GUIDELINES TO DETECT AND REPORT ADRs IN BURUNDI
HEALTH SYSTEM

Introduction

The purpose of this Guide is to help health professionals to participate in the very important process of continuous surveillance of safety and efficacy of the pharmaceutical products which are used in their clinical practice. Continuous evaluation of their benefit and harm will help to achieve the ultimate goal to make safer and more effective treatment available to patients.

The objectives of the Guide are to raise awareness of the magnitude of the drug safety problem and to convince health professionals that reporting of adverse reactions is their moral and professional obligation.

The ultimate goal of the Guide is to reduce drug morbidity and drug mortality by early detection of drug safety problems in patients and improving selection and rational use of drugs by health professionals.

This national Guide is based on WHO’s model guide to detecting and reporting ADRs (EDM/QSM/2002.2)

The magnitude of the problem.

During the last decades it has been demonstrated by a number of studies that medicine morbidity and mortality is one of the major health problems which is beginning to be recognised by health professionals and the public. It has been estimated that such adverse drug reactions (ADRs) are the 4th to 6th largest cause for mortality in the USA,2. They result in the death of several thousands of patients each year, and many more suffer from ADRs. The percentage of hospital admissions due to adverse drug reactions in some countries is about or more than 10% 3, 4, 5.

Norway 11.5%
France 13.0%
UK 16.0%.

Beside ADRs, medicine-related problems include also – drug abuse, misuse, poisoning, therapeutic failure and medication errors.

There is very limited information available on ADRs in developing countries and countries in transition. However, one may expect that the situation is worse rather than better. This problem may be aggravated by a lack, in Burundi, of legislation, quality control and proper drug regulations, including ADR reporting, a large number of substandard and counterfeit products circulating in our markets, a lack of independent information and the irrational use of drugs.

Definitions:

1. A drug or medicine is ‘a pharmaceutical product, used in or on the human body for the prevention, diagnosis or treatment of disease, or for
the modification of physiological function’

2. An **adverse drug reaction (ADR)** is ‘a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man’.
   In this description it is of importance that it concerns the response of a patient, in which individual factors may play an important role, and that the phenomenon is noxious (an unexpected therapeutic response, for example, may be a side effect but not an adverse reaction).

3. An **unexpected adverse reaction** is ‘an adverse reaction, the nature or severity of which is not consistent with domestic labelling or market authorisation, or expected from characteristics of the drug’.

4. A **side effect** is ‘any unintended effect of a pharmaceutical product occurring at doses normally used by a patient which is related to the pharmacological properties of the drug’.
   Essential elements in this definition are the pharmacological nature of the effect, that the phenomenon is unintended, and that there is no deliberate overdose.

5. An **adverse event or experience** is defined as ‘any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment’.
   The basic point here is the coincidence in time without any suspicion of a causal relationship.

6. A **serious adverse event** is any event that:
   - Is fatal
   - Is life-threatening
   - Is permanently/significantly disabling
   - Requires or prolongs hospitalisation
   - Causes a congenital anomaly
   - Requires intervention to prevent permanent impairment or damage

7. A **signal** refers to ‘reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously’.
   Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information.

8. **Pharmacovigilance** is the Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-
related problem.

**Why postmarketing surveillance and reporting ADRs is needed in Burundi.**

The information collected during the pre-marketing phase of drug development is inevitably incomplete with regard to possible ADRs. This is mainly because:

- Most of available information about tests have been healed overseas.
- Patients used in clinical trials are selected and limited in number, the conditions of use differ from those in clinical practice and the duration of trials is limited especially for newer drugs;
- Information about rare but serious adverse reactions, chronic toxicity, use in special groups (such as Children, the elderly or pregnant women) or drug interactions is often incomplete or not available nor understood.

Thus, post-marketing surveillance is important to permit detection of less common, but sometimes very serious ADRs. Therefore health professionals world-wide should report on ADRs as it can save lives of their patients and others.

The pharmacovigilance is needed because information obtained in one country (e.g. the country of origin of the drug) may not be relevant to other parts of the world, where circumstances may differ. Therefore, drug monitoring is of tremendous value as a tool for detecting ADRs and specifically in relation to counterfeit and substandard quality products. ADR monitoring is to help ensure that patients obtain safe and efficacious products.

The results of ADR monitoring have also a very important educational value.

**Report suspected adverse drug reactions.**

**How to recognize ADRs**

Since ADRs may act through the same physiological and pathological pathways as different diseases, they are difficult and sometimes impossible to distinguish. However, the following step-wise approach may be helpful in assessing possible drug-related ADRs:

1. Ensure that the medicine ordered is the medicine received and actually taken by the patient at the dose advised;
2. Verify that the onset of the suspected ADR was after the drug was taken, not before and discuss carefully the observation made by the patient;
3. Determine the time interval between the beginning of drug treatment and the onset of the event;
4. Evaluate the suspected ADR after discontinuing the drugs or reducing the dose and monitor the patient’s status. If appropriate,
restart the drug treatment and monitor recurrence of any adverse events.
5. Analyse the alternative causes (other than the drug) that could on their own have caused the reaction;
6. Use relevant up-to-date literature and personal experience as a health professional on drugs and their ADRs and verify if there are previous conclusive reports on this reaction. The National Committee and Drug regulation authority are very important resources for obtaining information on ADR. The manufacturer of the drug can also be a resource to consult;
7. Report any suspected ADR to the person nominated for ADR reporting in the hospital or directly to the health District (BPS).

Why should I report?
Health professionals are in the best position to report on suspected ADRs observed in their every day patient care. Physicians, Pharmacists, Nurses, Dentists and others should report ADRs as part of their professional responsibility, even if they are doubtful about the precise relationship with the given medication. This to reduce the suffering and save thousands of patients lives by reporting suspected ADRs.

What should be reported?
. For “new” drugs - report all suspected reactions, including minor ones. (In Burundi drugs are still considered “new” up to five years after marketing authorisation);
. For established or well-known drugs - report all serious or unexpected (unusual) suspected ADRs;
. Report if an increased frequency of a given reaction is observed;
. Report all suspected ADRs associated with drug-drug interactions especially for ACT;
. Report ADRs in special fields of interest such as drug abuse and drug use in pregnancy and during lactation;
. Report when suspected ADRs are associated with drug withdrawals;
. Report ADRs occurring from overdose or medication error;
. Report when there is a lack of efficacy or when suspected pharmaceutical defects are observed.
Who should report and to whom?

Physicians, Pharmacists and Nurses will report to the national pharmacovigilance committee via the BPS who will collect the completed Case Report Form and draw them to this board.

How to report ADRs?

Local Case Report Forms (CRF) should be obtained from the National Drug Regulatory Authority. Our form will have at least four sections which should be completed:

1. Patient information:
   — patient identifier
   — age at time of event or date of birth
   — gender
   — weight

2. Adverse event or product problem:
   — description of event or problem
   — date of event
   — date of this report
   — relevant tests/laboratory data (if available)
   — other relevant patient information/history
— outcomes attributed to adverse event

3. **Suspected medication(s):**
— name (INN and brand name)
— dose, frequency & route used
— therapy date
— diagnosis for use
— event abated after use stopped or dose reduced
— batch number
— expiration date
— event reappeared after reintroduction of the treatment
— concomitant medical products and therapy dates

4. **Reporter:**
— name, address and telephone number (if available)
— speciality and occupation

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**References**

**WHO** www.who.int/medicines/
Section: Quality Assurance and Safety: Medicines

**WHO Collaborating Centre for International Drug Monitoring (Uppsala Monitoring Centre)**
www.who-umc.org