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Current Scenario Of Adverse Drug Reactions In India: A Review On Adr Reporting, Management, Obstacles And Possible Solutions

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ABSTRACT

Monitoring adverse drug reactions is an essential aspect of drug use. In addition to influencing its illness patterns, India's vastness, surrounding different sociocultural and biotic regions, and healthcare system put its residents at risk for adverse reactions to drugs (ADRs). This necessitates a pharmacovigilance system that is both culturally sensitive and well-planned. This study examines India's Adverse Drug Reaction (ADR) tracking system. The objective is to present an understandable and comprehensive image of the ADR monitoring system, emphasizing its advantages and disadvantages and its salient characteristics. With more than two hundred Adverse Drug Monitoring Centers (AMCs) operating around the country, it was noted that the Central Drugs Standard Control Organization (CDSCO) regulates quality, safety, and effectiveness of pharmaceutical products. The situation can be improved by increasing the participation of nurses, pharmacists, and consumers in addressing adverse drug reactions (ADRs), streamlining and expediting the process through electronic means, implementing training programs and educational interventions for healthcare providers, and raising awareness of the reporting system among both caregivers and recipients. It can be difficult to give the system of pharmacovigilance impetus and guarantee a strong reporting procedure. Still, with careful planning, workable solutions, and concentrated efforts, the change can be brought about by guaranteeing patient security—the ultimate purpose of pharmacovigilance.

Keywords: Adverse drug reactions, spontaneous reporting, underreporting

INTRODUCTION

Each and every pharmaceutical medicine that is released onto marketplaces is anticipated to result in some negative side effects when given to patients outside of clinical trial settings. "An unpleasant and unexpected response to a drug that occurs at doses used in humans for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function" is how the World Health Organization (WHO) defines an adverse drug reaction (ADR)".[1] India is referred to as "the pharmacy of the world" since it manufactures a significant quantity of generic pharmaceutical items for the global market. For this reason alone, it needs a well-designed healthcare system in which all medical personnel are aware of the potential risks and advantages of medications and the need to monitor and report adverse drug reactions to conduct better-quality drug testing and ensure patient safety.[2] It is crucial for both patients and medical experts to identify these side effects, which may then be utilized to create "warnings" about unforeseen drug-related incidents and prove the drug's safety. In general, medications are released to the public before relatively rare but possibly significant adverse drug reactions have been identified and measured.[3] Post-marketing surveillance is routinely carried out by pharmacovigilance systems to obtain a comprehensive safety profile of medications worldwide. Any kind of medication-related adverse drug reaction that is recognized or that this system is known to detect. In July 2010, the Government of India created a technology-based system called the Pharmacovigilance Program of India (PvPI) to manage the stable adverse drug reporting system in the Ministry of Health and Family Welfare. Additionally, on April 15, 2011, the Ministry of Health and Family Welfare, Government of India, redesigned the pharmacovigilance program and moved the system to the National Coordination Center at the Indian Pharmacopoeia Commission (IPC), Ghaziabad, to carry out adverse drug monitoring in a populous nation like India.[4,5] At first, the National Coordination Center (NCC) was run by the All India Institute of Medical Science (AIIMS), New Delhi. Herbal remedies, conventional medications, blood products, biologicals, vaccines, and medical gadgets are all included under the purview of pharmacovigilance. Following the Thalidomide event in the early 1960s, WHO started the International Drug Monitoring Program. Through its Collaborating Center in Uppsala, the WHO promotes pharmacovigilance, which strives to improve patient safety and offer pertinent and trustworthy data for the ongoing risk-benefit analysis of marketed medications.[6] This encourages people to come forward and report bad drug reactions. Every Indian individual who has experienced an adverse medication reaction can report it to the NCC using a specific form that is available in multiple languages for healthcare professionals.[7] PvPI is primarily responsible for playing a significant role in India and encouraging the best possible use of medications to prevent adverse drug reactions. PvPI is in charge of educating individuals about adverse drug reactions brought on by active pharmaceutical ingredients after they are required to do so.[8] With the aid of adverse drug reaction forms, PvPI, which is currently operating throughout India with Adverse Drug Monitoring Centers (AMCs), encourages precise and accurate reporting of adverse drug reactions. Individual Case Safety Reports (ICSRs) are completed online in the WHO database, VigiFlow, using the information gathered via suspected adverse drug reaction reporting forms. A group of clinicians should evaluate the reported reports once they are given to "PV Associates" who work directly under the direction of the Coordinator or Deputy Coordinator at various adverse drug monitoring centers. The ICRs form that PV associates (AMC) provided was then reported to NCC using the Vigiflow program. After being verified and evaluated for veracity based on the data supplied to NCC, these ICSRs are progressively sent to the Uppsala Monitoring Centre (UMC), Sweden.[9]

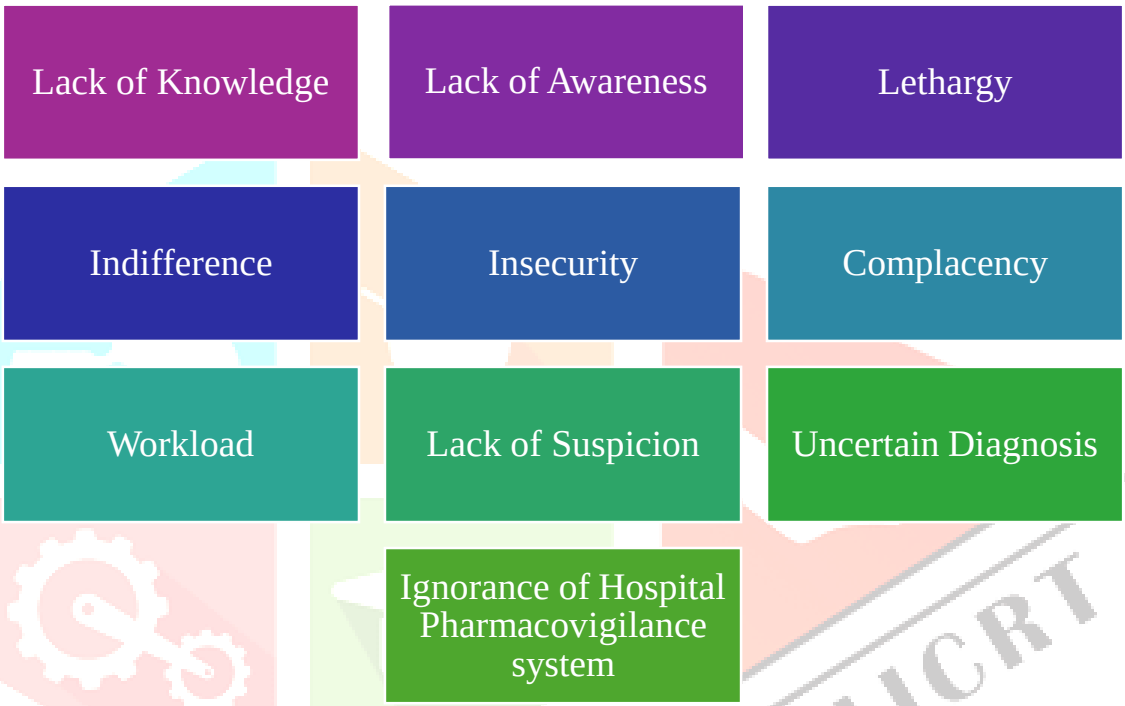
ADR Reporting Rate in India

With more than 1.21 billion people, India has the second-largest population in the world, according to the 2011 census.[10] ADRs can be prevented in some cases. One of the most important things that healthcare practitioners can do to prevent or minimize ADRs is to report them spontaneously. India's ADR reporting rate is less than 1%, while the global rate is 5%.[11] In India, ADR management might cost the patient or the institution anywhere from $15 to USD 150.[10] One possible explanation for the lower occurrence in India is that Indian healthcare

practitioners are more aware of pharmacovigilance and ADR monitoring. According to the yearly report published by the Pharmacovigilance Program of India (PvPI), out of the 52810 ADRs that were reported in India between April 2020 and March 2021, 28.10% were serious events.[12]

Potential Obstacles to the Spontaneous ADR Reporting

Figure 1: Potential Obstacles to the Spontaneous ADR Reporting

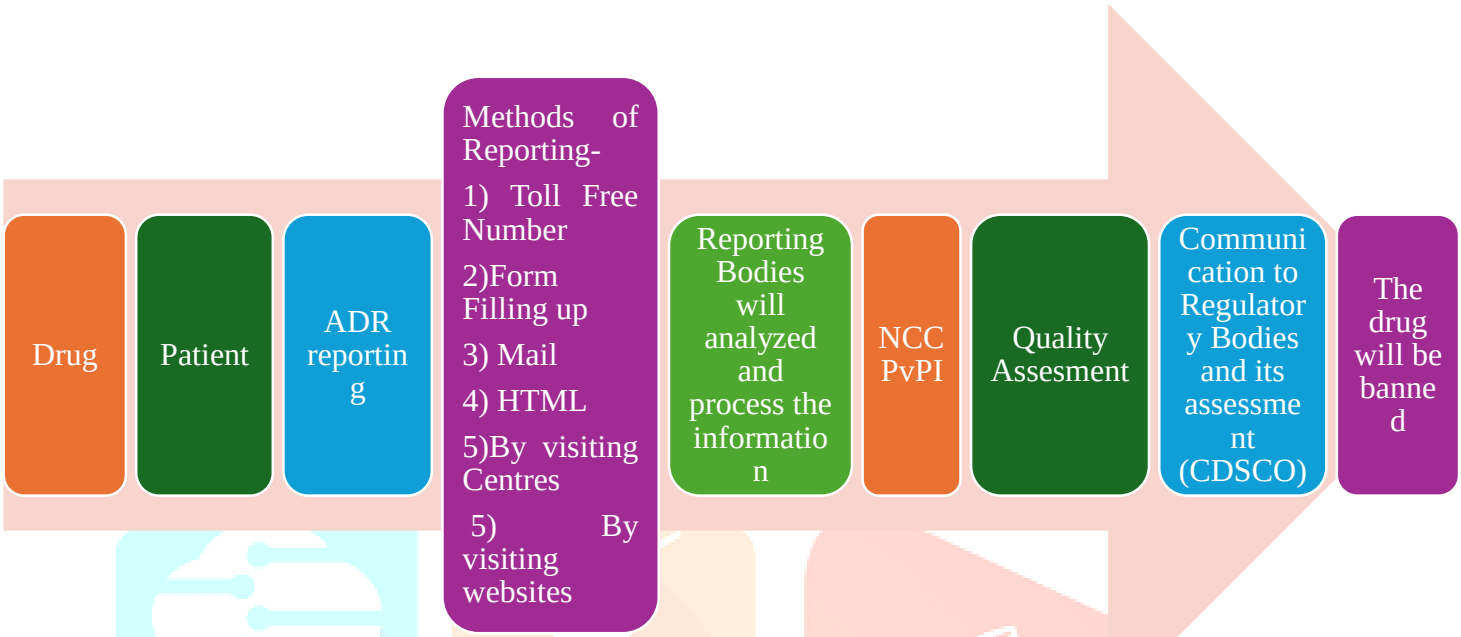


Committees Responsible for ADR Monitoring

A variety of committees have been established in India to monitor medication side effects and make sure pharmacovigilance functions smoothly within each committee. These committees cover a range of entities, from the Adverse Drug Reaction Monitoring Centers (AMCs) to the Uppsala Monitoring Center (UMC), guaranteeing a comprehensive and structured approach to monitoring drug safety. These groups are crucial for monitoring and controlling potential issues with drugs, playing a significant role in ensuring pharmacovigilance efforts work well.[13]

ADR Monitoring and Reporting in India

Figure 2: ADR Monitoring and Reporting in India



To improve safety and promote public health, healthcare professionals have a primary duty to report adverse drug reactions brought on by marketed medications. All Indian citizens should be informed of adverse drug reactions and possible ways to report them.[14] PvPI encourages people to report any suspected adverse drug response related to pharmaceutical products, regardless of whether it is severe or mild, common or uncommon, or unfamiliar. If someone is experiencing an adverse drug reaction, they should report it right away. The medical professional can complete the suspected adverse drug reaction form and notify AMC if any incidents involving a specific medication occur while they are treating the patient. In addition, patients can visit the closest AMC under PvPI to report an adverse drug reaction. The IPC's official website has information about AMCs. Healthcare professionals can report adverse drug reactions (ADRs) using the "Suspected Adverse Drug Reaction Reporting Form," which is available at "link 1." Patients, their families, relatives, and any Indian citizen can complete the "Medicines side effect reporting form" by clicking on "link 2." Customers can also email the HTML straight to NCC or to the closest AMCs. To report any type of adverse drug response, an official email address is also provided.

Official website of IPC: www.ipc.gov.in

Link 1: https://cdsco.gov.in/opencms/export/sites/CDSCO_WE B/Pdf-documents/Consumer_Section_PDFs/ADRRF_2.pdf.

Link 2: https://www.mkcgmch.org/admin/MenuDocument/Dow nloadForms_171.pdf. Official mail id: pvpi@ipcindia.net or ipclab@vsnl.net.

Toll-free number: 1800-180-3024.

Mobile app for Android users: “ADR PvPI”

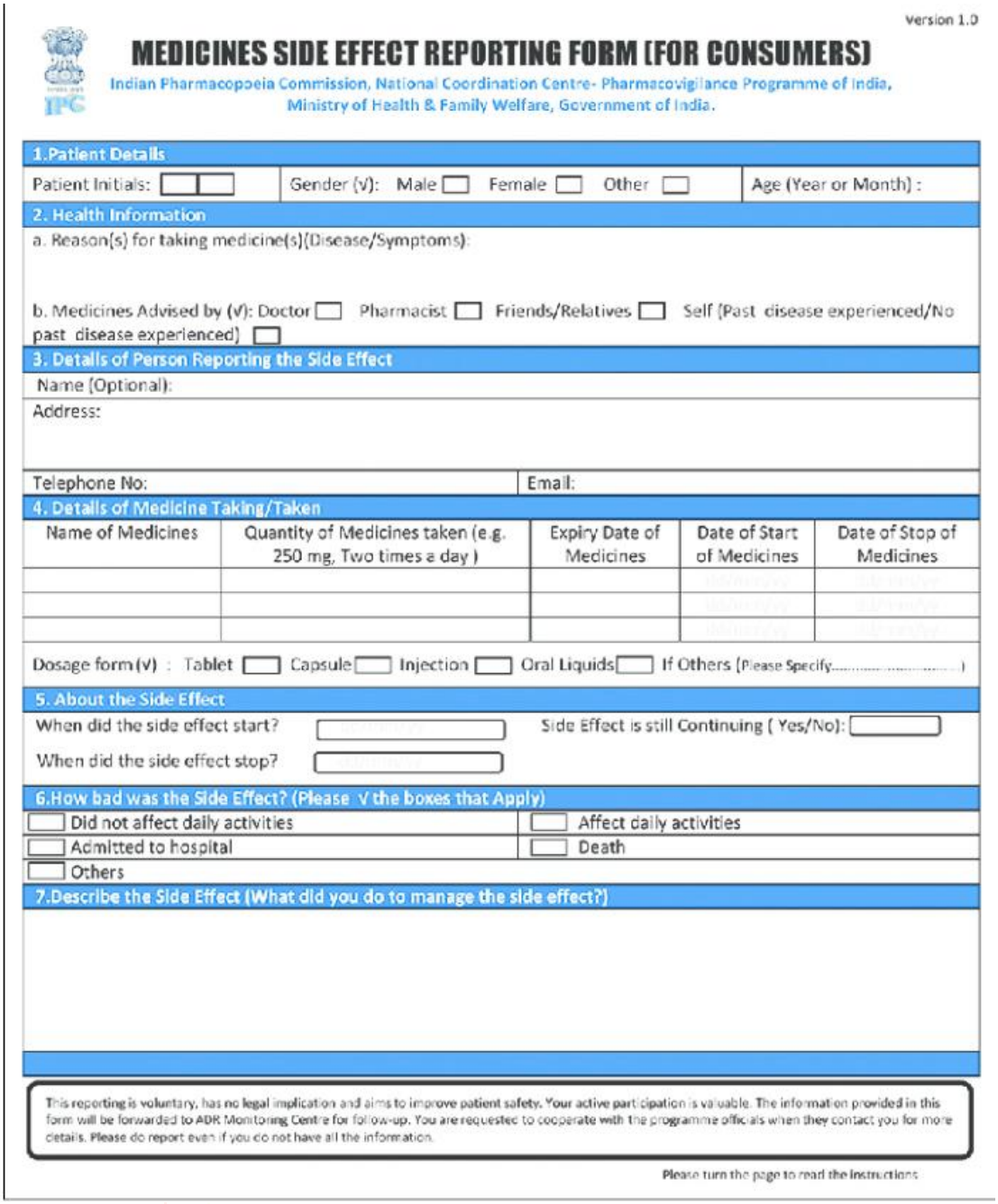
ADR Reporting Approaches

1. **What to Report?**

PvPI encourages the reporting of all suspected adverse drug reactions (ADRs), whether they are known or unknown, significant or non-serious, common or uncommon, and regardless of whether a clear causal connection between a drug and the reaction has been established. The use of contrast media, medical equipment, immunizations, allopathic pharmaceuticals, and traditional remedies can all result in adverse drug reactions (ADRs).

2. **Where to Report?**
3. ADRs may be reported to NCCs or AMCs by patients or consumers as well as by any healthcare provider, including physicians, dentists, pharmacists, and nurses. Pharmaceutical companies may also submit individual case safety reports for their goods to the NCC.
4. **How to Report?**

   On the IPC website, consumers and healthcare professionals can find suspected ADR Suspected ADR reporting forms [Figure 3] are available for consumers and healthcare professionals to use on the IPC website. To overcome the language obstacle related to ADR reporting, the consumer reporting form [Figure 4] is available in eleven common languages (Hindi, Tamil, Telugu, Kannada, Bengali, Gujarati, Assamese, Marathi, Oriya, and Malayalam). On weekdays, ADRs can also be submitted by phone at the PvPI helpdesk (18001803024) from 9:00 am to 5:30 pm. The Android mobile application for ADR reporting is now available to the general public.



Version 1.0

MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Government of India.

1.Patient Details

Patient Initials: ☐☐ | Gender (√): Male ☐ Female ☐ Other ☐ | Age (Year or Month) :

2. Health Information

a. Reason(s) for taking medicine(s)(Disease/Symptoms):

b. Medicines Advised by (√): Doctor ☐ Pharmacist ☐ Friends/Relatives ☐ Self (Past disease experienced/No past disease experienced) ☐

3. Details of Person Reporting the Side Effect

Name (Optional):

Address:

Telephone No: | Email:

4. Details of Medicine Taking/Taken

Name of Medicines	Quantity of Medicines taken (e.g. 250 mg, Two times a day)	Expiry Date of Medicines	Date of Start of Medicines	Date of Stop of Medicines

Dosage form (√) : Tablet ☐ Capsule ☐ Injection ☐ Oral Liquids ☐ If Others (Please Specify.....)

5. About the Side Effect

When did the side effect start? ☐☐/☐☐/☐☐☐☐ Side Effect is still Continuing (Yes/No): ☐

When did the side effect stop? ☐☐/☐☐/☐☐☐☐

6.How bad was the Side Effect? (Please √ the boxes that Apply)

☐ Did not affect daily activities ☐ Affect daily activities

☐ Admitted to hospital ☐ Death

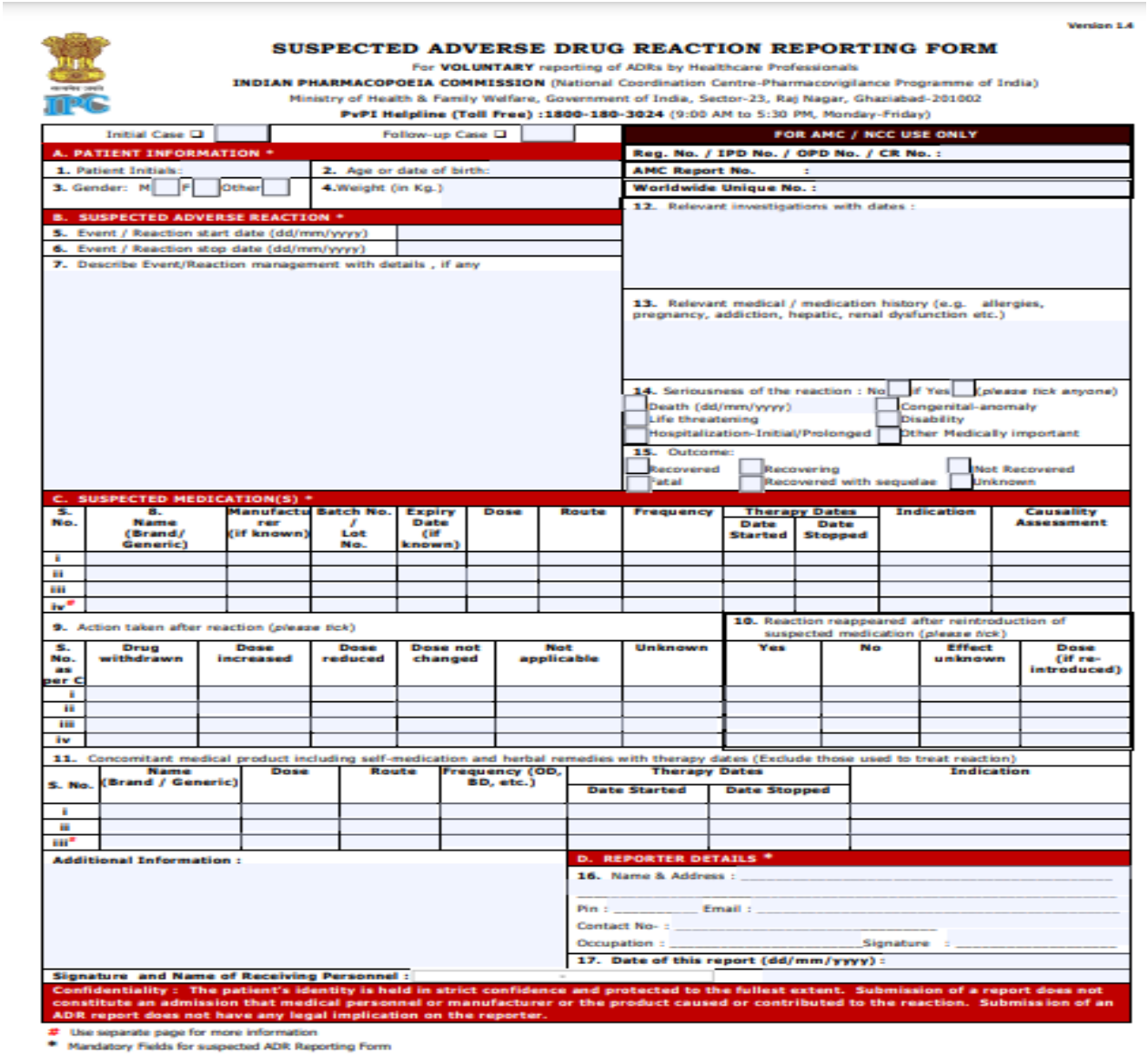
☐ Others

7.Describe the Side Effect (What did you do to manage the side effect?)

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable. The information provided in this form will be forwarded to ADR Monitoring Centre for follow-up. You are requested to cooperate with the programme officials when they contact you for more details. Please do report even if you do not have all the information.

Please turn the page to read the instructions

Figure 3: Suspected ADR reporting form



Version 1.4

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For **VOLUNTARY** reporting of ADRs by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India)

Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002

PvPI Helpline (Toll Free) :1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ☐ Follow-up Case ☐

FOR AMC / NCC USE ONLY

Reg. No. / IPD No. / OPD No. / CR No. :

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION *

1. Patient Initials:
2. Age or date of birth:
3. Gender: M ☐ F ☐ Other ☐
4. Weight (in Kg.)

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy)
6. Event / Reaction stop date (dd/mm/yyyy)
7. Describe Event/Reaction management with details , if any
12. Relevant investigations with dates :
13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)
14. Seriousness of the reaction : No ☐ If Yes ☐ (please tick anyone)
Death (dd/mm/yyyy) ☐ Congenital-anomaly ☐
Life threatening ☐ Disability ☐
Hospitalization-Initial/Prolonged ☐ Other Medically important ☐
15. Outcome:
Recovered ☐ Recovering ☐ Not Recovered ☐
Fatal ☐ Recovered with sequelae ☐ Unknown ☐

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication	Causality Assessment
i											
ii											
iii											
iv#											

9. Action taken after reaction (please tick)

10. Reaction reappeared after reintroduction of suspected medication (please tick)

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if re-introduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication
i							
ii							
iii#							

Additional Information :

D. REPORTER DETAILS *

16. Name & Address :
Pin : Email :
Contact No- :
Occupation : Signature :
17. Date of this report (dd/mm/yyyy) :

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

Use separate page for more information

* Mandatory Fields for suspected ADR Reporting Form

Figure 4: Medicines Side effect reporting form

To whom should one report?

The NCC or the nearest AMC is where reporters can turn in completed reported ADR forms. Regarding AMC, such findings are checked by medical professionals, entered into Vigiflow, and sent to NCC for further assessment. Following a final assessment at NCC, these reports are committed to the WHO-Uppsala Monitoring Center. To find new signals, the professionals evaluate, analyze, and record the information in the medication safety database. There are no legal ramifications for the reporters of the submitted ADR report. The patients' identities are completely secured and kept in strict confidentiality.[15,16]

5. **Who can Report?**

When it comes to reporting adverse drug reactions, healthcare providers are given priority. Health professionals, doctors, pharmacists, dentists, and Indian citizens can all report adverse drug reactions if they occur as a result of certain medications or medical equipment.[17]

Solutions to Under-Reporting of ADR

Inadequate ADR reporting eventually results in the missed or excessively delayed detection of numerous important signals, allowing potentially dangerous medications to continue on the market and endangering patient safety. Several actions that can be implemented to enhance India's unplanned system of adverse event reporting are identified based on the evidence that is currently available, including surveys of medical experts.

1. Increased participation from every participant involved in ADR reporting

1.1. Nurses and Pharmacists

Although the proof that is currently available shows that nurses usually don't understand their reporting responsibilities for adverse drug reactions on their own, research has indicated that increased nurse involvement in reporting and recording ADRs in addition to collecting and handling them helps to enhance the system.[18,19] ADR reports from nurses increased from 2–3% in the mid-1990s to 12% in 2004 according to a Swedish study that analyzed the data both quantitatively and qualitatively.[20,21] A great supplemental resource for recognizing and disclosing adverse medication reactions is healthcare workers. ADR reporting rates and the percentage of dangerous and unlabeled ADRs have also been shown to significantly increase in a few other studies involving nurses who received adequate training on reporting ADRs.[22,23] Along with doctors, pharmacists must be involved in ADR reporting because consumers frequently interact with pharmacists, who can offer trustworthy and helpful information to supplement clinician reports.[24,25] Concerns that patients may have regarding adverse drug reactions are also included in the reports. The availability of Pharmacy-provided consumer reporting forms might significantly increase the immediate reporting of patients of adverse drug reactions (ADRs), despite the perception that India's drug delivery system leaves little room for pharmacists.[26]

1.2. Consumers and Patient

Increasing the number of clients or customers who report adverse drug reactions (ADRs) is a crucial action that can assist in resolving the problem of underreporting. Hunzel et al.'s 11-country survey emphasized the significance of providing the public with a way to report adverse reactions and enhancing the scientific value of the pharmacovigilance data gathered.[27]According to the results of another investigation on reporting of patients, patients are more probable than medical experts to identify and disclose any adverse response they encounter. Furthermore, by shedding insight into potential novel reactions, patients give professionals' reports of ADRs more context and significance. Positive experiences have been had thus far by nations that have included patients or consumers as reporters.[28] Patients' viewpoints can be better understood and the general perspective on ADR reporting can be expanded by including them. As far as India is concerned, this inclusion is new, but it should improve and enhance the current program. According to current estimates, consumers account for fewer than 12% of ICSRs reported to PvPI.[29]

2. Improving the ease, convenience, and efficiency of the reporting process

2.1. Promoting eHealth reporting tools

Several healthcare expert polls on enhancing spontaneous ADR have recommended developing methods to expedite and simplify the reporting procedure. Regulatory agencies are increasingly using information gathered from Smartphone applications and social networking sites to streamline ADR reporting and improve the ability of consumers to immediately report unfavorable incidents. In India, such initiatives have previously been started, but acceptance rates are still low because, in 2015–16, fewer than 1% of individual case safety reports (ICSRs) were received through mobile apps.[29] Online ADR reporting can be beneficial to use a website that enables online form submission and completion to expedite and improve the efficiency of the reporting process.[30] A French study claims that this method notably

shortened the reporting period while simultaneously increasing the number of reports by almost 50%. It has also been proposed to automatically fill up specific sections of the report form (online if available) to enhance the reporting status.[31] A hyperlink to an online ADR reporting form can be added to an electronic patient record in hospitals that have the capability, particularly in the mostly unexplored private sector. According to research conducted in Portugal, the average number of ADR reports increased from one to four when a website link was included.[32]

2.2. Enhancing the forms' usability and design for impromptu ADR reporting

The format and content of spontaneous reporting forms are a crucial component of the pharmacovigilance program that could positively affect the process. Expanded availability of ADR documents is also deemed essential. In addition to being shorter and easier to use, reporting forms can be updated to encompass all required details. Medical care personnel if the form is too cumbersome, can be deterred from freely reporting an undesirable incident. Malaysia had the best form in terms of completeness and capturing the required information, according to research evaluating the quality of ADR reporting forms from different nations. Due to disparate designs, the data acquired for the others varied. To streamline the reporting process and reduce misunderstandings, it's critical to standardize the forms and create a thorough one.[33]

3. Tools to improve the pharmacovigilance system and promote clinician reporting

An educational program aimed at raising awareness and information about PV and ADR notification drop boxes was implemented in an Indian study [60]. Simplified reporting forms were included with these boxes, which were placed in every hospital ward and outpatient department. When a doctor saw an ADR, they had to fill up the form and submit it to the drop box.[34] A large number of these forms were subsequently forwarded to the National Pharmacovigilance Center. Over three months, this nearly increased the frequency of ADR reporting. To improve reporting outcomes, hospitals can test and use these cutting-edge strategies. Based on a survey of local physicians and nurses, the respondents preferred drop boxes and telephones as communication methods. Regular text and/or email alerts have also been proposed as low-cost and efficient means of motivating doctors to report ADRs they see in their patients, both indoors and in the outpatient department. Some may view financial incentives as a means of motivating medical personnel to report adverse drug reactions. However, according to a survey, nearly 80% of participants didn't think that using financial incentives could make the process better. In addition, it is typically not allowed to use financial incentives to stop excessive and biased reporting. The long-term effectiveness of the program greatly depends on fostering positive relationships between stakeholders, including pharmacovigilance centers and clinicians, and changing the way that ADR reporting is observed. Clinicians must ensure that reporting negative reactions is an essential component of their everyday work and that all medical personnel consider this to be their responsibility. The culture of volunteer reporting can also be strengthened by providing individuals or groups of HCPs with regular feedback regarding reported ADRs.[35]

4. Training and educational initiatives for medical students and medical professionals

The vast majority of participants in several studies that looked into measures to enhance the spontaneous reporting of adverse events across India recommended the introduction of training programs and a sequence of continuous medical education (CME). Physicians participated in a randomized controlled experiment to determine whether educational programs for pharmacovigilance could enhance the spontaneous reporting of adverse events. The results showed that the intervention group's reporting rate rose by roughly 65%, indicating the intervention's significant impact.[36] Another RCT that developed a multimodal training intervention for physicians that comprised a weekly outreach visit, a reminder card, and an ADR report form

found that the intervention group was over 10% more likely to report ADRs than controls (adjusted RR 10.23%). ADR reporting increased significantly within the first four months, and the effect lasted during the first year. These focused outreach initiatives can increase doctors' ADR reporting rates.[37]

CONCLUSION

The review examines numerous aspects of ADRs, their reporting, and monitoring. It looks at how the general public and medical professionals report adverse drug reactions to higher authorities. To comprehend the current system in India, pharmacovigilance—the working program about ADRs and their function—is explained. For a better knowledge of ADR monitoring and reporting, all government programs, committees, and mechanisms are discussed. With its large population, a nation like India necessitates effective drug monitoring systems and appropriate pharmaceutical use. The use of drugs is widespread throughout this large nation, making ADR monitoring difficult. The process is made more complex by the use of several drug types for various purposes in various age and ethnic groups. Nonetheless, there is a methodically organized ADR monitoring program in India. Urban residents are more informed than their rural counterparts, and awareness can constantly be raised through various awareness campaigns. The use of multiple medication types for different purposes by different age and ethnic groups complicates the procedure. In India, however, there is a well-structured ADR monitoring mechanism. Compared to their rural counterparts, urban dwellers are better informed, and knowledge may be continuously increased through a variety of awareness efforts. It is a challenging task that can only be completed by carefully observing the limitations, strategizing how to overcome them, and creating workable, reasonably priced, and significant solutions in the Indian context—where there is a significant patient inflow and a shortage of medical professionals. By first trying to change the mindset through education and awareness-raising, then gradually but significantly changing practice and the general attitude, a more effective system of pharmacovigilance can be established that is not only well-equipped to capture ADRs but also capable of making informed and evidence-based decisions for the safety of patients and the community at large.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

ADR: Adverse Drug Reaction; **AMCs:** Adverse Drug Monitoring Centers; **CDSCO:** Central Drugs Standard Control Organization; **WHO:** World Health Organization; **PvPI:** Pharmacovigilance Program of India; **IPC:** Indian Pharmacopoeia Commission; **NCC:** National Coordination Center; **AIMMS:** All India Institute of Medical Science; **ICSRs:** Individual Case Safety Reports; **UMC:** Uppsala Monitoring Centre;

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