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Role of Pharmacist in Effective ADR Reporting – A Need of the Hour

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ABSTRACT

Globally, adverse drug reactions (ADRs) are one of the foremost causes of morbidity and mortality and will endure posing a threat to public health as long as drugs are being used to treat several conditions. The most important criteria in assessing drug safety are effective and rapid ADR reporting. This review paper aims to highlight the role of pharmacists in effective reporting of ADRs, to recognize barriers and provide an appropriate solution to this issue. Pharmacists hold a crucial responsibility in monitoring the on-going safety of medicines as a part of their professional practice. They can ensure a trusted environment by counselling patients to minimize medication errors, improve safety and quality of care.

INTRODUCTION

Pharmacist's plays a vital role in field of therapeutic medications including safety of drugs, i.e., Pharmacovigilance.[1] Nowadays the occurrence of Adverse Drug Reactions (ADRs) through any medication is very common. In such conditions, pharmacists act as back bone that is qualified to advice patients regarding benefit and risk ratio of prescribed medicines, make individual aware of various ADRs related to drugs and reporting those adverse reactions to the responsible authority.[2]

Pharmacovigilance plays an important role in guaranteeing patient's drug safety and providing clinical consideration making it a fundamental tool for practicing clinical care within the country.[3-4]

For safe and effective utilization of the pharmacotherapy process, it often requires teamwork of health professionals and patient. Giving suitable pharmaceutical care involves considering the risk on a patient by recognizing and tackling drug treatment issues. Despite the fact prescription is written by medical experts in most countries, pharmacists have their responsibility in follow-up, since they will screen, monitor and determine drug-related problems; therefore keep up safe utilization of prescriptions.[5-6]

According to WHO, an Adverse Drug Reaction can be defined as "A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" .[7]

CLASSIFICATION OF ADVERSE REACTIONS[8]

Type-A (Augmented): Commonest (up to 70%) – These type of ADRs are dose dependent and severity increases with dose. These reactions subside by dose reduction. Reactions can be predicted from the known pharmacology of drug. e.g., headache from nitrates, hypotension by beta-blockers, NSAID induced gastric ulcers.	**Type-B (Bizarre):** Rare, idiosyncratic, genetically determined, unpredictable, mechanisms are unknown, serious, may be fatal; non-dose related reactions, e.g., anaphylaxis caused by penicillin, hypersensitivity by anticonvulsants.

Type-C (Continuous drug use): Occurs due to continuous drug use. Reactions might be irreversible and unpredictable. E.g. tardive dyskinesia during continuous use of antipsychotics, osteoporosis during continued high dose glucocorticoid therapy.	**Type-D (Delayed):** Delayed onset ADRs, mostly occur after the cessation of treatment, e.g., corneal opacities after thioridazine, ophthalmopathy after chloroquine, or teratogenic effects as a result of phenytoin use during pregnancy.
Type-E (End of dose): Also known as Withdrawal reactions. Occurs classically with the depressant drugs, e.g., hypertension and restlessness in opiate abstainer, seizures on alcohol or benzodiazepines withdrawal, adrenocortical insufficiency by steroid withdrawal.	**Type-F (Failure of therapy):** Occurs as a result of ineffective treatment (previously excluded from analysis according to WHO definition), e.g., accelerated hypertension because of inefficient control, and decreased effect of antibiotic due to resistance.

REASONS FOR UNDERREPORTING OF ADR

A challenge that remains in Pharmacovigilance (PV) is under-reporting (UR) of adverse drug reactions (ADRs).[9] This is as a result of a spontaneous or voluntary system of ADR reporting followed in most countries.[10]

- ✓ Uncertainty of whether ADRs occur happen because of medicine or not.
- ✓ Community pharmacy lacking legitimately qualified pharmacist
- ✓ Unavailability of ADR reporting form
- ✓ The reporting process is being tedious.
- ✓ Lack of time
- ✓ Financial issues can be resolved if the steps are taken at governmental level.
- ✓ Having poor knowledge on reporting mechanisms

Imparting fundamental and adequate training and awareness to health care professionals through closest pharmacovigilance centres will improve further the issue of under

reporting in unconstrained framework and result in successful pharmacovigilance programme.

PROTOCOL FOR EFFECTIVE REPORTING

Identification of ADRs

✓ The development of a new symptom is the foremost motive to identify an ADR. In a drugstore, patients frequently look for guidance from the pharmacist to treat various side effects at home. This gives an opportunity for the pharmacist to ask about the patient's manifestations to determine whether they might have been caused by an ADR.

✓ Asking open ended questions concerning the patient's symptoms, instead of quickly giving a treatment suggestion, could reveal an ADR and prevent unnecessary drug therapy or further ADR symptoms.

✓ Laboratory testing can aid in recognizing an ADR. Another order for a serum drug level may make the professional aware whether an ADR caused by drug toxicity or treatment failure is occurring. Monitoring of laboratory parameters can help determine improvement or decline after a change in therapy.

✓ Often, an ADR is detected by noticing sudden, unexpected discontinuation of a drug or a significant dosage increment or decrease. New medication orders can occasionally make the pharmacist alert that an ADR has occurred.

I. What to report?

✓ Life-threatening event or death

✓ Patient hospitalisation

✓ Congenital anomaly

✓ Medically noteworthy event

✓ The inefficiency associated with use of a medical device or drug product.

All suspected drug interactions; all regarded or unknown, serious, non-serious, common or uncommon reaction caused due to use of vaccine or drug must be reported.

II. When to report?

✓ All spontaneous cases ought to be accounted for within 10 days.

✓ All suspected ADR should be reported as soon as possible because over-reporting is always better than under-reporting.

✓ Death event must be accounted as quickly soon as time permits, while all other serious ADR/event needs to report within 7 days only.

✓ All non-serious cases must be reported within 30 days.

✓ Reporting delay may make a major problem.

III. Who can report?

An effective healthcare team is the preferred source of information in PV, for instance:

✓ Health care specialists and providers

✓ Manufacturers of product

✓ Health care centers

IV. How to report?

✓ Duly filled ADR reporting form needs to send to the closest AMC or straight forwardly to the NCC.

✓ Dial toll-free helpline number-1800 180 3024 to report ADRs.

✓ Filled ADR reporting form has to be mailed directly to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com

V. Where to report?

The proposed centres in India are – Peripheral, Regional and Zonal.[11]

✓ **Peripheral PV center**: It acts as primary ADR operation centre. It consists of small clinical centres, private hospitals, dispensaries, nursing home and pharmacies. Regional pharmacovigilance centres or Zonal pharmacovigilance centres are responsible for recognizing and coordinating of ADRs.

✓ **Regional PV center:** Considered as secondary PV Centre. They are situated in medical college having comparatively larger facilities. They are recognized and coordinated by zonal centres. There are 5 such regional centres in India.

✓ **Zonal PV centres:** It's regarded as Tertiary PV Centre. Generally placed in metro city's medical college having attachment of satisfactory facility. It is recognized by CDSCO and operates as first ADR data collection centre. The zonal centre for North and East zone is AIIMS.[11]

PHARMACOVIGILANCE AND THE REPORTING OF ADVERSE DRUG REACTIONS

Pharmacovigilance is the science of collecting, monitoring, assessing and evaluating reports from healthcare professionals and patients on ADRs Pharmacovigilance is important because there is still much to learn about ADRs, their risk factors and epidemiology.[15]

In most countries, the Pharmacovigilance systems developed after the thalidomide disaster in the 1960s where thousands of children were affected with phocomelia as a side effect by birth. The thalidomide tragedy raised several questions about the safety of drugs and raised the challenge of establishing systems to evaluate and make sure the safety of medicines in all countries.[16]

It is voluntary for patients and health professionals to report ADR; however pharmaceutical manufacturers are required to provide ADR reports to the FAERS database whenever they become aware that a reaction has occurred. ADR-monitoring and reporting programs encourage ADR supervision, facilitate documentation and promote reporting of ADRs, monitoring the protection of drug use in high-risk populations, and promote the training of health professionals for potential ADRs.[15]

Because of the absence of proper clinical trials within the pediatric population, drug prescription in children tend to have a high chance of developing unknown or rare adverse drug reactions (ADRs). The spontaneous reporting of suspected ADRs is amajor way to promote reasonable warning signals. Pharmacist's definitely is the chief personnel for the improvement of Pharmacovigilance system.[16]

Generally, physicians aren't very aware of ADR reporting program mainly because they focus more on providing treatment to patient rather than spending time on reporting.[16]

Medical practitioners are the foremost important component of ADR reporting system but every healthcare expert who has the knowledge, attitudes and perceptions about ADR can play their responsibility in reporting ADRs.

ROLE OF PHARMACIST IN ADR REPORTING –THE MEDICINE EXPERT

Pharmacists in health care systems need to improve comprehensive, ongoing programs for tracking and reporting detrimental adverse drug reactions (ADRs). It is the pharmacist's duty and professional commitment to report any suspected ADRs.[13]

In the professional face the practice of pharmacists has reached some distance beyond serving the community other than dispensing of drugs it has become more patient-centric.[15] Pharmacists make a contribution to the drug safety by means of preventing, identifying, documenting, and reporting of ADRs.[15]

Hospital pharmacist's usual practice of going ward rounds and medication reconciliation is one factor that proved to be helpful in handling ADRs. [17-20] Their regular visits to patients enable to work out current problems regarding the drug treatments, the effectiveness of therapy and therefore the presence of ADRs .[21]

The role of the pharmacist in the field of pharmacovigilance fluctuates with different countries but, professionally their responsibility remains the same independent of the jurisdiction.[16]Pharmacist has the capacity of reporting ADRs on their own, although his/her clinical experience may additionally vary with respect to that of a physician .[5]

Pharmacists act as an open-arm to clinical expertise in sharing of knowledge. Pharmacist plays a vital function in developing communication materials like newsletters and different guides through the drug information and poison centres, which can be utilized by distinct professions for disseminating drug alerts and other drug safety information .[22]

Pharmacists can assure a positive environment to the patients by counseling the patient which may help in reducing the number of medication errors, improve patient safety and quality of life.[22-23] In a study conducted out by Mohmoud *et al*., almost 23% of the pharmacists were aware of ADR reporting process and rest 77% had never reported ADRs. Major reason for not reporting ADRs is due to a lack of understanding about the method of reporting.[24]

CONTRIBUTION OF PHARMACIST IN REPORTING ADR:

1. Pharmacist as a reporter of ADR: The prime step in ADR detection is gathering of information. By efficient interaction with patients, taking history interview and through proper ward visit it helps pharmacist in early detection of ADR and other drug-associated problems. Pharmacist is accountable to record any suspicion of drug unexpectedly causing a risk situation for a patient. Pharmacist plays an essential function to ensure safety of medication by identifying and investigating certain patient subgroups with exceptional sensitivities and monitoring the patients prescribed with drugs highly susceptible to cause ADRs.[25-26] The gathered ADRs report with all relevant data are entered into VigiFlow for completeness and dispatched to NCC for further quality review.

2. Pharmacist in ADR assessment: Pharmacist ought to review all suspected ADRs for its nature, probability, severity, identify the comorbidities, past and present illness.[25] Also evaluate the reported ADRs to distinguish amongst suspected ADRs and medicinal drug error, along expand risk reduction strategies and helps to reduce the chance of ADRs through detecting, reporting and assessing suspected ADRs.[27] They play key function in figuring out the probability that the event is drug related, categorize severity, track ADRs and incidence.[28-29] They monitor and document the suspected ADRs and does vital evaluation of drug information for in addition reporting of the suspected ADRs to the NCC-PvPI.

3. Pharmacist in ADR prevention: Pharmacist should keep a record for details taken and monitor patients who are at high risk. They keep the follow up of patients to evaluate the outcome of the reaction, its management and counsel patients while they are discharged. Pharmacists play an indispensable function in educating patient's on numerous aspects of medication use, including safety as many patients are not aware of risk benefit of the drugs they consume.[30-32] Timely conferences and training sessions should be organized for the awareness and betterment of public health.

PRINCIPLES TO BE FOLLOWED TO PREVENT DRUG INDUCED ADVERSE REACTIONS:

✓ First, one should be knowledgeable about the patient's medications (e.g. drug allergy, drug duplication with similar pharmacologic activity).

✓ Second, whilst an additional drug is prescribed, it is important to have a detailed understanding of its pharmacology (to prevent various drug interactions).

✓ Third, one should be familiar about the individualities of the patient himself (e.g., age, concomitant disease, baseline renal and liver function).

✓ Finally, the patient have to be given the fewest medication possible (use only those medications which are absolutely essential).

Pharmacists can make considerable contributions to the objective of improving the efficacy and diminishing the risks of drug therapy. Continuous awareness of the hazards of drug therapy and careful consideration of risk to benefit ratio when using medications are vital.[33] Pharmacists are the health professionals most easily reached to the public. They make sure an accurate delivery of proper products, their professional activities also cover counselling of patients at the time of dispensing of prescription and non-prescription drugs, to patients and the general public, and take part in well-being advancing programme.[19,27]

Pharmacist can easily recognize the problem of public in terms of health and pass on any ADR or other drug alerts to the relevant authority. Globally the reporting of ADR by a pharmacist is not acceptable but in contrast India is one among those countries that widely accepts and promotes ADRs reporting through pharmacist.[34]It is necessary that other healthcare professionals accept pharmacists to detect and control ADR and involve them as a part of the health care sector.[14]

REMAINING VIGILANT FOR ADVERSE DRUG REACTIONS

Ensuring that medicines are utilized safely is fundamental to the role of healthcare professionals. Prescribed medicines have many advantages, but they are also associated with adverse effects that are ‘a pharmacist concern’. Significantly, drug specialists are knowledgeable and aware of ADRs, and consistently consider whether any new side effect a patient is encountering could show an ADR Being vigilant for ADRs requires familiarity with all the medicines a patient is taking, including prescribed medicines, any over-the-counter medicines, and herbal and homeopathic remedies.

Getting some information about herbal remedies is important since some herbal treatments can cause potentially serious ADRs. For e.g.; St John’s Wort which is an effective therapy for depression interacts with a wide range of conventional medicines like anticoagulant,

anticonvulsant, antiretroviral, antidepressant, immunosuppressant, antimicrobial and hypoglycemic drugs, as well as oral contraceptives**.** It is important to know whether patients have a history of idiosyncratic reactions or drug allergies so that the use of drugs known to cause problems can be avoided.

It is likewise essential to be aware of at-risk patient groups, particularly older people, children, patients with renal or liver impairment, and pregnant women. Healthcare professionals should consult appropriate sources of information about medicines, such as the BNF or SPCs, before prescribing or administering any medicines that they are not thoroughly familiar with.

Patients who are taking drugs known to cause predictable dose-related adverse effects should be carefully monitored. For example, established medicines such as diuretic, NSAIDs, anticoagulant and antiplatelet drugs are responsible for a significant burden of drug-induced morbidity and mortality. The risk of some ADRs can be mitigated or eliminated by avoiding the use of such drugs or by ensuring that suitable precautions are taken; for example, in the case of a reaction to NSAIDs, alternative analgesia can be prescribed or the lowest dose possible prescribed for the shortest time necessary.

For patients for whom the drug is essential, the appropriate use of concomitant treatment to protect against ADRs might be needed, such as co-prescribing a proton pump inhibitor with NSAIDs to prevent gastrointestinal bleeding. It is especially important to be alert for ADRs or unexpected events with new medicines. It is essential to ensure that any specific monitoring requirements, such as biochemical testing such as liver function tests, international normalised ratio and blood counts, are carried out on a regular basis.

Patients need clear information about their medicines, how to take them, what side effects they may encounter when taking them and what to do if they experience a harmful effect. Many patients are reluctant to disclose information about ADRs, therefore healthcare professionals especially pharmacists need to look out for and specifically ask about adverse effects when administering medicines. Asking patients about their experience of medicines use and listening to any concerns they have is important in revealing perceived and actual harms to ensure appropriate interventions.[12]

CONCLUSION

Healthcare professionals have a key role in ensuring that medicines are used safely. This requires knowledge and awareness of common ADRs that cause morbidity and mortality. There is still much to learn about ADRs. Nurses and other healthcare professionals must work with patients to optimize their medicines use, are alert to the possibility of ADRs, and suspected reactions reported using the ADR form to identify and reduce harm from medicines. Pharmacists have an important role in medicines optimization, helping patients to improve their quality of life and outcomes from medicines use.

Research in pharmacovigilance will make stronger the clinical pharmacist's role in pouring out clinically valuable information. Educational training programs and workshops must be conducted so that knowledge of ADR reporting and how causality assessment of ADR is done can be improved. This will aid the pharmacists to portray a noticeable role in reporting ADRs and patient safety in the coming future.

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