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Pharmacovigilance and Drug Safety in India - An Unmet Need or Challenge?

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Abstract

Present review described Pharmacovigilance and drug safety in India. Challenges related to Pharmacovigilance programme, roles of physicians/health professionals as well as role of public/patients for successful monitoring are discussed herewith as nowadays, in India a safety of medicines is one of the key parameters along with therapeutic efficacy for success of any drug as ever-increasing range and potency of medicines. A successful Pharmacovigilance programme related to drug safety should be able to answer the key questions. How quickly has the case been identified? As well as what proportion of patient has successfully monitored collectively by doctor, Pharmacist/health professionals. As early detection is the key in reducing adverse events to minimum level or at lateral stage it may be a fatal or challenge to the health professionals. Challenges related to Pharmacovigilance programme in India can be avoided by strictly implementing proper rule and regulation everywhere. Strengthening of public campaigns for drug safety to improve awareness, addition of drug safety study to the curriculum, minimising the level of adverse effects by having sound knowledge about the side effect of the drug as day by day increasing number of medicines may help in monitoring the Pharmacovigilance programme. Interestingly, Improvement of communication regarding Pharmacovigilance between public and health professionals creates awareness so as to minimize adverse occurring. Proper knowledge on Pharmacovigilance would help to health professionals to understand the effectiveness or risk of medicines that they prescribe and ensure a better healthcare to patient.

Keywords: Challenges; Doctor; Drug safety; Patient; Pharmacist; Pharmacovigilance

Introduction

Pharmacovigilance [1] (defined by the World Health Organization, WHO as "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem") continues to play a crucial role in meeting the challenges posed by the ever-increasing range and potency of medicines, all of which carry an inevitable and sometimes unpredictable potential for harm [2]. Thanks to Indias' recent exposure to phased clinical trials and outsourced Pharmacovigilance processes of global pharmaceutical companies, the need to understand and implement Pharmacovigilance is now increasing. After the launch of the Pharmacovigilance programme of India in 2010, Indian Pharmacovigilance has progressed compared to how it used to be in the past, but a lot more has to be done to make the country a truly pharmacovigilant country. An increase in drug safety concerns in recent years with some high-profile drug withdrawals have led to raising the bar by various stakeholders, more importantly by the regulatory authorities.

The numbers of Adverse Drug Reactions (ADRs) reported, have also resulted in an increase in the volume of data handled. To understand Pharmacovigilance a high level of expertise is required to rapidly detect drug risks as well as to defend the product against an inappropriate removal [3]. Generally, Pharmacovigilance is the knowledge of amassing, observing, examining, assessing and estimating evidence from health care workers and patients on the contrary effects of drugs, natural products, herbal and traditional medicines with a view to:

- Finding new risks associated with remedies.

- Prevention and control of infectious diseases in patients.
- Reporting requirements in special situations.

Pharmacovigilance is an important and integral part of clinical research. Both clinical trials safety and post marketing Pharmacovigilance are critical throughout the product life cycle when adverse effects and toxicity do appear, especially when previously unknown, it is essential that these are reported, analyzed and their significance is communicated effectively to the audience having knowledge to interpret the information. For all medicines, there is a trade-off between the benefits and the potential for harm. The harm can be minimized by ensuring that medicines of good quality, safety and efficacy are used rationally, and that the expectations and concerns of the patient are taken into account when therapeutic decisions are made. To achieve this is to serve public health, and to foster a sense of trust among patients in the medicines they use that would extend the confidence in the health service in general, ensure that risks in drug use are anticipated and managed, provide regulators with the necessary information to amend the recommendations on the use of the medicines, improve communication between the health professionals and the public and educate health professionals to understand the effectiveness or risk of medicines that they prescribed given below [2-4].

Role of Doctors/ Physician [5]

- Only the professionals who are invited to report as judging whether disease or medicine causes a certain symptom by exercising the skill of differential diagnosis.
- It plays a vital role in ensuring together with the patient, have enough information to make a decision when it comes to choosing a drug for treatment.

Role of Public/Patients [4,6]

- Only a patient as they know the actual benefit and harm of a medicine taken, can report drug related problems to doctors as soon as it appears.
- The perception of benefit, harm and the level of acceptable risk of medicines in the face of these rapid developments have not been considered soon by patients and reported to health professionals in a meaningful way without wasting a time.

Role of Pharmacist [7-9]

- The role of pharmacists in Pharmacovigilance systems is amplified under Affordable Care Act or the current health care reform, because people, who otherwise had no insurance, now qualify for insurance; and this could increase the demand for pharmacy services.
- Pharmacist's role has become essential for the management of chronic diseases in patient-centered medical facilities where pharmacists are constituents of primary care.
- Pharmacists can identify adverse drug reactions in developing countries where quality control of medicines is questionable.
- In developing countries, pharmacists have a distinct role in in the health care system since many patients in prefer going to pharmacies for primary care. In such countries, pharmacists are more involved in the treatment process as well as the patient education
- Pharmacists helped in delivering health education, including education on drug-drug interactions.
- Pharmaceutical care is improved when pharmacists are actively involved in the treatment procedure by fostering the pharmacist–patient relationship and enhancing the value of the clinical outcome of the treatment
- Pharmacists through its knowledge helps in detecting safety signals of drugs of any origin

Pharmacist from traditional 'drug dispenser' concept towards 'pharmaceutical care provider' expanded the role of pharmacists and now become an essential for the management of chronic diseases in patient - centered medical facilities where pharmacists are constituents of primary care.

Challenges Related to Pharmacovigilance [8-12]

Challenges facing in relation with Pharmacovigilance nowadays are

- Non - priority in healthcare delivery.
- Personal bias related drug in healthcare delivery system.
- Poor staffing, poor funding and mostly political pressures creating barrier in implementation of Pharmacovigilance programme
- Limited number of health professionals as compare to the many prescriber.
- Non-covering of drug safety in medical training.
- Low motivation of health professionals due to their busy schedule.
- Lack of continuing medical education as well as difficulty in availability of drug information.
- Availability of many types of drugs in households as well as dispensing the drugs by untrained persons.
- Some other drug use problems include wide spread use of injections, high levels of antibiotic use, Inadequate treatment guidelines, poor prescribing and dispensing practices, counterfeit drugs and using of traditional medicines

- Confounding illness in diseases like tuberculosis, HIV/AIDS, malnutrition requires multiple drug therapy and adverse event occurs due to drug interactions, leading to severe health hazard.

Discussion

A successful Pharmacovigilance programme related to drug safety should be able to answer the key questions. How quickly has the case been identified? As well as what proportion of patient has successfully monitored collectively by doctor, Pharmacist/ health professionals. As early detection is the key in reducing adverse events to minimum level or at lateral stage it may be a fatal or challenge to the health professionals.

Challenges related to Pharmacovigilance programme in India can be avoided by strictly implementing proper rule and regulation everywhere. Strengthening of public campaigns for drug safety to improve awareness, addition of drug safety study to the curriculum, minimising the level of adverse effects by having sound knowledge about the side effect of the drug as day by day increasing number of medicines may help in monitoring the Pharmacovigilance programme.

Conclusion

Present review described Pharmacovigilance and drug safety in India -An unmet need or challenge? Interestingly, Improvement of communication regarding Pharmacovigilance between public and health professionals creates awareness so as to minimize adverse occurring. Proper knowledge on Pharmacovigilance would help to health professionals to understand the effectiveness or risk of medicines that they prescribe and ensure a better healthcare to patient.

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