ELECTRONIC SUPPLEMENTARY MATERIAL # 2

Article title: The burden of adverse drug reactions due to Artemisinin-based anti-malarial treatment in selected Ugandan health facilities– an active follow-up study.

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Suspected Adverse Drug Reaction Reporting Form- FORM

CONFIDENTIAL

REPUBLIC OF UGANDA
MINISTRY OF HEALTH

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

A. PATIENT DETAILS

Patient name	Patient Number	Sex: M/F*
Age at time of onset(yrs)*	Health Facility	Last Menstrual Period
Weight (kg)	District	Trimester (if pregnant)

B. SUSPECTED DRUG (S) DETAILS

Generic Name*	Brand Name	Dose ,Route Frequency	Date* started	Date stopped	Prescribed for	Expiry date	Batch No

C. SUSPECTED REACTIONS

Please describe the reaction as observed and any treatment given to manage the reaction

Outcome

Recovered ☐ Recovering ☐ Continuing ☐ Death due to reaction ☐

Date reaction started*	Date reaction stopped	Date of notification

SERIOUSNESS OF THE REACTION

Patient died ☐ Prolonged inpatient Hospitalization ☐ Involved disability ☐ Life Threatening ☐
Congenital abnormality ☐

D. CONCOMITANT DRUGS

Please give information on the drug(s) the patient has been taking together with the suspected drug including those taken for chronic diseases (include self medication and herbal preparations)

Generic Name	Brand	Dosage	Date started	Date stopped	Indication(prescribed or OTC)

Relevant laboratory tests including dates	**Additional relevant information (medical history, allergies, failure of efficacy)**

E. REPORTER'S DETAILS

Name/designation*	Telephone and Email Address	Date of reporting	Health facility

* Mandatory field

Suspected Adverse Drug Reaction Reporting Form-BACK

What to report

Report all adverse drug reactions/events suspected both serous and those that are not serious.

report any adverse reaction even if you are not certain the product caused the event

A reaction is serious when the patient outcome is:

- Is fatal
- Is life-threatening
- Is permanently/Significantly disabling
- Requires or prolongs hospitalization
- Causes a congenital anomaly
- Requires intervention to prevent permanent impairment or damage.

For product quality report problems such as:

- Questionable stability
- Poor packaging or labeling
- Expired drugs
- Suspected contamination
- Defective components
- Therapeutic failures

WHEN TO REPORT

- report the event soon after it occurs

WHO IS TO REPORT

- All Healthcare Providers e.g. Doctors, Dentists, Pharmacists, Midwives, Nurses and Allied Health Professionals in Uganda should report as part of their professional responsibility report any suspected adverse drug reactions

WHERE TO REPORT

- reports should be sent to the national centre
- reports can also be sent to the regional centres
- NDA regional offices (Zonal plus regional)

How to report

- fill in the sections that apply to your report
- Start date of administration for the suspected drug and the date when the suspected reaction occurred are mandatory.

How to recognize Adverse Drug Reactions in a Patient

- Take proper history and conduct proper examination of the patient.
- Ensure that the medicine ordered is the medicine received and actually taken by the patient at the dose advised.
- 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.
- Determine the time interval between the beginning of drug treatment and the onset of the event.
- Evaluate the suspected ADR after discontinuing the drugs or reducing the dose and monitor the patient's status (De-challenge). If appropriate, restart the drug treatment and monitor recurrence of any adverse events (Re-challenge).
- Analyze the alternative causes (other than the drug) that could on their own have caused the reaction.
- 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

please note that submission of a report doesn't imply that the health worker or the product caused or contributed to the adverse event

Address

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