Framework for Development of HIV Related POCT QA Policy

Implementation and Quality:
Ensuring Reliable and Accurate Patient Results
Consultative Meeting June 23-25
Dar es Salaam
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Policy Sets Goals and Authorities: Guides Planning & Implementation

Testing & Capacity Needs
by level and geography determines

Means & Methods (facilities, equipment, referral & transport)
Used to project

Human Resources Needs
| Workforce needs, recruitment, retention | training curriculum | education & training schools |
Foundations of Laboratory Leadership and Management: Core Curriculum (Workshop and TOT formats)

National Laboratory Policy Development

Task Specific training

QMS & EQA

In-service training

Biosafety

Equipment & inventory

Information Systems

Building Quality Laboratory Practices – APHL Model

Implementation plans

Mentoring

Pre-service training capacity

Strategic Plan Development

GWU/APHL Management Course

Sufficient to assure

Essential for Sustainability

Essential for Continual improvement

Essential for leadership & coordination

Prerequisite knowledge

Sufficient to assure

Essential for Sustainability

Essential for Continual improvement

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Prerequisite knowledge
Purpose of policy

• Vision, mission and objectives: You can not plan, manage and serve effectively if you have not defined these elements of the laboratory system.

• Laboratory policy: define the national lab system

• QMS policy: define the quality system

• POCT policy: define and integrate QA
Why a national laboratory policy?

• The laboratory system must have a policy framework to guide all providers in a common purpose that meets the country’s laboratory service needs.
Elements of the policy

• Organizational structure (How many levels?) and the mission and objectives for each level

• Management structure of the laboratory division within the Ministry of Health

• Manage implementation and integration of new technologies, e.g., POCT
Elements of the policy (2 of 3)

• Services provided at each level and how staff positions and numbers are determined
  o Tests and techniques
  o Education, skills, abilities
Elements of the policy (3 of 3)

• Quality management system
  – Standards and licensing/accreditation of personnel and facilities
  – Data standards: minimum data set, information collection
Policy drives planning

Testing & Capacity
- By level
- By Area
- Used to standardize

Methods
- Equipment
- Facility
- Referral & transport
- Used to determine

Human resources
- Training curriculum
- Education & training schools
Environmental scan (Gap analysis or SWOT)

• What elements exist already?

• What legal authority? Are new laws or amendments needed? Regulations?
Develop the policy

• What is the process for development and proposal of the national laboratory policy?
• What group develops the policy recommendations?
• Who will approve the policy?
Maintaining the system

• How will policy be continually updated?
• What advisory body or bodies are needed to oversee the on-going quality of the laboratory system? For example,
  o Laboratory technical advisory group
  o Medical technology board
  o Accreditation body
Strengthening Laboratory Capacity through Policy

• Strengthen political commitment and ensure adequate and sustained funding

• Collaboration between all donors and partners with coordination from national governments

• Health System Strengthening: Piggy-back on resources to support strengthening of the tiered laboratory system
Strengthening Laboratory Capacity

- Development of national laboratory policies within the national health development plan that will guide the implementation of a national integrated laboratory strategic plan that includes POCT
Assuring quality of POCT

POCT SPECIFIC PROCESSES
PROCESS AND GOAL

Draft Framework developed Feb-June

Dar Consult Meeting June 23-25

Framework document published July/August

Ministries of Health
Develop National POCT
Policy or Review and Update Existing Policy

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PURPOSE OF FRAMEWORK

• Provide process steps and examples of policy content to guide policy development
• Describe function and reason for components of policy and facilitate adaptation to country situation.
• Support timely, efficient action.
PURPOSE OF POCT POLICY

- Define mandates and authorities
  - Access to POCT services
  - Organization, management, standards, practices and resources

- Provide an enabling environment and guidelines for coordination
  - Integrate diagnostic test systems, laboratory and non-lab based
Diagnostic testing goals

• Accurate (QC/QA) and reliable
• Accessible (patients and providers)
• Reportable accurately to the right person(s) on time
• Entire process is quality assured (timely measurement and analysis of test data)
WHAT IS A POCT POLICY

• Statements of the national health authority on POCT organization, management and delivery that specify intent and direction.

• General in nature
POCT POLICY CONTENT

• Ministry of Health and Advisory Bodies

• Strategic and Operational Plans

POCT System

Information Technology

Human Resources

Regulation and Quality

Financial Planning and Partners

• Stakeholder Roles

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POCT Content Detail

1. OBJECTIVES
2. SITUATIONAL ANALYSIS
3. ORGANIZATION & INFRASTRUCTURE
4. POCT SERVICES
5. POCT SELECTION
6. QUALITY ASSURANCE CYCLE
7. LABORATORY COMMODITY SUPPLY & DISTRIBUTION
8. PARTNERS AND VOLUNTEERS
9. MONITORING AND EVALUATION
10. POCT TECHNOLOGIES REVIEW AND APPROVAL
11. LEGAL AND REGULATORY FRAMEWORK
12. RESEARCH AND DEVELOPMENT
Fitting the government structure

• Policy essential to enabling action and can be developed in two general forms
  a. Separate document for laboratory policy that supplements MoH health policy
  b. Written as standards, regulations and guidelines as authorized by MoH policy

• In the case of (a.) still requires standards, regulations and guideline documents to be developed (not part of policy)
Enabling authority

• The specifics to enable action may be in a policy document or in documents authorized by a main authority

• Objective is written definition of roles and authorities sufficient to enable effective and efficient action in implementation
Example Policy Content for Quality

• “Agency Head” with advice of the Diagnostic Technical Advisory Committee shall establish standards and guidelines for certification, practice and quality assurance of diagnostic testing including point-of-care testing.

• Outcomes: Ministry of Health establishes standards and POCT is available and performed accurately.
Policy properties

- Enables but does not provide specific rules
- High bar to establish: time consuming and may require parliamentary approval
- Defines unambiguous authority, i.e., clear and unique roles of government agencies to assure efficient operations
Key questions for POCT policy

• What are the access challenges and how can POCT increase access?
• What are the challenges of providing accurate POCT, reporting results and linking test results to follow up?
• What are the costs of options (POCT vs. other)?
• How can performance be monitored and success measured?
General Principles

- **Patients First** requires accurate testing
- Create structure and authority but not prescribe specific procedures; use advisory bodies for recommending specific standards
- Government endorsement and support
- Set goals and guidance for sustainability
- Use scientific and medical evidence available
- Partnership (participation of stakeholders)
- Transparency
- Effective communication
Operations vs. Vision and Priorities

POLICY

STRATEGY

IMPLEMENTATION

ENABLE & SUSTAIN

OBJECTIVES & MEANS

MEASUREABLE ACTIONS

REAL WORLD EVENTS AID AND INTERFERE

DECISION MAKERS & IMPLEMENTERS

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POLICY DEVELOPMENT STEPS

1. Lead team selection and pre-planning
2. Team training, draft procedures and process approval
3. Situational analysis

4. Document draft zero*
5. Stakeholder consultations to revise proposed policy
6. Validation meeting and stakeholder consensus

7. MOH review and approval

*If POCT Policy is in place, the framework can be used as a checklist by the lead team to assess what efforts may be made to strengthen the policy.

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BUY-IN

• CONVINCING NEED

• MEASURED BETTER CARE AND HEALTH OF PATIENTS

• SUSTAINABILITY

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INCLUSIVE

• MINISTER SUPPORT

• CREDIBILITY OF LEAD TEAM

• INCLUDE INPUT OF STAKEHOLDERS
Lead Team

• Lead team responsibilities
  o Communication
  o Environmental Scan / Situation Analysis
  o Identify policy alternatives
  o Risk assessment and costs of options
  o Start policy formulation (draft zero)
Environmental Scan

• What elements exist already?
• What legal authority? Are new laws or amendments needed? Regulations?
• What are the challenges?
• What is the overall government policy direction and priorities?
National Health Policy

Minister of Health

Lab and POCT Policies

Lab

POCT

Strategic and Operational Plans

Hospitals

Programs

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POLICY DEVELOPMENT PROCESS

BUY-IN
- Minister of Health
- Resources

Develop
- Lead Team
- Stakeholders

Implement
- Consensus
- Approve & Issue

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DEVELOP

• COMMUNICATE PROCESS

• EVIDENCE, FEASIBLE, CONSENSUS

• NOT PRESCRIPTIVE, AUTHORIZE PROCESS

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Policy Formulation

• Lead Team roles in formulation
  o Policy statements for each defined thematic area (content) for Draft Zero
  o Plan for the stakeholder meetings
  o Coordinate stakeholder inputs into the draft policy
  o Prepare policy draft for stakeholders validation
  o Submit and accomplish MoH approval
IMPLEMENTATION

• Strategic and operational plans follow policy or plans revised if developed previously
• Monitoring and evaluation essential to plans
• Continual improvement and modifications to policy and plans

• Access must be to quality assured services

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Operations vs. Vision and Priorities

- Policy
- Strategy
- Implementation
- Real World Events AID and Interfere
- Enable & Sustain
- Objectives & Means
- Measureable Actions

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Draft framework document for Dar es Salaam consultation developed with input from stakeholders at meetings in February, March and June 2014 including

CDC, OGAC/PEPFAR, CHAI, GLOBAL FUND, UNICEF, UNITAID, USAID, WHO AFRO, WHO GENEVA, U.S. STATE DEPT., APHL, ASCP, ASLM, ASM, CIFF, CLSI, FIND, MSF, NEQAS, NHLS SOUTH AFRICA, NIAID, PGAF, PFSCM, CHIEKH ANTA DIOP UNIVERSITY, DUKE UNIVERSITY, EMORY UNIVERSITY, HARVARD UNIVERSITY, LONDON SCHOOL OF TROPICAL MEDICINE & HYGIENE, UNIV. OF MARYLAND, NATIONAL REPRESENTATIVES FROM LESOTHO, MOZAMBIQUE, TANZANIA, ZIMBABWE AND MANY OTHERS

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