

Framework for Development of HIV Related POCT QA Policy

Implementation and Quality:
Ensuring Reliable and Accurate Patient Results
Consultative Meeting June 23-25

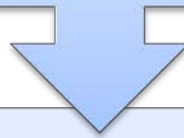
Dar es Salaam
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Policy Sets Goals and Authorities: Guides Planning & Implementation

Testing & Capacity Needs

by level and geography determines



Means & Methods (facilities, equipment, referral & transport)

Used to project



Human Resources Needs

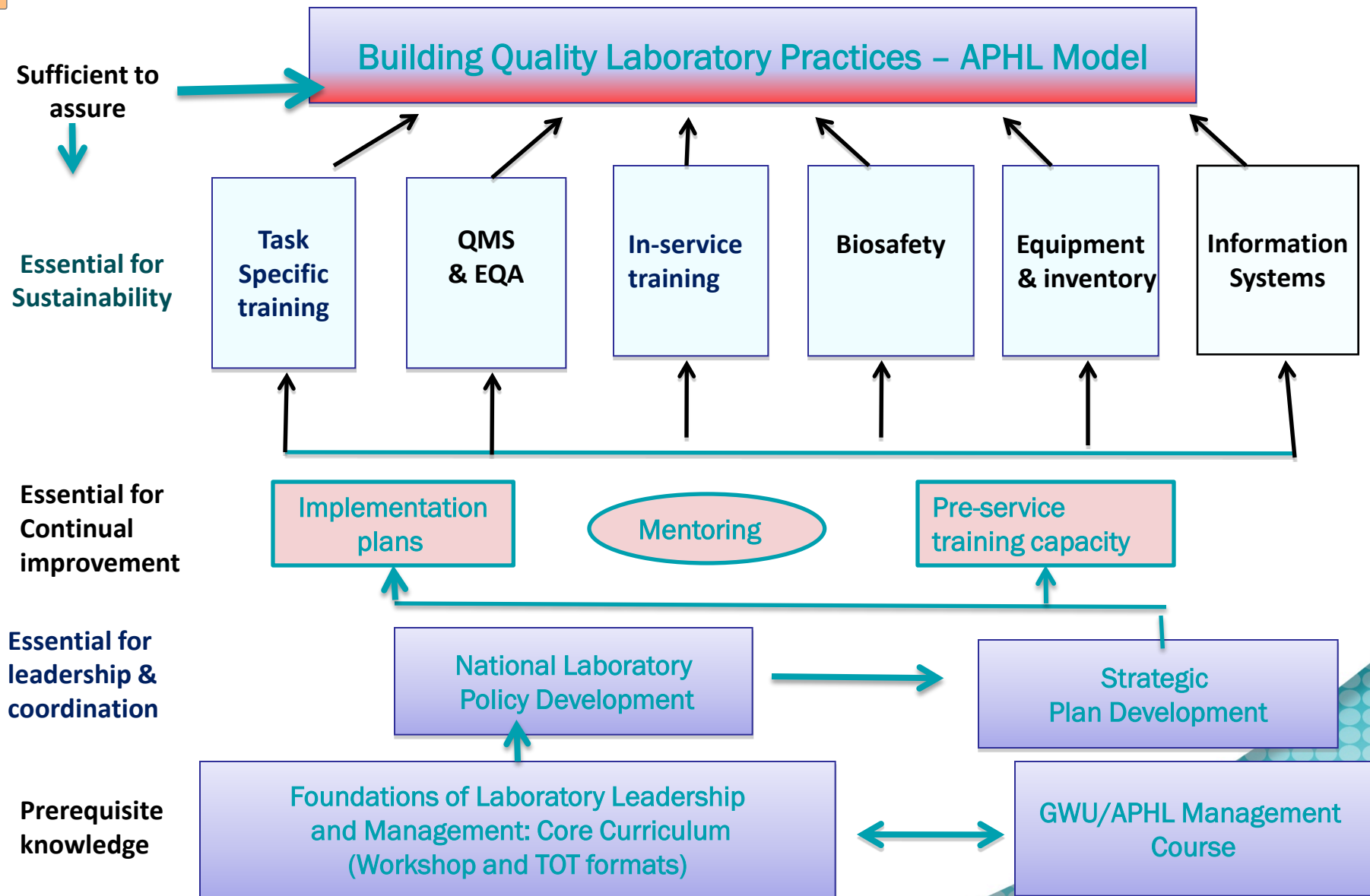
Workforce needs,
recruitment, retention

training curriculum

education & training
schools



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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

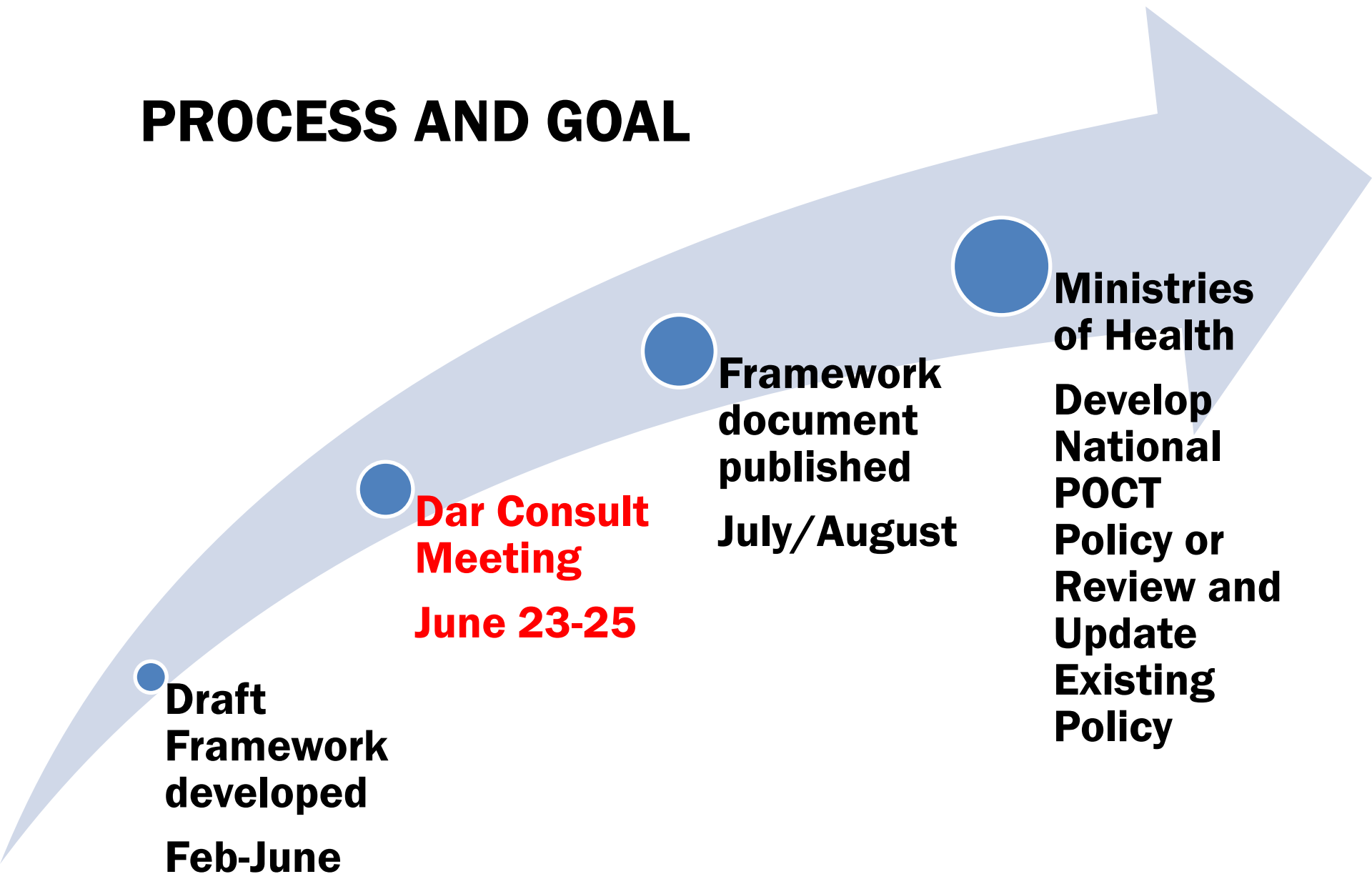
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PROCESS AND GOAL



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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
 - o Access to POCT services
 - o Organization, management, standards, practices and resources
- Provide an enabling environment and guidelines for coordination
 - o 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)

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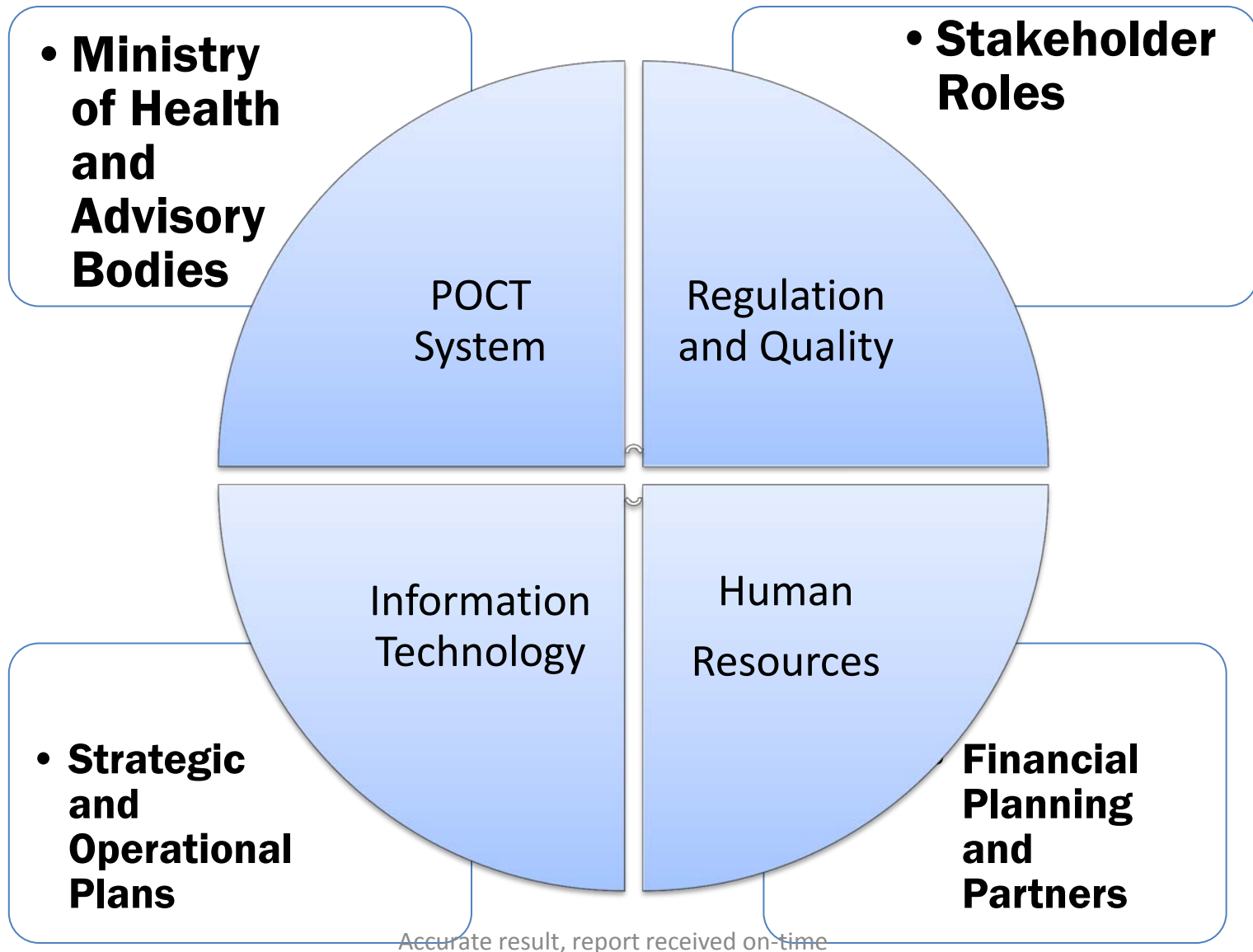


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WHAT IS A POCT POLICY

- Statements of the national health authority on POCT organization, management and delivery that specify intent and direction.
- General in nature

POCT POLICY CONTENT



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

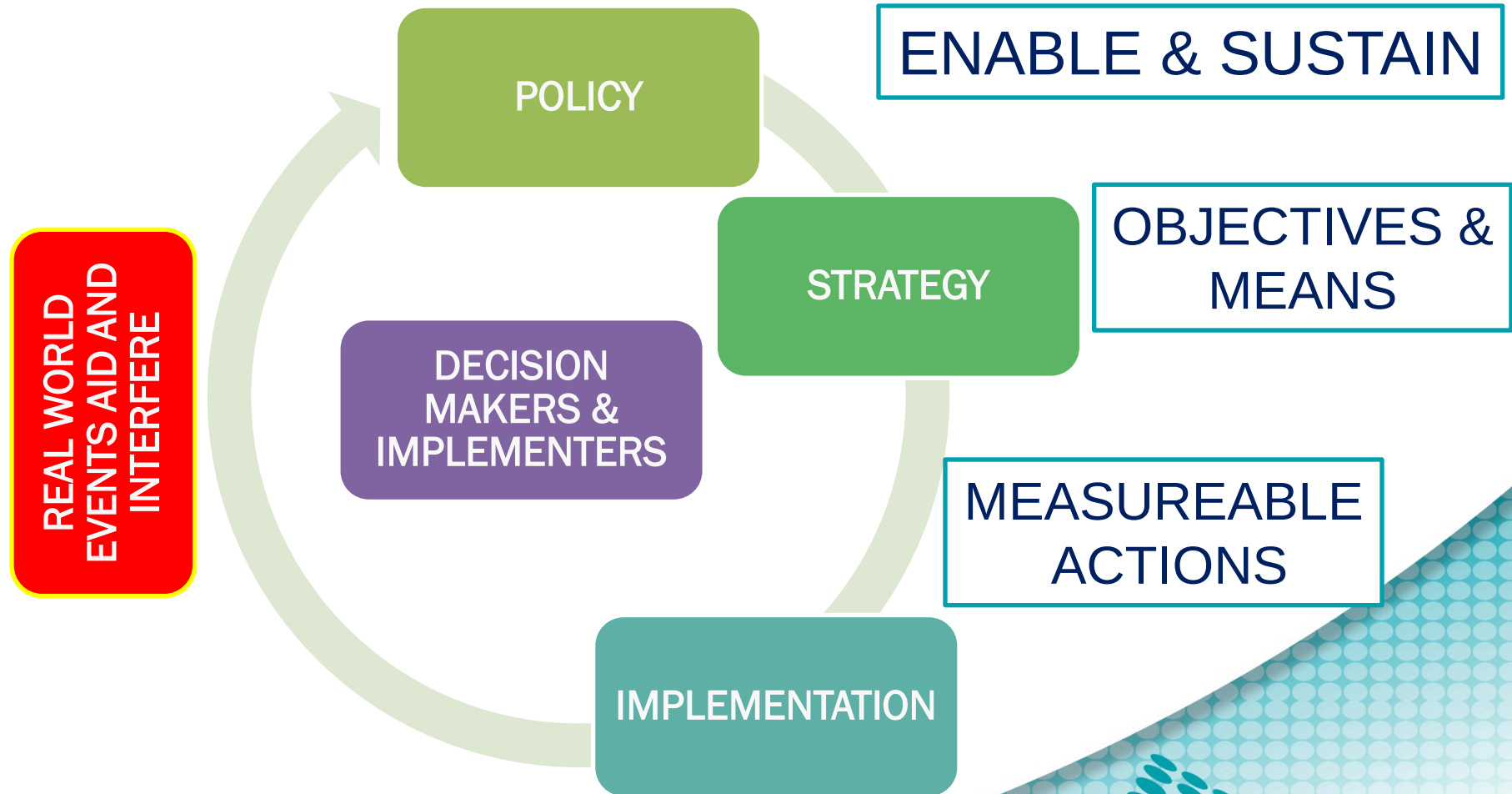
Key questions for POCT policy

- 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

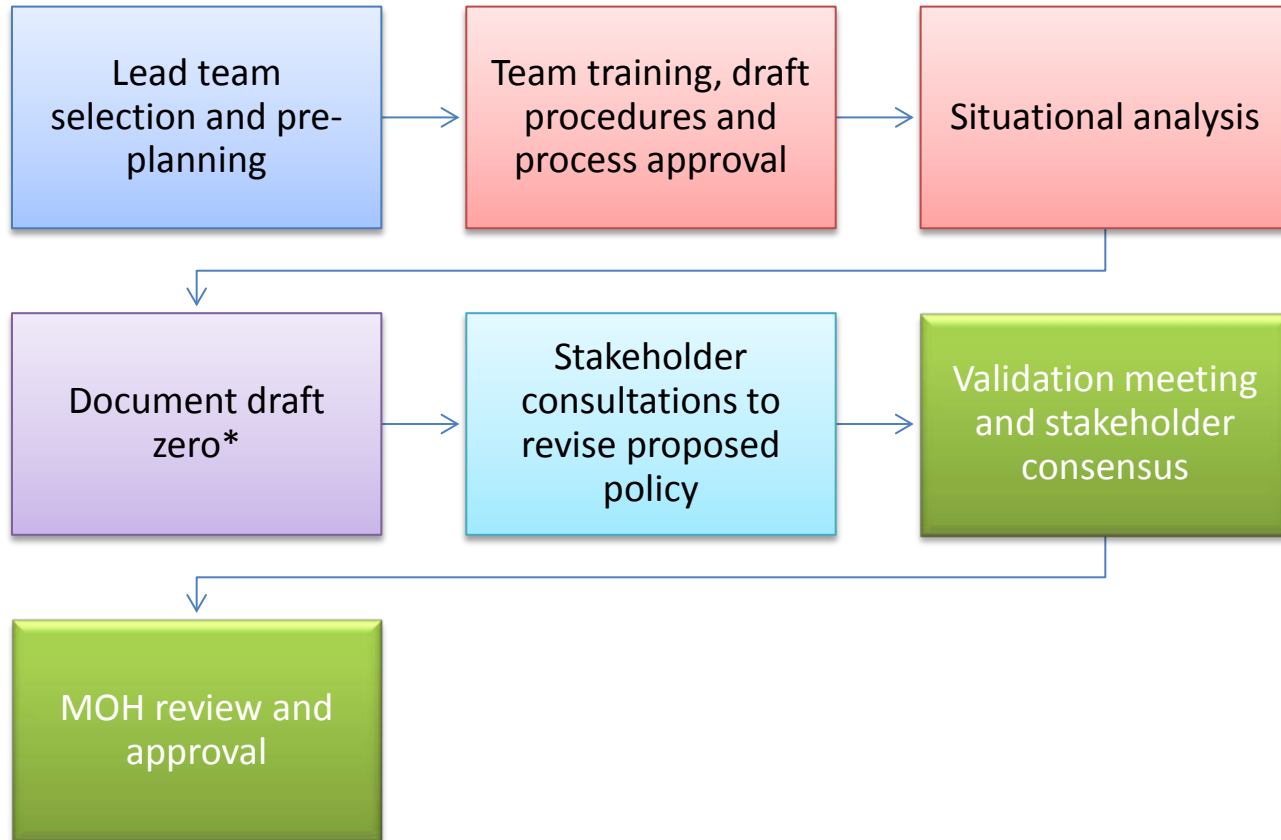
- Patients First requires accurate testing
- Create structure and authority but not prescribe specific procedures; use advisory bodies for recommending specific standards
- Government endorsement and support
- Set goals and guidance for sustainability
- Use scientific and medical evidence available
-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

Operations vs. Vision and Priorities



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POLICY DEVELOPMENT STEPS



*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.

BUY-IN

- **CONVINCING
NEED**
- **MEASURED
BETTER CARE
AND HEALTH OF
PATIENTS**
- **SUSTAINABILITY**



INCLUSIVE

- **MINISTER
SUPPORT**
- **CREDIBILITY OF
LEAD TEAM**
- **INCLUDE INPUT OF
STAKEHOLDERS**



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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

Stakeholders

Lab and POCT Policies

Lab

POCT

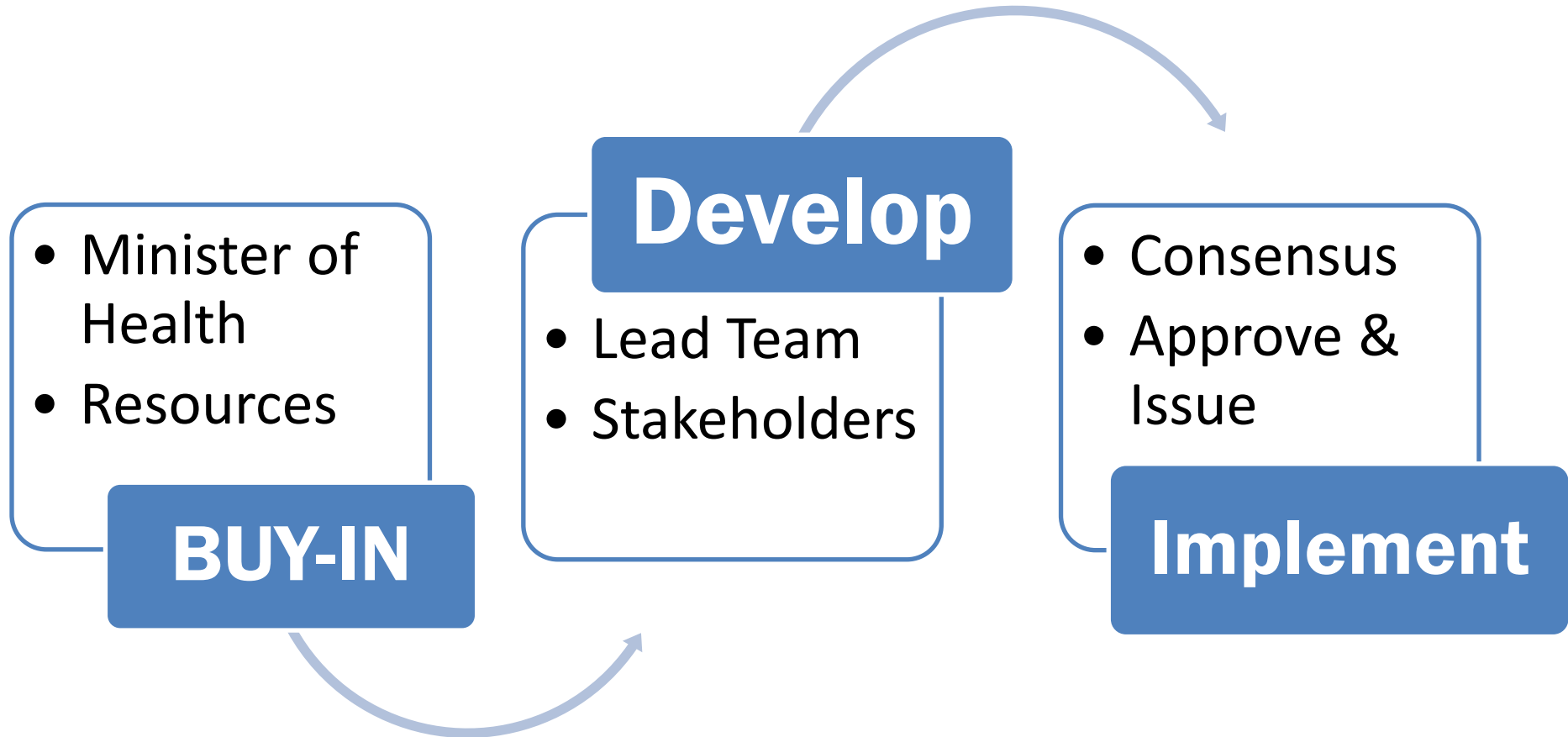
Strategic and
Operational Plans

Hospitals

Programs

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POLICY DEVELOPMENT PROCESS



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DEVELOP

- **COMMUNICATE
PROCESS**
- **EVIDENCE,
FEASIBLE,
CONSENSUS**
- **NOT
PRESCRIPTIVE,
AUTHORIZE
PROCESS**

teamworkpictures.com



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Policy Formulation

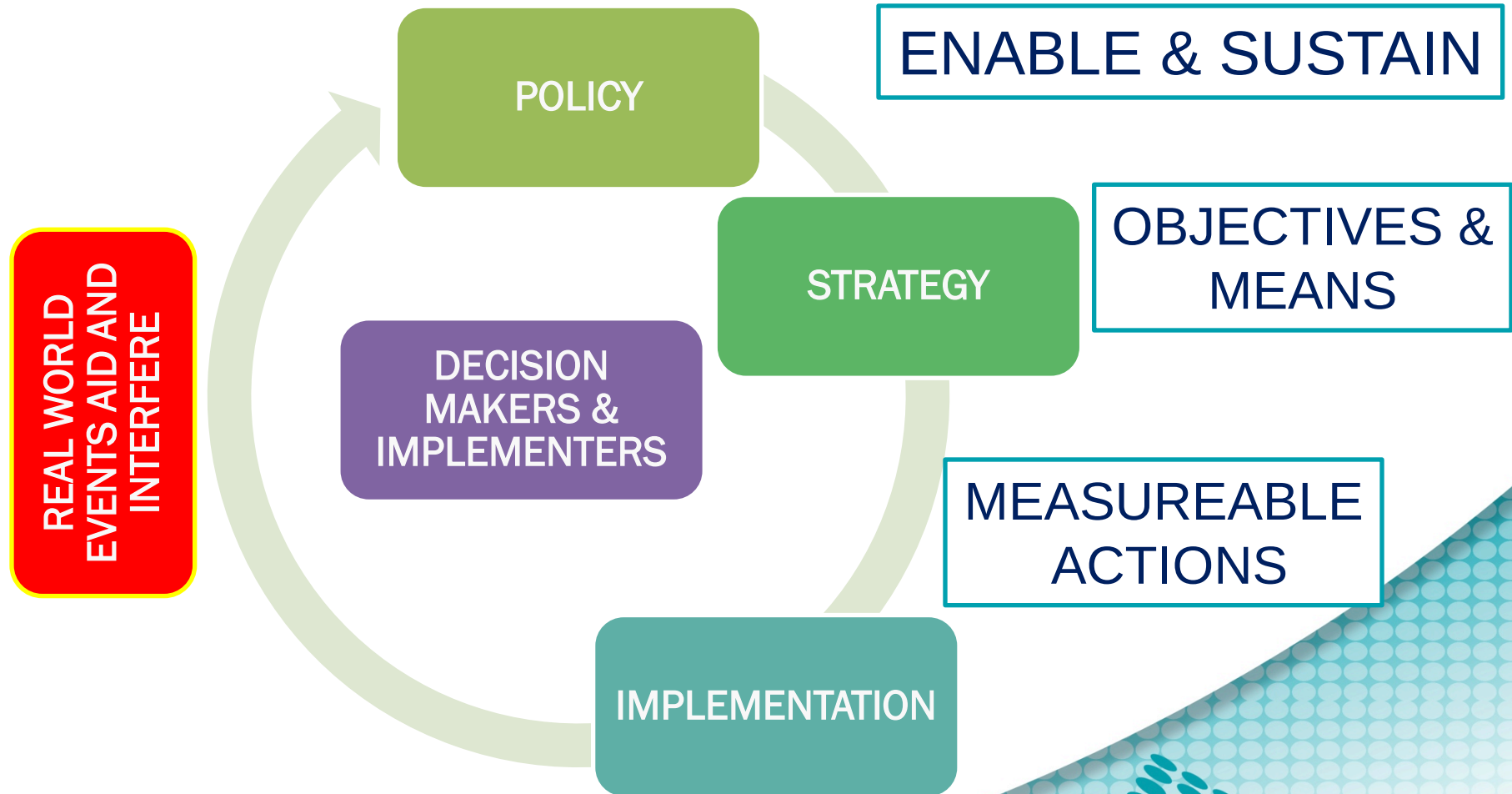
- Lead Team roles in formulation
 - o Policy statements for each defined thematic area (content) for Draft Zero
 - o Plan for the stakeholder meetings
 - o Coordinate stakeholder inputs into the draft policy
 - o Prepare policy draft for stakeholders validation
 - o Submit and accomplish MoH approval

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



Operations vs. Vision and Priorities



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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