



# Botswana National Laboratory Harmonization and Standardization June 4-12, 2014

Botswana Open Day  
March 27, 2014



# Overview

- Maputo Declaration
- Progress and challenges
- Goal
- Standardized approach
- Findings
- Impact
- Harmonization and standardization exercise
- Strategic plan
- Recommendations

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# Strengthening laboratory systems: The Maputo Declaration of 2008

## Called for:

- Standardization of tests, reagents, consumables and equipment needed at each level of the tiered laboratory system within a country.
- Harmonization and standardization of these laboratory commodities to improve the laboratory supply chain system and equipment maintenance.



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# The Maputo Declaration elevated the importance of lab harmonization and standardization

- Global perspective and commitment
- Harmonization is a gateway to improving the lab supply chain
  - Focuses on an agreed standard list of tests, laboratory supplies, instruments, and equipment at each level of the laboratory network
- Positively impacts traditional supply chain functions:
  - Product selection
  - Forecasting and supply planning
  - Procurement
  - Laboratory service performance related to equipment availability and utilization
  - Staffing requirements
  - Referral networks
  - Quality management systems



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# Over the last 10 years progress has been made in the lab supply chain, but challenges remain in ensuring consistent supply

Medical laboratory services have advanced along with the local health system and the medical diagnostics industry

Resulted in high instrument density and increase in the number of products to be procured and instruments to be maintained and serviced

Difficult to ensure continuous and consistent availability of the many diverse laboratory products required for these instruments

***Disruption in the provision of laboratory testing services***

**Lack of a national laboratory policy also hinders implementation of standardization and harmonization**

# Goal of harmonization and standardization

**Create awareness** around laboratory harmonization and optimization approaches to assist Botswana in defining an **evidence-based approach** to achieving harmonization and standardization.



# Arriving at a standardized approach to ensure consistency

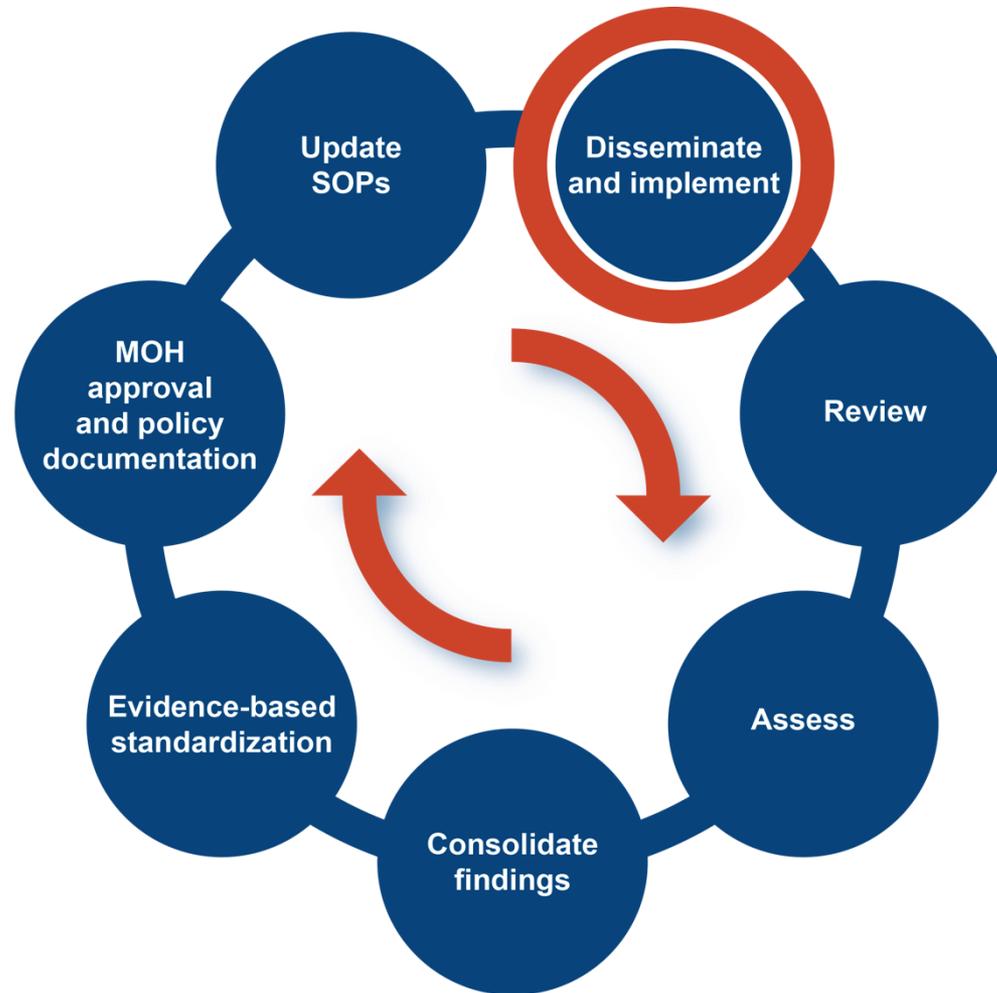
- **High level stakeholder agreement**, regardless of affiliation
  - To ensure consistency in and adherence to methods, instruments, tiers, and quality services
- Lab technicians review standardized approach to **ensure the services are in alignment** with stakeholder needs
- **Continuous process**, should not be a one-off activity

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# Harmonization cycle: Should occur every two years



# Harmonization and standardization positively impacts health service delivery

1. **Streamlines** product and supply lists
2. **Improves utilization and availability** of laboratory instruments ensuring consistent service provision
3. **Improves efficiency of laboratory services** through measured improvements in critical process factors:
  - Product selection, quality assurance, forecasting and supply planning, procurement, and budgeting
4. **Patients benefit from continuous and consistent services** through timely prognosis and management

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# In 2014, SCMS led the Botswana Harmonization and Standardization Exercise

- **Consulted** with clinicians ,laboratory personnel, health programs and policy makers to review all current and preferred laboratory tests
- **Assessed** all instruments placed in Botswana medical laboratories and updated inventory list
- **Determined** instrument distribution ,utilization, and diagnostic contribution rates
- **Reviewed** laboratory staffing requirements by service level based on identified tests to be performed by service level and instruments proposed for each service level

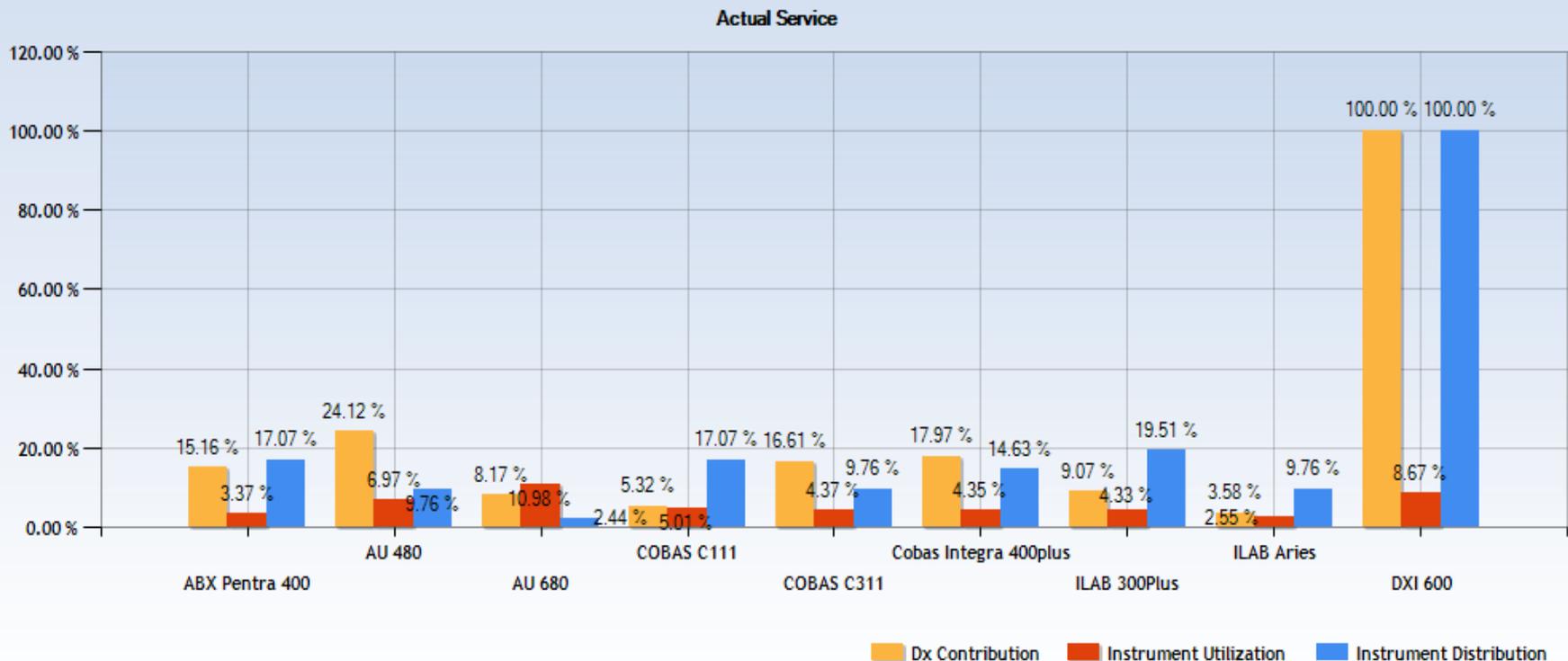
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# What we found out: Instrument utilization and equipment management are inadequate

- There is massive underutilization of laboratory instruments in the country
- Instrument density is very high



# What we found out: Instrument utilization and equipment management are inadequate (cont.)

- Underutilization and density are cost drivers for laboratory services provision as the **cost per test is usually high when utilization is low**
- Equipment management is **critical, but currently improperly managed**:
  - Inadequate procedures to manage equipment information
  - Inconsistent and uncoordinated equipment information reporting

# Users scored diagnostic instruments using standard instrument evaluation criteria

- **Recommended test lists and related instruments** for each service level
- **Proposed staffing requirements** for laboratories based on these lists
- **Suggested a standard list of ancillary equipment** for every laboratory



# SCMS followed the Maputo criteria for instrument review

- 5 critical criteria:
  1. **Equipment assessed and validated** by government, CDC , or WHO; reports must be available
  2. **Equipment in current production** (Not end of life)
  3. **Machine can interface with computer** (LIMS)
  4. **Local engineers available and trained** to service instruments
  5. **Regional engineers available** to service instruments
- 42 important and desirable criteria
- 6 additional cost-focused considerations:
  - Purchase price, start-up kit, instrument accessories, quality control materials, service contract, cost of consumables to run 1,000 tests

# 5 steps to leveraging lab harmonization activities to inform the strategic plan

- 1. Leverage existing momentum** following completion of the baseline harmonization and standardization exercise
  - 5-year laboratory strategic plan
  - laboratory quantification exercise
  - Revise and integrate health commodity logistics system
  - Conduct a quality management system standardization project
- 2. Review** current instrument placement, overall diagnostic contribution and utilization rates, and use a standard evaluation criteria to evaluate local instruments
  - Propose harmonized instruments by service level including a standardized ancillary equipment list

# 5 steps to leveraging lab harmonization activities to inform the strategic plan (cont.)

3. **Obtain final consensus** by service level on:
  1. Test selection
  2. Categorize existing labs according to service level
  3. Methodology
  4. Minimum standardized equipment
  5. Human resource requirements
4. **Establish a dedicated team** (Technical Working Group) to re-evaluate the harmonization framework **every 2 years** due to rapid changes in diagnostic technologies and policy and regulatory implications

# 5 steps to leveraging lab harmonization activities to inform the strategic plan (cont.)

## 5. Coordinate harmonization implementation:

- **Develop** a well-communicated, responsive strategy with Ministry management commitment
- **Ensure** continued advocacy, reporting, monitoring technology development
- **Guide** Ministerial policy and regulatory advances in laboratory network development, and other national laboratory interests
- **Finalize** the framework by allocating current and future laboratory facilities to service levels

# Recommendations

Beyond the 5 steps, the laboratory services department should **initiate discussions and scenario planning** on:

1. **Optimizing** the laboratory network
2. **Costing out** laboratory services provision
3. **Finalizing** a comprehensive national laboratory policy
4. **Strengthening** laboratory leadership, communication and laboratory staff training at all levels
5. **Strengthening** data management and supply chain systems

All to ensure delivery of effective ,efficient, accessible, equitable and affordable quality laboratory systems

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# Questions?

