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Original Research Article

Effectiveness of the Trigger Tool Approach in Identifying Adverse Drug Reactions: A Study at a Tertiary Care Teaching Hospital

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Abstract:

Background: Patients in tertiary care hospitals are often affected by significant ADRs that increase illness and the duration of their hospital stays. Often such systems neglect to detect many ADRs for two reasons: people do not report them and their observers have biases. By using Trigger Tool, designed by the IHI, clinicians can proactively recognize ADRs with the help of several clinical, laboratory and prescription-based indicators.

Aim: To evaluate how well the Trigger Tool works in finding adverse drug reactions, relative to the way adverse events are reported by health personnel.

Methods: The study was designed as prospective, cross-sectional research at Department of Pharmacology, ESIC Medical College and Hospital, Bihta, Patna, Bihar, India for one year. Using a modified Trigger Tool checklist, we screened 200 inpatients who had been admitted to the hospital to find incidents to review. Causality of the identified triggers was assessed using the WHO-UMC causality scale, the Naranjo algorithm, Hartwig and Siegel's severity scale and Scheumock and Thornton's preventability assessment. ADRs reported spontaneously by people using the drug were also recorded to check for similar results.

Results: 200 patients examined, 67 had signs that suggested an ADR and a detailed review confirmed 51 ADRs. Among all ADRs confirmed, more than half were considered possible (54.9%) and the severity was mostly listed as moderate (64.7%). 43.1% of the ADRs in the study were tagged as preventable. Meanwhile, the spontaneous reporting system captured 21 reports of ADRs during those six months and had both fewer moderate-to-severe cases and lower preventability rates (19.0%).

Conclusion: The Trigger Tool method was far better than spontaneous reporting at finding both the number and clinical importance of ADRs. It is a useful tool for improving patient safety and improving pharmacovigilance practices in healthcare settings with limited resources since it can find preventable and moderate-to-severe ADRs.

Keywords: Adverse Drug Reactions, Trigger Tool, Pharmacovigilance, Tertiary Care Hospital, Preventable ADRs, Naranjo Scale.

Introduction

ADRs are any negative reactions to drugs that happen when using them properly and at the normal dose for therapy, prevention or diagnosis. They affect the health of many people worldwide and often result in illness, admission to a hospital, extended stays and death. According to WHO, in some countries, ADRs are a leading reason for death and worldwide they affect up to 10% of hospital admissions [1]. Due to weak drug regulation and monitoring in many parts of India, ADRs are likely underreported and often affect the outcomes of patients. In the majority of hospitals, traditional pharmacovigilance is built around SRS, with health professionals providing details about ADRs they notice on their own. Still, experts know that the system experiences underreporting, bias and inconsistency in detecting knowledge and skills. Experts believe that just 6–10% of all ADRs are captured and reported this way [2,3].

Failing to accurately spot medication-related harm makes it hard to prevent future cases caused by medicines. As a result of this issue, Trigger Tools have appeared as useful methods to immediately identify ADRs in hospitals. The IHI developed the first Global Trigger Tool (GTT) which showed how the Trigger Tool Methodology began. It uses certain "alerts"—including stopping a drug, prescribing the opposite or unusual bloodwork—to slice the data and identify cases connected to ADEs [4]. When you go through patient records purposefully and use pre-set warning signs, you'll catch ADRs that are easily missed by usual reporting. Trigger tools can be connected to both handwritten charts and digital health records which makes them usable in many

different hospital situations. It has been shown in Western research that data collected using trigger tools can reveal between 50% and 80% more ADRs than what was seen with earlier systems [5]. Researchers Rozich et al. used a trigger tool in a prospective study, finding it helped detect ADEs more efficiently and led to fewer missed events [6]. Using trigger tools, medicine safety professionals can divide ADRs by what caused them, how preventable they were and how serious they were which allows for focused medical help and better policies. Though trigger tool methods have benefits, they are not used widely in tertiary care hospitals in India's government sector. Problems such as lacking knowledge, inadequate resources, missing standard trigger lists and inadequate teacher education are preventing large-scale implementation. These studies suggest that tools designed especially for the Indian hospital setting are both practical and effective [7, 8].

The study demonstrated that surveillance triggered by events is efficient and also more economical than other methods, especially in environments where electronic monitoring tools have not been built. Because Indian tertiary care hospitals deal with a wide variety of patients and treatment approaches, keeping a sharp eye on medicine safety matters is very important. Learning about ADRs quickly with tools such as the trigger tool cut down on unplanned harms to patients, manage drugs better, decrease hospitalization time and improve general patient safety results. The researchers are motivated by the important need to connect what is known about ADR monitoring with real-world hospital practice in India. Many national initiatives, including PvPI, help drug safety surveillance, but hospitals are not regularly using new approaches such as trigger tools. We aim to provide data showing how the trigger tool approach works in practice at a tertiary care teaching hospital in India to affect policy and practice. Aim of the study to assess whether the trigger tool methodology works better than the usual spontaneous reporting system for finding adverse drug reactions in a large teaching hospital.

Methodology

Study Design: To evaluate the Trigger Tool methodology for spotting adverse drug reactions in inpatients, the current study was a prospective cross-sectional observational analysis. Through this approach, real-time adverse drug reactions were detected using a previous system built on the Institute for Healthcare Improvement (IHI) Global Trigger Tool and some local customizations.

Study Setting: The study was designed as prospective, cross-sectional research at Department of Pharmacology, ESIC Medical College and Hospital, Bihta, Patna, Bihar, India for one year. Because the hospital treats many patients in different departments, general medicine, surgery, pediatrics and intensive care, it provides an ideal place for ADR surveillance.

Study Duration: Observations were made for one year. Selected wards admitted during the study were checked for signs of ADRs with the help of the Trigger Tool checklist for all patients.

Study Size: The Trigger Tool approach was used to screen all 200 inpatients who were enrolled during the study period.

Inclusion Criteria:

- The study covered people aged 18 years and up.
- People who spend at least 48 hours in the hospital's medical, surgical or ICU wards
- People whose full medical history and medicine list were on hand

Exclusion Criteria:

- Elders who lack certain pieces of their medical history
- Patients sent home within 24 hours after their arrival
- Known ADRs have occurred prior to or at the time of admission.

Trigger Tool Checklist: The checklist used in this investigation is a reworked version of the Trigger Tool from the Institute for Healthcare Improvement (IHI), adjusted to fit the hospital's environment. It contained various types of medical indicators that might indicate an adverse reaction to a drug. Reviews of the patient records examined sudden changes in drug use, giving of antidotes, unusual findings in liver or renal function tests, unforeseen hypotension, seizures, and hypoglycemia. Trained pharmacovigilance staff monitored information every day to make sure all potential adverse drug reactions were screened and identified by using this tool.

Detection and Assessment of Adverse Drug Reactions: The cases identified by the trigger tool were studied again with standard evaluation methods. Causality was figured out using the WHO-UMC scale and the Naranjo algorithm and severity was determined with the Hartwig and Siegel scale. Through the Schumock and Thornton criteria, the research team decided on preventability. A team of two pharmacologists independently checked every suspected ADR report. Using several steps helped ensure that ADRs were recognized, grouped appropriately and tested properly so that doctors could draw the right conclusions.

Comparator Method: Spontaneous Reporting

At the same time, we obtained data from the hospital's self-reported ADR process (submissions made through the PvPI form). The number of ADRs

found passively was checked against those found using the Trigger Tool.

Data Collection Procedure: A Staff who works in pharmacovigilance viewed patient files daily to identify adverse drug reactions triggered by predefined signs. When a trigger was found, it was recorded right away by following the study's special data collection form. They included the patient's clinical background, other drugs used and anything seen to trigger symptoms. Each identified ADR was then added to an Excel database. The fields included in the database were patient information, possible drugs involved, category of trigger, detail of ADR, cause evaluation, severity score and whether it was preventable, making certain that information was clear and complete for further analysis.

Statistical Analysis: All statistical analysis was performed with SPSS software v27.0. I used frequency, mean, standard deviation and percentages to summarize all the data I collected. Chi-square tests were performed to check if ADR occurrence is associated with variables such as age, gender, the number of drugs or type of ward. The research team considered a p-value smaller than 0.05 to be statistically significant.

Result

You can see from Table 1 that different types of triggers were identified in the study and the number of times they occurred. Of the 67 samples, 41.8% were the result of taking the drug suddenly away from the person. It appears that sudden stopping of medication may increase the risk of adverse reactions happening. Drug-related complications or emergency interveners were linked to the second most listed trigger: using antidotes which was present in 28.3% of cases. Around one out of five cases showed abnormal lab results, showing the need for following up on lab findings soon and frequently. Clinically, nearly 9% of patients had rashes, so it is important to monitor them closely. Altogether, the results underline that proper management of medicines, close monitoring by clinicians and regular lab tests help prevent and treat drug-related complications.

Table 1: Frequency of Triggers Identified

S. No.	Trigger Type	No. of Cases	Percentage (%)
1	Sudden Drug Discontinuation	28	41.8
2	Use of Antidotes	19	28.3
3	Abnormal Lab Results	14	20.8
4	Clinical Symptoms (e.g., Rash)	6	8.9
	Total	**67**	**100**

In Table 2, causality is evaluated for confirmed adverse drug reactions (ADRs) using standard criteria. Of the 51 confirmed cases, the greatest percentage, 54.9%, were put in the "Possible" category. More than half of the results showed a chance the ADR was caused by the drug, yet other explanations could not be completely excluded. Of the cases we looked at, 31.4% were described as "probable" ADRs, indicating that there was a greater link between the drug and the reaction and less doubt about the reason. Only 13.7% of the cases were labeled "Definite," meaning it was certain that the drug led to the problem. Such findings point out how hard it is to clearly identify drugs as the cause of side effects and stress the importance of detailed evaluation and record-keeping by doctors in ADR cases.

Table 2: Causality Assessment of Confirmed ADRs

S. No.	Causality Category	No. of Cases	Percentage (%)
1	Definite	7	13.7
2	Probable	16	31.4
3	Possible	28	54.9
	Total	**51**	**100**

The Hartwig and Siegel scale is used in Table 3 to describe the different severities of Adverse Drug Reactions (ADRs). About 64.7% of the 51 ADR cases were designated as "Moderate." In other words, most of the ADRs didn't threaten life and still needed adjustments in treatment or clinical care. About a quarter of the reactions were "mild" and did not cause the treatment to stop. In only 9.8% of the cases, people met the definition of "severe," indicating that even though it was a rare event, some ADRs seriously affected individuals and could be likely to persist over time. They reveal that constant monitoring and proper care can stop mild or moderate reactions from worsening.

Table 3: Severity Grading of ADRs Based on Hartwig and Siegel Scale			
S. No.	**Severity Grade**	**No. of Cases**	**Percentage (%)**
1	Mild	13	25.5
2	Moderate	33	64.7
3	Severe	5	9.8
	Total	**51**	**100**

Table 4 shows how Adverse Drug Reaction (ADR) is detected using the Trigger Tool Method and Spontaneous Reporting. With Trigger Tool Method, far more ADRs were noticed, accounting for 51 safety issues identified over just 21 from Spontaneous Reporting. Trigger Tool Method was found to identify more moderate to serious events (38) than Spontaneous Reporting (11), thus showing it is more likely to detect significant reactions. Moreover, 43.1% of ADRs found using the Trigger Tool Method were identified as preventable, whereas using Spontaneous Reporting; this percentage fell to only 19.0%. The results show that the Trigger Tool Method improves ADR detection and helps point out important and avoidable incidents, demonstrating its usefulness in clinical settings.

Table 4: Comparison of ADR Detection: Trigger Tool vs. Spontaneous Reporting			
Method	**ADRs Detected**	**Moderate/Severe ADRs**	**Preventable ADRs (%)**
Trigger Tool Method	51	38	22 (43.1%)
Spontaneous Reporting	21	11	4 (19.0%)

Discussion

This study tested whether Trigger Tool could help discover cases of adverse drug reactions (ADRs) in a tertiary care hospital. Of the 200 patients examined in the hospital, 67 (33.5%) had recognized triggers and 51 ADRs were confirmed. As compared to the usual spontaneous reporting method, the new detection rate was much higher, covering 95.5% of ADRs in the group. The findings demonstrate that the Trigger Tool approach is now more sensitive in the real practice of pharmacovigilance. Studies by Menat et al. (2021) suggested that the Trigger Tool is almost five times better than spontaneous reporting at spotting ADRs which was noted in 12.25% of hospitalized patients [11]. Similarly, Gadde et al. (2018) discovered that their detection rate was 33.6%, showing that the approach is reliable and effective in different tertiary care settings [12]. The most common cause in our study was when patients suddenly quit taking their medication (41.8%), second to use of antidotes (28.3%) and then abnormal results from laboratory tests (20.8%). The patterns we see are very similar to the main triggers mentioned by Arulmani et al. (2008) in their study of hospital cases [13]. A decade ago, Rozich and co-workers also emphasized that using structured screening indicators is important for recognizing adverse drug events [14]. We discovered in our analysis that most of the analyzed ADRs were "possible" (54.9%), followed by "probable" (31.4%) and “definite” (13.7%). A similar pattern was seen by Desai et al (2011) in a tertiary hospital, where 57.5% were marked as “possible” and 35% as “probable” [11]. Consistency of the data confirms we can rate trigger-based ADRs using standard tools like WHO-UMC and the Naranjo algorithm. We found that 64.7% of the ADRs we studied were classified as moderate, 25.5% as mild and 9.8% as severe. The team of Tripathi et al. (2023) observed that the majority of ADRs discovered using trigger tools were moderate, confirming that the tool correctly alerts hospitals to important drug reactions [6]. A significant problem is moderate-to-severe ADRs which may call for treatment from the doctor or might lead to hospital patients staying longer. A major result from our findings showed that using Schumock and Thornton criteria, 43.1% of the confirmed ADR cases could have been prevented. Tripathi R and their team (2019) reported that trigger tools indicated 39.4% of ADR events could have been prevented, showing again how they can also help improve medication safety [15]. Still, Patel et al. (2007) indicate that a big reason behind preventable ADRs is errors in prescribing or insufficient assessments. Integrating the support of such tools may aid clinicians in addressing those oversights as they happen in real life [6]. All in all, what we found during our study agrees with national and global evidence, showing that using the Trigger Tool boosts the reliability of hospital pharmacovigilance. This way of looking at ADRs allows us to address important harm to patients and lead to better outcomes in therapeutic care.

Conclusion

The research demonstrates that using the Trigger Tool methodology can greatly help detect adverse drug reactions (ADRs) in hospitals. From among 200 hospitalized patients, the Trigger Tool procedure found 67 cases of suspected adverse drug reactions and 51 of them were confirmed by a standard set of assessment tools. This demonstrates that proactive surveillance is more powerful than the

typical reporting method. The findings in this study agree with earlier studies and demonstrate the method used is reliable and simple. Most of the confirmed adverse drug reactions were average in severity and more than one-third (43.1%) were judged to be preventable. The results suggest it is important to monitor for triggers in routine drug safety monitoring, especially in places where many different drugs are used due to the complexity of treatments. Thanks to the Trigger Tool, doctors report more ADRs and the audits and strategies used to reduce risks are more effective. Through spotting risky drugs, procedures and mistakes that could be prevented, the method suggests practical tools for setting policies and improving care quality. Although there are benefits, the study admits that manual review and variations among reviewers can cause problems. Future work should attempt to increase the use of trigger-based tools in electronic health records by improving their automation. All in all, using the Trigger Tool helps make ADR monitoring both better and more practical in Indian healthcare, using a method that anyone can apply and follow.

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