Measuring adverse events in pediatric inpatients with the Global Trigger Tool

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ABSTRACT

Introduction: The safety of inpatients is a priority in the health care system. The Global Trigger Tool seems to be suitable to estimate the incidence of adverse events (AE) in pediatric inpatients.

Objectives: To describe the incidence and categories of AE in pediatric inpatients using the Global Trigger Tool and to identify risk factors associated to their development.

Population and methods: Retrospective study. Medical records of 200 patients hospitalized at Hospital Elizalde during 2013 were included. Outcome measures: number of AE/100 admissions and distribution of harm. A chi² test, Student´s t test and Pearson's correlation test were carried out. Significance level = $p < 0.05$.

Results: The study detected 289 triggers (1.4/patient); 52 AEs (26 AEs/100 patients, 95% CI: 20.4-32.5). There was at least one AE every 36 patients; 7 patients had more than one AE; 45 AEs were in the E and F categories (temporary harm). Medical care triggers were associated to AEs (OR 8.1; 95% CI: 3.7-17.3, $p < 0.001$). A positive correlation was found between the number of triggers and the number of AEs per patient (R= 0.46; $p < 0.001$). Being hospitalized in a closed unit (OR 2.8; 95% CI: 1.2-6.5; $p= 0.03$) and a longer hospital stay were associated to AEs ($p < 0.001$).

Conclusion: An AE frequency of 26% was identified, and most AEs resulted in temporary harm. The presence of AEs was associated to hospitalization in a closed unit, longer hospital stay, higher number of triggers and general care triggers.

Key words: *patient safety, medical error, indicator of healthcare quality.*

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INTRODUCTION

The safety of inpatients has become a priority in the healthcare system. It is defined as accidental harm caused by medical care. Since the Institute of Medicine issued its report "To err is Human," actions have been implemented to detect and reduce harm, and to improve the quality of care.[1,2]

AEs incidence in adult inpatients differs, according to the literature, from 3% to 16%. Children are more vulnerable to AEs, mainly because there is an increased risk of medication errors, with a reported frequency of 11%.[3,4]

Moreover, the incidence of AEs related to medical care and medication errors varies with the method used for their detection.[5,6] The Global Trigger Tool (GTT) seems to be the best to detect AEs, both in the adult and in the pediatric population, with a sensitivity of 94% and a specificity of 100%.[7]

The GTT was developed by the Institute for Healthcare Improvement, in order to identify AEs and measure their incidence rates. It consists of a retrospective assessment of a random sample of medical records to find triggers and identify potential AEs. These triggers are organized in 6 modules related to medical care, medication, surgery, emergency, intensive care and perinatal-obstetric.[7]

The authors of the GTT found 36.7 AEs every 100 patients and 76.3 AEs every 1000 patients/day. Most AEs resulted in temporary harm. This number was almost three times higher than the values published so far, indicating that this tool may be useful and sensitive enough to identify AEs.[7]

Although several healthcare policies have been implemented in recent years to increase patients' safety, there is no accurate data on this issue at a local level, in particular, in the population of children hospitalized at Hospital General de Niños Pedro de Elizalde (HGNPE). Determining the frequency and

distribution of AEs related to medical care would be useful to develop strategies aimed at reducing harm.

The objectives of this study were to describe the incidence of AEs and their categories in pediatric inpatients, using the GTT, and to identify AE related risk factors.

POPULATION AND METHODS

Design: Retrospective study. Medical records of patients hospitalized at the HGNPE during at least 48 hours in 2013 (January 1st- December 31st) were randomly included. Medical records had to be complete, their pages numbered, and had to include a discharge summary and be accurately coded. If the medical record selected described more than one hospitalization during the study year, the most recent hospitalization was considered. Medical records belonged to patients hospitalized in multipurpose and closed units (Pediatric ICU and Neonatology Division).

Medical records of patients hospitalized due to psychiatric disorders and social reasons were excluded.

Medical records were systematically screened for AEs using the GTT. This tool includes 52 preset triggers, organized in 6 modules (cares, medication, surgical, emergency, intensive care and perinatal-obstetric) to identify possible causes of healthcare-related harm. A trigger is an element that is present in the medical record and that may be associated to the presence of an AE, and requires reviewers to investigate further into such record (see the *Annex*).

The hospital has no maternity unit; therefore, the triggers in the perinatal-obstetric module (applicable to pregnant women) did not apply to our population.

Medical records were reviewed in depth (progress reports, medication, lab reports, surgical reports, nurse sheets, consultation records, etc.).

Reviewers underwent the same training and were the same along the study. Each reviewer received 7-10 medical records per week and afterwards medical records were exchanged. In case of discrepancy, they were evaluated by a third reviewer.

If at least one trigger was found, the record was reviewed more thoroughly to search for an associated AE. If found, the event was categorized. If no trigger was found, the review of that medical record was concluded. This procedure was in place until the required sample size was achieved. The observation of medical records was completed in 7 months.

AEs were defined as unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death.[8]

The study outcome measure was the number of AEs/100 admissions. Harm resulting from the AE was classified into 5 categories: temporary harm requiring intervention (category E), temporary harm requiring a prolonged hospitalization (F), permanent harm (G), permanent harm requiring specific intervention to sustain life (H) and death (I).[9]

Outcome measures to be controlled were age, sex, total hospital length of stay, length of stay at the general care unit, ICU and Neonatology Unit, and diagnosis that led to the hospitalization.

Statistical analysis

Categorical outcome measures were expressed as percentages with 95% confidence intervals. Numerical outcome measures were described using an average and a deviation.

To estimate the incidence of AEs using the GTT, the total number of AEs was used on the total number of patients and was multiplied by 100 to express it as a percentage.

The degree of inter-observer agreement was evaluated for the observation of triggers and AEs by means of the Kappa coefficient.

The t test was used to determine the association between the mean value of triggers per patient and the presence of AEs. The chi^2 test was used to assess if there was an association between the presence of AEs and the place where they occurred, the kind of harm and the site, and the kind of trigger and the presence of an AE. The correlation between the number of triggers and AEs was measured using Pearson's coefficient. A significance level of $p < 0.05$ was adopted (SPSS 11.1).

Sample size and sample selection

Out of 10,000 hospital discharges every year, a sample size of 200 medical records was calculated, based on an AE frequency of 15% ± 5%, for a 95% confidence interval and considering a simple random sampling (Epi Info 7.1).[3]

Sampling was carried out through simple randomized selection from the medical records repository. If the selected medical record was not found, or if it did not meet the inclusion criteria or met any of the exclusion criteria, the next record was immediately used.

Ethical considerations

Since this was a retrospective study on the analysis of medical records, it was not considered necessary to obtain an informed consent. Data were recorded keeping patients' identities anonymous.

The study was approved by the Research and Teaching Committee and the Bioethics Committee of the HGNPE (file no. 782014).

RESULTS

Medical records of 211 patients hospitalized at the HGNPE were reviewed. Five (5) records were excluded because they were incomplete and 6 because a discharge summary had not been included. The final sample consisted of 200 medical records corresponding to a total of 1690 days of hospitalization. All records were reviewed by 2 investigators and there was a discrepancy as regards the presence of a trigger in 12 records, which were evaluated by a third investigator.

Table 1 shows the main characteristics of the population.

The reasons for hospitalization were; firstly, the diagnosis of acute low respiratory tract infection; secondly, non-respiratory infections (cellulites, abscess, acute diarrhea, urinary tract infection, febrile neutropenia); thirdly, surgical causes (acute abdomen); and, lastly, other diagnoses (convulsive syndrome, apparent life-threatening event, onset of oncological disease, trauma) (*Table 1*).

Two hundred and eighty nine triggers (1.4/patient) were detected and 52 AEs were identified (26 AEs/100 patients, 95% CI: 20.4- 32.5; and 30.7 AEs/1000 hospitalization days, 95% CI: 23.5-40.1). Eighty two (82) medical records did not have triggers nor AEs. Out of the remaining 118 records most included 1 trigger (range 1 to 16). Thirty six (36) patients had at least one AE and 7 patients had more than one (2-8 AEs).

Forty five percent (45%) (95% CI: 38.4-49.6) of triggers corresponded to the general medical care module; 27% (95% CI: 21.8-31.8) to the medication module; 16% (95% CI: 13.8-19.1) to triggers related to the emergency department and the ICU; and the remaining 10% (IC 95%: 8.2-12.7), to the surgical module (*Table 2*).

Sixteen percent (16%) (n= 21) of triggers associated to the module of medical care were identified by the item "other triggers", which mostly corresponded to the description of phlebitis, infiltration of the peripheral line and pneumothorax secondary to surgical procedures. These situations were not described in the GTT (*Table 2*).

Eighty three percent (83%) (n= 43) of AEs were identified based on triggers under the medical care module; 11% (n= 6), under the surgical module; 4% (n= 2) under the medication module; and the remaining 2% (n= 1), under the emergency department and pediatric ICU module (*Table 2*).

TABLE 1. *Main characteristics of the population. Medical records reviewed, N= 200*

	Total (%)	Mean	SD	95% CI
Age in months		52.2	60.9	43.7-60.6
Male	102 (51%)			44.2-57.4
Female	98 (49%)			42.1-55.9
Hospital length of stay in days				
Total	1690	8.45	11.6	7.9-9.1
- Multipurpose Unit	1355	7.13	7.08	6.7-7.5
- ICU	196	11.5	21.5	10.3-12.6
- Neonatology Unit	139	15.4	13.8	13.1-17.7
Place of hospitalization				
- Multipurpose Unit	174 (87%)			81.6-90.9
- ICU	17 (8.5%)			5.3-13.1
- Neonatology Unit	9 (4.5%)			2.3-8.3
Diagnosis at admission				
- ALRTI	72 (36%)			29.6-42.8
- Source of infection	52 (26%)			20.4-32.5
- Reason for the surgery	48 (24%)			18.6-30.4
- Other	28 (14%)			9.8-19.5

SD: standard deviation; CI: confidence interval; ALRTI: acute low respiratory tract infection; ICU: Intensive Care Unit.

Adverse events detected per GTT module and the severity of harm are described in *Table 3*.

Nosocomial infections accounted for 70% of detected AEs.

There was an adequate inter-observer agreement for the identification of triggers and AEs (kappa 0.56, p= 0.01; kappa 0.96, p= 0.01).

When evaluating the association between the number of triggers per patient and the presence of AEs, it was observed that the mean number of triggers in the group of patiens who did not experience any AEs was 0.8, in contrast with 4.3 ($p < 0.001$) in the group with at least one AE. Moreover, a positive correlation was found between the number of triggers and the number of AEs per patient (Pearson's correlation R = 0.46; $p < 0.001$).

Triggers associated to general medical care showed a significant association with AEs when compared to other triggers: 43/131 vs. 9/158 (OR: 8.1; 95% CI: 3.7-17.3, $p < 0.001$).

With respect to the place of hospitalization, it was observed that 10/26 patients hospitalized in a closed unit experienced AEs, compared to 24/174

TABLE 2. *Triggers detected and associated adverse events*

Adverse event module	No. of triggers	No. of adverse events
Medical care		
C1: Transfusion or use of blood products	15	0
C2: Code, cardiac or pulmonary arrest, or rapid response team activation	6	1
C4: Positive blood culture	15	2
C5: Emboli or deep vein thrombosis	2	1
C6: Decrease in hemoglobin or hematocrit > 25%	6	0
C7: Accident/fall/injury in the hospital	1	0
C8: Pressure ulcers	1	1
C9: Readmission within 30 days	33	7
C11: Nosocomial infections	28	28
C14: Any procedural complication	3	0
C15: Other	21	3
Total of cares	*131*	*43*
Medication		
M2: QUICK > 100 seconds	3	0
M4: Glucose < 50 mg/dL	3	0
M5: Rising BUN or serum creatinine greater than two times (2x) baseline	4	0
M6: Vitamin K administration	2	0
M7: Diphenhydramine use	29	0
M10: Anti-emetic use	20	0
M11: Over-sedation/hypotension	3	0
M12: Abrupt medication stop	13	0
M13: Other	2	2
Total de medication	*79*	*2*
Surgical		
S1: Return to surgery	4	0
S2: Change in procedure	4	0
S3: Admission to ICU	7	0
S4: Reintubation in the Operating Room	4	1
S5: Intra-operative x-ray	1	0
S7: Mechanical ventilation greater than 24 hours post-op	4	0
S8: Inotropics, naloxone or flumazenil	1	0
S11: Other	6	5
Total surgical	*31*	*6*
Emergency/ICU/perinatal-obstetric		
E1: Readmission to ED within 48 hours	21	0
E2: Time in ED greater than 6 hours	17	0
I1: Nosocomial pneumonia	2	1
I2: Readmission to the ICU	2	0
I4: Intubation/reintubation	6	0
Total Emergency/ICU/perinatal	*48*	*1*
Total	**289**	**52**

ICU: Intensive Care Unit.

patients hospitalized only in a multipurpose unit (OR 2.8; 95% CI: 1.2-6.5, p= 0.03).

The average hospital length of stay was higher in patients with AEs than in those who did not experience AEs (21.1 vs. 5.7, respectively; p= 0.001).

No association was found between the type of harm and the place where it occurred. In addition, no association was noticed between the age or the diagnosis and an AE.

DISCUSSION

In our study, using the GTT, a frequency of 26% of AEs was observed in hospitalized patients. An association was found between the number of triggers, hospitalization in a closed unit and hospital length of stay, and the presence of AEs. About half of the triggers found were under the general medical care module. Most of the AEs corresponded to temporary harm to the patient.

The frequency observed of AEs was lower than that reported by Kirkendall with the same tool (36%). Moreover, in the same study, the number of triggers per patient was slightly lower than that reported in our study (1.4 vs. 1.7).[7] This difference may be attributed to the type of medical records and coding (manual in our case and electronic in the study published by Kirkendall). The electronic medical record may be more specific and sensitive to detect triggers.[10]

Stockwell described an AE frequency of 40% using the Pediatric All-Cause Harm Measurement Tool (PACHMT), a specific tool for pediatric use based on the GTT.

This difference in frequency with respect to our study may be due to the fact that the new tool has even more sensitive triggers to detect AEs in the pediatric population, a greater complexity of the study population or a potential different interpretation of AE.[11]

Eighty three percent (83%) of AEs were identified based on triggers belonging to the medical care module of the GTT, which was partially consistent with Kinkerdall who observed that 95% of the AEs detected were associated to medical care and medication modules.[7] In both studies, the possible cause of this high percentage is that main triggers –such as nosocomial infections–, are also considered AEs on their own.

Our study showed that the greater the number of triggers per patient, the higher the possibility of detecting an AE; this was in line with findings reported by other authors.[12,13] This last finding may be the starting point for future investigations aimed at evaluating what combinations of triggers have a closer association with AEs, or a better chance of predicting them.

With respect to harm distribution, most AEs were in categories F and E. However, in certain cases harm was permanent or required an intervention to sustain life (> 10%), a percentage that was remarkably different to that reported by Kirkendall,[7] who found only 2%. Nevertheless, other authors also reported values closer to our findings: Stockwell[11] (10.4%) and Naessens[12] (8%).

The most frequent AE was nosocomial infection. Other authors also described infiltration of venous catheter, hypoglycemia, pressure ulcers and procedural complications.[11,14,15]

Nosocomial infections require specific management within the concept of medical errors and AEs. There are protocols in place for their monitoring and the reduction of their incidence.

In line with other studies, AEs were more frequent in closed units. This is probably linked to variables such as prematurity, unstable clinical condition and prescription errors.[16-18]

Our study observed a significant association between the presence of AEs and total length

TABLE 3. *Adverse events detected per Global Trigger Tool module and severity of harm*

Severity of harm **Modules**	**All categories**	**E**	**F**	**G**	**H**	**I**
Medical care	43 (83%)	17	22	1	2	1
Medication	2 (4%)	1	1			
Surgical	6 (11%)	3	1		2	
Emergency/ICU	1 (2%)				1	
Total (n)	52	21	24	1	5	1
%	100%	40%	46%	1.9%	9.6%	1.9%
95% CI		28.1-53.9	33.3-59.5	0.34-10.1	4.1-20.6	0.34-10.1

ICU: Intensive Care Unit; E: requires intervention; F: prolonged hospitalization; G: permanent hospitalization; H: permanent to sustain life; I: death; CI: confidence interval.

of stay –as reported by Härkänen and Najjar–, probably related to complex disorders, comorbidity and multiple medications.[19,20] However, Rutberg, based on a similar finding, suggested that AEs could be the cause and not the consequence of prolonged hospitalizations.[15]

Nineteen percent (19%) of AEs found were detected by "other triggers", which reflected the possibility that some AEs that are frequent in the pediatric population were underrepresented by specific GTT triggers. AEs related to peripheral venous lines, such as phlebitis and infiltration, and pneumothorax secondary to surgical procedures, are some examples of triggers that are not included in the GTT. Their inclusion in the future may improve the tool's AE detection capacity.

This study has some limitations that should be considered. Firstly, the sample size selected was aimed to determine the incidence of AEs. In this sense, the goal was achieved; however, some associations could not be confirmed. This may be attributed to a beta error effect, which could have been avoided had the sample size been larger.

Secondly, observers were investigator physicians trained in the use of the GTT, but they were not specialized in the screening of triggers and AEs. As a consequence, the recommendation of using two observers was adopted, with a third observer in case of discrepancies.

This study also shows some strengths that should be noted. A simple random sampling method was used, which is the best strategy to control unknown confounding variables. Moreover, the studied population had similar characteristics to the population hospitalized at our facility. Finally, this study uses the GTT, one of the most sensitive and specific tools to identify AEs. It offers a user friendly method to evaluate the incidence of AEs in hospitalized patients. Results of this study could contribute with valuable data on the frequency of AEs experienced by our population, which would facilitate the design and implementation of strategies to improve the quality of care in specific areas of our facilities. Further research on this topic is needed.

CONCLUSIONS

The AE frequency was 26% and most AEs resulted in temporary harm. Only the number of triggers per patient, hospitalization in a closed unit and total hospital length of stay were associated to the presence of AEs. ■

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ANNEX
Global Trigger Tool – *Triggers*

Adverse event modules

General care (C)

C1: Transfusion or use of blood products
C2: Code, cardiac or pulmonary arrest, or rapid response team activation
C3: Dialysis
C4: Positive blood cultures
C5: X-Ray or Doppler studies for emboli or deep vein thrombosis
C6: Decrease in hemoglobin or hematocrit > 25%
C7: Accident/fall/injury in the hospital
C8: Pressure ulcers
C9: Readmission within 30 days
C10: Physical restraint
C11: Nosocomial infections
C12: In-Hospital stroke
C13: Transfer to higher level of care
C14: Any procedural complication
C15: Others (the name of the trigger should be filled in here)

Medication (M)

M1: *Clostridium difficile* positive culture
M2: QUICK > 100 seconds
M3: INR > 6
M4: Glucose < 50 mg/dL
M5: BUN or serum creatinine greater than two times (2x) baseline
M6: Vitamin K administration
M7: Diphenhydramine use
M8: Flumazenil use
M9: Naloxone use
M10: Anti-emetic use
M11: Over-sedation/hypotension
M12: Abrupt medication stop
M13: Other (medication trigger module)

Surgical (S)

S1: Return to surgery
S2: Change in surgical procedure
S3: Admission to the Pediatric Intensive Care Unit
S4: Intubation or reintubation at the operating room or recovery unit
S5: Intra-operative x-ray or in the recovery unit
S6: Intra- or postoperative death
S7: Mechanical ventilation greater than 24 hours postoperatively
S8: Intra-operative use of inotropics, naloxone or flumazenil
S9: Postoperative Increase in troponin levels greater than 1.5 ng/mL
S10: Organ injury, repair or removal
S11: Any surgical complication

Emergency (E), pediatric ICU (I) and perinatal-obstetric (P)

E1: Readmission within 48 hours
E2: Time in ED > 6 hours
I1: Nosocomial pneumonia
I2: Readmission to the ICU
I3: In-Unit procedure
I4: Intubation/reintubation
P1: Use of terbutaline
P2: 3rd- or 4th-Degree lacerations
P3: Platelet count < 50 000/mL
P4: Estimated blood loss > 500 mL (vaginal) or > 1000 mL (c-section)
P5: Specialty consult
P6: Oxytocic agents
P7: Instrumented delivery

INR: International Normalized Ratio.