

## Implementation of a Module Encouraging Patient Participation in Pharmacovigilance: A Snapshot

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Received: 01-02-2026 / Revised: 15-03-2026 / Accepted: 21-04-2026

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Conflict of interest: Nil

### Abstract

**Background:** Detection & reporting of adverse drug reactions (ADRs) is an important source of information about drug safety. Patients are most important stakeholders in pharmacovigilance. Many previous studies have explored the awareness of pharmacovigilance among healthcare professionals but very few similar studies have been done on patients so far.

**Methodology:** This is a questionnaire based cross-sectional study comprising of 8 pretested & prevalidated questions. The study was conducted in Out-patient Department of Medical College, Kolkata among 200 voluntarily participated patients who were above the age of 18 years. A printed copy of the questionnaire was provided & their responses were recorded. Then they were informed regarding ADR reporting by showing flash cards & other tools. After that, their responses against the same questionnaire were recollected and descriptive statistics were used to analyze the data.

**Results:** Among our study participants, 44% never reported an ADR to anyone. However, 80% participants said that they can report an ADR only to the doctors. Only 55% of the respondents believed that all ADR reporting must be mandatory whereas only 56% considered reporting in future. After showing flash cards, all (100%) of them agreed, that all ADRs should be reported, can be reported via different modes and ensured to report all ADRs in future in order to improve patient's safety.

**Conclusions:** Lack of motivation & knowledge regarding ADR reporting among participants is a major concern. Such initiatives will increase awareness among patients and will improve reporting of ADRs in future among them.

**Keywords:** Adverse Drug Reaction, Pharmacovigilance, Patients, Doctors.

**DOI:** 10.25258/ijcpr.18.5.202

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### Introduction

Any drug when administered at therapeutic dose, may also cause some undesirable effects along with its beneficial effects. These unwanted effects are considered as adverse drug reactions (ADRs). [1] The incidence of adverse drug reactions (ADRs) is on a hike globally that demands attention of all stakeholders. [2]

ADRs have been reported as a significant cause of morbidity and mortality among all age groups, leading to increased number of hospital admissions or increased duration of hospital stay, creating a substantial financial burden on the healthcare system and as a whole on the society [3]. Pharmacovigilance is a system that promotes the prevention, detection and evaluation of suspected adverse drug reactions & minimises their impact on patient health, hence, considered crucial in respect to drug safety. [4] It is of no doubt that

pharmacovigilance plays a crucial role in the healthcare system and should be an integral part of practice of medicine. [5] Spontaneous ADR reporting system by the healthcare professionals remains the cornerstone of pharmacovigilance activities [6]. However, the current trends in pharmacovigilance systems are also focusing towards the involvement of patients in spontaneous reporting of adverse drug reactions (ADRs). [7] In the beginning, such ADRs reporting was restricted to only the physicians, with a belief that only a doctor is capable of providing high-quality information on ADRs.[8]. Later, other healthcare professionals (HCPs) namely the pharmacists and nurses were also added to this spontaneous ADR reporting system (SRS), who today contribute a lot to the pharmacovigilance system [9,10].

Furthermore, now a days, not only the healthcare professionals but the patients are also been allowed to report ADRs directly to the authorities [11] It is believed that participation of patients in this regard is vital to the success of pharmacovigilance programme. [12] After an extensive literature search, we identified that, a handful number of research works on knowledge, attitude and practice of pharmacovigilance, have been done in India among healthcare professionals including nurses, pharmacists, medical students and doctors. But, the same research among the patients were least explored. It is quite obvious that patients are sources of firsthand information regarding ADRs and considering this, their perceptions towards ADRs reporting and their vital role in reporting ADRs, need to be evaluated. The objective of our study was to assess the extent of patient's participation in ADR reporting and encourage them for future reporting of the same. The present study will help the healthcare professionals to encourage and enhance the involvement of patients in reporting ADRs in future.

### Materials & Methods

This is a cross-sectional questionnaire-based study, conducted among patients attending outpatient departments (OPDs) of Medical College & Hospital, Kolkata. The pretested & prevalidated questionnaire had two parts, the first part being the socioeconomic & demographic details of the participants & the second part includes eight (8) questions, regarding participant's knowledge regarding pharmacovigilance, their attitude and practice toward practice of pharmacovigilance. [13] This study was conducted only after obtaining approval from the institutional ethics committee, Medical College, Kolkata. Patients attending various OPDs of the hospital were approached and explained in detail about the study. A written informed consent was taken from those who agreed to voluntarily participate in the study. The study was carried out between 10th to 17th January 2025 among 200 participants, selected based on the systematic random sampling technique. The interview was conducted in vernacular language of the patients (English, Hindi or Bengali) and the responses were recorded by the interviewer. Data were entered in the Microsoft excel and analysed using the descriptive statistics in terms of charts, figures and tables.

### Results

In our study, total number of participants was 200 of which 62% (124) were female and mean age of participants was 41.38 years. Among our study subjects, 54% (108) belong to urban areas and 73% (146) were married. 62% (124) of them continued their education till school level and 28% (56)

completed their graduation while 10% (20) were illiterate. Among the participants, 57% (114) were unemployed, 31% (62) were self-employed and only 12% (24) were doing some kind of services.

Among our study participants 82% (164) said that they seek physician's advice when they fall sick while only 42% said that they got information regarding expected adverse effects of the prescribed medications from the doctor's side. The other 27% (54) said they got information about the same from the nursing staffs but unfortunately 20% (40) participants never got any such information from any of the healthcare stakeholders.

86% (172) of our respondents have suffered from some kind of adverse effects related to ingested medications in the past. While answering the question about to whom someone can report the ADRs, 80% (160) of our study participants said that they can report the same to the doctors. But in reality, only 48% (96) of them reported the adverse effects to the doctors and unfortunately, 44% (88) of them did not report the adverse effects to anyone.

Regarding reporting of each of the adverse effects of all medications, 55% (110) of our study participants said all ADRs should be reported, 20% (40) mentioned not every ADRs need to be reported and 25% (50) respondents did not know what should actually be done. Among our study participants 59% (118) agreed that such reporting of adverse drug reactions will improve the drug safety, 8% (16) denied such benefit and 34% (68) had no idea whether drug safety will be affected or not. During the interview, initially 56% (112) of our study participants said that they will report medication related adverse reactions in future, 8% (16) disagreed to report such and 36% (72) of them were not decided whether to report ADRs or not.

After the interview session, we had a discussion with our study participants regarding the importance of ADR reporting by showing some flash cards, diagrams & other tools. We discussed about the different ways of reporting such ADRs including the toll-free number for ADR reporting, the email address and the availability of ADR reporting form on internet for free download. We also informed our study participants that they can also visit the ADR reporting center, present in the Department of Pharmacology, Medical College, and Kolkata for reporting adverse drug reactions, if they wish for. After the session, all, 100% (200) of our study participants were convinced regarding the importance of adverse drug reaction reporting, understood the different tools for reporting the same and agreed to report all the adverse drug reactions related to ingested medications in future.

**Table 1: Questionaries**

| Sl. No. | Questions   | Options & responses  |                         |                      |                        |                                   |                      |
|---------|---|----------------------|-------------------------|----------------------|------------------------|-----------------------------------|----------------------|
|         |   |                      |                         |                      |                        |                                   |                      |
| 1.      | Who do you consult when you are diseased?                             | Doctors<br>164 (82%) | Pharmacists<br>36 (18%) | Self-0<br>(0%)       |                        |                                   |                      |
| 2.      | From where do you get information about the side effects of medicines | Doctors<br>84 (42%)  | Pharmacists<br>54 (27%) | Nurse 2<br>(1%)      | Leaflets<br>10 (5%)    | Friends &<br>Relatives<br>10 (5%) | Noone<br>40<br>(20%) |
| 3.      | Have you ever suffered from side effects of any medicines?            | Yes 92<br>(46%)      | No 108<br>(54%)         | Don't know 0<br>(0%) |                        |                                   |                      |
| 4.      | To whom did you report regarding these side effects?                  | Doctors<br>96 (48%)  | Pharmacists<br>2 (1%)   | Nurse 0<br>(0%)      | All 14<br>(7%)         | None 88<br>(44%)                  |                      |
| 5.      | How can you report the adverse effect of drugs?                       | Doctors<br>160 (80%) | Phone 4<br>(2%)         | Online 2<br>(1%)     | Form fill-up 0<br>(0%) | All 28<br>(14%)                   | None 6<br>(3%)       |
| 6.      | Do you think every side effect should be reported?                    | Yes 110<br>(55%)     | No 90<br>(45%)          | Don't know 0<br>(0%) |                        |                                   |                      |
| 7.      | Do you think this reporting will improve patient's safety?            | Yes 118<br>(59%)     | No 82<br>(41%)          | Don't know 0<br>(0%) |                        |                                   |                      |
| 8.      | Will you report the adverse drug reactions in future?                 | Yes 112<br>(56%)     | No 88<br>(44%)          | Don't know 0<br>(0%) |                        |                                   |                      |

### Discussions

Among our study participants 82% (164) said that they seek physician's advice when they fall sick. A study by Rehman AU et al revealed that 74.2% of patients immediately consult doctors when suffering from any illness.[14] In our study, only 42% said that they got information regarding expected adverse effects of the prescribed medications from the doctor's side. The other 27% (54) said they got information about the same from the nursing staffs but unfortunately 20% (40) participants never got any such information from any of the healthcare stakeholders. In a previous study published in 2018, only 6% of the participants got information regarding side effects of medicine from their health care workers.[15]

In the present study, 86% of our respondents have suffered from some kind of adverse effects related to ingested medications in the past. However, in different studies 24.7% [16] and 45.9% [14] of the participants experienced adverse reactions by medications during their lifetime. While answering the question about whom someone can report the ADRs, 80% (160) of our study participants said that they can report the same to the doctors. An Indian study of 2020 showed only 57.7% of their participants considered reporting ADRs to the doctors. [17] Another study by Jha N et al supported similar findings of our study where 78.26% thought that ADRs can only be reported to doctors and rest thought it can also be reported to nurse or pharmacist.[18] Regarding reporting of

each of the adverse effects of all medications, 55% (110) of our study participants said all ADRs should be reported, 20% (40) mentioned not every ADRs need to be reported and 25% (50) respondents did not know what should actually be done. Study by Adisa R et. al. stated that only 18.6% patients reported the previously experienced ADRs while the remaining either believed the adverse drug reactions were not serious enough to get reported or did not put importance to the ADRs. [16] Similar data was also mentioned in another study of 2023 where the participants did not report the ADRs as either they did not realize this was an ADR (52.38%) or they thought the ADR was not severe (40.48%) to report. [19]

Among our study participants 59% (118) agreed that such reporting of adverse drug reactions will improve the drug safety, 8% (16) denied such benefit and 34% (68) had no idea whether drug safety will be affected or not. During the interview, initially 56% (112) of our study participants said that they will report medication related adverse reactions in future, 8% (16) disagreed to report such and 36% (72) of them were not decided whether to report ADRs or not.

Previous study showed that a total of 35.2% respondents knew that adverse reactions by the drug were the harmful response, while 75.2% participants identified correctly in the interventional survey.[14] Study by Van Hunsel F et al came up with the finding that 93.8% responders shared the opinion that reporting an

ADR can prevent harm to other people, 97.9% believed that reporting contributes to research and knowledge, 90.7% stated that they felt responsible for reporting an ADR and 92.5% stated that they will report a possible ADR once again in the future.[20] In an established study by Tejus A et al most of the participants felt it is important to report ADRs (91.6%) however only 37.7% had ever thought of reporting ADRs. Most of the participants felt consumers should be involved in reporting ADRs (37.7%), while 57.7% stated it is appropriate to report to doctors.[17]

After the session, all, 100% (200) of our study participants were convinced regarding the importance of adverse drug reaction reporting, understood the different tools for reporting the same and agreed to report all the adverse drug reactions related to ingested medications in future. Rehman AU et al also confirmed in his findings that a total of 45.9% of the participants experienced adverse reactions by drugs during their lifetime, but the reporting rate was only 30.2%.

The attitude toward reporting was modified by pharmacist counselling sessions and health brochure intervention, and 99.3% of respondents showed the intention to report in the future which is quite similar to our present study.

Media reports were recalled by 56.7% of the patients in the initial response and 60.8% in the final response. The prerequisite of the pharmacovigilance center in hospitals was improved significantly from 56.7% to 97.9%. [14]

**Acknowledgement:** Authors would like to thank all the patients who were included in the study, for their participation. Authors would also thank all the faculties and non-teaching staffs of the Department of Pharmacology and Out Patient Department, Medical College Kolkata for their kind support.

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