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Hospital Pharmacists' Perception of Pharmacovigilance

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ABSTRACT: As it is a well acknowledged fact, that with each passing day the importance of pharmacovigilance is increasing. Pharmacovigilance acts as a sunshade against the ADRs and tries to improve and improvise the safety and efficacy of any drug coming to the market. The importance of pharmacovigilance would be lost if healthcare personnel, especially hospital pharmacists, did not contribute their expertise..Their clinical experience makes the ADR monitoring more efficient. The interdependence of pharmacovigilance and hospital pharmacist is considered to be one of the most important factors in drug development process. From reporting ADRs to providing medications for therapy, the hospital pharmacists put in their enormous contribution. Certain perceptions including the present development in pharmacovigilance and trends that affect pharmacovigilance has been regarded as a field of concern.

Keywords: Clinical, ADR, safety, medical, drug, contribution.

I. INTRODUCTION

According to the World Health Organization, Pharmacovigilance essentially aims at the detection, assessment and prevention of adverse effects or any kind of drug-related issues.[2]. Regardless of the numerous benefits of various pharmaceuticals, adverse drug reactions (ADRs) are one of the leading causes of human suffering. Before any drug is marketed and used by the general public it is very essential to make sure that it is safe and does not cause any ADR. The importance of pharmacovigilance in the field of science is undeniable.[1]

Drug postmarketing surveillance is based on reports of suspected adverse drug reactions (ADRs). The discovery of phocomelia linked to thalidomide used by pregnant women in the 1960s raised awareness of the importance of detecting symptoms as early as possible.[3]

The adoption of ADR reporting elements into educational curricula, hospital pharmacist training, and pharmacist participation in ADR reporting are all vital to accomplishing safety goals and protecting health.[5].

Due to the introduction of a huge number of highly harmful substances as medications in the last two or three decades, the identification of adverse drug reactions (ADRs) has become more and more crucial.[4]. The pharmacist plays an essential role in the reporting of suspected ADRs in a number of countries.[3]. According to our country's ADR monitoring system, very little attention has been paid to this issue.[4]. With the growing number of pharmacological molecules entering the market, the rise in medication recalls due to high health hazards has led to pharmacovigilance becoming increasingly important.[5].

PHARMACOVIGILANCE: IMPORTANCE AND ROLE

Pharmacovigilance describes the collection , analysis ,monitoring and prevention of adverse effects in drugs and therapies. Pharmacovigilance deals with two outcomes and the two outcomes are safety and efficacy.It aims at improving patient's care and safety in relation to the use of medicine and all medical and paramedical intervention.[6]

Certain science relevant issues include:

- Substandard medicines
- Lack of efficacy reports
- Medication error
- Case reports of acute and chronic poisoning
- Abuse and misuse of medicines
- Adverse interaction of medicines with certain chemicals and foods

Pharmacovigilance main responsibility includes reporting of adverse effects , gathering information on the reports of adverse events, then it evaluates the record of clinical cases ,next it focuses on comparing ,analyzing of adverse events and forming an evaluation ,further it recommends and initiates regulatory action in response to final

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result then it describes the alertness to generation and publication of new risks from adverse events followed by immunization, finally sharing the adverse events reports for drug monitoring.[7]
Post-marketing pharmacovigilance uses tools such as data mining and investigation of case reports to identify the relationship between drugs and ADRs. Pharmacovigilance is particularly concerned with ADRs ,which are drug responses that are noxious and unintended and occur at doses for modification of physiological function.[6]

RELATIONSHIP BETWEEN HEALTH CARE WORKERS AND PHARMACOVIGILANCE

In the pharmacovigilance structure, the health care workers play a significant part .The majority cases of the pre-marketing clinical trials involved children or old people. Those patients who use dietary supplements or many drugs simultaneously are generally not involved in these trials. [8]

The essential requirement of the health care personnels is abundant knowledge and proficiency in the area of the safety of medication that will assist effectively through prior recognition, management and reporting of safety issues of the medicine. The health care workers have to be well educated about the need and methods of adverse event reporting with the skills of both training and research in this field. [9]

The main pillar of pharmacovigilance is spontaneous adverse reaction which is needed to make hypotheses regarding the further investigation of the possible harms of the medicines. And this spontaneous reporting serves as an assistance in the recognition of delayed or very rare reactions which could not be determined in the short period of clinical trials. Hence, after the acceptance, the safety of the medicines can be examined.[9]

In spite of worldwide concern against medication safety affairs, an insufficiency of awareness and knowledge of pharmacovigilance and adverse drug reaction reporting can be seen among the health care personnels.[9]

Hence, the perception and knowledge of the healthcare workers into the secure profile of medicines is very necessary. The professionals should be conscious of the probable cause of unpredicted adverse reactions and outline about the reactions to the Medicinal Regulatory Authorities in order to ease the observation and evaluation of drug safety signals. The health care workers should be aware that no medicine is completely safe for all the individuals under all circumstances, so they should always exercise with some estimated uncertainties.[9]

CONTRIBUTION OF HOSPITAL PHARMACISTS IN PHARMACOVIGILANCE

Hospital pharmacists have been recognised as a highly accessible set of professionals that can help patients get the most out of their medications and improve their self-care. They have a major role to play in ADR reporting. ADR reports from hospitals improve the accuracy of ADR monitoring. It is due to their high-quality documentation.[3]

There are examples that show the necessity of preventing and monitoring adverse occurrences in hospitals in order to reduce both the negative consequences and the expenses associated with these events. Hospital pharmacists would be the best people to oversee this procedure, especially if they are actively involved in patient care. .[3]

Pharmacists play a significant role in providing information, advice and support about medication and therapy due to their access to interpersonal communication.[14]

Furthermore, hospital pharmacists have access to much more modern tools for monitoring medication safety, such as sophisticated computer systems and databases, as well as the ability to evaluate suspicious lab test reports.[3]

In the United States, hospital pharmacists provide the utmost contribution to ADR reporting. The fact that they play such an important role is due to a Joint Commission on Accreditation of HealthCare Organizations demanding the hospitals to maintain an ADR monitoring programme.

In the United Kingdom the hospital pharmacists are given an active role in monitoring the ADRs. Also, there is structural collaboration between Hospital Pharmacists and Clinical pharmacists to increase the efficiency of monitoring ADRs..[3]

Pharmacists with clinical experience are more aware of the ADR reporting system and interact with prescribers more frequently. Moreover, constant interaction with patients, along with access to their medical data, helps hospital clinical pharmacists to gain a better knowledge of potential ADRs.[13]

Pharmacists recruiting at public hospitals can not only detect and report ADRs. However, it

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also prevents them from lowering the humanistic and financial costs associated with them.

When we examine how pharmacists view their involvement in ADR reporting, we discover that they are not only highly motivated, but also see it as an important aspect of their job. However, a variety of obstacles to pharmacists reporting ADRs have also been found..[13]

The most commonly quoted hurdle is a lack of understanding of local reporting standards and laws, as well as proving ADR causality with a suspected medication. Another common misunderstanding among pharmacists is that only serious and/or new ADRs should be reported.

Consequently, the studies concluded that ongoing training, providing feedback to reporters, and providing incentives (either financially or in the form of continuing pharmacy education points) could be effective methods for persuading hospital pharmacists to participate more actively in Pharmacovigilance activities.[13]

Additionally, it is encouraging pharmacists to report ADRs, continuous professional development programmes would address their knowledge and skill gaps in recognising and reporting ADRs.[13]

In recent years, pharmacists' roles have shifted reasonably, with a stronger focus on pharmacotherapy outcomes through the provision of complete medication review services. This should encourage pharmacists to become more involved in the detection and reporting of adverse drug reactions. This will allow them to contribute more and more towards pharmacovigilance by monitoring ADRs. So, that they can effectively reduce and prevent the adverse effect due to drug related issue.[15]

FROM THE PERSPECTIVE OF A HOSPITAL PHARMACIST

A. PRESENT DEVELOPMENT IN PHARMACOVIGILANCE

In the past, India's regulatory agencies and drug companies based their safety assessment on experiences derived from long term drug use in the western markets and there was no real urgency for the government to establish a strong pharmacovigilance system of its own. In recent years, however, the lag between when a drug is placed in the market and its subsequent availability in India has decreased considerably , so that the much needed longer term safety data is no longer available. In addition, India based drug companies have increased their capacity to develop the launch of new drugs through their own research efforts and this has heightened the importance of developing adequate internal pharmacovigilance standards to detect adverse drug events.[14] Currently new drugs are being introduced into the market like vaccines, High- tech Pharma products. Drugs which were commercial and continue to be available in the Indian market were banned for their proven adverse effects. Few medications are still being used due to the benefits outweighing its risks.[10]

The field of drug safety has been receiving a great deal of attention lately. The contribution of pharmacists to pharmacovigilance is not only limited to ADR reporting. A number of medical institutions have advanced ADRs and medication error close watch systems in their clinics wards and emergency rooms. Academic centers of pharmacology and pharmacy have played an important role through teaching , training, research ,policy development, clinical research ,institutional review board and the clinical services.[11]

Machine learning and artificial intelligence in Pharmacovigilance:

When processing Individual case study reports, the use of technology on scale may enable the pharmacovigilance industry to increase operational efficiency and the consistency of data quality.[10]

New core competencies:

As Artificial Intelligence is introduced to pharmacovigilance , these core competencies are not considered all inclusive for the field of computer science but serve as an indication of what skills a pharmacovigilance professional should acquire to work with Artificial intelligence in pharmacovigilance.[10] A pharmacovigilance professional should be able to understand and interact with safety database they are using. Artificial Intelligence in Pharmacovigilance is a novel concept and would require more efforts and time to be invested in training personnel.

Social networking sites and their relevance to pharmacovigilance:

Recent years have seen the emergence and proliferation of Social networking sites dedicated to healthcare communities usually consisting of healthcare professionals and/or consumers or patients. Social networking sites and applications allow for the exchange of user-generated content whereby people communicate , share information, network and participate in community activities.[11] Social support is deemed extremely beneficial in combating health concerns like

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depression and mental illness. Social media serves as a platform that allows patients to exchange information about their health condition with others who are battling with the same health issues and receive peer to peer support.

Specialised healthcare social networks and forum includes:

Generic health -centered Social networking sites ,where users discuss their health related experiences, including use of prescription drugs, side effects and treatments. Sites includes: MedHelp (www.medhelp.org); WebMD (https://exchanges.webmd.com/); Cure Together (https://curetogether.com/)

Medicine focused sharing platforms ,which allows patients to share and compare medication experiences. Sites includes : Medication.com (http://www.medications.com/); Ask a patient (https://www.askapatient.com/) [10]

All these studies were carried out after ADR had been identified. This discipline needs to develop further to meet public expectations and the demands of modern public health.[11] This development is partly attributed to the fact that many national and regional centers are housed with hospitals , medical schools or drug information centers , rather than within the limits of a drug regulatory authority.[10]

B. TRENDS AFFECTING PHARMACOVIGILANCE

An expansion in reliance on the third party services have become a major trend in the promotion of pharmacovigilance. Further, utilising reduced turnaround times for rapid market capitalisation and the necessity of skillful professionals for observing the side effects are also included in the trends. [12]

The market is segregated on the basis of phase of drug development, type of reporting methods and type of service providers. On the basis of phase of the drug development, the market is divided into preclinical studies, phase I clinical trials, phase II clinical trials, phase III clinical trials and post-marketing supervision. On the basis of reporting methods, the market has been classified into spontaneous reporting, intensified adverse drug reaction reporting , targeted spontaneous reporting, cohort event monitoring and EHR mining.On the basis of service providers, the market is segregated into in-house and contract outsourcing. [12]

THE TRENDS THAT MAY AFFECT PHARMACOVIGILANCE ARE CITED BELOW :

Good Practice of Pharmacovigilance : The objective of good pharmacovigilance practice is to make certain about the suitable methods for the assembling , processing , evaluation and dispensing data. It also aims for the protection of the interests of both public health and individual patients.[2]

Incorporation of Drug Management , Drug Details and Pharmacovigilance in the Justification of Drug Use: Typically, the authorities for the regulation of drugs were in charge of evaluation and acceptance of the drugs. Normally, the legal needs were concentrated towards the safety use and effectiveness of the drugs. In the last few years an increased interest in coherent use of drugs and improved prescribing execution. Pharmacovigilance serves as an influential tool for these reasons. Poisoning has been realised as an essential factor in drug regulation and the regulators appears to be extending interests to act as the centre for excellence and supremacy by expanding their efficiency towards the department of education as well as information.[2]

Marketing Ventures of Companies : Even though the chief responsibilities of the government are the risk, benefit and assessment of established drugs as well as rationalising drugs , the pharmaceutical companies appear to be more influenced towards increasing marketing activities of their organisations. More attention is paid over prior registration, instant market invasion , high profits and firm competitions. Hence , these evolutions may have some consequences with respect to pharmacovigilance. [2]

Cost Containment : The governments are dedicated to decreasing the expense on the pharmaceuticals as a part of the campaign that aims in maintaining good quality healthcare for the impoverished majority of the citizens at a reasonable value. Although the new drugs are usually costly and frequently used for the purpose of treatment of common disorders. For an attempt of influencing the cost of drugs, the following ways are taken by the government in order to decrease the expenses on drugs :

- Restrictions regarding the reimbursement of drugs.
- Encouragement of generic drug use.
- Expansion of self-medication [2]

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Globalisation of Drug Marketing : Over the years , at different times in different countries newly discovered drugs were frequently registered. An increase in the utilization of drugs in a country has an impact on the majority of the population and this experience gained from one country can be applied to other countries as well. The formation of huge global markets will have a direct influence on pharmacovigilance. Also, the higher the number of new drug users, the larger the number of victims of an unexpected effect of adverse drug reactions. So, we can deduce that the increase of globalisation of registration of drugs increases the importance of efficient international pharmacovigilance. [2]

II. CONCLUSION

Pharmacists are the experts by profession when it comes to drugs and medicines. They have an important role in not only detecting, reporting and monitoring ADRs but also preventing ADRs , and the hospital pharmacists can play a significant role in ADR reporting because the most serious adverse drug events occur in hospitals and ADRs account for a considerable proportion of hospital admittance. The contribution of pharmacists to pharmacovigilance should, however , not only be limited to ADRs reporting. Modifications of the pharmacy curriculum as well as changes in the interpretation of the Pharmacist's scope of duties are required. There is a need to inform the treating doctors about the importance of observing for ADR following Pharmacotherapy, recording them meticulously, and reporting them to the concerned authority. This practice will prove to be very valuable in making the drug therapy safer and rational.

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