THE NEED FOR A NATIONAL ADVERSE DRUG REACTION MONITORING SYSTEM IN GHANA

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ABSTRACT

Monitoring of adverse drug reaction (ADRs) has become an integral part of drug development and patient care. In most developing countries, however, ADR monitoring is virtually non-existent. Suggestions are offered for the setting up of a National Committee to initiate and oversee ADR monitoring in Ghana. The advantages of such systematic ADR monitoring are given. Problems that may hinder efforts to initiate and maintain ADR monitoring are reviewed and solutions suggested. It is hoped that the two Teaching Hospitals in Kumasi and Accra will take the lead in setting up ADR monitoring systems that would spread to involve most parts of the country.

KEYWORDS: Adverse drug reactions, monitoring, drugs.

INTRODUCTION

The clinical trials conducted before a drug is released on the market can only include a limited number of patients treated for a limited period. It is therefore necessary to continue to monitor drugs for ADRs after they are released on the market (Post-Marketing Surveillance) especially in order to detect uncommon (but potentially serious) side effects.

Many western countries have evolved various Post-Marketing Surveillance systems to monitor ADRs on a routine basis. An example of "spontaneous" ADR monitoring system is the "Yellow Card" system in the UK[1] in which doctors are required to fill in and post (free) to the Committee on Safety of Medicines (CSM) all suspected ADRs.

Adverse drug reaction monitoring is also advance in Sweden. In most developing countries, however, structured ADR monitoring is virtually non-existent. Recently a spontaneous ADR monitoring system was introduced in India[2]. The recent influx of several brands of drugs especially from Eastern Europe, and the attempts to integrate herbal and other traditional medicines into mainstream clinical practice, make it imperative that an ADR monitoring system be introduced in Ghana.

SETTING UP A CENTRAL MONITORING COMMITTEE

The first step in instituting a national ADR monitoring system is to set up a national Central Committee to oversee and coordinate the work. This committee could be on the lines of the CSM of the UK[1]. Such a Committee would be made up a Clinical Pharmacologists, Physicians, Pharmacists, Epidemiologists, Biostatisticians and would work in concert with the Pharmacy Board and other bodies responsible for drug policies in the Ministry of Health, as well as the Ghana Standards Board. The functions of the committee could include:

1. The scrutiny of all new locally manufactured drugs by requiring a clinical trial certificate to be issued only after thorough pre-clinical pharmacology and toxicology studies.

2. The scrutiny of all imported brand name and generic drugs to ensure that they possess a valid product licence in the originating countries.

3. Supervision of the release of drugs manufactured locally under license by the requirement of minimal data on bioavailability and efficacy.

4. Rationalisation and standardization of the many herbal and traditional medicines in the country.

5. The setting up of an ADR monitoring system.

6. The dissemination of information to improve the education of all prescribers.

The Pharmacy and Drugs Act of 1961 which set up the Pharmacy Board confers on the Board the power to ensure the quality of drugs supplied in Ghana. Section 31 states: "No person shall supply any drug which is unfit for its purpose by reason of deterioration, impurity, adulteration or other defect". Section 32 gives the Board the power to call for information on proprietary drugs while Section 33 empowers the Board to prohibit sale of proprietary drugs which are substandard.

However, the Act does not make it mandatory for companies to submit data on pre-clinical pharmacology and toxicology studies except at the invitation of the Board.

The Ghana Standards Board is responsible for ensuring the quality of all manufactured goods, including pharmaceutical products, in Ghana. Since the range of goods for which they are responsible is so wide, it would be more appropriate, in the case of pharmaceutical products, to have a more specialized outfit to ensure the quality of drugs.

The Directorate of Herbal Medicine of the Ministry of Health and the Centre for Scientific Research into Plant Medicine at Mampong are mainly responsible for the coordination of the work of herbal practitioners and establishing the scientific basis of herbal medicine respectively. At present, efficacy of herbal preparations seems to be the main concern of these two bodies while little attention is paid to adverse drug reaction and toxicological profiling of various herbal preparations. The Central Monitoring Committee can take care of the latter problem and also assist in the compilation of a "herbal drug pharmacopoeia".

Drugs are big business now and increasingly we are witnessing the importation of fake or shoddily-produced drugs into the country. Locally, many firms are manufacturing drugs of all kinds. It is necessary to have a highly specialised body to ensure the quality and SAFETY of drugs used in Ghana.

The Pharmacy Board, as currently constituted, does not give the problem of monitoring of ADRs the deserved attention; the regulation of the pharmacy profession seems to be one of its central roles. The envisaged central Monitoring Committee could be established by amending the Pharmacy and Drugs Act of 1961, to establish a specialised body. This body would then work under the umbrella of the Pharmacy Board but with a large degree of autonomy.

ADVANTAGES OF ADR MONITORING

The detection of ADR is very much dependent on doctor education. When the ADR is undocumented, extreme vigilance by doctors is required to detect it. This was the case with the serious toxicities of epithelial structures caused by Practolol[3] and the respiratory distress associated with chemotherapy of tuberculosis[4]. But even routine monitoring of already documented ADRs will lead to accumulation of a useful database, making it possible to pick out vulnerable groups[5].

Information on ADRs received from doctors from all over the country could be analyzed, published and distributed to doctors to improve their knowledge and awareness of ADRs. This has been done effectively by the CSM of the UK which has drawn attention to the hepatotoxicity of Amiodarone[6], deaths after the use of Co-trimoxazole, Ampicillin and Trimethoprim[7], and the hypotension, renal failure and angioneurotic oedema associated with Enalapril[8].

All these have been highlighted in the "CURRENT PROBLEMS"; series of publications. Even with a well-documented ADR such as hepatotoxicity with halothane anaesthesia, cumulative data can help evaluate the size of the problem[8].

PROBLEMS OF ADR MONITORING IN GHANA

Several obstacles peculiar to Ghana and other developing countries make ADR monitoring a formidable undertaking. A major problem is the fact that patient records are usually not kept very efficiently, making retrieval of information difficult. Secondly, patients tend to move from doctor to doctor or from hospital to hospital and hence creating a lack of continuity in medical records.

One of the greatest problems is the fact that a large proportion of the Ghanaian population use the "informal medical sector" - traditional or herbal medicine. These patients may be given potions of dubious efficacy and totally unknown toxicity profiles. The problem is made worse because such patients may move from"orthodox" to traditional medical practitioners several times in the course of a chronic illness. This may make it difficult to extricate the source of possible ADRs. Furthermore, those using the informal sector are more likely to be poor, malnourished, rural dwellers or elderly.

Adverse drug reactions occur more commonly among elderly than younger patients[9,10,11], while poverty, ignorance and malnutrition may enhance the development of ADRs. Thus the people who patronise traditional medicine may be more vulnerable.

The sale of prescription drugs "over the counter" in pharmacy shops, in lorries, buses, trains and by the roadside may make the monitoring of ADRs complicated. This is because the patient may not know the name of a drug bought at the wayside and any suspected reaction may not be traced to the offending drug.

Finally, illiteracy and superstition may hamper the monitoring of ADRs in Ghana. For example, an unexpected adverse reaction to a drug may be wrongly attributed to a disease brought about by evil spirits and witches, or to retribution from an angry deity.

SUGGESTIONS AND CONCLUSIONS:

The problems of ADR monitoring in Ghana can be overcome. Retrieval of information on drug treatment can be simplified by providing a summary of all drugs taken by the patient in the past or still being taken. This sheet (or card) can then be placed on the first page of the inpatient folder on discharge of the patient. Information on dose, indication and duration of treatment can then be easily retrieved.

There is an urgent need to devise means of enforcing current legislation regarding the sale of prescription drugs. A CSM - like committee could lead in efforts to correct the situation whereby antibiotics, steroids and all kinds of drugs are sold on the open market. An intense public education programme can reinforce efforts to enforce the law.

Involving traditional medical practitioners in ADR reporting is a formidable challenge. Initially, a few educated practitioners can be involved. If the programme is non-threatening in nature the cooperation of these traditional doctors would be forthcoming; especially so when they

realise that ADR reporting could improve their practice and give them access to expert professional and academic help.

The participation of private medical practitioners would be crucial. Here again the doctors should be reassured that reporting ADRs casts no slur on their therapeutic competence.

Cost is always a consideration in Ghana. An ADR monitoring system will not be free but the cost should be manageable. The Ministry of Health is currently giving deserved attention to health research and should be able to contribute most of the budget.

Drug companies may also be asked to contribute to the cost of ADR monitoring but must not be allowed to influence policy unduly. To keep down costs initially, the scheme could be started on a pilot scheme in one or both of the Teaching Hospitals with gradual expansion to involve other parts of the country. Monitoring of ADRs can bring benefits such as the withdrawal of toxic drugs and enhanced prescriber education. This enhanced education can, in turn, help prescribers to tackle the problems of recognition, evaluation and notification of ADRs.

In the long run, the patient will benefit from more informed prescribing, and the doctor from a sense of satisfaction of a job well done.

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