and 45.5% of these incidents were among newborns between 37 and 42 weeks of gestation and 56.8% of incidents occurred among neonates with birth weight between 2000- and 3500-gram birth weight.

The present study revealed that category (F) was the most prevalent harm category (45.7%) followed by group (E) adverse events (28.8%) and both resulted in temporary harm. It means that more than 70% of adverse events fall into less severe adverse event category. Group G adverse events were (3.1%) while H category was (22.4%) and both resulted in permanent harm.

The present results agreed with the study by **Sharek *et al.*** [4], as about 77% of adverse events fall into the less severe harm category that result in temporary harm. Moreover, category (E) was 60%, category (F) was 17.3%, category (G) was 6.5%, category (H) was 6.5% and I was 9.7%. Harm categories in a study done by **Suresh *et al.*** [18] showed that minor harm occurred in 25%, serious harm in 1.9% and death was reported in 0.15%. The study's classifications depended on those developed by the National Coordinating Council for Medication Error Reporting and Prevention. In a study done by **EL Meneza *et al.*** [17] harm grades diverse from low in 25.6% to severe in 2.96% of cases while **Suresh *et al.*** [18] reported that minor harm occurred in 25% and serious harm was 1.9% of cases.

The relation between harm category of adverse events at NICU and baselines characteristics of the studies sample, found that neonates with permanent harm had significantly lower gestational age 30.50±5.50 weeks or less while temporal harm took place in neonates with gestational age of 33.88±7.24 weeks.

Neonates with permanent harm had lower birth weight 1691.67±836.3 gram or less while temporal harm took place in neonates with birth weight above 2375.48±789.1 gram. Longer length of stay in NICU above 18.33±9.11 was associated with permanent harm while temporal harm took place in neonates with shorter stay in NICU less than 8.96±6.83 day. The present study agreed with a study done by **Lanzillotti *et al.*** [1] that reported that permanent harm was significantly associated with infants with less gestational age and lower birth weight and a more extended stay.

In the present study NI incidence rate was 55.2% and this nearly agreed with the outcomes of a trial done which showed an incidence of 50.7%. [1]

There is considerable heterogeneity in the reported rates of NI among various studies; for example, the incidence of NI was reported to range from 6.2 percent to 50.7 percent [19]. **Sharek *et al.*** [4] reported an incidence rate of 27.8% and another study by **Couto *et al.*** [20] stated an incidence of 36.6%. A study done by **Lanzillotti *et al.*** [1] showed that nosocomial infection was 20.2% [1]. **Mahmud *et al.*** [15] conveyed an incidence rate of 17.5% of nosocomial infection.

The high rate of NI in the current research can be determined by the fact that most similar research were carried out in developed countries, which is consistent with a study that found NI rates to be three to twenty times higher in developing countries than in developed countries [21].

In the present study catheter infiltration rate was 12.5%. This nearly agreed with the results of the study was done by **Sharek *et al.*** [4], which revealed a rate of 15.5%. However, it is much lower than that reported by a study done by **Atay *et al.*** [22] that revealed an incidence rate of catheter infiltration was 57% to 70%. Another study done by **Lanzillotti *et al.*** [1] reported that catheter infiltration rate was 24.9%. **Pettit,** [23] reported that catheter infiltration ranged from 23 to 78 %.

Hypotension in NICU in the present data was 5.5%. It is nearly agreed with **Sharek *et al.*** [4] that was 7.6%. However, it is lower than that reported by **Dempsey and Barrington,** [24]. They reported that the incidence of hypotension ranged between 20 to 50 percent in much decreased birth weight infants. **Peter *et al.*** [25] reported also that 41% of neonates had 1 or more episodes of MAP less than 30 mm Hg within the first 3 days.

Respiratory arrest in the present study was 4.7%. It is double that mentioned by **Sharek *et al.*** [4] that was 2.3%. Respiratory arrest affects up to 7% of all term newborns [26].

Accidental extubation in the present study was 4.1% while in the study by **Sharek *et al.*** [4] it was much higher (8.3%). In a trial done by **Berkow and Kanowitz,** [27] the rate of unplanned extubation was as high as 12%. Moreover, **EL Meneza *et al.*** [17] reported that unplanned extubation varied between 11.5 and 19.2%. While **Lanzillotti *et al.*** [1] reported in 2015 that accidental extubation rate was 8.5%. **Ligi *et al.*** [28] reported incidence rate of 58 %. On the other hand, **da Silva *et al.*** [29] reported a very low figure (1.28%).

Seizures in the present study were 0.6%. It is much lower than that reported by **Sharek *et al.*** [4] that were 5.1% and that reported by **Glass,** [30], as seizures rate ranged between 1 to 5 per 1000 live births. A study done in 2017 by **Hu *et al.*** [31] revealed that seizures were 18.32%. **Pisani *et al.*** [32] reported neonatal seizures were 2.29 per 1000 live births. While **Inder *et al.*** [33] reported that the frequency rate of neonatal seizures was 1.5%. The actual rate of seizures during this period may be higher due to inaccurate diagnosis of subclinical seizures [30].

Renal insufficiency in the present study was 2% which agreed with **Sharek *et al.*** [4] as it was 2.5%. While **Agras *et al.*** [34] reported a rate of 3.4%.

Death in the present study was 3.5%. It is slightly lower than that reported by **Sharek *et al.*** [4] that was 4.9% and nearly double that mentioned by **Wang *et al.*** [35] that the death rate was 1.2% of all admitted neonates in 26 NICUs in tertiary neonatal intensive care unit in China.

CONCLUSION

The present study is one of the few studies attempt to construct and assess trigger tool to notice adverse events in the NICU setting. The results suggested that newborns with an inadequate birth weight and an earlier gestational age are the most vulnerable to adverse events. The most typical adverse events are infections that occur in the hospital, catheter infiltration, and hypotension with more than 70% of events falling into the less harm category of E and F. In comparison with non-trigger chart review and other methods of detection like hospital-based incidence reporting or administrative databases, the trigger tool method seems to be more efficient, effective and more accurate in identifying adverse events. Good inter-rater reliability was observed, with mean Kappa values among 0.53 and 0.73; the method's sensitivity to detect people who had at least one adverse event was 94.9%, while its specificity to detect individuals with no incidents was 100%. Our results support this opinion and we should use it to provide prevention techniques to lessening the risk to neonatal patient population and enhance neonatal outcome.

DECLARATIONS

- **Consent for publication:** I attest that all authors have agreed to submit the work.
- **Availability of data and material:** Available
- **Competing interests:** None
- **Funding:** No fund
- **Conflicts of interest:** no conflicts of interest

REFERENCES

1. **Lanzillotti S, De Seta M, de Andrade C *et al.* (2015):** Adverse events and other incidents in neonatal intensive care units. Ciencia and Saude Coletiva, 20(3): 937-46. doi: 10.1590/1413-81232015203.16912013.
2. **Kaushal R, Bates D, Landrigan C *et al.* (2001):** Medication errors and adverse drug events in pediatric inpatients. JAMA., 285(16):2114-20. doi: 10.1001/jama.285.16.2114.
3. **El-Shazly A, Al-Azzouny M, Soliman D *et al.* (1995):** Medical errors in neonatal intensive care unit at Benha University Hospital, Egypt. EMHJ., 23(1): 32-8.
4. **Sharek P, Horbar J, Mason W *et al.* (2006):** Adverse events in the neonatal intensive care unit: development, testing, and findings of an NICU-focused trigger tool to

identify harm in North American NICUs. Pediatrics, 118(4):1332-40. Doi: 10.1542/peds.2006-0565.

5. **Resar R, Rozich J, Simmonds T *et al*. (2006):** A trigger tool to identify adverse events in the intensive care unit. The Joint Commission Journal on Quality and Patient Safety, 32(10):585-90. doi:10.1016/S1553-7250(06)32076-4.
6. **Mortaro A, Moretti F, Pascu D *et al*. (2017):** Adverse events detection through global trigger tool methodology: Results from a 5-year study in an Italian hospital and opportunities to improve interrater reliability. Journal of Patient Safety, 17(6): 451-457. DOI: 10.1097/PTS.0000000000000381.
7. **Kirkendall E, Kloppenborg E, Papp J *et al*. (2012):** Measuring adverse events and levels of harm in pediatric inpatients with the Global Trigger Tool. Pediatrics, 130(5):e1206-14. Doi: 10.1542/peds.2012-0179.
8. **Classen D, Resar R, Griffin F *et al*. (2011):** Global trigger tool shows that adverse events in hospitals may be ten times greater than previously measured. Health affairs, 30(4):581-9. Doi: 10.1377/hlthaff.2011.0190
9. **Landrigan C, Parry G, Bones C *et al*. (2010):** Temporal trends in rates of patient harm resulting from medical care. New England Journal of Medicine, 363(22):2124-34. DOI: 10.1056/NEJMsa1004404
10. **Naessens J, O'Byrne T, Johnson M *et al*. (2010):** Measuring hospital adverse events: assessing inter-rater reliability and trigger performance of the Global Trigger Tool. International Journal for Quality in Health Care, 22(4):266-74. Doi: 10.1093/intqhc/mzq026
11. **Griffin F, Resar R (2009):** IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement, 10(4):153-158.
12. **Rodrigues C, Santos V, Sousa P (2017):** Patient safety and nursing: interface with stress and Burnout Syndrome. Revista Brasileira de Enfermagem., 70(5):1083-8. Doi: 10.1590/0034-7167-2016-0194.
13. **Alghamdi A, Keers R, Sutherland A *et al*. (2019):** Prevalence and nature of medication errors and preventable adverse drug events in paediatric and neonatal intensive care settings: a systematic review. Drug safety, 42(12):1423-36. Doi: 10.1007/s40264-019-00856-9.
14. **Caeymaex L, Lebeaux C, Roze J *et al*. (2020):** Study on preventing adverse events in neonates (SEPREVEN): A stepped-wedge randomised controlled trial to reduce adverse event rates in the NICU. Medicine, 99(31): 20912. doi: 10.1097/MD.0000000000020912.
15. **Mahmud M, Kumar A, Ali A *et al*. (2023):** Prevalence of nosocomial infection Pre-and Post-COVID 19 Pandemic in a Tertiary Care Hospital in Karachi. The Professional Medical Journal, 30(06): 722-726. Doi: 10.29309/TPMJ/2023.30.06.7423.
16. **Kugelman A, Inbar-Sanado E, Shinwell E *et al*. (2008):** Iatrogenesis in neonatal intensive care units: observational and interventional, prospective, multicenter study. Pediatrics, 122(3):550-5. Doi: 10.1542/peds.2007-2729.
17. **ELMeneza S, Abd ELMoean A, Abd ELmoneem N (2020):** Study of medical errors triggered by medical devices in neonatal intensive care unit. Edelweiss Pediatrics J., 1(1):7-12.
18. **Suresh G, Horbar J, Plsek P *et al*. (2004):** Voluntary anonymous reporting of medical errors for neonatal intensive care. Pediatrics, 113(6):1609-18. Doi: 10.1542/peds.113.6.1609.
19. **Zafar N, Wallace C, Kieffer P *et al*. (2001):** Improving survival of vulnerable infants increases neonatal intensive care unit nosocomial infection rate. Archives of pediatrics and adolescent medicine, 155(10):1098-104. doi:10.1001/archpedi.155.10.1098.
20. **Couto R, Carvalho E, Pedrosa T *et al*. (2007):** A 10-year prospective surveillance of nosocomial infections in neonatal intensive care units. American Journal of Infection Control, 35(3):183-9. Doi: 10.1016/j.ajic.2006.06.013.
21. **Zaidi A, Huskins W, Thaver D *et al*. (2005):** Hospital-acquired neonatal infections in developing countries. The Lancet, 365(9465):1175-88. DOI: 10.1016/S0140-6736(05)71881-X.
22. **Atay S, Şen S, Cukurlu D (2018):** Phlebitis-related peripheral venous catheterization and the associated risk factors. Nigerian Journal of Clinical Practice, 21(7):827-31.
23. **Pettit J (2003):** Assessment of the infant with a peripheral intravenous device. Advances in neonatal care: official journal of the National Association of Neonatal Nurses, 3(5):230-40. DOI: 10.1053/S1536-0903(03)00171-1.
24. **Dempsey E, Barrington K (2007):** Treating hypotension in the preterm infant: when and with what: a critical and systematic review. Journal of Perinatology, 27(8):469-78. Doi:10.1038/sj.jp.7211774.
25. **Peter D, Gandy C, Hoffman S (2017):** Hypotension and adverse outcomes in prematurity: comparing definitions. Neonatology, 111(3):228-33. Doi: 10.1159/000452616
26. **Edwards M, Kotecha S, Kotecha S (2013):** Respiratory distress of the term newborn infant. Paediatric respiratory reviews, 14(1):29-37. Doi: 10.1016/j.prrv.2012.02.002
27. **Berkow L, Kanowitz A (2020):** Unplanned extubation: A common and costly complication of airway management. Patient Safety, 2(1):22-30. DOI: 10.33940/med/2020.3.2.
28. **Ligi I, Millet V, Sartor C *et al*. (2010):** Iatrogenic events in neonates: beneficial effects of prevention strategies and continuous monitoring. Pediatrics, 126(6):1461-8. Doi:10.1542/peds.2009-2872.
29. **da Silva P, Reis M, Aguiar V *et al*. (2013):** Unplanned extubation in the neonatal ICU: a systematic review, critical appraisal, and evidence-based recommendations. Respiratory care, 58(7):1237-45. Doi: 10.4187/respcare.02164.
30. **Glass H (2014):** Neonatal seizures: advances in mechanisms and management. Clinics in perinatology, 41(1):177-90. DOI: 10.1016/j.clp.2013.10.004.
31. **Hu S, Hung K, Chen H (2017):** Neonatal seizures: incidence, etiologies, clinical features and EEG findings in the neonatal intensive care unit. Epilepsy J., 3(117):2472-0895. DOI: 10.4172/2472-0895.1000117.
32. **Pisani F, Facini C, Bianchi E *et al*. (2018):** Incidence of neonatal seizures, perinatal risk factors for epilepsy and mortality after neonatal seizures in the province of Parma, Italy. Epilepsia, 59(9):1764-73. Doi:10.1111/epi.14537.
33. **Inder T, Darras B, de Vries L *et al*. (2017):** Volpe's Neurology of the Newborn E-Book. Elsevier Health Sciences,15(8):361-370. Doi: 10.1159/000456615.
34. **Agras P, Tarcan A, Baskin E *et al*. (2004):** Acute renal failure in the neonatal period. Renal failure, 26(3):305-9. Doi: 10.1081/JDI-200026749.
35. **Wang C, Du L, Ma X *et al*. (2016):** Analysis of in-hospital neonatal death in the tertiary neonatal intensive care unit in China: a multicenter retrospective study. Chinese Medical Journal, 129(22):2652-8. DOI:10.4103/0366-6999.193458.