Trigger Tool: An Effective Method for Ensuring Patient Safety

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I. Introduction

Patients run a high risk of being harmed during hospital admissions. Adverse events occur in up to 10% of hospitalizations and can cause temporaryorpermanent disability or even death [1]. A number of methods that have been employed to monitor for AEs in healthcare rely on either voluntary reporting systems, direct observation, complaints, mortality and morbidity review, or patient care documentation review. While these methods may be effective for specific patients or defined high risk procedures, there is little evidence to suggest they provide a comprehensive system of AE detection. A novel approach known as the Trigger Tool methodology has been shown to be a more time effective, cost-effective means of identifying AEs when compared with more traditional methods [2].

The Global Trigger Tool (GTT) developed by the Institute of Healthcare Improvement (IHI) is widely used for retrospective reviews of medical records. The GTT can be used as a quality improvement tool in clinical practice to estimate and track AE rates over time. The Swedish version of the GTT was published in 2008 and includes evaluation of preventability of harm. The same preventability assessment was used in a study of the incidence of AEs in Swedish hospitals.

At the university hospital in Linkoping, in southeast Sweden, the GTT method has been applied since 2009 with a monthly review of 20 randomly selected medical records [3].

Most research on trigger tools used to identify ADEs has focused on hospitalised patients. Singh et al created a 36-item trigger tool and investigated its efficacy in the outpatient settings for detecting ADEs among older patients seen in primary care settings [4].

Kirkendall et al. used the GTT developed for adult care on a pediatric sample, and found that 25.8% of the patients had atleast one AE. This study showed the potential use for the GTT in pediatric populations, but it also pointed out that the review process needs to be developed since definitions and reference values in existing tools are not adapted to pediatric care.

A promising comprehensive trigger tool for hospitalized children in Canada, based on the Harvard medical practice study review methodology, found AEs in 15.1% and 9.2% of the admissions. Another pediatric trigger tool was launched in the United Kingdom in 2010 and a recently published study reported that at least one AE occurred in 14.2% of the patients [5].

A number of studies have evaluated its performance, compared it to alternative strategies to detect adverse events, and described its adaptation and/or use by hospitals, healthcare systems, or government entities in various countries. Recently, it has been used to examine temporal trends in AEs in North Carolina hospitals and a large multihospital system in Florida, and to assess incidence of AEs in three large US tertiary care centers [6].

A recent study showed the superiority of trigger tool methods to reporting methods as active surveillance for ED patient safety. Other studies have suggested that combining measurement methods may be a promising solution for identifying adverse events in the ED [7].

IMPORTANCE OF MONITORING ADR

Monitoring is a process of checking a system that changes with time, in order to the system that will maintain it or improve. Monitoring has three components: proactive, targeted observation; analysis and action. There are some obvious requirements for monitoring to achieve its aim. It should be clear from the outset of the process which observations are to be monitored. The observations have to reflect important characteristics of system variation relative to the goal of monitoring, and be made with sufficient frequency and accuracy to capture important changes [8]. Patients worldwide may experience adverse drug events after they have been discharged from hospital. A recent study reported that the prevalence of medication errors after discharge from hospital to be around 51.3%. Community pharmacists have an important role in monitoring medication use among patients in the community settings. In line with the recent *Jeddah*Declaration on patient safety 2019 to promote medication safety in community pharmacies, pharmacists working in the community should be encouraged to share their knowledge and experience [9].

The oxygen saturation monitor, which sounds an alarm if the patients oxygen saturation drops below some threshold value, illustrates the process. The monitoring in this case is designed to improve the safety of the system by warning of a need to increase the concentration of oxygen in inspired air, so that the patient does not suffer from the consequences of hypoxia. The monitoring of blood haemoglobin concentration in a patient known to have aplastic anemia provides a related example. The monitoring is designed to ensure that there is sufficient hemoglobin for the patient to remain safe. If the concentration falls too low, then transfusion is required. Monitoring in this example is intermittent but remains reasonably accurate. Clinicians and patients themselves can monitor response to treatment of a specific condition –for example, monitoring the temperature during antibacterial treatment. If a drug has a narrow therapeutic range, samples can be taken to allow dose to be adjusted so that the concentration remains between a minimum value for efficacy and a maximum value for safety. This therapeutic drug monitoring (TDM) has been widely used to adjust dosages of antiepileptic drugs such as phenytoin. Monitoring is often advocated as way of avoiding or mitigating the harm from adverse drug reactions[8]

CLASSIFICATION OF ADRs

Adverse drug reactions were originally classified into two subtypes. Type A ADRs are augmentations of known pharmacologic effects of the drug, such as orthostatic hypotension with antihypertensive medications. Type B ADRs are uncommon and unpredictable, depending on the known pharmacology of the drug; they are independent of dose and affect a small population. Two further types were eventually added: chronic reactions (Type C) and Delayed reactions (Type D). withdrawal later became the fifth category (Type E) and most recently, unexpected failure of therapy became the sixth.

About 80% of ADRs in the hospital setting or causing admission to a hospital are type A. These ADRs are potentially avoidable and often predictable. The drug classes most commonly responsible for ADRs in adults are adrenal corticosteroids, antibiotics, anticoagulations, antineoplastic and immunosuppressive drugs, cardiovascular drugs, nonsteroidal anti- inflammation drugs, and opiates. For children, the most prevalent drug classes for ADRs are anti-infective drugs, respiratory drugs, and vaccines[10]

| Type of Reaction (Mnemonic) | Features | Examples | Management |
|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| A: Dose related (Augmented) | Common Related to the pharmacologic action of the drug – exaggerated pharmacologic response Predictable Low mortality | Dry mouth with tricyclic antidepressants, respiratory depression with opioids, bleeding with warfarin, serotonin syndrome with SSRIs, digoxin toxicity | Reduce dose or withhold drug Consider effects of concomitant therapy |
| B: Non-dose related (Bizarre) | Uncommon Not related to the pharmacologic action of the drug Unpredictable High mortality | Immunologic reactions: Anaphylaxis to penicillin Idiosyncratic reactions: Malignant hyperthermia with general anesthetics | Withhold and avoid in future |
| C: Dose related and time related (Chronic) | Uncommon Related to the cumulative dose | Hypothalamic-pituitary-adrenal axis suppression by corticosteroids, osteonecrosis of the jaw with bisphosphonates | Reduce dose or withhold; withdrawal may have to be prolonged |
| D: Time related (Delayed) | Uncommon Usually, dose related Occurs or becomes apparent sometime after use of the drug | Carcinogenesis Tardive dyskinesia Teratogenesis Leucopenia with lomustine | Often intractable |

| E: Withdrawal | Uncommon | Withdrawal syndrome with opiates or | Reintroduce drug and withdraw slowly |
|-----------------------------------------------------|--------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| (End of use) | Occurs soon after withdrawal of the drug | benzodiazepines (e.g., insomnia, anxiety) | |
| F: Unexpected failure of therapy (Failure) | Common Dose related Often caused by drug interactions | Inadequate dosage of an oral contraceptive when used with an enzyme inducer Resistance to antimicrobial agents | Increase dosage Consider effects of concomitant therapy |

PHARMACIST ROLE IN ADR MONITORING

Several studies have found that most of the ADRs could be detected and prevented. Pharmacist play an essential role in detection, identification, and prevention as well as management of ADRs. Clinical pharmacists have accurate knowledge about medication and drugs, so regular interaction with drug prescribers will help to bridge the gap between clinical pharmacists and physicians. Clinical pharmacists check the prescription of physicians to make sure the rational use of medication in the right dose, duration, and time, and in case of presence of any variance they inform the prescriber an make appropriate intervention. Although all health professionals perform their roles regarding medication, pharmacists experience about drugs plays a more important role in ADRs reporting and this helps in withdrawing the product or causing labeling changes. Reporting ADRs is an essential component in monitoring and evaluating the activities performed in hospitals. A hospital based reporting program helps in providing important information about drug usage problems and resolving them, patient care will be improved. A study from India reported that ADRs were the major drugrelated problems identified by clinical pharmacists and its incidence was 0.082%. The studies demonstrated that clinical pharmacists are the upcoming breed of pharmacists in their community and they contributed to improving patients outcomes by monitoring the patients drug therapy and they could guide patients for rational use of drugs. Another study conducted in Iran reported that the intervention of clinical pharmacists regarding ADR committees establishment in hospitals resulted in an improved output of the pharmacovigilance system [11].

TRIGGER TOOL

Health care organizations use a variety of strategies to detect safety hazards in order to prevent harm. These methods are often referred to by various names such as Targeted Injury Detection Systems and most commonly as triggers[12]. The use of "triggers," or clues, to identify adverse events (AEs) is an effective method for measuring the overall level of harm from medical care in a health care organization. Traditional efforts to detect AEs have focused on voluntary reporting and tracking of errors. Hospitals need a more effective way to identify events that do cause harm to patients, in order to select and test changes to reduce harm.

Trigger Tools provide an easy-to-use method for accurately identifying AEs (harm) and measuring the rate of AEs over time. Tracking AEs over time is a useful way to tell if changes being made are improving the safety of the care processes [13]. The IHI Global Trigger Tool (GTT) is a retrospective method for monitoring patient safety levels within a healthcare provider organization. Its aim is to enable longitudinal comparisons and assessment of implemented patient safety measures and support the identification of target areas for improvement. A distinct feature of the IHI Trigger Tool methodology is its focus on actual harm (restricted to physical injury) inflicted to patients [14].

Triggers have become a widely used way to retrospectively analyze medical records in order to identify errors and adverse events, measure the frequency with which such events occur, and track the progress of safety initiatives over time. Triggers alert patient safety personnel to possible adverse events so they can review the medical record to determine if an actual or potential adverse event has occurred. The main value of triggers is efficiency, since a complete review of every medical record to find adverse events is laborious and expensive, even in the era of electronic medical records. Triggers provide a way of screening medical records for possible harm and identifying cases that merit a more detailed review.

For example, the administration of naloxone (a drug used to reverse the effect of opioid medications) to a hospitalized patient would be a reasonable trigger that could help identify instances where a patient was given a harmful dose of an opioid drug. When naloxone is administered in an inpatient ward, it may be because the patient received an excessive dose of morphine or another opioid medication. Therefore, pharmacists and patient safety personnel could use that trigger to identify cases that may represent problems with the ordering or administration of opioid medications. This method would miss many less severe cases (ones that weren't severe enough to merit naloxone administration), but the cases it did identify would very likely represent preventable adverse events. Well-defined, specific triggers like this also lend themselves to automated electronic detection, making them particularly efficient for ongoing monitoring activities. When the trigger correctly identifies an adverse event, causative factors can be determined and interventions developed to reduce the frequency of such events. Triggers can also be used to track rates of adverse events over time [12].

ADVANTAGES IN IMPLEMENTING TRIGGER TOOL

The Global Trigger Tool provides the whole system outcome measurement by applying a clinical perspective to the systems outcome; harm as an outcome reflects the overall effectiveness of the hospital's safety program. Hospitals of all sizes can use a small random sampling of patient medical records to understand AEs that remain elusive to even the best incident reporting systems or individual chart audits. Even small hospitals can reap the benefits of such whole-system safety measurement without costly technology and clinical decision support through manual chart review.

Although the Global Trigger Tool accuracy, reliability, and reproducibility as an inter-hospital measurement system is sure to be improved through further research, the early implementation of an outcome harm tracking tool is an essential first step. As electronic health records and clinical data ware-houses proliferate, innovations such as electronic triggers and automated clinical decision support may supplant the manual identification of harm through chart audit, incident reports, sentinel event tracking, and trigger tools.

The global trigger tool is a valid, low-cost, and easily adopted measurement system for frontline hospitals that is available to help improve patient safety. This tracking system provides ample evidence that demands action, which can ultimately save lives, save money, and deliver value to the communities our hospitals serve [15].

| NAME OF THE AUTHOR AND YEAR | PURPOSE OF THE STUDY | SAMPLE SIZE | METHEDOLOGY | RESULTS | INFERENCE |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Pandya AD et al. 2020 | Global trigger tool: proficient adverse drug reaction autodetection method in critical care patient units | 463 | A prospective study was conducted in the ED for the presence of triggers in patient records to monitor and report ADRs by applying the Institute for Healthcare Improvement (IHI) trigger tool methodology. Type of ADR was analysed according to Rawlins and Thompson classification. Causality assessment of the ADRs was done using WHO- UMC criteria. Harm categorization was assessed for the observed ADRs using NCC- MERP. The data collected was also uploaded to the WHO Uppsala Monitoring Centre via VIGIFLOW | 463 medical records were analysed randomly using 51 trigger tools, where triggers were found in 181 and ADRs in 62 patients. The prevalence of ADR was 13.3%. According to the WHO-Uppsala Monitoring Centre causality scale, 47 were classified as probable and 15 as possible, wherein 39 were predictable and 8 were definitely preventable. Most common triggers were abrupt medication stoppage, antiemetic use, and time in ED > 6 hours. Presence of five or more triggers has statistically significant chances of developing an ADR. | Trigger tool could be a viable method to identify ADRs when compared to the traditional ADR identification methods, but there is insufficient data on IHI tool and its use to identify ADRs in the general outpatient setting. |
| Liu Y et al. 2020 | Establishment of a pediatric trigger tool based on Global Trigger Tool to identify adverse drug events of children. | 200 | This study attempts to establish a trigger tool based on GTT to detect ADEs in pediatric inpatients, and to investigate the factors associating with the occurrence of ADEs. The trigger tool was established by three steps including literature search, triggers extraction and revision, and expert investigation. A retrospective cohort study was conducted to detect ADEs by using 200 pediatric in-patient records of Sichuan provincial people's hospital. | 33 preliminary triggers were established, and 2 rounds of expertsinvestigaton were conducted. In the retrospective review, the positive trigger rate was 64.0%, while the PPV was 24.9%. The occurrence of inpatients with ADEs was 20.5%. ADEs/100 admissions were 49.0. ADEs/1000 patient days were 46.89. The most common ADE categories were leukocyte disorders, skin disorders and platelet disorders. The severity of 39 ADEs was grade 1, 55 ADEs was grade 2, 4 ADEs was grade 3. | The 33 pediatric triggers may detect ADEs effectively, but still need to optimized. This study may provide some references for further research in order to improve the rationality and safety of medication. |
| Lee WH et al. 2019 | Comparing the outcomes of reporting and trigger tool methods to capture adverse events in the emergency | 69, 327 | One year Prospective observational cohort study evaluated a monitoring system that combined 2 reporting methods and 5 trigger tool methods to capture adverse events in the ED of an academic medical center. Measurement | Among 69,327 adult nontrauma ED visits, 285 adverse events were identified. Of these adverse events, 77.2% were identified using reporting methods, 26% using trigger tool methods, and 3.2% using both methods. Of the adverse events | The reporting methods more effectively captured greater numbers of adverse events,whereas the adverse events captured by the |

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| | department | | outcomes included the number, type, and physical impact of the captured adverse events. | that occurred, 86.7% were related to clinical performance. Compared with reporting methods, trigger tool methods had a lower positive predictive rate to identify adverse events. | trigger tools method were more likely to be severe physical impacts. The combined use of the different methods had synergistic benefits for monitoring adverse events in the ED. |
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| Menat U et al. 2019 | Evaluation of trigger tool method for adverse drug reaction monitoring at a tertiary care teaching hospital. | 400 | A prospective, single-center, observational cum interventional study was conducted in two phases in the department of medicine over 15 months. In phase I, preliminary trigger tool list (PTTL) comprising 55 triggers was evaluated by pharmacologist in terms of detection of ADR in 400 patients and then, modified trigger tool list (MTTL) was prepared. In phase II, the TTM using MTTL was compared with the spontaneous method of ADR monitoring after educational interventions in resident doctors of the two units of medicine department. | Of the 55 triggers in PTTL, 34 triggers were observed in 327 patients, of which 19 triggers lead to the detection of 66 ADRs. The rate of ADRs was 16.5%/100 patients. PPV of each trigger ranged from 0% to 100%. PPV for drug trigger, laboratory trigger, and PT was 14.4%, 4.5%, and 23.3%, respectively. Sensitivity and specificity were 100% and 21.66%, respectively. MTTL consists of these 19 triggers. In phase II, resident doctors reported 16 ADRs, using spontaneous method and 23 ADRs using mttl. The rate of ADEs per 100 patients was 1.63 and 2.13, respectively, with these methods. A total of 105 ADRs were reported during both phases. | TTM is an effective method of ADR reporting if it is utilized by a trained person. This method could be used as add-on method to spontaneous method to improve ADR reporting. |
| Martins M et al. 2018 | Evaluation of accuracy of IHI trigger tool in identifying adverse drug events. | 300 | A prospective observational study was conducted in a public university hospital in 2015 with patients over the age of 18. Triggers proposed by IHI and clinical alterations suspected to be ADRs were searched daily. The number of days in which the patient was hospitalized was considered as unit of measure to evaluate the accuracy of each trigger. | Mean age was 56.3 years and 154 were female. The frequency of patients with ADRs was 24.7% and with atleast one trigger was 53.3%. From those patients who had at least one trigger, the most frequent triggers were antiemetics (57.5%) and abrupt medication stop (31.8%). The sensitivity of triggers ranged from 0.3 to 11.8% and the positive predictive value ranged from 1.2 to 27.3%. specificity and negative predictive value were greater than 86%. No triggers were identified in 40 ADRs. | IHI trigger tool did not show good accuracy in detecting ADEs in this prospective study. The adoption of combined strategies could enhance effectiveness in identifying patient safety flaws. |
| Nagai KL et al 2018 | Use of triggers tools to search for adverse drug reactions in the elderly admitted to emergency departments. | 287 | A retrospective cross-sectional study was carried out at an ED that used an adaptation of the institute of Health Care Improvement triggers. In this study, patients aged 60 years or older were included. For this study, only suspected ADRs were investigated. Suspected ADRs were classified according to the WHO-ART, which presents classification levels. The SOC systems was used. Naranjo algorithm is utilized for causality analysis. | A total of 287 medical records were analyzed and 38 triggers were found, identifying 7 suspected ADRs. One was found without the use of triggers. Thus, in total, 8 ADRs were found of which 6 were considered serious. There was a higher prevalence of ADRs in females and in those over 80 years of age. The medications most implicated were those for alimentary tract and metabolism and cardiovascular system. | Triggers have proved useful for an active search for suspected ADRs at EDS including severe ones, identifying problems occurring outside hospital settings and signaling medications that pose an increased risk to the elderly. |
| Almeida SM et al. 2017 | Use of a trigger tool to detect adverse drug reactions in an emergency department | 866 | Retrospective study from January to December, 2014, applying the institute for healthcare Improvement Trigger Tool (IHI) methodology for patients treated at the emergency room of a tertiary care hospital. Inclusion | The estimated prevalence of adverse reactions in patients presenting to the emergency department was 2.3%. 28.6% of cases required hospitalization. The common triggers were hydrocortisone (57%), | It showed to be a viable method that can provide a better understanding of adverse drug reactions in the |

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| | | | criteria included the administration of specified trigger medications, drugs that might be given in response to suspected adverse reactions to other drugs. The Naranjo scale was used to assess causality, and the cases were classified as doubtful, possible, probable or definite. | diphenhydramine and fexofenadine, musculoskeletal drugs, cardiovascular drugs (14%), anti-infectives (19%). According to naranjo scale. 71% were classified as possible and 29% as probable. | selected patient population |
|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Synderman AL et al. 2017 | To assemble a set of clinical triggers in the medical record and assess the extend to which triggered events identified AEs. | 400 | A retrospective cohort study was conducted to assess the performance of an oncology medical record screening tool at a comprehensive cancer center. The study cohort included 400 patients age 18 years or older diagnosed with breast, colorectal, or lung cancer, observed as in- and outpatients for up to 1 year. The overall positive predictive value was calculated for the tool for identifying AEs and potentially preventable or mitigable AEs and PPVs of the individual triggers. | They identified 790 triggers, or 1.98 triggers per patient. 304 unique AEs were identified from medical record reviews and existing AE databases. The overall positive predictive value of the original tool was 0.40 for total AEs and 0.15 for preventable or mitigable AEs. The final modified tool included 49 triggerss, with an overall PPV of 0.48 for total AEs and 0.18 for preventable or mitigable AEs. | A valid medical record screening tool for AEs in oncology could offer a powerful new method for measuring and improving cancer care quality. |
| Karpav A et al. 2016 | Performance of trigger tools in identifying adverse drug events in emergency department patients. | 1151 | This study was a sub-study of a prospective cohort study which enrolled adults presenting to one tertiary care emergency department. Clinical pharmacists evaluated patients for ADEs at the point-of-care. Twelve months after the prospective study's completion, the patient's medical records were reviewed using eight different trigger tools. ADEs identified using each trigger tool were compared with events identified at the point-of- care. The primary outcome was the sensitivity of each trigger tool for ADEs. | Among 1151 patients, 152 were diagnosed with one or more ADEs at the point-of-care. The sensitivity varied from 99.3% to 100%. Most events were rated as moderate in severity and warfarin, paracetamol with codeine, aspirin, phenytoin, olanzepine and hydrocholothiazide were the most commonly implicated medications. | The trigger tools examined had poor sensitivity for identifying ADEs in emergency department patients, when applied manually and in retrospect. |
| Sam AT et al. 2015 | To determine the extent and types of adverse drug events from the patient cases sheets and identify the contributing trigger factors. | 100 | A retrospective study was conducted. Hundred patient case sheets were randomly selected, modified version of the Institute for Healthcare Improvement (IHI) global trigger tool was utilized to identify the ADEs. Causality and severity were calculated utilizing the WHO probability scale and Hartwig's severity assessment scale, respectively. | In total, 153 adverse events were identified using the IHI Global trigger tools. Majority of the AEs are due to medication errors followed by 60 adverse drug reactions, 15 therapeutic failure incidents, and 7 over dose cases. Out of the 153 AEs, 60 are due to ADRs such as rashes, nausea, and vomiting. Therapeutic failure contributes 9.80% of the AEs, while overdose contributes to 4.58% of the total 153 AEs. Using the trigger tools, they were able to detect 45 positive triggers in 36 patient records. | The IHI global trigger tool is an effective method to aid effective method to aid provisionally- registered pharmacists to identify ADEs quicker. |
| Sam AT et al 2015 | A retrospective study on the incidence of adverse drug events and analysis of the contributing trigger factors. | 100 | Hundred patient case sheets were randomly selected, modified version of the IHI Global trigger tool was utilized to identify the ADEs. Causality and severity were calculated utilizing the Who probability scale and Hartwig's severity assessment scale, respectively. | 153 adverse events were identified using IHI Global Trigger Tool. Majority of the AEs are due to medication errors followed by 60 adverse drug reactions, 15 therapeutic failure incidents, and 7 over- dose cases. Using the trigger tools, they were able to detect 45 positive triggers in 36 patient records. Among it, 19 AEs were identified in 15 patient records. The percentage of AE/100 patients is 17 %. The | The IHI Global Trigger Tool is an effective method to aid provisionally- registered pharmacists to identify ADEs quicker. |

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| | | | | average ADEs/1000 doses is 2.03%. | |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Rutberg H et al. 2014 | To describe the level, preventability and categories of adverse events identified by medical record review using the Global trigger tool. To estimate when AE occurred in the course of the hospital stay and to compare voluntary AE reporting with medical record reviewing. | 960 | Two-stage retrospective record review. 20 randomly selected medical records from all department except pediatric and psychiatric departments and obstetric ward were reviewed every month for a 4 year period from 2009 to 2012. Patient harm severity was categorized according to the NCC MERP on a scale from E to I. preventability was graded on a scale from 1 to 6 where 1 indicates virtually no evidence for preventability and 6 indicates virtually certain evidence for preventability. At a rating of at least 4, AEs were classified as preventable. | A total of 271 AEs were detected in the 960 medical records reviewed, corresponding to 33.2 AEs/ 1000 patient-days or 20.5 % of the patients. Of the AEs, 6.3% were reported in the voluntary AE reporting system. Hospital- acquired infections were the most common AE category. The AEs occurred and were detected during the hospital stay in 65.5% of cases; the rest occurred or were detected within 30 days before or after the hospital stay. The AE usually occurred early during the hospital stay, and the hospital stay was 5 days longer on average for patients with in AE. | Record reviewing identified AEs to a much larger extent than voluntary AE reporting. Healthcare organisations should consider using a portfolio of tools to gain a comprehensive picture of AEs. |
| Kennerly DA et al. 2014 | To report 5 years of adverse events identified using an enhanced Global Trigger Tool (GTT) in a large health care system. | 3430 | Records from monthly random samples of adults admitted to eight acute care hospitals from 2007 to 2011 with lengths of stay ≥ 3 days were reviewed. They examined AE incidence overall and by presence on admission, severity, stemming from care provided versus omitted, preventability and category; and the overlap with commonly used AE-detection systems. Professional nurse reviewers abstracted 9017 records using the enhanced GTT, recording triggers and AEs. Medical record/ account numbers were matched to identify overlapping voluntary reports or AHRQ Patient Safety Indicators (PSIs). | Estimated AE rates were 61.4 AEs/1000 patients-days, 38.1 AEs/100 discharges, and 32.1 percent of patients with ≥1 AE. Of 1,300 present-on-admission AEs, 78.5 percent showed NCC-MERP level F harm and 87.6 percent were "preventable/possibly preventable/possibly preventable"; the most common category was "surgical/procedural". Voluntary reports and PSIs captured < 5 percent of encounters with hospital- acquired AEs. | AEs are common and potentially amenable to preventation. GTT- identified AEs are seldom caught by commonly used AE-detection systems. |
| Unbeck M et al. 2014 | Validation of triggers and development of a pediatric trigger tool to identify adverse events. | 600 | Using a broad literature review and expert opinion with a modified Delphi process, a pediatric trigger tool with 88 triggers, definitions, and descriptions including AE preventability decision support was developed and tested in a random sample of 600 hospitalized pediatric patients admitted in 2010 to a single university children's hospital. Four registered nurse-physician teams performed complete two- stage retrospective reviews of 150 records each from either neonatal, surgical/orthopedic, medicine, or emergency medicine units. | Registered nurse review identified 296 of 600 records with triggers indicating potential AEs. Records with only false positive triggers not indicating any potential AEs were not forwarded to the next review stage. On subsequent physician review, 204 of patients were found to have had 563 AEs, range 1-27 AEs/ patient. A total of 442 preventable AEs were found in 161 patients, range 1-22. Overall, triggers were found 3598 times in 417 records, with a mean of 6 triggers per patient. The overall positive predictive value was 22.9%. | The pediatric trigger tool can help healthcare organisations to measure and analyze the AEs occurring in hospitalized children in order to improve patient safety. |
| Zapata AI et al. 2014 | Detection of adverse events in General Surgery using the Trigger Tool methodology | 350 | Retrospective, observational study on patients admitted to a general surgery operation in a third level hospital during the year 2012. The identification of AE was carried out by patient record review using an adaption of Global Trigger Tool methodology. Once an AE was identified, a harm category was assigned, including the grade in which the AE could have been | The prevalence of AE was 36.8%. there were 0.5 AE per patient. 56.2% were deemed preventable. 69.3% were directly related to the surgical procedure. The tool had a sensitivity of 86% and a specificity of 93.6%. The positive predictive value was 89% and the negative predictive value 92%. | The adapted Global Trigger Tool methodology has demonstrated to be highly effective and efficient for detecting AE in surgical patients, identifying all the serious AE with few false negative |

| | | | avoided and its relation with the surgical procedure. | | results. |
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| Rozenfield S et al. 2013 | To estimate the frequency of and to characterize the adverse drug events at a tertiary care hospital. | 128 | A retrospective review was carried out of 128 medical records in 2007, representing 2092 patients. The instrument used was a list of triggers, such as antidotes, abnormal laboratory analysis results and sudden suspension of treatment. A simple random sample of patients aged 15 and over was extracted. Oncologic, obstetric and patients who were hospitalized for 48 hours or in the emergency room were excluded. | Around 70% of the medical records assessed showed at least one trigger. Adverse drug events triggers had an overall positive predictive value of 14.4%. the incidence of adverse drug events was 26.6 per 100 patients and 15.6% patients suffered one or more event. The most common drugs associated with ADEs were tramadol, dypirone, glibenclamide and furosemide. Over 80.0% of events provoked or contributed to temporary harm to the patient and required intervention and 6% may have contributed to death of the patient. | The instrument used may prove useful as a technique for monitoring and evaluating patient care results. |
| Brenner S et al. 2012 | Applying a laboratory trigger tool to identify adverse drug events among primary care patients. | 516 | The authors used six abnormal laboratory triggers for detecting ADRs among adults in outpatient care. Eligible patients were included if were > 18 years, sought primary or urgent care between November 2008 and November 2009 and were prescribed at least on medication. They used the clinical/ administrative database to identify patients with triggers. Two physicians conducted indepth chart review of any medical records with identified triggers. | They reviewed 1342 triggers representing 622 unique episodes among 516 patients. The trigger tool identified 91 ADEs of which 49 occurred during medication monitoring, 41 during patient self- administration and one could not be determined. 96% of abnormal INR were ADRS, followed by 12% of abnormal BUN triggers, 9% of abnormal alanine aminotransferase triggers, 8% of abnormal serum creatinine triggers and 3% of aspartate aminotransferase triggers. | The findings imply that other tools such as text triggers or more complex automated screening rules, which combine data hierarchically are needed to effectively screen for ADEs in chronically ill adults seen in primary care. |

II. Conclusion

The use of trigger tool in identifying and reporting ADRs, when integrated with event monitoring, spontaneous reporting, charted review, and other techniques to improve trigger usefulness could enhance effectiveness for patient safety and can be an important strategy for indicating possible flaws in the process of using medications for hospitalized patients [16]. Application of trigger tools to identify ADRs can be used to better understand the ADRs of patients treated in the ER and to direct actions related to pharmacovigilance [17].

Triggers have proved useful for an active search for suspected ADRs at Eds, including severe ones, identifying problems occurring outside hospital settings and signaling medications that pose an increased risk to the elderly [18].

Trigger tool methods were better able to capture adverse events with severe physical impacts. The combined use of reporting and trigger tool methods had synergistic benefits for the detection of adverse events in [7].

Adverse events are coomon in pediatric patients and most are preventable. More than one fifth of the pediatric inpatients experienced at least one ADRs, and most of the experiences caused temporary harm. The pediatric trigger tool can help healthcare organisations to measure and analyze the AEs occurring in hospitalized children in order to improve patient safety. Triggers that had high PPV could be incorporated into routine screen systems to improve inpatient safety in the future [19].

The pharmacists must be oriented to this trigger tool and appropriate training can be given to ensure rational usage of medications is practiced, leading to improved prognosis and patient's quality of life. This tool can also be used, especially by pharmacists to detect and identify ADEs in in-patient settings. With regard to the hospital settings, increasing awareness of the pharmacists about the IHI Global Trigger Tool can definitely aid them in detecting and identify ADEs faster, thereby improving the QOL of the patients in the long-term [20].

Reference

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