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Development of Pharmacovigilance for Better Public Health in India

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Abstract: ***Pharmacovigilance basically is Detection, assessment, understanding and prevention of adverse drug reaction associated with any drug or medicinal product. Detection- Refers to identification of adverse effect of drugs/ molecule. It starts from the moment when any molecule is given to human to assess its efficacy or safety. Assessment- It is basically drug relatedness of the AE/ADR. Understanding- To understand the causality of the ADR/AE. Prevention- To prevent that AE/ADR from occurring. The role of pharmaceutical industries in the improvement of pharmacovigilance system is very important to maintain the safety data, Detection and Evaluation of drug safety signals through manual and medical devices reporting. Maintaining public confidence has become very complex in aspect of drug safety. Pharmaceutical companies should proactively assess and manage risk related to any drug throughout its lifecycle, from development to post market surveillance instead of just monitoring it. To improve awareness about pharmacovigilance and reporting of ADRs various systems for reporting and effective National Programme measures are required. As proper ADR detection and reporting are the key role to this system; various regional, zonal and outer centres have been proposed. Anyone can report ADR by filling the suspect ADR reporting form to the nearest centre in suitable language available online or offline. Due to Indian huge population and mobile network connectivity, for timely and effective reporting of ADR a toll free number and the mobile app is also provided.***

Keywords: Pharmacovigilance, Drug Safety, Public Health, Adverse Drug Reactions

1. Introduction

Pharmacovigilance is becoming important day by day due to the potentially adverse or harmful effects of drugs on patient's health. The recording, collection, analyses and assessment of the reports in PV process promotes the safe use of drugs. The growth should be there in both to report and to observe unwanted and unexpected medical events in all areas where medicines are being used as it will help to recover patient safety and care, improve public health, increase education and clinical training by supplying to the assessment of benefit, harm, effectiveness and risk of medicines, support effective communication to public and encourage rational and protected use of medicines. The safety of patients is totally linked with the safety of medicines [1]. The understanding regarding ADRs monitoring and reporting is rapidly increasing in India. Use of multi-modal practices, poor patient compliance are the factor also requires ADRs monitoring and reporting [2]. In clinical oriented activities such as drug interaction monitoring, adverse drug monitoring and reporting, prescription analysis/ auditing and patient counselling for good pharmaceutical care by reducing therapeutic failure results in patient safety which are mainly determined by clinical pharmacist. 179 Adverse drug reactions (ADRs) monitoring centres in India reported ADRs to NCC operating under the supervision of Steering Committee, which is under PvPI. Recommend procedures and guidelines for regulatory interventions are taken by India. Presently, seven new district-level AMCs in eastern Uttar Pradesh were introduced by PVPI, who store mainly whole data on safety of medicine [3-4].

2. Literature Review

PV is the developing field which deals with all types of medicines and medical devices [5-6]. Information is collected from patients and heath care providers regarding Suspect product to detect and prevent abnormalities associated with it [7]. ADRs have a major impact on public health by imposing considerable economic burden on the society. Moreover, in India, large number of Allopathic, Ayurveda, Homoeopathic, Unani and Siddha medicines are available and being practiced in combinations [8-10]. Hence, reporting of ADRs should be a priority area [11]. Underreporting is the major limitation associated with spontaneous ADR reporting system [12]. The current status of pharmacovigilance in India is far from satisfactory and this is mainly attributable to under reporting (UR) of adverse drug reactions (ADRs) that has become a widespread and a daunting challenge in Pharmacovigilance (PV) [13-15]. Underreporting can be attributed to patient-related factors like failure to recognize ADR or inability to link the ADR with a drug or feeling of guilt or UR may be because of doctor related reasons like the fear of taking legal action, ignorance, time consuming, inadequate risk perception about newly marketed drugs, not getting reward, insufficient training to identify ADRs, and lack of awareness and communication about Pharmacovigilance program [16]. Moreover, due to lack of knowledge of medical teams to recognize ADR or correlate precisely with biochemical, pathological or radiological abnormality [17]. The detection of ADRs increased by intensive monitoring in PV [18]. To intensify ADR reporting various approaches have been recommended [18-25]. Pharmacovigilance is a shared responsibility of all the stake holders. The participation of health care professionals and doctors is the most important for this programme. Proper training regarding PV to Medical students can bring rapid development and could play important role in the successful implementation of pharmacovigilance program [26]. Through culture of proper reporting of ADRs can be fostered and educational interventions awareness about the importance of monitoring and reporting can be increased [27-28]. Rational use of drugs includes right drug, right dose, and right time with the

right patient could improve the quality of the public health. To improve PV activity various steps were taken like:

- Considering the use of telecommunication and phone connectivity in India, PvPI-NCC launched a toll free helpline number (1800 180 3024) on 11 October, 2013 which helps to increase the participation of the stakeholders, patients and public in reporting of ADRs [29].
- Several Clinical Research Organizations (CRO's) or companies to create and own user friendly ADR reporting app and websites [30].
- To Improve of PV activity HCPs feedback is collected at the PvPI. By filling a prescribed form available on the official website HCPs can write their views, problems and suggestions to the PV authority which will indirectly boost up the PV process [32].
- Consumer can directly report ADR, suggestions and any other problems related to the product by filling a respective feedback form, via email or post.
- In India, it is mandatory for Marketing Authorization Holders (MAHs) to submit PSUR to CDSCO twice a year for 2 consecutive years to check the safety of marketed product [31].
- ADR reporting form is available in different languages like Hindi, Marathi, Bengali, Kannada, Assamese, Odiya, Telugu, Tamil, Malayalam and Gujarati languages and can be downloaded from official website of IPC www.ipc.gov.in [29].
- Communication of important finding is the best practice to upgrade the knowledge of stakeholders. NCC shares major knowledge and findings related to ADR reporting, risk-benefit with HCPs and also common public and proper use of medicines.
- PVPI collaboration with various private and government hospitals. 250 authorized reporting centres approved in India till Jan 2017 from various states. The NCC in collaboration with other national and international organizations promotes safety of medicines [32].
- Collaboration with other health authorities and WHO-UMC [32].

3. Conclusion

To create more awareness about pharmacovigilance we need to improve the reporting of ADRs. The issues of underreporting are resolving due to available reporting facilities like every hospital in India to monitor and report the ADR should have the special PV cell, toll free dial number, message, mail and ADR form in vernacular languages and collaboration with other health authorities. Many of the multinational companies in India have started the outsourcing of PV activity and various universities have incorporated PV courses in their curriculum as compulsory or elective subject which is creating the good PV culture. Hence, simpler reporting procedures need to be adopted. Still government needs to focus on the awareness and enhancement facilities to conduct PV activity.

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