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Lucky Yadav
Senior Resident, Department of Dental and Maxillofacial Surgery, Lady Hardinge Medical College and Associated Hospitals, New Delhi, India

Pankaj Pareek
Senior Lecturer, Department of Orthodontics and Dentofacial Orthopaedics, Rajasthan Dental College and Hospital, Jaipur, Rajasthan, India

Ashish Kumar
Senior Lecturer, Department of Orthodontics and Dentofacial Orthopaedics, Rajasthan Dental College and Hospital, Jaipur, Rajasthan, India

Akanksha Jaswal
Senior Lecturer, Department of Orthodontics and Dentofacial Orthopaedics, Mhatma Gandhi Dental College and Hospital, Jaipur, Rajasthan, India

Renuka Bamal
Senior Lecturer, Department of Orthodontics and Dentofacial Orthopaedics, NIMS Dental College and Hospital, Jaipur, Rajasthan, India

Corresponding Author:
Lucky Yadav
Senior Resident, Department of Dental and Maxillofacial Surgery, Lady Hardinge Medical College and Associated Hospitals, New Delhi, India

Pharmacovigilance and materiovigilance in India: A review

Lucky Yadav, Pankaj Pareek, Ashish Kumar, Akanksha Jaswal and Renuka Bamal

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Abstract
Pharmacovigilance defined by the world health organization as "the science and activities relating to the detection, assessment, understanding, assessment and prevention of adverse effects or any other drug related problems". It plays a key role in ensuring that patients receive safe drugs. Our knowledge of a drug's adverse reactions can be increased by various means, including spontaneous reporting, intensive monitoring and database studies. New processes both at a regulatory and scientific level are being developed with the aim of strengthening pharmacovigilance and materiopvigilance. On a regulatory level, transparency and increased patient involvement are two important elements [1]. similarly Materiovigilance is the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices and protection of patient's health by preventing its recurrences. Postmarketing surveillance of medical devices has been initiated in many countries, but it is still not as developed and robust as that of medicines. Materiovigilance program of India was launched on July 6, 2015, at Indian Pharmacopeia Commission with objectives to track the adverse events associated with the use of medical devices, to generate safety data, create awareness among the different stakeholders, and recommend the best practices and interventions to improve the patient's safety.

Keywords: Pharmacovigilance, materiovigilance, ADRs

Introduction
Pharmacovigilance is the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problems. These adverse drugs reactions (ADRs) not only add to suffering of patients but also increase morbidity and mortality along with a financial burden on society. The overall incidence of ADRs in hospitalized patients is estimated to be 6.7% (range 1.2-24.1%) and that of fatal ADRs 0.32% (0.1-0.85%) [2]. Data indicates that in patients who experience ADRs, death rates are 19.18% higher and the length of hospital stay is 8.25% higher. Total medical cost for patients with ADRs are increased by an average of 19.86% [3]. However the lack of ability of clinicians to suspect or detect such adverse events related to drugs might lead to inappropriate management of adverse events, thus exposing the patients to additional drug hazards. To minimize the suffering of the patients from ADRs, though difficult, it is essential to establish casual relationship between the drug and the event which is the causality. By definition, Causality assessment is the evaluation of the likelihood that a particular treatment is the cause of an observed Adverse Event [4]. It assesses the relationship between a drug treatment and the occurrence of an adverse even. It is an important component of pharmacovigilance, contributing to better evaluation of the risk-benefit profiles of medicines [5] and is an essential part of evaluating ADR reports in early warning systems and for regulatory purposes [6].
Materiovigilance is the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices and protection of patient's health by preventing its recurrences. Postmarketing surveillance of medical devices has been initiated in many countries, but it is still not as developed and robust as that of medicines. Materiovigilance program of India was launched on July 6, 2015, at Indian Pharmacopeia Commission with objectives to track the adverse events associated with the use of medical devices, to generate safety data, create awareness among the different stakeholders, and recommend the best practices and interventions to improve the patient's safety [7].

National Pharmacovigilance Program (NPP)

The National Pharmacovigilance Program was officially inaugurated by then honorable Health Minister Dr. Anbumani Ramadoss on 23 November, 2004 at New Delhi. Central Drugs Standard Control Organization (CDSCO) initiated a well structured and highly participative National Pharmacovigilance Program which is build on the structure recommended by WHO in a document titled as "Safety Monitoring of Medicinal Products – Guidelines for Setting up and Running a Pharmacovigilance Centre". The Main focus of National Pharmacovigilance Program was to collate, analyze and archive adverse drug reaction data for creating healthy environment for the Regulatory Authorities to analyse the drugs to be marketed in India.

National Pharmacovigilance Program is a three layered structure consisting of peripheral, regional and zonal centres. These are monitored by an apex body i.e. National Pharmacovigilance Advisory Committee and the National Pharmacovigilance Centre which are based at the Central Drugs Standard Control Organization, New Delhi. The 3 tier structure report the serious, unexpected Adverse Drug Reactions to the National Pharmacovigilance Centre directly so as the regulators to act on it promptly.

Aims of pharmacovigilance [8]

1. To Increase public protection from the new drugs
2. To contribute to assessment of benefit efficiency and risk of medicines.
3. Endorse healthy communication to the community.
4. To promote rational and safe use of medicines.
5. Efficacy of drug and their monitoring about adverse effects of drugs.
6. Pharmacovigilance keeps way of any drastic effects of medicines. Improve public health and safeties in relation to the use of promote understanding, education and clinical training in pharmacovigilance.

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Goals of pharmacovigilance programe

Short term goals

1. To develop and implement pharmacovigilance system in India
2. To encourage the health professionals in reporting of adverse drugs, vaccines, medical devices, and biological products
3. Collection of case reports and data.
4. All MCI approved medical colleges conducted the programs.

Long term goals

1. To expand the pharmacovigilance programme to all hospitals and centers public health programs located in India
2. To make ADR reporting mandatory for healthcare professionals.
3. To develop and electronic reporting system.

Adverse drug reaction

At a normal dose sometimes the given medications may harm the patients which are called Adverse Drug Reactions (ADR) [9]. Adverse drug reaction is different from side effect. The evaluation of ADRs is most critical in the field of pharmacovigilance.

Concerning marketed remedies, a suitable definition of an adverse drug reaction is as follows

1. Unlisted/Unexpected Adverse Drug Reaction An adverse reaction is the nature or harshness of drug which is not reliable with the proper product data available at the time of clinical trials [9]. Company is needed help during investigators brochure for an unapproved drug. Brief summary of drug data sheet for an official product.
2. Listed / Expected Adverse Drug Reaction The information about ADR like nature or severity and specificity of the drug is already recorded [10].

Advice about reporting [8]

Report adverse experiences with medications:

1. Report serious adverse reaction : Reaction is serious when patient outcome is – Death, life threatening, hospitalization, required intervention to prevent permanent impairment or damage
2. Who can report: Any health care professional (doctors including dentists, nurses, and pharmacists) Where to report: please return the completed form to the nearest Adverse Drug Reaction Monitoring Center or to National Coordinating center.
3. What happens to the submitted information: information provided in this form is handled in strict confidence. The causality assessment is carried out at ADR monitoring centers by using WHO –UMC scale. The analyses form forwarded to national centers through ADR database.
4. The report are periodically review by national coordinating centers. The information generated on the basis of this report helps in continuous assessment of the benefit risk ratio of medicines.

Major challenges in pharmacivigilance

Pharmacovigilance facing the challenges in healthcare delivery because of not getting priority. Biasness of drug in healthcare delivery system is also a big issue [12]. Poor staffing, poor funding and mostly political pressures creating barrier in implementing of pharmacovigilance programme. Other challenges are associated with health professionals are few in number but many prescriber. Lack of continuing medical education and difficulties in availability of drug information is another big issue. Some drug use problems contributing to the barriers in pharmacovigilance programme of India are availability of many types of drugs in households and dispensing the drugs by untrained persons [13]. Some other drug use problems are wide spread use of injections, high levels of antibiotic use, inadequate treatment guidelines, poor prescribing. Diseases like tuberculosis, HIV/AIDS, malnutrition requires multiple drug therapy and adverse event occurs due to drug interactions and can lead to severe health hazard. Due to the above reasons risk of adverse drug events are very high. So following challenges can be avoided by implementing proper rule and regulation of pharmacovigilance programme strictly everywhere. Improvement of communication regarding pharmacovigilance between public and health professionals creates awareness and adverse occurring can be minimized. Proper knowledge on pharmacovigilance would help to health professionals to understand the effectiveness or risk of medicines that they prescribe and ensure a better healthcare to patient [14].

Conclusion
India is the fourth largest producer of pharmaceuticals and now emerging as an important clinical trial hub in the world. with introduction of new drugs, a energetic pharmacovigilance system is need of the hour in our country to protect the population from the potential harm and adverse effect due to some of the new drug molecules. Pharmacovigilance plays a major role in meeting the challenges posed by the ever increasing range and potency of medicines. But the pharmacovigilance system in India is still not well developed. Disfavor of recent implementation of a well-structured pharmacovigilance program in India in accordance with the objectives and recommendations of WHO by CDSCO, desired success is still a distant dream. However increased awareness and training of public and medical professions, framing of strong regulations for reporting of ADRs, effective implementation and collaborative efforts between government, regulatory officials, pharmaceutical companies, health care professionals and patient may lead to an effective pharmacovigilance system in India to insure the availability of safe medicines to public.

Materiovigilance
Medical devices are defined as any instrument, apparatus or materials used for diagnosis, treatment or cure of any undesirable ailments which cause health issues to the people. These medical devices during their use can cause certain undesirable adverse events that need to be monitored and solved. In India, a programme has been initiated which is known as the “Materiovigilance Programme of India" to monitor the adverse events that occur from the use of the medical device and to take necessary actions to solve the adverse actions occurred from the use of medical devices. So, therefore a vigilance system is necessary to monitor the adverse events. The word materiovigilance is derived from two words “materio"-which means materials and "vigilance"-monitoring for a secured and safe life. The adverse actions that occurred from the use of the medical devices need to be identified, monitored, reported and recorded by an authorized and qualified person or team. In India, Materiovigilance Programme of India was started as a vigilance system to monitor and take necessary actions to prevent the occurrence of adverse actions arisen from the use of medical devices to safeguard the people's health [15].

Materiovigilance Programme of India
The commencement of Materiovigilance Programme of India with the Indian Pharmacopoeia Commission has been approved by the Ministry of Health and Family Welfare, Government of India on 10th February 2015. This programme was launched by Drugs Controller General in India on 6th July, 2015 at Indian Pharmacopoeia Commission. The Indian Pharmacopoeia Commission functions as the National Coordination Centre. The Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram functions as the National Collaborating Centre. The National Health System Resource Centre, New Delhi, functions as the Technical Support Partners and The Central Drugs Standard Control Organisation of India functions as the National regulator. This programme has ten Medical Device Adverse Events Monitoring Centers all over the country. To ensure effective of Adverse Events reporting from all respective individuals centres, the programme had introduced various tools for Adverse Event reporting to develop India specific data [16].

Mission
To ensure the advantages of use of the medical devices is more profitable than the risks associated with its use in order to safeguard the health of the people [17].

Vision
To monitor the adverse events and reduce the risk associated with the purpose of medical devices in order to improve the safety and welfare of the patients [17].

Aim
- Systematically and scientifically analyze the data collected from the adverse actions related with the use of the medical devices.
- To monitor medical devices benefit risk profile.
- Create awareness about the importance of medical device adverse event reporting in India among health professionals [18].

Documenting and reporting adverse events
All types of adverse events related to medical devices used in India irrespective of whether they are known or unknown, serious or non-serious, frequent or rare can be reported. Along with that any malfunction or deterioration in characteristics or performance of medical device or inaccuracy in labeling or instructions for use can be reported. A reporting format, two pages medical device adverse event reporting form has been prepared by MvPI which contain all information in detail regarding the patient, adverse event, device, regulator, and reporter. This form is freely available on the official website of IPC (www.ipc.gov.in). The duly signed form can be sent to the nearest medical device monitoring center (MDMC) or can be directly sent to the National Collaborating Center (NCC). It can also be scanned and mailed @sctismt.ac.in and copy to moc.liamg@aidnicpi.ipvm. The reporter can also call the helpline number created by NCC-PvPI (1800-180-3024) and report the adverse event. Documenting and reporting adverse events due to the device and seamless flow of information involves various aspects and interrelationship among different stakeholders.
- Role of health-care service providers
- Role of manufactures
- Role of research associate and coordinator at MDMC
- The responsibility of National Collaborating Centre
- The responsibility of National Coordinating Centre (NCC)
- The responsibility of technical support and research center (TSRC)
- The responsibility of CDSCO.

Conclusion
There is an upsurge in the use of medical devices in recent years. Despite that, there are not adequate measures to protect the patients from the untoward occurrences associated with the use of medical devices. Materiovigilance program is meant to analyze, scrutinize, and prevent the recurrence of harmful effects occurs due to use of medical devices. MvPI is a good initiative to ensure the safety of medical devices among the device users in India. The

guidance document of MvPI has laid down the policy guidelines, procedures, and enunciated the role and responsibilities of different stakeholders to enable safety data collection in a systematic manner. It is expected that effective implementation of this program will safeguard the safety of device users substantially by preventing the recurrence of adverse effects and reducing the risk associated with the use of medical devices.

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