

Pharmacovigilance in India: Evolution and Change in Scenario in India

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Abstract: *In healthcare medicines play a crucial role in therapeutics, diagnostics and also in prophylaxis of diseases. Drugs sometimes acts as a dual edged sword. At one end it heals and cures diseases at other end it comes with adverse drug reactions (ADRs). Monitoring of ADRs is very essential as it has significant effect on the morbidity, mortality and economic status of a patient. National Coordinating Centre (NCC) at Indian Pharmacopoeia Commission started the Pharmacovigilance programme of India (PvPI) with an aim to monitor, assess and report the suspected ADRs to them. Healthcare professionals (HCPs) forms the cornerstone for the ADR reporting and key persons for PvPI. Even after continuous efforts the ADR reporting was not up to the mark. Prime reason for underreporting was attributed to lack of knowledge and awareness regarding pharmacovigilance among the HCPs. NCC-PvPI has taken multiple steps to hasten the ADR reporting from all stakeholders and is continuously working to keep the tempo going. With these continuous efforts we can hope a new horizon in the future where India will stand as one of the leading nations in promoting safe, effective and rational usage of drugs.*

Keywords: Pharmacovigilance; Adverse drug reactions; PvPI, ADR reporting

1. Introduction

In current scenario drugs play a very crucial role in the medical sciences. Drugs are being used in medicine for therapeutic purposes, for prophylactic and even diagnostic purposes. With the escalating usage of drugs, the pharmaceutical industry has also hastened its discovery process for new molecules. Although the drugs are meant to benefit the humans, yet they do not come free of adverse effects. The monitoring of adverse effects is crucial to know about the adverse effects of a particular drug and also to prevent its further occurrence. The Adverse drug reactions (ADRs) is defined as: "A response to a drug which is noxious and unintended, and which occurs at doses normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function. [1] The monitoring and surveillance of ADR are done by a process called as Pharmacovigilance (Pv). The word pharmacovigilance has derived from the Greek word pharmakon means "drug" and the Latin word vigilare means "to keep awake or alert, to keep watch." World Health Organization (WHO) defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problem, particularly long term and short-term adverse effects of medicines. [1,2] The monitoring of drugs with regards to adverse effects have changed a lot both nationally and internationally which has led to expansion in clinical trials safety and post marketing surveillance in the pharmaceutical product life cycle. The drug regulatory agencies in a country have the responsibility of establishing a well-established Pv system to monitor ADRs during the clinical trial phase and later throughout the post approval phase of the drug.

The thalidomide tragedy which occurred in 1960's triggered the first spark of establishment of some organization to ensure drug safety. International drug monitoring programme was established in 1968 to globalize and strengthen the drug safety issues. [3] Because of the

variation in drug response among individuals, various prescribing habits, drug regulatory system, availability of drugs etc., it has been suggested for every country to set up their own pharmacovigilance programs. The ultimate aim of pharmacovigilance is to ensure safe and rational use of medicines and avert the negative sequel of pharmacotherapy. The burden of ADRs has a huge impact on the morbidity, mortality and economic front among the patients globally. [4,5] In India, with over a billion population and development of the health sector literature reveals that ADRs are one of the leading causes of hospital admissions and they take a heavy toll on the economic front to patients in India. [6,7,8]

2. Pharmacovigilance in India: The Origin

The first picture of Pv came way back in 1986 with a formal ADR monitoring system consisting of 12 regional centers was proposed for India. However, the idea did not get much attention and there was lack of advancement till 1998 unless India joined WHO ADR Monitoring Programme established in Uppsala, Sweden. [9] Even after international participation there wasn't enough assistance or support from the health care professionals (HCPs). In 2010, Ministry of Health and Family Welfare (MoHFW), Government of India launched the Pharmacovigilance Programme of India (PvPI) in the to encourage HCPs to monitor the ADRs and report them in order to ensure safety of medicines. [10] Initially All India Institutes of Medical Sciences (AIIMS), New Delhi selected as National Coordinating Centre (NCC) for ADR monitoring and safety of the newly developed medicines. In 2010 total 22 ADR monitoring centres (AMC) were established. In 2011 the NCC was transferred from AIIMS to Indian Pharmacopoeia Commission (IPC), Ghaziabad for smooth and efficient functioning of program. [9] Selected eligible Medical colleges, hospitals and centres those were found competent and acceptable were approved as ADR Monitoring Centres (AMCs) whose duty was to collect the Individual Case Safety Reports (ICSRs), analyze them and further report it to IPC or Drug regulatory authority.

[11] These centers are covered by zonal offices of Central Drugs Standard Control Organization (CDSCO) for all administrative and logistic purposes. These AMCs report ADRs to NCC via a software VigiFlow, owned by WHO-UMC, (Sweden). [12]

3. Evolution and Barriers of Pharmacovigilance Programme in India

Even after repeated measures taken by CDSCO and IPC the reporting in India was very dismal. HCPs are considered the cornerstone of this programme and the major human resource for a health-care system and most crucial element for the successful implementation of the Pv programme. But on the contrary the scenario was a bit different. Literature reveals that a study conducted on 90 AMCs in India reported that the major part of HCPs like 68% of the doctors, 80% of nurses, and 81% of pharmacists were ignorant of the fact regarding the PvPI and ADR reporting system in India. [13] There are some studies conducted by Meheret al. [14], Kumari S et al. [15], Upadhyaya HB et al. [16], Karelia BN et al. [17], Chenchu Set al. [18] in India which shows that there is a lack of knowledge, awareness and attitude (KAP) regarding pharmacovigilance among HCPs that has taken a toll on the ADR reporting. Looking into these studies there was a huge need to create awareness among HCPs and general public regarding ADR reporting and Pv.

A Leap Forward to The Future:

In view of such deficiency in the KAP among HCPs, NCC-PvPI has taken multiple steps to develop the programme. The following are the new measures taken by NCC to overcome the lagging ADR reporting and to strengthen their stand on Pv.

- a) Toll free helpline number for ADR reporting- In current scenario telecommunication and phones play an indispensable role. In view of increase in usage of telecommunication NCC-PvPI launched a toll-free assistance number (18001803024) for ADRs reporting for the HCPs and general public in 2013. This was done to increase the involvement of the patients, stakeholders and public in ADR reporting.¹⁹ This effort of PvPI helped to create awareness among HCPs and has improved the data collection. This facility was upgraded by initiation of an acknowledgement SMS service to the reporter of ADRs. This feedback facility was started keeping in mind that it would increase the participation and build confidence for all stakeholders of PvPI. [19]
- b) Android mobile application for ADR reporting- Currently India's growth in information technology sector is one of the biggest advantages which can be utilized in improving public health. With the increase in usage of mobile phones and easy internet connectivity it was a right step to develop a mobile app which could be easily used to report the ADRs via smart phones. [20]
- c) Collaborations with CDSCO and WHO-Uppsala Monitoring Centre (UMC)- The NCC in collaboration with other national and international organizations promotes safety of medicines via knowing the global scenario with an aim to build a strong PV system in India. UMC also helps in training of the HCPs and staffs at PvPI-NCC and AMC throughout the country apart from giving access to Vigi-flow. [21]

- d) Availability of ADR reporting form in vernacular languages- India has a vast diversity of culture and so in the languages. This facility was started in 2014 to increase the reporting from all parts of the country regardless of creed and culture. The form can be downloaded from official website of IPC www.ipc.gov.in. [22]
- e) Integration of PvPI and Revised National Tuberculosis Control Program (RNTCP)- A patient diagnosed with TB takes multidrug therapy with duration of 6 months to 2 years or even more. The likelihood of ADRs increases proportionately with the number of drugs, so is quality of life and morbidity. In view to improve patient care and safety associated with such anti-tubercular therapy, RNTCP was formally collaborated with the PvPI in 2013. [8]
- f) Integration of Pharmacovigilance Programme of India and National Aids Control
- g) Organization (NACO)- patients on antiretroviral therapy (ART) are similarly at an increased risk of encounter with ADRs so to ensure safety NCC-PvPI and NACO formally collaborated in 2014. [8]
- h) Collaboration with Adverse Events Following Immunization- NCC-PvPI assists with adverse events following immunization (AEFI) at Immunization Technical Support Unit (ITSU) to ensure the vaccine safety. [8]
- i) Educational courses and training program on Pv and Feedback from the HCPs
- j) Timely communication through media, newspapers and electronic media.
- k) Newsletter- publishes three to four issues every year which serve as a lead to HCPs. All information regarding PvPI, meetings, proceedings new information, drug alerts and reviews are being published and distributed to HCPs and stakeholders. [23]
- l) Scientific journals- NCC-PvPI publishes review article on pharmacovigilance which are helpful for the HCPs in strengthening their knowledge and keeping them up to date with the current scenario.

With intensification of all measures taken by NCC-PvPI we can hope that in near future, all medical college associated with hospitals would get enrolled under the PvPI. Dedicated pharmacovigilance center should be established with persons with expertise on drug safety and assessments of ADRs. There should be access to comprehensive and unbiased relevant drug information to all HCPs. The newsletters and pamphlets should be sent to all medical colleges and personally mailed to all possible HCPs which would boost the dissemination of ADR related information. Acknowledge and recognize the contribution of reporters and AMCs those are consistent with high quality reporting by publishing their names in the newsletters and recognizing them on the website to set an example for others and prompt others to start participating in the programme. The pharmacovigilance should be incorporated in the undergraduate curriculum as compulsory or elective subject to incorporate the idea and practice of ADR reporting.

4. Conclusion

Medicine acts a dual edged sword. When used properly under prescribed condition can heal a person on the contrary unusually sometimes is also associated with undesirable or adverse effect. The ADRs can be monitored and patient safety can increase by Pharmacovigilance. ADR not only increase morbidity and mortality but also tends to be an economic burden on the society. PvPI was a breakthrough step towards safeguard of patients and rational use of medicines. The key element of the ADR reporting solely lies on the HCPs. Unfortunately lack of knowledge, awareness and resources had led to dismal performance with regards to ADR reporting. IPC-NCC with help of stakeholders is continuously giving push to PvPI to achieve its objectives. It has multiple new steps to increase awareness among people regarding ADR reporting and resolving of the issues of underreporting by HCPs. With effective implementation of Pv and collaborative efforts between government, drug regulatory authorities, pharmaceutical industry, HCPs and patient may lead to an effective pharmacovigilance system in India to ensure the availability of safe medicines to public.

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