



**Africa Pharmacovigilance Meeting April
18-20, 2012:**

Meeting Proceedings

October 2012



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SLAPS 
Systems for Improved Access
to Pharmaceuticals and Services

Africa Pharmacovigilance Meeting 2012: Technical Report

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September 2012



This report is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of cooperative agreement number AID-OAA-A-11-00021. 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 SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

Recommended Citation

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Ouma, C., and E. Abwao. 2012. *Africa Pharmacovigilance Meeting 2012: Technical Report*. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services Program. Arlington, VA: Management Sciences for Health.

Key Words

Pharmacovigilance, Medicines Safety, Sub-Saharan Africa

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ACRONYMS AND ABBREVIATIONS

AE	adverse event
ADR	adverse drug reaction
AEFI	adverse event following immunization
AMFm	Affordable Medicines Facility–malaria
AMRH	African Medicines Regulatory Harmonization
ART	antiretroviral therapy
BMGF	Bill& Melinda Gates Foundation
CDC	US Centers for Disease Control and Prevention
CEM	cohort event monitoring
DRC	Drug and Therapeutics Committee
EMA	European Medicines Agency
EU	European Union
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HCSM	Health Commodities and Services Management program
ICH	International Conference on Harmonization
ICSR	individual case safety reports
INDEPTH	The International Network for the Demographic Evaluation of Populations and their Health in Developing Countries
INESS	Effectiveness and Safety Studies of Antimalarial Drugs in Africa
M&E	monitoring and evaluation
MAH	Market authorization holder
MMV	Medicines for Malaria Venture
MSH	Management Sciences for Health
NAFDAC	National Agency for Food and Drug Administration and Control, Nigeria
NEPAD	The New Partnership for Africa's Development
NMRA	National medicines regulatory authority
NRA	National regulatory authority
PEM	Prescription event monitoring
PHP	national public health program
PMS	post-marketing surveillance
PSURs	periodic safety update reports
PTCs	Provincial therapeutic committee
PV	pharmacovigilance
QA	quality assurance
QC	quality control
ROI	Return on investment
SCCS	Self-controlled case series
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	standard operating procedures

SPS	Strengthening Pharmaceutical Systems program
SSA	sub-Saharan Africa
UMC	Uppsala Monitoring Center
USAID	US Agency for International Development
USFDA	US Food and Drug Administration
WHO	World Health Organization
WHO CC/Accra	WHO Collaborating Center–Accra

EXECUTIVE SUMMARY

The US Agency for International Development (USAID)-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program, a follow on to the SPS program, implemented by Management Sciences for Health (MSH), is implementing an interagency agreement between the USAID and US Food and Drug Administration (FDA) that is aimed at fostering collaboration between the two agencies to strengthening regulatory systems to ensure the quality and safety of health products in the supply chain of developing countries.

The objective of the interagency agreement is to—

- Raise awareness of the importance of regulatory systems and highlight the public health value of regulatory system investments among governments and relevant stakeholders, thus leading to potential future funding opportunities by development partners for these efforts
- Provide frameworks and tools to regulatory authorities and other partners like USAID missions and other bilateral donors and global facilities to strengthen their safety systems
- Enable regional and global information sharing on safety of medical products in the supply chains by stakeholders, including with the FDA

Through this interagency agreement, an assessment in 46 sub-Saharan African countries was conducted to assess medicines safety and quality systems performance. In 2011, the assessment report *Safety of Medicines in Sub-Saharan Africa: Assessment of Pharmacovigilance Systems and their Performance* was published. The publication was launched at the 2012 Africa Pharmacovigilance Meeting held at the Intercontinental Hotel in Nairobi, Kenya, held April 18–20, 2012.

The meeting was attended by 110 participants from 32 countries and included a one-day assessment dissemination conference and two-day workshop to identify priority package of tools and guidance documents related to pharmacovigilance (PV) and regulatory systems strengthening. The meeting brought together partners from the global regulatory and pharmacovigilance community, including the World Health Organization (WHO), the Bill & Melinda Gates Foundation (BMGF), the European Medicines Agency (EMA), the US Centers for Disease Control and Prevention, the FDA, the USAID, as well as national regulatory authorities and national public health programs.

The report below contains proceedings from the three-day meeting. Slides, photographs, and other related materials are available at: africapv2012.wordpress.com.

PROCEEDINGS: DAY 1. OPENING CEREMONY



Day 1 opened with presentation of the report, *Safety of Medicines in Sub-Saharan Africa: Assessment of Pharmacovigilance Systems and their Performance*. It focused on the dissemination of the findings from the study, discussions on regulatory harmonization initiatives in Africa, and an examination of global perspectives on medicine safety by various stakeholders and players in the PV arena. During the session, the importance and approaches to pharmacovigilance (PV) metrics was discussed. The day concluded with a panel discussion on access and safety.

Dr. Mary Wangai, chief of party of the USAID-funded Health Commodities and Services Management program, managed by MSH, welcomed the participants to Nairobi. She stated that PV is a key activity for the program in Kenya and that the program has over the years worked the Medicines Regulatory Authority in Kenya, the Pharmacy and Poisons Board, to promote patient safety through various activities. [*opening slides*]

Mr. Anthony Boni, pharmaceutical management specialist with USAID/Washington spoke on behalf of USAID/Washington Global Health Bureau (GHB) and the USAID/Kenya Mission, stating that the meeting was an important part of ongoing efforts to assure therapeutic effectiveness and patient safety through the use of needed tools and approaches. He added that increased access to essential medicines has also signified a greater need to monitor and promote their safety and effectiveness. Mr. Boni noted that there is growing recognition that product quality has to be assured and system strengthening interventions promoted to preserve the

effectiveness of currently available therapies and contain the emergence and spread of drug resistance. He concluded by highlighting key milestones of USAID-supported Strengthening Pharmaceutical Systems (SPS) program PV activities as—

- Development of the SPS seminal paper entitled *Supporting Pharmacovigilance in Developing Countries: The Systems Perspective*. This provides a comprehensive systems perspective for monitoring safety and effectiveness and the operational strategy that encompasses the full spectrum of medicine safety.
- Development and implementation of the Indicator-based Pharmacovigilance Assessment Tool (IPAT) which allows countries to conduct PV assessments to understand and improve upon the structures and performance of their medicine safety and risk management systems.
- A workshop to disseminate the IPAT in Nairobi in 2010. This addressed how countries can assess their PV systems and develop phased interventions as part of a comprehensive national medicine safety program.
- An USAID and USFDA agreement in 2010 to support PV assessment in Africa to provide a comprehensive description and analysis of national PV systems in SSA, identifying best practices that are scalable and recommending options for enhancing PV systems.
- A second USAID and FDA interagency agreement in 2010 to disseminate findings of the SSA study, to conduct a workshop to develop required PV tools' and to conduct subsequent in-depth PV assessments in selected countries in Asia. [*opening remarks*]

Dr. Beverly Corey, FDA senior regional advisor for sub-Saharan Africa (SSA), outlined key USAID initiatives and activities by the FDA in expanding its work outside the United States as products used within the United States are increasingly imported from overseas and ensuring safe food and drugs increasingly depend on regulators elsewhere. She stated that the FDA has been engaged in global activities, including establishing foreign posts in selected countries/regions, strengthening regulatory capacity in developing countries, harmonizing science-based standards, leveraging knowledge and resources, performing risk-based monitoring and inspection, gathering global information gathering and data-driven risk analytics, and leveraging resources. She added that the FDA's work in SSA stems from the increasing funding for access to medicines through programs like PEPFAR, and the corresponding need for systems to assure these medicines can be delivered and used safely. Dr. Corey concluded by stating that the various interagency agreements with USAID and associated activities are part of the FDA's goal to be a catalytic force for regulatory capacity building and that the next steps for FDA's global engagement are contained in its recently released publication, *Pathway to Global Product Safety and Quality*, which highlights the Agency's envisaged move from a reactive to a proactive approach in medicine regulation. [*opening remarks, opening slides*]

Dr. David Kiima, representing Kenya's Minister of Medical Services, stated that a key challenge facing the Kenya health system is the presence of poor quality medicinal products and those that

are of doubtful efficacy. He added that substandard, unregistered, and medicines of unknown safety profiles were the priorities being addressed by the Pharmacy and Poisons Board. He reiterated that the findings and recommendations of the Safety of Medicines in SSA Report need to be taken up by all countries included in the report to enhance patient safety.

Dr. Kiima then officially opened the meeting.

Presentation of Findings from the SSA Study, Jude Nwokike and Hye Lynn Choi, SIAPS

The study found that despite the huge pharmaceutical market in SSA, the capacity for regulation of health products is limited and thus inadequate attention is paid to medicine safety. In addition, membership of these countries to the WHO Program on International Drug Monitoring does not necessarily indicate that they have a functional PV system in-country. Non-adherence to standardized reporting systems in these countries reduced the usefulness of individual case safety reports (ICSRs) generated both locally and globally. Moreover, these countries have limited capacity to assess and evaluate signals from the received reports. Ultimately, the countries do not typically use these data for decision making and only a few take regulatory action based on the reports.

Another key finding is the limited involvement of the SSA pharmaceutical industry in medicine safety monitoring, with minimal post-marketing surveillance by industry apart from that done by South Africa, which has relatively good systems and structures. A positive finding of the assessment is that national public health programs are involved in PV although there was limited information sharing between public health programs and the national PV systems.

The report gives a number of recommendations that include—

- Improve active surveillance and explore opportunities to collaborate with academia
- Address product quality issues
- Strengthen drug and therapeutics committees' (DTCs) role in medicine safety
- Strengthen data for decision making and information sharing
- Increase responsibility for medicine safety by the pharmaceutical industry

African Medicines Regulatory Harmonization, Dr. Margareth Ndomondo-Sigonda, New Partnership for Africa's Development (NEPAD) African Medicines Regulatory Harmonisation (AMRH) Programme

The session discussed regulatory harmonization initiatives in Africa as they relate to the quality and safety of medicines. The meeting attendees were informed that resource constraints for regulation exist and weak or nonexistent legislation and regulatory capacity and different regulatory requirements for industry are constraining the growth of the pharmaceutical industry. To address these challenges, a pharmaceutical manufacturing plan for Africa was developed in 2005 with the support of the African Union with the New Partnership for Africa's Development (NEPAD) Planning and Coordinating Agency providing oversight for implementation.

Through the African Medicines Regulatory Harmonisation (AMRH) Programme, a consortium of partners has been brought together to accelerate African regulatory harmonization building on existing regional efforts, political mandates, and initiatives. The target is to reduce the continent's 54 independent national medical regulatory authorities (NMRAs) through harmonization of five to seven regional MRAs with stronger institutionalized regulatory capacity based on regional economic blocks such as the Economic Community of West African States, the East African Community, and the Southern African Development Community. The other initiative goals include having a single set of requirements with clear guidelines and transparent regulatory processes and timelines, and promoting resource pooling and information sharing.

The WHO PV Toolkit, Alex Dodoo, WHO Coordinating Centre–Accra

The recently launched WHO PV toolkit was presented by the WHO Collaborating Centre (WHO-CC/Accra) and consists of PV tools, resources, and accompanying guidelines that has been developed or compiled to support PV systems implementation in limited resource setting. It can be used to assist countries to quantify resources required for a functional PV system and support proposal writing for funding from donors with PV requirements. It also contains disease-specific toolkits for malaria and HIV/AIDS. However, there is need to develop TB- and vaccine-specific toolkits that address PV and also to bring on board more stakeholders for improved governance for the WHO PV toolkit. The tool kit can be accessed at www.pvtoolkit.org

PV Metrics, Dr. Andy Stergachis, University of Washington, Seattle, WA, USA

The session highlighted the approaches to and importance of measuring performance and outcomes of PV systems. Monitoring and evaluation (M&E) of PV allows tracking of progress and performance and improves accountability, thereby leading to better decisions and better spending. The desired attributes of PV indicators include relevance, scientific soundness, feasibility, comparability, evidence-based, transparency and collaboratively developed. A number of metrics are available including (1) those contained in the IPAT, (2) the minimum requirements for a functional PV system published by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and WHO, and (3) the proposed set of indicators for M&E of PV systems presented during the 2011 ICIUM conference. Still, there is a need for additional work in defining and reaching consensus on PV metrics.

IPAT, which was used in the SSA study, consists of 25 core and 18 supplementary indicators—43 in all, and is designed to evaluate structural components, processes, and outcomes of PV systems. Because the tool is modular, indicators relevant to different health system segments can be pulled out to monitor specific medicine safety issues.

Metrics are needed to assess PV system performance and improvement including inputs, processes, and results (outcomes and impact). However, the challenges of implementing PV metrics include—

- Defining evidence-based metrics
- Producing data of sufficient quality to permit regular tracking of progress and evaluation
- Need for harmonized approaches

The Way Forward: Global Perspectives

The session was designed to obtain and discuss perspectives on PV systems by selected stakeholders—WHO, EMA, BMGF, Medicines for Malaria Venture (MMV), and Malaria Access to Medicines Partnership.

World Health Organization (WHO), Dr. Shanthi Pal

The WHO Programme for International Drug Monitoring currently has 110 official member countries and 32 associate member countries, with about 40 located in Africa. The growth of the WHO PV program is due to a number of interventions including developing and focusing on norms and standards for PV, capacity building activities, providing technical assistance, establishing global outreach centers such as the Uppsala Monitoring Center (UMC) and WHO CC-Accra, and working the national public health programs. To date, seven million individual safety reports are available at UMC with Namibia leading in Africa.

The *Safety of Medicines in SSA* report reinforces previous findings and provides an objective way of scoring pharmacovigilance performance and proposes recommendations. However, there is a need to interpret and determine the reasons for the findings and link them with previous works and analysis. Moreover, it may be necessary to define how to implement the proposed recommendations and ensure sustainability. In conclusion, the *Safety of Medicines in SSA* report defines what needs to be done along with the already identified areas in the global PV strategy which identified the stakeholders, defines roles and responsibilities, proposes resources, defines the coordinating mechanisms, and provides implementation solution.

European Medicines Agency, Mr. Xavier Kurz

The European Medicines Agency (EMA) shared lessons learned in strengthening pharmacovigilance systems in Europe where the public health impact of adverse drug reactions (ADRs) is huge, with societal cost of ADR amounting 79 billion euro (EUR) per year.

The EMA, begun in 1995, primarily coordinates the existing scientific resources of member states for evaluation, authorization, and supervision of medical products. It provides member states with the best possible scientific advice on medicines. The approaches used by the agency include centralized procedures for authorization of medicinal products and support for making new pharmacovigilance legislation.

The EMA's four main areas of activity include (1) collection of key information, (2) better analysis and understanding of data and information, (3) regulatory action to safeguard public health, and (4) communication with stakeholders. The approaches used in collection of key information include implementation of risk management plans, post-authorization safety studies, and electronic submission of core medicine information by market authorization holders (MAHs). For better analysis and understanding of data and information, the agency uses EudraVigilance data and signal detection. Dr. Kurz noted that EMA and member states must collaborate to monitor the EudraVigilance data and perform signal detection for all active substances authorized in the European Union.

To strengthen regulatory action to safeguard public health, some products are subject to additional mandatory monitoring—EMA publishes the list of names and active substances subject to this requirement and the criteria for inclusion. To communicate with the public and stakeholders, the agency publishes information online, coordinates dissemination of safety messages, and holds public hearings. Moreover, the EMA is also implementing the PROTECT Project (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium), an innovative medicines initiative which aims to strengthen the monitoring of medicines benefit/risk in Europe to enhance early detection and assessment of ADRs.

Bill & Melinda Gates Foundation, Mr. Thomas Bollyky,

Mr. Bollyky presented the various initiatives of the BMGF in strengthening regulatory systems capacity worldwide. BMGF's work in PV includes pilot programs on HIV/AIDS at sentinel sites, supporting the conduct of PV activities for new product launches, supporting PV activities within national public health programs, the WHO Global Vaccine Safety Blueprint project, and a global network for post-marketing surveillance of newly prequalified vaccines. The foundation's newly created Safety Surveillance Working Group, composed of regulators, industry, academia, technical agencies, and other stakeholders, builds on past PV initiatives to develop practical and scalable strategies to strengthen PV in low- and middle-income countries. The foundation is initially focusing on supporting risk-based prioritization; leveraging regional approaches, existing infrastructure, government and industry partners to improve sustainability and ensuring scalability; and ensuring compatibility with existing international pharmacovigilance initiatives.

Medicines for Malaria Venture, Dr. Stephan Duparc

Dr. Stephan Duparc presented the Medicines for Malaria Venture's (MMVs) work in monitoring the safety of antimalarial medicines in Africa through active surveillance. The various active surveillance initiatives supported by MMV worldwide are—

- International Network for the Demographic Evaluation of Populations and their Health in Developing Countries (INDEPTH) Effectiveness and Safety Studies of Antimalarial Drugs in Africa (INESS)
- Implementation–safety (INESS) study with dihydroartemesinin/piperazine) in Africa
- Implementation–safety study with Pyramax® (pyronaride /artesunate) in the Mekong region
- European and Developing Countries Clinical Trials Partnership longitudinal repeat dose study
- Effectiveness and cohort event monitoring (CEM) with artesunate with sulfadoxine-pyrimethamine in Orisa, India

Malaria Access to Medicines Partnership, Dr. Francois Bompert

Malaria Access to Medicines Partnership presented a case study on implementing risk management plans in Africa—the ASAQ Winthrop® Risk Management Plan. ASAQ is Winthrop’s artesunate/amodiaquine product. The objective of the risk management plan is to gather good quality safety and efficacy data in a variety of malaria transmission settings to quantify potential risk and document missing information. A variety of approaches have been employed to gather information including randomized comparative clinical studies, randomized comparative cohorts, field monitoring programs, and large scale safety studies covering over 20,000 malaria episodes treated with ASAQ. As of July 2012, 12 controlled studies were completed in various study sites in Africa, covering 3,622 patients with 6,468 malaria episodes treated with ASAQ.

Achieving Regional Excellence

During this session, a number of selected countries shared experiences and current practices in pharmacovigilance tools and guidelines.

Kenya, Dr. Jayesh Pandit, Department of Pharmacovigilance and Post Market Surveillance, Pharmacy and Poisons Board, Kenya

The PV system was launched in 2009 with the mandate of enhancing patient safety and also covers product quality monitoring. The country is a member of the WHO International Drug Monitoring Program.

PV system strengths include—

- Legal framework is in place
- Various PV tools are available including yellow forms (forms for reporting ADRs) and pink forms (forms for reporting poor quality medicinal products)
- Strong collaboration with public health programs.
- There is extensive implementation of post-marketing surveillance (PMS) activities including a developed strategy and a number of PMS exercises for HIV/AIDS (antiretroviral therapy), tuberculosis, and malaria medicines conducted and reports disseminated.
- The impact of the PV system is clearly visible through numerous regulatory actions taken including product recalls and closure of manufacturing plants.
- Systems for communication and sharing PV information have been set up including newsletters (*Lifesaver*) and an e-mail-based medicine safety information sharing system, E shot.

PV system challenges include—

- Nonexistence of a national PV policy; however, it is implied in the revised Kenya National Pharmaceutical Policy, 2010
- Limited capacity for data management and PV information communication/dissemination
- Limited risk assessment, evaluation and management activities
- Lack of MAH involvement and commitment to PV

Democratic Republic of Congo, Prof. Tona Lutete, National Pharmacovigilance Center

The Government of the Democratic Republic of the Congo is committed to supporting PV through the National Pharmacy Policy of 2005. Various subsequent decrees were issued to operate PV in the country.

PV system strengths include—

- There is a functional National Pharmacovigilance Centre with a clear mandate.
- Various PV tools are available including reporting forms (ADRs, adverse events following immunization [AEFI], hemovigilance,¹ medication errors, counterfeit medicines), training tools, data collection tools, analysis tools, awareness campaign tools (for sensitization trainings), and communication tools (PV newsletter and Dear Doctor Letters)

PV system challenges include—

- The PV National Advisory Committee is not functional; this limits decision making regarding PV data and information
- No national guidelines exist, instead good PV practice guidelines from the Morocco PV center are used
- Low reporting rates—less than 20 reports/million
- Low utilization of the data from PV
- No regular funding
- No collaboration with pharmaceutical companies

¹ Hemovigilance refers to the identification and prevention of transfusion-related unwanted events.
<http://www.who.int/bloodsafety/haemovigilance/en/>

South Africa, Mr. Mukesh Dheda, National Pharmacovigilance Centre

South Africa has a strong policy, legal, and regulatory framework and well established systems and structures for PV. PV in South Africa is categorized into (1) regulatory pharmacovigilance covering quality and efficacy of all medicines, and (2) programmatic PV covering medicines used in public health programs. Reporting is mainly spontaneous and in addition covers poor quality medicines and medication errors. There are a large number of pharmaceutical companies in South Africa and their compliance to policies on PV, standard operating procedures (SOPs) for reporting ADRs, periodic safety update reports, and understanding of the national regulatory framework varies greatly.

PV system strengths include—

- There is a National Medicines Policy and National Policy related to PV and medicine safety.
- There is a legal mandate to monitor medicine-related ADRs.
- There is a legal provision for MAH to report all serious ADRs to the NMRA.
- Fifty percent of all ADR reports from Africa are from South Africa; however, there are wide variations in reporting between different regions/provinces.

PV system challenges include—

- The Government of South Africa does not significantly acknowledge the importance of PV.
- There is a lack of proper collaboration with the pharmaceutical industry.
- There is poor coordination and collaboration in data management, i.e., the national PV database does not include data from all sources.
- The Ministry of Health and the NMRA lack capacity for PV.

Nigeria, Ms. Adeline Osakwe, National Pharmacovigilance Center

Like South Africa, Nigeria has a strong policy, law, and regulatory framework for PV. The national mandate for PV and The National Agency for Food and Drug Administration and Control (NAFDAC) were established by a decree in 1993, requiring NAFDAC to ensure the quality, safety, and efficacy of regulated medicine products. Additional medicines safety policies and guidelines include the National Medicines Policy (2005), draft Good Pharmacovigilance Practice Regulations, and the drafted PV Policy (2010).

PV system strengths (and challenges) include—

- Various tools available including guidelines for detecting and reporting ADRs; individual case safety report (ICSR) forms (paper-based and downloadable on-line forms).
- Communication of safety information including PV/FDIC newsletter; public alert notices; agency-sponsored TV programs, and dear health care provider letters.
- Causality assessments conducted and analyzed in-country (an additional level of screening) before reports are shared with UMC (which may explain the low reporting rates for Nigeria).
- High level of PV activities in tertiary institutions where DTCs exist (however, most of the generated information is not shared or fed by institutions into the national PV system).
- PV is strong within public health programs especially for the malaria program.
- There are several zonal PV centers (though coordination is poor).

Priority PV activities include—

- Awareness creation and advocacy including stakeholder forums and information, education, and communication activities
- Capacity building of health care providers and market authorization holders
- Surveillance of medicines
- Signal generation and data management
- Implementation of consumer reporting

Panel Discussion: Access and Safety

At the close of the day, a panel was brought together to discuss the issues of access and safety of medicines. The panel was chaired by Dr. Margareth Ndomondo-Sigonda (NEPAD AMRH), while other members of the panel included Dr. Paul Orhii (NAFDAC, Nigeria), Dr. Shanthi Pal (WHO, Geneva), Dr. Alex Doodoo (WHO Collaborating Centre, Accra, Ghana), Mr. Anthony Boni (USAID, Washington), Dr. Stephan Duparc (MMV), and Dr. Jayesh Pandit (representing Dr. K.C. Koskei from the Pharmacy and Poisons Board).

In her introduction, Dr. Ndomondo-Sigonda stated that the economic impact of ADRs worldwide is high; however, most NMRAs lack capacity to effectively execute their function of safeguarding citizens' health from medicines quality and safety problems. She added that the SSA study had identified gaps in PV systems and provides a basis for implementing interventions to improve patient safety in a holistic manner through comprehensive health systems strengthening programs. Dr. Ndomondo-Sigonda stressed that there is a need for collaboration between NMRAs, industry, national public health programs, and other stakeholders in advancing the PV agenda. The panelists were then allowed five minutes each to contribute to

the discussion followed by questions from the audience and a wrap-up by the panel moderator listing conclusions and recommendations, summarized as follows:

NAFDAC, Nigeria, Dr. Paul Orhii

Dr. Orhii said that PV and patient safety are not subordinate to access and there is need for capacity building to strengthen PV in SSA. He also highlighted the growing problem of counterfeit medicines as this is compromising patient safety.

WHO, Geneva, Dr. Shanti Pal

Dr. Pal stated that currently huge quantities of medicines are being imported into countries with limited PV capacity and this poses a big challenge to medicine safety. She added that it is encouraging to note that PV is increasingly gaining greater prominence. However, to ensure sustainability in efforts to strength medicine safety, PV will have to be adopted as an approach/measure to improve quality of care, greater attention will have to be devoted to PV metrics to measure and demonstrate return on investment, and costs saved by PV programs and funding for PV may have to be built in to product registration fees.

WHO Coordinating Centre–Accra, Dr. Alex Dodoo

Dr. Dodoo stated that previously when access to medicines was poor, medicine safety issues were considered a luxury, but this is no longer so. He stressed that medicine safety issues are important in the public realm and decried the fact that funding for PV was not requested by countries in Global Fund applications although this funding was available.

USAID, Washington, DC, Mr. Anthony Boni

Because access to medicines has improved, there is increased attention on effectiveness and patient safety, Mr. Boni said. He said that ethical responsibility of donors in providing medicines requires that the issue of medicine safety to be addressed and that PV should extend beyond just reporting ADRs to managing and communicating risk information in all countries. Mr. Boni cautioned that multiple challenges exist in implementing PV programs including funding, human resources, and the emergence and spread of antimicrobial resistance.

Medicines for Malaria Venture, Dr. Stephan Duparc

Dr. Duparc stated that funding for PV is inadequate compared to funding available for the procuring commodities. He then cautioned that not generating and using data on medicine safety weakens the case for PV and limits funding.

Pharmacy and Poisons Board, Kenya, Dr. Jayesh Pandit

Dr. Pandit stated that it is encouraging that PV continues to grow. He added that PV however may need to be repositioned or anchored under pharmaceutical care to ensure sustainability.

Panel Recommendations

The following recommendations were synthesized from the panel discussions and Q&A session.

- Regulators in Africa should play their assigned roles as they have the mandate for medicine safety. They should not just register products and collect fees but should also address safety issues. Capacity building and challenges of retention should be addressed.
- Stakeholder collaboration within SSA countries and regions needs to be strengthened.
- Funding for PV is available but not utilized fully, i.e., Global Fund monies for PV.
- In addition to available resources (i.e. Global Fund), need to explore long-term solutions.
- Mentorship for capacity building in PV, twinning, exchanges and other approaches can improve implementation of PV activities. There is a need to strengthen capacity of the WHO Collaborating Center–Accra to provide training on PV in SSA.
- Recommendations for reducing preventable ADRs—
 - Fifty percent of ADRs are estimated to be preventable. There is need to document these events, quantify them, and identify key classes of medicines that are most responsible; epidemiological studies can be conducted.
 - Monitoring should be done in a non-punitive manner and root cause analyses done to determine causes.
 - Measures to reduce preventable ADRs should include training and capacity building to address knowledge gaps and provision of required tools, i.e., guidelines for use by PV centers to address the issue of preventable ADRs.
- Need for strong PV centers and appropriate communication of risk to users
- Building sustainable PV systems
- Build systems for collecting longitudinal data over the long term
- Improve funding of PV, i.e., funding PV activities within registration fees, consider introducing fees for PV services and advocate that PV be incorporated into standard/routine health care delivery system activities
- PV should be adopted as a standard of care
- Develop and implement risk management plans by SSA NMRAs
- Develop and implement PV communication strategies and strengthen pharmaceutical information systems to include medicine safety information
- Increase consumer involvement in medicine safety activities

DAY 2. TOOLS WORKSHOP



Priority PV Tools Workshop Introduction, Dr. David Lee, SIAPS

Dr. David Lee took the participants through the workshop's objectives—

- Discussion of current PV practices and existing tools
- Comparison of current systems and practices with best practices and gaps
- Identify NMRAs with best practices in each component of PV system
- Identify frameworks and operational tools needed to support implementation of effective PV systems

FDA Drug Safety Tools and Practices, Dr. Gerald Dal Pan, FDA/Center for Drug Evaluation and Research

Meeting members were informed that passive surveillance is the backbone for PV despite having challenges such as lack of adequate clinical details in reports. In addition, the USFDA has adopted a three-pronged approach to active surveillance: disease-based, drug-based, and setting-based approaches. Other methods used to supplement the two include observations studies, clinical trials, and drug use surveys. The FDA Sentinel Initiative, a collaboration with the private sector to implement a national integrated electronic system for monitoring medical products safety, has enabled FDA to access the capabilities of multiple existing data systems to augment

the agency's current capability. FDA is paying more attention to managing benefit/risk throughout a medicine's life-cycle. The key challenges for PV were identified as the need to improve the science, better stakeholder engagement, and capacity building through increased collaboration and sharing of best practices.

Global Trends in PV Tools and Practices, Mr. Jude Nwokike, SIAPS

Mr. Nwokike identified the top three global trends in PV as—

- Harmonizing PV requirements through the International Conference on Harmonization guidelines, standard terminologies, statutory powers to regulators to demand post-marketing authorization safety studies, and risk minimization plans
- Managing benefit and risk through the product life cycle
- Growing focus on governance and transparency and increased public scrutiny

The benefits of having PV tools include facilitating harmonization, improving and standardizing work processes, capacity building of regulators, and enabling and enhancing regulatory decision making, and communication of risk information to stakeholders.

The following approaches can be used for the development of required tools—

- Adopting tools developed by stringent regulatory authorities
- Adapting existing tools to local context and/or prioritizing most impactful/essential tools
- Collaborating with several NMRAs on developing similar regulatory needs/demands

The following tools and emerging practices grouped under the PV systems categories were identified and discussed—

- Policy, law, and regulation: National medicines policies, regulatory policies, PV policies, and laws/regulation providing statutory mandate for PV and medicine safety activities, i.e., EU statutory requirements for MAH for PV activities
- Systems, structures, and stakeholder coordination: Facilitate functioning of PV system including NMRA websites, institutional capacity, resources, and metrics for delivery of PV activities; databases of regulatory documents; human resources/staffing models for PV; and inspections and audits, e.g., MHRA good pharmacovigilance practice: risk-based inspection questionnaire
- Signal generation and data management: Tools for documentation and management of drug exposure and outcome data; electronic reporting systems for ADR, product quality, and medication errors; local databases for logging PV center activities; and use of standard terminologies for medical products and the Medical Dictionary for Regulatory Activities terminology for regulatory functions and processes
- Risk assessment and evaluation: Active surveillance tools for proactive assessment of data on utilization and outcome of the use of health products, characterization and

quantification of outcomes, discovery of new knowledge about drug-induced disorders; increasing recognition of need for active surveillance and development of associated tools; study database for clinical trials registration and results and also for observational studies; guidelines for methodological standards; and benefit/risk assessment tools (quantitative and qualitative methods)

Risk management and communication: Tools for communication risks and patient safety; communication strategies, tools, and practices to prevent harm, reduce morbidity and mortality, and improve treatment outcomes; and examples from the EU include the EU Rapid Alert System and Non-Urgent Information System

Before and during the meeting, participants from NMRAs and PHPs were invited to participate in an electronic survey to identify priority tools for implementation of pharmacovigilance system. Of 70 meeting attendees invited to participate, 58 (83 percent) provided responses. Key priority tools identified through the survey included (listed in order of reported priority)—

- Local data warehouse
- Protocols, SOPs, and software for active surveillance
- Risk management plans
- Real-time sharing of global and regional safety information
- Comprehensive guideline for PV
- Benefit/risk assessment tools
- E-reporting and submission system
- Protocols and SOPs for conducting medication errors surveys
- Regulatory policy template
- PV policy template
- Regional regulatory information website
- Human resource for PV
- PV quality management system
- Vaccine epidemiology study infrastructure
- Risk communication tools

Country Presentations—National Regulatory Authorities

The objective of the session was to discuss country specific experiences and approaches to post-marketing safety and quality; use of PV tools; use of information from WHO and stringent regulatory authorities and communication of safety information

Ghana, Ms. Adela Gwira, Food and Drugs Board

Approaches taken to address post-marketing safety and quality of medicines include—

- Revised legislation to adequately address safety monitoring is ongoing, for example legally mandating industry to report serious adverse events to NRA (bill developed)
- Revised comprehensive national PV guidelines
- Three CEMs of antimalarials studies have been conducted (2008—all antimalarials; 2011—Affordable Medicines Facility for malaria (AMFm); 2012—all antimalarials)
- Poor data management and analysis are challenges
- Use of PV tools and forms including adverse reaction reporting form, AEFI forms, PV training manuals, and PV information, education, and communication tools targeting consumers and health professionals
- Medicines safety communication using information from WHO and stringent regulatory authorities including FDA and EMA—
 - Sources of information include WHO, UMC, FDA, EMA
 - Daily review of websites (above) for safety information of relevance
 - Timely use of information from WHO and stringent regulatory authorities; information disseminated within seven days
 - Communication of safety information
 - Dear Doctor letters, posts on FDB website, press releases for product quality issues; newsletter being developed

Uganda, Ms. Hellen Ndagije, National Pharmacovigilance Centre

Actions on post-market safety and quality of medicines—

- Policy: The National Drug Policy 2002 covers PV
- The National Drug Policy and Authority Act does not address PV
- In 2011, mandatory reporting by industry and health workers proposed
- Routine surveillance systems in PHP used for monitoring, collecting, and reporting ADRs (Treatment Success Rate project for ARVs and AMFm project)
- Insufficient funding commitment for PV at 10 percent of NDA budget

Use of PV tools—

- ADR reporting forms, guidelines, poor quality medicinal products forms, bulletins, information, education, and communication activities
- Risk management and communication including development of structured procedures for risk management and communication for high risk medicines
- Dear Doctor letters and press conferences on safety of medicines
- Stakeholder coordination strategy development
- Communication improvement

Burkina Faso, Dr. Kieta Berenger, Direction de la Prévention par la Vaccination

Actions on post-marketing safety and quality—

- PV activities initiated in 2008 following introduction of new vaccines and the growing need to monitor related ADRs. This provided an opportunity to put PV structures in place.
- Burkina Faso now member of WHO International Drug Monitoring Program
- Regulatory framework: Presidential decree issued in 2011 for formally establishing PV system and pre-requisite structures at national and regional levels
- Active surveillance activities: Vaccine-related with post-marketing surveillance of meningitis A conjugate vaccine

Tools—

- Four tools in use including the AEFI vaccine notification form and training manuals

Conclusion—

- PV in Burkina Faso remains in the early stages; the legislation and legal framework is weak with the main challenges being human resources and low reporting rates (6 reports in 2009, 11 reports in 2010, and 80 reports in 2011)

EMA and European Network of Centres for Pharmacoepidemiology and Pharmacovigilance Drug Safety, Mr. Xavier Kurz

The EU societal cost of ADR amount to 79 billion EUR, therefore there is a worldwide need to further strengthen PV. Spontaneous reporting systems are an important source for safety monitoring in post-authorization real life settings.

EMA safety practices and tools—

- EudraVigilance: This is a data processing network and management system for reporting and evaluating suspected ADRs in EEA involving 30 independent authorities. It is the third largest database on ADRs in the world with 72,000 ICSR received monthly.

Cumulatively, about 5 million ICSRs have been submitted and include data from clinical trials. Approximately 24,000 queries have been performed on the database by competent NMRAs.

- Electronic Reaction Monitoring Report: This tool is used for signal detection and facilitates screening and filtering of EudraVigilance data to support signal detection activities.
- European PV Issues Tracking Tools: This database facilitates tracking and sharing of safety information related to medicinal products between NCAs and the EMA. It has four modules (1) Safety Issues, (2) Safety Signals, (3) Periodic Safety Update Reports, and (4) Risk Management Plans.
- The Health Improvement Network Database (THIN Database): This database collects all data from a subset of general practice computer systems.
- Clinical databases: These databases are intended for patient management but allow opportunities to conduct rapid analyses on a wide range of pre-existing clinical data. They are particularly useful as research tools.
- European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). ENCePP brings together experts in pharmacoepidemiology and PV (103 centers, 14 networks, and 24 data sources from 17 European countries) to further strengthen post-authorization monitoring of medicinal products in Europe and facilitate post-authorization studies (high quality, independent, and multicenter). ENCePP guiding principles are independence, standards, and transparency, and the network aims to reinforce the public's, other researchers' and regulators' confidence ENCePP-conducted studies.

Country Presentations—National Regulatory Authorities

Senegal, Dr. Birame Drame, Direction de la Pharmacie et des Laboratoires

Actions on post-market safety and quality include—

- First decree on PV issued in 1998 and PV activities began in earnest in 2007
- Senegal's NMRA monitors and coordinates PV activities and collaborates closely with immunization program and other PHPs
- An advisory National PV commission and an expert safety review panel for evaluation of safety information exists
- Plan to work to improve reporting, data and information sharing, communication, engagement in active surveillance activities, and private sector involvement

Use of PV tools—

- National PV guidelines, training manuals, harmonized reporting forms, investigation form (AEFI), pharmaceutical bulletin, quarterly newsletter for AEFI available
- One form is used by all public health programs for AE reporting

Challenges—

- Lack of manpower, inadequate funding, lack of training for health workers, low motivation for reporting, little private sector engagement, poor quality reports, and slow information flow

Tanzania, Dr. Alex Fabian Nkayamba, Tanzanian Food and Drugs Authority

Actions on post-market monitoring and safety of medicines—

- Tanzania joined the WHO International Drug Monitoring program in 1993.
- Tanzania Food and Drug Administration established in 2003 with PV as a core function.
- Passive reporting is the main approach used and covers all registered medicines.
- Active surveillance: Tanzania has conducted two CEM studies for artemether-lumefantrine and dihydroartemesin-piperazine. A CEM for ARVs funded by Global Fund is planned.

Use of PV tools—

- Guidelines for monitoring of medicines safety, Tanzania PV training manuals, various reporting forms, and patient alert cards

Challenges—

- Poor information sharing with stakeholders
- Limited publication of information from PV activities
- Low capacity of PV officers
- Patients enrolled in CEM projects lost to follow-up

Pharmacovigilance in Public Health Programs

Namibia—Monitoring Long-Term Toxicities of ARVs in HIV/AIDS Program, Mr. Johannes Gaeseb, Namibia Medicines Regulatory Council

In Namibia, both passive and active surveillance activities are conducted including signal strengthening and signal validation, i.e., assessment of the risk of anemia associated with zidovudine-based highly active antiretroviral therapy. The Namibia Therapeutics Information and Pharmacovigilance Centre, the official Ministry of Health and Social Services center for promoting rational and safe use of medicines, provides oversight for PV activities. In assessing

the risk of anemia associated with zidovudine-based highly active antiretroviral therapy, a mix of approaches was used and included retrospective cohort to determine the incidence of anemia, nested case control for identifying and adjusting risk factors, and use of automated data bases and record linkage (Electronic Dispensing Tool, MEDITECH, and ePMS) to support evidence-based decision making.

Next steps:

- Improve reporting and quality of ICSRs
- Strengthen PV data management
- Increase active surveillance activities, i.e., CEM of selected medicines
- Increase local capacity for PV
- Improve communication of safety information and patient/public awareness

South Africa—Monitoring the Safety of Antiretrovirals and Implementing an Active Surveillance System in Kwazulu-Natal, Ms. Simangele Hlongwana, Department of Health KwaZulu Natal

In South Africa, three levels of active surveillance are in place. These are solicited reporting from 14 sentinel sites from which selected indicators are collected and CEM performed mainly through the ACADEMIK cohort study covering five facilities. This study commenced in December 2010 and ends in June 2012. It has a target of 10,000 patients but to date 1,800 have been enrolled and are currently in the data analysis phase. Implementation of active surveillance activities has resulted in an exponential growth of adverse event reports.

General challenges for active surveillance in South Africa—

- Poor budget allocation
- No dedicated PV unit
- Sustainability challenges
- Quality of reports not optimal
- No provincial PV committees
- Reports not submitted to regulatory authority

Successes—

- Platforms developed for continued solicited and sentinel site surveillance
- Electronic system available to capture reports
- Increased reporting by facilities

Strategies and next steps—

- Revive PV committees at all levels and link these to DTCs at all levels
- Strengthen reporting by sentinel sites and establish flagship sites for monitoring adverse events of interest
- Strengthen electronic reporting and expand PV reporting to cover TB

Tanzania—Monitoring Safety and Quality of Antimalarials in National Malaria Program, Ms. Rosemary Silaa, Tanzania National Malaria Control Programme

Artemisinin-based combination therapy (ACT) is the first-line treatment for malaria at all health facilities since 2007, and to date, over 60 million treatments have been administered. In the Tanzania private sector, ACT scale-up has been achieved with the support of the Affordable Medicines Facility for malaria (AMFm) program with more than seven million doses delivered. This rapid scale-up of ACT requires availability of information on the safety profile of these medicines. Several PV activities have been conducted to monitor the safety and efficacy of these relatively new medicines, including—

- Coartem[®] CEM with as estimated study population of 10,000
- INESS, an evaluation of safety of artemether + lumefantrine through comprehensive PV in large populations. Over 8,000 patients have been followed in Tanzania with few ADRs reported. A key finding of the Tanzania study is that most of the reported events for which artemether + lumefantrine was the suspected drug are attributable to the disease (malaria).

mHealth for Product Quality Monitoring, Dr. Paul Orhii, NAFDAC, Nigeria

Counterfeiting and substandard medicines is one of the biggest challenges facing regulatory agencies worldwide. It is a huge business worth about 75 billion US dollars and is increasingly becoming very sophisticated, making detection of counterfeits difficult.

In Nigeria, product quality monitoring is a continuous exercise. A study conducted in 2006 indicated that counterfeit products stood at 16.7percent against the previous 40 percent in 2000. NAFDAC is now applying cutting-edge technologies to detect counterfeits. These include—

Technologies—

- TruScan (Raman spectroscopy)
- Minilabs
- Mobile Authentication Service, which allows consumers to check authenticity of their medications by sending a unique code found on the product package via SMS

Implications/consequences—

- Public health: Decreased cost of controlling diseases, increased confidence in the health care system
- Regulatory system: Provides intelligence information; ensures quality of regulated products and strengthens the regulatory system

Surveillance of Pharmaceutical Product Quality and Safety, Dr. Abdelkrim Smine, US Pharmacopeia Promoting the Quality Medicines Program (USP-PQM)

Quality assurance (QA) of medicines includes all measures taken to assure a medicine's quality right from the development phase to use by the patient. Medicine safety should be built into the product as early as the development stage and continue through post registration via post-marketing surveillance and pharmacovigilance activities.

In Africa, most ADRs are related to quality issues; ADR monitoring and reporting should integrate with quality monitoring programs as part of PMS activities. There is an urgent need for promoting medicines safety in Africa including quality monitoring, ADR reporting, medication errors, based on adequate and Africa-specific medicine regulation and enforcement.

Dr. Smine outlined the USAID-funded USP-PQM Program.

PQM objectives—

- Build capacity and strengthen QA systems
- Help increase supply of QA medicines
- Combat availability of counterfeit medicines
- Provide technical leadership regarding medicine quality

PQM activities—

- Medicine quality monitoring and building QC capacity in various countries
- Building regulatory functions through support for accreditation of QC labs
- Regional initiatives through collaborative studies and establishment of QC lab networks

Key observations/findings—

- QA of medicines is still weak in most USAID-supported countries (weak medicines regulation, limited PMS programs, poor assessment of quality, safety, and efficacy during registration, lack of resources, and HR)

Conclusion—

- Need to build effective QA systems for medicines in Africa
- Because of the strong links among quality, safety, and efficacy, model ADR reporting alone will not be sufficient to address all safety risks

Tools for Measuring Impact— A model for Potential Return on Investment for Pharmacovigilance in Africa, Dr. Joseph Babigumira, University of Washington

Despite the fact that PV has tangible benefits, it is important to demonstrate to policy makers and stakeholders the potential return on investment (ROI) for money spent on PV. To date no rigorous ROI assessment in national PV systems have been reported in literature. To address this gap, SIAPS and the University of Washington Department of Global Health, Global Medicines Program are working to develop a model that can be used to estimate the potential return on investment for PV.

Project objective—

- To provide a framework for country policy makers and development partners to assess the potential investment return on resources spent on PV
- To develop a generic analytical tool that can be customized at country level using context-relevant data

A draft decision analytic ROI model has been developed, which compares the four PV classification groups. The model architecture is composed of an investment side representing itemized costing of resources needed to set up and maintain different levels of PV activity and the return side represents the monetized reduction in ADR- related outpatient visits and hospitalizations, mortality, and regimen switches.

Operationalizing the Systems Perspective (Break-out Session)

Session Objectives—

- Determine critically needed tools for PV operations from the systems' perspective
- Provide recommendations for tools development, utilization, and evaluation

Activities—

Participants were divided into five groups with each group required to discuss and prioritize tools for development based on a list of potential tools provided for each of the five PV system components: (1) policy, law and regulation; (2) system, structure, and stakeholder coordination; (3) Signal generation and data management; (4) risk assessment and evaluation; and (5) risk management and communication. The groups then provided feedback on their deliberations during a plenary session on Day III (see Day III session on summary of priority tools).

DAY 3. TOOLS WORKSHOP AND VACCINE SAFETY METHODS WORKSHOP



Tools Workshop—Wrap-Up

Welcome, Mr. David Lee, SIAPS

Dr. David Lee reviewed themes from Day 2 and walked participants through the Day 3.

Objectives—

- Discuss active surveillance for safety monitoring
- Examine the application of active surveillance methods for monitoring vaccine safety

The day's program included sessions on—

- Summary of priority tools
- Plans for priority tools development
- Active surveillance approaches
- Vaccine safety workshop
- Wrap-up and closing

Summary of Priority Tools, Dr. Andy Stergachis, University of Washington

The session was developed based on the discussions and feedback from the five Day II break-out groups which were required to discuss and prioritize tools for development based on a list of potential tools for each of the five PV system components. The following tools were recommended to be a priority for development.

Priority Tools: Policy Law and Regulation

- The group recommended that all the listed tools are required and priority listing was acceptable. They further recommended including guidelines on stakeholder roles and responsibilities.
- To speed up development of the required policies, laws, and regulations, high level support/international pressure through resolutions (donors, WHO assembly) is required for countries to commit to these processes.

Priority Tools: Systems, Structures, and Stakeholder Coordination

- PV organization chart model/template
- Model/template for stakeholder identification
- Tools for economic evaluation
- Comprehensive guideline for PV activities
- Simple consumer reporting
- Information flow chart for decision making
- Model quality management system for performing PV activities

Priority Tools: Signal Generation and Management

- Model/template of a local database to collate data from all sources, which could be generic and them customized to country specifications
- Model/template for electronic reporting covering ADRs, medication errors, and product quality defects, which can be harmonized and web-based
- Electronic spreadsheet to track workload (emphasis on management of safety cases)
- Vigiflow with improvement for local specificities and data mining technologies

Priority Tools: Risk Assessment and Evaluation

- Decision-tree/algorithm/root cause analysis tool
- Tools to identify resource requirements
- Model protocols, i.e., pregnancy registry tools beyond guidelines, sentinel site-based active surveillance tools

Priority Tools: Risk Management and Communication

- Standardized approach to risk management and risk communication, with a risk communication model defining who, what, when, why, and how
- Tools to appropriately localize messages from external source (global) to internal audiences (in-country)
- Tools for crisis management including behavior change materials, safety management signals, and sequential flow and breakdown of information

Priority Tools: Other

- Pre-service curriculum training materials for PV
- Metrics/indicators for PV monitoring and evaluation

Plans for Priority Tools Development in Africa, Mr. Jude Nwokike, SIAPS

The need for strengthening PV in SSA is known. As no single organization, institution, or agency can accomplish all the required tasks, work sharing and collaboration in tools development is important once priorities and standards have been agreed upon. The next steps will involve—

- Develop a protocol and implementation plan for producing new tools.
- Identify priority tools followed by development, field testing/pilot, revision, and eventually dissemination.
- Deploy tools: Various options are available including WHO PV tool kit, countries including those that participated in the planned pilot, and AMRH and regional harmonization groups.

Below are summaries of questions asked during the session and responses. Participants were additionally invited to submit additional questions and comments to SIAPS pharmacovigilance e-mail address: pharmacovigilance@msh.org.

- Q.** Many tools have been prioritized for development; is there a need to reprioritize to reduce this number?
- A.** Priorities in different countries may differ; the best approach may involve prioritizing tools with cross-cutting impact across multiple countries or tools that are easily available and lead to substantial impact.

Q. Which are the pilot countries?

A. This has not been decided—possible criteria for selection may include virgin countries, i.e., those with no PV system in place.

Q. Where is expertise available to develop and implement tools?

A. It may be necessary and useful to bringing together the required expertise from different countries and institutions, an approach similar to the European ENCePP model

Comment: Use of pilot countries is important; however, it may be necessary to specify the selection criteria for these countries, such as countries with no PV system or countries with an already established QA system.

Comment: The minimum requirements for PV tools for countries need to be identified.

Active Surveillance in Africa, Dr. Peter Bassi, NAFDAC, Nigeria

Active surveillance is important for determining rates of ADR and obtaining comprehensive data on ADRs related to a medicine. There are a number of approaches to active surveillance including prescription event monitoring, record linkages, registries, and CEM.

CEM is a prospective, observational study that involves formal and continuous monitoring for the purposes of generating signals or evaluating and confirming hypotheses related to medicine events. CEM has the ability to produce rates and complete adverse event profiles. However, it is costly and labor intensive. Dr. Bassi presented a case study based on CEM in Nigeria.

- **Objective:** Evaluate safety in use of ACTs among populations in Nigeria; develop safety profile of ACTs, i.e., artemether-lumefantrine and artesunate-amodiaquine.
- **Methodology:** The study was both prospective and observational. ACTs were administered and follow-up assessments were conducted 3 days and 7 days after commencement of treatment.
- **Enrollment:** Patients were enrolled between January–April 2009. A cohort of 3,000 was achieved at six sentinel sites with 500 patients per site.
- **Results:** Adverse events with ACTs are common, but severe adverse events were not a common occurrence in the observed cohort.

Dr. Bassi concluded that active surveillance through cohort event monitoring studies can help in identifying adverse events and serious adverse events following use of ACTs.

Active Surveillance for Safety Monitoring, Mr. Jude Nwokike and Ms. Hye Lynn Choi, SIAPS

Active surveillance complements passive reporting and enables quantification and characterization of specific adverse events. It is an important tool within PHP and findings can impart practice and improve treatment outcomes.

Framework for active surveillance—

- Should leverage existing M&E structures and resources by using existing data collection tools such as data contained in electronic medical records; new tools should ideally be required only at national level for data collation and analysis
- Should build on sustainable platforms contributing to other surveillance activities by using existing structures, i.e., PV centers, drug and therapeutic committees
- Use surveillance data for decision making and improving treatment outcomes. It is important to have coordinating centers with drug safety committees.

Country specific examples of SPS/SIAPS global active surveillance activities—

- Namibia: Conducted retrospective cohort record-linkage study for zidovudine associated anemia; developed prospective active surveillance protocol and implementation plan for the ART program.
- South Africa: Conducted a CEM activity in KwaZulu-Natal (ACADEMIK STUDY); developing sentinel-site based active surveillance of multidrug-resistant TB patients co-infected with HIV
- Vietnam: Developed sentinel-site based prospective active surveillance of antiretrovirals
- Rwanda: Developed a draft protocol for cohort ART adverse event monitoring

Tools—

- SPS/SIAPS supported the development of various tools to support active surveillance activities in Vietnam. These are site-based tools—a Microsoft Access[®]-based data entry and transmission tool and a data collection and analysis tool (DCAT).

Conclusion—

- Active surveillance activities can provide useful data for improving medicine safety and treatment outcomes.
- Active surveillance can be sustained by building on existing and routine data collection systems.

Vaccine Safety Workshop—Methods for Epidemiological Investigation of Vaccine Safety Concerns

The Global Vaccine Safety Initiative, Dr. Patrick Zuber, WHO

Ensuring the safest possible use of vaccines should be the standard for immunization programs. Unsafe vaccines can have serious consequence and safety crises can derail immunization programs. However, few of the developing countries have the ability to monitor and assure safe use of vaccines. Overall there is a huge capacity gap for vaccine PV in low-income countries despite the expanded use of new vaccines in these countries.

The Global Vaccine Safety Blueprint project was initiated with the aim of assisting countries to improve and enhance capacity for vaccine PV. This blueprint is to be implemented through a Global Vaccine Safety Initiative composed of government institutions and agencies, intergovernmental organizations including WHO and international NGOs, academic and research institutions, industry, and WHO collaborating centers. WHO serves as the secretariat to the initiative.

The Global Vaccine Blueprint project goals are—

- To assist low- and middle-income countries to have at least minimal capacity for vaccine safety activities
- To enhance capacity for vaccine safety assessment in countries that introduce newly developed vaccines
- To establish global vaccine safety support structures
- To ensure minimum capacity for vaccine safety activities, there should be available national dedicated PV resources, such as national reporting form for AEFI; national AEFI expert review committee; strategies for risk communication; and national database or system for collating, managing, and retrieving AEFI reports
- To establish managerial principles for example, framework, clear lines of accountability for the conduct of vaccine safety work, institutional development plan and commitment to sharing information on vaccine safety with other countries
- To enhance capacity for an increased level of vaccine safety activity
- Necessary for countries introducing newly developed vaccines
- Includes ability to carry out active surveillance activities rather than relying solely on spontaneous reports for signal detection and when necessary, ability to carry out epidemiological studies

Eight strategic objectives support main goals of the blueprint and include strengthening vaccine safety monitoring systems, strengthening ability to evaluate vaccine safety signals, developing vaccine safety communication plans and establishing systems for appropriate interaction between national governments, multilateral agencies and manufacturers.

Vaccine Safety and Adverse Events Following Immunization, Dr. Hector Izurieta, FDA Center for Biologics Evaluation & Research

Vaccines are amongst the most effective public health interventions. But most communities worldwide have low tolerance for vaccine adverse events and safety scares have the potential to rapidly compromise vaccine programs worldwide. There is an increasing trend towards introduction of new vaccines (e.g., meningitis A in Africa, rotavirus vaccine in Latin America) into low- and middle-income countries even before they are licensed in Europe or the United States, despite these countries having limited capacity to implement vaccine epidemiological safety studies.

Vaccines are now manufactured globally and because development of vaccines targeting the developing world is increasing, globalization of evaluation is required. In addition, potential variability in susceptibility to ADRs required a diverse population to evaluate vaccine safety. Collaborative studies can facilitate the study of vaccine-related ADRs in large populations enabling the identification and quantification of even rare events. Therefore, establishing a global vaccine safety network is useful in addressing issues of capacity gaps in developing countries as well as allowing evaluation of safety concerns over large populations ultimately supporting evidence-based decision making on vaccine safety.

KEMRI/CDC Research and Public Health Collaboration and the INDEPTH Network in International Collaborative Studies of Pharmacovigilance, Dr. Kayla Laserson and Ms. Stephanie Dellicour, KEMRI/CDC

The KEMRI/CDC collaboration began in 1979. The partnership aims to conduct collaborative surveillance, research and program implementation, and promote training and strengthen capacity of Kenya Government staff and institutions. Recently, the partnership looked at the INDEPTH's potential capacity for contributing to international collaborative studies to address Kenya's vaccine safety concern.

INDEPTH consists of 43 member health and demographic surveillance systems in 20 low- and middle-income countries that conduct longitudinal health and demographic surveys. The network conducts household surveys every four months that cover approximately 50,000–200,000 persons and collects standardized information, i.e., pregnancies, births, surveillance of bed nets use, and household data linked to continuous facility/morbidity data.

Two international population-based surveillance platforms for infections have been established in Kenya that evaluate population-based disease burden, spectrum of disease, risk factors, outcomes, and etiologies for various pathogens. In addition, the platforms evaluate public health interventions (i.e., vaccine and treatment trials) and conducts both passive and active PV for monitoring medicine and vaccine safety. The platforms have been used specifically to monitor adverse effects following immunization (i.e., pneumococcal conjugate vaccine), and the safety of antimalarial drugs (ACTs)

used during pregnancy to provide a better estimate of the risk-benefit profile of these medicines. In summary, population-based surveillance platforms around the world are available for post-marketing assessments and are useful cost-effective platforms for pharmacovigilance. Moreover, the Ministry of Health Systems may provide additional platforms.

Vaccine Active Surveillance Study I, Ms. Caitlin Dodd, Cincinnati Children's Hospital

Various epidemiological studies, e.g. case control studies and cohort studies can be used for active vaccine surveillance. A novel method, self-controlled case series (SCCS) is increasingly being used in pharmacoepidemiology, particularly in vaccine safety studies. The method can be used to study the temporal association between a time-varying exposure and an adverse event using data on cases only. It can be thought of as a case control study in which subjects act as their own controls.

Key advantages of the approach:

- High efficiency relative to the cohort method
- Self-controlled
- Time invariant confounders are controlled for implicitly

Limitations of the approach:

- Requires that probability of exposure is not affected by the occurrence of the outcome event
- Risk must be small for non-recurrent event
- Produces estimates of relative (not absolute) incidence

In conclusion, SCCS is a powerful tool for vaccine safety studies and the method continues to be modified and improved by vaccine safety researchers.

Vaccine Active Surveillance Study II, Hector Izurieta, FDA/CBER

Multiple H1N1 influenza vaccines were developed/distributed worldwide for the H1N1 pandemic in 2009 and used in diverse populations and countries, some with limited capacity for epidemiological vaccine safety studies. The resultant vaccine safety concerns provided opportunity to demonstrate feasibility of a global collaborative vaccine safety consortium.

The international study on Guillain-Barré Syndrome (GBS) and H1N1 was initiated to pilot test a WHO coordinated international collaborative approach toward implementing a simple and reliable epidemiological study methodology and investigate the association between GBS and H1N1 pandemic vaccines. An international team of advisors is using the SCCS methodology to perform simulations to define the most efficient approach. After the pilot phase, the approach should be generalizable to other countries and should become part of the standard WHO vaccine safety monitoring toolbox

Vaccine Safety Workshop Exercise and Concluding Discussion, Dr. Hector Izurieta, FDA/CBER, and Ms. Caitlin Dodd, Cincinnati Children's Hospital

During the session, participants were taken through a case study and exercises on the use of the SCCS as an epidemiological method for investigating vaccine safety.

Closing Sessions

Technical Wrap-up: Highlights and Next Steps, David Lee, SIAPS

Access to pharmaceuticals and services requires pharmacovigilance systems whose ultimate aim is reduction of medicine-related mortality and mortality. The *Safety of Medicines in Sub-Saharan Africa* report categorized countries into four groups depending on the level of development of their PV systems. A change in mindset requires that, at a minimum, each country should have in place each of the PV system components: policy, law and regulation; systems, structures and stakeholder coordination; signal generation and data management; risk assessment and evaluation; and risk management and communication. Categorization (from basic to advanced) would then be based on the level of the overall development and complexity of their PV systems.

The way forward for strengthening PV systems in Africa include:

- Advocating and adopting a system perspective based on the SSA report and with a focus on performance and results
- Use of tools to enhance performance where existing tools are disseminated and complementary tools developed
- Use of metrics to assess performance beyond just ADR reporting rates and to demonstrate benefits/return on investments on PV
- The approach used should include the following elements:
 - Coordination and collaboration within country and also within regional economic communities
 - Leveraging resources within country stakeholders and intra-regional economic communities
 - Country priorities to include a complete system development encompassing all the pharmacovigilance system components

Closing Remarks, Mr. Anthony Boni, USAID

Mr. Anthony Boni thanked the Honorable Minister, Ministry of Medical Services, for officially opening the Africa Pharmacovigilance Meeting and launching the *Safety of Medicines in Sub-Saharan Africa* report. He stated that most sub-Saharan African countries are conducting some activities related to PV but steps are needed to link them into a comprehensive system that uses PV data to protect patients while improving treatment outcomes. He added that the SSA report will provide a baseline that will permit countries to monitor how they perform over time.

Mr. Boni stated that the panel discussion on access and safety unequivocally concluded that PV is not a luxury or a distraction but is actually a necessity and an ethical responsibility. He further highlighted the fact that the tools workshop helped identify priority tools that can be helpful in improving PV and with the support of governments, donors, and other stakeholders, these solutions will facilitate the work being done in ensuring quality and safety of health products within the supply chain in sub-Saharan Africa.

Regarding the way forward, Mr. Boni stated that the next steps involve SIAPS working collaboratively with all stakeholders to develop some of the tools that USAID/FDA interagency agreement can support with coordination; harmonization; information sharing; and resource mobilization being the key to success going forward.

In conclusion, he stated that PV across the life cycle of medicines transcends national boundaries, is the right thing to do, and represents at least five public health “rights,” i.e., right for the patient; right for the health system; right for keeping life-saving medicines on the market; right for global development in these resource constrained times; and right for global cooperation and health equity. He then thanked the participants for attending the meeting and their invaluable efforts in improving PV and patient safety.



ANNEX A. AGENDA

AFRICA PHARMACOVIGILANCE MEETING 2012

Ensuring Quality and Safety of Medicines in Sub-Saharan Africa

NAIROBI, KENYA
APRIL 18-20, 2012



SIAPS



AFRICA PHARMACOVIGILANCE 2012 MEETING AGENDA

INTERCONTINENTAL HOTEL, NAIROBI
CONFERENCE CENTER: MARA NORTH

Wednesday April 18, 2012
Day 1. Dissemination Conference

Chair: Fred M. Siyoi
Co-Chair: Mary Wangal

Session Title	Time	Objective	Presenter/Facilitators
[Registration]	7:30 – 8:45		
Opening Ceremony	9:00 – 10:15	Welcome and Introduction	Kenya Pharmacy and Poisons Board (Fred Siyoi) HCSM Kenya (Mary Wangai) USAID (Anthony Boni) USFDA (Beverly Corey) Ministry of Medical Services and Pharmacy and Poisons Board (K.C. Koskei) Ministry of Medical Services (Francis Kimani) Ministry of Medical Services (Mary Ngare)
[Tea Break]	10:15 – 10:45		

Annex A. Agenda

Program Overview & Objectives	10:45 – 11:00	Provide an overview of meeting objectives & content	HCSM Kenya (Mary Wangai)
Presentation of findings from the SSA study	11:00 – 11:30	Communicate findings of study on PV systems and performance	SIAPS (Jude Nwokike, Hye Lynn Choi)
African medicines regulatory harmonization	11:30 – 11:50	Discuss regulatory harmonization initiatives in Africa as it relates to quality and safety of medicines	NEPAD AMRH (Margareth Ndomondo-Sigonda)
The WHO PV Toolkit	11:50 – 12:10	Discuss the recently launched PV tool kit	WHO CC/Accra (Alex Dodoo)
PV Metrics	12:10 – 12:30	Discuss importance of PV metrics Discuss return on investment from drug safety interventions	UW (Andy Stergachis)
[Lunch Break]	12:30 – 1:30		
The Way Forward: Global Perspective	1:30 – 3:00	Global stakeholder perspective on pharmacovigilance systems	1. WHO (Shanthi Pal) 2. EMA (Xavier Kurz) 3. BMGF (Thomas Bollyky) 4. MMV (Stephan Duparc) 5. Malaria Access to Medicines Partnership: (Francois Bompert)
[Tea Break]	3:00 – 3:30		
Achieving Regional Excellence	3:30 – 4:30	Share current practices in pharmacovigilance tools and guidelines	1. Kenya (Jayesh Pandit) 2. DRC (Tona Lutete) 3. South Africa (Mukesh Dheda) 4. Nigeria (Adeline Osakwe) Chair: NEPAD AMRH (Margareth Ndomondo-Sigonda) NRA: NAFDAC (Paul Orhii) WHO (Shanthi Pal) WHO CC/Accra: (Alex Dodoo) USAID (Anthony Boni) PDP: MMV (Stephen Duparc) PPB/Kenya (K.C. Koskei)
Panel Discussion: Access and Safety	4:30– 5:55	Ensuring that patient safety is not subordinate to access	
Closing Remarks	5:55 – 6:00	Closing remarks	SIAPS (Sameh Saleeb)

Africa Pharmacovigilance Meeting 2012: Meeting Proceedings

Thursday April 19, 2012		Day 2. Tools Workshop		Chair: David Lee
Session Title	Time	Objective	Presenter/Facilitators	
[Sign In]	8:00 – 8:30			
Introduction & Workshop Welcome	8:30 – 8:45	Intro and Objectives	SIAPS (David Lee)	
FDA Drug Safety Practices and Tools	8:45 – 9:10	Discuss FDA drug safety tools and practices	FDA/CDER (Gerald Dal Pan)	
Global trends in PV tools and practices	9:10 – 9:35	Discuss tools and practices from other NRAs outside Africa Discuss feedback from the tools survey	SIAPS (Jude Nwokike)	
Country presentations: National Regulatory Authorities	9:35 – 10:20	Outline how countries' regulatory system addresses post-market safety and quality; Pharmacovigilance tools in use in country; Timely use of information from WHO and stringent RAs; Communicating and sharing safety information with healthcare providers, consumers, and other NRAs.	<ol style="list-style-type: none"> 1. Ghana (Adela Gwira) 2. Uganda (Helen Byomire Ndagije) 3. Burkina Faso (Kiema Bérenger) 	
[Tea Break]	10:20 – 10:40			
EMA and ENCePP Drug Safety	10:40 – 11:00	Discuss EMA & European Network of Centre's for Pharmacoepidemiology and Pharmacovigilance drug safety tools and practices	EMA (Xavier Kurz)	
Country presentations: National Regulatory Authorities	11:00 – 11:30	Outline how countries' regulatory system addresses post-market safety and quality; Pharmacovigilance tools in use in country; Timely use of information from WHO and stringent RAs; Communicating and sharing safety information with healthcare providers, consumers, and other NRAs.	<ol style="list-style-type: none"> 4. Senegal (Birame Dramé) 5. Tanzania (Alex Fabian Nkayamba) 	
Country Presentations: Public Health Programs	11:30 – 12:20	Pharmacovigilance in national public health programs	<ol style="list-style-type: none"> 1. HIV/AIDS: Namibia (Johannes Gaeseb) 2. HIV/AIDS & TB: South Africa (Simangele Hlongwana) 3. Malaria: Tanzania (Rosemary Silaa) 	
LUNCH & NRA Exhibition	12:20 – 1:30			
mHealth for Product Quality Monitoring	1:30 – 1:45	Discuss use of mobile technology related to product quality monitoring	NAFDAC (Paul Orhii)	
Surveillance of Pharmaceutical Product Quality and Safety	1:45 – 2:15	Discuss the importance of exploring the link between the safety and the quality of medicines	USP PQM (Abdelkrim Smine)	
Tools for measuring impact	2:15 – 2:30	Economic evaluation of the impact of PV systems and tools	UW (Joseph B. Babigumira)	
Operationalizing the systems perspective (Break-out Session)	2:30 – 4:00	Determine critically needed tools for operationalizing PV from the systems perspective; Provide recommendations for tools' development, utilization and evaluation	All Participants, Assigned Groups	
[Tea Break]	4:00 – 4:30			
Break-out Groups: Report Back	4:30 – 5:45	Report out and discuss summary of findings/needs/opportunities	Designated Group Spokesperson Moderator (UW, Andy Stergachis)	
Wrap up	5:45 – 6:00		UW (Andy Stergachis)	
[Cocktail Reception]	6:00 – 9:00	<i>Join us for a social event in Le Chateau Reception Hall, Room, 8th Floor</i>		

Annex A. Agenda

Friday April 20, 2012

Day 3. Tools Workshop and Vaccine Safety Methods Workshop

Chair: Andy Stergachis

Session Title	Time	Objective	Presenter/Facilitators
[Sign In]	8:00 – 8:30		
Welcome	8:30 – 8:40	Welcome and Themes from Day 2	SIAPS (David Lee)
Summary of priority tools	8:40 – 9:00	Summary of priority tools	UW (Andy Stergachis)
Plans for priority tools development	9:00 – 9:30	Plans for priority tools development	SIAPS (Jude Nwokike)
Active Surveillance in Africa	9:30 – 9:45	Discuss ACTs cohort event monitoring studies	NAFDAC Drug Safety Advisory Committee (Peter Bassi)
Active surveillance for safety monitoring	9:45 – 10:15	Discuss SPS/SIAPS global active surveillance activities	SIAPS (Jude Nwokike, Hye Lynn Choi)
[Tea and Coffee Break]	10:15 – 10:30		
Vaccine Safety Workshop - Methods for The Epidemiological Investigation of Vaccine Safety Concerns			
The Global Vaccine Safety Initiative	10:30 – 10:50	Strengthening capacity for vaccine pharmacovigilance: The Global Vaccine Safety Initiative	WHO (Patrick Zuber)
Presentation of the workshop objectives and format	10:50– 11:00	Discuss workshop objectives, format, and expected outcome	FDA/CBER (Hector Izurieta)
Vaccine safety and Adverse Events Following Immunization	11:00 – 12:30	Rationale for international collaboration in vaccine safety studies	FDA/CBER (Hector Izurieta)
LUNCH	12:30 – 1:30		
Vaccine active surveillance I	1:30 – 2:30	Comparison of epidemiological study methods, benefits of self-controlled case series (SCCS) study methodology	Cincinnati Children's Hospital (Caitlin Dodd)
Vaccine active surveillance II	2:30 – 3:30	An international collaborative proof of concept study of the association between pandemic influenza vaccines and Guillain Barré Syndrome	FDA/CBER (Hector Izurieta)
[Tea and Coffee Break]	3:30 – 3:45		
Potential for the INDEPTH network to contribute to international collaborative epidemiological studies of vaccine safety	3:45-4:00	Present the INDEPTH network's potential capacity for contributing to international epidemiological studies of vaccine safety for high priority new vaccines	(KEMRI/CDC) Kayla Laserson (KEMRI/CDC) Stephanie Dellicour
Exercises and discussions	4:00 – 5:15	Exercises with participants on steps towards using SCCS methods for international collaborative studies to address their vaccine safety concerns	FDA/CBER (Hector Izurieta) Cincinnati Children's Hospital (Caitlin Dodd) Kayla Laserson (KEMRI/CDC)
Technical Wrap Up: Highlights and Next Steps	5:15 – 5:30	Technical Wrap Up	SIAPS (David Lee)
Closing Remarks	5:30 – 5:45		USAID (Anthony Boni)
Closing Ceremony	5:45 – 6:00		Local Organizing Committee (Fred Siyoi); SIAPS (Sameh Saleeb)

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