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Role of Hospital Pharmacists in Reporting Adverse Drug Reactions – A Review

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Abstarct

Adverse drug reactions (ADRs) are one of the leading causes of morbidity and mortality. ADRs account for about 5% of the hospital admissions, though 60% of the ADRs are preventable. Being a medicine expert, the pharmacists in the hospital sectors can play a significant role in detecting, monitoring, and reporting ADRs. With sound knowledge on drug therapy and disease management, they are the preferred group of professionals in ensuring drug and patient safety. Under-reporting of ADRs is a serious problem; and the possible reasons for that include the lack of awareness among healthcare professionals and inadequate patient education. There is a need for proper training to hospital pharmacists on ADR reporting. Implementing good pharmacovigilance (PV) practice in the hospital settings can lead to proper reporting of ADRs. This manuscript reviews the published literature on the consequences and under-reporting of ADRs, importance of PV, and the hospital pharmacists' contributions in drug and patient safety.

Key words

Adverse drug reactions, pharmacist, pharmacovigilance,

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Introduction

World Health Organization (WHO) says ADR as any noxious and unintended reaction(s) of a drug in man, at doses used for the prophylaxis, diagnosis, or therapy [1]. No drug is safe and risk-free. ADRs are threats to patient care and are known safety issues [2, 3]. ADR monitoring and reporting systems started evolving in various countries, mainly in the wake of the Thalidomide tragedy, during the 1960s [4]. WHO has started its International Drug Monitoring (IDM) Programme, in response to this disaster. Since 1978, it has been operating from the Uppsala Monitoring Centre in Sweden. Aimed at improving care and safety of the patients by providing reliable and balanced information for the effective assessment of the risk-benefit profile of medicines, the programme now has 134 participating countries [5]. According to WHO, PV is defined as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem" [6]. Spontaneous reporting of suspected ADRs is the key feature of PV [7]. With round the clock observation of the inpatients, the hospital setting is very favorable in detecting and reporting the signals for ADRs [8]. Under-reporting of ADRs is a cause to concern [9, 10]; and the possible reasons for that include the lack of awareness among healthcare professionals and inadequate patient education [11, 12]. Literature showed that pharmacists and nurses reported ADRs more than the physicians [8]. With sound knowledge on drug therapy and disease management, pharmacists are the preferred lot in ensuring drug and patient safety. In addition to the traditional job functions like dispensing and counseling, hospital pharmacists can play a vital role in ADR reporting [13]. Being an integral part of the healthcare team, hospital pharmacist can substantially contribute to the medicine management and safe use of drugs [14, 15].

Adverse Drug Reactions – A Costly Affair

ADR, being the key safety issue, is the common cause of hospitalization and adds huge costs to the community [16-18]. ADRs account for about 5% of the hospital admissions [19]. It has been estimated that 106,000 hospitalized patients died in 1994, in the United States (US) due to ADRs. Fatal ADRs seemed to be between fourth and sixth leading cause of death in patients [20]. ADRs are one of the main reasons for discontinuation of medication therapies (eg: antiretroviral therapy) [21]. Apart from the negative health impacts, ADRs impose large financial burden on patients. It mainly includes the costs due to increased duration of hospital stay [22]. Large

number of prescriptions, polypharmacy [23-24], irrational prescribing, and lack of proper system to monitoring and detection are considered as the key factors that lead to ADRs. Geriatrics population, with multiple drug therapy for chronic diseases, is more prone to ADR induced hospital admissions [25]. It has been calculated that ADRs add 1.56 to 4 billion US dollar in direct hospital costs per year in the US [26, 27]. Many researches evaluated the direct costs incurred due to ADRs; rather than the total cost [22, 28, 29]. From the financial front, it is necessary to identify the correct balance between the costs and benefits [16]. Table-1 lists the major causes of ADRs.

Pharmacists – The Medicine Expert

Many publications have documented the hospital pharmacists' role in detecting, monitoring, reporting and preventing ADRs, in the inpatient setting. Hospital pharmacists' involvement in the ward rounds and medication reconciliation has proved to be helpful in handling ADRs [30-33]. Their regular visits to patients enables to determine current problems regarding the drug treatments, the effectiveness of therapy and the presence of ADRs [34]. ADR reporting by pharmacists is a crucial part of the drug safety process [35]. More importantly, it is the attitude of the pharmacists towards ADR reporting, that makes the process more successful. A good number of studies across the globe have suggested that the pharmacists possess a more favourable and positive attitude towards reporting ADRs [35-47]. Thanks to a pharmacy based ADR reporting system, the number of ADR reports increased 8-fold through in the United Kingdom (UK) [48] and the ADR reporting by hospital pharmacists significantly enhanced the UK Yellow Card Scheme, the nation's PV programme [49]. Pharmacists' contribution in ADR reporting to contrast media in a radiology department had resulted in greater awareness for treating and preventing ADRs [50]. In September 2002, a popular survey conducted among the pharmacists of participating countries of the WHO IDM programme reported that the number of ADR reports submitted by pharmacists is substantial and the reports are highly valued [51]. Another study reported the involvement of pharmacy students in PV. Even the students' involvement has led to a more considerable rise in the number of ADR reports [52].

Under-reporting and Training Needs

Under-reporting of ADRs is a serious issue. The lack of awareness and knowledge on how to report ADRs have led to poor reporting in the past [37]. It has been reported by pharmacists that ADR reporting was time consuming and disrupted the routine workflow [36]. The work setting, the number of years in practice, and the number of hours worked per week, regular work load, poor confidence in recognizing ADRs, and the fear of breaching patient's confidentiality influenced the reporting practices and attitudes of the pharmacists [38–42]. It has been suggested earlier that a computer supported programme can result in a better ADR monitoring [39]. Many countries have come up with the surveillance systems to support proper reporting of the ADRs. The US' MedWatch and the UK's Yellow Card Scheme have gained more significance over the years. A number of developing nations have also adopted their own drug safety initiatives. In India, the Central Drugs Standard Control Organization has started the '*PV programme of India*' in 2004 [53]. ADR under-reporting could be decreased through educational interventions [54]. To enhance drug safety, the awareness and attitude towards ADR reporting among pharmacists have to be improved [36]. Hospital pharmacists should be taught with the value of ADR reporting which would alter their attitude towards a social responsibility [35, 54]. Providing customized trainings and educational sessions would help improve ADR reporting. It has also been suggested that a hospital written policy on PV would certainly add value in the process of detecting and reporting ADRs [42].

Table 1: Various Causes of ADRs [55]

S. No.	Causes
1.	Incorrect diagnosis of the medical condition(s)
2.	Prescribing wrong drug(s) or wrong dosage of the right drug(s)
3.	Undetected medical, genetic or allergic condition(s)
4.	Self-medication with prescription drug(s)
5.	Noncompliance to instructions for taking the drug(s)
6.	Drug-drug and drug-food interaction(s)
7.	Using sub-standard medication(s)
8.	Using counterfeit medicines with no or wrong active ingredient(s)

Discussion

ADRs are significant health problems for many years. ADR related costs, such as hospitalization, surgery and lost productivity, may exceed the cost of the medications, in some countries. About 60% of the ADRs are preventable [55]. Inappropriate medication prescribing, discrepancies between prescribed and actual regimens, poor adherence, and inadequate surveillance for adverse effects are considered as common reasons for ADRs [56-58]. Pharmacists' knowledge and exposure in therapeutics makes them a favourable choice for PV [59]. In order to decrease the ADR costs, it is essential to adopt preventive programmes, which can include educational training sessions; identifying risks and signals, implementing good PV practice, clinical and laboratory monitoring for ADRs, proper understanding of the patients' medical history including allergies and drug abuses, promoting pharmacoeconomic studies, avoiding medication errors, and also promoting co-operation between the key healthcare stake holders like physicians, pharmacists, and nurses etc [22].

Conclusion

We reviewed the documented proof of hospital pharmacists' contributions in reporting of the ADRs. The most significant studies reported that the pharmacists from various countries showed positive approach towards ADR reporting. This attitude should be improved more among the hospital pharmacists in the developing countries. Having gained comprehensive knowledge on physiology, pathology, and pharmacology, pharmacists have great potential to become the key player in ensuring drug and patient safety. Proper training and establishing proper written policy or standard operating procedure will ensure reporting of ADRs with more quality.

Contributions

All authors contributed equally to this manuscript.

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