Journal of Pharmacovigilance
ISSN: 2329-6887

Reis et al., J Pharmacovigil 2015, 3:6
DOI: 10.4172/2329-6887.1000184

Research Article Open Access

Efficacy of Trigger Tool in Identification of Suspected ADR in Secondary Hospital in Cape Verde

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Abstract

Background: Adverse drug events (ADEs) are a major health and economic problem. There is no information regarding incidence of ADEs in Cabo Verde and trigger tools are an efficient active data collection method.

Objective: To identify efficacy of the trigger tool in identification of suspected ADRs.

Method: The Global Trigger Tool (GTT) developed by the Institute for Healthcare Improvement (IHI) was used for a retrospective review of medical records. The ADE trigger tool included 21 triggers. 383 records were randomly selected, 190 in a first period and 194 in second period. Hospitalization for less than 48h, time spent in intensive care unit and lack of drug administration records was excluded.

Results: 287 triggers and 182 ADEs were found. Medical records with at least one trigger were 67.7% and 42.7%, respectively. In the same periods, 28.4% and 19.6% of total patients presented at least one ADE but it was 50% and 67.9% when calculating for the records with a trigger. In both periods, most common and robust trigger was nurse description. The least robust were abrupt medication stop and use of antiemetic drug.

Conclusion: The trigger tool had a good performance detecting ADE. The GTT is not feasible as routine PV method but an option to complement spontaneous notification. Further studies are needed using prospective method and extended period.

Keywords: Pharmacovigilance; Cape Verde; Safety monitoring; Adverse drug event monitoring; Trigger tool; Hospital pharmacovigilance; Efficacy of trigger tool

Background

The relevance and study methodologies in hospital

Adverse drug events (ADEs) are an important problem in the practice of healthcare professional. The increase use of medicines, polypharmacy and the existence of multiple diseases can be appointed as some of the risk factors for ADEs. Besides, it is known that adverse events are significant causes of hospitalization; increase the length of hospitalization and even death. The overall incidence of ADEs is unknown; however, studies have shown that about 5-10% of the patients who come to emergency rooms are due to ADEs and that 10-20% of those who are hospitalized suffer from ADE [1,2]. Moreover, about 3% and 6% of ADEs are fatal or have serious consequences. In addition, it is estimated that 14.8% to 59% of the ADEs could be prevented [3]. In Cabo Verde, a recent study in this same secondary hospital estimated an incidence of 28.4 % and 19.6% of ADE in hospitalized patients [4].

Different approaches and methodologies have been used to characterize the incidence of ADEs. The clinical studies, the spontaneous reporting (NE), the algorithms for database search and the chart review proven to have disadvantages form being expensive, insensitive or largely ineffective [5,6]. The use of triggers, occurrences found during review of medical records, appears as an alternative to overcome this disadvantages emerging as the premier measurement strategy for patient safety [7,8]. These triggers has been used as part of monitoring activities in US [9], in Europe [10,11] and in Brazil [12,13].

The Institute for Healthcare Improvement (IHI) developed the trigger tool method to random review sample of inpatient hospital records using "clues" to identify possible adverse events. This method consists in a list of *triggers* previously tested, including medicines, laboratory results and information on assistance to the patient and clinical outcome that act as clues to identify ADEs [9,14].

In Cabo Verde, in the context of a research project to develop a proposed model for the implementation of a pharmacovigilance system adapted to the national reality it was deemed important to have national data on the incidence of ADEs. This study was undertaken in hospital using existing triggers tools and made possible to assess trigger tool efficacy.

Method

Study settings and design

The study was done at a secondary care hospital in Santiago, Cabo Verde. This hospital is a referral hospital for the North health region of Santiago. The hospital has been operating since April 2008, covering six municipalities whose population represents 48.8% of the population of the island of Santiago and 27.2% of the country, about 112 000 inhabitants.

It is a hospital of medium complexity, with 90 beds in the inpatient services Surgery, Gynecology and Obstetrics, Medicine and Pediatrics. The existing hospital pharmacy is primarily engaged in the supply of drugs to inpatients and outpatients; inventory control and quality of drugs through visits, as well as the control of narcotic and psychotropic

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Received October 26, 2015; **Accepted** November 20, 2015; **Published** November 27, 2015

Citation: Reis CD, Veiga CE, Martins JJ (2015) Efficacy of Trigger Tool in Identification of Suspected ADR in Secondary Hospital in Cape Verde. J Pharmacovigil 3: 184. doi:10.4172/2329-6887.1000184

drugs. The electronic prescription is only made for outpatients.

The hospital has no standard procedure to reporting ADR; however they established recently a pharmacovigilance focal point. The focal point received basic pharmacovigilance training from the national pharmacovigilance centre and is responsible to collect suspect ADR that may arise, to report to the national pharmacovigilance centre, to sensitize the colleagues and to disclose safety warning about medicines.

The study plan was submitted to the Ethics Committee for Health Research at the Ministry of Health and then approved by the hospital board. A multidisciplinary team was appointed to discuss procedures and to follow up the study.

The calculation of sample size for the review of medical records was made based on inpatient data from hospital activity reports, as a simple random sampling (SAS), 5% error and the files randomly chosen to take a distribution equitable per month. According to the 2012 activity report, the hospital had a total of 2746 hospitalizations for which it was estimated a sample of 231 medical records for enrollment.

In the first phase it was decided to randomly select 190 medical records for the period of October 2012 to March 2013, based on date of admission, to allow a 9% increase from the calculation in order to prevent incomplete files or impossible to evaluate. A subsequent random selection of other 193 medical records for the period October 2013 to March 2014. A total of 383 medical records for a period of analysis corresponding to 12 months were selected in two phases based on the date of admission.

The two periods were chosen to be comparable as per epidemiological incidence of diseases. Therefore, the same months were included (October to March) in two subsequent years. During the interval between two periods, the national pharmacovigilance centre realized pharmacovigilance training sessions.

The inclusion criteria used to include medical records was a minimum hospitalization period of 48h, records with drug administration, complete discharge summaries and coding. Cases of emergency ward and intensive care were excluded (Table 1).

About 21 trigger were used to review the medical records, being 9 related to medication, 7 related to laboratory findings and 5 to sign and symptoms.

Adverse event definition

ADEs are the occurrence of any harm to the patient potentially related to medical intervention with the use of medication, resulting in a temporary or permanent physical or psychological disturbance in the body or in its structure. The definition includes prescribing, dispensing and administrating errors and adverse reactions [10].

Data collection and statistical analysis

A review of the processes was performed using the trigger developed by IHI as adapted in published studies on the implementation and performance of those triggers [13,15]. The collection and review of medical records was planned and executed by a team of a pharmacist a biomedical and a statistical.

The data collected refer to the demographic, social, health and hospitalization: gender, age, occupation, education, date and inpatient reason, diagnosis, concomitant diseases, discharge summary, medication administered and whether or not one or more of the triggers were identified. When triggers are identified, the reviewer has to further analyze if there is an ADE (Table 2).

The performance of the triggers was analyzed to assess the efficacy and usefulness of the global trigger tool in these specific conditions. The performance of the triggers and the ability to capture ADEs were evaluated based on: 1) number of ADEs identified by triggers divided

	Trigger		**Potential ADEs**
Medication	T1	Anti-Allergic	Hypersensitivity Reaction
	T2	Coagulant	Overdose of warfarin
	T3	Benzodiazepine Antagonist	Sedation for benzodiazepines
	T4	Anti-emetic	Nausea /vomiting
	T5	Opioid Antagonist	Narcotic drugs overdose
	T6	Antidiarrheal	Gastrointestinal Effects
	T7	Ion Exchange Resin	Hyperkalemia
	T8	Digoxin	
	T9	Abrupt medication stop	
Laboratory results	T10	Partial thromboplastin time greater than 100 seconds	Excessive anticoagulation with heparin
	T11	International Normalized Ratio (INR) greater than 6	Excessive anticoagulation with warfarin
	T12	White blood cell (WBC) count less than 3000 x 10^6/µl	Neutropenia
	T13	Glucose less than 50 mg/dl	Hypoglycemia associated with insulin use
	T14	Increase in serum creatinine	Renal failure
	T15	*Clostridium difficile* positive stool	Exposure to antibiotics
	T16	Platelet count less than 50.000	
Signs and Symptoms	T17	Over-sedation, lethargy, fall	ADEs
	T18	Rash	ADEs
	T19	Transfer to higher level of care	ADEs
	T20	Medical description	ADEs
	T21	Nurse description	ADEs

Table 1: List of triggers to identify on medical records.

by the total number of medical records evaluated and 2) the number of ADEs identified by each trigger.

The data collected was introduced in database specifically designed for the purpose. Data analyzes and data processing was performed, using SPSS version 20.

Results

A total of 383 medical records were reviewed. About 287 triggers were identified. A mean of 0.74 trigger (SD=0.21) were found per medical records and in the first period 54.4% had 1to 4 trigger per medical records.

The performance of each trigger is presented in the (Table 3). The most found triggers in the first period were: "description of nurse" (33%); "abrupt medication stop" (22%); "Anti-emetic" (18%); "description of physician" (14%); and "anti-allergic" (5%). In the second period the most found triggers were: "description of nurse" (29%); "description of physician" (28%); "Anti-emetic" (14%); Transfer to higher level of care (6%) and "abrupt medication stops" (6%). The trigger with best performance was: "description of nurse"; "abrupt medication stop"; "description of physician" and "Anti-emetic" (Table 3).

Discussion

As regards to triggers identification, in both periods, nurses described most events (33 and 29%). This result is consistent with the information described in a previous study on spontaneous reporting where these are the professionals that report the most. Furthermore, the trigger that identified higher number of events was expected, since they are related to the trigger most found.

The ADEs mainly captured by the description of nurse and medical was fever, nausea; vomiting; headache; oedema and diarrhea. However, it's important to highlight that some of the events such vomiting and nausea could be detected by the trigger "Anti-emetic" but due to poor quality record about the pharmacotherapy it was only possible to detect such events trough the description of nurse and medical. In terms of level of harm, most of the events detected were classified as "temporary harm to the patient and required intervention".

The "abrupt medication stop" although the difficulty to assess whether discontinuation of a medication is or is not related to dosage adjustments, scheduled or administrative suspension, this trigger is useful, as it allows identifying diverse events and gravity.

Number of triggers	Number of medical records 1st period (%)	Number of medical records 2nd period (%)
0	87 (44.6%	138 (70.1%)
1 to 4	106 (54.4%)	532 (6.9%)
≥ 5	2 (1,0%)	3 (1.5%)

Table 2: Distribution of triggers for the 2 periods.

TRIGGERS	SEMESTERS							
	Semester 1				Semester 2			
	TRIGGERS TOTAL	TRIGGERS%	TOTAL SUSPECT ADE	% SUSPECT ADE	TRIGGERS TOTAL	TRIGGERS %	TOTAL SUSPECT ADE	% SUSPECT ADE
Nurse description	61	22,2%	47	44,8%	30	12,4%	27	35,1%
Abrupt medication stop	40	14,5%	19	18,1%	6	2,5%	4	5,2%
Anti-emetic	34	12,4%	14	13,3%	14	5,8%	3	3,9%
Medical description	26	9,5%	13	12,4%	29	12,0%	24	31,2%
Anti-Allergic	10	3,6%	2	1,9%	2	,8%	2	2,6%
Increase in serum creatinine	3	1,1%	3	2,9%	3	1,2%	2	2,6%
Transfer to higher level of care	3	1,1%	3	2,9%	6	2,5%	5	6,5%
Antidiarrheal	1	,4%	0	,0%	0	0,0%	0	0,0%
Digoxin level, arrithymia, bradycardia, nausea, vomiting, anorexia or visual disorders	2	,7%	1	1,0%	4	1,7%	3	3,9%
Glucose less than 50 mg/dl	1	,4%	1	1,0%	3	1,2%	2	2,6%
Others	1	,4%	0	,0%	1	,4%	1	1,3%
Rash	1	,4%	1	1,0%	2	,8%	2	2,6%
Excessive sedation, somnolence, drowsiness, lethargy, falling, hypotension	1	,4%	1	1,0%	2	,8%	1	1,3%
White blood cell count less than 3000x106/µl	0	0,0%	0	0,0%	1	,4%	1	1,3%

Table 3: Trigger performance.

The results regarding the performance of this method described based on the most identified triggers and the most robust triggers are similar with the findings in the Brazilian study [12,13].

The association between medication use and the ADE (causality) was critical mainly because of the difficulty in distinguishing possible ADE from complications or evolution of the disease, which were aggravated by lack of information of medical records.

The quality issues of medical records, especially the illegibility, had an impact on the time required to review the medical record. Instead of 20 minutes recommended by the IHI, the average was more than 60 minutes. Again, this is comparable with findings in the Brazilian study [12,13].

Despite this major limitation, to enhance the usefulness of this method, it should be noted that there was no

ADE identified that is not associate with a trigger.

As concluded in previous study [6], it suggests that this method can be used to determine national rates of adverse events. This information has crucial importance in a context of establishment of the pharmacovigilance system, of including hospitals as a key element and for promotion of notification by health care professionals.

Conclusion

This trigger tool, even without the use of electronic databases, has proven possible to be used to detect ADEs and may realistically be expected to be useful.

The limitations usually appointed to the use of the trigger tool for quantifying ADEs do not have impact in a context where no information is available.

The results indicate that the method is efficient to identify suspected ADR. Regarding the Pharmacovigilance perspective of prevention or identification as soon as possible of ADR, further studies would be desirable with prospective design, extended period and much more resources available regarding human resources, laboratory tests and information systems.

Acknowledgement

To the Hospital Director, Clinical Director and Statistic technician, Dr Dalia Monteiro, Dr Khadija Carvalho and Cecilia Joel, respectively.

To Agência de Regulação e Supervisão dos Produtos Farmacêuticos e Alimentares (ARFA) To the Direction of Pharmaceutical Regulation, Dr. Eduardo Tavares.

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