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Applying The Global Trigger Tool in a Turkey's Hospital: in Obstetrics and Gynecology: A Pilot Study

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ABSTRACT

The Global Trigger tool (GTT) is considered one of the most reliable methods in evaluating adverse events (AEs). This study aimed to evaluate the feasibility and potential of the GTT to identify AEs in clinical applications. 240 patient records were randomly selected from the Obstetrics and Gynecology department of a university hospital. Patient files were retrospectively examined as 20 patient files per month in a two-year period. The records were reviewed using GTT an approach developed by the American Institute for Health Development (IHI). Percentage of hospitalizations with AEs 9,58, AEs per thousand patient days 47.81, and AEs per thousand patient hospitalizations 95.83 were found. By applying GTT, 45 cases in category E (Damage is temporary and requires intervention) and 35 cases in category F (Damage is temporary and requires hospitalization or prolonged hospitalization) were detected. CRP elevation (5/11), vaginal surgeries (3/15), and use of Dynoprostone (6/22), helped detect AEs in category E (3 cases) and category F (11 cases). GTT detected 8.3 times more AEs than VRS. The application of the GTT is feasible in Clinical practice and a reliable and effective instrument for detecting AEs when adapted to the departmental specifics. High CRP, vaginal surgeries, and the use of vaginal Dynoprostone could be used as a trigger.

Keywords: adverse event; patient safety; global trigger tool; obstetric; gynecology

INTRODUCTION

One of the most fundamental subjects of the patient safety discipline is adverse events (AEs). Accurate measurement, frequency, cost, and social burden of AEs should be evaluated in terms of patient safety (PS). For example, the frequency, cost and burden of surgical errors are calculated in millions of dollars (Harrison et al., 2015). The interest in studies aimed at preventing the harm caused by undesirable (sentinel) events in the patient care process is increasing day by day. In terms of the concept of PS, the publication of the American Medical Institute's "To Err is Human Building a Safer Health System" report has been a turning point in terms of applications to prevent medical errors on a global scale (Kohn et al., 2000).

There is no clear unity in the categorization of AE investigation methods in the literature. The most prominent approaches are voluntary (Milch et al., 2006; Silas, 2010; McMillan, 2016), mandatory (Leape, 2002; Howie, 2009; Frankos et al., 2010), anonymous (Runciman et al., 2001; Grant, 2007) and patient file-based analysis (O'Neil et al., 1993; Thomas et al., 2002; Hwang et al., 2014). Among these approaches, the first technique studied is the examination based on patient files (Medical Record Review). In 1974, the first study was conducted by Jick (Resar et al., 2003).

The voluntary reporting system (VRS), which is the traditional method, is generally used in health institutions to identify AEs. Considering the reports made with this method, it was determined by public health experts that only 10 to 20% of AEs were reported and 90-95% of them did not cause any harm to the patient. It is necessary to accurately define AEs, to follow up on the events that develop over time, and to monitor whether the safety of health care processes has increased by performing the necessary studies (Griffin, 2009).

The question of "When compared in terms of AE reporting systems, which approach has the highest case detection rate?" is the main problem of the research. Although four approaches (anonymous, mandatory, voluntary, and retrospective approach) stand out, AE detection techniques can be examined under seven headings (Klein et al., 2020; Schwendimann et al., 2018).

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The Global Trigger Tool (GTT) is one of the most effective AE detection techniques. It is stated that it is more effective because it detects more cases with a retrospective method compared to other tools (Kurutkan et al., 2015).

In 2009, IHI developed a system adapted from the NCC MERP (The National Coordinating Council for Medication Error Reporting and Prevention) index on a global scale to report AEs. It is a methodology that allows retrospective examination of randomly selected hospital records to determine AEs. Many hospitals use this tool to identify AEs, assess the level of harm on the patient, and determine whether AEs decrease over time as a result of remediation efforts. The developed GTT consists of six modules and 54 triggers. GTT modules are Health Services, Medicine, Surgery, Intensive Care, Perinatal and Emergency Department.

GTT takes into account all AEs that harm the patient decisively, whether as a result of an error or not, and draws particular attention to events between Category E and Category I (Griffin, 2009). GTT takes into account damages, negligence is not evaluated. Indicators indicating AEs are detected and rated according to the condition of harm to the patient. NCC MERP Errors Classification Index is used for damage degrees. Although the index was developed to classify medication errors, these definitions can be easily adapted to any type of error or AE (Griffin, 2009). This study aimed to evaluate the feasibility and potential of the GTT to identify AEs in clinical applications.

METHOD

In this study, a cross-sectional study was carried out as data for 2018 and 2019 were examined. From the point of view of the method, both quantitative and qualitative research techniques were used in this study. Document analysis (retrospective examination of the patient file) was carried out from qualitative research techniques and frequency analysis was performed on the results. The main purpose of this study is to measure AEs in an Obstetrics and Gynecology clinic (OGC) in terms of two reporting approaches (GTT and VRS). VRS is an approach to AE assessment that is currently available and encouraged by Ministry of Health. GTT, on the other hand, is an approach developed by the American Institute for Health Development (IHI), which is almost non-practical in Turkey. The general population of our study is a training and research hospital. In order to ensure the authenticity of the GTT, not all clinics have been studied. Considering the inadequacy of the number of studies related to the OGC, it was decided to determine a single clinic as a sample. Between 15.08.2018 and 15.08.2020, 1807 patient files over 18 years old and hospitalized in the OGC for more than 24 hours were identified. Psychiatric patients were excluded from the study group in accordance with the instructions of the GTT. The sample group consisted of 20 patient files selected by random sampling method over the hospital automation system at the end of each month, who were hospitalized in that month. A total of 240 patient files were examined. Research model is shown in Figure 1.

Since the patient files are followed by both the physical patient file and the hospital automation program (KARMED), the total number of inpatients in 2018 and 2019 was determined in order to process the data. In the next step, patients with a history of gynecological surgery were selected. For patients matching ICD -10 codes, a code was written for SQL-based querying and the final version of the data was clarified. For the GTT, triggers were identified using forms for six modules for each patient file. Between 15.08.2018-15.08.2020, patient files were retrospectively examined with 20 patient files per month in a two-year period. Since re-hospitalizations within 30 days are considered an indicator, patient records discharged 30 days before the date of examination were selected so that re-hospitalizations were also checked within the sample.

Adverse event data obtained using GTT and VRS were classified according to the NCC MERP scale. Data in categories E, F, G, H, I were included in the study.

- Category E – Damage is temporary and requires intervention
- Category F – Damage is temporary and requires hospitalization or prolonged hospitalization
- Category G – Permanent patient harm
- Category H – Care is required to sustain life
- Category I – Patient dies

Data Collection

An AEs Evaluation Commission, consisting of 1 Doctor, 1 Nurse, 1 Quality Management Unit employee and 1 Assistant Physician, was established in the OGC of the Training and Research Hospital. GTT and modules were introduced to the evaluation committee on 31 July 2019, and a retrospective file review was conducted. In addition, a 4-hour practical training was organized to train evaluators. A pilot study was conducted with the nurse in the team and the results were shared with the advisor.

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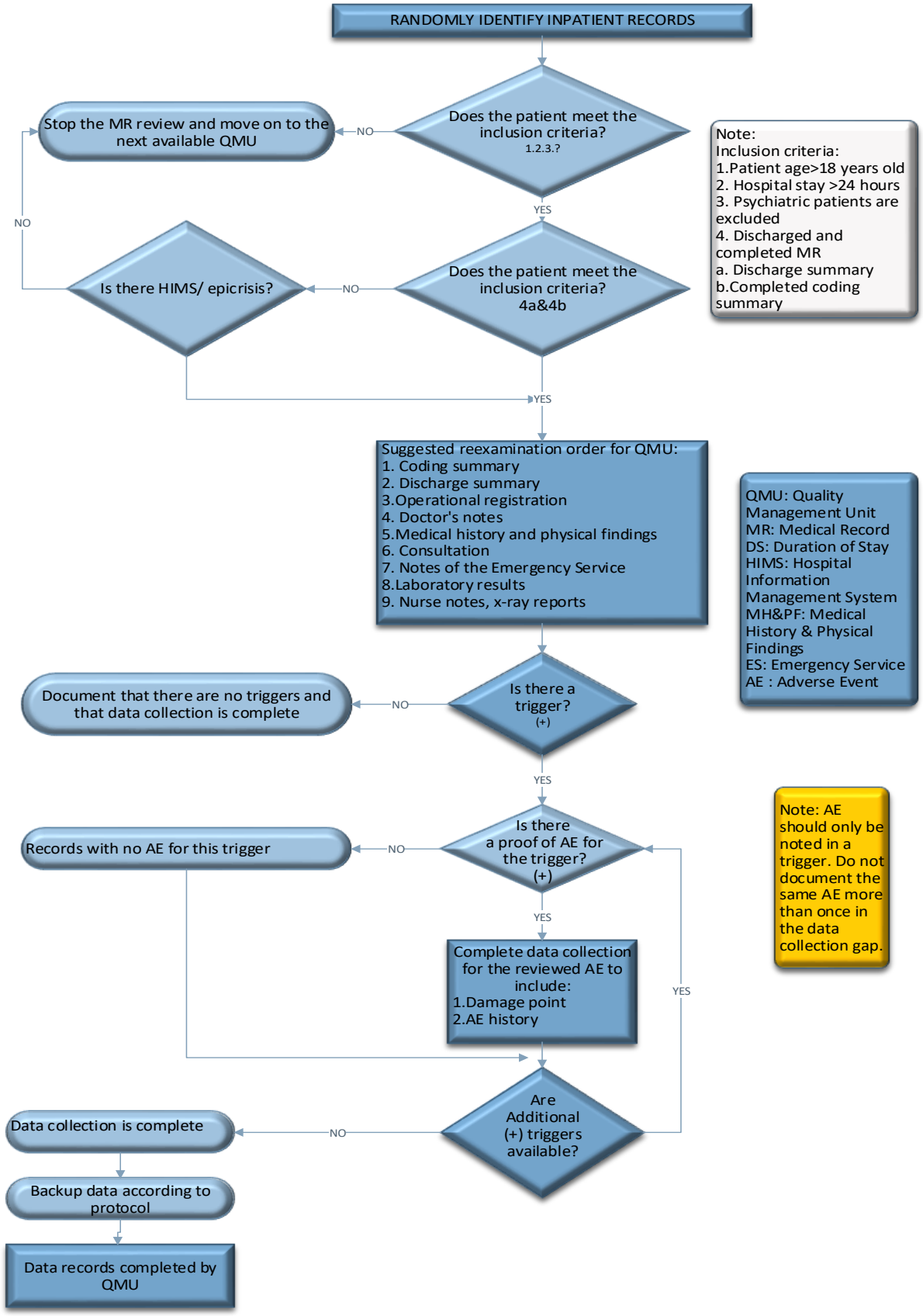

Figure 1. Research model

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Three Newly Identified Triggers

Expert academics were given a 3-hour training on GTT. At the end of the training, physicians were asked to find a trigger by using their literature knowledge and experience. With the feedback and literature review from expert academicians, three triggers were identified with the level of evidence determined. High CRP and Vaginal Surgery triggers were added to the Surgical modüle, and Vaginal Dynoprostone (Propess) Use for labor induction were added to the Perinatal modüle.

RESULT

Demographic indicators and key performance were shown in Table 1. Total number of patients 240, mean patient aged 37.3 years (95% CI 32.2 to 42.4) and total number of hospitalization days 481 were found. AEs per 1000 patient days 47.81, AEs per 1000 patient hospitalizations were 95.83, Percentage of hospitalizations with AEs 9.58% and Sensitivity rate of triggers 15.6% were found.

Table 1. Demographic Indicators, Key Performance, and Obstetrics and Gynecology Indicators

	Demographic Indicators and Key Performance Indicators		
Total number of patients	240		
Total number of hospitalization days	481		
Number of AEs causing harm	83 (in only 23 patients)		
Total number of degrees of harm seen in a patient	8		
Sensitivity rate of triggers	83/532=0,156 (%15,6)		
Number of Positive Markers	532		
AEs per 1000 patient days	23/481*1000=47.81		
AEs per 1,000 patient hospitalizations	23/240*1000= 95.83		
Percentage of hospitalizations with AEs	23/240*100= 9.58		
Number of people exposed to AEs			
E	13		
F	10		
	Mean	Min	Max
Age(years)	37.3	19	82
Hospitalization day	2	1	8

It is seen in Table 2 that the employees of the Training and Research Hospital reported 54 incidents in 2018 and 31 cases in 2019. Healthcare professionals can make event notifications to the https://grs.saglik.gov.tr/ system or to the quality management unit. When the notifications were examined, it was seen that there were no notifications of the OGC in 2018. In 2019, two of the 31 event notifications were related to the OGC.

Table 2. 2018-2019 VRS Notifications

Notification type	2018	2019	Total	%
Fall	16	8	24	28
Drug Safety	10	6	16	18
Medical Device - Material Safety	4	5	9	10
Sharps Injury	17	2	19	25
Blood and Body Fluid Splashes	2	-	2	2
Blood Transfusion	2	10	12	14
Radiation Safety	1	-	1	1
Side Marking	1	-	1	1
Patient Identification	1	-	1	1
Total	54	31	85	100

When the notifications of the VRS system are examined, the first notification relates to the violation of the blood storage conditions required for the OGC, which is not stored under appropriate conditions. The second notification is that the blood that the OGC employees noticed belongs to a different group. It is the notification made in the blood center that

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the blood/blood product requested belongs to a different blood group. When the two event notifications were evaluated according to the NCC MERP scale, it was seen that the notifications made were "Category B: An error that did not reach the patient". Event notifications belong to events that do not reach patients and do not require additional treatment or intervention.

When the AE notifications made to the VRS system were analyzed according to the NCC MERP scale, 3 events were evaluated in the "E" category in 2018. These events were reported one in Fall of the patient and 2 in category of medical device and material safety. Notifications made to the VRS for 7 AEs in 2019 are in the "E" category according to the NCC MERP scale. It was determined that five patients experienced a fall, and two patients were exposed to events related to Medical Device-Material Safety.

Table 3. Damage Degree and Sensitivity of GTT Modules

No	Modules	E	F	High sensitivity indicator	Poor sensitivity indicator
1	Health Care	16	23	9	6
2	Surgery	0	4	5	7
3	Medicine	7	6	5	7
4	Perinatal	22	2	6	3
5	Intensive Care Unit	-	-	-	4
6	Emergency room	-	-	-	2
	Total	45	35	25	29
	Main Total	80		54	

Damage Degree and Sensitivity of GTT Modules are shown in Table 3. From the point of view of all modules, the degree of damage was determined only in the “E” and “F” groups according to the NCC MERP scale. No findings were obtained for the “G”, “H” and “I” categories. In terms of the six modules of the GTT, it is seen that the two modules (intensive care and emergency) do not have a positive sign or degree of harm in the context of the data of the OGC. In terms of the “E” category, the most AEs were detected in the Health Services module 16 and perinatal 13 modules. In terms of the “F” category, the most AEs were detected in the health services module 23, drug 6 and surgery 4 modules. There are 25 triggers with the highest sensitivity. There are 29 triggers in GTT modules that can not detect any damage. This is a pioneering sign for the development of triggers specific to the OGC. Indicators with high sensitivity are the triggers that should definitely be included in the trigger set to be prepared for the OGC. Among the 54 triggers developed by the GTT, the most sensitive triggers in the OGC, and PPV of Triggers are shown in Table 4. NineTriggers were detected in the Health Services module, 5 Triggers in the Surgical module, 5 Triggers in the Medication Module, and 6 Triggers in the Perinatal Module Indicators.

Use of the Restrictive Apparatus with 240 triggers, Antiemetics with 97 triggers, and Oxytocic Agents with 55 triggers are the top 3 most sensitive triggers. The PPV was calculated to measure the sensitivity of each trigger. To calculate the PPV, it was determined how many AEs were included in the number of triggers. The most positive triggers were Restrictive Apparatus Use 20, Oxytocic Agents 13, Antiemetic Use 11. When the 5 indicators with a PPV of 100% were examined, it was seen that the number of triggers and the number of AEs that occurred were equal. These indicators are Partial Thromboplastin Time More Than 100 Seconds, International Normalized Ratio (INR) > 6, S10 Organ Injury, Repair or Removal, All Kinds of Operative Complications. Predictive Blood 53.33% and 30-Day Re-hospitalization 47.05% PPV are in the first two places. Triggers that fail to detect AEs although a negative predictive value is a trigger include X-Ray or Doppler Examination for Embolism, Change in Procedure, Giving Vitamin K and Expert Consultation. The sensitivity of these triggers to detect AEs in the OGC was evaluated as poor.

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Table 4. Trigger Tool List and Positive Predictive Value of Triggers

Triggers	TS	NT	NPV%	PT	PPV %
C1 Blood Product Transfusion or Use	26	23	88.46	3	11.53
C9 Re-Hospitalization Within 30 Days	17	9	52.94	8	47.05
C10 Use of Restrictive Apparatus	240	220	91.66	20	8.33
C11 Health care-related infection	4	0	0	4	100
C14 Development of Complications due to Any Procedure	2	0	0	2	100
C16 Other	4	2	50	2	50
S10 Organ Injury, Repair, or Removal	1	0	0	1	100
S11 All Kinds of Operative Complications	1	0	0	1	100
S13 Other	7	5	71.42	2	28.57
M2 Partial Thromboplastin Time (> 100 Seconds)	1	0	0	1	100
M3 International Normalized Ratio (INR)> 6	1	0	0	1	100
M10 Antiemetic Use	97	86	88.65	11	11.34
P4 Estimated Blood Loss >500ml (Vaginal) or >1000ml (Cesarean section)	15	7	46.66	8	53.33
P6 Oxytocic Agents	55	42	76.36	13	23.63
P7 Interventional Birth	35	33	94.28	2	5.71
P8 General Anesthesia	2	1	50	1	50

*TS: Number of Triggers; NT: Negative Triggers; PT: Positive Triggers; PPV: Positive Predictive Value (% PPV): Negative Predictive Value (%NPV)

In the High CRP indicator, 5 cases were detected in category F. It was determined that these women were rehospitalization within 30 days, and treatment due to vaginal vault infection or abscess, urinary system infection, wound infection. Increased CRP levels in the first two days after surgery could be an indicator of complications. İncreasing CRP levels which After the second postoperative day, is strongly linked to health care infections, additional surgical or medical treatments and hospitalization. It could be use it as a trigger.

Adverse events were detected in, 4 of the 22 patients with propess use for birth induction in category "F", and 2 in category "E". It was determined that 4 patients who developed fetal distress as a result of propess leading to long-lasting uterine contraction (uterine tachysystole) with adverse effects had to return from normal birth to cesarean section. The planned birth pattern of these patients changed, and their hospital stay was extended. In these 4 patients, postpartum uterine hemorrhage was developed due to uterine tachysystole and therefore treated with excessive use of uterotonic drugs. In addition, 2 patients developed postpartum bleeding due to the uterine tachysystole effect of propess and were treated with more than 25 units of uterotonics, so these patients were recorded as category "E".

İn the Vaginal surgery, gauze (tampon) could often be placed on the vaginal sutures at the end of the surgery in order to prevent bleeding. It was determined that gauze was forgotten in the vagina in 3 of 15 patients who underwent vaginal surgery, and 2 patients received inpatient parenteral treatment after the tampon was removed due to infection. These 2 patients were in category F, and 1 patient who was treated as an outpatient after tampon removal was in category E.

DISCUSSION

In this study, the GTT and the AE reporting system were compared during the AE evaluation process, and it was adapted to the GTT in the OGC. GTT data were obtained by processing the data of the patient file with a retrospective study in a two-year period. When the notifications made to the VRS for the years 2018-2019 were analyzed retrospectively in the training and research hospital where we conducted the research, it was determined that the "E" category events that did not harm the patient were reported. Reported AEs are respectively 28% falling, 25% sharp-stab injuries, 18% drug safety and 10% medical device and material safety. When the notifications were examined according to the NCC MERP scale, 10 patients were harmed in category "E". In these patients, non-permanent but intervention-requiring damage has occurred. There was 1 (1%) report of side marking as a requirement for safe surgery, and this is one of the few items. In the study of Çakmak et al. (2018), the rate of not marking the operation area/side was determined as 15%. In our study, it was observed that the notification regarding the lack of side marking was made in 2018, but no notification was made in 2019. In the same study, the patient's fall was found to be 29%, and in our study, it was found to be 28%. Similar values were reached in both studies.

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The top ten PS error reports most frequently reported to the VRS in 2016 were reviewed. In this report, falling is in the first place with 281 notifications. In the process-based distribution of errors, Device/Equipment/System-related errors are in the 5th place with 138 notifications. In our study, it is in the 4th place with 9 notifications on medical device-material safety. Among the top 10 surgical process errors most frequently reported to the Security Reporting System (SRS) in 2016, side marking is the leading one with 346 reports. In our study, only one of the 85 notifications made in 2018-2019 was the notification that "side marking was not done" based on the Ministry of Health SRS 2017 (Sağlık, 2016).

In 2015, the population of the single-center studies of Kurutkan et al. (2015) consisted of 219 patients and the number of AEs per-1000 patient days was 80.7. The population of the study conducted by Kirkendall et al. (2012) in a single-center hospital in the USA is 240 patients and the number of AEs per-1000 patient days is 76. In our study, AEs per-1000 patient days was 47.81. In the study of Asavaroengchai et al. (2010), it was 50 and 37.4 in the study of Mattsson et al. (2014) and 32.2 in the study of Rutberg et al. (2014). Similar results were obtained with our study. Within the scope of this study, it was concluded that the IHI was below the average because it was carried out in the OGC of a training and research hospital. In other studies, the number of AEs in Hooper and Tibballs's study (2014) was 600, and 530 in Larsen et al.'s (2007) study. Both studies are well above the overall average. In the study of Kirkendall et al. (2012), the number of AEs per-1000 patient days was 76, and 80.7 in the study of Kurutkan et al. (2015), which is the closest to the average in institutions using GTT.

High CRP and the use of process for labor induction can potentially be associated with AEs. The degree of damage obtained in this study also supports this.

VRS is a system designed to enable health professionals working in health institutions to report errors they experience and witness in medical processes. However, in the designed system, only drug safety, surgical safety, patient safety, and laboratory safety notifications can be made. There is no section on the outcome of all cases reported (such as disability, permanent organ damage, shock, or death). In addition, notifications to VRS are not subject to any harm rating classification. No notification is made in categories E and I in the NCC MERP damage category.

CONCLUSION

Global Trigger Tools were found to be more reliable than VRS in detecting AEs in the OGC. GTT is an AE assessment tool that can be easily adapted to both general and branch hospitals. GTT can be used on a unit basis and throughout the hospital. High CRP underwent vaginal surgery and use of propess for labor induction have the potential to be associated with AEs and may be use as trigger in the OGC. In this context, multicenter studies with more data are needed.

CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this manuscript.

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