Challenges for the Detection of Adverse Drug Reactions in Resource Poor Settings: Review

Solomon Mequanente Abay

Department of Pharmacology, Faculty of Medicine, Addis Ababa University
P O Box 55151, Addis Ababa, Ethiopia;. Email: solomonabay@gmail.com

Summary

Adverse drug reaction (ADR) detection tasks started from clinical trial and it is be a continuous process while patients are involved in therapeutic managements. Practitioners in developing countries, nevertheless, encounter many challenges in the detection of ADR. Hence this paper will review the possible challenges in the detection of ADR in resource poor settings in an attempt to forward possible solutions.

Keywords: ADR Detection, Developing Country, Resource Poor Setting, Challenge.

Introduction

ADR represent an important public health problem. Despite efforts to reduce the incidence of medication-related adverse events, morbidity and mortality from drug-induced disease continue to be unacceptably high. Furthermore, methods for ADR detection, evaluation, and monitoring remain inadequate. Although some ADRs are idiosyncratic and unpredictable, others can be anticipated based on knowledge of a medication's clinical pharmacology. In fact, an estimated 30–60% of ADRs may be preventable (1).

There are several reasons for not reporting ADRs. Among the most important ones is the fact that the reaction is already well known. Even if the reaction is fatal, many physicians may abstain from reporting, for example a fatal cerebral haemorrhage due to anticoagulants. Other factors, responsible for the high degree of under-reporting, are a lack of time, giving priority to other issues in one's daily activities and forgetfulness to report (2, 3, 4). Under reporting may not be the only reason for the reduction of measuring the level of ADR but inability of detection of the ADR from adverse events.

Case reports are among the most important tools for observational research in addition to the information obtained during clinical trial (5). In the case of phocomelia due to thalidomide, for instance, recognition should have been easy but because of the unfamiliarity with drug safety problems at that time it took several years to identify a causal relation (6).

When an adverse effect is non-specific and has an appreciable background incidence, detection is more difficult. Similarly, it may be difficult to detect an adverse effect that is indistinguishable from the disease being treated—for example, arrhythmia as an adverse effect of antiarrhythmics. Such adverse effects may therefore remain unnoticed.

Adverse reactions can result from the use of drugs, diagnostic agents, biologicals (including vaccines), nutrients, fluids, electrolytes, and complementary or alternative products. Adverse effects may be attributable to the parent compound, a metabolite, a pharmaceutical excipient, or even a component of the drug delivery system (1).

ADR detection tasks started from clinical trial and it is a continuous process while patients are involved in therapeutic managements. Practitioners in developing countries, nevertheless, encounter challenges in the detection of ADR. Hence this paper will review the possible challenges in the detection of ADR in resource poor settings. The reviewer looks the challenges from the practitioner, patient and system point of view.

Practitioners Competency

Adverse effects cannot be detected without astute professional observers (5). This can be ensured with the proper training of students who potential practitioners in the detection of ADR. To the present time, the medical and nursing program curriculum in developing country did not give attention to the diagnosis of iatrogenic disease, ADR in general. As a result clinicians involved in delivering health care might not be involved with their full capacity in detection of their patients, who are developing ADR. Students need to be familiar with ADR programs via the college curriculum. Through incorporation of ADR detection as part of pre-service training can improve practitioners' competency.

Our research team on the ADR revealed that about 26 % of health professionals did not encounter patients with ADR because they did not able to diagnose ADR from the disease progression (4). Strategies are, therefore, necessary to improve the competency of practitioners. In fact this needs the assistance of clinical laboratory services in detection of ADR.

From previous study, a few practitioners [9%] who did not encounter patients with ADR have wrong attitude on drug effect (4). They replied that marketed drugs are safe and the ADR is not that much need monitoring. This gap raises the issue of effort not only on skill but attitude on ADR detection.

Patients

ADRs are sometimes not recognized and often go unreported. In fact, the principal limitation of ADR detection methods is the lack of awareness of what constitutes an ADR. Most ADRs are brought to medical attention by subjective reports and patient complaints (1). Patients take a part in ADR detection. In developing country most patients might not complain and associate the adverse event.

This can be one challenge for the physician not to take attention to ADR. The patient education level and low physician/nurse/pharmacist to patient ratio might be the basic reason why patients do not complain about the untoward effects. Patient awareness about ADR is important in developing country where there is lack of getting the basic health service.

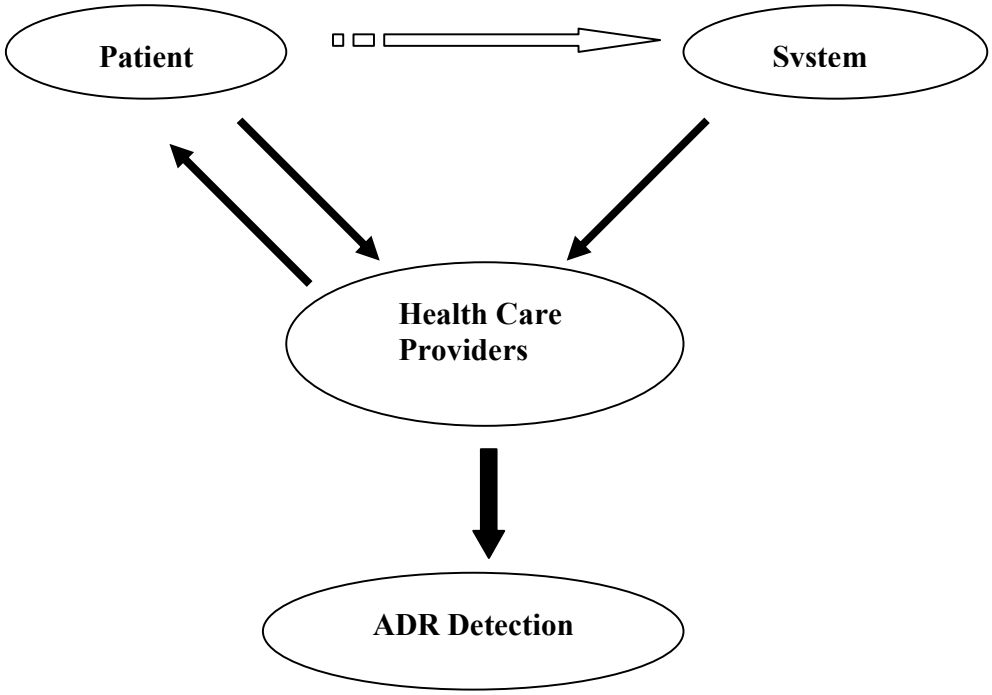

Figure 1 System to scale up ADR detection in health facility. Patients need to report any untoward effect and health care providers through the established system detect ADR.

System

Medications should be carefully screened and systematically ruled out as possible causes of any abnormal finding on physical examination or from laboratory tests or diagnostic procedures (1). Developing countries fail to cover the basic health service for patients visiting health facilities for the first time. Laboratory test and physical examination for the detection of ADR incurs extra cost in health service. Health authorities' involvement in building the capacity of health facilities set up is required.

Spontaneous reports to the drug authority and drug manufacturers, post-marketing surveillance provide other means for detecting important ADRs that may have not been detected during drug development. Drug authorities in different countries, including Drug Administration & Control Authority of Ethiopia, launch a system to collect filled yellow card from health professionals (7). Health professionals detect ADR in their full capacity provided that there is functional system.

For instance in Ethiopia the National Drug Administration & Control Authority is the responsible body to collect, collate and analyze data as a means of establishing new knowledge and generating early signals of possible drug complications not reported through clinical trails. Health professionals, however, did not know to which organization the identified adverse drug event would be reported In addition, practitioners lack form, phone or fax number for reporting (4, 8). Drug Authority should, therefore, activate the system they launch to detect ADR.

The challenges in ADR detection particularly in resource poor settings include deficiency from health professional, system and health care providers. Figure 1 depicts that work on every corner (practitioners, patients and system) is essential to scale up the ADR detection.

Conclusion

ADR detection is not a simple task in developing country. There are lots of challenges, which include lack of health professionals' competency, patient not complaining of untoward effect, lack of set up and strong system. Capacity building on the system and human power is necessary for the improvement of level of ADR detection in resource poor setting. In addition, patients need to get drug education.

References

1. Calis KA, Sidawy EN and Young LR Clinical Analysis of Adverse Drug Reactions. In: Principles of clinical Pharmacology. Ed. Atkinson *et al*. Academic Press New York 2007; PP: 389-99
2. Inman W, *et al*. Detection and investigations of drug safety problems. In Epidemiology Issues in Reported Drug-Induced Illnesses, Gent M, Shigamatsu I, Honolulu X (eds). McMaster University Library Press: Hamilton, Ontario, 1976.
3. Milstein JB, Falch G, Hsu JP, Knapp DE, Baum C, Dreis MW. Factors affecting physician reporting of adverse drug reactions. Drug Inf J 1986; 20: 157–164.
4. Abay SM and Dires T. Spontaneous Adverse Drug Reaction Reporting and the Obstacle in Amhara Region Referral Hospitals, Ethiopia. *Pharmacologyonline* 2008; 3: 26-33
5. Vandenbroucke JP. In defense of case reports and case series. *Ann Intern Med* 2001;134: 330-4
6. Maio G. Zur Geschichte der Contergan-Katastrophe im Lichte der Arzneimittelgesetzgebung. *Dtsch Med Wochenschr* 2001;126: 1183-6
7. DACA. Guideline for Adverse Drug Reaction Reporting. 2003: 2
8. Li Q, Zhang SM, Chen HT, Fang SP, Yu X, Liu D, Shi LY, Zeng FD. Study on the knowledge and attitude to adverse drug reactions reporting among healthcare professionals in Wuhan city. *Zhonghua Liu Xing Bing Xue Za Zhi* 2004; 25:894-7.