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Review Article

A review on adverse drug reaction reporting pattern

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ABSTRACT

Pharmacovigilance is a practice aimed at monitoring drug safety in real-life situations as well as capturing adverse drug reactions during post-marketing drug life cycles. But under-reporting of adverse reactions is a major cause for concern and a threat to pharmacovigilance systems. The current article looks at major obstacles affecting the automatic reporting of drug response (ADRs) in India and possible solutions. In line with available scientific literature, major barriers to ADR reporting are inadequate information and awareness of health professionals, the views of clinicians in reporting, problems in establishing hospital reporting systems and inadequate training to monitor ADRs. Measures to improve the situation include greater involvement of nurses, pharmacists and consumers in reporting ADR the most common cause of ADR was antimicrobial agents such as Penicillin and the Cephalosporin group of antibiotics. Oral drugs were often involved in causing ADR.

Keywords: Adverse drug reaction monitoring centre (AMCs), ADR reporting pattern in pharmacovigilance,adverse drug reaction, pharmacovigilance programme in India,PvPI, CDSCO, NCC.

INTRODUCTION

Every drug that enters the market is expected to have a negative reaction when used by patients without clinical trial settings. An adverse Drug Reaction (ADR), as defined by the World Health Organization (WHO), is "a reaction to a dangerous and unintentional drug that is used in human form to prevent disease, diagnose, or treat disease or alter physiologic function" [1].

It is very important for both consumers and health professionals to find these side effects that can be used to create "warnings" about unexpected drug-related events and to ensure their safety. As a rule, drugs are usually made available to the public before taking unusual but potentially very important ADRs [2]. Science and activities related to detection, exploration, understanding and adverse prevention35the consequences of any other drug-related problem." The range of pharmacovigilance includes herbs, tradi-36

After approval, a significant amount of information about drug safety is obtained through 'pharmacovigilance'. According to the World Health Organization, pharmacovigilance is defined as "the science and activities associated with the discovery, testing, understanding and prevention of side effects and any other drug-related problem." The range of pharmacovigilance includes herbs, traditional medicines, blood products, biologicals, vaccines and medical devices as well. The International Drug Monitor Program was launched by WHO after a thalidomide incident in the early 60's. Pharmacovigilance is promoted by the WHO through its operational center in Uppsala and aims to improve patient safety, and provide relevant and reliable information for further evaluation of the risk benefit of commercially available drugs [3].

Adverse drug reaction monitoring centre

The Indian Pharmacopoeia Commission (IPC), operates as the National Coordination Center (NCC) of the Pharmacovigilance of India (PvPI) Program from 15 April 2011 under the framework of the Department of Health and Family Welfare, Government of India.1 Jobs The main ones of the NCC are collecting, compiling and analyzing Adverse Drug Reactions (ADRs) data to reach a decision to recommend a controlled intervention to the Central Drugs Standard Control Organization (CDSCO), without compromising health and community health risks through the PvPI Newsletters.[4]Collecting ADRs to patients ADRs Monitoring Centers (AMCs) are established under the NCC. The reason for setting up AMCs is to make it possible to diagnose rare ADRs that have not been detected by clinical trial programs. The NCC provides practical support and staffing capacity to AMCs through its efficient and effective reporting of ADRs. [5]

Procedure for selection of AMCs

A 'Letter of Purpose' is required to be submitted to the Head of Institutions to participate in this national drug safety monitoring program. After assessing eligibility, the affected institution may be classified as AMCs (ADR monitoring centers) under PvPI. The NCC (national liaison center) next submits AMC data to the WHO-Uppsala Monitoring Center (UMC), Sweden for Vigi Flow (WHO-UMC online software) for uploading. ADR. [6]

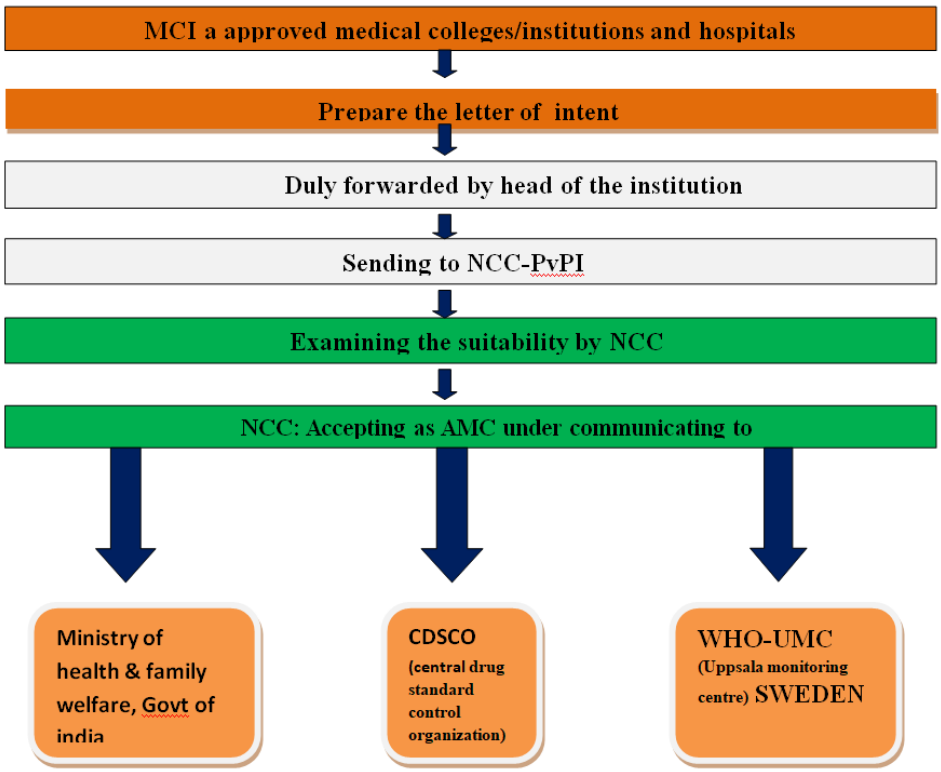

Fig: 1 process of induction ADRs monitoring centreunder PvPI.

ADVERSE DRUG REACTION

ADR is defined by the World Health Organization (WHO) as a response to a dangerous, unintended, and over-the-counter drug commonly used to prevent, diagnose or treat disease or alter body function. PV is defined by the WHO as science, and activities related to the detection, testing, understanding, and prevention of side effects and any other drug-related problems. [7]

ADR REPORTING PATTERN IN PHARMACOVIGILANCE

Individual case safety reports

Individual reports (technically, 'individual safety reports', although dealing with injuries) include reports to national regulatory authorities, such as the UK Medicines and Healthcare products Regulatory Agency's yellow drug testing system and unexplained reports in medical journals. They talk about real concerns about real-life ADRs. Their ability to identify the causal associations between medical products and adverse events depends on the skill and knowledge of the journalist as well as the literature and features of the event, including its duration and the effect of withdrawal and / or re-importing of suspected drugs.[8]

Many security alerts are based on information collected from a number of independent sources, but robust and well-documented case reports may from time to time prompt action itself. [9-10]

On the other hand, premature ADR warnings may be possible in the absence of reliable indications in the absence of a definitive description of the apparent over-reporting level of the event. [11] Case reports represent the first line of evidence and provide powerful ways to detect unforeseen occurrences. [12]

Their status as a basis for drug safety monitoring is clear. For example, it was the most frequently cited support mechanism for regulatory action for the withdrawal of medical products from UK and US markets between 1999 and 2001. [13]

Clinical review of case reports

The reports for each case are complex and varied. Not all reports are sent to medical testing programs by health professionals (such as doctors, dentists, nurses and

pharmacists). Some are published in journals and some appear in co-op cases. Direct patient reporting provides additional opportunities and challenges. The level of reports varies, and some important information is only available in the form of free text, not as standard website fields. Detailed clinical reviews are therefore essential for effective information.[14]

At the same time, the clinical review covers the main bottle: majornational and international organizations collect hundreds of thousands of reports each year, each of which will not be reviewed by existing specialists. For example, the World Health Organization (WHO) Program for International Drug Monitoring currently has more than 4.7 million reports from 94 countries and an additional 300,000 are added each year. Even if each report is not reviewed, important reporting patterns will be missed in the large amount of data involved. Thus the calculations methods are designed to help highlight the urgent problems of clinical review [15] and to identify complex patterns such as those that suggest drug interactions or sets of related reports. [16-17]. The aforementioned measurements help to prioritize outstanding reporting patterns based on their clinical relevance and urgency. [18]

Cohort-event monitoring

In order to fulfill the case reports, some countries have used cohort event monitoring systems (CEM) to track selected pharmaceutical products. Examples include New Zealand's Intensive Medicines Monitoring Program16 and monitoring of a doctor's event in the UK. CEM encourages health professionals to report adverse events and requests information about events that may not otherwise be reported. Group sizes usually range from a few thousand to tens of thousands of patients. [19]

Longitudinal electronic patient records

Long electronic patient collections are very important but they are used sparingly in the analysis of real-world drug use. They cover a wide range of people, provide detailed information on extended sections of medical histories and compile information on both exposed and undisclosed patients. The range of available clinical information may include instructions, results of laboratory tests, referrals and hospitalizations, as well as notes for symptoms, symptoms and diagnoses. Ideally, anonymous information is extracted directly from computer systems where physicians store patient data, so that no further effort is required to provide information and the risk of omission is reduced. Protecting the privacy of patients and doctors is very important and requires careful control. In the UK, general practitioner records provide an important source of information and form the basis of the General Performance Research Database. [20]

Screening patient records

Patient records are already an important resource for validated pharmacoepidemiological studies. In recent years interest has increased in increasing their use in experimental drug testing and general drug testing. [21-22]

Graphical presentation of temporal associations

To find the true open pattern, the extended sections of the patient's history below need to be read simultaneously; it may be helpful to present the results with drawings. [23]

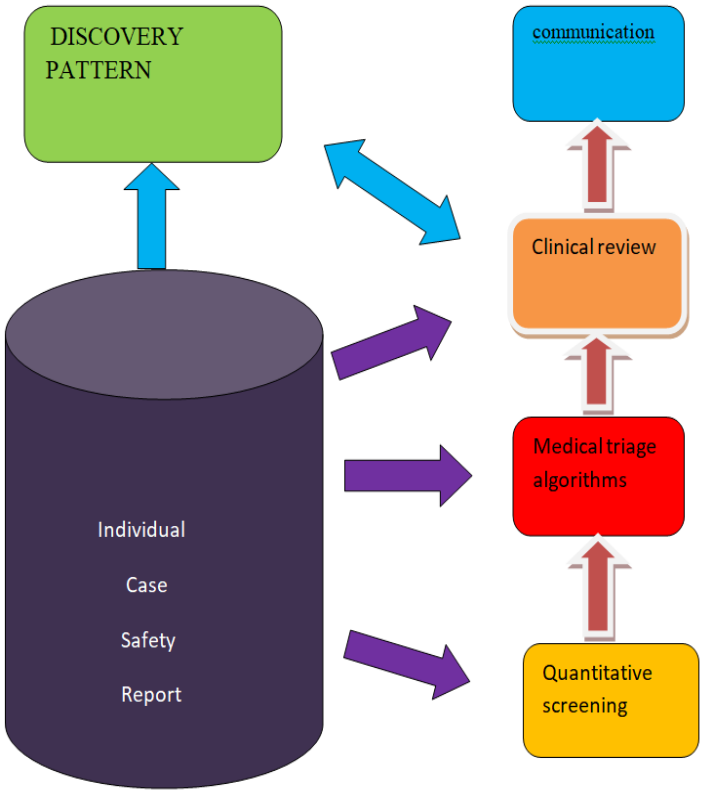

Fig 2: Schematic overview of individual case safety report of adverse drug reaction monitoring in pharmacovigilance[24]

PHARMACOVIGILANCE PROGRAM IN INDIA

Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services under Ministry of Health & Family Welfare, Government of India in collaboration with Indian Pharmacopeia Commission, Ghaziabad launches National Medication Monitoring Program for Health Protection of people. Patients by promising drug safety. The program will be co-ordinated by the Indian Pharmacopeia commission, Ghaziabad as the National Liaison Center (NCC). The center will function under the direction of the Steering Committee.

The Pharmacovigilance of India (PvPI) program was launched by the Government of India on 14 July 2010 with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordinating Center for Drug Response (ADRs) in the country to protect public health. [25]In 2010, ADR monitoring centers including AIIMS, New Delhi were established under this Program. To secure the effective implementation of this program, the National Liaison Center was moved from the All India Institute of Medical Sciences (AIIMS), New Delhi to the Indian Pharmacopoeia Commission, in Ghaziabad, Uttar Pradesh on April 15, 2011. [26]

CONCLUSION

There is no one-size-fits-all approach to global ADR monitoring. Reports from each case have a significant amount of potential adherence for drug users in their daily lives, including knowledge of medication errors, drug and drug interactions, and risk factors. CEM allows for estimates of adverse event rates and is better than case reports for receiving ADRs that may not be visible to health professionals or patients. Patient length records allow comparisons of a group of exposed patients with themselves as controls when they were not exposed to the drug (especially prior to treatment). Collectively, these three sources allow for early detection of hazards. Further testing may require targeted and enabled tests or test studies.

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