

**Attend conference on National Pharmacovigilance Systems organized by  
Strengthening Pharmaceutical Systems (SPS)**

**Nairobi, Kenya  
August 16-18 2010**

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***Trip Report***

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## **About PQM**

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical leadership to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

## **Abstract**

The PQM director attended the conference on national pharmacovigilance (PV) systems organized by Strengthening Pharmaceutical Systems (SPS/MSH) and presented on activities PQM has undertaken to assist countries establish a national PV system. He highlighted assistance provided to Madagascar and Senegal in strengthening their pharmacovigilance programs to ensure the safety of medicines.

Other presenters included the World Health Organization, USAID, Global Fund, Medicines for Malaria Venture, and country case studies from Africa, Asia, and Latin America.

## **Recommended Citation**

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## **Key Words**

Pharmacovigilance, safety of medicines and systems approach

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## **ACKNOWLEDGEMENTS**

My thanks go to SPS/MSH conference organizers for inviting me to speak at the conference.

Thanks to the Malaria Control program staff in Madagascar, Mali, and Senegal for partnering with PQM to strengthen their pharmacovigilance programs.

Thanks to Anthony Boni, PQM Agreement Officer Technical Representative at the Office of Health, Infectious Diseases and Nutrition at USAID/Washington, for his guidance and leadership.

Thanks also the editorial team for their diligent editorial services.

## ACRONYMS

ACT	Artemisinin-based Combination Therapy
ARV	Antiretroviral medicine
COP	PEPFAR Country Operational Plan
DQ	Drug Quality
FDC	Fixed Dose Combinations
GFATM or Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practices
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PPB	Pharmacy and Poison Board of Kenya
PQM	Promoting the Quality of Medicines Program
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
SPS/MSH	Strengthening Pharmaceutical Systems Program, implemented by Management Sciences for Health
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

## Purpose of Conference

- Highlight and promote a systems approach to pharmacovigilance (PV);
- Discuss systems-oriented approaches to medicines safety and mechanisms for collecting, interpreting, and using information;
- Inform on global initiatives and coordination mechanisms;
- Discuss metrics for assessing country activities in PV; and,
- Discuss ways for local United States Agency for International Development (USAID) Missions to support pharmacovigilance activities.

## Source of Funding

These activities were funded by the USAID/Health, Infectious Diseases and Nutrition Mission Common Agenda funds

## Conference Title and Theme

*National Pharmacovigilance Systems: Ensuring the Safe Use of Medicines* (Agenda, [Annex 1](#))

- A Systems Approach to Pharmacovigilance
- Capacity Building and Country Ownership
- Information Sharing, Collaboration and Coordination

## Conference Deliberations

### Opening statements

The conference opening remarks were given by Mr. Jack Dodoe, World Health Organization (WHO)-Kenya country office; Dr. K.C. Koskei, chief pharmacist, Ministry of Medical Services and Registrar, Pharmacy and Poison Board; Dr. S. K. Sharif, director, Public Health and Sanitation, welcoming the permanent secretary of the Ministry of Public Health and Sanitation.

All of the speakers expressed the importance of pharmacovigilance in ensuring the safety of medicines, especially the newly-introduced fixed-dose combinations for the treatment of malaria, tuberculosis (TB), and HIV/AIDS. The Kenya Ministry of Public Health and Sanitation officials pledged the support of the Kenyan government to continue PV efforts in the country under the leadership of the Pharmacy and Poison Board (PPB) of Kenya.

Mark K. Bor, EBS, permanent secretary, Ministry of Public Health and Sanitation, gave the keynote address. He praised efforts of the PPB in leading the PV activities in Kenya and asked all stakeholders and partners to continue to support this important activity in their countries.



Above: Dr. Lukulay with CDC/PMI rep Gladys Tetteh;  
Below: with WHO-Kenya reps;



### Highlights of Conference Deliberations and Presentations

- Countries are not taking advantage of provisions by multilateral and bilateral organizations to support PV activities. For example, according to Shanthi Pal (WHO) and Serge Xueref of the Global Fund, only 31% of applicants from Rounds 4–9 asked for PV support, and, since the inception of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) Country Operational Plan (COP) program, only 47% of participating countries have asked for support of PV activities.
- WHO highlighted the minimum requirements for a functioning pharmacovigilance system which includes a national PV center, a national database for capturing PV information, spontaneous reporting, presence of an advisory committee, a strategy for communication of information, and a strategy for obtaining drug quality information.
- PV strategy must adopt a systems approach which includes the establishment of a structure, systems and roles, and a staff with the right skills and tools.
- There is need to standardize PV methods and approaches.
- In Africa, 20 countries are full members of the WHO safety monitoring program and 12 countries are associate members.
- PV systems should be holistic, cutting across all disease programs.
- Spontaneous reporting can be enhanced by stimulated reporting where reports are solicited in some cases; this falls in between spontaneous reporting and cohort event monitoring.
- “Record linkage” PV methods can be useful under certain conditions, such as limited time to conduct PV, privacy issues, limited budget, and where a denominator is needed.
- SPS has developed a performance-based metric to assess the functionality of a PV system; this system considers 43 indicators on policy, law, regulation, signal generation, risk assessment, and risk management.



The Afghanistan delegation with Dr. Lukulay

### Conference Materials and Sources of References

The PQM presentation is attached ([Annex 2](#)). Other conference materials, including those listed below, can be obtained online at <http://www.msh.org/projects/sps/Resources/Conferences/SPS-PV-Conference.cfm> or upon request from PQM staff (phl@usp.org):

- All slide presentations given by conference presenters (see the conference Agenda ([Annex 1](#)));
- WHO guidance documents on pharmacovigilance; and,
- Pharmacovigilance literature and resources.

### **Annexes**

[Annex 1](#): Conference agenda

[Annex 2](#): PQM slide presentation



**National Pharmacovigilance Systems: Ensuring the Safe Use of Medicines**



InterContinental Hotel - August 16-18, 2010

MONDAY, AUGUST 16				
Session Title	Time	Objectives	Key Messages/Content	Presenter/Facilitator
BREAKFAST & REGISTRATION	7h00 – 8h45			
Welcome & Official Opening	09h00 – 10h00 [60 min]		<ul style="list-style-type: none"> <li>Welcome by SPS/Kenya (hosts)</li> <li>Welcome and opening statements by the Government of Kenya</li> </ul>	SPS/ Kenya (Mary Wangai)  WR Representative (Jack A Dodoe)  Pharmacy & Poisons Board (K.C. Koskei)  Ministry of Public Health & Sanitation (S.K Sharif)  The Permanent Secretary Ministry of Public Health & Sanitation (Mark Bor)
Conference Program Overview & Introductions	10h00 – 10h15 [15 min]	Provide an overview of the conference objectives & content	<ul style="list-style-type: none"> <li>Inform on global initiatives promoting pharmacovigilance</li> <li>Provide a framework for building, strengthening &amp; optimizing medicines safety systems at country level</li> <li>Identify ways in which donors can support pharmacovigilance capacity building</li> <li>Introduction of participants</li> </ul>	SPS (Tina Brock & Ndinda Kusu)

MONDAY, AUGUST 16				
Session Title	Time	Objectives	Key Messages/Content	Presenter/Facilitator
Strengthening National Pharmacovigilance Systems for Promoting Patient Safety	10h15 – 10h35 [15 min presentation + 5 min Q&A]	Describe the evolution and present- day global practices of pharmacovigilance, including challenges and opportunities	<ul style="list-style-type: none"> <li>• Framework for pharmacovigilance that includes toxicity, medication errors, and issues with product quality</li> <li>• Increasing interest in global medicines' safety and need for pharmacovigilance over a medicine's life- cycle</li> <li>• Overview of pharmacovigilance as practiced in resource- limited settings</li> <li>• Opportunities for greater coordination and strengthening of pharmacovigilance systems</li> </ul>	SPS Partner Organization: University of Washington (Andy Stergachis)
TEA BREAK	10h35 – 11h00			
Global Pharmacovigilance: The World Health Organization and The Global Fund	11h00 – 12h00 [45 min presentation + 15 min Q&A]	<p>Provide an overview of the roles of WHO and GF in promoting pharmacovigilance</p> <p>Define minimum requirements for pharmacovigilance</p> <p>Provide a brief overview on available guidance documents and tools</p>	<ul style="list-style-type: none"> <li>• Describe the functions and minimum requirements of a National Pharmacovigilance System</li> <li>• Provide an overview of WHO guidance documents and tools for pharmacovigilance</li> <li>• Describe the GF initiative to ensure that its applicants and grantees actively incorporate pharmacovigilance activities</li> <li>• Describe the GF requirements for pharmacovigilance</li> </ul>	WHO (Shanthi Pal)
Promoting the Quality of Medicines (PQM): Interventions in Countries	12h00 – 12h05 [5 min presentation]	Provide an overview of PQM's role in pharmacovigilance	<ul style="list-style-type: none"> <li>• Describe PQM's activities in medicines quality</li> </ul>	PQM (Patrick Lukulay)
Wrap up for Global Initiatives	12h05 – 12h15 [10 min Discussion & Q&A ]	Summarize key messages		Facilitator SPS (Joseph Mukoko)
LUNCH BREAK	12h15 – 13h15			

<b>MONDAY, AUGUST 16</b>				
<b>Session Title</b>	<b>Time</b>	<b>Objectives</b>	<b>Key Messages/Content</b>	<b>Presenter/Facilitator</b>
Pharmacovigilance: A Systems Perspective	13h15 – 14h15 [60 min interactive]	Describe the SPS perspective on pharmacovigilance	<ul style="list-style-type: none"> <li>• Definition of “pharmacovigilance system”</li> <li>• The SPS pharmacovigilance framework</li> <li>• The SPS capacity building pyramid</li> <li>• The SPS pharmacovigilance curriculum</li> </ul>	SPS (David Lee)
Collecting and Interpreting Safety Information	14h15 – 15h15 [60 min interactive]	Provide overview of key pharmacovigilance approaches	<ul style="list-style-type: none"> <li>• Sources of information on medicines safety</li> <li>• Complementarity of passive (spontaneous reporting) and active (e.g., registries, cohort studies) surveillance methods</li> </ul>	SPS (Jude Nwokike)
<b>TEA BREAK</b>	<b>15h15- 15h45</b>			
Using Information to Manage Medicines Safety at the National Level	15h45 – 16h45 [60 min interactive]	Provide an overview of safety risk management and communication	<ul style="list-style-type: none"> <li>• Regulatory actions (label changes, package insert changes, safety alerts, batch/lot recalls, marketing suspensions, market withdrawals, formulation changes)</li> <li>• Program actions (product quality assurance, treatment regimen/guideline changes, levels of use controls, educational or training on appropriate use)</li> <li>• Safety communication/public reassurance actions (mass media communications)</li> </ul>	SPS (Francis Aboagye- Nyame)
Wrap up on SPS Perspectives	16h45 – 17h00 [15 min dicussion]	Summarize SPS pharmacovigilance framework		Facilitator – SPS (Jude Nwokike)



**National Pharmacovigilance Systems: Ensuring the Safe Use of Medicines**

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<b>TUESDAY, AUGUST 17</b>				
<b>Session Title</b>	<b>Time</b>	<b>Objectives</b>	<b>Key Messages/Content</b>	<b>Presenter/Facilitator</b>
BREAKFAST	7h30 – 8h15			
Warm up & recap	8h30 – 8h45	Recap day 1 key messages & prep for day 2		SPS (Tina Brock)
Pharmacovigilance in Resource- limited Settings	8h45 – 9h15 [20 min presentation + 10 min Q&A]	Provide an overview of existing pharmacovigilance programs in low- and middle- income countries	<ul style="list-style-type: none"> <li>Results of the survey of pharmacovigilance systems, focusing on key findings</li> </ul>	WHO Collaborating Center for Advocacy & Training in Pharmacovigilance (Alex Dadoo)
Kenya Case Study	9h15 – 9h35 [15 min + 5 min Q&A]	Provide an overview of Kenya's pharmacovigilance system		Kenya Pharmacy & Poisons Board (Jayesh Pandit)
South Africa Case Study	9h35 – 9h55 [15 min + 5 min Q&A]	Provide an overview of South Africa's pharmacovigilance system		KwaZulu- Natal Department of Health (Viloshini Manickum)
Namibia Case Study	9h55 - 10h15 [15 min + 5 min Q&A]	Provide an overview of Namibia's pharmacovigilance system		Namibia Therapeutics Information and Pharmacovigilance Centre (Assegid Mengistu)
Pharmacovigilance System Examples from Asia & Latin America	10h15 – 10h35 [15 min + 5 min Q&A]	Provide information from pharmacovigilance examples in Asia & Latin America		SPS (David Lee)
TEA BREAK	10h35 – 11h05			

<b>TUESDAY, AUGUST 17</b>				
<b>Session Title</b>	<b>Time</b>	<b>Objectives</b>	<b>Key Messages/Content</b>	<b>Presenter/Facilitator</b>
Synthesis of Lessons from National Models	11h05 – 11h20 [15 min discussion]			Facilitator SPS (Francis Aboagye- Nyame)
Monitoring Safety through Disease Surveillance Systems	11h20 – 11h45 [20min + 5 min. Q&A]	Briefly describe active safety surveillance in malaria programs and the roles of different active surveillance methods in addressing concerns about safety & effectiveness of antimalarials; Discuss antimalarial safety studies conducted in Uganda	<ul style="list-style-type: none"> <li>Pharmacovigilance is important for the success of malaria control programs</li> <li>Active surveillance is required in monitoring safety and effectiveness of antimalarial medicines</li> <li>As shown from examples, active surveillance can be implemented in Africa</li> </ul>	Medicines for Malaria Venture (Ambrose Talisuna)
Leveraging Existing Sentinel Sites for Monitoring Safety & Effectiveness	11h45 – 12h10 [20min + 5 min Q&A]	Provide an overview of the challenges in implementing sentinel surveillance sites in Africa;  Describe opportunities for routine safety monitoring by leveraging existing sentinel surveillance sites	<ul style="list-style-type: none"> <li>There are several challenges confronting routine surveillance systems in Africa</li> <li>There are opportunities for leveraging existing surveillance systems to monitor safety of medicines</li> </ul>	INDEPTH Effectiveness & Safety Studies of Antimalarial Drugs in Africa (Alex Doodoo & Sharon Ako- Adounvo)
Observational Studies: Community- based Assessment of Antimalarial Use During Pregnancy	12h10 – 12h30 [15 min + 5 min Q&A]	Describe the role of surveys and observational studies in exposure ascertainment of drug use; Discuss community- based assessment of antimalarial use in pregnancy in Uganda	<ul style="list-style-type: none"> <li>Simple surveys and cross- sectional studies are useful in identifying patterns of drug use</li> <li>Observational study designs are useful in studying the frequency of self- administered medicines like antimalarials</li> </ul>	SPS Partner Organization: University of Washington (Laura Sangaré)
<b>LUNCH BREAK</b>	12h30 – 13h30			

<b>TUESDAY, AUGUST 17</b>				
<b>Session Title</b>	<b>Time</b>	<b>Objectives</b>	<b>Key Messages/Content</b>	<b>Presenter/Facilitator</b>
Pregnancy Exposure Registries	1330 – 13h55 [20 min + 5 min Q&A]	Provide an overview of the pregnancy registry; Describe the experiences of pilot study in Kenya  Describe the approach adopted in capacity building	<ul style="list-style-type: none"> <li>• Pregnancy exposure registries can provide important safety information</li> <li>• There are opportunities for building capacity &amp; implementing pregnancy registries in developing countries</li> </ul>	WHO/TDR (Joyce Lavussa, Mackensie Yore, & Edwin Were)
Cohort Event Monitoring Studies in ART Programs	13h55 – 14h20 [20 min + 5 min Q&A]	Describe existing regional and international cohort collaborations  Describe an example of a cohort event monitoring study being implemented; Provide lessons learnt in the conduct of ART CEM	<ul style="list-style-type: none"> <li>• There are several cohort collaborations in existence to better understand the safety and effectiveness of ARV medicines</li> <li>• There are opportunities for building capacity and implementing CEM in developing countries</li> </ul>	Tanzania Food & Drugs Authority (Henry Irunde)
Prospective Safety Monitoring in Preventing Mother- to- Child Transmission of HIV	14h20 – 14h45 [20 min + 5 min Q&A]	Describe the need for safety monitoring in PMTCT programs;  Describe the EGPAF multi- country study for monitoring outcomes in PMTCT programs  Describe opportunities for building capacity for routine safety surveillance in maternal and child health programs	<ul style="list-style-type: none"> <li>• Safety of new medicines are least understood in children and women of reproductive age</li> <li>• Data obtained from safety surveillance can inform treatment guideline revisions to improve PMTCT programs outcomes</li> </ul>	Elizabeth Glazer Pediatric AIDS Foundation (John Ong'ech)
Electronic Health Records in Retrospective Surveillance	14h45 – 15h10 [20 min + 5 min Q&A]	Describe the use of electronic records in safety studies; Describe prospective electronic patient information system	<ul style="list-style-type: none"> <li>• Electronic health records can provide an insight on tolerability and effectiveness of medicines</li> <li>• There are several challenges in using electronic health records for safety studies in developing countries</li> </ul>	SPS Partner Organization: University of Washington (Andy Stergachis)

<b>TUESDAY, AUGUST 17</b>				
<b>Session Title</b>	<b>Time</b>	<b>Objectives</b>	<b>Key Messages/Content</b>	<b>Presenter/Facilitator</b>
Antiretroviral Risk Management	15h10 – 15h35 [20 min + 5 min Q&A]	Discuss clinically significant adverse events associated with ARVs  Describe risk drivers leading to adverse events in clinical settings  Discuss risk management practices that can mitigate adverse events	<ul style="list-style-type: none"> <li>• Adverse events associated with ARVs can impact adherence and treatment outcomes</li> <li>• There are several risk management strategies that can improve outcomes associated with the use of ARVs</li> </ul>	HUCE/PACE South Africa (Henry Fomundam)
TEA BREAK	15h35- 16h00			
Synthesis of Lessons from Disease, Population & Active Surveillance Models	16h00- 16h15 [15 min discussion]			Facilitator – SPS (Niranjan Konduri)
Strengthening National Pharmacovigilance Systems	16h15 – 16h45 [30 min discussion]	Country reviews “own” situation relative to pharmacovigilance systems discussed during the conference	Small group break- out discussions	Group
Wrap up on Country, Disease & Population Perspectives	16h45 – 17h15 [30 min discussion]	Summarize key messages		Facilitator SPS Partner Organization: University of Washington (Andy Stergachis)
RECEPTION	18h00 – 20h00	Host - Assistant Minister, Ministry of Medical Services (Hon. Mr Stephen Kazungu Kambi)		



**National Pharmacovigilance Systems: Ensuring the Safe Use of Medicines**



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WEDNESDAY, AUGUST 18				
Session Title	Time	Objectives	Key Messages/Content	Presenter/Facilitator
BREAKFAST	8h00 – 8h45			
Warm up & recap	8h45 – 9h00	Recap day 2 key messages & prep for day 3		SPS (Tina Brock)
Strengthening National Pharmacovigilance Systems II	09h00 – 10h30	Reports of country situation relative to pharmacovigilance systems	Plenary discussion/reporting back	Group
TEA BREAK	10h30 – 11h00			
Measuring Outcomes of Pharmacovigilance Activities	11h00- 11h45 [40 min presentation + 5 min Q&A]	Describe the indicator- based pharmacovigilance assessment tool (IPAT)	<ul style="list-style-type: none"> <li>Illustrative indicators for assessing and monitoring outcomes of pharmacovigilance activities</li> </ul>	SPS (Jude Nwokike)
Ways for USAID to Support Pharmacovigilance Activities	11h45 – 12h00 [10 min presentation + 5 min Q&A]	Discuss what USAID has been doing via SPS, PQM and other initiatives; discuss using the term pharmacovigilance broadly including issues such as rational use & antimicrobial resistance; discuss support for GF recipients		USAID (Anthony Boni)
LUNCH	12h00 – 13h00			
Ways for Countries to include Pharmacovigilance in Global Fund Applications	13h00 – 13h30 [20 min presentation + 10 min Q&A]	Discuss guidance for how to include PV activities in Round 10 applications		The Global Fund (Alex Dodoo)
Conference Summary & Next Steps	13h30 – 14h00 [30 min discussion]			SPS (Douglas Keene)
Conference Closing	14h00 – 14h30			SPS/ Kenya (Mary Wangai)



**National Pharmacovigilance Systems:  
Ensuring the Safe Use of Medicines**  
Nairobi, Kenya, August 16-18

**PQM Interventions in Countries**

**Patrick Lukulay, Ph.D.**  
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**PQM Interventions in Pharmacovigilance**

Promoting the Quality of Medicines Program

A good PV system requires adequate ADE reporting

- ◆ Assists countries to establish an adequate reporting system under a holistic national PV program that cuts across all health programs
- ◆ Facilitates training in ADR reporting at all levels, causality assessment at the central level
- ◆ Equips the national PV center with necessary supplies, tools, and reference materials
- ◆ Sensitizes health professions on the importance of PV and builds their capacities in PV practices — *local ownership and leadership*




**PQM Interventions in Pharmacovigilance**

Promoting the Quality of Medicines Program

- ◆ Madagascar – Helped develop a functional national PV system at the central, regional and district levels
- ◆ Senegal – Facilitated establishment of a national PV program from fragmented disease-specific systems
- ◆ In collaboration with partners, provides needed tools to sustain PV practices
- ◆ Assists countries in becoming full members of WHO's International Monitoring Programme
- ◆ Evaluates and monitors PV activities




Promoting the Quality of Medicines Program

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