SEPTEMBER 2017

SWAZILAND MEDICINE SAFETY WATCH

THIS ISSUE INCLUDES:

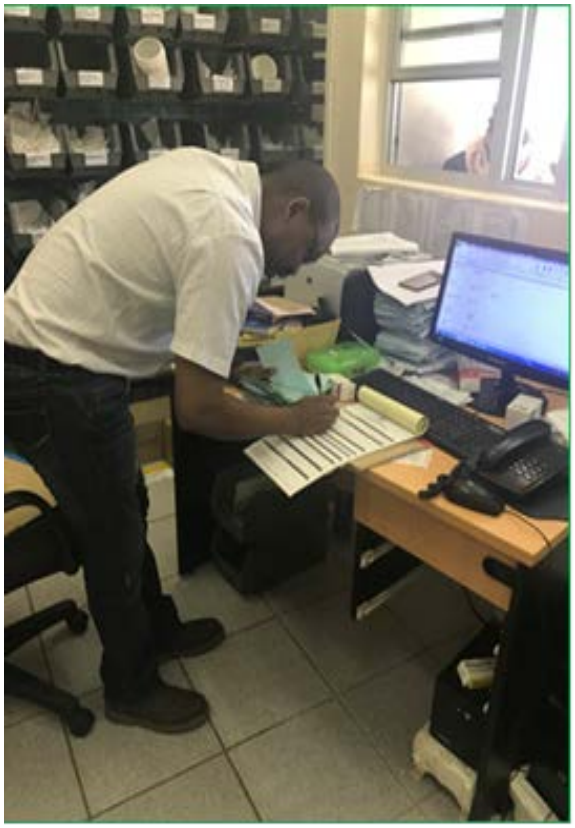
PHARMACOVIGILANCE IN SWAZILAND

Pharmacovigilance is necessary for improving patient management, making evidence-based treatment decisions, and promoting rational medicine use.

Swaziland undertakes both passive and active pharmacovigilance. Passive or spontaneous pharmacovigilance is reporting whenever a health care worker comes across an adverse drug reaction (ADR). It is passive because it depends on the willingness of a health care worker to report the suspected ADR. It involves unsolicited voluntary reporting of suspected ADRs/adverse drug events (ADEs) in a patient being treated with one or more medicines. It is the moral and ethical responsibility of all health care workers to report suspected ADRs. Reporting of suspected ADEs can be done using the ADE form provided by the National Pharmacovigilance Unit (NPVU). See page 3 for details on how to report an ADE.

Active surveillance is the ongoing systematic collection, analysis, interpretation, and dissemination of patient-medicine safety data. It involves routine screening of all patients on treatment at every visit for signs and symptoms indicating possible adverse reactions, following up, and documenting all suspected adverse reactions observed after treatment is initiated.

Active pharmacovigilance or surveillance to monitor antiretroviral and TB medicines has been piloted in seven sentinel sites in Swaziland using the Sentinel Site-based Active Surveillance System for Antiretroviral and Anti-TB (SSASSA) computer software for data collection and the Data Collation and Analysis Tool (DCAT) for data analysis at the NPVU.



Friezland Oswatch, a pharmacy technician at Mankayane Hospital, reports an ADR he identified using the ADE reporting form

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Region	Piloted sentinel sites
Manzini	National TB Hospital
	Mankayane Hospital
	AHF Matsapha
	AHF Manzini
	RFM Hospital
Shiselweni	Hlatikulu Hospital
Lubombo	Good Shepherd Hospital

In this pilot active surveillance system, clinicians in health facilities (sentinel sites) enroll treatment-naïve HIV patients and TB patients starting a new regimen in the program and follow them up at each review visit to determine whether they experience any adverse events. Relevant patient information captured using paper-based patient files is then entered into SSASSA by data clerks. Data are collated monthly and analyzed centrally using DCAT.

> ***"Completion of ADR form is not an admission of guilt or negligence."***
>
> **Taken from Swaziland's ADR Report Form**

UPDATE ON 2016–2017 SPONTANEOUS REPORTING SYSTEMS

Between October 2016 and March 2017, health care providers across the country submitted 225 reports on suspected ADRs and other medicine-related problems to the NPVU through the spontaneous reporting system. The reports were analyzed to inform clinical practice (rational medicine use) and improve patient outcomes. A thorough review of the reports showed that 216 (96%) were considered valid (i.e., contained an identifiable patient, a suspected ADR, a suspected medicine, and an identifiable reporter) and were retained for further analysis. We present the results of the analyzed data in this edition of the newsletter.

Summary of Findings

A total of 44 medicines, either in combination or as a single entity, were suspected of causing 307 ADRs and/or other medicine-related problems that consisted of 70 distinct reactions. Antiretroviral medicines were the highest proportion of suspected medicines in the reports, with the TDF/3TC/EFV and TDF/3TC/NVP combinations having the highest counts. Antiretroviral therapy accounted for 54% of the reported indications for use of suspected medicines in the reports. A total of 70 different types of ADRs were reported. Gynecomastia was the most frequent at 15.3%, followed closely by rashes at 13%. There was a significant association between the number of medicines and the number of ADRs in a report. Among the reported ADRs, 12.8% resulted in hospitalization, while 4.3% were life threatening. Reactions were categorized as minor (75.8%), major (5.9%), or product use error (0.5%). Three cases each of death and persistent disability were recorded. At the time of reporting, 71.3% of patients had not recovered, while 23.8% had fully recovered. Doctors reported the majority of cases, followed by pharmacy technicians. No reports were received directly from patients/consumers.

Conclusion

Pharmacovigilance works to achieve the best outcome from treatment with medicines. This can be accomplished through several means, including the spontaneous reporting system, which aims to detect problems related to medicine use, communicate the findings in a timely manner, and improve rational and safe medicine use by educating and providing relevant information to consumers (health care providers and patients) about medicines. This can only be achieved when locally generated data are used to inform locally relevant decision making. Health care providers are encouraged to continue reporting ADRs and medicine-related problems to the NPVU.

Medicines Safety Alerts

Viagra Usage

- The use of phosphodiesterase 5 (PDE5) inhibitors, such as sildenafil (Viagra®, Levitra®, and Cialis®) for the treatment of erectile dysfunction and Revatio® for the treatment of pulmonary arteria hypertension might cause sudden decreases or loss of hearing.
- In some cases, the sudden hearing loss is accompanied by tinnitus and dizziness.
- Physicians who prescribe Viagra, Levitra, or Cialis for erectile dysfunction should advise their patients to immediately stop taking the medicine

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and seek prompt medical attention if they experience any sudden decrease or loss of hearing.

- Source: https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124841.htm (Accessed 2017/09/08)

Codeine and Tramadol

The FDA restricts the use of prescription codeine pain and cough medicines and tramadol pain medicines in children and recommends against their use in breastfeeding women. These medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk for children younger than 12 years and should not be used in these children.

It also strengthened its warning to mothers that breastfeeding is not recommended when taking codeine or tramadol due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death.

Therefore codeine and tramadol are strictly contraindicated in children under 12 and 18 years of age, respectively.

Source: https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm (Accessed on 2017/09/08)

- HOW TO REPORT AN ADE

1. Complete the ADE reporting form (available in all health facilities and at the National Pharmacovigilance Unit).

2. Submit the original form (and retain the duplicate—please note that forms are self-carbonated) to the National Pharmacovigilance Unit by:
   a) Delivering the form to the Central Medical Stores marked attention Quality Assurance/ Pharmacovigilance Pharmacist
   b) Scanning and emailing the completed form to **swazilandpharmacovigilance@gmail.com**
   c) Faxing the completed form to **25186279,** attention Pharmacovigilance Unit

Your comments, questions, and feedback on the content of this newsletter or other pharmacovigilance-related issues are important to us.

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