

Laboratory System Development to Support ART Programs

Trevor Peter and Bill Rodriguez

Clinton Foundation HIV/AIDS Initiative

August 2006



The Clinton Foundation HIV/AIDS Initiative mission is to increase access to care and treatment

Mission

To bring high-quality care and treatment to people living with HIV/AIDS and to improve healthcare systems in developing countries

The identification of key bottlenecks has continued to evolve as we work with country programs

Identified Barrier

Solution

(2002) Care and treatment is inaccessible due to high cost

Negotiations with suppliers to reduce cost of lab diagnostics

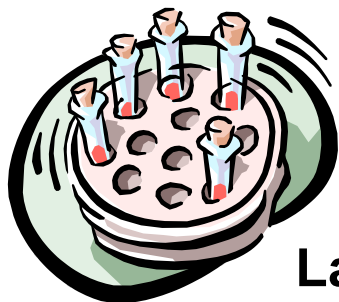
(Present) Inadequate capacity to successfully scale lab services to meet ART program demand

Provide additional technical assistance to help countries improve their laboratory systems

TODAY the strengthening of laboratory capacity remains a significant challenge for many countries

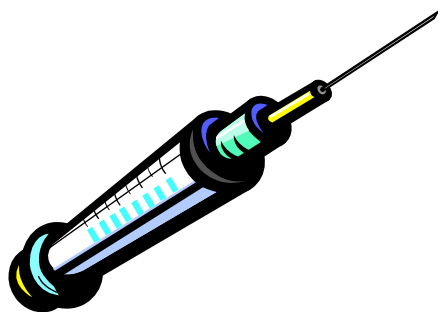
Lab testing is essential to the continuum of care

Programmatic components to containing the HIV epidemic



Lab

VCT services
Case findings & referrals
Access to laboratory monitoring
Access to ARVs
Clinician and laboratory training
Peer counseling
Adherence
Access to OIs and other treatment
Prevention and harm reduction
Management and supply



What are we trying to achieve for labs?

Capacity and access

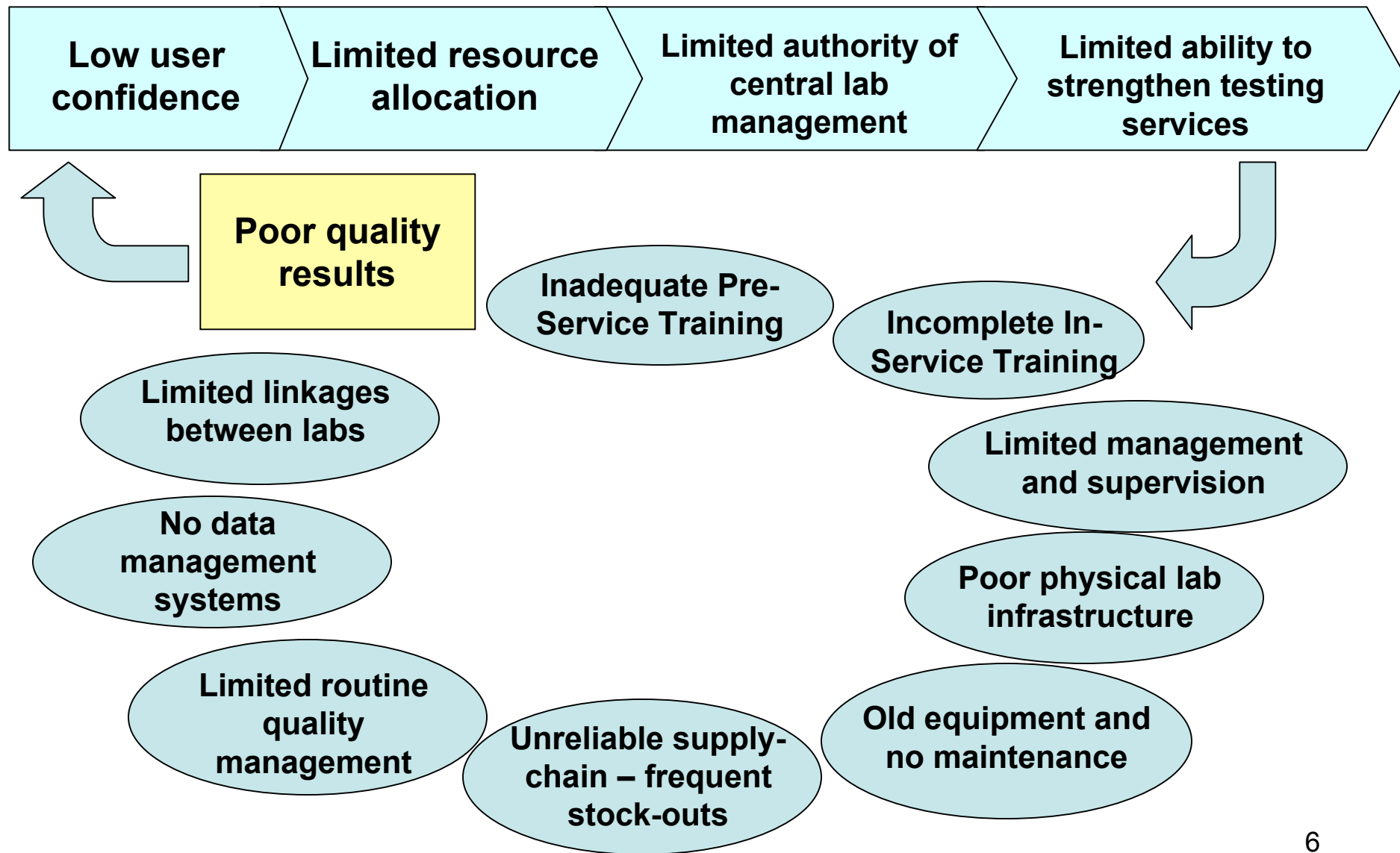
Quality and reliability

Cost-effectiveness and sustainability

What constrains the delivery of effective laboratory services?

- HIV testing demands have quickly increased beyond existing lab capacity as ART scales up
- Existing laboratory networks were designed to cope with pre-HIV public health challenges mainly in a primary care setting
- The focus of treatment programs catered first to needs such as clinical capacity and drug supply
- Lab deficiencies were recognized late in many countries and are not simple or quick to resolve
- There are few organizations working systematically on laboratory development
- Many of the existing efforts are not coordinated or standardized, leading to fragmented and punctuated development

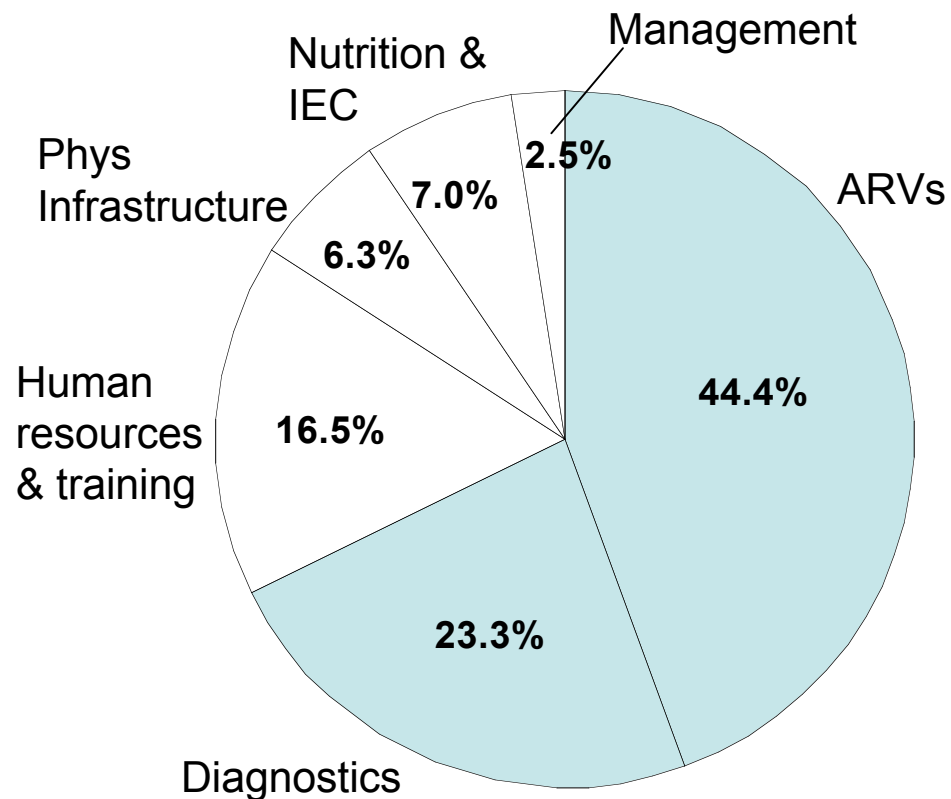
Labs have been caught in a cycle of under-appreciation and low quality



Substantial investments are now being made in laboratory services

Cost breakdown of example country ART budget*

Illustrative



Diagnostics can be the largest operational component of ART cost

- In order to contain costs while scaling up the program, investments in labs today have to be made with the **objective of developing sustainable capacity**.
- Much of the current investment in labs is targeted at **infrastructure development** and **basic operations**.
- These are relatively easy to implement.
- **Systems building and improving the efficiency of laboratory operations** will be the next major challenge.

* Example Country in which 60% of population that needs ARVs are on ARVs

Which strategic areas need the greatest focus today?

Leadership and planning

Laboratory network development

Supply chain management

Training

Leadership and Planning

Leadership: What role does it play?

Central management often needs strengthening in order to play a meaningful leadership role in the laboratory network at a national level



Standardize infrastructure and operations across the laboratory network



Coordinate lab development efforts by different development partners



Budget and allocate resources at the national level



Provide technical leadership and direction-setting

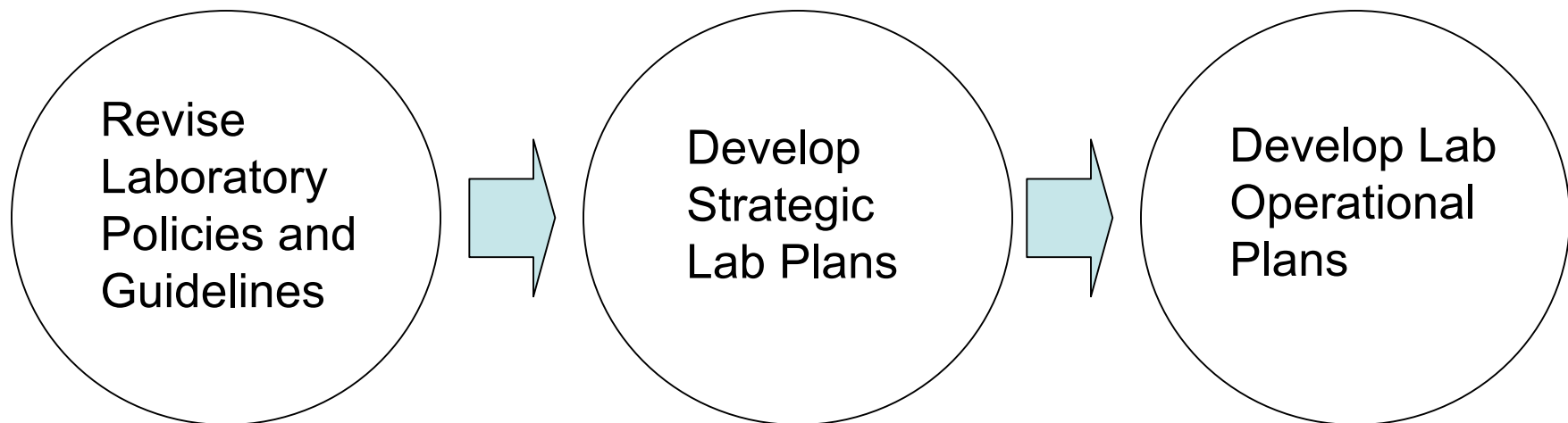


Strengthen quality management

Often, central laboratory leadership is limited to a Ministry of Health administrative position and the laboratory director at the Central or Reference laboratory. **New management positions are often needed.**

Strengthened leadership leads to improved resource management


Many countries have started a 3-step process to improve coordination of lab program resources



These provide a working framework for programs and operations.

Revise Laboratory Policies and Guidelines

Strengthening national laboratory policy and testing guidelines



- Revising workplace practice standards for equipment, human resources, laboratory hierarchy and testing menus, quality management guidelines
- Publishing revised National Laboratory Policies and Testing Guidelines, e.g., CD4 Guidelines, Viral Load Guidelines, Workplace Procedures, Standard Operating Procedures
- Publishing quality policies

Develop Laboratory Strategic Plans

Multi-year strategic plans can be useful for coordination of local and international support

Illustrative

OBJECTIVE 1: IMPROVE CAPACITY AND ACCESS TO TESTING SERVICES

SUB-OBJECTIVE 1.1: IMPROVE THE ORGANISATIONAL AND MANAGEMENT STRUCTURE OF LABORATORY SERVICES

Specific Objective	Activities	2006				2007	2008	2009	2010	Responsibility	Outcomes and Planned Results
		Q1	Q2	Q3	Q4						
Strengthen the institutional framework for laboratory management at national and sub-national levels	Define the institutions over which the MOHS'W DS has responsibility or regulatory oversight; define roles and responsibilities between national and sub-national levels of the laboratory system		X	X						MOHS'W DS, TBD	Mandate of MOHS'W DS defined
	Finalize the administrative and technical management structures of the MOHS'W DS, propose structures for lower levels of the		X	X						MOHS'W DS, TBD	New organizational structure of the MOHS'W DS approved
	Revise administrative and legal documents as needed to reflect the proposed changes			X	X					MOHS'W DS, TBD	Administrative and legal documents revised
	Finalize TORs and establish positions within the MOHS'W DS, appoint or hire staff to fill these		X	X	X					MOHS'W DS, TBD	Staff in place at the National Laboratory <<AU>>
	Designate a laboratory head or supervisor at each testing site to provide oversight of the routine laboratory activities and to coordinate overall management of the laboratory services within the facility.				X	X	X			MOHS'W DS, TBD	Laboratory heads/supervisors in place at each site
	Establish a National Laboratory Technical Working Group with provincial representation to advise the Head of the MOHS'W DS		X							MOHS'W DS, TBD	National Laboratory Technical Working Group in place

SUB-OBJECTIVE 1.2: STRENGTHEN THE LABORATORY NETWORK AND DISTRIBUTION OF TESTING CAPACITY

Specific Objective	Activities	2006				2007	2008	2009	2010	Responsibility	Outcomes and Planned Results
		Q1	Q2	Q3	Q4						
Plan laboratory services around a comprehensive set of clinical testing guidelines	Participate with local clinical leadership and international recommendations on development of required tests and testing frequency		X	X	X					Clinical bodes, MOHS'W DS, TBD	
	Forecast test volumes to ensure that testing guidelines are in line with available and foreseeable laboratory capacity		X	X	X					MOHS'W DS, TBD	Forecasted test demand and laboratory testing capacity
	Adopt, publish and distribute testing guidelines to clinical and laboratory sites				X	X				Clinical bodes, MOHS'W DS, TBD	Updated set of clinical testing guidelines

Develop Laboratory Operational Plans

Detailed, step-by-step operational plans can be useful as management tools and for identification of resources needed

Illustrative

2	Activity	Tasks/Sub-activities	2006			2007			2008		Govern't Division & Partners Responsible	Additional Resource s Required	Activity Output (Date)	Estimated Budget (US\$)*			Potential Funding Sources
			Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1				Q 3	2006	2007	
3																	
50	Objective 1: To address immediate, critical HR shortages and to develop a plan for longer term human resource development																
51	Main Outcome Indicators: To fill 50% of the most critical positions by the end of 2006																
52	Address immediate, critical HR shortages	From previous assessments, identify critical positions that should be filled as soon as possible (e.g., central management staff; empty positions at high-volume laboratories)									Laboratory Services		List of critical positions to be filled				n/a
53		Adopt a near-term budget for filling critical human resources gaps									Laboratory Services, partners		Funds available for short-term gaps				n/a
54		Assign staff to fill identified, critical human resources gaps at a central level during interim period									Laboratory Services, partners	Approval from MOH HR Dept.	Interim assignments for critical positions (estimated 6 positions)	\$60,000	\$60,000		Partners
55		Assign staff to fill identified, critical human resources gaps for routine laboratory work during interim									Laboratory Services, partners	Approval from MOH HR Dept.	Interim assignments for critical positions (estimated 40)	\$200,000	\$200,000		Partners
56	Define the staffing norms and manpower requirements for laboratory services over a multiyear period	Review and revise (as needed) National Policy Guidelines establishing minimum laboratory staffing at each level of healthcare facility, based on forecasted workload demands									MOH HR Department, Laboratory Services		Updated policy for minimum laboratory staffing levels				n/a
		Conduct HR assessment to quantify the total staff									Laboratory Services	Data entry person,	Quantification of required staff	\$833			Partner

Successful planning requires follow-up or failure is likely

Adopt

- Policies and plans should be:
 - Formally adopted by national governments;
 - Signed off on and agreed to by all relevant partners supporting labs need;
 - Used for decision-making; and
 - Integrated into programs, e.g., quality, infrastructure development, training.

Distribute

- Policies should be widely distributed and easily available. Managers, staff and partners should be familiar with the policies.

Implement

- Implementation needs dedicated management and adherence by operational managers, quality managers, partners, related divisions, supervisors, staff members

Coordination of efforts is essential for success

- National systems with long-term, countrywide focus will replace treatment projects with limited scope and timelines.
- Coordination of lab efforts by different partners will support this process and help build sustainable national systems.

Few groups have sufficient resources to cover all needs

Consolidated efforts promote standardization

Initiatives such as planning, supply chain, training and network building are best achieved through consolidated efforts between governments and all partners.

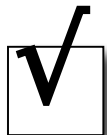
Laboratory Network Development

Laboratory network development

Lab networks have numerous advantages over multiple independent labs:



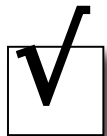
Easier to standardize on technologies, human resources, quality systems, data management and communications



Facilitate standardized supply chain management and consolidated procurement practices



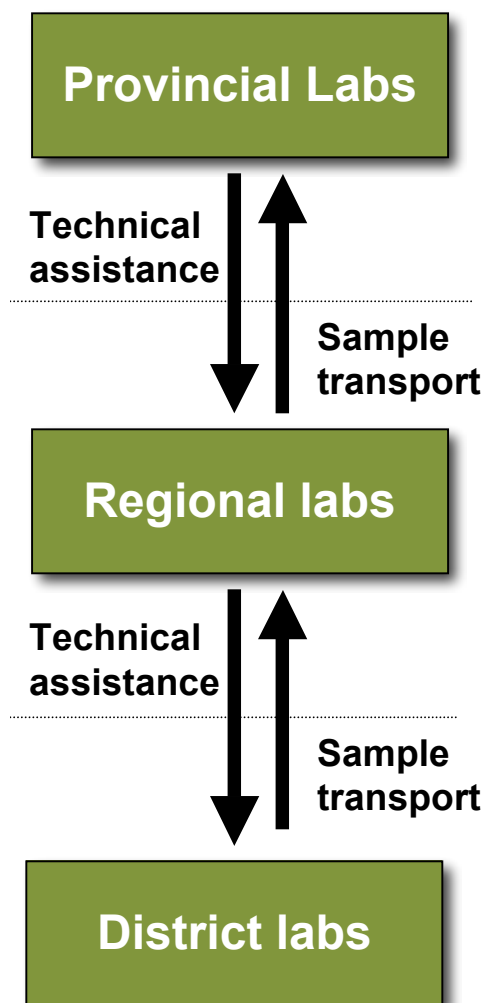
Facilitate referral of specimens to referral labs and testing depots, thereby improving efficiency, reducing costs and optimizing laboratory instrumentation, staffing and other resource usage



Create systems through which national programs can be implemented and supervised, e.g., quality management and training

Linkages between labs are based on collective responsibility, sample transport and technical assistance

Illustrative



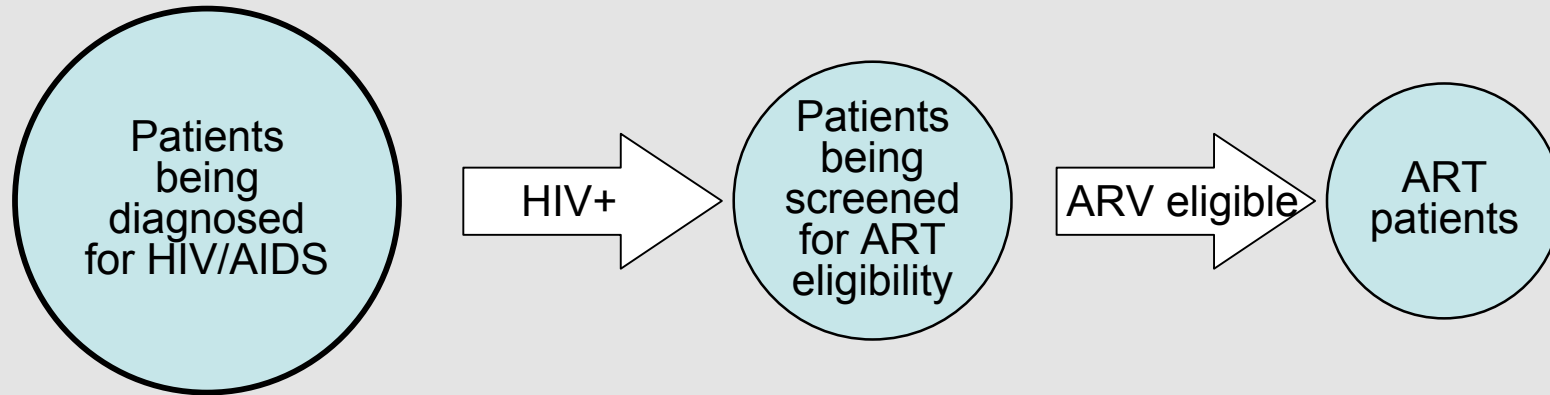
Test	District Labs	Regional Labs	Provincial Labs
HIV rapid test (diagnosis/confirmation)	✓	✓	✓ (+ ELISA)
HIV DNA PCR	-	-	✓
Hemoglobin	✓	✓	✓
Hematology	✓	✓	✓
Pregnancy test	✓	✓	✓
TB sputum smear	✓	✓	✓
STI diagnosis	✓	✓	✓
CD4 count	(select)	✓	✓
Viral load (optional)	-	-	✓
Clinical chemistry	✓	✓	✓

Sample transport is often feasible and inexpensive and is needed for CD4, as well as DNA PCR (early infant diagnosis), TB culture and viral load samples, where available

Supply Chain Management

Direct links between access to diagnostics and the supply chain

Access to diagnostics is prerequisite for referral to HIV/AIDS care and treatment



- HIV diagnosis depends on having counseling services and the appropriate diagnostic tools on hand.
- To support diagnostic tools, the supply chain must:
 - Result in selection of accurate diagnostic tests
 - Ensure sufficient quantities of blood collection and sample transfer supplies
 - Ensure uninterrupted supply of diagnostic tests at laboratories, as patients may not be willing to return for blood re-draw
 - Involve distribution network wide enough to cover any new diagnosis sites or testing laboratories

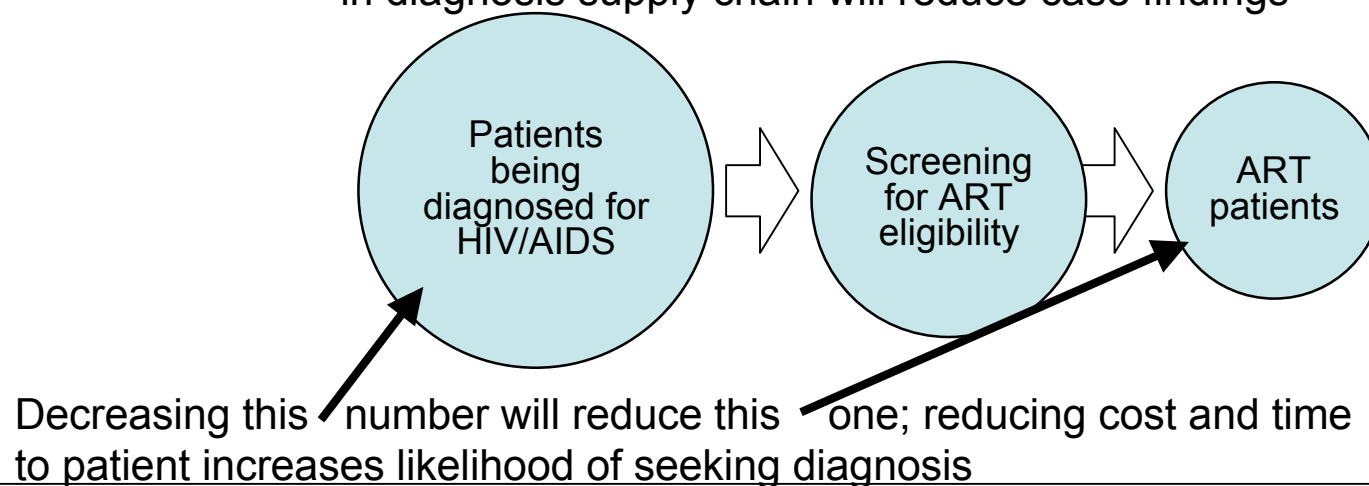
Indirect links between success of the ART program and the supply chain

Program Component

Correlation with supply chain

I. Case findings & referrals

As HIV diagnosis is basis for case findings, interruption in diagnosis supply chain will reduce case findings



II. Clinician and laboratory training

Didactic training will quickly lose effect if stock-outs prevent trainee from gaining sufficient in-service experience.

III. Adherence

Variable supplies and diagnostic services do not model good adherence behavior for patients

Management of the supply chain requires coordinated efforts by multiple parties

National Level

- Produce national total lab budgets using both projection and consumption data
- Enhance coordination by consolidating funding from multiple sources under one national budget, even if the consolidation is virtual
- Strengthen forecasting, budgeting and accounting skills
- Strengthen communications between medical stores and local labs

Medical Stores

- Implement improved systems for stock management and monitoring consumption

Local Labs

- Implement simple consumption tracking, stock management and forecasting
- Improve communications with Medical Stores and National Lab management

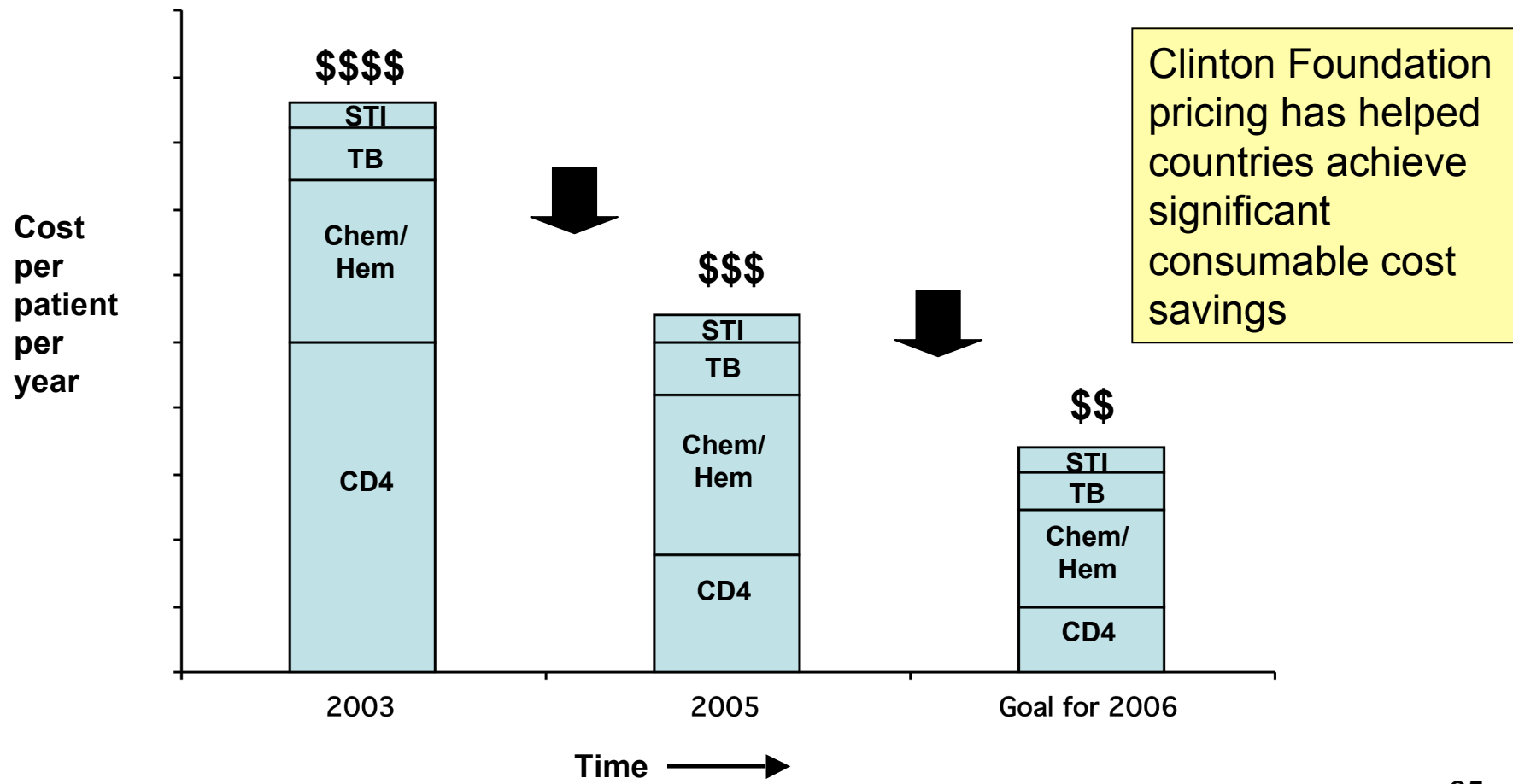
Mapping out roles and responsibilities will help identify system bottlenecks and problem areas

Roles & Responsibilities	Owner	Frequency	Time Required
Planning			
<ul style="list-style-type: none"> <input type="checkbox"/> Establish roles and responsibilities of each participating institution / individual in HIV/AIDS commodity management <input type="checkbox"/> Develop and revise treatment guidelines for: <ul style="list-style-type: none"> <input type="checkbox"/> Adult ARV Treatment <input type="checkbox"/> Pediatric ARV Treatment <input type="checkbox"/> VCT <input type="checkbox"/> <u>pMTCT</u> <input type="checkbox"/> PEP <input type="checkbox"/> Laboratory Tests <input type="checkbox"/> Plan and manage commodity cycle <input type="checkbox"/> Develop and implement SOPs for all processes within commodity management (e.g., site-level pharmacist training on stock-management) <input type="checkbox"/> Develop protocols for dealing with special situation (over stocks, stock-outs, de-listings, changes in protocols) <input type="checkbox"/> Decide on quality assurance program (in-country, fast-tracking process) <input type="checkbox"/> Ensure necessary drugs are registered for 		<p>Annually</p> <p>Annually</p> <p>Annually</p> <p>Annually</p> <p>Annually</p> <p>Annually</p> <p>Annually</p> <p>Annually</p> <p>As necessary</p>	

Consolidated procurement assists access to volume-based discounts

Laboratory consumable costs drive total lab costs and should be contained

Illustrative



Lab budgets need to include more than just reagents and must be carefully planned to avoid shortfalls

Example: Cost Elements for CD4

Illustrative

Instrument & Other Equip.

+

Reagents & Consumables

+

Service

+

Lab Techs

+

Lab Overhead

+

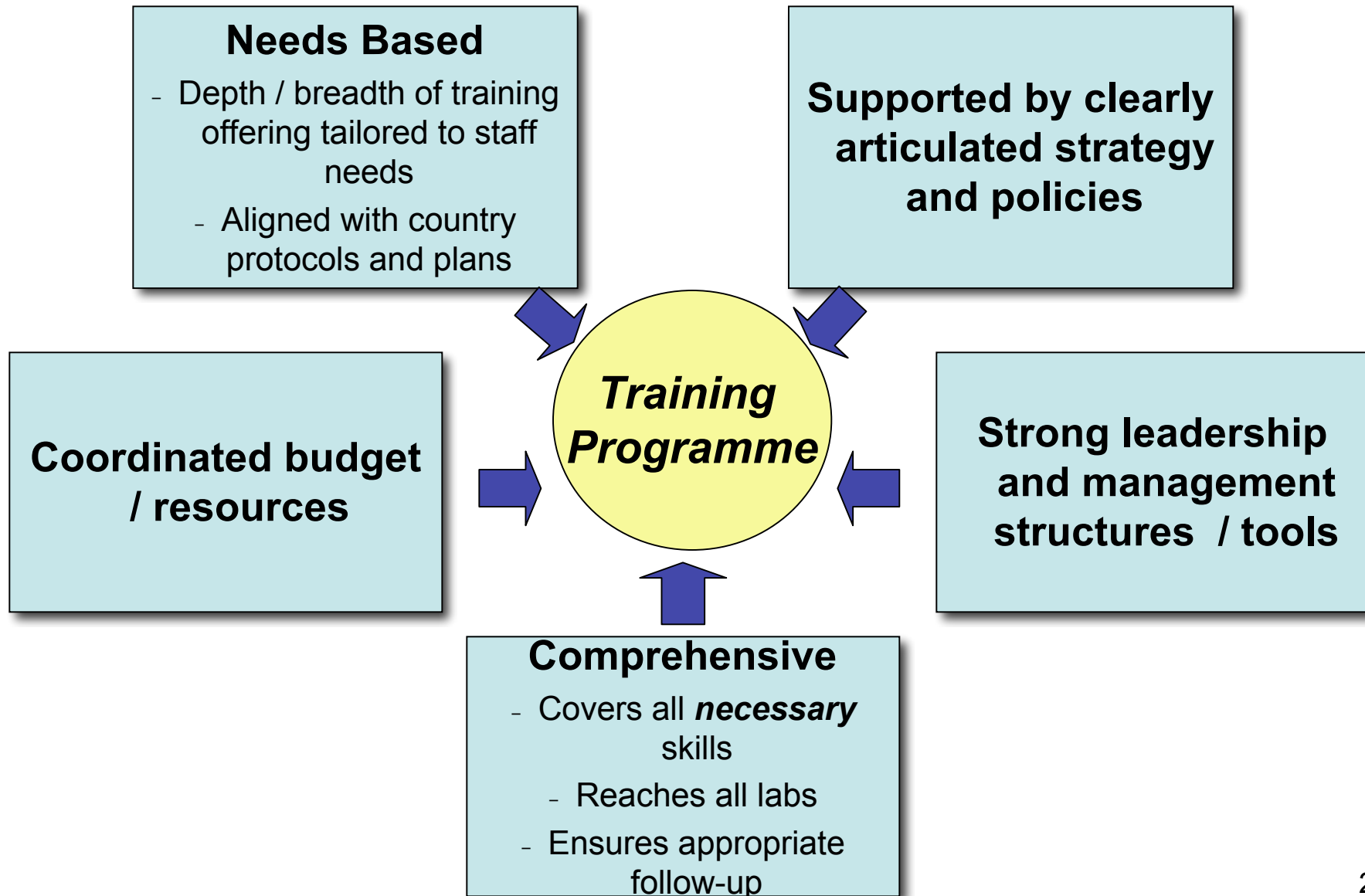
Sample Transport

- Each instrument purchased requires additional capital outlay (US\$30-US\$75k/instrument)
- Price per test multiplied over large number of tests
- Each new instrument requires new service contract (annual cost US\$3k-US\$10k)
- 2-4 lab techs required/ machine (depending on # of tests, staff efficiency & machine type)
- Administrative and other overhead costs are added each time a new lab is utilized
- Transport costs increase with an increasing number of transport routes

Total Cost

Training

Elements of an effective training program



Despite significant resources and effort, gaps exist in the roll-out of current training programs

Coordination & Planning

- Overlap and duplication in content and among training audiences
- Training is often driven by funding availability rather than a clear assessment of need
- Individual training sessions are conducted without consideration given to critical data (e.g., testing demand by site, number of staff by site, etc.)

Training Content

- Existing curricula are often missing key subject areas (e.g., laboratory management and clinic relations)
- Content sometimes is not tailored to specific audience (e.g., all lab techs don't need to have full theoretical background)

Training Models

- Didactic training sessions on laboratory technical topics are often dense and difficult to absorb, and alternative training methods (e.g., case studies, discussion) are often not used
- Limited follow-up to didactic training to ensure that material is adequately absorbed

Training programs need to address multiple areas

Test-specific technical training

- Theory behind each test
- Practical information to run the test
- E.g., HIV diagnostics, CD4, chemistry/hematology and TB testing

Lab management / Good Lab Practice

- Practical information required to manage labs:
 - daily workflow
 - human resource management
 - quality management
 - data management
 - supply management
 - safety

Lab / clinic relations

- Lab technicians take on role of training clinics in lab procedures:
 - Sample packing and transport
 - Policies related to transfer of blood and data
 - Safety
- Training on communication mechanisms required to manage relationships with clinics

Needs assessments provide key data for the design of training programs

Data Collected

Illustrative

Implications

Lab Name: LAB A
Level: District Lab

Staffing	Number
Lab assistant/attendant	2
Technician	2
Senior Technician	0
Technologist	1
Supervisor/Manager	0
Administrative	0
TOTAL	5

Pre-Service Training
Vendor Training
In-Service Workshop
Learned on Job

			Pre-Service Training	Vendor Training	In-Service Workshop	Learned on Job
HIV Rapid Test	Yes	4	1	0	2	2
HIV Diagnosis ELISA	No	0	1	0	1	0
Infant Diagnosis	No	0	0	0	0	0
CD4	Yes	3	0	2	0	1
Full Blood Count	Yes	3	3	0	0	0
White Blood Count	Yes	3	3	0	0	0
Hemoglobin	Yes	3	3	0	0	0
Chemistry Panel	Yes	3	3	3	0	0
TB Diagnosis	Yes	3	3	0	0	0
TB Culture	No	0	3	0	0	0

HIV Diagnosis

- 2 staff should attend an in-service workshop.
- Mentor should observe and review all staff skills when on-site.

Infant Diagnosis

- Mentor should observe and review DBS preparation.

CD4: 3 staff perform CD4 testing with limited training.

- Vendor should conduct training for 1 staff who did not receive as well as refresher course once per year
- 3 staff should attend expert training course.

31

Lack of follow-up is the main reason training efforts fail to have lasting impact

Several mechanisms for follow-up can be built into training programs



- Link training to the quality management program and ongoing performance assessments. Accreditation with achievable goals should be a target.
- Incorporate training on national lab policies and guidelines.
- Enable existing lab supervisors to conduct follow-up on uptake of new skills and improved practices.
- Create a cadre of mentors to provide intensive on-site follow-up and consolidation of skills development. Mentoring programs have been successful for other healthcare workers.

Which strategic areas need the greatest focus today?

Leadership and planning

Laboratory network development

Supply chain management

Training

More appropriate diagnostics

Thank you

Acknowledgements: Maurine Murtagh

Emily Wu

Brad Barkin

Kate Condliffe