Assessment of Pharmacovigilance and Medicine Safety System in Rwanda

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Printed July, 2009

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This report is made possible by the generous support of the American people through the U.S. Agency for International Development (USAID), under the terms of cooperative agreement number GHN-A-00-07-00002-00. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

Recommended Citation

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Nwokike J. and Joshi M. 2009. *Assessment of Pharmacovigilance and Medicine Safety System in Rwanda.* Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

Key Words

Pharmacovigilance, Medicine Safety, Assessment, Indicators

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CONTENTS

Purpose of Trip 2

Scope of Work 2

Collaborators and Partners 9

Immediate Follow-up Activities 11

Recommendations 12

Annex 1. Scope of Work 14

Annex 2. Itinerary for the assessment 17

Annex 3. In-brief presentation 19

Annex 4. Out-brief presentation 28

Annex 5. Revised indicators 41

ACRONYMS

ACT	Artemisinin combination therapy
AIDS	Acquired immunodeficiency syndrome
CDC	Centers for Disease Control and Prevention
CHW	Community health worker
DTC	Drug and Therapeutics Committee
HIV	Human immunodeficiency virus
IPAT	Indicator-based pharmacovigilance assessment tool
MoH	Ministry of Health
NPMIC	National Pharmacovigilance and Medicine Information Center
PhV	Pharmacovigilance
PNILP	Programme National Integre de Lutte Contre le Paludisme, PNILP (National Malaria Control Program)
PTF	Pharmacy Task Force
TB	Tuberculosis
TRAC	The Treatment and Research AIDS Center
VAS	Visual analogue scale
WHO	World Health Organization

BACKGROUND

Access to new essential medicines for HIV/AIDS, TB and malaria has dramatically improved in resource-constrained settings. This can be attributed to the global response by the international community and donor agencies working together with governments to address the challenges of access to essential medicines used in these conditions. According to the 2008 report on the global AIDS epidemic, substantial, although variable, progress has been made in the scale up towards universal access with several countries already achieving their national universal access targets for the prevention of mother to child transmission and the antiretroviral therapy programs.[1] Progress is also being made in improving access to TB and malaria medicines. Strengthening pharmacovigilance systems is important to ensure that donors' heavy investments in improving access to these new medicines are supported by equal attention to the safe use of those products. The WHO defines Pharmacovigilance as the science and activities relating to the detection, evaluation, understanding and prevention of adverse reactions to medicines or any other medicine-related problems.[2] Pharmacovigilance has also been referred to as post-marketing surveillance which is crucial to quantify previously recognized adverse drug reactions, to identify unrecognized adverse drug events, to evaluate the effectiveness of the drugs in real-world situations and to decrease mortality and morbidity associated with adverse events.[3]

A Pharmacovigilance system includes all organizations, institutions and resources that contribute to ensuring medicines safety. Ensuring medicines safety includes any effort, whether in personal health care, public health services or intersectoral initiatives to protect the public from harm related to the use of medicines. The implementation of a comprehensive pharmacovigilance and medicine safety system requires efforts beyond adverse events data collection and should include risk evaluation, risk mitigation, and communication. Spontaneous reporting and other forms of data collection for early warning on safety are part of the risk identification. Risk mitigation and communication are the preventive part of pharmacovigilance and includes strategies for mitigating known risks, communication of drug safety information, and the promotion of rational use of medicines. There is a lack of consensus on what constitutes a well functioning pharmacovigilance system. There is currently no performance monitoring tool for assessing where a country stands in achieving a functional pharmacovigilance system. The MSH/SPS program developed an indicator-based pharmacovigilance assessment tool (IPAT) that will guide countries in monitoring their pharmacovigilance and medicine safety system from regulatory pharmacovigilance to safe use of medicines. The IPAT will be useful for addressing the gap created by the current lack of medicine safety performance metrics and will be essential in the diagnostic assessment of pharmacovigilance systems in developing countries. It will support evidence-based options analysis and development of relevant and feasible recommendations reflecting each country's local realities, existing regulatory capacity and priorities, identified system gaps, and resource availability. Additionally, the standardized and indicator-based approach included in the tool will allow longitudinal measurement of progress after the

[1] Joint United Nations Programme on HIV/AIDS (UNAIDS). 2008 report on the global AIDS epidemic. UNAIDS/08.25E / JC1510E. Available from: http://viewer.zmags.com/publication/ad3eab7c#/ad3eab7c/106. Access on July 08, 2009

[2] The Importance of Pharmacovigilance. World Health Organization, 2002.

[3] Eguale T. et al. Detection of adverse drug events and other treatment outcomes using an electronic prescribing system. Drug safety 2008; 31 (11): 1005-1016

recommended interventions are implemented. The indicator-based assessment tool will complement other MSH/SPS support for in-country capacity-building and system strengthening for monitoring and addressing medicines safety, therapeutic ineffectiveness, and pharmaceutical product quality issues.

Purpose of Trip

To conduct a diagnostic assessment of Rwanda pharmacovigilance and medicine safety system using Indicator-based Pharmacovigilance Assessment Tool (IPAT) developed by MSH/SPS and provide feasible recommendations for improvement. The detailed scope of work is attached as Annex 1.

Scope of Work

1. Prior to in-country visit liaise with MSH/SPS Country Office to identify key informants and health facilities to be interviewed and assessed. Develop plans to facilitate the collection of data elements included in the tool
2. Hold meetings with MSH/SPS staff and focal persons at MoH's Pharmacy Task Force (PTF) to review the data collection tool for the indicator-based assessment tool
3. Using the indicator-based assessment tool, collect data at the national center and review available documents relevant for the assessment
4. Conduct field visits to health facilities in collaboration with PTF to collect facility-based data
5. Provide preliminary feedback to the PTF, MoH, and the MSH/SPS Country Office
6. Hold in-brief and debrief meetings with the USAID and CDC mission as requested.

ACTIVITIES

Prior to in-country visit liaise with MSH/SPS Country Office to identify key informants and health facilities to be interviewed and assessed. Develop plans to facilitate the collection of data elements included in the tool

After the initial phase of work on the development of the MSH/SPS indicator-based pharmacovigilance assessment tool (IPAT), Mohan Joshi (SPS Senior Technical Manager for AMR) and Jude Nwokike (SPS Country Program Manager/Pharmacovigilance Focal Person) discussed plans for the use of the tool to help assess pharmacovigilance and medicine safety systems in Rwanda with the MSH/SPS Rwanda team. The team subsequently engaged the Pharmacy Task Force (PTF) of the Ministry of Health and introduced the IPAT to them and advocated on the need to use the tool to obtain a baseline of the status of pharmacovigilance activities in Rwanda. This will help to benchmark progress with current efforts at developing and strengthening medicine safety systems in Rwanda. The IPAT could potentially become a tool for longitudinal monitoring and evaluation of the efforts of the MoH in improving medicine safety over time. The PTF and the MSH/SPS Rwanda office agreed that the assessment could be conducted from 25th May to 2st June, 2009. Several discussions were subsequently held to develop the assessment itinerary. The itinerary for the assessment is attached as Annex 2. These meetings held prior to in-country visit helped in identifying key informants, data collectors and assessment team, assessment sites, and the logistics for the assessment. The draft IPAT was also sent to the MSH/SPS Rwanda office ahead of the trip. Plans were made to facilitate the training of the data collectors immediately upon arrival in Rwanda. The PTF led the assessment preparations and sent out letter of invitation on 22nd May for the general in-brief presentation for Partners scheduled for Tuesday 26th May, 2009.

Hold meetings with MSH/SPS staff and focal persons at MoH's Pharmacy Task Force (PTF) to review the data collection tool for the indicator-based assessment tool

On the first day of the activity, a meeting was held at the MSH/SPS office to discuss the assessment itinerary. Subsequently a brief meeting was held with the coordinator of the PTF. Thereafter the in-brief meeting and presentation was held at the MoH conference room on Tuesday 26th May, 2009 at 10.00AM. During the meeting Jude Nwokike made a presentation on the objectives of the assessment and provided a background on the need for performance metrics in monitoring pharmacovigilance and medicine safety system and how the IPAT was developed. The presentation highlighted that the IPAT would enable Rwanda define and agree on the scope, functions, and activities to include within its efforts to address medicine safety systems. The assessment would provide some information on the current status of the pharmacovigilance system and diagnose system strengths, opportunities, weaknesses, and gaps and propose feasible and locally relevant interventions for improving the system. The results of the assessment would also provide the benchmark for monitoring of pharmacovigilance and medicine safety systems and enable comparison across regions and programs. The IPAT has been developed to be relevant to developing countries, to emphasize on systems and capacity building, and to be flexible so that countries, health programs, and health facilities can plug out the indicators and

assessment questions relevant to their environment and use it. The in-brief presentation is attached as Annex 3. The public health programs and PTF had also requested that MSH/SPS use the opportunity for the assessment to provide some preliminiary advice on how to intiate active surveillance activities in Rwanda. With the recent operationalization of the community health worker (CHW) as part of the healthcare delivery system, the MoH is interested in ensuring that systems are developed to ensure the monitoring of safety of essential medicines administered by these non-professional health workers. Of key interest is the distribution artemisinin combination therapy (ACT) through the CHW. Therefore the presentation in Annex 3 alluded to this issue.

Later in the afternoon on Tuesday 26th, a training for the data collectors was organized. This training provided an opportunity for farmiliarizing the data collectors with the IPAT, the data collectors guide, supporting resources for benchmarking responses, and data collation tools. The data collectors guide provided details for every indicator including the indicator number and title, the description and rationale for the indicator, and data collection guide. An example of a data collection guide for one of the indicators is shown below.

Indicator #1:	Existence of a policy document that contains a statement on pharmacovigilance or medicine safety (standalone or as a part of some other policy document)			
Rationale:	A policy statement on PhV or medicine safety is the guiding document and authority that mandates the need, scope, direction, and activities that should be done in a country			
Description:	To determine if Policy exists either within the National medicines Policy, NMP or as part of other MOH policy documents with a section that clearly addressed PhV and medicine safety issue			
Data Collection				
Collection Level	Where to Go	Who to Ask	Assessment Questions	What Documents to Review
MoH, PHP	NDA, Pharmacy department, PHP	Directors or Heads of NDA, Pharmacy department, PHP	1. Is there an approved national policy on PhV or medicine safety 2. Is the policy recently reviewed (in the last 10years) or do you consider it still relevant	National medicine policy, National PhV policy, MOH policy documents Other related policy documents

Comments

In a scale of 1 to 10 (1 being for low and 10 being for high) please indicate (i) Relevance and (ii) Feasibility of this indicator to your country

Data collectors were requested to improvise the data collectors guide for documenting the respondents' feedback and also use the comments column for noting comments and suggestions. During the assessment it was identified that respondents had problems with the use of the visual analogue scale (VAS) for scoring the relevance and feasibility of each indicator.

Using the indicator-based assessment tool, collect data at the national center and review available documents relevant for the assessment

The assessment of the pharmacovigilance and medicine safety systems in Rwanda was commenced on Wednesday 27th May, 2009 by a 6 member team from PTF and MSH/SPS. The

assessment involved document reviews, structured questions, and key informants interviews. The structured part of the assessment include 14 core indicators, 42 supplementary indicators, and 93 assessment questions. The assessment team agreed to initiate the assessment with the health facilities and reserve the assessment of the drug regulation system and the public health programs for the last day. At the national level, 5 national departments/programs were assessed. The assessment at this level included 48 indicators and 92 assessment questions for the PTF as the department is currently charged with medicine regulatory activities. The following public health programs were assessed; the National Malaria Program (Programme National Integre de Lutte Contre le Paludisme, PNILP), the HIV/AIDS Program (The Treatment and Research AIDS Center, TRAC), the Rwanda's TB Control Program, and the Rwanda Maternal and Child Health Program. Due to the effective coordination provided by the PTF, key informants were always available to provide feedback to the assessment team when requests for appointments and information were made.

Conduct field visits to health facilities in collaboration with PTF to collect facility-based data

The PTF sent out letters to the health facilities for conducting assessments and requested that key informants including staff from the Pharmacy and a representative of the Drug and Therapeutics Committee (DTC) be available to respond to questions and guide the assessment. The assessment was conducted in the following health facilities: Kanombe Military Hospital; Rwinkwavu Hospital; CHU Butare; Nyanza Hospital; King Faysal Hospital; CHU Kigali; Gisenyi Hospital; and Ruhengeri Hospital. The assessment gave a real-time opportunity to also provide some relevant technical advice to some of the participating facilities in terms of how to initiate or improve simple and no-cost systems for medicine safety. Several health facilities are already implementing some sorts of medicine safety activitities but in most settings there were no standard operating procedures or formalization of those practices. Because of this, important opportunities for collecting and documenting adverse events data and putting in place simple tools for preventing medication errors may be lost.

Provide preliminary feedback to the PTF, MoH, and the MSH/SPS Country Office

At the end of the assessment the resulting data were collated and inputted into a master sheet and analyzed. The data collation and analysis worksheet is available on request at the MSH/SPS Rwanda Office. While analyzing and averaging the responses on feasibility and relevance of the indicators obtained using the VAS (see the Indicator #1 example above), we included non-responses also and counted them as zero; this obviously impacted on the overall scores for feasibility and relevance in terms of lowering the values. We preferred to err on the side of caution and include non-responses. The overall scoring was quickly done that way partly also because of the limited time available for the analysis before providing feedback. More detailed analysis will be conducted on these data. Using findings from the analysis we conducted a SWOT analysis to identify strengths, weaknesses, opportunities, and threats and used that to build recommendations that were presented to Rwanda. We recommended that as immediate next steps, the following key activities can be addressed:

- Finalize/approve the pharmacovigilance-related policy, legal provisions and guidelines
- Establish the National Pharmacovigilance and Medicine Information Center (NPMIC) as early as possible
- Prepare an initial core group of in-country experts and trainers by providing them a training of trainers (TOT) course on pharmacovigilance
- Establish a multi-disciplinary "Medicines Safety Committee" to assist NPMIC on technical matters
- Strengthen the National Pharmacovigilance Working Committee to enable it to advance pharmacovigilance activities

Several other recommendations were also made with respect to critical immediate next steps to be taken to ensure that pharmacovigilance and medicine safety systems are developed and sustained in Rwanda. The detailed out-brief presentation (including the recommendations related to strategies for monitoring safety of medicines used by the CHW) is attached as Annex 4. Experiences and feedback obtained from the use of the IPAT in Rwanda also informed its subsequent revision. The revised version of the indicators developed after the Rwanda assessment is attached as Annex 5.

Hold in-brief and debrief meetings with the USAID and CDC mission as requested

The in-brief presentation at the start of the assessment on Tuesday 26th May, 2009 was attended by Annett Cotte from CDC/Atlanta who was already in-country providing technical assistance to the National Malaria Program. She also participated in the training of the data collectors for the assessment. Patrick Condo overseeing the PMI aspects of USAID/Rwanda attended both the in-brief and out-brief presentations at the MoH.

Collaborators and Partners

The following health facilities and public health programs were very supportive and collaborated with the assessment team to ensure successful implementation of the assessment exercise:

1. Kanombe Military Hospital
2. Rwinkwavu Hospital
3. CHU Butare
4. Nyanza Hospital
5. King Faysal Hospital
6. CHU Kigali
7. Gisenyi Hospital
8. Ruhengeri Hospital.

Also the following public health programs collaborated in providing useful information to inform the assessment:

- National Malaria Program (Programme National Integre de Lutte Contre le Paludisme, PNILP)
- Treatment and Research AIDS Center, TRAC (the National HIV/AIDS Program)
- Rwanda's TB Control Program
- Rwanda Maternal and Child Health Program

The following individuals worked closely with the assessment team:

Name	Address
Viateur Mutanguha	Coordinator, Pharmacy Task Force, PTF Ministry of Health, Rwanda
Anicet Nyawakira	Pharmacy Task Force, PTF Ministry of Health, Rwanda
Alex Ruzindaza	Pharmacy Task Force, PTF Ministry of Health, Rwanda
Claire Nyinawikindi	King Faisal Hospital, Kigali
Laurent Munuankindi	Kigali University Teaching Hospital, Kigali
Damian Uwase	Kigali University Teaching Hospital, Kigali
Juliet Mbabazi	King Faisal Hospital, Kigali
Stephen Rulisa	Kigali University Teaching Hospital, Kigali
Annett Cotte	CDC Atlanta (CDC/CCID/NCZVED)
Patrick Condo	USAID/Rwanda

NEXT STEPS

Immediate Follow-up Activities

The immediate follow-up activities that should be implemented to advance and sustain what has been achieved through this assessment include the following:

- PTF should ensure that all the pharmacovigilance-related policy, national guidelines for medicine safety surveillance, standard operating procedures and other related documents already developed and finalized should be published and circulated as soon as possible. The publication of these documents will set the stage for the implementation of medicine safety system and ensure standards and harmonization of discrete efforts at addressing pharmacovigilance in Rwanda.

- During the assessment it was communicated that the MoH has finalized plans for the establishment of the National Pharmacovigilance and Medicine Information Center (NPMIC). NPMIC has the mandate to develop and implement medicine safety surveillance systems that will provide unbiased information, monitor safety and effectiveness, and improve rational use of essential medicines in Rwanda. The NPMIC should be empowered to address broad-based medicine safety issues from regulatory pharmacovigilance to safe use of medicines in Rwanda. It is recommended that the NPMIC be immediately established and necessary institutional capacity provided to enable it meet its mandate

- Rwanda has made efforts to develop an initial draft of a national training curriculum for medicine safety and pharmacovigilance. This curriculum is aimed at improving the knowledge, skills, and practice of healthcare workers towards an improved prevention, detection, and management of adverse events related to the use of health products. Efforts should be made immediately to finalize the training curriculum and use it for the implementation of the first national training of trainers in pharmacovigilance. The national curriculum for medicine safety and pharmacovigilance should also be shared with the Pharmacy, Medical, and Nursing schools to initiate discussions towards adaptating and inserting some relevant topics intothe pre-service education programs.

- Immediately strengthen the roles of the DTCs in improving medicine safety in health facilities. At the national level, a multi-disciplinary “Medicines Safety Committee” should also be established to assist and advise NPMIC on technical matters

- Opportunities exist for using the currently existing monitoring register for community health worker for routine monitoring of the safety of ACT use in the CHW Program. A simple system for the development of sentinel sites for the implementation of such a surveillance mechanism on a routine basis should be immediately established to address current concerns on the safe use of the ACT by non-professional health care workers.

Recommendations

The MSH/SPS Program and other partners should provide support to MoH towards the achievement of all the above immediate follow-up activities. It is particularly recommended that support be provided to MoH towards the establishment of NPMIC, implementation of the training of trainers, development of systems for safety monitoring in the CHW Program, and coordination of efforts for the initiation of active surveillance studies in Rwanda.

Annex 1. Scope of Work

Request for Country Clearance

TO: Kristina Lantis, USAID Rwanda
Patricia Mwanuyera, SO2 Secretary, USAID Rwanda
Patrick Condo, Malaria Officer, USAID Rwanda
Rose Ntirandekura, USAID Program Assistant, Rwanda
Wayne Stinson, PMI Advisor, USAID Rwanda
Roopal Patel, PMI advisor, CDC/Rwanda

FROM: Management Sciences for Health (MSH)/Strengthening Pharmaceutical Systems (SPS) Cooperative agreement # GHN-A-00-07-00002-00

SUBJECT: Request for Country Clearance for travel to Rwanda for Mohan Joshi, Sr Technical Mngr for AMR and Jude Nwokike, Country Program Manager/PhV focal person

COPY: Anthony Boni, USAID/GH/HIDN/HS, CTO RPM Plus and SPS
Veerle Coignez, USAID/GH/HIDN/HS, Pharmaceutical Management Advisor
Douglas Keene, Director, MSH/RPM Plus and SPS
Sameh Saleeb, Program Manager, MSH/RPM Plus and SPS
Michael Gabra, Regional Technical Advisor, MSH/SPS
Mark Morris, Country Program Manager, MSH/SPS Rwanda
Inès Buki Gege, Senior Technical Advisor, MSH/SPS Rwanda
Mohan Joshi, Sr Technical Mngr for AMR, MSH/SPS
Jude Nwokike, Country Program Manager, MSH/SPS

1. The SPS Project wishes to request country clearance for proposed travel to Rwanda for Mohan Joshi, Sr Technical Mngr for AMR and Jude Nwokike, Country Program Manager from 25th May to 1st June, 2009

2. Background:

Access to new essential medicines for HIV/AIDS, TB and malaria has dramatically improved in resource-constrained settings. Strengthening pharmacovigilance systems is important to ensure that USAID and other donors' heavy investments in improving access to these new medicines are supported by equal attention to the safe use of those products. The implementation of a comprehensive pharmacovigilance system requires efforts beyond adverse events data collection and should include risk evaluation, minimization and communication. Spontaneous reporting and other forms of data collection for early warning on safety are part of the risk identification. Risk minimization and communication is the preventive part of pharmacovigilance and includes strategies for mitigating known risks, communication of drug safety information, and the promotion of rational use of medicines. As the definition, scope, and roles of pharmacovigilance continues to evolve, there are

increasing concerns that developing countries are unclear about what constitutes a well functioning pharmacovigilance system. There is currently no performance monitoring tool for assessing where a country stands in achieving a functional pharmacovigilance system. The MSH/SPS indicator-based assessment tool will be useful for addressing this gap and in the diagnostic assessment of pharmacovigilance systems in developing countries. It will support evidence-based options analysis and development of relevant and feasible recommendations reflecting each country's local realities, existing regulatory capacity and priorities, identified system gaps, and resource availability. Additionally, the standardized and indicator-based approach included in the tool will allow longitudinal measurement of progress after the recommended interventions are implemented. The indicator-based assessment tool will complement other MSH/SPS support for in-country capacity-building and system strengthening for medicines safety, therapeutic ineffectiveness, and pharmaceutical product quality issues.

3. Purpose of Proposed Visit:

Mohan Joshi and Jude Nwokike are traveling to Rwanda from 25th May to 1st June, 2009 to field-test the indicator-based pharmacovigilance assessment tool drafted by MSH/SPS.

4. Scope of Work:

1. Prior to in-country visit liaise with MSH/SPS Country Office to identify key informants and health facilities to be interviewed and assessed. Develop plans to facilitate the collection of data elements included in the tool
2. Hold meetings with MSH/SPS staff and focal persons at MoH's Pharmacy Task Force (PTF) to review the data collection tool for the indicator-based assessment tool
3. Using the indicator-based assessment tool, collect data at the national center and review available documents relevant for the assessment
4. Conduct field visits to health facilities in collaboration with PTF to collect facility-based data
5. Provide preliminary feedback to the PTF, MoH, and the MSH/SPS Country Office
6. Hold in-brief and debrief meetings with the USAID and CDC mission as requested.

5. Anticipated Contacts:

- USAID and CDC Rwanda Mission
- Representatives from the PTF and MoH

6. Logistics:

Mohan Joshi and Jude Nwokike will arrive in Kigali on 26th May, 2009 and will stay at Novotel Umubano. They will depart Kigali on 2nd June, 2009.

7. Funding:
MSH/SPS Core AMR funds.

8. Action:

Please inform the MSH/SPS Program whether country clearance is granted for the activity to take place as proposed. Please reply via e-mail to the attention of Anthony Boni, USAID/GH/HIDN/HSD, e-mail address: aboni@usaid.gov, tel: (202) 712-4789, fax (202) 216-3702. Please send carbon copies to Veerle Coignez at vcoignez@usaid.gov, Douglas Keene at dkeene@msh.org, Sameh Saleeb at ssaleeb@msh.org, Mohan Joshi at mjoshi@msh.org, Jude Nwokike at jnwokike@msh.org, Inès Buki K. Gege at gbuki@msh.org, and James Riviere at jriviere@msh.org

9. No further Mission assistance is required from USAID/Rwanda.

Thank you for Mission cooperation.

Annex 2. Itinerary for the assessment

Proposed Itinerary for Rwanda PhV Assessment

Arrival Monday 25th May (Hotel Laico Umubano)				
Date	***hours***	***Activity***	***Comments***	***venue***
Tues 26th	8.30: 9.30	Introductory meeting with PTF		PTF meeting room
	10.00-12.00	General inbrief presentation for Partners	Invitees: USAID/CDC,PTF,TRAC Plus(Malaria, HIV and TB), MCH with CCM, UDPC	MoH Conference room
	1.30-3.30	Training of data collectors	data collectors with Jude and Mohan	MSH Conference room
Wed 27th, Thurs 28h and Frid 29th		Travel to location of health facilities, Data collection at health facilities, Data collection at PTF, HIV/TB/Malaria & Immunization programs	Team 1 : data collectors with Jude and Alexis from PTF	TB, Malaria and HIV program, Kanombe Military hospital, Nyamata hospital, CHU Butare and Nyanza hospital
			Team 2 : data collectors with Annex 1. **DisplayText cannot** Mohan and Anicet from PTF	PTF, MCH (Immunization and Community Case desk), King Faysal hospital, CHU Kigali, Ruhengeri hospital and Gisenyi hospital
Tues 2nd	9.30 - 11.00	Debriefing meeting	Invitees: USAID/CDC,PTF,TRAC Plus(Malaria, HIV and TB), MCH with CCM, UDPC	MoH Conference room
	11:00	**Departure**		

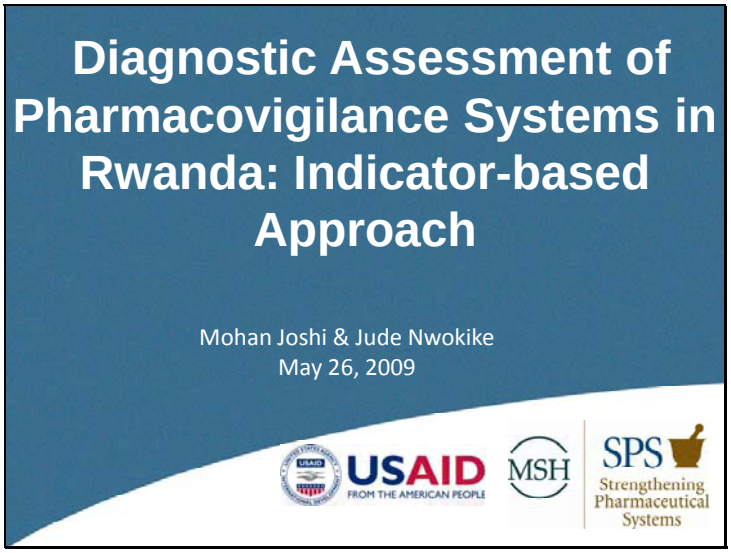
Facilities and MOH/Units to be visited are checked

PROVINCE		LOCATION (DISTRICT NAME)	DISTRICT HOSPITAL	REFERRAL HOSPITAL
KIGALI CITY	1	GASABO		1. KING FAYCAL HOSPITAL
	2	NYARUGENGE		2. KIGALI UNIVERSITY TEACHING

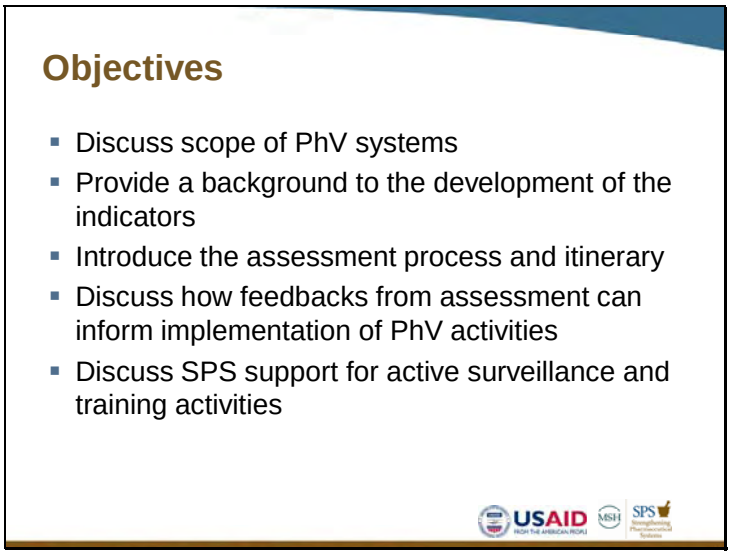
				HOSPITAL		
	3	KICUKIRO		3. KANOMBE MILITARY HOSPITAL		
EASTERN PROVINCE	4	KIREHE	4.RWINKWAVU		**Date of the visit**	**Team members**
WESTERN PROVINCE SOUTHERN PROVINCE	5	RUBAVU	5. GISENYI		May 29th,09	Team 2 with Mohan, 1 SPS staff and Anicet from PTF
	6	NYANZA	6. NYANZA		May 29th,09	Team 2 with Mohan, 1 SPS staff and 1 PTF and Anicet from PTF
NORTHERN PROVINCE other visits	7	HUYE		7. BUTARE UNIVERSITY TEACHING HOSPITAL	May 28th,09	Team 1 with Jude,1 SPS staff and and Alexis from PTF
	8	MUSANZE	8. RUHENGERI		May 29th,09	Team 1 with Jude,1 SPS staff and and Alexis from PTF
	9	Malaria Unit			May 27th, 09	Team 2 with Mohan, 1 SPS staff and Anicet from PTF
	10	TB Unit			May 27th, 09	Team 1 with Jude,1 SPS staff and Alexis from PTF
	11	HIV unit			May 27th, 09	Team 1 with Jude,1 SPS staff and Alexis from PTF
	12	MCH			May 27th, 09	Team 2 with Mohan, 1 SPS staff and Anicet from PTF
	13	PTF			May 28th,09	Team 1 with Jude,1 SPS staff and and Alexis from PTF
					May 28th,09	Team 2 with Mohan, 1 SPS staff and Anicet from PTF

Annex 3. In-brief presentation

Slide 1



Slide 2



Slide 3

Pharmacovigilance System

- A Pharmacovigilance system includes all organizations, institutions and resources that contribute to ensuring medicines safety
- Ensuring medicines safety includes any effort, whether in personal health care, public health services or intersectoral initiatives to protect the public from harm related to the use of medicines

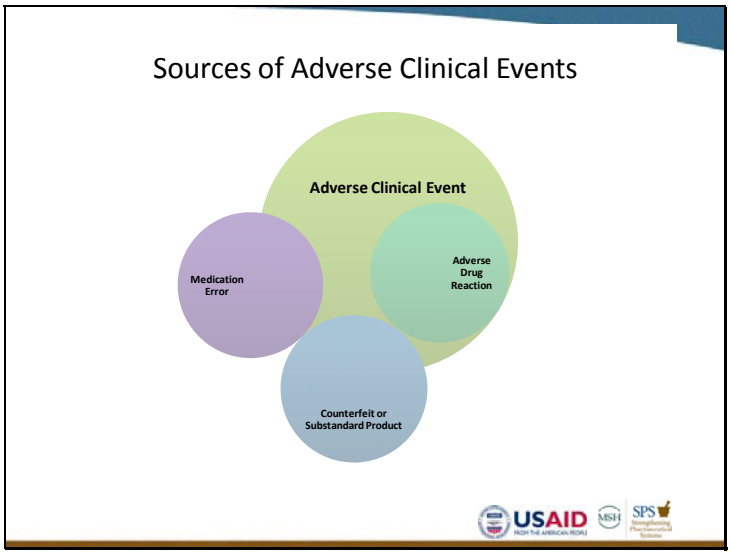
Slide 4

Scope of Pharmacovigilance activities

- Pharmacovigilance programs must monitor events that may be related to **product quality**, **medication errors**, and **previously known or unknown adverse drug reactions**
- Post-marketing surveillance is crucial to quantify previously recognized adverse drug reactions, to identify unrecognized adverse drug events, to evaluate the effectiveness of the drugs in real-world situations and to decrease mortality and morbidity associated with adverse events

Eguale T. et al. Detection of adverse drug events and other treatment outcomes using an electronic prescribing system. Drug safety 2008; 31 (11) 1005-1016

Slide 5



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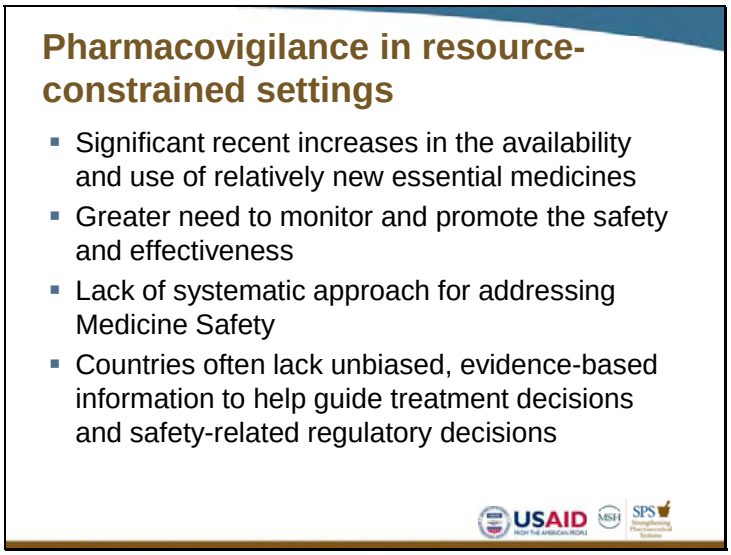


Slide 7

Access, Safety, and Rational Use

- Strengthening Pharmacovigilance systems is important to ensure that USAID and other donors' heavy investments in improving access to new essential medicines are supported by equal attention to the safe and rational use of those products
- Monitoring safety and effectiveness in real-life use is critical for new essential medicine used in large populations
- Primary focus:

  "Health systems strengthening"

Slide 8

Rationale for the development of the Assessment Tool

- Opinions differ of what constitutes a well functioning Pharcovigilance system
- Performance monitoring tools for measuring country's situation in achieving functional PhV system does not exist
- Indicators are useful in measuring what changed and how it changed with regards to outcome of interest

Slide 9

Indicator-based Assessment Tool will enable countries

- Define and agree on scope, functions, and activities
- Assess status of PhV systems and diagnose the system strengths, weaknesses, and gaps
- Design and plan interventions based on local realities, existing regulatory capacity and priorities, identified system gaps, and available resources
- Monitor and evaluate PhV and medicines safety activities
- Compare PhV activities across regions and programs, and with those of other countries

Slide 10

Key Features of the Indicator-based assessment tool

- Relevant to resource-constrained settings
- Emphasis on systems issues
- Diagnose system weaknesses
- Modular in nature making it possible to use one or more subsets of the tool independently
- Flexible as to how data can be gathered (structured/semi-structured assessment, self-assessment)

Slide 11

Development process

- Literature review & mapping
- Indicator assessment criteria
- Review indicators — Delphi method, 3 rounds of consultations
- Generate final draft and assessment questions
- Field test in 3 countries

Slide 12

SPS Operational Approach

- Assess the existing Pharmacovigilance system
  - —***Stakeholders***, ***Functions*** (risk identification, evaluation, and minimization), ***Structures & Systems***
- Develop a customized system improvement model
- Implement the identified interventions
- Monitor and evaluate medicines safety activities

Slide 13

Assessment method and process

- Document review
- Structured: 14 Core indicators, 42 Supplementary indicators, 93 Assessment questions
- Collection sites include 5 national departments/programs and 16 health facilities in 8 regions
- Key informants interview
- Respondents can address other locally relevant issues/questions/indicators

Slide 14

Feedback to inform implementation

- Assessment will determine gaps
- Relevance, feasibility, and prioritization using the capacity building framework
- Interventions will be recommended and prioritized with relevance to local realities and capacity
- Ongoing PhV activities and stakeholders mapping to identify opportunities for leveraging resources and addressing critical gaps

Slide 15

Outcomes of a strengthened PhV system

- Pharmacovigilance policies, laws, and regulations formulated and implemented
- Improved governance and transparency in regulatory Pharmacovigilance
- Improved medicines regulation
- Pre-qualification schemes adopted and implemented
- In-country quality monitoring improved
- Data collection on product quality and drug utilization improved

Slide 16

Outcomes of a strengthened PhV system

- Improved reporting and coordination of ADR reports and data management
- Systems and infrastructures developed for medicine safety surveillance
- Pharmacovigilance instituted in health systems and public health programs
- Capacity developed for the implementation of active surveillance activities
- Pharmacovigilance information applied in medicine selection
- Provision of drug information on the safety of medicines improved
- Medicine safety monitoring activities integrated in DTC scope of activities

Slide 17

Active surveillance in Rwanda ART & Malaria programs

- Current challenging with quantifying known ADRs related to ARVs and ACT an opportunity for active surveillance
- Retrospective cohort study/Sentinel surveillance (Namibia example)
- Data can quickly be collected and analyzed to inform treatment guidelines decision
- Pregnancy exposure registry for ACT

Slide 18

Involving Community health-workers in safety monitoring

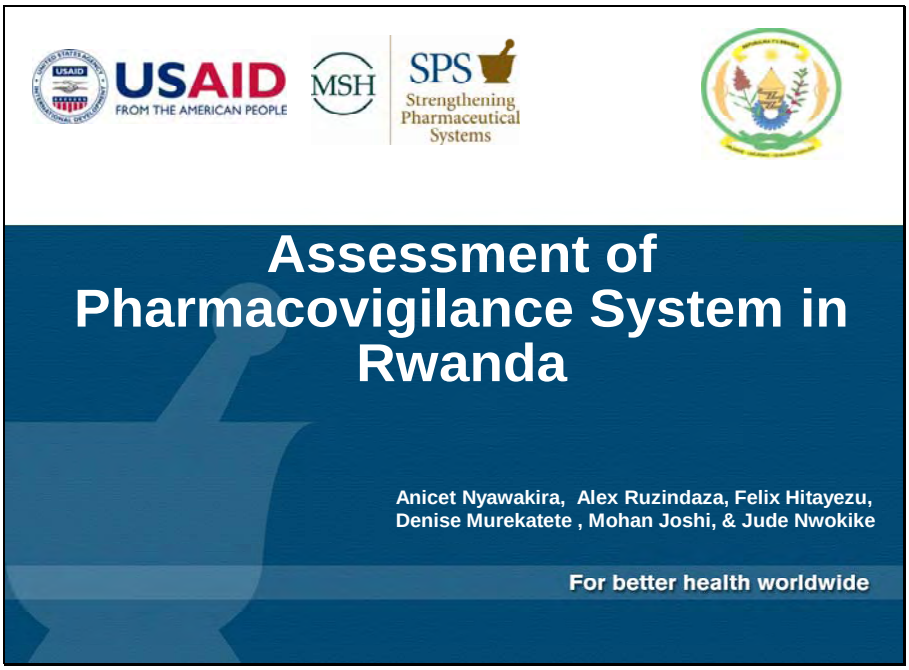
- Simplify reporting system and process
- Focus group discussion with patients exposed to medicines to elicit detailed ADR information (Uganda example)
- Sentinel surveillance
- Empower patient, explore patient reporting
- Provide dedicated toll-free lines for patients to send in simplified reports
- Training

Slide 19

Mohan Joshi & Jude Nwokike
May 26, 2009

Annex 4. Out-brief presentation

Slide 1



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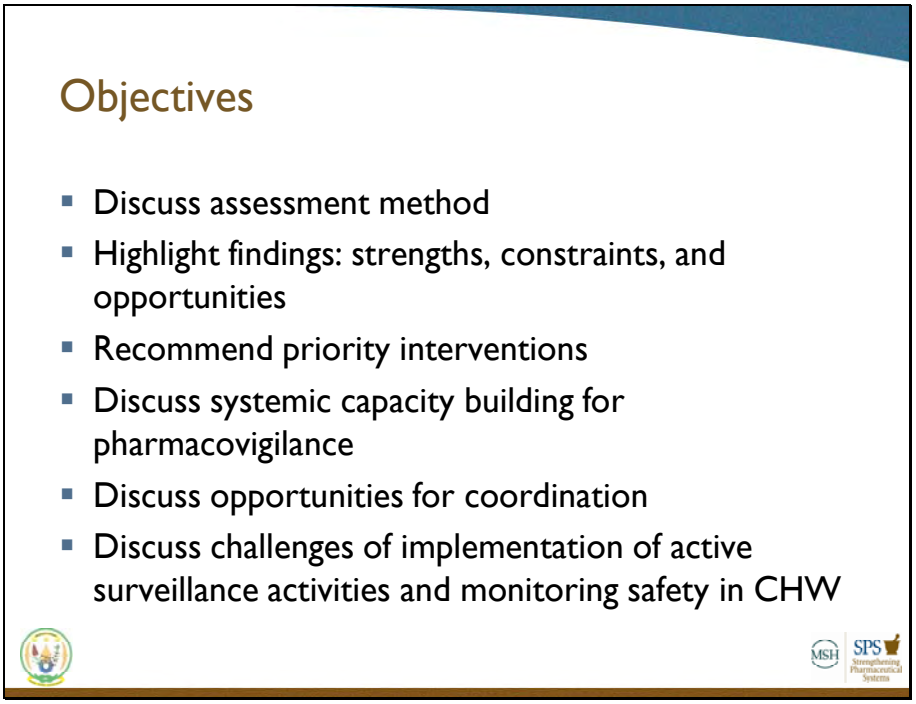


Slide 3

Assessment objectives

- To conduct a diagnostic assessment of country's Pharmacovigilance system using the Pharmacovigilance indicator-based assessment tool to provide feasible recommendations that reflect local realities

Slide 4

Methods (1)

- Key documents reviewed
- Key informants interviewed:
  - Pharmacy Task Force (PTF)
  - Public Health Programs (PHPs)
    - HIV/AIDS; TB; Malaria; MCH
  - Health Facilities
    - Kanombe Military Hospital; Rwinkwavu Hospital; CHU Butare; Nyanza Hospital; King Faysal Hospital; CHU Kigali; Gisenyi Hospital; Ruhengeri Hospital

Slide 5

Methods (2)

- Data inputted into a master sheet and analyzed
- Opportunities identified based on SWOT analysis
- Recommendations developed and prioritized based on local realities and feasibility

Slide 6

Overall Findings - Strengths

- Drafts of the following exist:
  - National Medicine Policy (PhV-related policy being part)
  - Food and Drug Act
  - Guidelines for Medicines Safety Surveillance in Rwanda
  - Notification system (including ADR form)
  - In-service training curriculum on PhV
  - Proposal for a National Pharmacovigilance and Medicine Information Center, NPMIC

Slide 7

Overall Findings - Strengths

- Active surveillance studies initiated in public health programs
- DTCs are growing in number and several of them are already addressing PhV-related issue
- In the past PTF took local actions relating to PhV based on 6 WHO drug alerts (e.g. Viracept)
- Pharmacy ART register collects ADR data longitudinally

Slide 8

Findings – Current Constraints (1)

Constraints	Impact
PhV policy finalized and waiting for official approval	Addressing medicine safety is not viewed as obligatory
Food and Drug Act and related Regulation not in place	Enforcement not possible; MAH not required to report ADRs
PhV center, guidelines, notification system not yet approved	PhV activities can not be formally operationalized
Insufficient in-service and pre-service training	HCP have limited skills to monitor adverse events
No formal mechanism of medicine safety information services	HCP and patients are not well informed

Slide 9

Findings – Current Constraints (2)

Constraints	Impact
No organized system to improve or monitor patient safety relating to medicine use	Opportunities to use adverse events incidences to prevent future occurrences are lost
Isolated and uncoordinated PhV activities	Inefficient use of resources
PHPs do not consistently track and consolidate ADR & treatment failure data	No data to inform treatment guidelines decision
Concerns about drug quality	Patients may lose confidence in the health delivery system

Slide 10

Findings – Opportunities (1)

- MOH and other stakeholders highly committed to the issue of PhV in Rwanda
- National PhV working committee exists to move agenda forward
- National Pharmacovigilance and Medicines Information Center (NPMIC) being established
- PhV-related trainings, DTC involvement in PhV activities, and medicine use surveys considered highly relevant by key informants
- Some facilities have risk mitigation strategies for high alert medicines
- Some PHPs are already tracking ADRs in patient treatment files

Slide 11

Findings – Opportunities (2)

- DTCs are already envisioned as "decentralized units" for NPMIC
- Donor community sensitized and supportive to the need for PhV system
- Besides MOH, other bodies such as PEPFAR, PMI, the Global Fund, CDC, USAID, and WHO are leveraging funding for PhV
- Drug quality study for ACT currently being conducted in collaboration with the University of Liverpool
- Active surveillance of ACT use in pregnancy being set up
- Plan underway for revision of pharmacy curriculum of the National University of Rwanda, thus providing opportunity for inserting PhV topics

Slide 12

Recommendations for Immediate Next Steps (1)

- Finalize/Approve the PhV-related policy, legal provisions and guidelines
- Establish NPMIC as early as possible
- Prepare an initial core group of in-country experts and trainers by providing them a TOT
- Establish a multi-disciplinary "Medicines Safety Committee" to assist NPMIC on technical matters
- Strengthen the National PhV working Committee to enable it advance PhV activities

Slide 13

Recommendations for Immediate Next Steps (2)

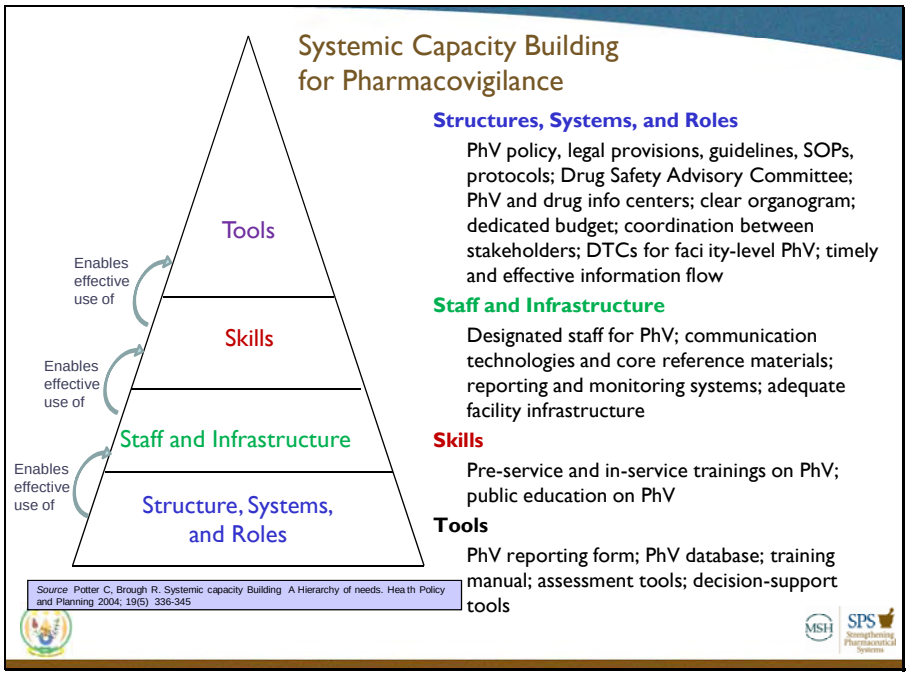
- Strengthen DTCs to monitor safety and treatment failure
- Develop system for tracking suspected treatment failure
- Support active surveillance:
  - —ACT in pregnancy
  - —Safety monitoring within the Community Health Worker, CHW program
  - —ADR data in HIV/AIDS program to inform guideline revision

Slide 14

Recommendations for Further Actions

- Initiate a cascade of trainings led by the TOT-exposed trainers
- Work with the National University of Rwanda to adequately address PhV topics in the pharmacy curriculum
- Implement locally suitable strategies to stimulate reporting on drug-related adverse events
- From early on, emphasize "medicines safety" by putting in place risk mitigation systems, protocols and SOPs
- Coordinate all players & stakeholders to improve efficiency
- Integrate a monitoring and supervision plan from the beginning

Slide 15



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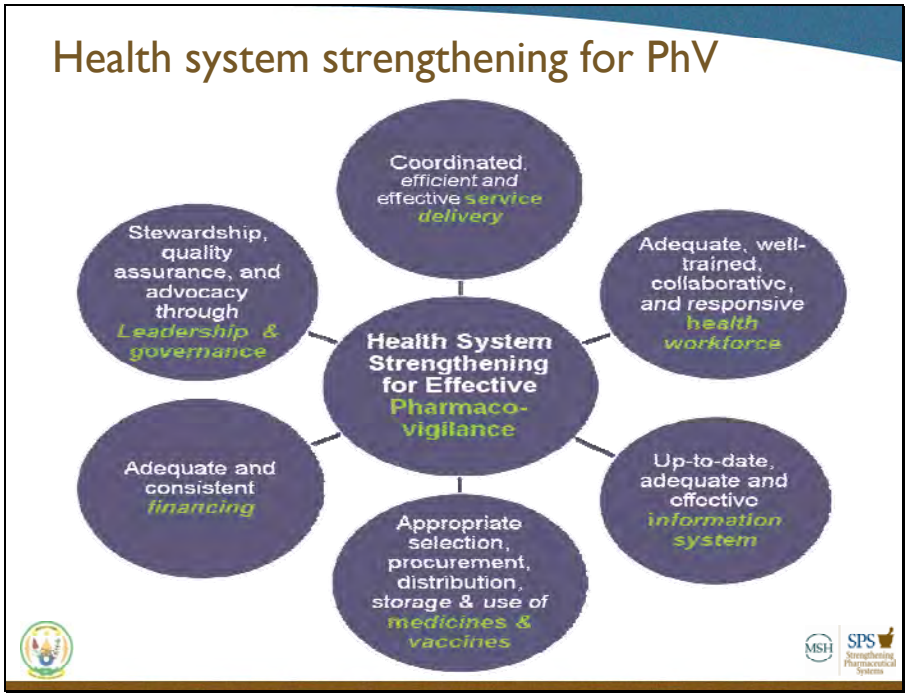


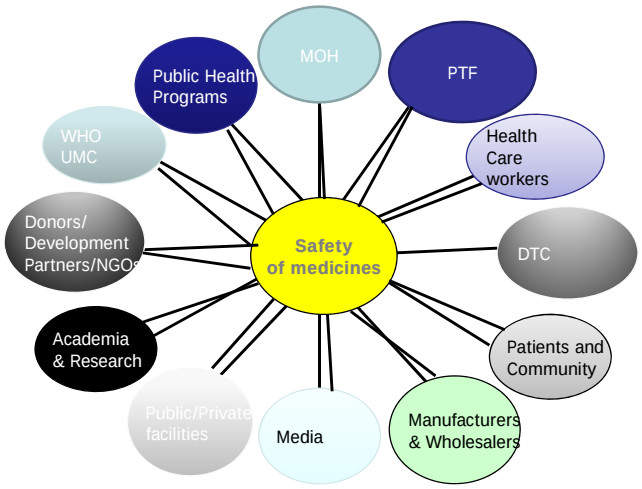
Slide 17

Opportunities for improving coordination to support PhV activities

- Several efforts are currently ongoing:
  - —ACT study (enhance the protocol for a consolidated active surveillance study)
  - —Quinine study, Bupivacaine
- National PhV working committee should be strengthened by the PTF to ensure regular meetings
- Mapping of stakeholders, launch of NPMIC as a good opportunity to bring all stakeholders together

Slide 18

Stakeholders in Pharmacovigilance



Slide 19

Challenges of monitoring

- Safety of ACT in pregnancy: "a pressing question"
- From collection to use → using data to inform guidelines decisions
- Pharmacy ART register

Review

Open Access

The safety of artemisinins during pregnancy: a pressing question

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Published: 14 February 2007

Malaria Journal 2007, 6:15 doi:10.1186/1475-2875-6-15

Received: 30 October 2006
Accepted: 14 February 2007

This article is available from: http://www.malariajournal.com/content/6/1/15

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Abstract

Background: An increasing number of countries in sub-Saharan Africa are changing to artemisinins combination therapy (ACT) as first or second line treatment for malaria. There is an urgent need to assess the safety of these drugs in pregnant women who may be inadvertently exposed to or actively treated with ACTs.

Objectives: To examine existing published evidence on the relationship between artemisinin compounds and adverse pregnancy outcomes and consider the published evidence with regard to the safety of these compounds when administered during pregnancy.

Slide 20

Opportunities for tracking already existing ADR data

Rapport des Visites à la Pharmacie

Noms:
No TRACNET:
Date de début des ARV:

Allergie:

Date de naissance :
Sexe:

ARV Régime et Dosage	Date Début	Date Arrêt	Raison(s) d'arrêt**

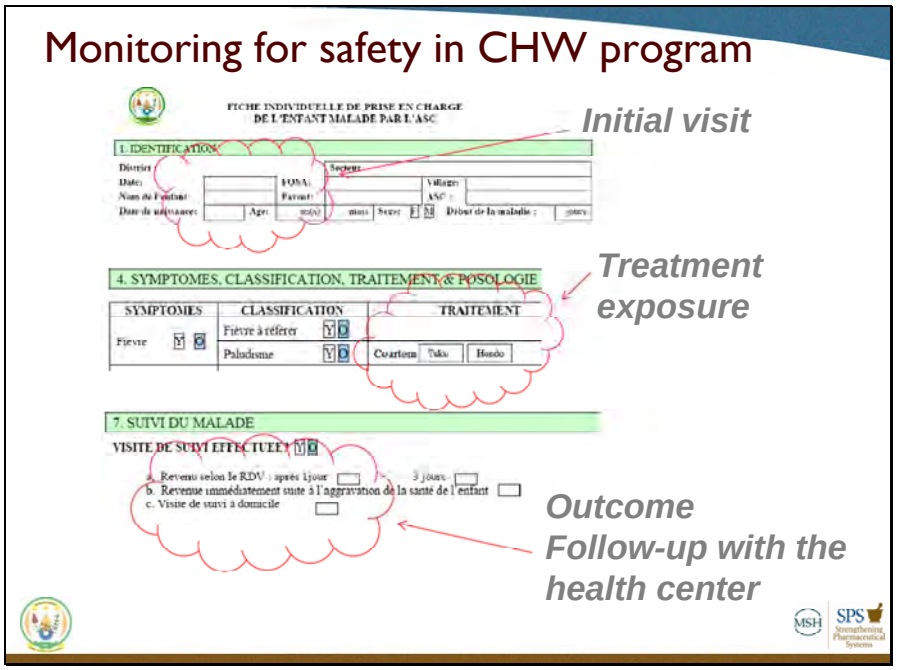
IO Régime et Dosage	Date Début	Date Arrêt	Raison(s) d'arrêt**
Bactrim			
Dapsone			
Fluconazole			
Anti TB			

**Raisons d'interruption des médicaments: 1=Echec; 2=Tuberculose/interaction médicamenteuse; 3=Effets secondaires/allergie; 4=Toxicité (spécifie); 5=Grossesse; 6=Rupture de stock; 7=Immunité complète; 8=Autre raison:

Abréviations des molécules:
INRT: AZT=ZDV=Zidovudine; D4T=Stavudine; 3TC=Lamivudine; ABC=Abacavir; TDF= Tenofovir; DDI= Didanosine
INNRT: NVP= Nevirapine; EFV= Efavirenz
IP: IDV= Indinavir; LOPR= Lopinavir/ritonavir; NFV= Nelfinavir; SQV= Saquinavir; Rv= Ritonavir; ap= stop

Date de Visite	Visite Respectée	Poids	Eruptions cutanées/ Prurit	Nausées Vomissement	Dyspnée	Pâleur conjonctivale	Mal de tête	Paresthésie	Vertiges, sauthemens, insomnie	Troubles psychiques	Douleur abdominale	Diarrhée	Jaunisse	# de doses manquées dans les 7 jours passés (ARV/Bactrim)	# de comprimés restants (ARV/Bactrim)	Date de Prochaine RDV médicale	Autre médicament	Actions

Slide 21



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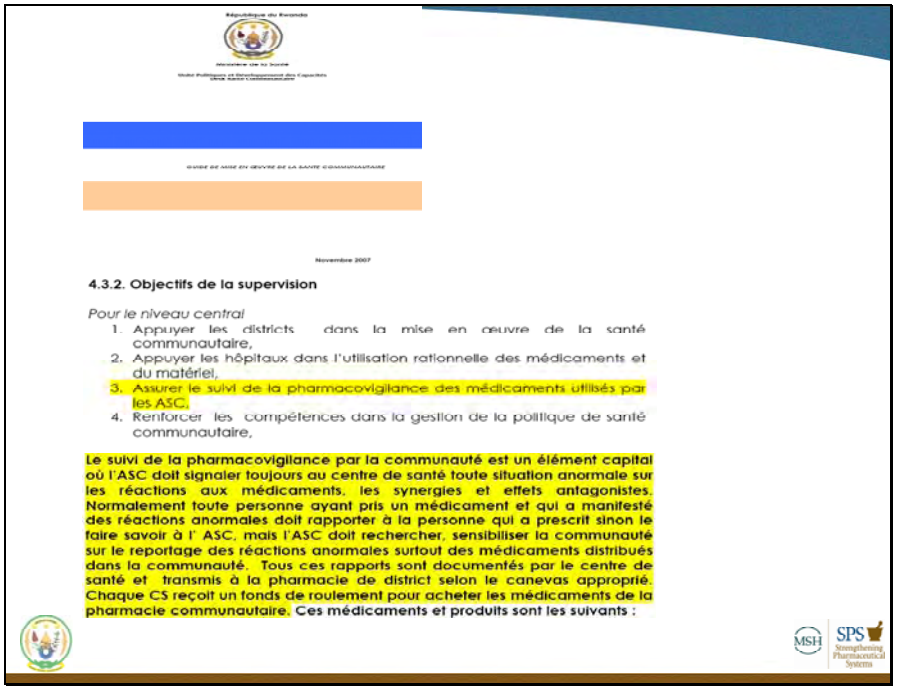

Novembre 2007

4.3.2. Objectifs de la supervision

Pour le niveau central

1. Appuyer les districts dans la mise en oeuvre de la santé communautaire,
2. Appuyer les hôpitaux dans l'utilisation rationnelle des médicaments et du matériel,
3. Assurer le suivi de la pharmacovigilance des médicaments utilisés par les ASC,
4. Renforcer les compétences dans la gestion de la politique de santé communautaire,

Le suivi de la pharmacovigilance par la communauté est un élément capital où l'ASC doit signaler toujours au centre de santé toute situation anormale sur les réactions aux médicaments, les synergies et effets antagonistes. Normalement toute personne ayant pris un médicament et qui a manifesté des réactions anormales doit rapporter à la personne qui a prescrit sinon le faire savoir à l' ASC, mais l'ASC doit rechercher, sensibiliser la communauté sur le reportage des réactions anormales surtout des médicaments distribués dans la communauté. Tous ces rapports sont documentés par le centre de santé et transmis à la pharmacie de district selon le canevas approprié. Chaque CS reçoit un fonds de roulement pour acheter les médicaments de la pharmacie communautaire. Ces médicaments et produits sont les suivants :

Slide 23

Recipes for Success (1)

- Recognize and build on foundations that already exist
- Introduce PhV as value-added to on-going initiatives, rather than as a "new" and "competing" initiative
- Prioritize the identified interventions and adopt a realistic and phased approach in implementing them
- Pay attention to not only developing policies, guidelines, and SOPs but also enforcing them
- Capitalize on opportunities to support *system strengthening* to bring lasting results

Slide 24

Recipes for Success (2)

- Use PHPs to catalyze PhV
- Improve coordination among all key stakeholders
- Exploit opportunities for integrating PhV functions in the already operational tools and software
- Ensure private sector participation from the beginning
- Ensure on-going supervision and monitoring for efficiency and better results
- Mobilize and coordinate with donors and diversity funding sources
- Strengthen governance, transparency, and accountability on matters relating to PhV

Slide 25

Merci beaucoup!
MSH
SPS
Strengthening Pharmaceutical Systems

Annex 5. Revised indicators

Nos.	Indicator	Type of Indicator	Data collection level
Component 1. **Policy, Law, and Regulation**			
1.1	Existence of a policy document that contains a statement on pharmacovigilance or medicine safety (standalone or as a part of some other policy document)	Structural	MoH, PHP, HF
1.2	Existence of specific legal provisions for pharmacovigilance in the medicines and related substances Act or a similar legislation	Structural	MoH
1.3	Legal provisions require the market authorization holder to mandatorily report all serious ADRs to the national drug regulatory authority	Structural	MoH
1.4	Legal provisions require the marketing authorization holder to conduct post-marketing surveillance activities for products that have such requirement by stringent regulatory authorities	Structural	MoH
Component 2. **Systems, Structures, and Stakeholder coordination**			
2.1	Existence of a pharmacovigilance center or unit	Structural	MoH, PHP, HF
2.2	Pharmacovigilance center or unit has a clear mandate, structure, roles, and responsibilities	Structural	MoH, PHP, HF
2.3	Existence of a medicine information or pharmacovigilance service that provides ADR and drug safety-related question-answer services	Structural	MoH, PHP, HF
2.4	A designated staff responsible for pharmacovigilance or medicine safety activities	Structural	MoH, PHP, HF
2.5	Dedicated budget available for pharmacovigilance-related activities	Structural	MoH, PHP, HF

2.6	Existence of a national medicine safety advisory committee or a subcommittee with similar functions that has met at least once in the past 1 year	Structural	MoH
2.7	Existence of national pharmacovigilance guidelines updated within the last 10 years	Structural	MoH
2.8	Existence of protocols or SOPs for improving patient safety relating to medicines use	Structural	MoH, PHP, HF
2.9	Existence of functioning communication technologies (eg. phone, fax, internet, email) to improve access to safety reporting and provision of medicines information	Structural	MoH, PHP, HF
2.10	Existence of an ADR or medicine safety bulletin (or any other health-related newsletter that routinely features ADR or medicine safety issues) published in the last 6 months	Structural	MoH, PHP, HF
2.11	Percentage of predefined core reference materials available in the medicine information or pharmacovigilance center	Process	MoH, PHP, HF
2.12	Percentage of predefined core pharmacovigilance topics present in the pre-service training curricula (disaggregated by medicine, pharmacy, nursing, and public health curricula)	Process	Universities, health professionals councils
2.13	Number of health care providers trained on pharmacovigilance and medicines safety in the past 2 years	Process	MoH, PHP, HF, health professionals training centers
2.14	Platform or strategy exists for the coordination of pharmacovigilance activities at the national level	Process	MoH
2.15	National Pharmacovigilance center is a full or associate member of the WHO Collaborating Centre for International Drug Monitoring	Structural	MoH
Component 3. **Signal generation/data management**			
3.1	Existence of a system for coordination and collation of pharmacovigilance data from all sources in the country (e.g., health programs, immunization program, active surveillance studies)	Process	MoH

3.2	Existence of database for tracking pharmacovigilance activities	Process	MoH, PHP, HF
3.3	Existence of a form for reporting suspected ADRs	Process	MoH, PHP, HF
3.4	Existence of a form for reporting suspected product quality issues (as a subset in the ADR form or as a separate form)	Process	MoH, PHP, HF
3.5	Existence of a form for reporting suspected medication errors (as a subset in the ADR form or as a separate form)	Process	MoH, PHP, HF
3.6	Existence of a form for reporting suspected treatment failure (as a subset in the ADR form or as a separate form)	Process	MoH, PHP, HF
Component 4. **Risk assessment and evaluation**			
4.1	Number of medicine utilization reviews carried out in the last 2 years	Process	MoH, PHP, HF
4.2	Pharmaceutical product quality survey conducted within the last 5 years	Process	MoH, PHP, HF
4.3	Incidence of medication errors quantified in the past 5 years	Process	MoH, PHP, HF
4.4	Number of ADR reports received in the last 1 year	Process	MoH, PHP, HF
4.5	Number of active surveillance activities currently ongoing or carried out in the past 5 years	Process	MoH, PHP, HF
4.6	Percentage of patients in public health programs for whom drug-related adverse events were reported in the last 1 year (disaggregated by type of adverse event drug, severity, outcomes, and demographics)	Process	MoH, PHP, HF
4.7	Percentage of patients undergoing treatment within a public health program whose treatment was modified due to treatment failure or adverse events in the past 1 year (disaggregated by treatment failure and adverse events)	Process	MoH, PHP, HF
4.8	Number of patients in public health programs for whom drug-related serious “unexpected adverse events” were reported in the past 2 years	Process	MoH, PHP, HF

Component 5. **Risk mitigation**			
5.1	Risk mitigation plans currently in place that are targeted at high risk medicines	Outcome	MoH, PHP, HF
5.2	Prequalification schemes (e.g., WHO prequalification program and Pharmaceutical Inspection Co-operation Scheme) used in medicine procurement decisions	Outcome	MoH, PHP, HF
5.3	Number of medicine safety information requests received and addressed by the pharmacovigilance or medicine information center in the past 1 year	Outcome	MoH, PHP, HF
5.4	Percentage of planned issues of the medicine safety bulletin (or any other health-related newsletter that routinely features ADR or medicine safety issues) published in the past 2 years	Outcome	MoH, PHP, HF
5.5	Number of medicine safety issues of local relevance identified from outside sources (eg, from another country, or form regional or international sources) and acted on locally in the past 2 years	Outcome	MoH, PHP, HF
5.6	Number of "Dear Healthcare professional letter" or other safety alerts developed and distributed in the past 2 years	Outcome	MoH, PHP, HF
5.7	Average time lag between identification of safety signal of a serious ADR or significant medicines safety issue and communication to health care workers and the public	Outcome	MoH
5.8	Percentage of the sampled Drug and Therapeutics Committees that have carried out pharmacovigilane activities or addressed medicine safety issues in the past 2 years	Outcome	HF (DTCs)
5.9	Number of public or community education activities relating to medicines safety carried out in the past 2 years	Outcome	MoH, PHP, HF
5.10	Percentage of medicines sampled in the past 2 years that passed product quality tests	Outcome	MoH, PHP, HF