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Review Article

Pharmacovigilance Programme of India: A Review

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Abstract

In India, a proper adverse drug reaction monitoring system was started in 1986 with 12 regional centres. In 1997, India became the member of World health organization Programme for International Drug watching managed by the Upsala Monitoring Centre, Sweden. At origination, 6 regional centres were created in Mumbai, New Delhi, Kolkata, Lucknow, Pondicherry, and Chandigarh for ADR watching within the country. Promoting safe use of drugs may be a priority of Indian Pharmacopoeia Commission that functions as the National Coordination Centre for Pharmacovigilance Programme of India. Today, 179 adverse drug reactions monitoring centres presently report adverse events to National coordinative centre in India.

Keywords: Vigiflow; UMC; Death;Thalidomide; Reporting Form; Phocomelia

Abbreviations

WHO: World Health Organization; CDSCO: Central Drugs Standard Control Organization; Pvpi: Pharmacovigilance Programme Of India; NCC: National Coordinating Centre; AIIMS: All India Institute Of Medical Sciences; IPC: Indian Pharmacopoeia Commission; PV: Pharmacovigilance; ADR: Adverse Drug Reaction; AMC: ADR Monitoring Centre; UMC: Uppsala Monitoring Centre

Introduction

According to World Health Organisation (WHO), Pharmacovigilance (PV) as the pharmacological science and activities relating to the monitoring, detection, assessment, understanding, and prevention of adverse drug reactions (ADRs), or any long-term and short-term medicine-related problems (Figure 1 and 2).

Figure 1: Diagrammatic representation of the Pharmacovigilance.

Figure 2: Pharmacovigilance framework.

Variety of ADRs associated with medication prompted the event of the science of PV [1-4]. This prompted WHO for systematic study of ADR of medicine, that is that the starting of PV. Thenceforth variety of ADRs were detected, a number of that square measure shows in (Table 1). ADR is taken into account to be the 6th leading reason behind death. India, with a current population of 1.27 billion, is that the 4th largest producers of prescription drugs within the world with quite 6000 licenced makers and over 60000 branded formulations within the market. In the United States of America, ADRs contribute 3-7% of hospital admissions. In England, 1% chronicles of the entire hospital admissions were due to ADRs throughout the year 1999-2008. ADRs square measure common in Australian healthcare system additionally and that they contribute to a 1% of hospital admissions [5,6]. The percentage of hospital admissions due to ADRs in bound countries is 100% or additional. Drug at-

tributed deaths square measure calculable to be 0.19% altogether medical inpatients. About 0.40% of ADRs known were directly joined to high costs. ADRs not solely increase the mortality and morbidity however additionally multiply the health care value [7]. The PV effort within the India is coordinated by the Indian Pharmacopoeia Commission (IPC) and conducted by the Central Drugs Standard Control Organization (CDSCO). The most responsibility of the IPC is to keep up and develop the PV database consisting of all suspected serious ADR to medicines observed. IPC is functioning as a National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI). NCC is working underneath the direction of committee that recommends procedures and guidelines for regulatory interventions [8]. The main responsibility of NCC is to watch all the ADR of medicines being observed within the Indian population and to develop and maintain its own PV information. The aim of the commission that acts just like the NCC for PvPI is for safety of the patient, safety of the population with relevancy use of the drug. The Commission has become absolutely operational from 1st January 2009 as associate autonomous body, absolutely supported by the central government with specific fund allocations under administrative control of the Ministry of Health and Family Welfare [9]. The Secretary, Ministry of Health and Family Welfare, is that the Chairperson and therefore the Chairman-Scientific Body is that the Co-Chairman of the Commission. The Secretary-cum Scientific Director is that the Chief Scientific and Executive officer of the Commission. The CDSCO, Directorate General of Health Services underneath the aegis of Ministry of Health and Family Welfare, Government of India unitedly with IPC, Ghaziabad is initiating a nation-wide PV programme for shielding the health of the patients by reassuring drug safety. The programme shall be coordinated by the IPC, as an NCC. The centre can operate underneath the superintendence of a steering committee. The PvPI was initiated by the govt of India on 14th July 2010 with the All India Institute of Medical Sciences (AIIMS), New Delhi as the NCC for monitoring ADRs in the country for safe-guarding public health. Within the year 2010, 22 ADR monitoring centres as well as AIIMS, was came upon underneath this programme [10-13]. To confirm implementation of this programme in an exceedingly simpler method, the NCC was shifted from the AIIMS to the IPC, Ghaziabad, Uttar Pradesh on 15th April 2011 (Figure 3).

Figure 3: Pharmacovigilance Programme of India.

S. No.	Drug	Year	Serious and unexpected adverse event
1	Chloroform (Anaesthetic)	1848	Episode of ventricular fibrillation and death
2	Sulphanilamide (Elixir)	1937	Death
3	Thalidomide	1961	Amelia, phocomelia and dysmelia
4	Clioquinol	1970	Subacute nephropathy
5	Practolol	1975	Sclerosing peritonitis
6	Benoxaprofen	1982	Nephrotoxicity and cholestatic jaundice
7	Terfenadine	1997	Torsade de pointes
8	Rofecoxib	2004	Cardiovascular effects
9	Veralipride	2007	Anxiety, depression and movement disorders

Table 1: 9 examples of serious and unexpected ADR cause to drugs [14].

History of Pharmacovigilance Programme in India

The concept of PV is not new, because the time of Charak Samhita in 700 BC had cautioned that properly understood however improperly administered drug is sort of a poison and Vagbhatta- a physician represented adverse events, reason, delayed ADRs to Ayurvedic Drugs' around 500 AD. Thereafter, many reports of ADRs from India area unit found within the history of modern medicine but there was no systematic effort of ADR monitoring since the primary try was created in 1989 [15,16].

Scope of Pharmacovigilance Programme of India

Before registration and selling of drugs within the country, its safety and efficaciousness expertise area unit primarily based totally on the employment of the drugs in clinical trials. These trials in the main notice common ADR. Some vital reactions, like those, that take a protracted time to develop, or those, that occur seldom, might not be detected in clinical trials. Additionally, the controlled conditions beneath that medicines area unit utilized in clinical trials don't essentially replicate the method they will be utilized in observe. For a drug to be thought-about safe, its expected advantages ought to be more than any associated risks of harmful reactions. So, so as to achieve a comprehensive safety profile of drugs, a continuous post-marketing monitoring system i.e. PV is crucial. So as to monitor the security of drugs, information from several sources is employed for PV [17]. These embrace spontaneous ADRs coverage mechanism; medical literature published worldwide; action taken by regulative authorities in alternative countries. Since there exist substantial social and economic consequences of ADRs and therefore the positive benefit/cost magnitude relation of implementing applicable risk management -there may be a have to be compelled to interact health care professionals and therefore the public at massive, during a well-structured programme to make synergies for watching ADRs within the country. The aim of the PvPI is to collate data, method and analyse it and use the inferences to advocate regulative interventions, besides human action risks to health care professionals and therefore the public [18].

Management of Pharmacovigilance Programme of India

This is headed by the Secretary cum scientific Director: Dr. Gyanendra Nath Singh, who is working with the help of Advisor and National Scientific Coordinator supported by the several committees like- Steering Committee, Working Group, Quality Review Panel, Core Training Panel etc. involving experts from all over the country. Current Status of NCC-PvPI Presently the PvPI programme has more than 200 Adverse Drug Monitoring Centres (AMCs) involving all states and Union Territories through-out India [19].

Reporting of Adverse drug reactions

Suspected ADR reporting forms for health care professionals (Figure 4) and for consumers (Figure 5) are unit available on the website of IPC to report ADR. To get rid of barrier in ADR reporting, the consumer reporting form are available in 10 vernacular languages (Hindi, Tamil, Telugu, Kannada, Bengali, Gujarati, Assamese, Marathi, Oriya, and Malayalam). ADRs will be conjointly reportable via PvPI helpline number (18001803024) on week days from 9:00 am to 5:30 pm. The mobile Android application for ADR reporting has conjointly been created available to the general public [20].

Version-1.2

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions 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

FOR AMC/NCC USE ONLY
AMC Report No. :

Report Type ☐ Initial ☐ Follow up
Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials _____
2. Age at time of Event or Date of Birth _____
3. M ☐ F ☐ Other ☐
4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)
6. Date of recovery (dd/mm/yyyy)
7. Describe reaction or problem

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)
☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent
☐ Hospitalization/Prolonged impairment/damage
☐ Disability ☐ Other (specify)

15. Outcomes
☐ 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.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
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 used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address:_____
_____
Pin:_____E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

17. Date of this report (dd/mm/yyyy):

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

Figure 4: Suspected ADR reporting form for Healthcare professionals.

Figure 5: ADRs reporting form for consumers. and the selections of emotions.

World Health Organization-Uppsala Monitoring Centre & India

The WHO Program for International Drug Monitoring provides a forum for WHO member states that has India to collaborate within the monitoring of drug safety. At intervals the Program, individual case reports of suspected ADRs are collected and keep in an exceedingly common information, presently containing over 3.7 million case reports. Since 1978, the Uppsala Monitoring Centre (UMC) in Sweden has dispensed the Program. The UMC is accountable for the gathering of knowledge concerning ADRs from around the world, particularly from countries that are members of the WHO together with India. Member countries send their reports to the

UMC wherever they are processed, evaluated and entered into the WHO International information. When there are several reports of adverse reactions to a particular drug this process may lead to the detection of a signal- an alert about a possible hazard communicated to member countries. This happens solely once elaborated analysis and expert review. These ADR reports are assessed regionally and will cause action at intervals the country. Through membership of the WHO International Drug Monitoring Program, a rustic will recognize if similar reports are being created elsewhere. India is a country with a large patient pool and healthcare professionals, yet ADR reporting is in its infancy (Table 2) [21-23].

Centre	Role
AMC	Collection of ADR reports, perform follow up with the complainant to check completeness as per standard operating procedure (SOPs), data entry into Vigiflow, reporting to PvPI-NCC through Vigiflow with the source data (original) attached with each ADR case Training/ sensitization/ feedback to physicians through newsletters circulated by the PvPI-NCC.
PvPI AMC other than medical colleges [Corporate hospitals, autonomous institutes, Pharmaceutical industry and public health Programmers]	Collection of ADR reports, perform follow up with the complainant to check, completeness as per SOPs, report the data to CDSCO- Headquarter (HQ).
PvPI NCC, IPC (Ghaziabad)	Preparation of SOPs, guidance documents & training manuals, data collation, Cross-check completeness, Causality Assessment etc as per SOPs, conduct Training workshops of all enrolled centres, publication of medicines safety newsletter, reporting to CDSCO-HQ, Analysis of the Performance measurement system, Periodic safety update report, Adverse event following immunization data received from CDSCO-HQ.
Zonal/Sub-zonal CDSCO Offices	Provide procurement, financial and administrative support to ADR monitoring centres, report to CDSCO-HQ.
CDSCO-HQ (New Delhi)	Take appropriate regulatory decision & actions on the basis of recommendations of PvPI NCC at IPC, propagation of medicine safety related decisions to stakeholders, collaboration with WHO-UMC, provide for budgetary provisions & administrative support to run PvPI.

Table 2: Responsibilities and functions of the stakeholders in the programme.

Aim of Pharmacovigilance Programme of India

PV has specific aims as follows:

1. Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions
2. Improve public health and safety in relation to the use of medicines
3. Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost effective) use
4. Promote understanding, education and clinical training in PV and its effective communication to the public [24].

Objectives of Pharmacovigilance Programme of India

1. To create a nation-wide system for patient safety reporting
2. To identify and analyse the new signal ADR from the reported cases
3. To analyse the benefit - risk ratio of marketed medications
4. To generate the evidence-based information on safety of medicines
5. To support regulatory agencies in the decision-making process on use of medications
6. To communicate the safety information on use of medicines to various stakeholders to minimise the risk
7. To emerge as a national centre of excellence for pharmacovigilance activities
8. To collaborate with other national centres for the exchange of information and data management
9. To provide training and consultancy support to other national pharmacovigilance centres located across globe [9,25,26].

Conclusion

The adverse drug reaction observation and reporting programmes or pharmacovigilance programme of India is aim to identify the risks related to the utilization of the drugs. The current analysis has disclosed opportunities or interventions particularly or avertible adverse events which is able to facilitate in promoting safer drug use, data to the health care professionals. Improve the standard of patient care and educate to extend awareness. Therefore, currently this point has return to aware the general public too for the reporting the adverse drug reaction to nearest hospital or ADR monitoring centre or to the health care professionals. They will directly report the adverse drug reaction through government. Toll-free number 18001803024, adverse drug reaction application, email and alternative methodology like social medias.

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Conflict of Interest

The authors declare that they have no conflicts of interest to disclose.

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