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Review Article

ADR Monitoring and Reporting in India

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ABSTRACT

Adverse drug reaction monitoring are crucial parts of drug use. India's grandeur, surrounding diverse sociocultural, biotic regions and healthcare environment influence its own disease patterns and expose its population to potential Adverse Drug Reactions (ADRs). This demands a well-planned and culturally-responsive pharmacovigilance system. This study examines the current system for tracking Adverse Drug Reactions (ADRs) in India. The goal is to provide a clear and detailed picture of the ADR monitoring system highlighting its strengths and weaknesses along with its key features. It was observed that the Central Drugs Standard Control Organization (CDSCO) is regulating the safety, efficacy and quality of pharmaceutical products having more than two hundred Adverse Drug Monitoring Centres (AMCs) operational nationwide. Within the Pharmacovigilance Programme of India (PvPI), these centres report ADRs to National Coordination Centres (NCC) at the Indian Pharmacopoeia Commission (IPC) located in Ghaziabad. Reporting ADRs involves a standardized form available in various languages accessible to both health professionals and every citizen of India for reporting to NCC if they experience ADRs. While electronics software called Vigiflow owned by World Health Organization Uppsala Monitoring Centre (WHO UMC) plays a crucial role in reporting the ADRs to NCC by AMCs. India contributes to global ADR monitoring through its national program and WHO collaboration. As a vast country, India has a systematic and structured programme on ADR monitoring to tackle the ADRs. India also contributes to Global ADR monitoring by providing necessary data to WHO UMC.

Keywords: AMCs, CDSCO, PvPI, National Coordination Centres.

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INTRODUCTION

There is no doubt that medication have proven its value for human being, it works against illness and suffering which can be considered as blessing. As everything have their own pros and cons medications also have potential dangers correlated with their use, which are called Adverse Drug Reaction (ADRs).[1] ADRs are sturdy, mild and severe in most cases, have the capability to cause abnormality and even leads to death.[2] World Health Organization (WHO) stated that, Harmful, unintended responses to medicines that happens at pre-decided normal doses are called adverse drug reaction.[3]

India produces a large number of generic pharmaceutical products to the world, hence, it is known as "the pharmacy of the world". Just because of this reason, it should must have a well-designed healthcare system, where all the healthcare professionals should aware about possible risks and benefits of the drugs and informed about the necessity of monitoring and reporting of adverse drug reaction to conduct better quality drugs to make sure the safety of every patient.[4] In India, the functional committee for adverse drug reaction assessment, detection, understanding reporting, monitoring and preventing is "Pharmacovigilance". It deals with any problems associated with drugs.[5] Pharmacovigilance system is regularly conducting the post-marketing surveillance to achieve fully surveyed safety profile of medicines in globally. Any type of adverse drug reaction associated with medicines, which are known or known monitored by this system. For running the stable adverse drug reporting in India, Ministry of Health and Family Welfare, technology-based system made by Government of India and it is named as Pharmacovigilance Program of India (PvPI) in July 2010. Initially, it was controlled by All India Institute of Medical Science (AIIMS), New Delhi as the National Coordination Centre (NCC). Further, to conduct the adverse drug monitoring in a populated country like India, the Ministry of Health and Family Welfare, Government of India rebuilt the pharmacovigilance programme and transferred the system to National Coordination Centre at Indian Pharmacopoeia Commission (IPC), Ghaziabad on 15th April, 2011.[6,7]

In India, it is the prime responsibility of PvPI to play an important role and promote best possible usage of medicines to avoid adverse drug reactions. After requirement, PvPI is responsible for providing awareness to people regarding adverse drug reaction caused by active drug substances.[8] People are getting inspiration

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to come forward and report the adverse drug reaction. To report the adverse drug reaction, there is a specific form available in different languages for healthcare professional and as well as for every citizen of India for reporting to NCC if they faced adverse drug reaction.[9] Currently functioning all over in India, with Adverse Drug Monitoring Centres (AMCs), PvPI inspires perfect and accurate reporting of adverse drug reaction with the help of adverse drug reaction forms. The informed data through suspected adverse drug reaction reporting forms is built and used for filling Individual Case Safety Reports (ICSRs) online in the WHO data-base that is VigiFlow. The reported information, reached to 'PV Associates' working the direct supervision of the Coordinator/Deputy Coordinator at different adverse drug monitoring centres, a team of clinician should asses the reported reports. Then the software Vigiflow used to report the submitted ICSRs form by PV associates (AMC) to NCC. These ICSRs are then validated, reviewed for their truthfulness scored on the basis of information provided to NCC and gradually submitted to Uppsala Monitoring Centre (UMC), Sweden.[10]

Adverse Drug Reaction Monitoring in India

Reporting adverse drug reaction caused by a marketed drug is the prime responsibility of healthcare professionals with respect to public health and improving safety, not only healthcare professionals but also all the citizen of India should be aware to adverse drug reaction and its reporting.[11] PvPI influence to report any types of suspected adverse drug reaction associated with pharmaceutical products, does not matter it is familiar or unfamiliar, severe or mild and frequent or rare, if anyone facing adverse drug reaction then immediately, they should report. If there are any events occurred with respect to a particular drug, during the healthcare professional attending the patients, the healthcare professional can fill up the suspected adverse drug reaction form and report to AMC. At the same time, the patients also can report the adverse drug reaction by visiting the nearest AMC under PvPI. The details of AMCs are available in the official website of IPC. For healthcare professionals to report the ADRs, there is a form called "Suspected Adverse Drug Reaction Reporting Form" available which is given in 'link 1' and for patients, family members of patients and relative / any citizen of India can fill the "Medicines side effect reporting form" by clicking on the 'link 2'. The html is also available for consumers to send to nearest AMCs or directly to NCC. There is an official mail id also available for reporting of any kind of adverse drug reaction. To make reporting easy a toll-free helpline number also can connect to AMCs to report adverse drug reaction. For reporting digitally, there is an application for mobile which is available in google play store (Figure 1).[12,13]

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

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

Link 2: https://www.mkcgmch.org/admin/MenuDocument/DownloadForms_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".

Committees Responsible for Adverse Drug Monitoring

In India, different committees have been set up to watch over side effects of medicines and ensure pharmacovigilance runs smoothly within each committee. These groups are important for overseeing and controlling the potential issues with drugs, playing a significant role in making sure pharmacovigilance efforts work well.[14] These committees cover a range of entities, starting from the Adverse Drug Reaction Monitoring Centres (AMCs) and including the Uppsala Monitoring Centre (UMC), ensuring a thorough and organized approach to overseeing drug safety.[15]

Adverse Drug Monitoring Centres (AMCs)

The AMCs are set up under NCC to collect the ADRs from patients. The intention is to find out the adverse drug reaction which is not found in earlier clinical trial programmes. For functioning the adverse drug reaction NCC provides manpower and logistic support to AMCs. Now, a large number of AMCs are operational all over the country interlinking with CDSCO in India. AMCs requirements are fulfilling by CDSCO for the purpose of reporting adverse drug reaction which are technical supports and administration.[16] With time the numbers of AMCs are increasing to dealing with the importance in monitoring and reporting of adverse drug reaction. There is software available by WHO UMC, where AMCs actively utilizing to report adverse drug reaction and Individual Case Safety Reports. This software allow to enter the data manually and supported by the latest version of the software with respect to WHO Drug Dictionary and WHO-Adverse reaction Terminologies.[17] As AMC operates as a committee, it comprises personnel who work within PvPI. First one is Coordinator (Department of pharmacology), the coordinator which is from department of pharmacology oversees the overall functioning of AMC. The work of coordinator is to dealing with collecting, ensuring the completeness of registered cases, performing causality assessments and examined ADR reports to maintain the Standard Operating Procedures (SOPs). If the coordinator will be absent, then the deputy-coordinator will take the charge to operate the AMC. Second important personnel in AMC are Technical Associate. The main role of technical associates is to collect the ADR reports. The technical associates submit the examined and signed ADR report to the software VigiFlow. All the reports signed and examined by AMC authority undergo central assessment at the NCC. The monthly reporting is being carried out by the coordinators from AMC to

the NCC. These personnels have some necessary responsibilities which enhance the working and influence suitability of AMC. Such as, Sensitization Activities and Feedback Mechanism. The coordinators also responsible for dealing with the awareness activities with physician, students, healthcare professionals and patients to inspire them to report the adverse drug reaction immediately. The encouragement and awareness may include lectures, emails, phone calls or posters and the feedback should be considered as the message that the AMC Coordinators provide to healthcare professionals involved in reporting. It will helps to overcome the communication loop respectively.[18]

National Coordination Centre (NCC) for PvPI

In the National Pharmacovigilance Programme of India, the NCC plays an important rule to collecting, analysing and disseminating information on ADRs reported all over the country. It has some vital function to run smoothly such as data Collection, data processing and analysis. Where AMCs are submitted the data electronically from all over the India to NCC. The reports contain details of patient information, specific drug details and suspected ADRs and verify the data, proceed forward is belongs to NCC staffs. They should analyse the data with respect to identify trends, safety signals and the data should require further investigation. The NCC is also responsible for sharing the crucial information to stakeholders, which are regulatory authorities to discuss regulatory final decision regarding drug safety. The healthcare professional should spread awareness about potential adverse drug reactions. Publication should be priorities of reports on ADR trend in India. The NCC located within Indian Pharmacopoeia Commission in Ghaziabad, Uttar Pradesh. Personal working in NCC are well qualified professionals with expertise in pharmacovigilance, medicines and data analysis.[19]

The Indian Pharmacopoeia Commission (IPC)

Indian Pharmacopoeia Commission which is known as IPC is playing an important role in dealing with medication in India. It is the central hub for PvPI with respect to safeguarding the drug's use nationwide.[20] In July 2010, Ministry of Welfare, Indian Government introduced a strong techno-science based system called Pharmacovigilance programme of India.[6] Which is considered responsible for reporting reliable system to report various problems associated with medication in India. In the starting it was under All-India of Medical Sciences (AIIMS) in New Delhi, acting as the central hub or National Coordination Centre. For improving certain criteria to protects the health of people in India which will improve the Pharmacovigilance Programme, Ministry of Health and Family Welfare made some changes.[21] The programme was rebuilt and moved the National Centre to the Indian Pharmacopoeia Commission (IPC) which is located in Ghaziabad. It was done on the date of 15th April 2012.[6] IPC is mainly deal with collection of all the reports regarding a drug's side effects and unexpected effect from hospitals and clinic all over the India. The reports contain details about patients, drug and adverse drug reaction. The reviewing of submitted report carried out by IPC for completeness and accuracy. Then they should analyse the data and identify the pattern according to specific medication reports.[19] The sharing of information to stakeholder also done by IPC. Which is including the government's health agency CDSCO; this helps them to taking decision regarding new rules and regulation in India. Doctors and other healthcare professionals should be aware of potential side effects and advice patients accordingly. Researchers can be able used this information for further studies to improve drugs safety in future.[19,22] IPC located in Ghaziabad, Uttar Pradesh, a group of well qualified professionals with expertise in pharmacovigilance and other necessary fields like medicine and data analysis are continuously working to ensure the effectiveness of the PvPI by collecting, analysing and examining information of adverse drug reaction to ensure the drug safety.[23] If the immediate and timely reporting of adverse drug reaction takes place from the hospitals and clinics then it will be the reason of making a success system of pharmacovigilance with respect to IPC. By the collaboration with international organizations influence exchange of data to strengthening the drug safety monitoring globally.[19,24]

CDSCO in adverse drug reaction monitoring

The approval of various medical equipment, drugs and cosmetics in India is carried out by CDSCO. For monitoring of adverse drug reactions in pharmaceutical industries the responsible working body is CDSCO. The collection of data regarding to safety and efficacy of drugs and evaluation carried out based on reported ADRs.[25] For the pharmaceutical company it is mandatory to report adverse drug reaction to CDSCO, further the information provides to healthcare professionals. By the sharing of information helps to developing the strategies to minimize the risk related to adverse drug reaction and will enhance the safety. CDSCO's main aim is to strengthen PvPI, which is lead to protect public health. NCC at the IPC conducts the pharmacovigilance activities under PvPI, which is helpful for new drug-related safety issues and safety monitoring of marketed drugs.[26] The role in pharmacovigilance or in monitoring the adverse drug reactions cannot be ignored, as it confirms that drugs are safe for patients to use, protect public health and improves patient health in a good manner. However, the reporting to CDSCO by pharmaceutical companies is essential to improve pharmacovigilance programme.[27]

Medical Council of India (MCI) in pharmacovigilance

MCI is collaborated with PvPI. This partnership influences awareness about PvPI among the stakeholders. Recent data are influenced the improvement of relation between these two government bodies. Hence, it is improving the adverse drug reaction reporting and monitoring in India. The impact of the collaboration is visible by the results of educational initiatives and workshops. This helps to aware healthcare professionals to play

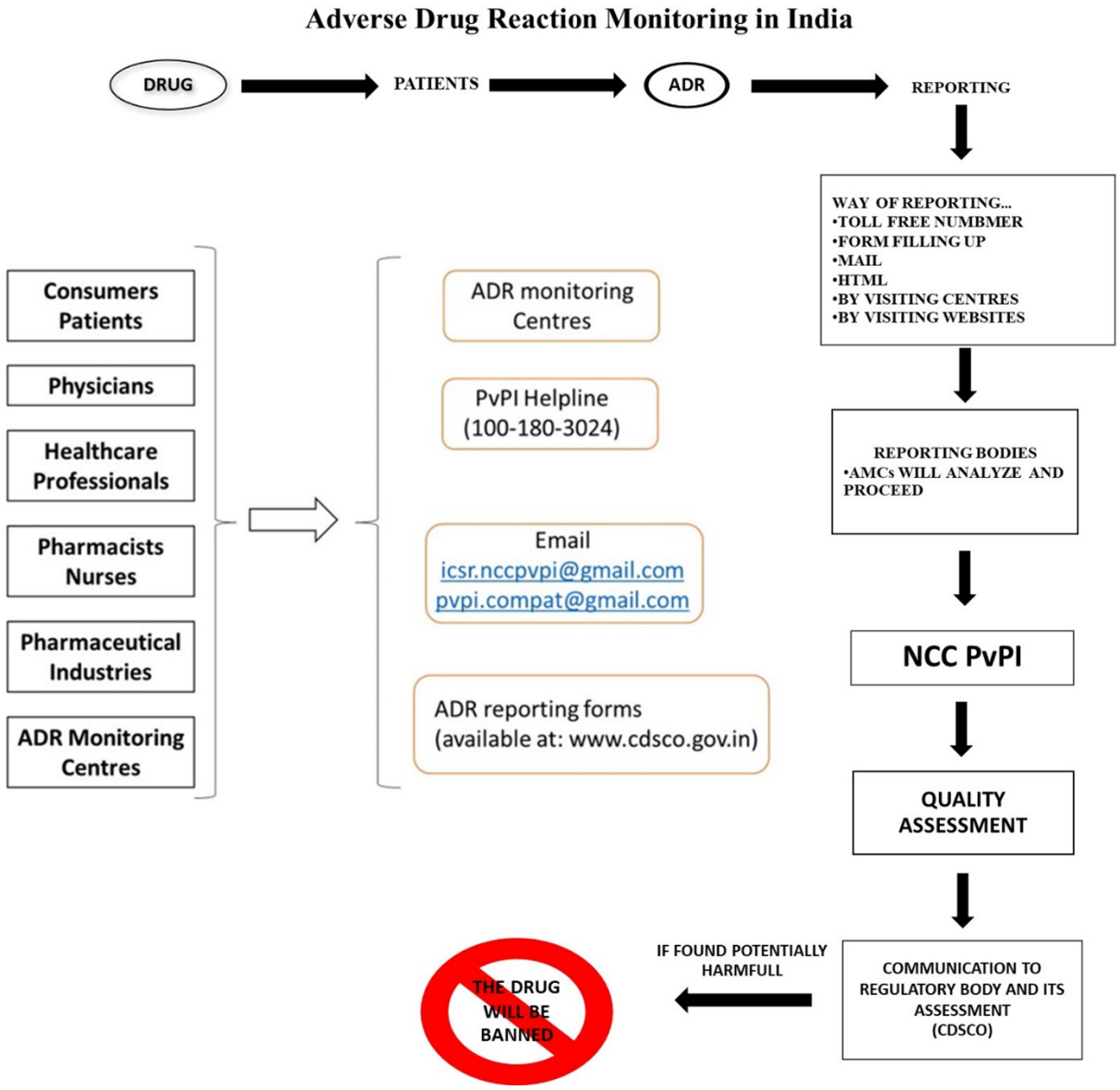

Figure 1: Overview of ADR Monitoring in India.[34]

a critical role of adverse drug monitoring in patient safety. This collaboration helps to focused and targeted approach to involving the medicinal and medical communities together. The impact of the collaboration is highly understanding and participating, resulting more proactive moves to improve adverse drug monitoring and reporting system ultimately leads to advance Cing patient safety in the country.[28,29]

World Health Organization Uppsala Monitoring Centre (WHO UMC)

The WHO which is responsible for International Drug Monitoring and its headquarters at Uppsala Monitoring Centre located in Sweden, plays an important role in adverse drug reaction monitoring in India. It is a global hub for collection and analysation of adverse drug reaction reported data from various countries. It provides tools and many resourced to India for establishing and maintaining the pharmacovigilance programme which is directly dealing with adverse drug reaction. It promotes the reporting and monitoring of adverse drug reaction in different country across the globe.[30] The PvPI is structure by inspiring from WHO UMC guidelines and recommendations as other countries. The processes and methods used by PvPI is aligned with WHO UMC system. The data collected by PvPI is submitted to WHO UMC. This is allowing the WHO UMC to collect the data from all

over the country and globe which provide a clear, confirmed and accurate data collection.[31,32]

ADR Reporting Approaches

What to report?

These are considered as the adverse drug events which should be reported to the nearer hospital or reporting centres.[33]

Death and deadly events.

If patients get hospitalized due to drug's adverse reaction.

Fetal abnormality due to certain drug.

If physician consider any particular health event as a harmful event.

If the drugs lacking efficacy.

Any drug action which is suspected.

When to report?

Any spontaneous events needed to be reported within 10 days.

Any adverse drug event which is suspected needs to be reported as soon as possible.

Unfortunate death due to adverse reaction should be reported immediately.

Other adverse drug reactions should be reported within one week.

Any adverse drug reactions which are non-serious should be reported within 30 days.

Reporting delay leads to create more problems. So, as far as possible immediate reporting considered as ideal decision.[34]

Who can report?

Health care professionals are priorities for reporting adverse drug reaction monitoring. Such as

Health professionals, physician.

Pharmacist.

Dentist.

The citizen of India also can report adverse drug reaction if it happens due to some specific drug and medical devices.[35]

How to report?

There is a form called "Suspected Adverse Drug Reaction Reporting Form" available for healthcare professionals. (Given in "adverse drug reaction monitoring in India)

The for which is available for consumers is "Medicines Side Effect Reporting Form" (given in "adverse drug reaction monitoring in India").[33]

Industrial Aspect of Pharmacovigilance

Pharmaceutical industries are the middle body between government and customer. Their responsibilities should must to fulfil the demand as well safety, efficacy and quality of the product. Conduct the proper clinical and pre-clinical research to identify possible ADRs related the drug products. All the phases of the clinical trials should be done with respect to the guidelines. After releasing the drug to market proper investigation should be conducted. If any ADRs reported by patients or health professional then organized survey should be implement on the basis of that specific drug. The pharmaceutical industries should follow the government guideline and should report information regarding ADRs to PvPI. All the parameters should be fulfilled by industries for smooth running of pharmacovigilance.[36-39]

Future of Pharmacovigilance in India

Pharmacovigilance system is going to be a strong and well-structured programme all over India in next five years. The latest ongoing study provides the data of PvPI states that, pharmacovigilance system is going to be an advanced and technically organized system. There are some major factors which are responsible for promoting pharmacovigilance systems are data analytics for signal detection, strengthening pharmacovigilance training and digital reporting platform with AI integration. The advanced technology is going to implemented in all branches of PvPI. Reporting system should be updated and should be assessable by common man or professionals. Monitoring system will be advanced and the reported data is going to predict the future severe cases of ADRs.[40-43]

DISCUSSION

Sanvidhan G Suke *et al.*, briefly discussed about the pharmacovigilance role to deal with adverse drug reaction. This research work's aim is to shift India's pharmacovigilance system from traditional monitoring to digital monitoring. Where the adverse drug reaction can be reported easily and the Pharmacovigilance will get the information accurately as soon as possible. It includes electronic medical record, different literatures such as biochemical and pharmacological literatures, patients reported data and health professional's reporting regarding adverse drug events.[36]

Nambari Hemanth Kumar *et al.* reviewed-on ADR reporting and monitoring, classification of ADRs, contrast between Adverse Effects and Adverse Reactions, Methods of monitoring adverse drug reactions in India. The main focus is on the systematic reporting and monitoring of adverse drug reaction in India. This research work intended to find out solution for problems like lack of awareness about drug use such as overdoses, poly pharmacy, drug-drug interaction, drug-food interaction with respect to all type of medicinal system.[44]

Sivanandy Palanisamy *et al.* correlated the frequency and types of ADRs, investigating any existing medical conditions and illnesses, analysing the causal relationships between these reactions and specific drugs and identifying the responsible medications. Additionally, the study aimed to monitor and document suspected ADRs, keeping records of the associated details. Finally, the research sought to estimate the financial costs associated with these adverse reactions. In essence, the study aimed to comprehensively understand and document the incidence, nature and economic implications of adverse reactions to drugs, providing valuable insights into patient safety and healthcare management.[45]

Ratan J *et al.* discussed the underreporting adverse drug reaction. The factors for underreporting adverse reaction focused in this research work are lack of time, incentive less extra work load and irresponsibility's. The solution for underreporting mentioned there are consistent medical educations, proper training and health professionals' ability improvement. These factors should be looked by authority to improve underreporting adverse drug reaction. The advertisement should be priorities by PvPI for awareness purpose. All these things are thoroughly discussed by the authors.[46]

Hemendra Singh *et al.* discussed enhancement of pharmacovigilance services, specifically adverse drug reaction monitoring and reporting at Maharishi Markandeshwar Deemed to be University (MMDU) hospital and other medical institution all over the India. The intention is clear to improve the quality and quantity of ADR reporting ultimately contribute to pharmacovigilance programme development.[47]

Tejas K. Patel *et al*. discussed ADR monitoring and reporting in context to India and western countries. The observed incidence of ADR among hospitalized patients is noted to be comparatively lower than in Western countries. Various factors like type of hospital words, different age groups, procedure followed to report adverse drug reaction, duration of study and building of a well-qualified team involved in adverse reaction monitoring have been identified as potential influencing factors on the occurrence of adverse drug reactions. This study deals with diverse contributing factors and the call for careful interpretation highlights the complexity and nuanced nature of ADR research and its implications for public health.[48]

Vikas Dhikav *et al.* discussed about the well-planned pharmacovigilance system in India. The authors observed that in future ADR monitoring system is going to be more accurate and will be easier. The improvement of pharmacovigilance system is occurring so rapidly and reaching every part of the country. This research work also dealing with the different types of adverse drug reaction and reporting procedure.[49]

Amrita P *et al*. reported that despite of doctor's solid knowledge about ADR monitoring and reporting the number of adverse drug reporting is low in AMC Delhi. The main reason of this low reporting's are lack of awareness and intention. For this problems, the physician and other health professional should be aware because it may leads to life threatening condition and serious outbreak of any particular drug products.[50]

CONCLUSION

The review discusses different aspects of ADRs, their reporting and monitoring. It examines the reporting of the ADR by a common man to health professionals and by health professionals to higher authorities. Pharmacovigilance, the working programme with respect to ADRs and their function described to understand the established system in India. All the government programs, committees and systems and systems are discussed for better understanding of ADR monitoring and reporting. A country like India has vast population that demands proper medication use and appropriate drug monitoring system. Drugs can be used in the lengths and breadths of this vast country and ADR monitoring is thus a challenge. Use of different varieties of drugs for different indications in different ethnic groups and age groups add in the complexities of the process. However, in India there is a systematically structured programme on ADR monitoring. The awareness in urban citizens is better than the rural citizens and can always be improved though different awareness programs.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

ADRs: Adverse Drug Reactions; **AIIMS:** All India Institute of Medical Science; **AMCs:** Adverse Drug Monitoring Centres; **CDSCO:** Central Drugs Standard Control Organization; **ICSRs:** Individual Case Safety reports; **IPC:** Indian Pharmacopoeia Commission; **MCI:** Medical Council of India; **MMDU:** Maharishi Markandeshwar Deemed to be University; **NCC:** National Coordination Centre; **PCI:** Pharmacy Council of India; **PvPI:** Pharmacovigilance Program of India; **SOPs:** Standard Operating Procedures; **UMC:** Uppsala Monitoring Centre; **WHO:** World Health Organization; **WHO UMC:** World Health Organization Uppsala Monitoring Centre.

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