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STRATEGIC SURVEILLANCE-IMPLEMENTATION OF CONCISE ADVERSE DRUG REACTION FORM AND PVPI-HELPLINE NUMBER IN IN-PATIENT CASE SHEETS AMONG CLINICIANS AT A TERTIARY CARE TEACHING HOSPITAL, TELANGANA, INDIA.

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Keywords:

Surveillance, Clinicians, Patient safety, PvPI-Helpline (Toll-Free) number, ADR form, Pharmacovigilance

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ABSTRACT: Background: Post-marketing surveillance *via* spontaneous Adverse drug reaction (ADR) monitoring and reporting method is in place, even though it is considered as one of the key challenge for under-reporting and establishing the quality of patient safety in the healthcare system. **Objective:** This study is intended to know the clinician's opinion (mindset) on the implementation of PvPI-Helpline (Helpline Number) and concise ADR form in In-patient case sheets at a tertiary care teaching hospital, Telangana India as they play a vital role for improving the reporting system of ADRs. **Materials and Methods:** A Cross-sectional Surveillance based study was carried out in Osmania medical college and affiliated hospitals, for 2-months duration among 160 Clinicians. The questionnaire consists of 4 questions and the participants were informed to provide their feedback. Data was collected and analyzed using SPSS version 25 software. **Results:** Only150 clinicians responded. 98.6% of Clinicians agreed to implement PvPI-Helpline (Toll-Free) number for quick reporting of ADRs.93.3% disagreed with creating a WhatsApp group for reporting ADRs as they taught it was not a secure platform to reveal patient details. Almost all Clinicians admitted that concise ADR form incorporation in In-patient case sheets helps easily identify ADRs along with the in-house set up of a smooth functioning Pv system. **Conclusion:** The results provided insight to clinicians on the importance of implementing Helpline Number and concise ADR form and the perception of Clinicians towards ADR reporting. The findings of our study highlighted the need to roll up quality care for patient safety.

INTRODUCTION: Indian healthcare system has its own idiosyncratic methods of treating patients. Due to its varied geographical stretch, disease patterns and different medicine practices, Indian public experiences both pros and cons with the use of the medicines, which could be entirely different from other countries [1]. Therefore, it is crucial to scientifically evaluate the safe use of medicines through a highly specialized system.

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Thus, this highly specialized system for high-quality public healthcare is defined as "Patient Safety" by WHO [2]. Patient safety has become an emerging concern in recent years and gained demanding attention in improving the quality of healthcare service in India within the broader Universal Health Coverage (UHC) context [3].

Patient safety has been recognized as one of the vital components of quality healthcare treatment and many initiatives have been implemented by the Indian Government both at central and state levels to address diverse issues about safe use of medicines [3]. Though many challenges are encountered for safe use and prescribing medicines, monitoring and reporting Adverse Drug Reaction (s) / Adverse Event (s) stands as the pin-point of

the health care system [2, 3]. To establish a safety profile of medicine in a real-world scenario, continuous post-marketing surveillance system is required and this could be achieved *via* patient safety practice tool as "Pharmacovigilance" [4]. Pharmacovigilance (Pv) is a practice aimed to monitor the safety of medications under real-world conditions and identify Adverse Drug Reactions (ADRs)/Adverse events (AEs) more emphasizing during the post-marketing phase of its life cycle [5]. "Medicines are double-edged weapons", so it is important to monitor and report ADRs/AEs for benefits outweighing the risks as still future is in our hands to improve [1, 6]. At the global level, medication toxicity is also playing a significant limitation in providing good health care to patients by affecting health and economic burden. The safety prescribing of medicines has become a need-of- the-hour topic for patient safety because most of the important ADRs/AEs are caused by routinely prescribed and used medications along with newly approved [1, 6].

World Health Organization (WHO) patient safety survey published every year; 134 million adverse events occur in hospitals in Low and middle-income countries (LMICs) [7] and global literature reviews stated that 4.2-30% of hospital admissions were due to ADRs [8]. Indian healthcare system reported incidence of ADRs is between 5.9 to 22.3%, while deaths due to ADRs account for 1.8% and hospital admissions account for 0.7%. The average economic burden of one ADR/AE is around 700-900INR per patient [8, 9].

Therefore, to encounter the global economic and safety challenges of using medicines in the healthcare system, WHO has established "International Drug Monitoring Program". In the year 2010 Ministry of Health and Family Welfare-Govt. of India (MOHFW-GOI), launched the nationwide Pharmacovigilance Program of India (PvPI) under the umbrella of the Indian Pharmacopoeia Commission (IPC), and it has been functioning as the National Coordination Centre (NCC) for PvPI from April 2011 [10]. IPC-PvPI has recognized Adverse Drug reaction Monitoring centers (AMCs) across India, such that a good in-house setup of monitoring and reporting of ADRs/AEs by healthcare professionals is implemented [11].

PvPI has established various tools For reporting ADRs/AEs with an aim to monitor the safety of medicines consumed by the Indian public and regularly recommends the drug regulatory authorities for regulatory interventions and suggests that healthcare professionals (HCPs) in improving the safe use of drugs by raising and circulating drug safety alerts [10, 11]. In connection with the compelling need for a stable ADR/AE reporting system in India, MOHFW-GOI has developed a "National Patient Safety Implementation Framework (NPSIF)", as a strategic objective and goal of NPSIF ADR/AE monitoring concept is interlaced with building blocks of the health system to assess the nature and scale-up ADRs/AEs reporting system [3]. Post-marketing surveillance via spontaneous monitoring and reporting method is in place. Despite the national-level program implementation, there is still a huge gap and demand for percolating awareness regarding the monitoring and reporting ADRs/AEs. This is considered one of the key challenges of establishing quality patient safety in the healthcare system.

Clinicians are responsible for prescribing medicines and many of them are unaware of modes of reporting ADRs/AEs and few know as well because the workload tends to forget to report is the second challenge. To overcome the challenges in ADR/AE reporting and establish the proper quality of the Pharmacovigilance monitoring system in a hospital setting up a clinician's perception is important for reporting ADRs [12].

Various studies are being conducted to assess the Knowledge, Attitude and Practice (KAP) of Pharmacovigilance among clinicians and observational drug safety surveys but there are no such studies on implementing strategic surveillance. Implementation of PvPI-Helpline (Toll Free) number and concise ADR form plays an important role in quick reporting as part of the ADR reporting system's challenge, improvement, and ease. The present surveillance study was aimed and focused on knowing the clinician's opinion(mindset) on the implementation of PvPI-Helpline (Toll-Free) number and concise ADR form in In-patient case sheets for the proper in-house set of ADR/AE reporting system and strengthen the health records in connection with

patient safety quality wise documentation and improving the ADR reporting for patient safety.

METHODOLOGY:

Site of Study: This study was conducted at Osmania Medical College, and it's affiliated hospitals, Telangana from May2022 to June2022. This study was approved by the Institutional Ethics Committee of Osmania Medical College, [IEC/OMC/2022/M. No. (6)/ Acad-51] before the study.

Study Design: This was a cross-sectional Pre-validated questionnaire-based study.

Study Duration: 2 months.

Sample size: Taking relative precision as 5% and the desired confidence level as 95%, the sample size was calculated to be 150 Clinicians (both males and females).

Selection Method: The study population was drawn from all clinical departments of Osmania medical college and affiliated hospitals and were given a questionnaire of total

4-Questions and asked to mention or indicate their opinion regarding implementing a Toll-free helpline number and concise ADR form in-patient case sheets. The study instrument was a self-administered questionnaire designed by the pharmacovigilance committee established at the Adverse drug reaction Monitoring Center (AMC) in the Department of Pharmacology Osmania Medical College under PvPI-IPC, MOHFW-GOI. Data were collected and analyzed.

Inclusion and Exclusion Criteria: All Clinicians who gave consent to participate in the study were included. The Clinicians who were unwilling to participate in the study and those on leave were excluded.

Statistical Analysis: Information from the returned questionnaire was entered and analyzed by Statistical Package for Social Sciences (SPSS) version 23 software; descriptive statistics and percentage calculations are expressed.

RESULTS:

Baseline Demographic Characteristics: Out of 160 questionnaire forms communicated among clinicians, a total of only 150 clinicians gave consent to participate in this study and responded by answering the questionnaire. The demographic details of participants involved in the study were categorized based on gender distribution and clinical departments are illustrated in **Table 1.**

TABLE 1: SOCIO-DEMOGRAPHIC VARIABLES OF THE STUDY PARTICIPANTS

Demographic variables – Clinicians	No of Participants (n)
Males	83
Females	67
General medicine	38
Dermatology	35
Paediatrics	32
Nephrology	6
Gastroenterology	4
Pulmonology	10
Ophthalmology	5
Cardiology	4
Endocrinology	10
Urology	6

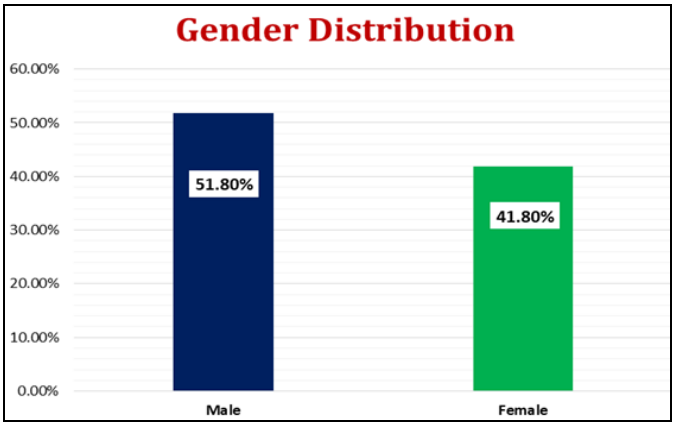

FIG. 1: DEMOGRAPHIC GENDER DISTRIBUTION AMONG CLINICIANS

From **Fig. 1**, n=83 (51.8%) males and n=67 (41.8%) females out of 150 Clinicians participated in the surveillance, whereas 10 (6.2%) were not willing to give consent to the study. All Clinicians from Osmania Medical College and it's affiliated hospitals were given questionnaire forms consisting of four questions, as mentioned in the tables, and the results are discussed below. The results were kept confidential. Among 150 participants, the majority (37%) were 55-65 years old and had more than 15-20 years of clinical experience, followed by 32% of them were 45-55 years old with over 10 years of experience, 17% and 14% of clinicians were in the age group of 25-35 years and 35-45 age group respectively. **Fig. 2** depicts the number of participants in percentages from different clinical

departments from Osmania medical college and Hospitals i.e, n=38(25%) clinicians from the General medicine department, n=35(23%) from the Dermatology department, n=32(21%) from paediatrics, 7% of Clinicians from Pulmonology (n=10) and Endocrinology (n=10), 4% from Nephrology (n=6) and Urology n=(6) departments and 3% of clinicians from Ophthalmology (n=5), Gastroenterology (n=4) and Cardiology (n=4) departments.

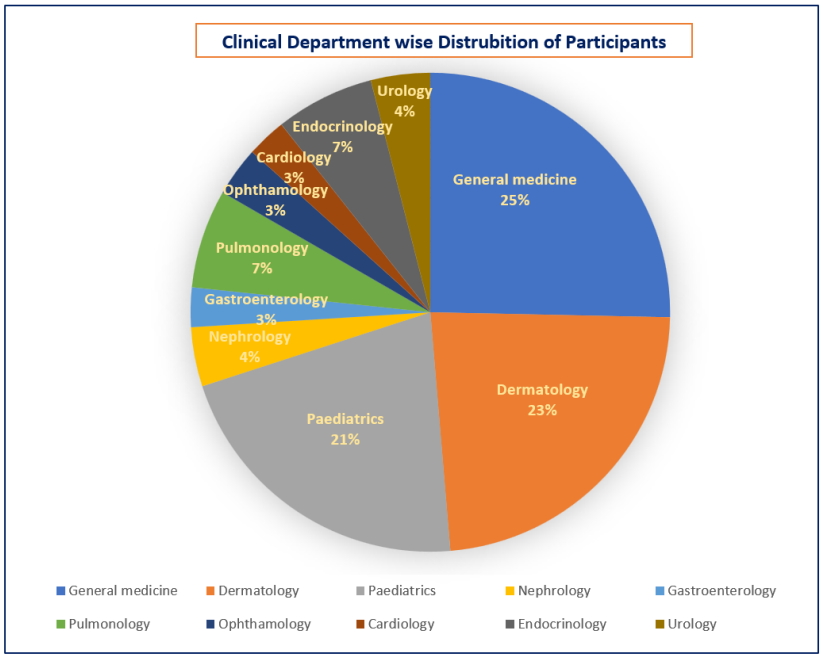

FIG. 2: PERCENTAGE OF CLINICIANS WHO PARTICIPATED IN SURVEILLANCE

Table 2: 148(98.6%) of Clinicians agreed to the implementation of PvPI-Helpline (Toll-Free) number would be helpful in quick and easy reporting of ADRs whereas 2(1.4%) clinicians disagreed.

TABLE 2: QUESTIONNAIRE-1 HELPLINE NUMBER IMPLEMENTATION

Questionnaire	Agree (%)	Disagree (%)
Opinion regarding the implementation of PvPI-Helpline (Toll-Free) number would be helpful for reporting ADRs quickly	148 (98.6%)	2 (1.4%)

Table 3 Clinicians 147 (98%) have a positive opinion regarding the concise ADR form in In-patient case sheets but 2% disagreed with the same. **Table 4** 139(92.6%) of Clinicians suggested that an ADR box section on the top of the In-patient case sheet would be helpful for quick referring of ADRs. 11(7.4%) Clinicians recommended the ADR section as a separate column in the case sheets.

TABLE 3: QUESTIONNAIRE-2 CONCISE ADR FORM IMPLEMENTATION

Questionnaire	Agree (%)	Disagree (%)
Opinion regarding concise ADR form in in-patient case sheets	147 (98%)	3 (2%)

TABLE 4: QUESTIONNAIRE-3 ADR REPORTING OPTION- FOR CASE SHEET

If a concise ADR form is not the best option, then suggest the best option		
1	ADR box section on the top of the In-patient case sheet	139 (92.6%)
2	ADR-section separate column	11 (7.4%)

TABLE 5: QUESTIONNAIRE-4WHATSAPP GROUP FOR REPORTING ADRS

Questionnaire	Agree (%)	Disagree (%)
Opinion regarding creating a WhatsApp group for reporting ADRs to ADR monitoring Centre (AMC)	10 (6.7%)	140 (93.3%)

Table 5 140 (93.3%) Clinicians disagreed whereas only 10(6.7%) agreed for creating a WhatsApp group for reporting ADRs to ADR monitoring Centre (AMC.

DISCUSSION: Perceiving the significance of Pv in recent years and the need for evidence-based indigenous data for policy decisions for ADR monitoring and reporting, PvPI has succeeded in establishing a nationwide network of 567 ADR monitoring Centres (AMCs) across the country in Govt. Tertiary care medical colleges and it's hospitals, Cooperate NAHB accredited hospitals and Pharmacy colleges. AMCs assist PvPI in an intensive and concerted effort to gather evidence-based medical information on ADRs/AEs monitoring from hospitals to analyze and evaluate the benefit-risk of medicines [10].

PvPI has set up different reporting tools such as Helpline (Toll-Free) number for reporting ADRs- "1800-180-3024", "ADR PvPI" Mobile app, and Suspected ADR forms. The suspected ADR forms are available separately for HealthCare Professionals (HCPs) and consumers and a different Serious- Case Notification Form (CNF) for reporting adverse event following Immunization (AEFI) [10]. Thus, these differential modes of reporting end up in the tedious process of searching and reporting, which in turn leads to under-reporting and lack of interest to report. But the most convenient helpline (Toll-Free) system is set up in a way such that it could be easily remembered and recollected as 30 days and 24 hours ("3024"). The Helpline (Toll-Free) number helps in easy and quick reporting of ADRs and significantly improves the success of Pharmacovigilance systems [10, 13].

PvPI encourages all types of suspected ADRs/AEs of known, unknown, serious, non-serious, frequent or rare, antibiotic resistance, medication errors, lack of efficacy, product quality defects, over-dose and off-label events due to medicines, vaccines and herbals products through the ADR reporting form. The submitted forms do not have any legal implementations on the reporters. Patient's identities are held in strict confidence and protected to the fullest extent [14]. Many studies have been published to assess the KAP of Pharmacovigilance among clinicians, but there are no such studies on surveillance regarding the implementation of Helpline (Toll-Free) number and concise ADR form in In-patient case sheets. Clinicians are generally unaware and uncertain about what to report and how to report ADRs [15, 16, 17] and they play a crucial role in post-marketing drug safety. The purpose of this surveillance is to elicit the opinion of clinicians. To the best of our knowledge, this was the first study in India designed to assess the Clinician's opinion (mindset) on the strategic implementation of PvPI-Helpline (Toll-Free) number and concise ADR form in In-patient case sheets. Clinicians across studies felt that ADR reporting was very necessary [18] but only 70%-78% of them knew that such systems were already in place [18-21].

In this study, **Table 2** (questionnaire no-1) illustrates that almost all clinicians (98.6%) have a positive opinion regarding the implementation of Toll-free number and would benefit from reporting ADRs quickly and easily before they forget to report or delay further, but 1.4% clinicians felt that it may misdiagnose disease-related symptoms as ADRs when Toll-free number provided to patients via printing on case sheets and if reported through PvPI-Helpline (Toll-free number) follow up might not be up to the quality. A study by Alsaleh FM, *et al.*, 2017, stated that among all the HCPs, treating clinicians play a key role in ADR reporting by direct observation of the effect of a medicine or through information provided to them by patients who have been exposed to the actual ADRs of a medicine. In this context, ADRs are observed and reported in the hospital settings and under-reporting among physicians is directly associated with the lack of information regarding reporting tools and details regarding the ADR Monitoring center [22].

It is evident from **Table 3** (questionnaire no-2) that 98% of clinicians felt concise ADR form helps in easy identification and recording of ADRs, smooth functioning of Pv systems, and proper patient safety quality wise documentation of record system in the hospital as well. These concise ADR forms save time in recording ADRs as only mandatory and precise information would be recorded and other essential information could be retrieved from the case sheet in anappropriate format. It would also be beneficial for proper quality care documentation and ADRs which are not reported to

the Pv system could be retrospectively retrieved when patients are not available at hospital by this manner it would also reduce errors of ADR reporting and missed safety alerts and signals could be retrieved easily. Many clinicians believe that it was not necessary to report adverse reactions that are already well recognized and known. Also, the most of the clinicians in the survey believed that only serious ADRs should be reported. Inclusion of concise ADR form specifies all information for reporting. **Table 4** (questionnaire no-3) was framed because the inclusion of concise ADR form would increase the 'paper-work' and it might again lead to extra work burden on clinicians.

Therefore the other opinions were framed and the results illustrated that, 139 (92.6%) clinicians agreed with the ADR box-section on the top of the In-patient case sheet, whereas 11(7.4%) suggested that an ADR reporting a separate column-section helps in quick recognition of ADRs with suspected drug(s). The results of a few published studies proved that most clinicians believed only ADRs for new drugs should be reported and only about two-thirds believed that the ADR declaration is a professional obligation for them to fulfil. Automatic filling of certain sections of the reporting form (online and by Hospital Information System-HIS) has also been suggested to improve the reporting status by Ganesan S [23]. The fact that about 47% of clinicians only have already been trained to report ADR is alarming [24].

93.3% of clinicians disagreed with creating a WhatsApp group for reporting ADRs to AMC from **Table 5** (questionnaire no-4) as they mentioned problems addressing confidentiality issues while reporting, it was not a secure platform to reveal patient details; also, few mentioned the reason as the follow-up might not be done and cases would be recorded with half information, and it was also given reason that there are too many Whatsapp groups, which might end up either in not reporting or delayed reporting without quality. Periodic e-mail and/or SMS alerts regarding safety alerts and signals to remind were also suggested as inexpensive and effective ways to encourage clinicians to report ADRs [25].

Limitations of the Study: Because of lack of time and busy schedules, only a few clinicians participated in the surveillance. Some clinicians did not respond appropriately to the questionnaire.

CONCLUSION: This study concludes that all clinicians who responded to the survey have a positive opinion regarding implementing PvPI-Helpline (Toll-Free) number and concise ADR form in In-patient case sheets provides momentum to Pharmacovigilance systems. Developing cordial relationships between clinicians and pharmacovigilance centres result in a drastic change in the perception that ADR reporting is extremely important in the long run. These implementations lead to easy and quick reporting and overcoming the under-reporting challenge. The findings of our study highlighted the need to roll up a pharmacovigilance practice tool by implementing the PvPI-Helpline (Toll-Free) number and concise ADR form in health records not only increase ADR/AE reporting but also ensures the safe use of medicines and finally establishing a robust reporting system for ADRs/AEs could boost in-house setup of good pharmacovigilance practice system along with the wise quality documentation of the health records for patient safety under NPSIF.

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CONFLICTS OF INTEREST: None Declared.

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