

Pharmacovigilance indicators

Sten Olsson

Chief WHO Programme Officer, UMC

Shanthi Pal

Manager, WHO Medicine Safety Programme

Indicators

- Objective measures that allow an evaluation of baseline situation and progress in healthcare services and interventions

Why pharmacovigilance indicators?

- Measure status of pharmacovigilance system
- Able to identify strengths, weaknesses, achievements, growth, impact
- Return on investments in PV

Requirements

- Simple to understand
- Easy to measure and interpret
- Reproducible (independent of investigator)
- Sensitive to detect problems
- Applicable to any facility engaged in PV

Classification

- Background: demographics, economics, healthcare system, pharmaceutical scenario
- Structure
 - qualitative - yes/no
- Process
- Output/impact
- Specific Indicators for Public Health Programmes

Development process

- PV consultants meeting 2007
- Working group at NC meeting 2008
- Ambrose Isah with support of Sten O, Shanthi P and Serge X
- NC meeting 2009
- Comments and prioritization by national centres
- ACSoMP 2011, 2012 and 2013

Hierarchy

- Core indicators (27)
 - structural (10)
 - process (9)
 - outcome/impact (8)
- Complementary indicators (36)
 - 11 s, 13 p, 12 o/i

Core **structural** indicators

Existence of :

1. A PV centre with a standard accommodation?
2. A statutory provision for PV? (legislation, policy)
3. A Drug Regulatory Authority/Agency
4. A regular financial provision for the PV centre?
5. Human resources to carry out its functions properly?
6. A standard ADR reporting form?
 - 4 subset indicators
7. A process in place for collection, recording and analysis of ADRs?
8. Is PV included in national curriculum of schools for health care professionals?
9. A newsletter/information bulletin/website for PV information dissemination?
10. A national ADR or PV advisory committee or expert committee in the setting?

Core **process** indicators (Tot 9)

1. Total number of ADR reports received last calendar year
2. Total number of reports in national/local database
3. Percentage of total annual reports acknowledged
4. Percentage of reports subjected to causality assessment in the year
5. Percentage of national reports satisfactorily completed and submitted to NC last year
 - a) Submitted to WHO
6. Percentage of reports on therapeutic ineffectiveness
7. Percentage of reports on medication errors
8. Percentage of registered MAH having functional PV system
9. No of active surveillance activities initiated, ongoing or completed the last 5 years

Core outcome/impact indicators

1. No of signals identified by PV centre the last 5 years
2. No of regulatory actions taken last year based on national data
 - Label change
 - Safety warning
 - Medicine suspension/withdrawal/other restrictions
3. Number of medicine related hospital admissions/1000 admissions
4. No of medicine related deaths/1000 persons served by hospital
5. No of medicine related deaths/ 100 000 in the population
6. Average cost of treatment of medicine-related illness
7. Average duration of extension of medicine-related hospital stay
8. Average cost of medicine related hospitalization

Core indicators for Public Health Programmes

1. PV activities in place within the PHP
2. All main treatment guidelines/protocols in use within the PHP systematically considers PV
3. Existence of standard ADR reporting form in the setting
4. Total no of ADR reports collected within the PHP the previous year
5. Total no of ADR reports/1,000 individuals exposed to medicines in the PHP the previous year
6. Total number of reports on therapeutic ineffectiveness in the previous year
7. Percentage of completed reports submitted to the National PV Centre in the previous year
 - a) To WHO
8. No of medicine-related hospital admissions/1,000 individuals exposed to medicines in the PHP the previous year
9. No of medicine-related deaths/1,000 individuals exposed to medicines in the PHP in the previous year

Core indicator format

The following elements are stated:

- Definition
- Description and Uses
 - What will it measure?
 - Why is it important ?
 - What is the scope of the indicator?
 - How can the results be interpreted
- Sources and methods of data collection and indicator calculation
 - Main sources, methods of data collection?
 - How should the indicator be calculated?
- Limitations

Assessment checklist

PART 1: CORE INDICATORS				
Core Structural indicators				
#	Assessment questions	Data sources used	Answer (Yes/No, or Value)	Optional: Proposed next steps?
CST1	Is there a Pharmacovigilance Centre / Department / Unit with a standard accommodation?			
CST2	Is there a statutory provision (national policy, legislation) for Pharmacovigilance?			
CST3	Is there a Drug Regulatory Authority/Agency?			
CST4	Is there any regular financial provision (e.g. statutory budget) for the Pharmacovigilance centre?			
CST5	Has the Pharmacovigilance Centre have human resources to carry out its functions properly?			
CST6	Is there a standard ADR reporting form in the setting?			
	CST6a: Are there relevant fields in the standard ADR form to report suspected medication errors?			
	CST6b: Are there relevant fields in the standard ADR form to report suspected counterfeit / substandard medicines?			
	CST6c: Are there relevant fields in the standard ADR form to report therapeutic ineffectiveness?			
	CST6d: Are there relevant fields in the standard ADR form to report suspected misuse, abuse and/or dependence on medicines?			
	CST6e: Is there a standard ADR reporting form for general public?			

Next steps

- Publication of version 1.0 by WHO
- Field testing
- Periodic self assessment
- Database at UMC for
 - Country support
 - Bench marking
 - Document general development of global PV situation

Indicator-based Pharmacovigilance Assessment Tool (IPAT)

Indicator-Based Pharmacovigilance Assessment Tool:
Manual for Conducting Assessments in Developing Countries

December 2009



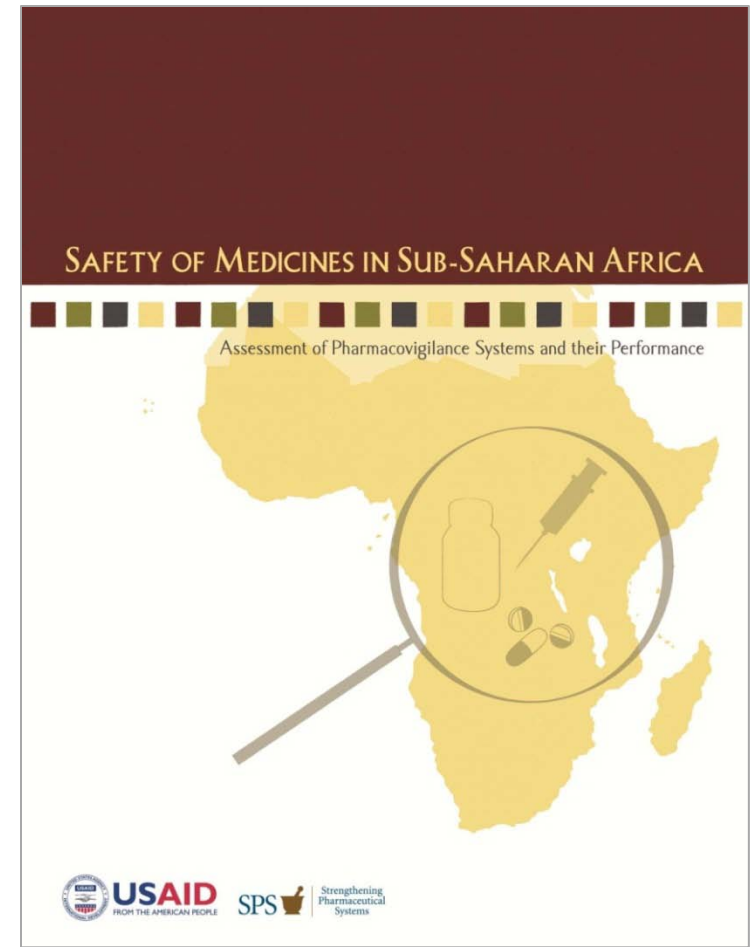
Strengthening Pharmaceutical Systems
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Phone: 703.524.8575
Fax: 703.524.7898
E-mail: sps@msh.org

- Indicator-based performance monitoring tool
- Informs the development and implementation of a customized system improvement model and priority interventions
- Monitor and evaluate interventions
- Assess PV at National, public health programs, and health facilities level



Safety of Medicines in sub-Saharan Africa

- Interagency agreement between the US Food and Drug Administration (FDA) and USAID, implemented by SPS program
- Assessment of Pharmacovigilance Systems and their performance in 46 African countries



USAID
FROM THE AMERICAN PEOPLE

SIAPS 

Thank you for your attention



info@who-umc.org
www.who-umc.org

