



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

Sharmila Nirojini P ^{1*}, Rama Rao Nadendla ¹, Valli Manalan B ¹, Habeeb Ibrahim AR ²

¹ Chalapathi Institute of Pharmaceutical Sciences, Guntur, India.

² Accenture Services Ltd., Bangalore, India.

Citation: Sharmila Nirojini P, Rama Rao Nadendla, Valli Manalan B, Habeeb Ibrahim AR. **Role of Hospital Pharmacists in Reporting Adverse Drug Reactions – A Review.** Archives of Pharmacy Practice. 2012; 3(3)pp197-201.

Abstract

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,

Manuscript History

Article Received on: 23rd Mar, 2012

Revised on: 10th June 2012

Approved for Publication: 15th June 2012

Corresponding Author

Sharmila Nirojini P., M.Pharm., Lecturer,
Chalapathi College of Pharmaceutical Sciences,
Chalapathi Nagar, LAM, Guntur, Andhra Pradesh, Pin: 522 034,
India. Phone: 0091 9642526199

Email: niro_shar@yahoo.co.in

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 pharmaco-economic studies, avoiding medication errors, and also promoting co-operation between the key healthcare stakeholders 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.

References

- World Health Organization. International Drug Monitoring: The Role of the Hospital. Geneva, Switzerland: World Health Organization; 1966. *Technical Report Series No. 425*. Available from: [http://whqlibdoc.who.int/trs/WHO TRS 425.pdf](http://whqlibdoc.who.int/trs/WHO_TRS_425.pdf) [Last accessed: 20 Jan 2012]
- Murray MD, Ritchey ME, Wu J, Tu W. Effect of a pharmacist on adverse drug events and medication errors in outpatients with cardiovascular disease. *Arch Intern Med*. 2009 Apr 27;169(8):757-63.
- Johnson JA, Bootman JL. Drug-related morbidity and mortality: a cost-of illness model. *Arch Intern Med*. 1995;155:1949-1956.
- D'Arcy PF, Griffin JP. Thalidomide revisited. *Adverse Drug React Toxicol Rev*. 1994;13:65-76
- World Health Organization – Uppsala Monitoring Centre [Internet]. Sweden. Available from: <http://www.who-umc.org/> [Last accessed: 20 Jan 2012]
- World Health Organization – Programmes and Projects – Medicine – Pharmacovigilance [Internet] Geneva. Available from: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/ [Last accessed: 20 Jan 2012]
- Rawlins MD. Pharmacovigilance: paradise lost, regained or postponed? *J R Coll Phys Lond* 1995;29:41–9.
- Pushkin R, Frassetto L, Tsourounis C, Segal ES, et al. Improving the reporting of adverse drug reactions in the hospital setting. *Postgrad Med*. 2010 Nov;122(6):154-64.
- Alvarez-Requejo A, Carvajal A, Bégau B, Moride Y, Vega T, et al. Under-reporting of adverse drug reactions. Estimate based on a spontaneous reporting scheme and a sentinel system. *Eur J Clin Pharmacol*. 1998 Aug;54(6):483-8.
- Y. Moride, F. Haramburu, A. A. Requejo, B. Bégau. Under-reporting of adverse drug reactions in general practice. *Br J Clin Pharmacol*. 1997 Feb;43(2):177–181.
- Alibhai SM, Han RK, Naglie G. Medication education of acutely hospitalized older patients. *J Gen Intern Med*. 1999;14:610-616.
- Calkins DR, Davis RB, Reiley P, Phillips RS, et al. Patient-physician communication at hospital discharge and patients' understanding of the postdischarge treatment plan. *Arch Intern Med*. 1997;157:1026-1030.
- van Grootheest AC, de Jong-van den Berg LT. The role of hospital and community pharmacists in pharmacovigilance. *Res Social Adm Pharm*. 2005 Mar;1(1):126-33.
- Nishihara S. Pharmacists contribute to the safety of medicines. *Yakugaku Zasshi*. 2011;131(6):865-9.
- Dos Santos DB, Coelho HL. Adverse drug reactions in hospitalized children in Fortaleza, Brazil. *Pharmacoepidemiol Drug Saf*. 2005; 15:635-40.
- Lundkvist J, Jönsson B. Pharmacoeconomics of adverse drug reactions. *Fundam Clin Pharmacol* 2004 Jun;18(3):275-80.
- Manasse HR Jr. Medication use in an imperfect world: drug misadventuring as an issue of public policy, part 1. *Am J Hosp Pharm*. 1989;46:929-944.
- Manasse HR Jr. Medication use in an imperfect world: drug misadventuring as an issue of public policy, part 2. *Am J Hosp Pharm*. 1989;46:1141-1152.
- Einarson TR. Drug related hospital admissions. *Ann Pharmacother*. 1993;27:832–839
- Jason Lazarou, Bruce H. Pomeranz, Paul N. Corey, PhD Incidence of Adverse Drug Reactions in Hospitalized Patients A Meta-analysis of Prospective Studies *JAMA*. 1998;279(15):1200-1205.
- Morillo Verdugo R, Fernández Lisón LC, Huertas Fernández MJ, Martín Conde MT et al [The role of the hospital pharmacist in the prevention, treatment and management of the side effects associated with antiretroviral treatment]. [Article in Spanish] *Farm Hosp*. 2010 Sep-Oct;34(5):237-50.
- Gautier S, Bachelet H, Bordet R, Caron J. The cost of adverse drug reactions. *Expert Opin Pharmacother*. 2003 Mar;4(3):319-26.
- Rollason V, Vogt N. Reduction of polypharmacy in the elderly: a systematic review of the role of the pharmacist. *Drugs Aging*. 2003;20(11):817-32.
- Beers MH, Dang J, Hasegawa J, Tamai IY. Influence of hospitalization on drug therapy in the elderly. *J Am Geriatr Soc*. 1989;37:679-683.
- Kongkaew C, Noyce PR, Ashcroft DM. Hospital admissions associated with adverse drug reactions: a systematic review of prospective observational studies. *Ann Pharmacother*. 2008 Jul;42(7):1017-25. *Epub 2008 Jul 1*.
- Bates DW, Spell N, Cullen DJ, Burdick E, et al. The costs of adverse drug events in hospitalized patients. *JAMA*. 1997;277:307-311.
- Classen DC, Pestonik SL, Evans RS, Lloyd JF, et al. Adverse drug events in hospitalized patients: excess length of stay, extra costs, and attributable mortality. *JAMA*. 1997;277:301-306.

28. Suh DC, Woodall BS, Shin SK, Hermes-De Sanitis ER. Clinical and economic impact of adverse drug reactions in hospitalized patients. *Ann Pharmacother.* 2000; 34:1373-9.
29. Dormann H, Neubert A, Criegee-Rieck M, Egger T, et al. Readmissions and adverse drug reactions in internal medicine: the economic impact. *J Intern Med.* 2004; 255:653-63.
30. Ratz Y, Shafir I, Berkovitch S, Sharristh M, et al. The importance of the pharmacist in reporting adverse drug reactions in the emergency department. *J Clin Pharmacol.* 2010 Oct;50(10):1217-21. Epub 2010 Apr 23.
31. Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL, et al. Clinical pharmacists and inpatient medical care: a systematic review. *Arch Intern Med.* 2006; 166:955-64.
32. Leape LL, Cullen DJ, Clapp MD, Burdick E, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA.* 1999; 282:267-70.
33. J. I. Shulman, S. Shulman, A. P. Haines. The prevention of adverse drug reactions—a potential role for pharmacists in the primary care team? *J R Coll Gen Pract.* 1981 July; 31(228): 429-434.
34. Ellenor GL, Frisk PA. Pharmacist impact on drug use in an institution for the mentally retarded. *Am J Hosp Pharm.* 1977 Jun;34(6):604-8.
35. Gavaza P, Brown CM, Lawson KA, Rascati KL, et al. Examination of pharmacists' intention to report serious adverse drug events (ADEs) to the FDA using the theory of planned behavior. *Res Social Adm Pharm.* 2010 Nov 3.
36. Gavaza P, Brown CM, Lawson KA, Rascati KL, et al. Influence of attitudes on pharmacists' intention to report serious adverse drug events to the Food and Drug Administration. *Br J Clin Pharmacol.* 2011 Jul;72(1):143-52.
37. Lee KK, Chan TY, Raymond K, Critchley JA. Pharmacists' attitudes toward adverse drug reaction reporting in Hong Kong. *Ann Pharmacother.* 1994 Dec;28(12):1400-3.
38. Generali JA, Danish MA, Rosenbaum SE. Knowledge of and attitudes about adverse drug reaction reporting among Rhode Island pharmacists. *Ann Pharmacother.* 1995 Apr;29(4):365-9.
39. Emerson A, Martin RM, Tomlin M, Mann RD. Prospective cohort study of adverse events monitored by hospital pharmacists. Hospital Adverse Event Monitoring Study (HAEMS) Group. *Pharmacoepidemiol Drug Saf.* 2001 Mar-Apr;10(2):95-103.
40. Jarernsiripornkul N, Krska J, Pongmanachai M, Nasritha N. Hospital pharmacists' activities and attitudes regarding the Thai safety monitoring program for new drugs. *Pharmacoepidemiol Drug Saf.* 2009 Sep;18(9):837-41.
41. Su C, Ji H, Su Y. Hospital pharmacists' knowledge and opinions regarding adverse drug reaction reporting in Northern China. *Pharmacoepidemiol Drug Saf.* 2010 Mar;19(3):217-22.
42. Sweis D, Wong IC. A survey on factors that could affect adverse drug reaction reporting according to hospital pharmacists in Great Britain. *Drug Saf.* 2000 Aug;23(2):165-72.
43. Christopher F Green, David R Mottram, Philip H Rowe, Munir Pirmohamed. Attitudes and knowledge of hospital pharmacists to adverse drug reaction reporting. *Br J Clin Pharmacol.* 2001 January; 51(1): 81-86.
44. Belton KJ, Lewis SC, Payne S, Rawlins MD. Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. *Br J Clin Pharmacol.* 1995;39:223-226.
45. Bateman DN, Sanders GLS, Rawlins MD. Attitudes to adverse drug reaction reporting in the Northern Region. *Br J Clin Pharmacol.* 1992;34:421-426.
46. Belton K. The European Pharmacovigilance Research Group. Attitude survey of adverse drug-reaction reporting by health care professionals across the European Union. *Eur J Clin Pharmacol.* 1997;52:423-427.
47. Green CF, Mottram DR, Rowe P, Brown AM. Attitudes of hospital pharmacists to adverse drug reaction reporting: a qualitative survey. *Int J Pharmacy Prac.* 1999;7:247-255.
48. Winstanley PA, Irvin LE, Smith JC, Orme ML, Breckenridge AM. Adverse drug reactions: a hospital pharmacy-based reporting scheme. *Br J Clin Pharmacol.* 1989 Jul;28(1):113-6.
49. Anne Leea, D Nicholas Bateman, Clive Edwards, James M Smith, Michael D Rawlins. Reporting of adverse drug reactions by hospital pharmacists: pilot scheme. *BMJ* 315 : 519 (Published 30 August 1997)
50. Damiani DR, Swanson DP. Pharmacist-managed monitoring of adverse reactions to contrast media. *Am J Hosp Pharm.* 1994 Feb 1;51(3):358-63.
51. van Grootheest, K., Olsson, S., Couper, M. and de Jong-van den Berg, L. (2004), Pharmacists' role in reporting adverse drug reactions in an international perspective. *Pharmacoepidemiology and Drug Safety*, 13: 457-464.
52. Karyn M. Sullivan and Linda M. Spooner Adverse-drug-reaction reporting by pharmacy students in a teaching hospital. *American Journal of Health-System Pharmacy*, Vol. 65, Issue 12, 1177-1179
53. Central Drug Standard Control Organization – Pharmacovigilance Programme in India [Internet]. New Delhi. Available from: <http://cdsco.nic.in/pharmacovigilance.htm> [Last accessed: 20 Jan 2012]
54. Herdeiro MT, Figueiras A, Polónia J, Gestal-Otero JJ. Influence of pharmacists' attitudes on adverse drug reaction reporting: a case-control study in Portugal. *Drug Saf.* 2006;29(4):331-40.
55. World Health Organization – Medicines: Safety of Medicines – adverse drug reactions. Fact sheet no. 293. Updated Oct 2008 [Internet] Geneva. Available from <http://www.who.int/mediacentre/factsheets/fs293/en/index.html> [Last accessed: 20 Jan 2012]

56. LaPointe NM, Jollis JG. Medication errors in hospitalized cardiovascular patients. *Arch Intern Med.* 2003;163:1461-1466.
57. Omori DM, Potyk RP, Kroenke K. The adverse effects of hospitalization on drug regimens. *Arch Intern Med.* 1991;151:1562-1564.
58. Cornish PL, Knowles SR, Marchesano R, Tam V, et al. Unintended medication discrepancies at the time of hospital admission. *Arch Intern Med.* 2005;165:424-429.
59. Evans RS, Pestotnik SL, Classen DC, Bass SB et al. Development of a computerized adverse drug event monitor. *Proc Annu Symp Comput Appl Med Care.* 1991; 23-7.

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.