Eswatini Active Drug-Safety Monitoring and Management (aDSM) System in the Implementation of New Drugs Training Report

July,2019

The World Health Organization (WHO) has defined pharmacovigilance (PV) as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems." The aim of PV system is to protect the public from medicines-related harm. Currently only a limited number of low- and middle-income countries have a well-functioning PV system to support the timely identification, collection, and assessment of medicine-related adverse events.

A baseline assessment (BLA) was conducted in June 2018; to present the situational analysis of the various aspects and needs of the PV systems in Eswatini at the start of the PAVIA project. One of the recommendations of the BLA was to capacitate NPVU and health care workers to routinely undertake causality/relationship assessment on collected ADR reports, such as through a work-sharing mechanism with members of the NPSMC.

To ensure the usage of PV data and interpretation, the training was conducted from 1st to 4th of July 2019 at the George Hotel for selected participants from all regions in the country through Technical support from USAID/TB Care II and Financial support from PAVIA.

Preparation

In preparation for the training, NPVU engaged stakeholders (ENAP, NTCP, USAID/TB care II) to choose a feasible day for the training and to establish training needs for the identified staff/participants. The list of participants was used to disseminate the invitation letter that was signed by the Principal Secretary (MOH)

Other preparatory activities carried out to ensure smooth and effective training were;

- The Consultant conducted site visits and engaged MOH stakeholders to get the overview of PV in the country
- Preparation and review of training agenda
- Securing of training venue and accommodation for participants
- Advance request for participants transport allowance

Facilitators

The training was mainly facilitated by USAID/TB Care II consultant; however the following in country team have also contributed.

Table 1 List of training facilitators

Name	Designation	Organisation
Dr. Bern-Nyangwa	TB care II consultant	USAID consultant
Alemayehu Duga	Technical Advisor Patient safety	Baylor/PAVIA
Siphesihle Nhlabatsi	Senior Pharmacist	NPVU
Dr. Debrah Vambe	Technical Advisor	NTCP

Training objectives

The objectives of the training were to;

1. Identify the key concepts and definitions of aDSM
2. Describe how to implement and manage aDSM within the NTCP and SNAP
3. Understand how to detect adverse events in the course of the clinical monitoring of TB (and HIV) treatment
4. Explain how adverse drug reactions are clinically managed
5. Record adverse events and ensure quality of data records
6. Understand key concepts of causality assessment, signal detection and safety risk management

The training agenda can be found in Annex 1.

Training Day 1

Overview of Pharmacovigilance

The purpose of this presentation was to set the tone for the training and provide participants with a bigger picture of Pharmacovigilance . Key areas covered include;

1. Pharmacovigilance principle
2. Rationale and mechanism for aDSM
    - ✓ why drug safety monitoring is important

- ✓ the recent changes in TB treatment policy which make the case for drug safety monitoring in NTCP and SNAP stronger
- ✓ why TB (TLD) drug safety monitoring and management should rely on active rather than spontaneous surveillance
- ✓ the main components of aDSM

3. Key definitions and concepts in pharmacovigilance
    - ✓ Understand the most common terms used in active drug safety monitoring and management (aDSM)
    - ✓ Use the concepts of seriousness and severity in relation to AEs
4. Clinical monitoring of AEs and ADR management
    - ✓ Clinical management of AEs for several case studies were practiced with the participants

Training day 2

On day two of the training, Pharmacovigilance in the context of Eswatini was discussed including the following points:

- ✓ the importance of methodical and organized documentation
- ✓ fundamental elements of data quality
- ✓ continuous quality improvement and how it applies to medical records
- ✓ the mechanisms for adverse event reporting within the country
- ✓ the mechanism for adverse event reporting to the global aDSM database
- ✓ the resources needed to ensure that the whole system works
- ✓ the standard aDSM indicators for programme management

Draft PV Road map as well as aDSM set up at NTCP and ENAP was also presented to the participants. Each facilities representative presented the snapshot of PV set-up in their respective health facilities.

Training Day 3

On the day three of the training Causality assessment & signal detection concepts and practical exercises were done.

The following topics were covered:

- ✓ Causality assessment & signal detection
- ✓ Causality assessment scales and measurement
- ✓ Causality assessment practice

- ✓ introduction to signal detection
- ✓ signal review practice
- ✓ Risk communication

Training day 4

aDSM implementation plans as well tools used in PV were reviewed. The following action points were also put up for discussion:

- ✓ National coordinating mechanism
- ✓ Implementation plan
- ✓ Management and supervision roles and responsibilities
- ✓ Data collection materials
- ✓ Staff training/supervision plans on data collection

Next Steps

The following are next steps and timelines from the training.

S/N	Action	Responsible	Timeline
	Circulate training materials with participants	Alemayehu	Done
	Meet with the consultant and Discuss on the way forward	Siphesihle/Alemayehu	Done

Annexes 1: Training Agenda

Eswatini Active Drug-Safety Monitoring and Management (aDSM) System in the Implementation of New Drugs

1st July – 4th July 2019
The George Hotel, Manzini

Time	Agenda Item	Facilitator
Day 1; July 1 2019		
08:00 – 08:30	Welcome and introduction to the training	Ms. Brenda Dlamini
08:30 – 10:00	Rationale and mechanism for aDSM	Dr. Bern-Thomas Nyangwa
Break		All
10:30 – 13:00	Key definitions and concepts in pharmacovigilance	
Lunch		
14:00 – 15:30	Clinical monitoring of AEs and ADR management	Dr. Bern-Thomas Nyangwa
Tuesday 2nd July		
08:00 – 09:00	Draft PV/aDSM roadmap	Mr. Alemayehu Duga
09:00 – 10:00	PV set-up best practice: NTBH, RFM, health centre, clinic	Mr. siphesihle Nhlabatsi
Break		
10:30 – 11:00	Records management and quality assurance of data	Dr. Bern-Thomas Nyangwa
11:00 – 12:00	aDSM in the NTCP: set-up + tools	Mr. siphesihle Nhlabatsi
12:00 – 13:00	aDSM in the SNAP: set-up + tools	Mr. siphesihle Nhlabatsi
Lunch		
14:00 – 15:00	Case study: SAE reporting	Dr. Bern-Thomas Nyangwa
Break		
15:30 – 16:30	Indicators of aDSM programme	Dr. Bern-Thomas Nyangwa

Wednesday 3rd July		
08:00 – 10:00	Causality assessment	Dr. Bern-Thomas Nyangwa
Break		
10:30 – 13:00	Introduction to signal detection	Dr. Bern-Thomas Nyangwa
Lunch		
14:00 – 15:00	Risk communication	Dr. Bern-Thomas Nyangwa
Break		
15:30 – 16:30	Data management	Dr. Bern-Thomas Nyangwa
Thursday 4th July		
08:00-12:00	Workshop - review of aDSM implementation plans + tools - National coordinating mechanism - Implementation plan - Management and supervision roles and responsibilities - Data collection materials Staff training/supervision plans on data collection	Dr. Bern-Thomas Nyangwa
12:00 – 13:00	Lunch and departure	All

Annex 2: Snap shots from the training

Training Participants

Ms. Brenda-Giving her opening remarks

Dr. Nyangwa- facilitating a training

Group exercise

one of the training participant presenting a facility PV snapshot

Mr. Nhlabatsi- From NPVU