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PHARMACOVIGILANCE PROGRAMME OF INDIA (PVPI): AN OVERVIEW

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ABSTRACT

The field of Pharmacovigilance (PV) has changed dramatically worldwide over a few decades as there are quite a few advancements in the field. In this article we would focus on the status of the PV system of India, highlighting its history of development, challenges and measures for the improvement of the system in addition. Under the Pharmacovigilance Program of India (PvPI) a major effort has been made to collect drug safety related information and make such information available to the world health organization as well which is a WHO database. The PvPI system is one of the minimum requirements to run a national PV system based on WHO. Indian Pharmacopoeia Commission (IPC) is the national coordination centre under PvPI. In India adverse drug events first and foremost get reported through a spontaneous mechanism. A significant issue for PV in India is the extent of under-reporting.Along with patient safety, the programme is trying to create the trust and understanding between the physician and the patient as well as increase the people's confidence in the country's health system, apart from detecting substandard drugs and errors in prescribing, dispensing, and administration. The IPC-PvPI has recently been recognized by WHO as a Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services. Despite these major successes, challenges have remained for the PvPI, mainly monitoring generic drugs, generic similarity products of original biopharmaceuticals and detection of disease-specific ADR to antidiabetic agents, cardiac drugs, antipsychotic agents etc and, above everything, awareness creation, a never ending process. Besides these efforts, there are other challenges being dealt with by the PvPI such as counterfeit medicines, antimicrobial resistance and surveillance during large-scale vaccinations and other national programmes.

KEYWORDS: Pharmacovigilance ADR, ADR Monitoring system.

1. INTRODUCTION

The world health organization (WHO) set up a system that collects and brings reports of all harmful or unpleasant side effects (also known as adverse reactions) that may be related to medications. This increased awareness in the identification and handling of adverse drug reactions has led to the development and recognition of a field known as pharmacovigilance. The term pharmacovigilance can be broken down into its root words: pharmac (Gk. drug) and vigilare (Ltn. keep awake or alert, to keep watch). Pharmacovigilance is described as the pharmacological science that is mostly concerned with the detection evaluation comprehension and prevention of medicines' side-effects that are both short and long lasting. Pharmacovigilance plays multiple roles such as first the identification of the drug-related problems, the second being the quantification of those problems, and then, the documentation. Once it passes the discovery and pre-clinical stages, a candidate drug goes to human trials, i.e. clinical trials. Clinical trials are a highly-regulated setting where investigators and product manufacturers closely monitor everything. It is compulsory to report all adverse events occurring during clinical trials to the authorities within an agreed deadline. The term "good clinical practice" in a clinical trial context has essentially transformed pharmacovigilance from a reactive to proactive approach. A thorough and well-formulated system for keeping track of the adverse events is in place for the assessment of the safety of the drugs through clinical trials.[(1)] Pharmacovigilance (PV) was officially started when a December 1961 letter (case report) written by Dr. W. Mc Bride in the Lancet The Australian doctor, who is credited with being the one that identified and first communicated to the medical world a causal link between the exposure of a fetus to the drug Thalidomide and its abnormal physical development, mainly phocomelia Thalidomide was given to pregnant women as sedatives and against morning sickness Thalidomide was first and foremost used as an anti- vomiting medication and sedative in pregnant women.[(2)] Ban on the drug came late: by that time over 10,000 children had been born with the most prominent issue of limb deformities, called 'phocomelia' (a term taken from the Greek word for seal-like limbs), ranging from very short or totally missing arms with hands just above the shoulders, a missing thumb and accompanying bone, lower arm bone; similar issues with the lower parts of the body have also been the results of taking this drug. The drug was teratogenic, so a large number of infants ended up having the eyes, the ears, the heart, the genitals, the kidneys, the digestive tract (including lips and mouth), and the nervous system damaged to one degree or another. The WHO Sixteenth World Health Assembly in 1963 passed a resolution (WHA 16.36) to confirm that timely decisions should be made on the sharing of news about adverse drug reactions (ADRs) and their consequences to protect people (1963). It was in 1968, that the World Health Organization Programme on International Drug Monitoring (PIDM), as a Pilot research project, developed a system for the international detection and monitoring of unknown or poorly characterized adverse effects of medicines and started collecting international ADR reports in a central database

through.[2]. It is a scientifically established fact that medicines bring about expected as well as unwanted effects. These may include adverse reactions, contraindications, and some of the cases of serious drug effects that result in life-long illness and sometimes even death. To ensure that a medicine continues to provide therapeutic benefit, it is essential that one keeps on monitoring drug effects so that the potential for benefit is maximized and the risk is brought down to the barest minimum. It is a well-known fact that the safety levels that one gets from a phase of pre-clinical and clinical testing alone are not enough when one releases a drug product in large quantities like during a global market launch which prescribes the medicine in many different contexts. Clinical trials are usually carried out on just a few thousand people, so many of the rarest side effects and drug-related adverse reactions (ADRs) will have been missed before putting a drug on the market. Post-marketing PV (pharmacovigilance) drug safety measures make use of data-mining techniques to find out if there could be a connection between a medicine and a reported ADR. Besides, case-report analysis also plays a big role. Drug licensing authorities are required to have set up a sound PV reporting system as part of their work monitoring drug-related suspected adverse reactions from the pre-clinical phase up to the period when the drug is already on the market.[3]

1.1 HISTORY

In India an official Adverse Drug Reaction (ADR) monitoring system commenced in 1986. It was set up with 12 regional centers initially. In the year 1997 India joined the WHO Programme for International Drug Monitoring that is the organization responsible by the Uppsala Monitoring Centre, (UMC), Sweden of these activities. Initially, 6 regional centers were established in the cities of Mumbai NewDelhi Kolkata Lucknow Pondicherry and Chandigarh to ADR monitoring of the country. Out of these 6 centers, only the centers in Mumbai and New Delhi were active which led to very few reports of ADRs through spontaneous ways being generated. Because of this, in 2004 November the Government of India launched the National Pharmacovigilance Programme (NPvP) having an annual grant of US$0.1 million supported by World Bank for 5 years. Unfortunately the World Bank funding was cut off in the middle of 2009 and this way this program came to a temporary stop. [4] The Pharmacovigilance activities in India are being managed by Indian Pharmacopoeia Commission and executed representing Central Drugs Standard Control Organization (CDSCO). The major work of IPC is keeping and enhancing the pharmacovigilance database comprising of all suspected serious adverse drug reactions. Indian Pharmacopoeia Commission (IPC) acts as a National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI). National Coordination Centre is functioning under the guidance of steering committee whose role is to suggest procedures and guidelines for regulatory actions. The major function of National Coordination Centre is that it supervises to track all the adverse effects of drug seen in Indian people. On top of this National Coordination Centre is developing and managing their own database for pharmacovigilance.[1] WHO Sixteenth World Health Assembly (1963) decided through a resolution

(WHA 16.36) to support prompt action on the distribution of news about drug adverse consequences (ADRs). Only two years after, in 1968, the WHO Program for International Drug Monitoring (PIDM) as a Pilot Research Project was launched with the goal of developing a drug safety system capable of worldwide application for detecting previously unsuspected or inadequately understood adverse events of medicines. The project began collecting international ADR spontaneous reports in a centralized database. About year 2010, there were 22 monitoring centres for ADR including the AIIMS and New Delhi under this programme. To have proper and effective implementation of the programme in a safe manner, the National Coordination Centre was moved from Institute of Medicine, India (AIIMS), New Delhi to Indian Pharmacopeia Commission Ghaziabad Uttar Pradesh, on 15th April 2011.[3]

1.2 OBJECTIVE OF PHARMACOVIGILANCE PROGRAM

The reason the pharmaceutical sector of India is making progress rapidly through pharmacovigilance can be partly attributed to the regulatory agencies, media and consumers, who now better understand the risks and benefits related to various drug uses. The major objectives of PvPI are:

1 The first goal of this programme is to establish the safety profile of various drugs by continuously monitoring drug use and assessing the benefit-risk balance in the medical market.

2 Second, the plan is to put up a patient safety reporting system across the country and to assist Regulatory Bodies in making decisions for drug use.

3 Third, it is expected to raise awareness among stakeholders on the safety issues of medicines used and through this, it shall be able to mitigate risks. As a national competence center for pharmacovigilance, it can provide training as well.

4 Fourth, a collaboration with the International Centers on pharmacovigilance will facilitate sharing of data and also mentoring while at the same time identifying and interpreting new signals.[5]

5 Pharmacovigilance is the science of monitoring adverse effects of drugs, like serious or unusual reactions.

6 Enhance public health and safety by drug use.

7 Help in evaluation of benefits, risks and effects of medicines to encourage their safe, rational and more effective (including cost-effective) use.

8 Advance education training research activities, and knowledge sharing on the topic of drug safety to professionals and public alike through various communication channels.[6]

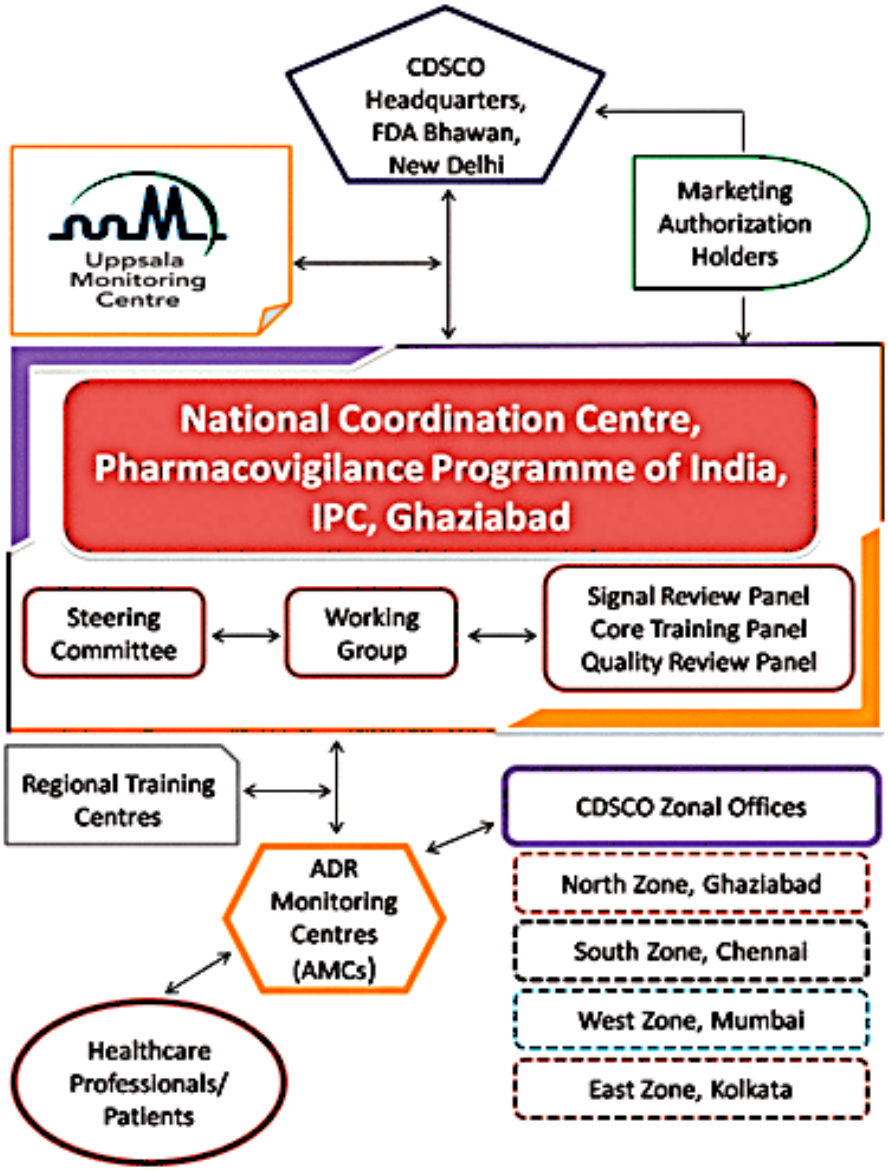


Fig. Channels of data flow in Pharmacovigilance Programme of India.[11]

1.3 WHY PHARMACOVIGILANCE NECESSARY?

The improvement in patient life has been largely enabled by a number of medicines, through the introduction and applications of these medicines, diseases are being controlled and managed. Medicines can cause adverse effects, and such effects if occur could result in an increased probability of morbidity and mortality. ADRs are the tenth leading cause of death and morbidity worldwide. Global evidence puts ADRs as the cause of 3 7% of all hospitalizations which account for 10 20% of all inpatients' stays. only one in 20 ADRs is identified and classed as a true reaction, this has led to the false conclusion that the incidence of ADRs is much lower than is actually the case ADRs not only increases chance of injury but is also costly on the contrary the cost of patients' hospital stay is increased .The burden on the nations' healthcare is so increased. Serious ADRs are the sixth leading

cause of death among hospitalized patients in the United States. Prolonged hospital stay doubled the cost of treatment. It is not surprising because of this that early detection and avoidance of ADRs is a shared goal of health teams and patients that they treat. Little is known about the safety of drugs in patients with a developing country. question of drug safety related issues often does not come up in clinical trials. Clinical trials involve carefully selected healthy individuals and heterogeneous groups in well-controlled conditions. Despite Really all human drugs undergo rigorous preclinical and clinical testing, questions of safety can still be raised during subsequent clinical trials. Genetic differences and drug interaction, may not be studied in all clinical trials and would so augment the incidence of ADRs . All drugs are supposed to go through phase I to phases III clinical trials before they are made available in the market. Though, clinical trials have limitations as they exclude special groups like children, pregnant and elderly e.g. children, pregnant and geriatrics. Trials with smaller sample sizes with diverse ethnic groups, manifold gene pools and short duration of time may fail to show a true efficacy of the drug. Also, toxicity in animals' trials, is not always a good predictor of similar effects in human trials .In this review article, we describe some of the events that have led to the emergence of pharmacovigilance.[7]

1.4 Importance of pharmacovigilance

Drug therapy can be defined as, "the use of drugs to treat medical conditions" A new medicine which is launched without long term safety studies may not claim to be therapeutically safe and effective at all; it may also cause some harmful or life threatening side effects. For instance, a few decades ago in India, safety evaluation of medicine was done by observing the use of that drug on a large scale chronically. This kind of evaluation was not reliable and could not be considered as giving the claim of being completely safe. In view of the circumstances, many Indian organizations or research funding bodies have begun to direct financial resources at conducting research on individual drugs and creating new products. After a product is made, new data gets created which could be either positive or negative. Such findings may affect the risk-benefit profile of that product. It is very important to thoroughly analyze or evaluate newly created information with the support of a PV system so that public health can be protected. The side effects of medicines often means diseases or deaths and the investigation of such effects is necessary for reducing risks and increasing benefits. Because of some recent prominent cases of drug recalls, pharmaceutical companies and Regulators have become very strict in ensuring drug safety in the market i.e PV. India is among a few countries that manufacture medicines for their own and a large number of countries. India has over 6,000 licensed pharmacists and manufacturers of medicines and about 60,000 brands are on market in the country. Sometimes patient uses more than two prescription or non-prescription drugs together that may interact and cause adverse effects. That's why, to stop from such situation and to save the patients from potential harm by new or existing drug there is essential to develop the PV system. PV is the task of collecting, assessing information on adverse drug reactions(ADR), and communicating

findings to relevant stakeholders for the safety, efficacy and rational utilization of medicines. Till date no university in India includes PV as a post graduation program and the existing curriculum in medicine, pharmacy and pharmacology is not sufficient to equip PV skills. Due to these conditions, several pharmaceutical companies in India have focused to invest funds in the research and development of new chemical entities A combination of these factors has resulted in India getting the status of the "pharmaceutical hub of the world". For example, in the past only new drugs developed in the other countries were marketed in India taking more time. PV protects the society health by identifying various risk factors and seriousness levels of the ADR and preventing further unexpected harms of drugs. [8]

1.5Adverse Drug Reaction Monitoring Centers under PvPI

The adverse drug reaction monitoring centres (AMCs) functioning under the Pharmaceutical Care Programmes provide essential support to patients for drug reactions. They are established throughout the country for collecting the adverse effect details from the patients. The AMCs are constituted of MCI approved medical colleges and hospitals, medical/central/autonomous institutes, public health departments, or corporate hospitals. Auditor members collect information on adverse events reported by the patients and check on them periodically to ensure completeness of adverse drug reaction (ADR) reports following Standard Operating Procedures; they also enter the records in the system software (Vigiflow) that they use and forward them to the NCC through the same software. Some AMCs also offer training and technical support at the regional level. At the start, the PvPI registered more than 22 AMCs across the country in year 2010. It had expanded to reach 90 AMCs at the end of year 2012 where 60 were phase I AMCs and 30 were phase II AMCs. All 90 AMCs have been grouped into four zones that is North South, East, and West respectively which correspond to zonal offices of CDSCO in the country as well and are under the NCC. The country has more than 2,000 pharmacy colleges, 90 Institute of PharmD, over 200 dental colleges, over 320 nursing colleges. Drug dispensation/retail, pharmacy practice, and paramedical colleges as well as dental ones which take care of their patients by providing safe and effective medication are part of patient care.For strong pharmaceutical drug safety monitoring, these colleges will be designated as Academic Medical Centers or AMCs of this program before long. India has over 360 medical colleges approved by Medical Council of India, with about 194 being privately-run. Through appropriate channels, all MCI Approved colleges and Pharmacy Council of India-approved colleges of pharmacy conducting pharmacy practice and PharmD programs will be integrated into PvPI project. Besides north south east and western sectors, all MCI approved medical colleges and hospitals will be joined under the program in various parts of the country and ultimately, hospitals run by both government and corporate bodies will be covered under the nation-wide program.[9]

1.6World Health Organization (WHO) Uppsala Monitoring Centre (WHO UMC)

Part of International Drug Monitoring (IDM), the WHO department in charge, is a major source of adverse drug reaction reporting information in India. It is a worldwide organization whose main activity is collecting and analyzing the data on adverse drug reactions from various countries. Besides WHO UMC is also a source of equipment and a vast array of India's resources for a nationwide program in pharmacovigilance. It is directly working on the matter of adverse drug reactions. The system is supporting medication reaction reporting by keeping track of and following-up of adverse drugs reactions in different countries around the globe. The PvPI is structured as the standards and recommendations of WHO UMC and like that to other countries. The method used by the PvPI is interlinked with the WHO UMC system. The PvPI is sending its data to the WHO UMC. This will help the WHO UMC to have a collection of data from the country and also other parts of the world, which will ultimately result in a verifiable, clear and precise data collection.[2]

1.7 Criteria for ADR and its Reporting to Regulatory Authority

Table. International Comparison of Pharmacovigilance Systems.[8]

Aspect	India (PvPI)	United States (FDA/FAERS)	Europe (EMA/EudraVigilance)
Regulatory Authority	CDSCO, IPC	FDA (FOOD and drug administration)	EMA
Reporting System	VigiFlow (WHO-based)	MedWatch, FAERS(FDA adverse event reporting system)	EudraVigilance
Mandatory Reporting	Recently for MAHs(Market Authorization Holders).	Mandatory for manufacturers; Voluntary for HCPs/patients	Mandatory for MAHs, HCPs, and patients
Public Data Access	Limited	Broad(FAERS database)	Broad (Eudra Vigilance database)
Integration with Pharmacovigilance Systems with Electronic Health Records (EHRs)	Integration of EHRs Emerging	Advanced(Sentinel Initiative)	Advanced
Patient Reporting	Available, limited use	Widely promoted	Widely promoted
Signal Detection	Centralized (PvPI)	Centralized, AI-supported	Centralized, Pharmacovigilance Risk Assessment committee (PRAC)

The following incidents can be reported to the nearest reporting center or authority

- Life-threatening incident or death
- Hospitalization of the patient
- Birth defect
- Any medical event that the physician is serious about
- Effectiveness that is not found with the use of a medical device or drug product
- Drug interactions that are suspected
- Regardless of whether they are known or unknown, all serious, serious/non-serious, frequent or rare reactions caused by vaccine or drug must be reported.[7]

1.8Pharmacovigilance in Adverse Event Following Immunization

By vaccinating a person with the help of the vaccine the body gets protection against the disease through its own defence system i.e. the production of antibodies after the disease agent has been

weakened or destroyed by the vaccine. The implementation of the immunization program started in April 1978 with the launch of "Expanded Programme of Immunization" in India. In 1985, the new form of the program "Universal Immunization Programme" (UIP) was introduced with the objective of being carried out on a large scale and covering all the districts in the country during 1989, 1990 which is one of the biggest health programmes in the world. Under UIP, the MoHFW vaccinates newborns, children and expectant mothers with various vaccines.Among these are BCG, polio oral vaccine, Hepatitis B vaccine, rotavirus immunisation DPT tetanus vaccine, etc. IPC and NCC-PvPI have collaborated with UIP from 28 Feb 13th and have taken over the responsibility to detect AEFI.[11]

1.9Reports received from the National AIDS Programme

They collected information about the adverse drug reactions from the National AIDS Programme from September 2006 to complete the data of the ADRs that were already reported to the Programme retrospectively up to 2002. The primary therapy was Zidovudine (AZT), Lamivudine (3TC), Nevirapine (NVP). Most of the patients being treated with this combination therapy was observed. The total number of patients who received ARVs between 2002 and 2008 was more than a thousand. The number of male ADR reporters (64) is slightly lower than female ones (68). 132 ARV-related ADRs are reported from the years 2002 to 2008 to the National AIDS Programme are collected. Out of the 132 ADRs reported, 110 resulted in changing medicines, 17 led to different actions (reducing the dose, prescribing additional medicines for the relief of the adverse drug reaction) and in 5 cases the ADR resulted in terminating the medicines. Adverse drug reactions that occurred during 2002, 2008 at least 79 patients have been referred to medical specialists and have been 45 hospitalizations. As to a total of 45 in-patient cases, Zidovudine was the direct cause of 19 instances, 15 of which were for anaemia and 2 for anaemia and leukopenia together (leukopenia).[12]

Table NO 1: Reported adverse drug reactions by ARV from 2002 to 2009.[12]

Anti-retroviral	Number of toxicities	%
Abacavir	3	2.4
Zidovudine	63	47.7
Stavudine	21	15.9
Didanosine	1	0.7
Efavirenz	4	3.0
Indinavir	7	5.3
Lopinavir	2	1.5
Nelfinavir	1	0.8
Nevirapine	29	22.0
Saquinavir	1	0.8
Total	132	100

1.10Consequences of antimicrobial resistance

It is natural for resistant pathogens to come about during antimicrobial/antibiotic use. But, this resistance, also known as antibiotics AMR, speeds up due to the excessive use of medicines or their misuse. If people or animals receive inappropriate antibiotics treatment like antibiotics used for simple cases of cough or cold, antibiotics over-the-counter (OTC) without professionals' consultation; and antibiotics being used as growth promoters in animals or to prevent diseases in healthy animals the outcome is that the antimicrobial-resistant bacteria or microbes produced by human activity or animal agriculture can also get introduced into the people food animals, soil environment water, and atmosphere.

The AMR has been one of the biggest threats to human health for quite some time and has been a big concern for patient safety in health-care systems around the world. AMR not being only a factor in hindering prevention and treatment from an increasing range of infections, but also one of the main reasons governments are facing a financial burden for the therapy of resistant infections. Based on the World Health Organization (WHO) estimate for extensively drug-resistant tuberculosis (XDR-TB) in which the bacterium is resistant to at least 4 of the core anti-TB drugs that was detected in 105 countries until 2016 and about 10% of worldwide multidrug-resistant TB patients are already turned into XDR-TB every year. Besides that, WHO also has been aware that AMR is already undermining the global HIV and malaria efforts.

1.11 Research-based pharmacovigilance to address antimicrobial resistance:

In fact, through a partnership with the Department of Microbiology, Nizam Institute of Medical Sciences, Hyderabad, and the National Institute for Research in Tuberculosis Chennai IPC, which is the implementing partner of NCC-PvPI, has aimed at deepening the awareness of the threat of antimicrobial resistance while at the same time encouraging the rational use of antimicrobials. The primary role of PvPI has been to enhance patient safety through careful monitoring of adverse drug reactions of antimicrobials and to motivate health-care professionals to adhere to the principle of evidence-based medicine

Collaboration centers are supposed to undertake research in the field of pharmacovigilance matching their core area of expertise, to meet the gaps as well as needs that can be fulfilled by the respective organization. These organizations have the highest level of expertise in their respective fields. Apart from being at the forefront, these institutes are given the data of the PvPI to work out the major cause of AMR and also, the containment of the same is expected from them. Partnerships of PvPI, in this scenario, will go a long way in setting up the database with the help of the reports of adverse reactions due to the misuse of antibacterial medicines and addressing the problem of AMR effectively.[13]

1.12 Methodology

All these ICSRs shall be processed at NCC as per operating protocol of PvPI, drug safety data contributed to VigiBase for further identification of drug safety signals at global level. ADR reports received by AMCs shall be transmitted to NCC-PvPI using VigiFlow tools provided to the AMCs. Secondary processing of ICSRs at NCC-PvPI involves the ICDRscreening, statistical signal detection functions (data mining, algorithms, and visualization tools) that assess possible associations using multiple decision making techniques with computed measures of strength of signal (information component of IC, Empirical Bayes Geometric Mean, and Proportional reporting ratios.) for identifying the suspected medication alone (disproportionality analysis) and medicationADR pairings (relation analysis). The initial causal relationships between the suspected drugs and ADRs mentioned in all ICSRs of responding AMCs are assessed through various quantitative and other approaches which include a check of the essential elements for causality as per the global guidelines of VigiFlow and the information from primary secondary tertiary data sources, and marketed information from the marketing authorization holder. The pharmacovigilance data obtained on comparison between information resources which include IACls and product information from the MAH and authorized government agency websites are performed to check the drug-ADR combinations which include in information component (IC) analysis which further check the strength of the relationship between particular drugs and ADRs in the IC value. The utilization of IC as a quantitative component of disproportionality analysis in signal detection has been discussed, based on the Bayesian measure for the degree of strength of association between a specific drug and an ADR in varying data size. The signal values derived from the system are spread among all stakeholders/partners of the NCC-PvPI, and the AMCs follow the alerts on each patient taking the suspected drug-ADR combination noted in the report at their respective sites. Any particular ADR among the suspect drug-ADR combinations would be reported immediately to initiate a TSR among the AMCs in initiating the country wide monitoring as well as sensitizing the HCPs for pharmacovigilance.[14]

TABLE NO 2: Details of Drug – ADR Combinations. [14]

Suspected drugs	Adverse reactions	Drug-ADR combinations	IC value	IC_{025} value
Phenytoin	Angioedema	9	−1.05	−2.14
Phenytoin	Osteoporosis	3	0.19	−1.86
Nicorandil	Risk of ulcer complication	1	0.83	−2.96
Olanzapine	Hyponatremia	3	−2.12	−4.18
Crizotinib	Risk of cardiac failure	2	2.21	−0.38
Roflumilast	Gynecomastia	1	1.58	−2.21
Clozapine	Neutropenia	3	−0.01	−2.06
Disulfiram	Erythroderma	2	2.26	−0.32
Peginterferon-alpha-2a	Vasculitis	1	1.56	−2.24
Piperacillin and tazobactam	Vision abnormal	2	−1.18	−3.77
Mometasone furoate, topical	Hypertrichosis/hirsutism, skin depigmentation	2	2.19	−0.4
		1	1.42	−2.38
		4	3.01	1.27
Ranibizumab	Myocardial infarction	2	1.98	−0.6
Amphotericin B	Bone marrow depression	3	1.52	−1.07
Doxorubicin	Photosensitivity reaction	2	−1.33	−3.92
Crizotinib	Pneumonitis, hepatic encephalopathy	1	1.58	−2.23
		1	1.57	−2.23
Febuxostat	Allergic vasculitis	1	1.58	−2.22
Oxcarbamazepine	SIADH	1	1.54	−2.25
Artemether and lumefantrine	Stevens–Johnson syndrome/toxic epidermal necrolysis	2	1.63	−0.95
		1	1.31	−2.48
Cefixime	AGEP	3	2.32	0.27
Hepatitis B immune globulin (human)	Encephalopathy	1	1.58	−2.22
Cefotaxime	Anaphylactic shock	9	2.51	1.41
Lacosamide	Red man syndrome	1	1.51	−2.29
Dimethyl fumarate (fumaric acid)	Osteonecrosis	1	1.58	−2.22
Sodium citrate/diphenhydramine hydrochloride/ammonium chloride	Myocardial infraction	3	2.71	0.66

1.13 Post-marketing safety surveillance

Officially it is now generally accepted that part of the process of drug safety assessment should take place in the post-marketing (approval) phase if important innovations are not to be lost in what has been described as an unacceptably restrictive regulatory net. It is still for the regulators to judge if and how this should happen. The stronger the national system of pharmacovigilance and ADRs reporting, the greater is the chance that reasonable regulatory decisions will be taken in the initial release of new drugs that offer therapeutic innovation. Regulations guiding the regulatory process in almost all countries (jurisdictions) to be exact permits dispositions to be put on approvals like the requirement that detailed pharmacovigilance should exist during the initial few years of the medicines release. This need for vigilance monitoring still, is not solely reserved for new medicines, it also plays an important part in the advent of generic medicines and in the evaluation of the safety profile of existing medicines where new safety issues may have arisen. While spontaneous reporting still remains firmly at the heart of pharmacovigilance in the regulatory setup, and is crucial for signal detection, the clear requirement for more active monitoring is now well appreciated .Without utilization and use data, to understand the rates of ADR attributable to a product, or the safety with a comparator, spontaneous reports are not able to provide the information .For these questions, more structured, appropriate epidemiological approaches that reflect the limitations of spontaneous reporting studies are required. These approaches will need to be integrated into post-marketing surveillance systems. There are also other areas of drug safety that had been neglected up to now, which should be added in the monitoring of latent and long-term effects of medicines. These are: detection of drug interactions assessment of

the environmental impact from drugs in large populations and evaluation of the adverse effects from 'inactive' ingredients (excipients).[15]

1.14 Data analysis

We carried out all the statistical computations with RevMan. Data synthesis was done via an odds ratio (OR) with 95% confidence levels (95%CI) are also provided as the result for adverse drug reaction (ADR) pooling. In pharmacovigilance, the knowledge and attitude scores were assessed for standardized mean differences (SMD) with 95%confidence levels as well. Meta-analysis was carried out using the random-effects method of all studies. The degree of variation among the studies (heterogeneity) was evaluated using the I test. Results from a significant heterogeneity were those with I > 50%. A Sub-analysis by the type of the educational intervention was done to find out the most effective one as well as to examine the heterogeneity of the studies. Consistency of the results was tested using sensitivity analysis where leave-one-out approach was applied, that is in each comparison, one study that showed the most bias was left out. A meta-analysis included only the data where the number of reported adverse drug reactions (totals), as a matter of serious, high probability, unpredictable and unanticipated, and new drugs, reported under control and intervention (before and after the educational program) [15]

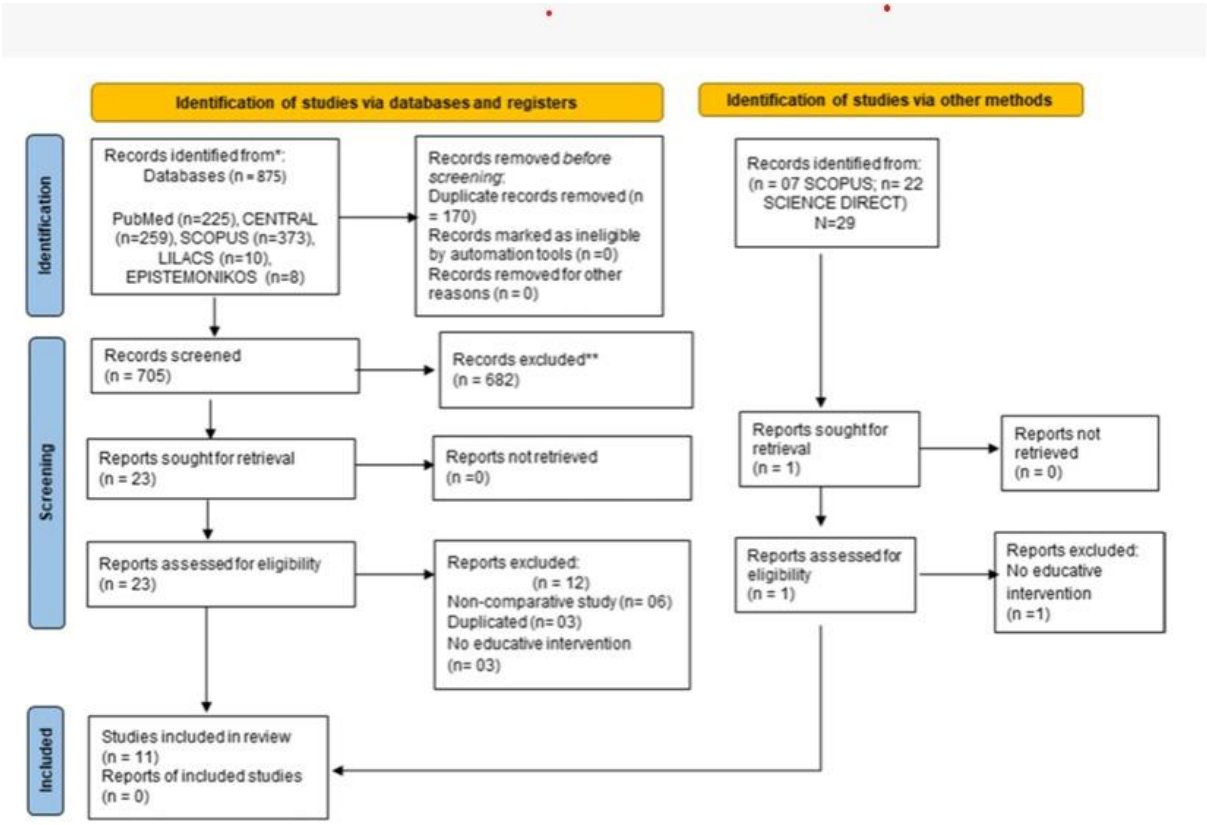


Fig 2: Flowchart for systematic review and meta-analysis (PRISMA) of educational intervention in pharmacovigilance, screening of articles, and selection process. [15]

1.15 Strategies for improving ADR reporting

And a general rule, strategies of intervention for enhancement of ADR reporting should be first and foremost targeted at both the health care system level and pharmacist level. Apart from motivating pharmacists to report ADRs, the inadequacy of knowledge and skills should also be met through education and training programs continuously. Yes, continuous education has been reported as an effective way of changing healthcare professionals' behaviour and attitude toward ADR reporting. The goal of this continuing education should not only be limited to improve pharmacists' knowledge for ADRs, but also change their attitude and perception toward ADR reporting. Several studies have also reported that, the more practice training people (pharmacists) received, the more likely they were to ADR reporting's 1 Nonmonetary incentives (e.g.certificate of recognition) for pharmacists (or healthcare professionals) with a complaint-driven ADR reporting system is another method of improving spontaneous reporting of ADRs. On health-system level, providing community pharmacists with access to their patients' medical records and medication history could enhance their ability to establish causation in ADRs and alleviate reported issues involving inability to establish a causal link between any agent and an adverse response as a deterrent to ADR reporting. There is other evidence that suggests that electronic ADR tools can also improve the spontaneous reporting of ADRs Introduction and integration of electronic ADR reporting system with hospital information system at a 400-bed tertiary hospital in Spain led to an increase in the ADR reports submitted to the PV center. The integrated ADR tool also facilitated the easier analysis of submitted ADR reports and automatic notification of suspected allergies to the allergy department. The effectiveness of electronic reporting system in improving the spontaneous reporting of ADRs has been also reported at a children's hospital in the UK. This study was conducted to evaluate the impact of electronic reporting and monitoring of ADRs in children and investigate whether this electronically enhanced system could complement the conventional Medicines and Healthcare Products Regulatory Agency Yellow card reporting system (the standard ADR reporting form used in the UK). During the study period, 87 ADR reports were submitted through the electronically enhanced system compared with just 8 ADR reports that were submitted to the Yellow card scheme suggesting the superiority of electronic reporting system compared with traditional paper-based reporting system. [16]

CONCLUSION

Pharmacovigilance and risk management are among the most important areas of pharmaceutical product development and marketing. In most regions of the world, these areas are tightly controlled. The identification of rare adverse events may require the observation of a large patient population before the side effect is seen. That is why pharmaceutical companies must keep their surveillance through all the product life cycles of the drug. Risk - benefits balance shall be an ongoing activity as we gather more knowledge about the drug from its users. To build up pharmacovigilance and risk

management capabilities, one has to go step by step to cover different aspects of safety and ensure they are properly monitored and taken care of. Still, as capacity building is a process of time and resources, outsourcing some of pharmacovigilance activities can help us develop in-house capabilities without waiting for the complete build-up. Using limited number of qualified centers is an efficient and affordable solution if there are good ways of process, tools, and communication of the duties and the events involved.

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