Swaziland MEDICINES | Safety Watch

JULY-OCTOBER 2013

INSIDE THIS ISSUE

Welcome to the second issue of the Swaziland Medicines Safety Watch for 2013.

Almost all known and new medicines have residual safety uncertainties that are best determined during real-life use of products by the general population. Moreover, some medicines have long latency periods, with adverse effects manifesting after many years of a product's use.

To understand the adverse effects and to identify them as early as possible, in May 2013, the Pharmacovigilance Centre of the Ministry of Health launched the first Tuberculosis (TB) and HIV Active Surveillance System at six pilot sites in the Kingdom of Swaziland. This was done in collaboration with the National TB Control Program and the Swaziland National AIDS Program.

In this and subsequent issues of this newsletter, we will provide safety reports and information on the implementation of the active surveillance activity. We will also continue to keep you informed of recent developments in monitoring the safety and effectiveness of medicines.

Happy reading,
Pharmacovigilance Centre

TB AND HIV ACTIVE SURVEILLANCE UPDATE: PATIENT ENROLLMENT AT SIX PILOT SITES (JULY–OCTOBER 2013)

Facility name	Number of patients recruited on ART	Recruitment rate (%)	Number of patients re-cruited on anti-TB medicines	Recruitment rate (%)
Mbabane Government Hospital	150	50	0	0
Good Shepherd Hospital	126	28	99	30
Raleigh Fitkin Memorial Hospital	57	29	20	16
TB National Hospital	0	0	0	0
MSF Matsapa Clinic	0	0	0	0
Hlathikulu Government Hospital	22	36	47	104

Note: The recruitment rate is the average number of treatment naïve patients per month/ number of expected patients per month times 100.

PEPFAR SWAZIS AND AMERICANS IN PARTNERSHIP TO FIGHT HIV/AIDS

USAID FROM THE AMERICAN PEOPLE

SIAPS Systems for Improved Access to Pharmaceuticals and Services

The total number of patients recruited as of September 2013 is 521. This includes 350 patients in the anti-retroviral treatment (ART) cohort and 171 patients in the TB cohort.

A comprehensive set of indicators to measure the outcomes of the activity will be developed in early 2014 in consultation with the participating facilities. The indicators may include:

- Patient adherence to treatment
- Spontaneous adverse drug reaction (ADR) reporting
- Incidence of preventable adverse events
- Patient satisfaction with service delivery

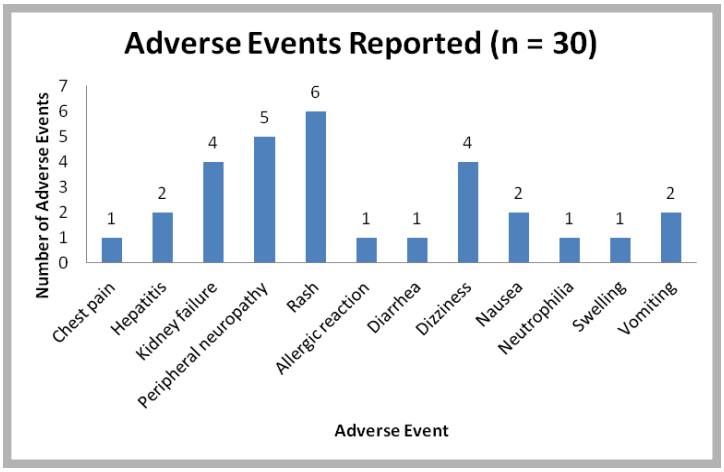
ADR REACTION ANALYSIS FROM THE ACTIVE SURVEILLANCE SITES, JULY–OCTOBER 2013

Since facilities initiated enrolment of patients in July 2013, data have been collected from the sentinel sites every month. The Pharmacovigilance Centre compiled, reviewed, and analysed data for the last four months. The long-term toxicity of antiretrovirals and anti-TB medicines should be monitored for a longer period of time. However, the interim analysis provides information on the characteristics of adverse events and the incidence of preventable adverse events.

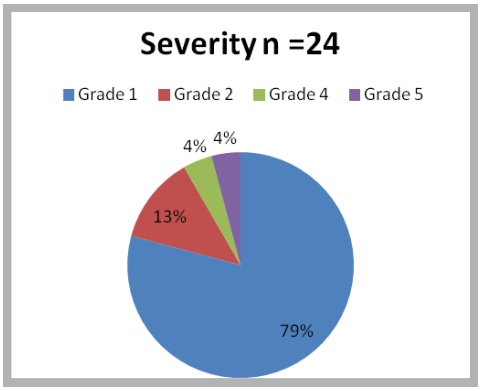
These data help clinicians and health facilities develop risk management plans to prevent harmful effects. Of the 521 patients enrolled, 5 percent (n = 26) reported the occurrence of 30 ADRs; 53 percent of the ADRs were reported by males and 47 percent were reported by females.

The most common adverse events reported over the last four months were rash, peripheral neuropathy, kidney failure, and dizziness. The anti-TB medicine RHZE (rifampicin + isoniazid + pyrazinamide + ethambutol) accounted for 47 percent of the ADRs, and the antiretroviral TDF/3TC/EFV (tenofovir/lamivudine/efavirenz) for 31 percent. Fortunately, most of the ADRs reported were grade 1 in terms of severity, which means that no antidote, therapy, or prolongation of hospitalization was required.

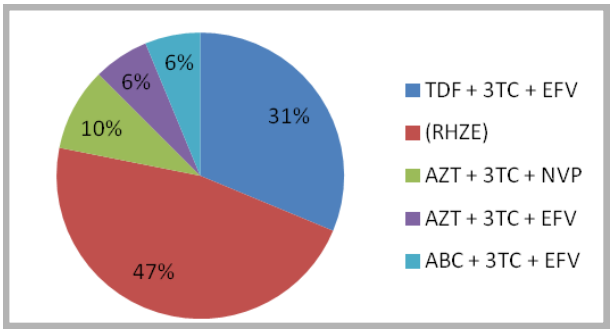
Adverse Events Reported



Severity of Adverse Events Reported



Adverse Events Reported by Regimen



Patient Recruitment

Facility Name	Patients recruited	Patients with events	%
Mbabane Govt Hospital	150	0	0
RFM Hospital	77	0	0
Hlathikulu Govt Hospital	69	7	10.14
Good Shepherd Hospital	225	19	8.44

Sentinel Site Performance

The performance of the participating sentinel sites was assessed during supportive supervisory visits based on seven performance domains developed by the Pharmacovigilance Centre.

Performance Domains

1. Work process and recruitment
2. Data completion
3. Follow-up on missing data
4. Data storage and confidentiality
5. Training of site staff
6. Transmission of data
7. Outcome measures

Only four facilities have started with patient recruitment and capture the information on the active surveillance electronic tool. All facilities need to improve patient recruitment.

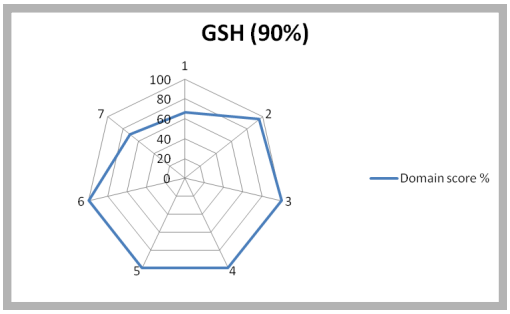
The four facilities are:

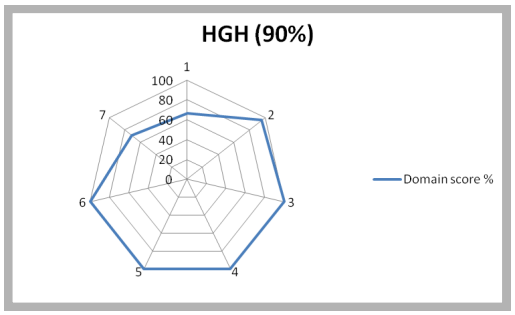
GSH: Good Shepherd Hospital

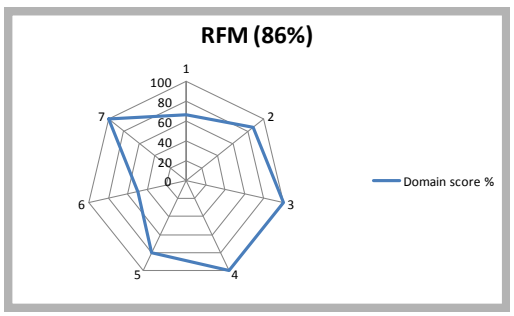
HGH: Hlathikulu Government Hospital

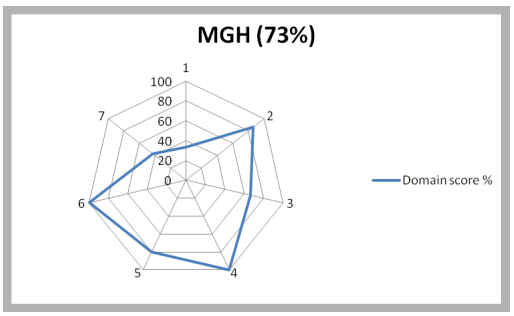
MGH: Mbabane Government Hospital

RFM: Raleigh Fitkin Memorial Hospital









FIRST SUPPORTIVE SUPERVISORY VISIT TO SENTINEL SITES

The Pharmacovigilance Centre conducted supervisory visits to all sentinel sites during the period July to September 2013, in collaboration with staff from the Swaziland office of Systems for Improved Access to Pharmaceuticals and Services (SIAPS). The objective of the visits was to provide on-site support and work with facility staff to address their immediate concerns. A follow-up visit to the six pilot sentinel sites is planned for October 2013.

At right Ms. Bonisile Nkambule is using the sentinel site-based active surveillance system for anti-retroviral and anti-TB (SSASSA) medicines at Hlathikulu Government Hospital.

Key Feedback and Recommendations from Sentinel Sites and the Central Level

- Files should be color-coded using stickers for those patients participating in the active surveillance activity.
- SSASSA date fields should be modified to improve data capturing at facilities.
- The SSASSA and the Data Collection and Analysis Tool should be updated to resolve compatibility issues.
- More frequent and immediate support to facilities on issues raised should be provided.
- Facilities should be involved in the dissemination and reporting of findings.

"You need not be certain… just be suspicious"

… Report all suspected ADRs and poor quality medicines to swazilandpharmacovigilance@gmail.com.

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