MEDICAL ERRORS CHALLENGES FOR THE HEALTH PROFESSIONALS: NEED OF PHARMACOVIGILANCE TO PREVENT

Das B P*, Rauniar G P*, B`hattacharya S K*

* BP Koirala Institute of Health Science, Dharan, Nepal.

ABSTRACT

The incidence of different aspects of iatrogenic problems due to drugs is Adverse Events (AEs) 3.7%, Adverse Drugs Events (ADEs) 2.4-6.5%, Adverse Drugs Reactions (ADRs) is 6.7%. Negligence in serious ADEs and death is 34% and 51% respectively, preventable ADEs is 28-50%. Medication Errors (MEs) occur most often in prescribing (29-56%). The most common cause of MEs is lack of knowledge about the drug (29%) and the patient about 18%. MEs result malpractice claims in 13-25% of cases which occur due to mistakes and slips of action & lapses of memory. The MEs can be prevented by establishing effective Pharmacovigilance control center, which frequently gives proper guidance to the prescribers. Use of computerized decision for prescription writing, effective communication with patient, families, pharmacists and nurses and continuing medical education on information of new drugs and new information on current drugs can be effective tolls to prevent the errors.

Key Words: Medical errors, Pharmacovigilance, Malpractice, Adverse effects.

INTRODUCTION

Iatrogenic injuries is not only the medical problem but have moved from the realm of text book chapters to court room discussion.[1] For decades, the medical profession denounced malpractice suits on the grounds that few quality problems existed. However, recent international data suggests that failure rate in medical profession is close to 1%,[2] which is substantially higher that is tolerated in industry. The above quote of WE Deming, Guru of total quality management, points out that even 99.9% may not be good enough. As drug therapy is the most common type of therapeutic intervention made, there has been increasing focus on Adverse Drug Effects (ADEs) due to medication prescribing errors. An editorial in Lancent considered Medical Errors (MEs) worse than a crime.[3] Medical Error (ME) that produce adverse effects from the basis of a sizeable proportion of claims for negligence.[4] However, many of these are potentially preventable. This article provides and overview of current literature.

Address for correspondence :
Dr. B. P. Das
BP Koirala Institute of Health Sciences, Dharan, Nepal
Email: bpdas2000@yahoo.com

Received Date : *17th Jun, 2005*
Accepted Date : *12th Apr, 2006*

The main objective of writing this review article is to present the strengths and weakness of current work in drug safety, with regard to the benefit to the individual patient and also from the point of view of the prescribing doctor, who most be a knowledgeable partner with the patient in making decisions about therapy.

Definition of common iatrogenic complications due to drugs

Adverse Event (AE)

Refers to "a definable injury caused at least in part by medical management". The injury must have prolonged the hospital stay or caused disability at the time of discharge or both.[5,6]

Adverse Drug Reactions (ADRs)

Only includes drug usage, which is in recommended dosage and is appropriate.

Adverse Drug Effects (ADEs)

Any injury resulting from medical intervention related to drug, which leads to prolonged hospital stay or causes disability at3 the time of discharge or both.[5,6]

Medication Error (MEs)

A failure in the drug treatment process that leads to or has the potential to lead to, harm to the patient.

METHODOLOGY

We have reviewed the medical errors globally by taking fact and figures from published articles. This review articles are reviewed in following headings. The data from developing country including Nepal is not sufficiently available as Pharmacovigilance system is not established.

Incidence of medication errors and their complications

In large hospital- based studies conducted by division of general medicine, Brigham and Women's hospital, Boston found incidence of AEs was 3.7%.[5] The leading cause of medical injury was use of drugs, accounting for 19.4% of these injuries and therapeutic mishap occurred in 7.5%. ADE rates vary from 2.4 to 6.5 per 100 admissions.[8,9] A meta-analysis of 39 hospital bedded prospective studies, covering 32 years revealed a 6.7% incidence of serous and fatal ADRS, and a 0.32% death rate.[7] In a outpatient study by revision of general medicine, Beith Isarel Desconess Medical Center, Boston, found 18% patient had a drug related complication.[10]

In Harvard Medical Practice study, ADEs and therapeutic mishap caused serious disability in 14% and in 35% respectively.[5] Bates at al found that 1% of ADEs was fatal, 12% life-threatening, 30% serious and 57% significant.[8] The drugs commonly involved in ADEs are antimicrobial, Cardio Vascular System (CVS), Gastrointestinal (GI), non-narcotic analgesic, anticoagulant, anti-diabetic, sedative, antineoplastic, antihypertensive and anticonvulsant.[6,8]

In the USA annually, AE are responsible for 180,000 deaths, the equivalent of three Jumbo-Jet crashes every 2 days.[2] ADRs are the fourth most common cause of death in USA accounting for more than 100,000 deaths per year.[7] in India, the extrapolated number of deaths due to AE would be around 700,000 and due to ADE would be approximately 400,000.

Medical negligence and malpractice claims

Negligent AE is an injury caused by the failure to meet standards of an average physician or institution.[11] The study conducted in non-psychiatric hospital in New York State in 1984 reviewed 30,121 randomly selected records in which negligence was reported in 18% to 30.9% of ADEs[5,6] and in 77% of therapeutic mishaps.[5] Unfortunately, negligence was more frequent in patients who had more severe events. About 28-50% of life threatening ADEs are preventable[8,9] and serious ADEs are preventable in 42% reported in a study of Brigham and Women's Hospital, Boston USA.[8] Many of these may be considered negligent by independent medial or non-medical arbiters.

Economic Impact of Drug- Related problems

Studies from USA show that ADEs prolong hospital stay by 1.7-2.2 days and increase in cost by US$2013-2595.[9,12] For preventable ADEs, the figures are 4.6 days and US$4685[10] and for serious ADEs, the figures are 3.6 days and US$3634.[12] The attributable cost for various types of

ADEs in US$ was fever 9022, bleeding 6702, diarrhea 4631, cardiac arrhythmias 4410, hypertension 3563, confusion 2232, rash 1800, renal failure 1300 and nausea vomiting 700.[12]

Malpractice litigation is intended in part to promote better quality care by fixing economic suctions on those to provide standard care that leads to injuries. Many medical injuries caused by the negligence of a physician, all of which are theoretically compensable under malpractice law, do not result in claims.[13] In western countries many patients may receive adequate health or disability insurance benefits and may not wish to spoil long standing doctor-patient relationship. Others may regard their injuries as minor consider the small chance of success not worth the cost or find lawyers repugnant. Many patients may not recognize negligent care. For each malpractice claim, 10 injuries were caused by negligent care. Malpractice claims /discharge in New York State was 0.13% and a ratio of negligence to claims of 7.6 to 1.[15] The UK Medical Defense Union has found that 25% of the 790 claims settled were directly related to errors in prescribing, monitoring, or administering medicines.[4] In a large insurer's study, injuries due to drugs were the most frequent cause of procedure related claim.[14]

The patients with high income are more likely to file malpractice claims. For permanent disability, the average settlement was over US$ 200,000 and for negligent AE over US$ 66,000.[13] The compensation for MEs varied depending on the severity of the patient's disability.[16] In one US study, 7% of million dollar claims were due to MEs.[17] In India, the compensation has been in the range of Rs.300,000. In some cases, there were substantial settlements only because the physicians in question would have made poor witnesses. Such type of data is not available in Nepal.

Common causes of MEs

Errors resulting in preventable ADE occurred most often in prescribing 39-56% (wrong dose, wrong choice, known allergy, wrong frequency, drug-drug related interaction). Amongst prescriptions the common errors were inadequate follow up (45%), wrong dose or method of use (38-42%), overdose (16%), avoidable delay in treatment (14%), decline in renal/hepatic function requiring alteration (14%), known allergy (12%), wrong route (2%), and physician practicing outside area of expertise 5%. The most common cause of MEs were lack of knowledge about the drug 29% (dose, fern, frequency, route of administration, error in the choice) and lack of information about the patient 18%.

In India, the reported incidence of ADR in hospital patients varies from 4.25%.[19] Malhotra et al reported that 5.9% of all visits to the medical emergency department were drug-related.[20] ADRs accounted fro 45% of all ADEs of all ADE related visits 52% acid of all ADE related admissions 55% were considered preventable. In a study of over 3500 prescriptions, the use of drug was unnecessary in 47% irrational in 19% and hazardous in 11%.[21] Voluntary consumer action Network, in a recent survey of 200 prescriptions, confirmed irrational drug use and has warned that doctors fond to be mis-prescribing would be sued in consumer courts for medical negligence.[22] Unless the Indian doctor uses sources of drug information, independent of pharmaceutical company promotional messages and regularly updates himself through continuing medical education programs.

Pharmacovigilance and its role

The emerging threat of infections, neurodegenerative and host of other disease has stimulated a tremendous pace in drug development. The interesting feature of this decade has been an increasing number of new drug approvals. Speedy fast tract approvals are often criticized for the fact that safety gets compromised. The recent withdrawal of a member of drug has, therefore, been a cause for concern. Reporting of adverse event forms the basis for assessing the safety and tolerability profile of any compound. Any clinical event during the course of treatment can be attributed to the drug. That the event is certainly due to the drug in question is based on the skills of the clinician, past experiences and most importantly, the existence of other plausible explanations.[24]

As the potential hazards of drug therapy are well recognized. No drug is absolutely safe even when prescribed in therapeutic doses. Pharmacovigilance aims at the detection,

assessment and prevention of adverse effects and other problems resulting from use of medicine.[25]

The primary function of pharmacovigilance is the provision of early warning (signals) with regards to previously unknown affects of medicines.[25]

In developing countries, there is a woeful dearth of ADR monitoring and reporting of data. This scarcity of reports can be attributed to:

1. Paucity of data
2. Pattern of drug usage
3. Alternative system of medicine
4. Large number of patients and
5. Inadequate number of doctors.[25]

Much time, effort and money is spent on drug safety, both before and after marketing. It is clear that common and in some cases obvious reactions may not be detected until a drug is used after it is launched. The proposed reasons for this include the following:[26]

- Animal toxicology is often not a good predictor of effects in humans.
- Before marketing, human exposure is such only events with frequencies in the 'per thousand' range or higher are likely to be detected.
- Even detected events will be incompletely described and understood, since they are very few.
- Particularly susceptible patients are unlikely to be included in pre-marketing studies and the effects of inter current disease or medications are poorly assessed.

Pharmacovigilance is concerned with the development of scientific regulation in the area of drug safety. There is a great deal of activity in academia, regulatory bodies and the pharmaceutical industry, focused on drug safety as each of these interest groups sees the issues. In the end, however all of this effort and the costs incurred, must result in tangible benefits to patients and health care practice.[23]

Some important suggestion to prevent MEs

Several suggestions are made for reducing MEs. Leap[2] suggests that many health care delivery systems, especially in hospitals, could be redesigned to significantly reduce the likelihood of error. Some obvious ways are:

1. Reduced reliance on memory by using checklists, protocols and computerized decision aids for prescriptions writing.
2. Improved information access with availability of computerized medical record at bedside.
3. Error proofing- use of forcing functions in computer programs so that a physician can not enter an overdose or prescribe a medication to which the patient is allergic.
4. Standardization of drug doses and times of administration, of information displays, equipment and supplies location in hospitals.
5. Training of doctors, nursing and other staff in safe practice.

Advice to individual doctors

The published articles from developed and developing countries are reporting prescribing errors. The study conducted in Bahrain[26] showed preventable errors. Similarly the prescribing errors are seen in study conducted in India and Nepal.[27,28,29] The global study showed lot of medical errors while prescribing needs to consider these facts seriously.

1. Prescribe legibly: Physician's prescriptions are often illegible and have led to MEs and litigation.
2. MEs occur due to mistakes (knowledge based and rule-based errors) and slips of action and lapses of memory.3 It interrupted during prescribing, review the process from beginning, then complete.
3. One should be very careful to write route, dose, duration and frequency.
4. Review basic patient characteristics such as age, weight, renal function etc and adjust therapy accordingly. Be aware of high- risk situations e.g. elderly and patient on multiple drugs.
5. Review basic drugs- related information from approved pharmaceutical leaflet (PL) or standard text book.
6. Use minimum drugs in lowest effective dose.
7. Avoid use of a drug for unproved unlabelled indications especially where risk of drug use is higher than

8. Communicated effectively when prescriptions are questioned by patients, families, pharmacists and nurses.
9. Please read up to date information prior to prescribing any unfamiliar drug.

CONCLUSION

As there is no strong pharmacovigilance system in developing countries, the sufficient data are not available. Therefore, to avoid potential lawsuits, the physician should be aware of how precarious managing patients are we must remember that "there are no biologically safe drugs; there are only safe physicians".

REFERENCES

1. Wein Traub MI: Medicolegal aspects of iatrogenic injuries: Neurological clinics of North America 1998;16:217-27.
2. Leap LL. Error in Medicine: JNMA 1994;272;:1851-7
3. Ferner RE, Aronson JK: Medication errors worse than a crime. Lancet 2000;355:947-8.
4. Editorial zeroing in on medication errors. Lancet 1997;349:369.
5. Brennon TA, Leap LL, Loird NM et al. Incidence of adverse events and negligence in hospital patient- results of Harvard Practice Study I: N Engl. J Med. 1991;324:370-6.
6. Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR et al: The nature of adverse events in hospitalized patients. Results of Harvard practice study II: N Engl. J Med. 1991;324:377-84.
7. Lozarou J, Pomeranz BH, Corey PN. Incidence of adverse drugs reaction sin hospitalized patients. A meta-analysis of prospective studies. JNMA 1998;279:1200-5.
8. Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD et al. Incidence of adverse drug events and potential adverse drug events: Implications for preventions. JNMA 1995;274:29-34.
9. Classen DC, Pestotnilc SL, Evans RS, Lloyd JF, Burke JP. Adverse drug events in hospitalized patients: excess length if stay, extra costs and attributable mortality JNMA 1997;277:301-6.
10. Weingart SN, Wilson McL, Gibbered RW, Harrison B. Epidemiology of medical error BMJ 2000;320:774-7.
11. Hiatt HH, Barnes BA, Brennan TA, Laird NM, Lawthers AG, Leape LL et al. A study of medical injury and medical practice. N Eng J Med. 1989;321:480-4.
12. Bates DW, Spell N, Cullen DJ, Burdick E, Laird N et al. The costs of adverse drug events in hospitalized patients. JNMA 1997;277:307-11.
13. Brennan TA, Sox CM, Burstin HR. Relation between negligent adverse events and outcomes of medical practice litigation. N Engl. J Med. 1996;335:1963-7.
14. Localio AR, Lawthers AG, Bernnan TA, Laird NM, Herbert LE et al. Relation between malpractice claims and adverse events due to negligence. Results of Harvard practice study III N Eng J Med 1991.
15. Leapse LL, Bates DW, Cullen DJ, Cooper J, Demonaco JH et al. Systems analysis of adverse drug events JNMA 1995;274:35-43.
16. Nelson - Jones R, Burton F. Medicine Negligence case Law format publishing London 1990;202-230.
17. Sites RL. 11 years of million dollar malpractice claims in Ohio J Health Care Risk management 1994;14:17-25.
18. Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing JNMA 1997;277:312-7.
19. Vaidy AD. Adverse drugs reactions- A perspective for clinicians in India. In Ahuja MMS Ed. Progress in Clinical Medicine in India series 5, 1st Ed New Delhi Arnold Heinemann 1980;819-59.
20. Malhotra S, Jain S, Pandhi P. Drug related visits to the medical emergency department a prospective study from India. Int J Clin pharmacol Ther 2001;39:12-8.
21. Phadke AR. The quality of prescribing in an Indian district. Nat

Med J Ind 1996;9:60-5.

22. India's consumer groups call for more rational prescribing BMJ 1996;312:76.

23. Edward I. Who cares about Pharmacovigilance? Eur J Clin Pharmacol 1997;53:83-88.

24. Editorial Letter. National Pharmacovigilance Centre. Department of Pharmacology. AIIMS, New Delhi 1999;1:1.

25. Editorial. Newsletter National Pharmacovigilance centre. Department of Pharmacology. AIIMS, New Delhi 2000;2:1.

26. AL Khaja KAJ, AL- Ansari TM, Sequeira RP. An evaluation of prescribing errors in primary care in Bahrain. International Journal of Clinical Pharmacology and Therapeutics. 2005;43(6);294-301.

27. Shishyla MV, Krishnamurthy Mahesh, Naga Rani MA. Prescription audit in an Indian hospital setting using the DDD (Defined Daily Dos) concept. Indian Journal of Pharmacology. 1994;26:23-28 .

28. Bajracharya S, Pandey S, Shakya YL. Drug prescribing pattern and disease pattern in KMC Duwakot Health Center. Kathmandu University Medical Journal 2994;2:35-42

29. Das BP, Naga Rani MA, Rauniar GP, Sangraula H. How cost effective is the treatment? Are prescribers concerned? JNMA 2003;42:86-88.

