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Knowledge, Attitude and Practice of Hospital Pharmacists towards Pharmacovigilance and Adverse Drug Reaction Reporting in RDT Hospital in Battalapalli

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ABSTRACT: Pharmacovigilance (PV) is essential for evaluating the risk-benefit ratio of medications and promoting their safe, sane, and efficient use, thereby improving patient safety and care. As specialists in drugs, pharmacists are jointly accountable for maintaining the safety of medications. An evaluation of hospital pharmacists' knowledge, attitudes, and practises regarding reporting adverse drug reactions (ADRs) and pharmacovigilance (PV), as well as the identification of variables that deter hospital pharmacists from reportage ADRs, were the goals of the study carried out at RDT Hospital in Battalapalli, Andhra Pradesh, India. Since they have little knowledge of PV and ADR, it is difficult to educate chemists and patients about them. To collect data, a pre-tested self-administered questionnaire was given to every hospital chemist who agreed to take part in the study. Data were gathered for the study over 26 months, from November 2017 to January 2020, and were then processed with Microsoft Excel 2023. The link between the various variables was investigated using descriptive statistics, frequency/percentage calculations, and Pearson's Chi-square test. The survey had 74 pharmacists in total, with Pharm D trainees, who provided answers to different questions in both Telugu and English. The study's key conclusion is that 95% of participants were aware of the ADR reportage system's existence. According to our study, there is a large discrepancy between adverse events that patients report and those that healthcare professionals (HCP) describe (39.71%). The study found that the participants had a favourable attitude towards reportage adverse drug reactions (ADR) and pharmacovigilance (PV).We deduced from the current study that there is a substantial difference between adverse events reported and those encountered; moreover, while our HCPs have excellent knowledge and attitudes on PV, their practises are subpar. ADR reporting is low among our trained HCPs, even though there is a substantial positive link between PV training and ADR reporting. However, the primary reasons preventing the reporting of ADRs were found as the lack of a professional setting to discuss ADRs and a lack of pharmacotherapy/clinical expertise. Overall, the chemists displayed strong ADR reportage practice and had average to good awareness of and attitudes concerning PV and ADR reportage. The research recommends that the idea of PV and ADR reportage be enhanced even further because there is so much room for development.

Keywords: Adverse drug reactions reporting, Pharmacovigilance, Pharmacists, Survey.

INTRODUCTION

According to the World Health Organization (WHO), pharmacovigilance (PV) is the science and practice of finding, evaluating, understanding, and preventing side effects or other difficulties with drugs (Herrera Comoglio, 2020). PV is essential to improve patient safety and wellness while taking medications, advance the discovery of previously undetected drug interactions, and increase the incidence of recognised adverse drug reactions (ADRs) (Gordhon and Padayachee 2020; Raja and Ahad 2022). Additionally, it promotes the cost-effective, safe, and appropriate use of pharmaceuticals and supports the detection of risk factors that can result in the emergence of ADRs. Furthermore, it enables the valuation of risk-benefit evaluations. Improvements in education, clinical practice, and public awareness are all under the scope of PVh.

Any unpleasant, unexpected, and unwelcome drug side effect that occurs at levels routinely used in humans for disease prevention, diagnosis, or treatment, or changing physiological function, is referred to as an ADR (Ahad *et al.*, 2021; Alhamadani *et al.*, 2022), according to the World Health Organization. ADRs have a reputation for raising therapeutic costs and lengthening hospital stays. They have frequently cited causes of patient-related morbidity and mortality. A study was carried out on

hospitalized inpatients at RDT Hospital in Battalapalli, A.P., India.

Before a medicine is approved for sale, it is tested for effectiveness and safety in a small group of carefully selected subjects, and these studies are frequently shorter in length. Potentially unusual and severe adverse drug reactions (ADRs) will be discovered once the medicine is authorized, promoted, and used by a larger number of patients with comorbidities, specialised demographics like children, the elderly, or pregnant women, as well as anyone else, and also utilising additional drugs (Abdul *et al*., 2020; Ahad *et al*., 2021; Barbaud *et al.*, 2022). A pharmacology profile's longer-term post-licensing follow-up also enables examination of its off-label use. As a result, PV systems can examine a drug's risk-benefit ratio and promptly identify any problems it poses.

There are several methods for reportage the ADR. The spontaneous reporting system (SRS) is most often used by pharmaceutical firms, healthcare providers (with physicians, dentists, nurses, and pharmacists), and even individuals to report adverse drug reactions. SRS may occur at any moment during the research, which is one of its key benefits. It is not restricted to one phase. SRS has lately helped to identify and disclose ADRs that were missed in premarketing clinical trials or even post-marketing surveillance studies. SRS can therefore be viewed as an essential part of PV (Ahad *et al*., 2021). ADRs can be described in many ways, such as by phone, email, and online coverage. A PV programme can only be successful if all parties collaborate and timely submit ADRs to PV centres (Skokou *et al.*, 2022).

The pharmacist, who is the healthcare professional on staff with the most knowledge of drug therapy, is essential to PV initiatives. Hospital pharmacists are more likely to report adverse medication reactions than other types of pharmacists because they work closely with doctors and other healthcare providers and have access to patients' medical information. Particularly for clinical pharmacists with substantial clinical expertise, this is true (Joshi *et al.,* 2022).

ADR notification is intimately tied to the knowledge, attitudes, and practice (KAP) of healthcare practitioners. Studies show that KAP about PV needs to be streamlined when creating strategies to encourage ADR reporting. Studies that looked at the KAP of pharmacists operating in community pharmacies or hospital pharmacies for ADR and PV reportage have been carried out in several Indian locations. In this study, the KAP of hospital pharmacists regarding the disclosure of ADRs and PVs was investigated (Swen *et al*., 2023). Such kinds of works wore also reported before (Alshabi *et al.,* 2022).

MATERIALS AND METHODS

Study design, participants and site. This cross-sectional survey was conducted among the pharmacists employed by the RDT hospital in Battalapalli. To find study participants, we employed an easy, convenient sampling procedure. In this facility, a 26-month prospective study was conducted from November 2017 to January 2020. All pharmacists who gave their agreement to participate in the survey were comprised of the observed population.

Study questionnaire. Using a 37-item self-administered opinion poll, hospital pharmacists' KAPs regarding ADR and PV reportage, as well as factors that prevent ADR reportage, were evaluated. Previous published national and foreign surveys had an impact on the survey's design. Four phases were comprised in the inquiry. The first one asks participants about their sociodemographic information in five categories, their knowledge of reportage PV and ADR in six questions, their preferred method of reportage ADR in five options, their thoughts on setting up an ADR reportage scheme in the hospital in four options, and their opinions on the influences that dishearten pharmacists from reportage ADRs in seven questions (agree/disagree) (Gosselt *et al.*, 2023). The survey was made in Telugu and English and contained both closed-ended and open-ended queries (Ali *et al.,* 2018; Jyothsna *et al.,* 2016).

Validation and dependability of the study survey. Before being distributed, the created questionnaire underwent quality assurance checks for readability, comprehensiveness, uniformity, and content validity. In pilot research, ten pharmacists from the RDT facility took part. Six of the participants had previous experience in management, clinical study, PV, and healthcare quality (Patra and Gogoi 2021). Four of the ten workers have backgrounds in both clinical and academic fields. Before the final evaluation, the tool's content experienced a few minor post-validity changes in reaction to their recommendations (Li *et al.,* 2023; Zazzara *et al.,* 2021). The data from the trial research did not contain the investigation's findings.

Collection and analysis of data. The pretested questionnaire and poll goals were physically delivered to the hospital department leaders and pharmacists. Participants had enough time to complete the poll. During normal hospital appointments over 26 months, information was gathered. Pharmacists who replied to the survey were deemed to have given their consent to take part (Shafiq *et al.*, 2019).

Microsoft Excel 2023 was used to conduct the statistical study. The data came from closed-ended queries, which were then categorised and evaluated using descriptive statistics.

Ethical approval and deliberations. The RIPER Institutional Evaluation Board (Reference No. RIPER-RDT/125-17-08) reviewed and approved the research. Participants were given an educated consent document, and the questionnaire guaranteed the privacy of the data gathered. All of the inquiries that asked participants for confidential information such as name, contact information, organisation name, etc. were optional. The promise that the study's results would be released anonymously was also given to the volunteers.

RESULTS AND DISCUSSION

A total of 74 hospital-based pharmacists received the survey. The response rate they gave was 70.3%, which is very near to the anticipated sample size. 74 of these

were fully completed and submitted. Our study's answer rate is on par with other studies that have achieved similar response rates (Al Rabayah and Al Rumman 2019).

Socio-demographic constraints. Table 1 provides specifics about the sociodemographic traits of the subjects. Participants aged between 21 and 30 made up 66.21% of the group, followed by those aged between 31 and 40, who made up 21.62%. The bulk of registrants (55.40%) were women. The results of the poll are thus typical of hospital pharmacists as a whole. Future research should focus on various groups of Indian pharmacists; the results will reveal the present reportage practises for PV and ADRs, which can be used to develop and employ innovative therapeutic approaches. The major participants were Pharm D (internship) (66.21%) followed by postgraduates (16.21%) and the others were bachelor and diploma holders in pharmacy.68.92% of survey respondents had a work experience<2 years, while 20.27% had 2-5 years and 9.41 with 5-10 years (Khan *et al.,* 2022).

Table 1: Socio-demographic constraints of the pharmacists (n = 74).

Distinctive	Number (*n*)	%
Age range		
21 to 30	49	**66.21**
31 to 40	16	**21.62**
41 to 50	8	**10.81**
51 to 60	1	**1.35**
Gender		
Male	33	**44.59**
Female	41	**55.40**
Nationality		
Indian	68	**91.89**
Foreigners	6	**8.10**
Qualification		
Diploma	6	**8.10**
Bachelor	7	**9.45**
Masters	12	**16.21**
Pharm D	49	**66.21**
Professional pharmacy experience		
<5 years	51	**68.92**
5–10 years	15	**20.27**
11–15 years	7	**9.46**
More than 15 years	1	**1.35**

Pharmacists' information on PV and ADR reportage. The knowledge and awareness of PV and ADRs among pharmacists were evaluated using a total of 10 questions. The specifics of the answers to the knowledge-related inquiries are shown in Table 2. The study found that pharmacists' knowledge of PV and ADRs varied from average to excellent. Pharmacy experts, however, were baffled or confused by some of the queries. When provided a selection of choices, 70.27% of participants thought that all doctors, pharmacists, and nurses were competent to report adverse medication reactions. 48.65 of participants are familiar with the PV definition, whereas, 74.32% know the purpose of PV. Among the 74 pharmacists, 70.27% believe that ADR must be reported by all healthcare professionals. 95% of pharmacists believe that the ADR system must be present in India. 75.68% are aware of the seriousness of ADR, and 58.11% of participants stated that all ADR must be reported (Alshabi *et al.*, 2022).

Only 61% of pharmacists were ready to incorporate ADR reportage into their practices, suggesting a potential lack of obligation, even though the majority of pharmacists believed reportage to be essential and a professional requirement. This is less energising than studies from India, where pharmacies were open to implementing ADR reportage. According to 74.32% of poll respondents, healthcare workers should be given a thorough introduction to PV. This demonstrates the pharmacists' favourable opinion of PV's significance and effect on patient safety. Another interesting result of our poll is that 58.11% of pharmacists responded positively to the question of whether pharmacists and other healthcare practitioners cooperate on ADR reportage and PV. The transfer of clinical information will be facilitated by this inter-professional team approach, which will also aid in case and causality valuation and, eventually, enhance the number of error-free quality reports. The sociodemographic traits and attitudes of the individuals did not significantly correlate (Kassa *et al.*, 2019).

Participants were asked what way they favoured (Fig. 1) for reportage ADR information, and 35.14% said direct communication, while 16.22% said by telephone and by e-mail (14.86%). Smartphone applications were favoured by 31.08%. Only 2.70% of respondents said they favoured filing by mail (Nabi and Rehman 2022).

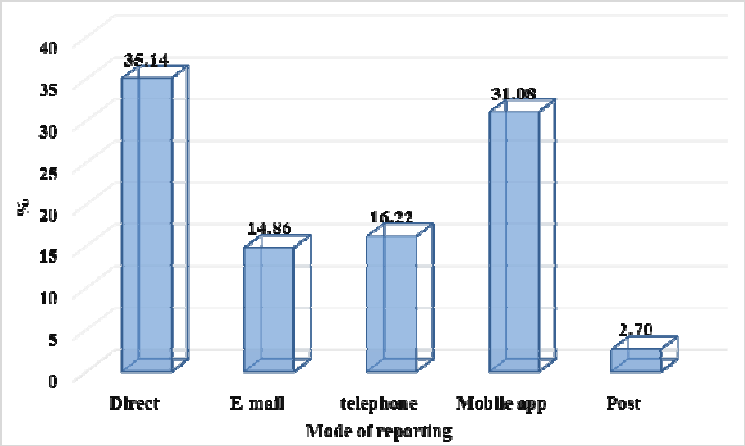

Fig. 1. Preferred mode of reportage ADR.

Table 2: Pharmacists' acquaintance of PV and ADR (n = 74).

Item	Number (*n*)	(%)
The best definition of PV		
The science of checking ADRs stirring in a hospital	18	24.32
The process of refining the welfare of drugs	11	14.86
The finding, valuation, empathy and deterrence of adverse effects (**Correct**)	36	48.65
The science of noticing the type and frequency of ADR post-marketing	7	9.46
Do not know	2	2.70
The drive of resonant out PV events (chose the most suitable answer)		
To progress patient's safety to drug use (**Correct**)	55	74.32
To recognize features upsetting ADR	9	12.16
To recognise unrecognised ADR	5	6.76
To compute the occurrence of ADR	3	4.05
Not aware	2	2.70
The healthcare expert answerable for reportage ADRs is/are		
Doctor (physician/surgeon/etc.)	5	6.76
Pharmacist	15	20.27
Nurse	2	2.70
All of the above (**Correct**)	52	70.27
Are you aware that India has an ADR reportage system?		
Yes	59	95.00
No	15	5.00
An ADR is considered serious, if		
ADR brings about death	3	4.05
It poses a hazard to life.	2	2.70
prolongs or leads to hospitalisation	4	5.41
Causes significant disability	7	9.46
This leads to congenital anomaly	2	2.70
the entire list (**Correct**)	56	75.68
Which ADRs need to be disclosed?		
any significant ADR	19	25.68
ADRs for new medicines	2	2.70
ADRs to herbal and complementary medicines	6	8.11
ADRs related to vaccinations	3	4.05
Old medications with unknown ADRs	1	1.35
The entire list (**Correct**)	43	58.11

Opinion on establishing the ADR reportage scheme in the hospital. The real reportage of suspected ADRs was evaluated using a total of four queries. ADR reportage experience, the number of ADRs discovered in practice over the preceding 26 months, and whether or not they had ever received instruction on the subject were all questions that were posed to the participants. Table 3 and Fig. 2 display the specifics of the answers to these queries.

Issues depressing pharmacists from ADR reportage. ADR underreporting is a problem for many PV programmes around the globe, particularly in developed nations. We looked into the challenges that this scenario presents for ADR reportage. The reasons why pharmacists don't disclose adverse medication responses were examined using a total of 8 closed-ended queries. The assertions were presented to the participants with the options "accept" or "disagree." In Fig. 3, the obstacles that prevent pharmacists from disclosing ADRs are visually represented (Dass *et al.,* 2018).

The most common reason given for not reportage an ADR was a non-appearance of a specialized atmosphere to do so (94%), followed by a lack of clinical expertise or medication understanding (82%).

Steady enduring education actions and exercise in workshops, meetings, and symposia concentrating on ADR tracking and reportage can help people gain a better understanding of the pharmacological and clinical components of a case report, counting but not imperfect to cause valuation. The focus should be on the commonly employed causality valuation techniques that can demonstrate a causal relationship between a medicine's side effects and an instrument. Employee efficiency and output are related to a pleasant work environment, which also inspires workers to reach their set objectives. Hospital professionals should have access to the proper setting and be free to carry out their responsibilities within the confines of their profession. In the right working setting, ADR monitoring and reporting will rise. Focus groups can be used to pinpoint problems with ADR monitoring and reportage and create remedies. Healthcare professionals should have access to the most recent PV guidelines, strategies, and measures created by the pertinent establishments and assistances to remain up to date on the most recent advancements (Alshabi *et al.*, 2022).

Suggestions. Above all, the Pharmacy Council of India (PCI) should keep up the excellent work it has been doing to improve PV and ADR reportage practises in India by educating and informing HCPs and the general public through workshops, sessions, and symposia. Participating patients in ADR reportage is a great concept. ADR reporting drop receptacles should be

positioned in key medical areas for HCPs and patients to facilitate reportage. HCPs should have access to both ADR reportage forms and ADR alert forms so that busy practitioners can finish the alert forms, which can then be handled by specialised staff. Additional KAP research in India's remote regions should be carried out to uncover knowledge breaks and behavioural patterns, requirements and difficulties, fences, and interferences that can improve consequences.

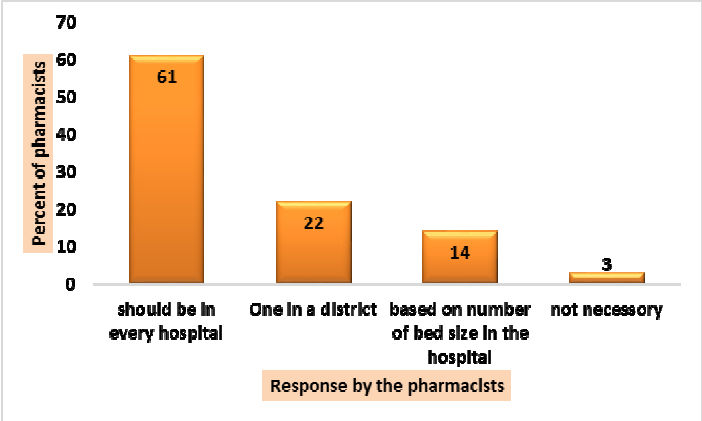

Fig. 2. Pharmacist's opinion on establishing the ADR reportage structure in the hospital

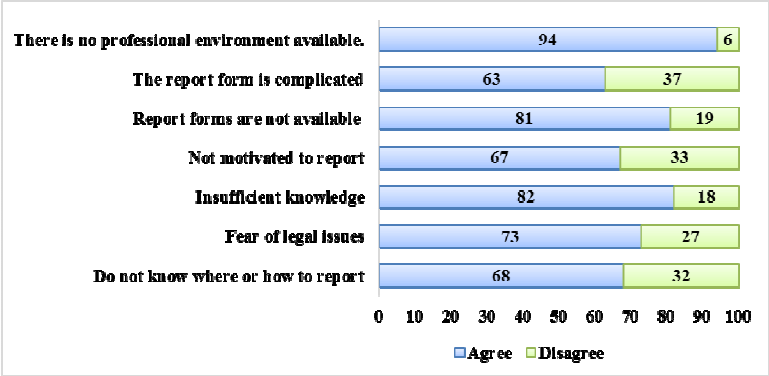

Fig. 3. Issues disheartening pharmacists from reportage ADRs.

CONCLUSIONS

The results of our research showed that the RDT hospital's pharmacists had a satisfactory KAP, positive attitudes, and usually sound information, which was apparent in their field of work. Most pharmacists concurred that required reportage will improve drug safety and recognise the significance of PV. The majority also agreed that pharmacists and other HCPs should work together and that HCPs need to receive comprehensive PV training. PV instruction and ADR filing had a strong relationship. The absence of a professional context was considered to be the greatest obstacle stopping pharmacists from recording. According to our research, India's current PV initiatives have a tonne of space for improvement.

FUTURE SCOPE

The significant prevalence of avoidable ADRs offers a compelling justification for doing future research targeted at implementing treatments helpful to lower drug-related responses. And giving the awareness of PV.

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Conflict of Interest. None.

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