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Review Article

Pharmacovigilance at a Glance: From Adverse Event Detection to Vaccine Safety

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ABSTRACT

From drug discovery to administration of drug in human body, there is need to keep watch on the drug effect in the body. Due to wide variation in social behaviour, standard of living, gene and many more, every human won't have same effect of drug. To ensure the safety of drug, we need to monitor it. In this article we will have brief look about pre pharmacovigilance time to current time, how to manage data related to adverse drug reactions and pharmacovigilance methods. Also, in the tough times of COVID 19, we learn that vaccine can be the biggest weapon to fight against any diseases and as most vaccines are injectables there is need to properly evaluate the adverse effects of drug. So, this article also puts light on vaccine surveillance in different countries and current international status of pharmacovigilance.

INTRODUCTION

In this era of medicines and vaccines, pharmacovigilance is becoming an integral part of the health care system. According to the World Health Organization, Pharmacovigilance covers all the activity and systemic evaluation related to detection, interception, measuring severity and causality of any problem or adverse effect which arises after intake of medical product [1].

By identifying the severity of adverse effect, risk to benefit ratio of particular dug can be accessed and based on same, health care providers can assist patients. Pharmacovigilance provides wide overview and information of drugs to medical practitioners, which assist them to decide the ideal prescription for patients. Many medicinal compounds have great potential to treat diseases but concurrently it has many adverse drug reaction or effects. Pharmacovigilance, the science of monitoring drug safety, evolved from early observations in the 1800s (like chloroform deaths) through major crises like the 1937 Sulfanilamide Elixir tragedy and the 1960s Thalidomide disaster, which spurred formal systems like the WHO's

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global program and national efforts (like India's PvPI) to detect, assess, and prevent adverse drug reactions (ADRs) and ensure medicines remain beneficial, transforming from isolated incidents into a structured, global public health practice [2].

Road towards pharmacovigilance

It was first observed in 1924, Gerrard WI discovered that patient treated with arsenic compounds to cure syphilis shows side effect in form of latent jaundice [3]. In 1937, raspberry flavoured elixir having sulfanilamide, an antibacterial drug against streptococcal infection causes mass killing of 105 patients by causing severe toxicity. It should be noted that till 1937 there were no provisions for any toxicity studies of pharmaceutical product before marketing it. After this elixir tragedy, in 1938 Federal Food, Drug act Cosmetic Act come into existence under Food and Drug Administration. According to FD&C Act 1938 it is mandatory for all pharmaceutical company to submit the proof of safety before marketing any drug [4].

Though safety reports were submitted to drug authorities before launching any medicinal product in market, there were reports of severe adverse drug events after its consumption by patients. Murray LR et. al., in 1950 with the help of autopsy finding and observations reported that there is development of severe aplastic anaemia after having long treatment of chloramphenicol [5]. It highlighted that beside having safety trials, there is need of continuous post marketing surveillance too. Thalidomide tragedy, a perfect example showing consequences of not having proper trial on every group of population. During their lab research, in 1950's German based company discovered thalidomide having potential tranquilizing effect. Later in 1960, thalidomide was prescribed to pregnant women to cure morning sickness. In 1961, German paediatrician found out that 150 infants are born with malformations of limbs. The common relation of this cases was "Thalidomide". Till complete withdrawal of thalidomide drug, approximately 12000 infants were born with abnormality around the world [6].

Drug development and Pharmacovigilance

During pre-marketing trials, the group for testing of the drug have less number of subjects. After marketing approval, drug reached to wide range of population. After intake of drug by broad range of people, exact adverse effect can be identified. To collect the data or reporting of the adverse events, PMS (Post marketing surveillance) comes into the picture. Tracking of adverse drug effect or any negative drug effect should be initiated from pre-clinical trials followed by clinical trials to launching of drug in market by marketing authorization holder company/institute. As per the regulatory process, before marketing any pharmaceutical product there should be proper clinical trial to be conducted. David BF identified various loopholes which affects clinical trials badly. Factors such as lack of financial sources, avoidance of ideal inclusion and exclusion criteria during recruitment of subjects during, dropouts, influential clinical trials, inadequate instruments for assessment of blood samples [7].

The main influential factor affecting results of clinical trial is number and diversity of subjects admitted. Generally, research organisation enrols subjects as per the minimum requirements of the regulatory agency but that too is small number in comparison of population which is going to use that product. There is also funding and subject unwillingness concern for new drug intake which negatively hampers clinical trials. In tough situations like pandemic, there is urgency to deliver new medicines, vaccines and health supplements to general public [7,8]. Though clinical

trials are carried out but this urgency leads to compromise of some observations. The above all factors related to drug development leads to record of inadequate adverse drug effects. In this situations pharmacovigilance plays important role. The scrutiny of drug during its testing (Clinical trial) and after its marketing (Usage of drug by patient) is centre focus in pharmacovigilance [9]. There will be decrease in usage of harmful drugs with the help of data collection by pharmacovigilance. Data will assist doctors to prescribe the medicines. So it can be said that pharmacovigilance is not just about adverse effect scrutiny but also helps to enhances the efficacy of prescription and in decreasing mortality rate [10].

In 1968, WHO launched a program having main focus on identifying and collecting all the negative effects of pharmaceutical products across the world. This program gave platform to all the countries to collaborate for betterment of patient's health. Program which was started with 10 countries, till now (December 2021) 149 countries have joined for collaborating as full-time members for drug monitoring with 23 associated members. From 1978, Uppsala Monitoring Centre (UMC) have become official headquarter of international drug monitoring program [11].

Clinical safety data management

Pharmacovigilance is an integral part of drug development. To maintain the standard and equality of safety monitoring, ICH E2 guideline is formed which is purely based on the pharmacovigilance. Pharmacovigilance is very well versed and should with Good Clinical Practice (GCP). There are many products which are under clinical trials in various countries, but same product is already approved in different country for marketing. So, the primary focus of regulatory department (of the country in which still investigation is going on) is on the safety data generated from marketing experience in approved country [12]. For easy, swift and also to identity clinical safety, pre marketing data (clinical phase) and post marketing data is very much related and equally important.

Data reporting

To avoid ambiguity among different regulatory authority, there is formation of ICH and CIOMS guidelines. They look after standardising definition and terminology in relation to clinical safety data generation and also give ideal path for reporting and handling severe ADR which needs to be reported on urgent basis. Few adverse drug reactions are expected from particular drug, example: having constipation with loperamide but few ADR are unexpected with high level of severity. This sort of ADR (unanticipated and acute) needs to be report on urgent basis. There should be simultaneous justification of the source of ADR reporting. There is no need to report urgently the ADR which is expected irrespective of the severity. The ADR which is not serious despite being unexpected also not need to report on priority basis. Causality estimation by qualified health care professional is important for the cases which are under the clinical trials/pre marketing trials [12,13].

Generally, the spontaneous reports which are identified after post marketing experience also needs to be causality evaluated. There are different timelines to report the ADR to authority which is based on the severity and level of expectedness. Unanticipated with severe level ADR which needs to be reported on urgent basis should be communicated to respective regulatory authority in writing or in telephonic conversation or in printed form within 7 days of observation and should also submit detailed report of same within 8 days after the completion of 7 days from observed day. Serious but unexpected adverse

drug reaction which are not having high death rate should be communicated within 15 days from the day on which sponsor get to know about respective ADR. There is no need to submit the full report to regulatory authority in above mentioned respective days. But there are minimum criteria which is to be fulfilled or gathered to submit the primary report i.e., an adequate patient information to locate him/her, information about medicine or medicinal product which is under investigation, an designated reporting area and an brief on adverse outcome which is identified as serious and unexpected. After submission of primary report, information should be actively sought and submitted as it becomes available. Ideal procedure to communicate the brief of ADR is through CIOMS 1 form. In some cases, it is not possible to obtain every information but few information related to patient, investigative product, detail such as onset and ending time of reaction, detail of sponsor and adverse reaction observer should be mentioned and if not available try to collect as maximum as possible [12].

Special case in reporting:

In clinical trials to avoid biased behaviour and false results, blind study are done. It can be blind double blind or sometimes triple blind too. But in case of severe and life taking ADR, sponsor reserved all the rights to disclose the blind study to subject. There is no need to open the blind or to inform investigator or evaluator. This rule is made in keeping in mind that out of large group of subjects, removing or disclosing any one will not affect results significantly [12,14].

But the quality and reliability of blind studies is compromised in cases where a life-threatening adverse reaction is the efficacy or observational endpoints in a clinical investigation. In this sort of trials where severe ADR is needed, there is relaxation in immediate reporting of ADR. In such cases there should be proper words of prior communication between sponsor and authority about reporting [15].

It is the sponsor's call to decide if they want to inform about ADR to manufacturer or not. Sponsors should report ADR to regulatory authority. Adverse events occurring in placebo group are exempted from immediate reporting. After end of clinical trial, if any adverse reaction observed to the subject, it should be reported to authority as report case with all the causality assessment report [12,13].

Software as helping hand's

As regulation gone more stringent, there is need to store the data of clinical trials with precise and accurate level of security. Data storage should be such that any sort of data should be easily available at time of need. Various software has been used by various CRO's to store and manage the data such as., Octalsoft 3.0, Clinion 3.1, SyMetric C6 and Medrio [16,17].

Pharmacovigilance methods

There are various pharmacovigilance methods employed to identify and report the adverse drug reaction. Different types of methods are Passive Surveillance, Stimulated Reporting, Active Surveillance, Comparative Observational Studies, Targeted Clinical Investigations and Descriptive Studies

In Passive Surveillance, Spontaneous report is a spontaneous communication by doctors, physicians or consumers to manufacturer or with the regulatory body that describes one or more ADRs in a patient who was given one or more medicinal products and that does not have any relation with organized data collection scheme. This type of reports plays a key role to recognize

the level of safety of drug in market. Generally, the drug manufacturer can be made aware by the sponsor of marketing authorization holder about some very rare adverse effect or event which were not present in any phase of clinical trials or any other study [18].

Currently, identification of safety signals from the report can be done by utilizing systematic methods. Many of these methods are still in development stages and their usage for detection is being checked. Bayesian technique and calculations of proportional reporting ratio are included in these methods. Drug-Drug interaction can be scrutinized by techniques of Data mining. Data mining is always utilized in combination with analyses of reports not in place of, analyses of case-reports. Data mining methods uses statistical methods to identify possible signals that can have better efficacy for further evaluation. Main drawback with this technique is it does not define the level of risk; it is important to be cautious when comparing drugs [19].

In Stimulated Reporting, several strategies have been employed to promote and enable reporting by health professionals for new medicinal product or for short time periods in certain scenarios (e.g., in-hospital settings). On-line reporting of adverse events and systematic stimulation of adverse event reporting based on a pre-designed procedure are examples of such strategies. Although these techniques have been found to increase reporting, they still have the drawbacks of lacking active surveillance which leads to partial, selective reporting and incomplete data. Companies should actively supply safety information to the medico professionals which are dealing with the drugs during the initial stage of marketing. They should also encourage careful usage of new drugs and the filing of spontaneous reports when an adverse event is discovered. Companies can employ stimulated adverse event reporting in the early post-marketing phase to warn healthcare experts about novel medications and give safety information to the broader public (e.g., Early Post-marketing Phase Vigilance, EPPV in Japan) [20].

In Active surveillance, as opposed to passive monitoring, is concerned with determining the specific number of adverse occurrences through a continuous, pre-planned procedure. In general, an active surveillance system is better capable of obtaining broad data on discrete adverse event reports than a passive reporting system [21].

Active surveillance can be accomplished by reviewing medical records or interrogating patients and/or clinicians in a subset of sentinel sites to ensure that thorough and exact data on reported adverse events is used and obtained. The chosen locations can provide data, such as data from specific patient subgroups, which would otherwise be unavailable in a passive spontaneous reporting system. Sentinel sites have several severe flaws and backlogs such as selection bias, a small number of patients, and increased expenditures. For drugs used largely in institutional settings such as hospitals, nursing homes, and haemodialysis facilities, active surveillance having sentinel locations is most helpful. Certain pharmacological treatments may be used more often in institutional settings, which might provide an opportunity for enthusiastic reporting. Intensive monitoring of sentinel sites can also help detect concerns in patients who are using orphan drugs [22].

Another method of studying medication safety and obtaining data using solo medical record of patient is prescription event monitoring (PeM). The UK Prescription Pricing Authority's prescriptions are utilised to establish cohorts of patients who got exposure to novel medications, and adverse drug reaction data is then collected from general

practitioner who have monitored and prescribed the medicine to the patient. Prescription event Monitoring has been proven to be practicable and helpful in Japan and New Zealand, and the concept may be applied to other scenarios. These registers are formed by the population of patient group of whom data is consistently gathered over a set period of time. Based on the drug exposure characteristics we can distinguish the population. The goal of such registries is to improve product safety awareness, particularly in long-term usage. A drug registry can be used for a single active pharmaceutical ingredient or a group of drugs [23].

Comparative Observational Studies provide more information on adverse events of in terest. By targeting and evaluating a specific population over time, surveying a cross-section of the targeted group of people at different time points, or by comparing cases of an event of interest to matched controls, such as patients having ingested drug but don't had the adverse event [24].

In cohort studies, there should be information of each and every treatment exposure throughout the time of clinical testing should be known. It able the software to compute the incidence of adverse events over long-term follow-up. A control group which should be ideally another cohort of patients having same characteristics should be made and frequently compared against the treatment of interest. Prospective cohort studies that are well-designed are thought to provide high-quality evidence. Rather of following up on individual patients, cross-sectional studies assess a sample of the population at specific time intervals. They might give data on the frequency of adverse occurrences as well as trends over time. Case–control studies can be used to identify that if a rare adverse event is linked to a drug or linked with the discover risk variables. Nested case–control, case–cohort, and case–crossover designs are among the other research design options. Observational research methods have been utilised to evaluate particular safety concerns about drugs in a number of cases [25].

In Targeted Clinical Investigations severe and large number of lives taking risks are identified during prior approval of drugs, additional clinical trials are needed to determine the identify the mechanism of action for the occurrence of adverse event [26]. Pharmacodynamics studies such as endpoint evaluation, Area Under Curve identification or pharmacological actions with pharmacokinetics studies such as absorption, distribution, metabolism and excretion are performed in some cases to see if a specific dosage form puts patients at an increased risk of adverse effects [27]. With the help of Genetic testing, we can identify the information of population, which will give rough idea about people who are at a higher risk of experiencing negative side effects. Furthermore, specialized studies based on the pharmacological characteristics and the predicted usage of the medication in general practice are needed to evaluate potential drug-drug interactions and food-drug interactions. Population pharmacokinetic studies and drug concentration monitoring in patients and healthy volunteers are frontline example of targeted clinical investigation[19].

Descriptive studies are an integral part of pharmacovigilance, with a lacking to confirm adverse events linked to medication exposures. These studies are planned to evaluate the baseline rate of occurred events and/or the prevalence of drug use in certain groups or population of people [28].

Vaccine Pharmacovigilance

As seen in COVID-19 and previous various epidemiology, vaccines are the most helpful and effective means of disease prevention and control. Vaccine have proved to be the most important tool for removing communicable or highly spreadable illnesses throughout the world. Major disease cured by vaccine are poliovirus, cervical cancer's next priority, or the current threat of the Corona Virus Disease 2019 (COVID-19) pandemic. Furthermore, human made biotechnological method, vaccinology is gaining much more importance with newly formulated vaccinations which primarily focus to combat a wider range of mortality issues such as flu and cancer. Vaccines can be preventative or therapeutic based on their functional efficacy will play a major part public health in the upcoming era [29].

Vaccines and common dosage form are commonly thought to be safe, however, like any other active ingredient, they are not without risk, any adverse drug reactions can occur after administered. Slight Adverse effects after the vaccination (AEFI) have been seen to have broader turbulence among the people. This is because vaccines are given/injected to healthy individuals, to vulnerable populations such as children, and the vaccine's detectable benefit is remote, in comparison, related adverse event is observed right away. The WHO/Council for International Organizations of Medical Sciences (CIOMS) working group has defined "adverse event following immunization (AEFI) as any untoward medical occurrence which follows the immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, an abnormal laboratory result, symptom or disease." CIOMS considers that an adverse event following immunization can be vaccine based, immunization error related, anxiety reaction and coincidental event. Vaccine pharmacovigilance can be defined as "the whole science, technolgy and activities relating to the detection, assessment, understanding, prevention, and communication of AEFI or of any other vaccine or immunization-related issues" [30].

Vaccine Pharmacovigilance in Various Countries

In United States, The Vaccine Adverse Events Reporting System (VAERS) is the main system for reporting potential adverse events which is caused after administering the vaccine in the United States. The CDC and the Food and Drug Administration jointly manage VAERS, which was launched in July 1990. VAERS allows voluntary reports from health care professionals, parents, patients, or anyone else as part of post licensure vaccination safety surveillance, as well as a small number of compulsory reporting of particular incidents. The VAERS database has 140 000 reports as at the end of 2002. Between 1991 and 2001, at least 1.9 billion vaccination doses were delivered in the United States. VAERS main goal is to discover early warning signs and produce ideas regarding potential new vaccination adverse events or changes in the frequency of existing ones. Clinical trials of investigational vaccinations often involve a limited number of people (usually fewer than 10,000), making it difficult to detect rare side effects. Several VAERS studies have been released, providing comforting data on the safety profile of newly approved vaccinations. VAERS data has always been accessible to the public, most recently through a database of case reports that has had personal identities removed and is frequently updated on the VAERS website (www.vaers.org). VAERS records that have not been recognised are nevertheless available under the Freedom of Information Act (FOIA). Both the FOIA replies and the public usage data collection

provide with information about VAERS's strengths and flaws [31].

The monitoring of vaccination safety in Canada is shared by Health Canada (HC) and the Public Health Agency of Canada (PHAC). Market authorization holders must report significant adverse events following vaccination (AEFIs) to Health Canada's Canada Vigilance Program (CVP). The Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) is authorized post-marketing vaccine safety watch system. CAEFISS is run by PHAC and is unusual in that it combines both passive and active monitoring (reports from FPTs) [32].

The CAEFISS has five goals: (1) to constantly monitor the safety of marketed vaccines in Canada; (2) Increases in the incidence or severity of known AEFIs must be identified; (3) To find previously undiscovered AEFIs that might be linked to a vaccination; (4) To highlight areas that need more inquiry and/or investigation; (5) To offer timely information on AEFI characteristics for vaccines sold in Canada to analysts and policymakers. Passive reporting is part of the system. If individuals feel an AEFI has happened, anybody can report it—families, patients, or the general public. Enhanced reporting (when several AEFIs are listed on a national report form and are considered to be of special public health importance) and active reporting (when specific serious events are sought among hospitalised children and reported if found to have occurred after immunisation) are both encouraged by government health authorities [33].

The Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom is in charge of overseeing the safety of all marketed medicines, including vaccines. The Yellow Card Scheme allows people to report possible adverse reactions to the Medicines and Healthcare Products Regulatory Agency (MHRA) [34].

India is a key vaccine provider to UNICEF, which supplies almost 100 poor countries with around 40% of the worldwide vaccine demand for regular children inoculation [35]. The Haffkine Institute in Mumbai (Bombay) was founded in 1899, making it the country's oldest vaccine maker. Here, the country's first Phase I trial was done, with the creator injecting himself with the plague vaccine he invented [36]. The government established the Central Research Institute in Kasauli in 1905, and it has been a forerunner in the creation of rabies vaccine, among other vaccines, and the Central Drugs Laboratory gets samples for testing from all around the nation. Mr Ramanbhai B. Patel founded Zydus Cadila in 1952, Dr V.K. Raju founded Biologicals E in 1953, and the Poonawalla group founded Serum Institute of India in 1966. In 1971, Bharat Serum and Vaccines was founded. In 1982, the National Dairy Development Board (NDDB) established Indian Immunological Ltd (IIL) with the goal of making the Foot and Mouth Disease (FMD) vaccine accessible to farmers. Panacea Biotech originally opened its vaccine manufacturing unit in 1988, and its recombinant vaccine manufacturing plant in 2002. Dr. K.I. Varaprasad Reddy, an electronics engineer by trade, created Shantha Biotechnics Ltd in 1993. In 1997, the company created the world's first recombinant DNA hepatitis B vaccine in India. In 1996, Bharat Biotech International Limited was founded [37].

Pharmacovigilance and CDSCO

The Drugs Controller General of India made the first attempt at creating a pharmacovigilance programme in India in the mid-1980s, when they established many ADR centres around the nation. In the late 1980s, the Indian Council of Medical Research (ICMR) established comparable

institutions. Both of these projects eventually came to an end owing to a lack of funding, infrastructure, and a persistent government commitment to promote pharmacovigilance. Another attempt was made on November 20, 2004, when the Central Standard Drugs Control Organization (CDSCO), with assistance from the World Bank, created the National Pharmacovigilance Program of India. For operational efficiency, this organised scheme has divided the entire country into numerous centres. The CDSCO is at the apex of the pyramid, with two zonal centres in New Delhi's All India Institute of Medical Sciences and Mumbai's Seth GS Medical College & KEM Hospital. There are five regional centres and 28 peripheral centres under them. A web-based reporting system is available at some of these facilities. Currently, all health care staffs, but not patients, can report ADRs using the program's one-page form [37].

In 2010, the Indian government started the countrywide Pharmacovigilance Programme of India (PvPI) to instil confidence and trust in the safety of medications among patients and healthcare providers. Since April 2011, the Indian Pharmacopoeia Commission (IPC), which is part of the Ministry of Health and Family Welfare, has served as the National Coordination Centre (NCC) for PvPI. In the last five years, healthcare practitioners have made significant progress in reporting ADRs. ADRs Monitoring Centres (AMCs) have been found at 179 Medical Council of India certified teaching institutions and corporate hospitals across the country. For administrative and logistical purposes, these centres are handled by four zonal offices of the Central Drugs Standard Control Organization (CDSCO). These AMCs are linked to worldwide networks (reporting through VigiFlow; WHO-Uppsala Monitoring Centre [UMC]. These AMCs use WHO-VigiFlow UMC's programme to submit ADRs to the NCC. The lack of willingness to report is changing now that the PvPI has released a comprehensive plan for a proactive pharmacovigilance system, raising awareness of the advantages of ADR reporting. Over the last five years, the NCC has played a key role in raising awareness among healthcare professionals about the need of reporting adverse drug reactions (ADRs), with over 1,49,000 ADRs recorded as of December 2015. India now contributes 3% of the worldwide Individual Case Safety Reports (ICSRs) database to the WHO. Feedback and newsletters are used to encourage healthcare providers to report [38].

CONCLUSION:

Drug safety monitoring is without doubt a most important part of drug development. Mainly adverse drug reaction reporting to concerned authority is based on the type and its severity. Data management with concise and precise reporting is foremost need of pharmacovigilance. There are various methods for pharmacovigilance, but it can be seen that early and direct observation is better than passive type reporting. More or less, there is not much big gap between different countries in relation to vaccine safety tracking. It can be concluded that with the equal and active contribution of drug product developer to investigator to patients, drug safety can be easily monitored and reported which can lead to increase awareness of rational use of drug.

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