AFRICA PHARMACOVIGILANCE MEETING 2012
Ensuring Quality and Safety of Medicines in Sub-Saharan Africa
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SAFETY OF MEDICINES IN SUB-SAHARAN AFRICA: ASSESSMENT OF PHARMACOVIGILANCE SYSTEMS AND THEIR PERFORMANCE

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USAID FROM THE AMERICAN PEOPLE
SIAPS Systems for Improved Access to Pharmaceuticals and Services

KEY FINDINGS AND RECOMMENDATIONS

STUDY LIMITATIONS

- Relied on survey and literature review for data on some countries.
- Local consultant led in-depth assessment was conducted only in 9 countries.
- Though contents of the report are based on documented evidence collected by local consultants at the time of the study or on references from other publications, there may still be errors contained in the report.

The electronic copy of the report will be posted at the same website after the launch together with errata sheet listing corrections.

PHARMACOVIGILANCE PROFILE

- Estimated pharmaceutical market size of 3.8-4.7 billion USD.
- Limited capacity to regulate health product.
- 33 countries are official or associate members of the WHO program for International Drug Monitoring.

IMPLICATION

Access with Safety

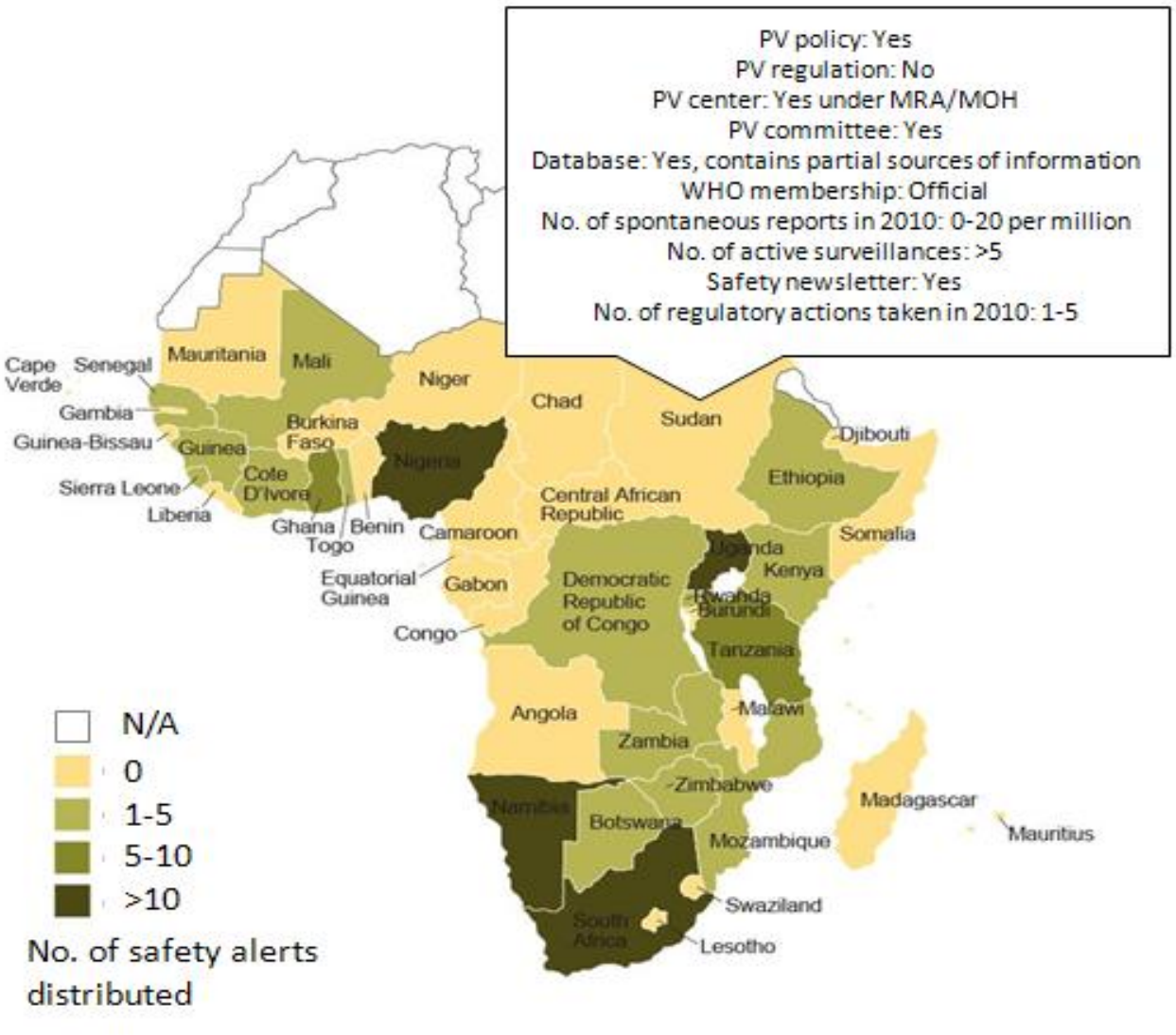
- The dramatic improvement in access imposes challenges for NRAs who are not well equipped with regulatory capacity.
- There is a need for stronger post-marketing surveillance systems to monitor new medicines introduced into the supply chain of countries.

POLICY, LAW, AND REGULATIONS

- **Regulatory infrastructure for PV is weak**
  - 41% have a national policy related to PV and medicine safety.
  - Only 30% as legislations for ADR reporting.
  - 28 % have legal provisions that require marketing authorization holders (MAHs) to report all serious adverse drug reactions (ADRs) and only 17% require MAHs to conduct post-marketing surveillance activities.

IMPLICATIONS

- Inadequate policy and regulatory mandate to protect the public health and monitor products in the supply chain.
- Lack of post-marketing commitments imposed on companies.
- Lack of transparency, consistency, and public accountability of regulatory decisions.


PV policy: Yes
PV regulation: No
PV center: Yes under MRA/MOH
PV committee: Yes
Database: Yes, contains partial sources of information
WHO membership: Official
No. of spontaneous reports in 2010: 0-20 per million
No. of active surveillances: >5
Safety newsletter: Yes
No. of regulatory actions taken in 2010: 1-5
Cape Verde
Senegal
Mauritania
Mali
Niger
Chad
Sudan
Djibouti
Gambia
Guinea-Bissau
Guinea
Burkina Faso
Nigeria
Cote D'Ivore
Sierra Leone
Liberia
Ghana
Togo
Benin
Camaroon
Central African Republic
Ethiopia
Somalia
Uganda
Kenya
Rwanda
Burundi
Equatorial Guinea
Gabon
Democratic Republic of Congo
Congo
Tanzania
Angola
Malawi
Zambia
Zimbabwe
Namibia
Botswana
Mozambique
Madagascar
Mauritius
Swaziland
South Africa
Lesotho
N/A
0
1-5
5-10
>10
No. of safety alerts distributed

System, Structure, and Stakeholder Coordination

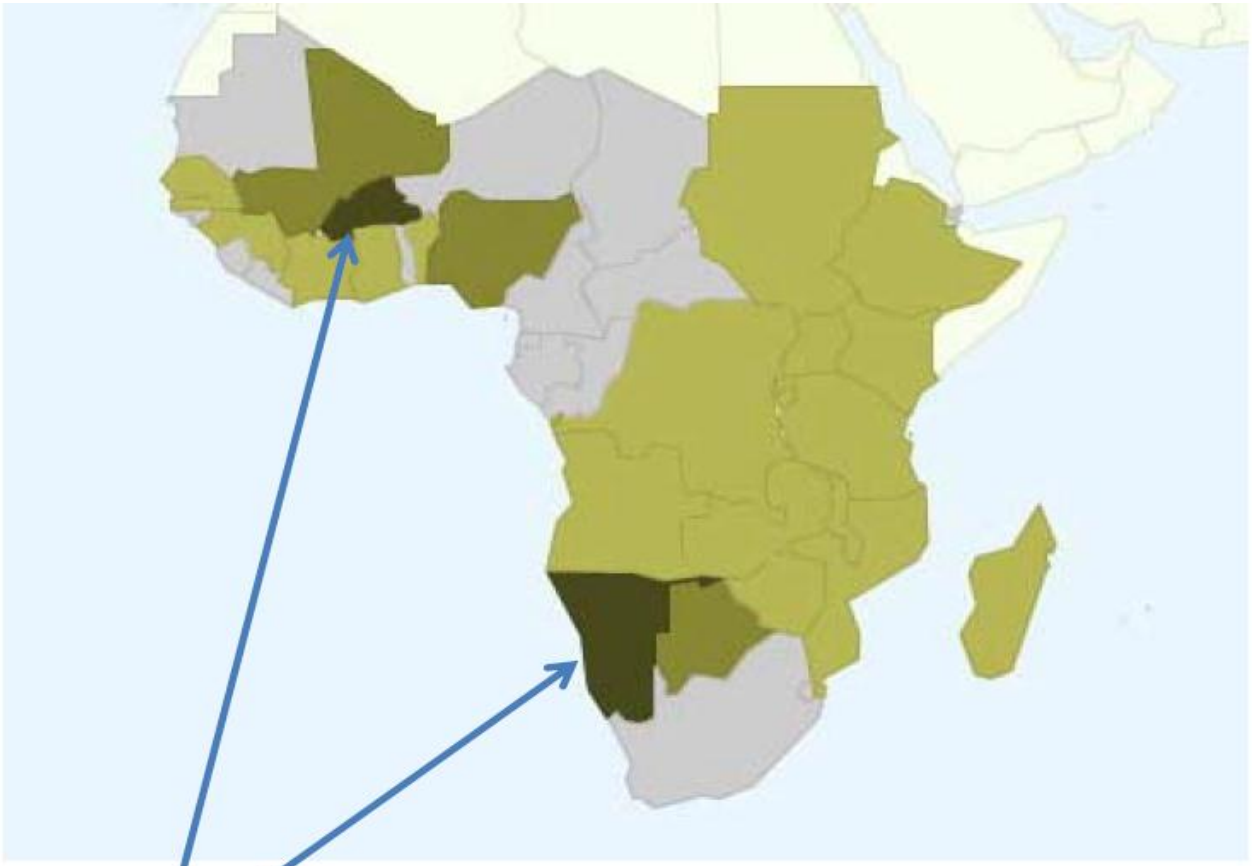
- PV basic structure (PV center, PV guidelines, and drug safety advisory committee) exist in many countries.
- Membership of the WHO program does not really mean a country has a functional system.
- Stakeholders responsibilities are not defined and are not coordinated.

IMPLICATIONS

- Even the marginal successes in PV system in SSA may not be sustainable.
- No advocacy for the gradual transitioning of donor support to in-country governments and the use of local resources.

Signal Generation and Data Management

- Limited scope and functioning of the spontaneous reporting system.
  - Only 50% report quality defects, 37% report medication errors, and 43 % report treatment ineffectiveness.
- Lack of data standards and interoperability may limit electronic exchange and transmission.



Countries with >100 reports per million population in 2010

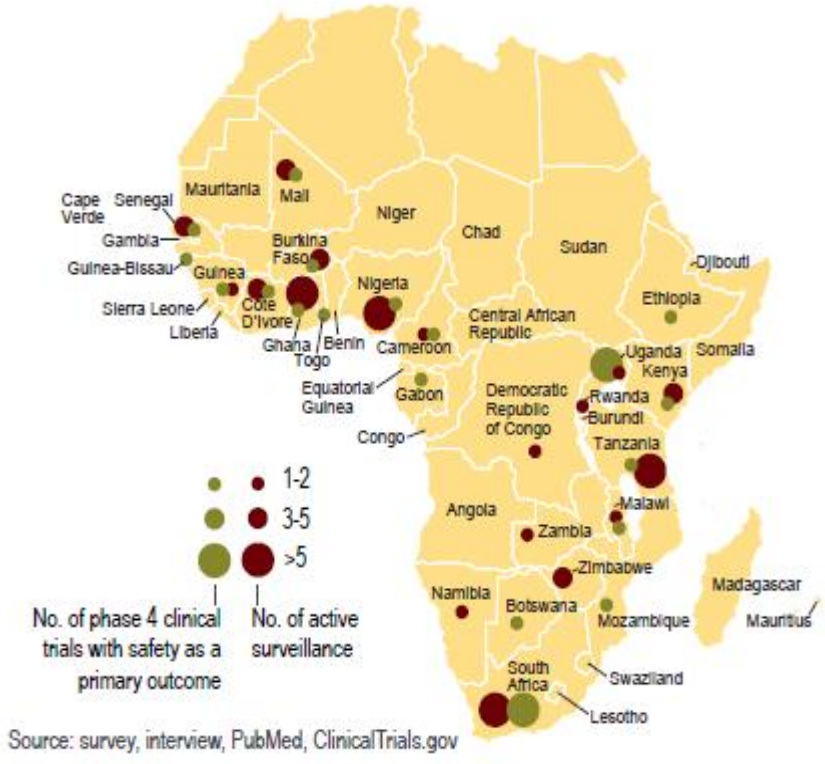
IMPLICATIONS

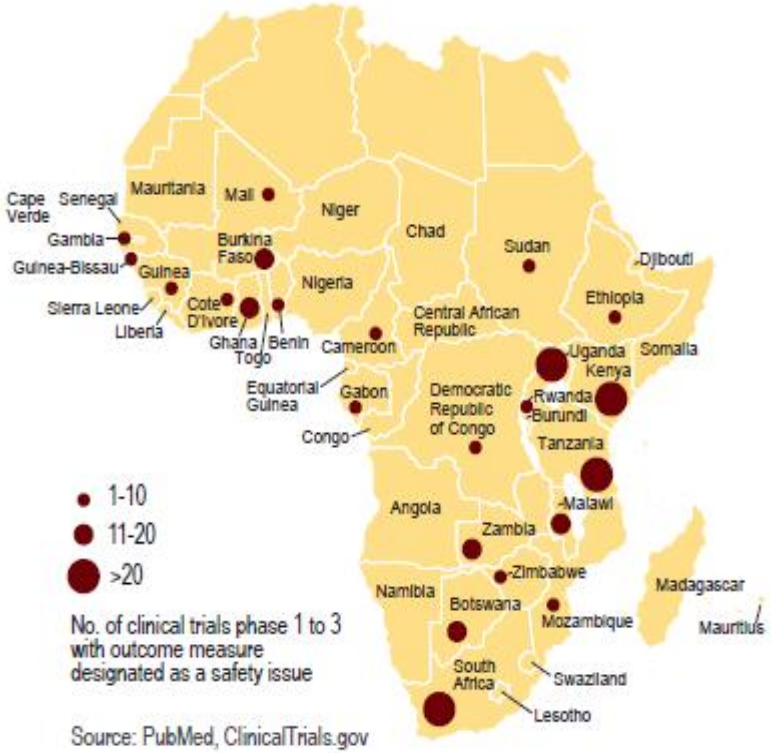
- Timely reporting of suspected ADRs and product quality problems are key in post marketing surveillance.
- Some reports from SSA may not use harmonized standards and therefore will have limited use for global monitoring of product quality and safety.

Risk Assessment and Evaluation

- **Lack of capacity to assess and evaluate signals.**
  - Only 50% have PV database.
  - Collation and coordination of PV data was poor.
  - Capacity for causality assessment and data mining is limited.
  - Pharmacovigilance data is often not analyzed for patient safety implications.
- **Limited medicines safety research occurring in these countries.**

MEDICINE SAFETY RESEARCH CAPACITY





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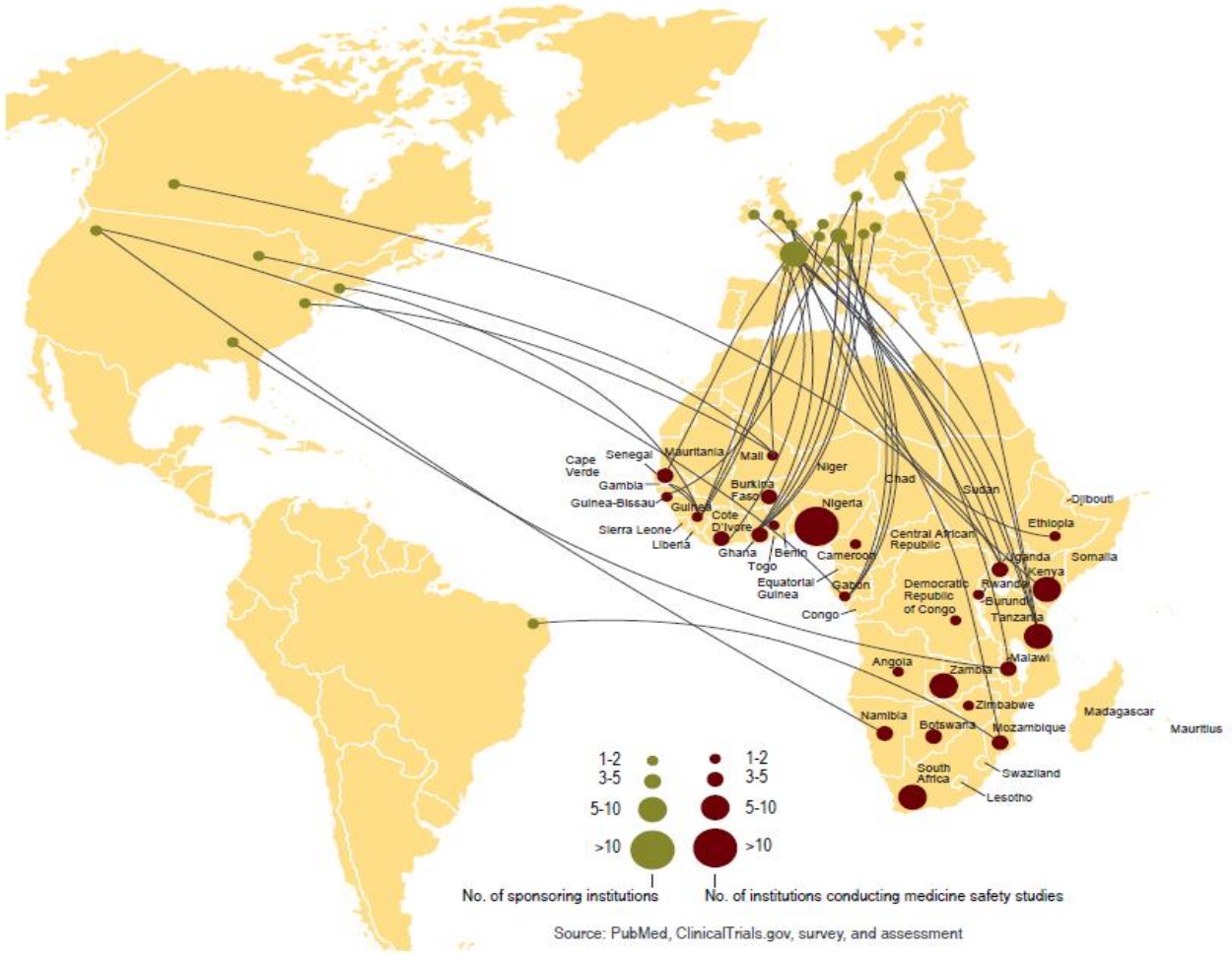
COLLABORATION ON MEDICINES SAFETY RESEARCH



HARAMBEE

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IMPLICATIONS

- The ongoing safety studies in SSA do not always address priority safety concerns.
- The pharmaceutical industry is not mandated to study safety uncertainties related to the products they registered in Africa.
- There are no regional initiatives amongst African research institutions or medical specialists to lead safety studies.

Risk Management and Communication

- Few countries take regulatory action based on findings from adverse event reporting.
- Risk management practices for high risk medicines are nonexistent.
- Timely sharing and use of information on the safety and quality of products is particularly weak.

IMPLICATIONS

- Benefit of sharing regulatory information on the safety and quality of products in the supply chain.
- Stringent regulatory authorities can facilitate this by working with developing countries to ensure timely communication of inspection reports, quality complaints, and emerging safety data.

PV ACTIVITIES IN PUBLIC HEALTH PROGRAMS

- Africa constitute more than 70% of person on ARVs but about 6% of ADR reports.
- Among 32 PHPs, 12 programs (38%) have policy statements on pharmacovigilance and 15 (47%) have basic infrastructure.
- PHPs did not routinely collect and share ADR data with national pharmacovigilance centers.

PV ACTIVITIES IN PUBLIC HEALTH PROGRAMS (2)

- National PV databases in five of eight countries do not contain data from PHPs.
- Only two of eight HIV/AIDS programs have implemented active surveillance in the last five years.
- Immunization programs in SSA have incorporated the safety monitoring of vaccines in routine surveillance activities.

PV ACTIVITIES IN HEALTH FACILITY

- Among 54 Drug and Therapeutics Committees (DTCs) in 8 countries, most DTCs have not implemented interventions to improve patient safety.
- Less than 40% of DTCs have implemented active approaches to monitor and investigate adverse events.
- 47% reviewed ADR reports and addressed medicine safety issues and 23% took any action related to medicine safety.

PV ACTIVITIES IN INDUSTRY

- Pharmaceutical industry involvement in PV was minimal.
  - Regulations to enforce the responsibilities of pharmaceutical industry with regards to safety reporting and basic infrastructure are lacking in most countries.
- Pharmaceutical companies in South Africa show some encouraging trends in PV development.
  - PV structure was in place in most companies.
  - However, the functions were often limited to collecting and reporting the adverse events and not expanded to risk evaluation and decision making.

RECOMMENDATIONS (1)

For Countries;

- Develop or revise policy and legal frameworks to adequately address medicine safety monitoring, including regulations for the pharmaceutical industry.
- Strengthen organizational structures for PV at all levels of the health system and coordinate PV activities among all stakeholders.

RECOMMENDATIONS (2)

- Incorporate active surveillance activities into national PV systems and develop national data warehouses to collate disparate PV data from all sources.
- Collaborate with academia and health authorities to ensure locally relevant PV topics are integrated in pre- and in-service training programs.

RECOMMENDATIONS (3)

- Strengthen passive and active surveillance of product quality throughout the supply chain.
- Incorporate medicines quality and safety surveillance within the existing health surveillance structures.
- Strengthen DTCs capacity to carry out PV activities and use safety information to improve treatment outcomes.

RECOMMENDATIONS (4)

For Technical Agencies;

- Help countries to develop standard procedures and operational tools for the review, assessment, and use of safety data for decision making.
- Support countries to build capacity for the development and implementation of risk management plans.
- Facilitate communication and informational exchange among the countries to widely disseminate and share safety information.

RECOMMENDATIONS (5)

For Donors;

- Encourage countries to mobilize financial and human resources to ensure sustainability of the system and its performance.
- Support countries to ensure coordinated and non-duplicative resource utilization.
- Support countries to strengthen national PV programs and effectively address the gaps identified.

RECOMMENDATIONS (6)

For Pharmaceutical Industry;

- Take responsibility for ensuring medicine safety in every country where their products are marketed.
- Apply due diligence and product stewardship in implementing pharmacovigilance activities in developing countries.

Way Forward — Can this Report Galvanize Change?

- **European Union** 2003: Assessment of European Community System of Pharmacovigilance
  - 2011: new PV legislation include detailed description of the PV system, consumer reporting, etc.
- **United States** 2006: The Future of Drug Safety
  - 2007: FDA Amendment Act of 2007 include Title IX on Enhanced Authorities Regarding Post-market Safety of Drugs
- **Sub-Saharan Africa** 2012: Assessment of pharmacovigilance systems and their performance
  - .???

CONCLUSION

- PV activities are already taking place in SSA.
- Greater efforts are needed to coordinate and sustain existing activities.
- Strengthening risk management and communication is key for improving patient safety and treatment outcome.

Thank You!