

Paediatric Focused Triggering Tool (PFTT) To Assess the Harm and its Utilization to Minimize the Levels of Harm among Children at a Tertiary Care Hospital

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ABSTRACT

Objectives: Very few paediatric trigger tools have been developed to assess harm in children. Hence, a Paediatric-focused trigger tool has been developed, assess its utility to measure the levels of harm, categorize and minimize them further. **Methodology:** The final 40 trigger tool developed by modifying IHI-GTT adult care, was prospectively tested for structural review of records (n = 520) of paediatric population of a tertiary care hospital for incidence of adverse events (AE's) with associated harm and categorized using modified NCCMERP (National Coordinating Council for Medication Error Reporting and Prevention) index from E-I. **Results:** Among 292 male and 228 female children, the incidence of AEs was 35%, more in the category of 1-5 years of age with harm assessment events. Out of 182 AEs identified, 107(58.80%) were found to be of E-category, 43(23.62%) were of category F, 22(12.08%) with category G, 9(4.95%) with category H and 1(0.55%) was category I. Two third of the paediatric population of category E and F (82.4%) had temporary harm and remaining (17.6%) were of non-preventable harm, category G-I. One example of AE identified with harm was, decrease in 25% in Haemoglobin or Haematocrit and number of blood transfusions. Further action was taken to strictly monitor and minimize further harm. **Conclusion:** The present study highlights on the harm assessment among the paediatric population with the help of developed Paediatric-Focused Trigger Tool (PFTT) modified by using IHI-GTT adult trigger tool. This helps paediatric set ups to assess its usefulness and further develop strategies to mitigate the harm.

Key words: Paediatric, Trigger tool, AEs, NCCMERP Index, Harm.

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INTRODUCTION

To achieve better patient care among children, efforts are being made to minimize the substantiated harm in the children which may be iatrogenic in nature. The efforts towards the same can allow for improvement in paediatric patient care and institutional healthcare policy. One such effort from the Institute for Healthcare Improvement's Global Trigger Tool (IHI-GTT), has become standard practice to identify and measure rates of AEs.¹⁻³

Patient harm over the period and its assessment in an accurate way remains as a challenge for most of the organizations. Only 2% to 8% of all harms has been

detected through voluntary reporting, which is the common method of detection of harm detection in most of the hospitals. Different studies showed that prevalence of adverse events (AEs) in hospitalised adult population range from 2.9% to 16.6%.^{4,5} Hence, concurrent use of complementary methods are used instead of the single voluntary method and has proved to be beneficial for the detection of adverse events.^{1,6-11} One such method known as 'Trigger tool (TT)' methodology, is considered to be the best single tool at present time. Also, it is one of the reliable and sensitive tools for detecting the adverse event related



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harm more accurately over the time by customising to different settings. The landmark Harvard Medical Practice Study has used screening method for reviewing charts to detect harm efficiently.¹²

The idea of a ‘trigger’ (clue) to detect adverse events in the patient’s medical records was introduced by Jick in the year 1974^{3,13,14} and manual record review using the triggers was initially developed by IHI in 1999 to identify adverse medication events. A ‘trigger’ is “an existence of, or signal in the patient medical records that may indicate an AE and serve as a clue or a hint indicating reviewers towards thorough investigation of the records, they focus on patient harm, not errors”.^{15,16} Once the harm is identified, causes and contributing factors should be assessed, then solutions to be found to increase the safety of care (WHO 2014b).¹⁷

The present study, using the developed paediatric-focused trigger tool (PFTT) at the paediatric setting, is a potential approach to measure the level of harm, assigning category and mitigate them in the paediatric population of a tertiary care teaching hospital.

MATERIALS AND METHODS

Setting

There was a need for determining the utility of IHI-GTT adult care in paediatric set up of different age groups at the institutions level of a large tertiary care hospital. After obtaining institutional Ethics Committee approval, a paediatric focused triggering tool (PFTT) was applied in different settings of the paediatric population to, delete triggers not positively predicting the adverse events and add more relevant triggers. Primary focus of this study was to examine the extent of harm through developed PFTT and secondly, to assess the usefulness of the different triggers, which includes the utility of individual triggers in identifying the harm.

Five trigger tools were identified from different literature search engines for IHI-GTT adult care tool, some triggers were added and modified with duplicate triggers eliminated. Adopting the modified Delphi process, the tool with 61 triggers was modified to a final tool with 40 triggers. It was prospectively tested for a structural review of records (SRR). To achieve validation, 20 charts every month were randomly selected across five age groups. 520 charts were reviewed by two internal primary reviewers (Clinical Pharmacists) with knowledge of and trained for identifying AE’s and one external reviewer (Clinician/Physician) with knowledge of and expatriation in the similar field. The prevalence of triggers and positive charts with AEs were recorded,

charts with AEs identified by Pharmacists and validated physicians were determined for positive predictive value.

Patient chart review of random Samples

Developed final trigger tool (40 final trigger list selected from the retrospective chart review process, carried out in stage I process of the study by modifying an adult version of IHI GTT) was used to assess the charts or records. The developed PFTT contains five groupings of modules or triggers. Five of the modules are developed to indicate for prevalence of adverse events that commonly appear in a paediatric patients; the five modules are:

- Care
- Medication
- Surgical
- Emergency and
- Laboratory

The Sampling process of the Patient Records/ charts

A prospective random sample of 520 records (by computerized randomization method) were selected to identify adverse events Assessed for harm from the patients of paediatric department of a tertiary care hospital each month. Every 10th admission/discharge record was selected for reliability.

Events Review and assessment by the Reviewers

- Harm assessment
- Severity Reviewed

The review team consisted of 03 people

- 1) Two primary record reviewers with pharmacotherapeutic background and knowledge about the contents of the assessment
- 2) A physician who authenticates or further validates the agreement of the two primary record reviewers.

Assigning category of ‘harm’

As per the “National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)”, harm was categorised and actions were taken to minimize it.

Definition of Harm

“Temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and/or pain requiring intervention” as per the NCC MERP definition.¹⁸ Accordingly, the PFTT (Paediatric focused triggering tool) eliminates the first

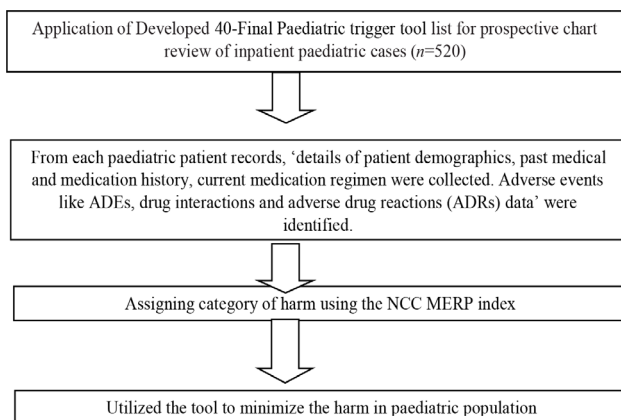


Figure 1: Prospective chart review of 520 paediatric case studies.³

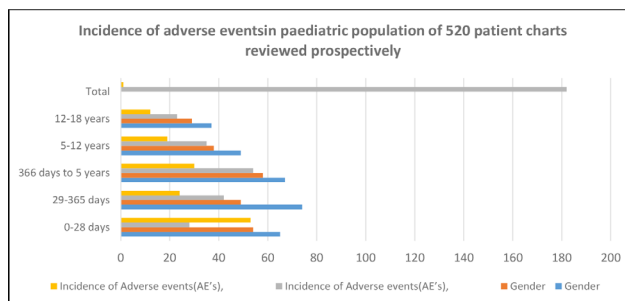
four categories of NCC MERP index as they consider the errors that do not cause harm. The present PFTT includes categories- E, F, G, H and I of the index as these categories consider the errors that cause harm.

RESULTS

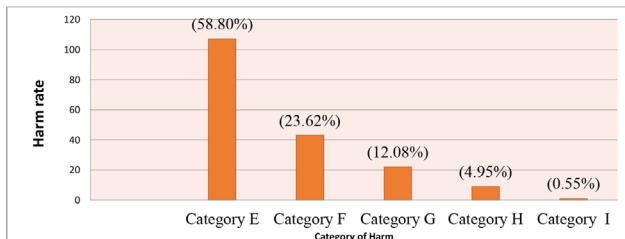
Application of 40-Final Paediatric trigger tool with 5 modules developed using IHI-GTT to monthly random samples of 520 hospitalized paediatric patient was prospectively reviewed in the present study. Initial trigger tool with 61 triggers tools has been modified to final trigger tool of 40 Figure 1. Demographic characteristics of prospective chart review of patients (N=520) was carried out with respect to frequency of Adverse Events (AE's) and harm, where 292 children were male and 228 were female. The incidence of adverse events was 35% and more among category of 1-5 years of age (Table 1 and Graph 1 respectively). Total number of AE's and their incidence with respect to 5 modules were 448 triggers and mean rate of triggers per patient was 0.86. AEs per 100 patient-days were 35% and 61.65 AEs per 1000 patient-days and two of the modules, care (42.86%) and medication (36.81%) had the maximum of harm events (Table 2). Out of 182 AEs identified, 107(58.80%) were found to be of E-category, 43(23.62%) were category F, 22(12.08%) with category G, 9(4.95%) with category H and 1(0.55%) was category I. (Table 3 and Graph 2). Two third of the paediatric population of category E and F (82.4%) had temporary harm (resulted in the intervention involving the treatment or initial/prolonged hospitalization and has caused temporary harm) and remaining (17.6%) were of non-preventable harm, category G-I (An error occurred that lead to the permanent patient harm, injury to the body organs or death). Minimizing the harm have also been highlighted in the present study (Table 4).

Table 1: Demographic details.

Age(Days/year)	Gender(N=520)		Incidence of Adverse events(AE's), n=182	
	Male	Female	No.s	%
0-28 days	65	54	28	15
29-365 days	74	49	42	24
366 days to 5 years	67	58	54	30
5-12 years	49	38	35	19
12-18 years	37	29	23	12
Total	292	228	182	100%



Graph 1: Incidence of adverse events in paediatric population of 520 patient charts reviewed prospectively.



Graph 2: NCC MERP Harm Review (in %).

DISCUSSION

Using the validated Paediatric focused trigger tool (PFTT) in the present study, incidence, types and severity of harm among children admitted to academic paediatric department of a tertiary care hospital was assessed. Incidence of 182 of harm, with 65 harm events per 1000 patient days and 35 harm events per 100 patient charts were in comparison with the study conducted by Kirkendall et al. where harm rate was 36.7 harm events per 100 patients and 76.3 per 1000 patient-days.³ Also, harm rate of 40 harm events per 100 patients and 54.9 per 1000 patient-days were identified in the study conducted by stockwell et al.⁵ Some other studies with higher harm rate within the paediatric intensive care population were of 26.1% to 62%.^{1,2,19,20} The results projected in the present and other studies

Table 2: Triggers with respect to no adverse events with severity of harm.

Sl.no	Modules	Trigger names	No. of AE's	No .of Triggers	AE % of PPV triggers	Severity of harm as per NCCMERP[E-I]				
						E	F	G	H	I
1. Care Module										
1	PC1	Transfusion/ use of blood products	08	16	50	05	02	01	0	0
2	PC2	Code/arrest/rapid response team	02	09	33	0	00	01	01	0
3	PC3	Positive blood culture	05	11	45	04	01	0	0	0
4	PC4	x-ray or Doppler studies for emboli or deep vein thrombosis	04	10	36	04	0	0	0	0
5	PC5	Sudden Decrease in 25% in haemoglobin or hematocrit value	08	16	50	05	01	02	0	0
6	PC6	Patient fall	03	10	30	02	01	0	0	0
7	PC7	Readmission within 30 days	11	19	59	06	02	02	01	0
8	PC8	Health care associated infection of any kind	06	10	60	02	01	01	02	0
9	PC9	Transfer to a higher level of care	04	10	40	02	01	01	0	0
10	PC10	Any procedure complication	02	06	33	02	0	0	0	0
11	PC11	Pain	05	11	45	05	0	0	0	0
12	PC12	Apgar score < 7	04	09	44	02	01	01	0	0
13	PC13	Abnormal body temperature	06	13	46	04	02	0	0	0
14	PC14	Loss of weight	03	10	30	03	00	0	0	0
15	PC15	Urinary retention	03	10	30	02	01	0	0	0
16	PC16	Fluid overload (pulmonary oedema)	04	09	44	03	0	0	01	0
Total of all Care module:16			78	177	44	51	13	09	05	0
2. Medication (M)										
17	PM1	INR >6/PTT >100 s	01	03	33	00	01	0	0	0
18	PM2	Glucose<50 mg/dL	04	08	50	02	02	0	0	0
19	PM3	Rise in BUN/ serum creatinine >2 times of the normal.	07	12	58	02	02	02	01	0
20	PM4	Vitamin K administration	02	14	14	01	01	0	0	0
21	PM5	Diphenhydramine use	11	22	50	08	02	01	0	0
22	PM6	Antiemetic use	06	12	50	04	02	0	0	0
23	PM7	Over sedation/ hypotension	02	08	25	01	01	0	0	0
24	PM8	Abrupt medication stop	11	21	52	09	01	01	0	0
25	PM9	Use of stool softener / constipation	12	26	46	07	02	02	01	0
26	PM10	Increased Glucose or administration of 300 or 500 mg/ml of glucose	08	17	33	04	02	01	01	0
27	PM11	Antidote administration	03	07	42	02	01	0	0	0
Total of all medication module:11			67	148	45	40	17	07	03	0
3. Surgical (S) module										
28	PS1	Intubation/re-intubation/bi level positive airway pressure in PACU	03	08	27	01	00	02	0	0
29	PS2	Mechanical ventilation>24 h postoperatively	02	08	33	0	01	01	0	0
30	PS3	Intraoperative epinephrine/ norepinephrine.	02	03	14	02	00	0	0	0
31	PS4	Any operative complication	01	06	33	0	0	0	0	01
Total of all Surgical module:04			07	25	20	03	01	02	0	0
4. Emergency Module(Perinatal+ intensive are merged)										
32	PE1	Readmission to ED within 48 h	01	06	30	0	01	0	0	0

Table 2: Cont'd.										
Sl.no	Modules	Trigger names	No. of AE's	No .of Triggers	AE % of PPV triggers	Severity of harm as per NCCMERP[E-I]				
33	PE2	Pneumonia onset	03	06	17	01	01	01	0	0
Total of all Emergency Module:02			04	12	23	01	02	01	0	0
5. Laboratory module										
34	PL1	Platelet count<50,000	04	15	27	02	01	00	01	0
35	PL2	Extreme hyper bilirubinaemia	06	16	38	02	03	01	0	0
36	PL3	Neutropenia and antibiotic treatment	03	09	33	0	02	01	0	0
37	PL4	Abnormal liver enzymes	05	11	45	04	01	00	0	0
38	PL5	Sodium: 120 mmol/l >Na >150 mmol/l	03	09	33	01	01	01	0	0
39	PL6	Potassium: 3.0 mmol/l >K >6.0 mmol/l	03	07	42	02	01	00	0	0
40	PL7	Leucopenia Age<1 month WBC<5000/mm ³ (5x10 ⁹ /l) Age 1-23 months WBC<4000/mm ³ (4x10 ⁹ /l) Age 2-18 years WBC<3000/mm ³ (3.0310 ⁹ /l)	02	06	33	01	01	0	0	0
Total of all laboratory Module:07			26	73	36	12	10	03	01	01
Overall total			182	448	41	107	43	22	09	01

Table 3: Classification of harm using the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) scale.

NCC MERP Scale	Definition of category of harm	NCC MERP harm rate
Category- E	An error occurred that resulted in the treatment or intervention and lead to temporary harm	107
Category- F	An error occurred that resulted in the initial or prolonged hospitalization but lead to temporary harm	43
Category- G	An error occurred that resulted in the permanent patient harm like injury to the organs	22
Category- H	An error occurred that lead to a near death event (e.g severe cutaneous reactions, cardiac arrest)	09
Category - I	An error occurred that lead to patient death	01
Total		182

Table 4: Few Examples of the adverse events caused harm and its minimization.

Sl. No.	Adverse events	Harm	Preventability/ Non- preventability (E-I)	Harm and its minimization
1.	Insertion of nasogastric feeding tube	Lead to temporary harm	E (Preventable)	Required intervention and medication management
2.	Decrease in 25% of Haemoglobin	Lead to temporary harm	E (Preventable)	Required intervention and transfusion of blood.
3.	Transfer to an intensive level of care	Lead to permanent harm	F (Non-Preventable)	Emergency care and strict monitoring was done
4.	Heparin use	Bleeding	E (Preventable)	Vit. K was administered and INR monitored
5.	Amoxycillin+ Clavulanic acid	Diarrhoea /Vomiting	E (Preventable)	Use of anti-diarrhoeal medication.
6.	Insulin dose	Hypoglycemia	E (Preventable)	Dose titrated and Hypoglycemia was addressed
7.	Sodium valproate	Steven's Jhonson syndrome	H (Non-preventable)	Drug was stopped, Intensive supportive care treatment was started
8.	Influenza Vaccine	Anaphylactic shock	H (Non-preventable)	Intensive supportive care treatment was started

reflected that, academic teaching hospitals or institutions probably represent higher rate of harm in paediatric patient due to diversity of population and disease severity. This was in contrast with the another study by Solevag *et al.* where, 21 harm events per 1000 patient days and 6 harm events per 100 patient consultations were found, the reason being 3 months short duration of study.²¹

Majority of the paediatric population of category E and F (82.4%) had temporary harm (required treatment or intervention and lead to temporary harm) whereas and remaining (17.6%) had non-preventable harm (permanent harm) in the present study. This was in similar with other studies like Takata *et al.*²² where, it was reported that 97% of AEs discovered were of category E, with the remainders in the category F. Kirkendall *et al.* study represents 76% of AEs of category E, 22% were category F and 2% were category H. where majority (92.3%) represented temporary harm while severe harm was rare of 7.8% of the harm identified.²

CONCLUSION

The present study highlights on the rate of harm assessed significantly among paediatric population with the help of developed Paediatric-Focused Trigger Tool (PFTT). This tool was modified using adult Global trigger tool (GTT), where triggers with low predictive value were deleted and with high predictive value were retained/added, to develop focused final trigger tool which was used to assess the harm more accurately in a measurable level experienced by children admitted in the hospital. Range of triggers will help with paediatric set ups to assess their usefulness and develop strategies to mitigate them. This emphasizes on the monitoring process and inter disciplinary approach towards mitigating the harm.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

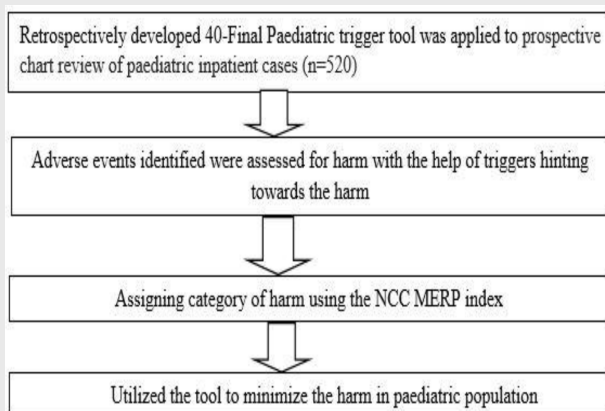
AE: Adverse events; **PPV:** Positive predictive Value; **NCCMERP:** National Coordinating Council for Medication Error Reporting and Prevention; **PC:** Paediatric Care; **PM:** Paediatric Medication; **PS:** Paediatric Surgery; **PE:** Paediatric Emergency; **PL:** Paediatric Laboratory; **APGAR:** Appearance, Pulse, Grimace, Activity and Respiration; **WBC:** White blood cells; **ED:** Emergency Department; **PTT:** Partial Thromboplastin Time; **BUN:** Blood Urea Nitrogen; **PACU:** Post Anaesthesia Care Unit.

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PICTORIAL ABSTRACT



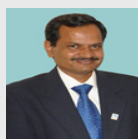
SUMMARY

- Patient safety among the children still remains to be a concern, especially in the developing countries as data necessary to assess harm is still lacking.
- Hence, it becomes a prerequisite to generate ideas and plans to improve the safety by developing strategies to assess and mitigate the harm in the paediatric population.

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