
How Technologies are Used on the Ground

CD4 Cell Count and Viral Load

Trevor Peter
Botswana-Harvard AIDS Institute
For Research and Education

Forum for Collaborative HIV Research Satellite Symposium
XV AIDS Conference, Bangkok July 11, 2004

Introduction

Laboratory systems for CD4 count and viral load

- Practical issues relating to use of monitoring technologies
 - Clinical decisions on monitoring algorithm
 - » Which tests?
 - » Frequency of testing?
 - » In many countries CD4 count is considered essential and viral load optional
- Evaluate testing platforms
- Laboratory hierarchy
 - » Centralized vs decentralized testing
 - » Vertical and horizontal integration
- Public and private laboratories

Laboratory Strategy

Creating a Coordinated Testing Strategy

- Laboratory framework validates use of testing technologies, laboratories, and quality of the testing
- Create a coordinated and sustainable laboratory strategy with many potential implementing partners
- Monitoring guidelines to be translated into technical capacity with adequate financial and HR support
- Guidelines and policies needed on use and interpretation of test results
 - Improve clinical care
 - Manage cost and capacity

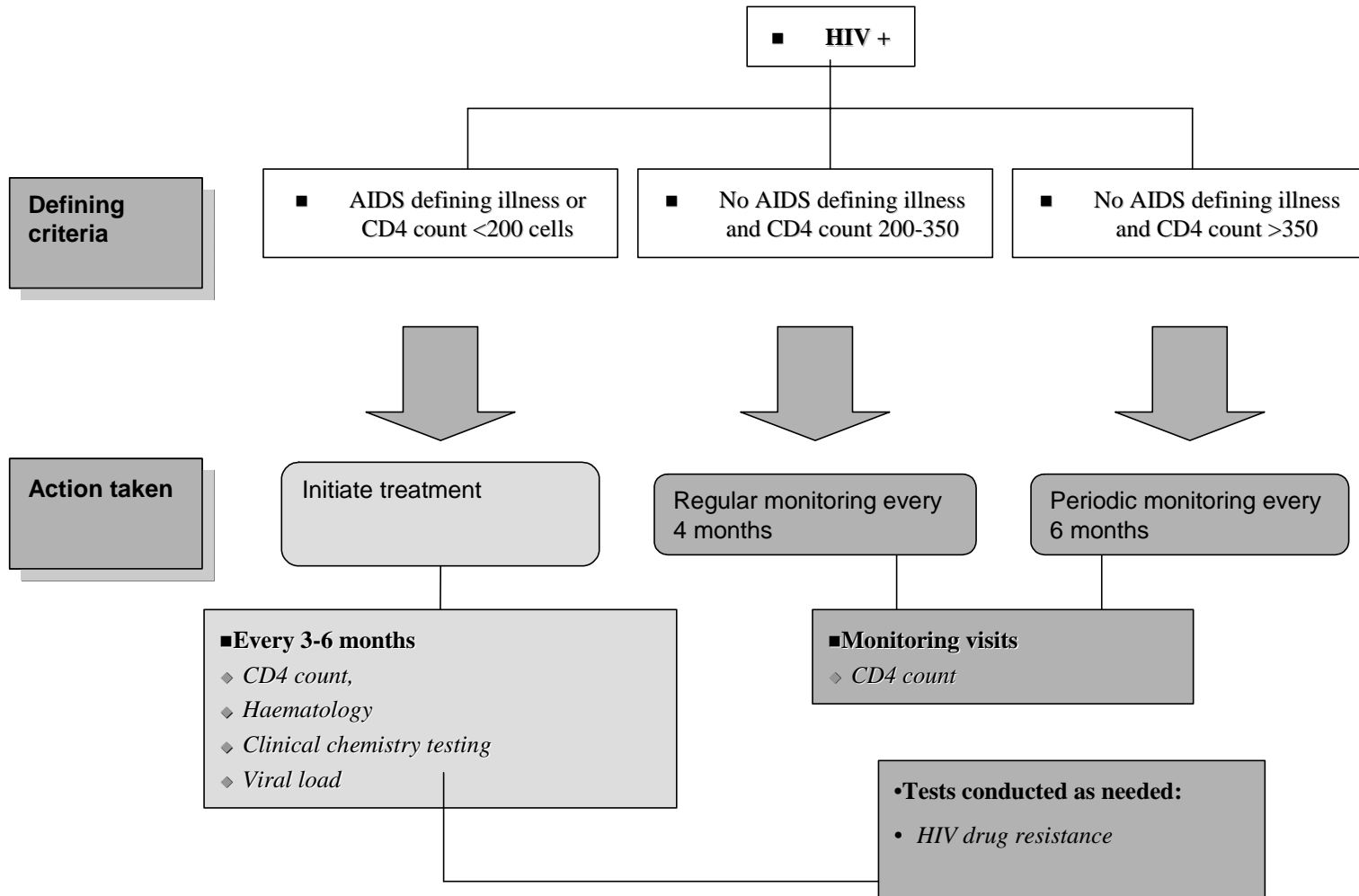
Laboratory Focus

- Procurement and distribution
- Data management
- Monitoring and Evaluation
- Management systems
- Training
- Quality Management
- Review of new technologies

Laboratory Tests for HIV Treatment

Laboratory

Example of Laboratory Testing Steps for ARV Treatment



CD4 Cell Counts

CD4 cell counts

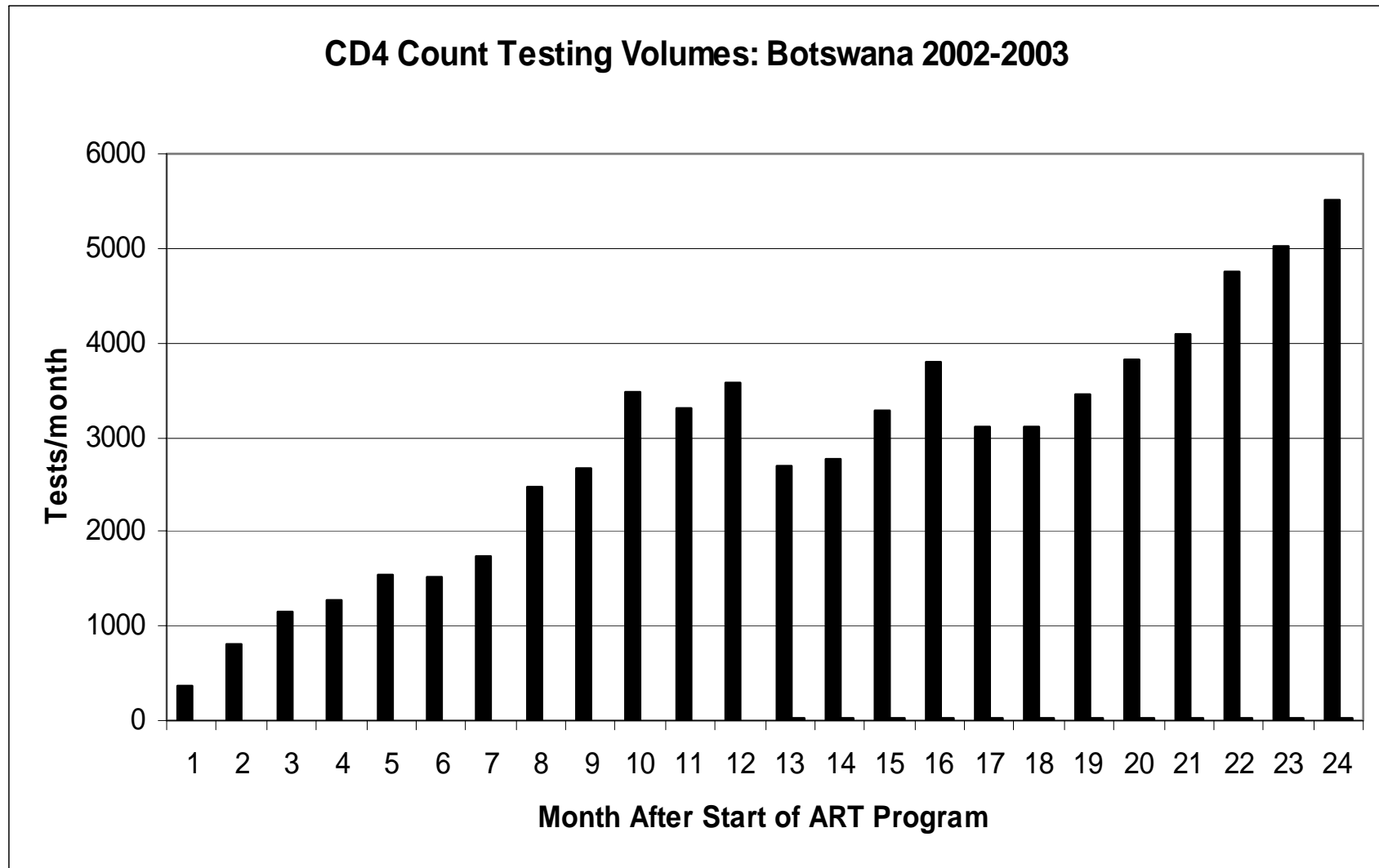
- Access to CD4 counts and testing capacity is available in most countries, though usually at a low level and mainly in urban centers
 - Reagent costs were high
 - Few labs have instruments
- Projected high volume
 - Staging test and eligibility criterion for therapy
 - Monitoring indicator for therapy efficacy and disease progression
 - Periodically track changes in cell count over time in patients
 - on therapy (2-4 times/year) depending on resources available or period after therapy initiation
 - off therapy (1-3 times/year) depending on initial CD4 count

-
- Sample stability limitations
 - Sample to be tested 1-4 days after collection
 - Robust but cannot be stored
 - Clinical requirements do not dictate testing in same time and space as clinic
 - Consolidated testing is possible at several levels
 - Higher throughput
 - Lower cost
 - Simpler management
 - Recently reduced prices (Clinton Foundation HIV/AIDS Initiative)
 - \$16-20/test to \$3-5/test including instrumentation
 - Further cost reductions likely
-

CD4 Cell Counts

- Variety of CD4 count systems exist:
 - Centralized: high volume flow cytometers (e.g. South Africa, Botswana)
 - Decentralized: low volume flow cytometers (e.g. Kenya)
 - Combination centralized and decentralized (e.g. Tanzania)
- Simpler technologies may be needed for most remote areas
- Systems have to be scalable and sustainable
 - Testing volumes may be initially slow but the scale up very quickly once a critical level of clinical space and HR capacity has been reached

Public ART CD4 Count Scale-up



CD4 Count Capacity

	Total CD4 Count Tests			
Patients on Therapy	Tests/Year	Tests/Month	Tests/Day	Platform Capacity
200	1,600	80	7	Low/consolidate
500	4,000	200	17	Low/consolidate
1000	8,000	400	33	Low/consolidate
2000	16,000	800	67	Low/consolidate
5000	40,000	2000	167	High
10,000	80,000	4000	333	High

Viral Load

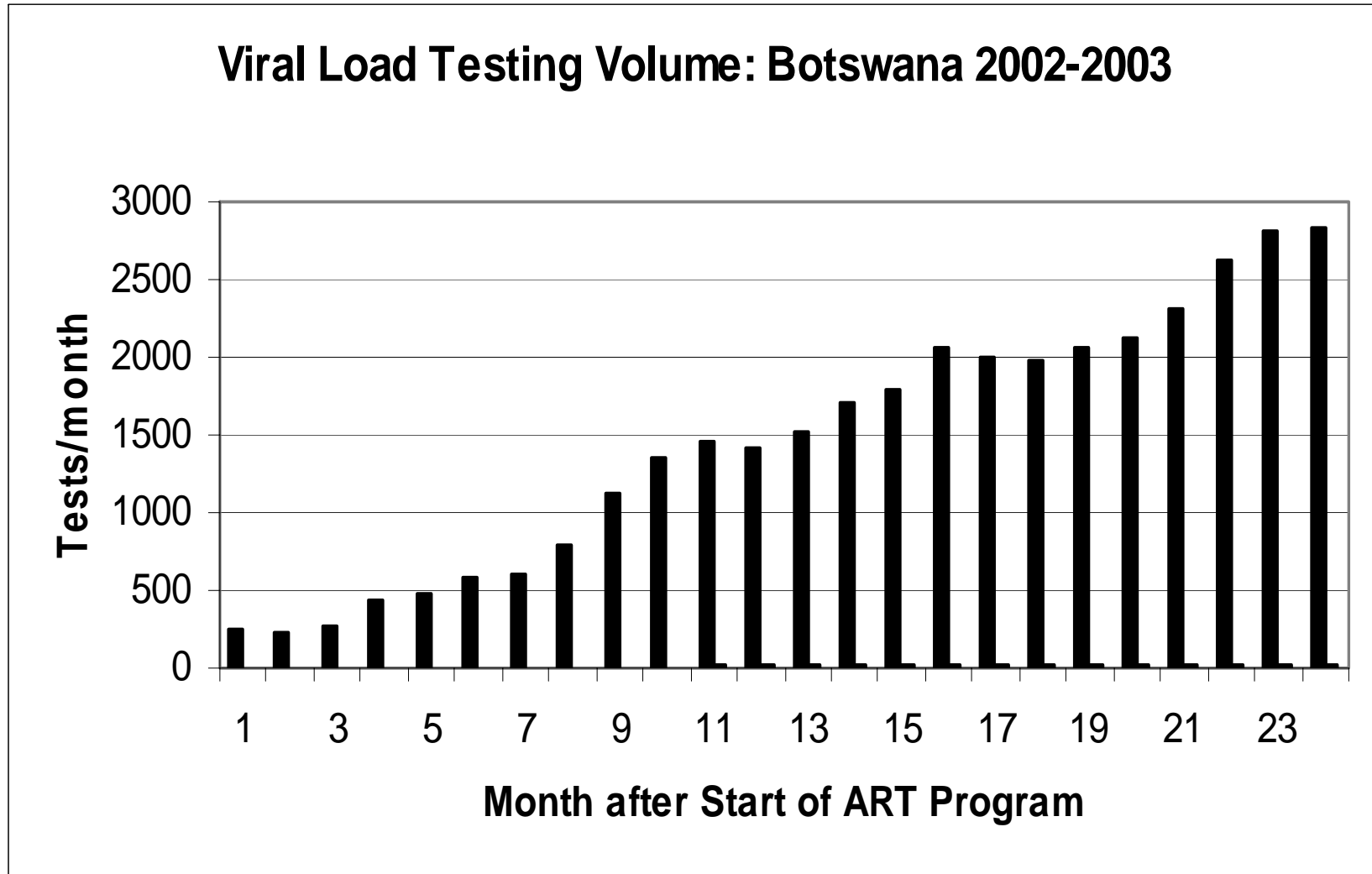
Viral Load

- Not widely available due to higher cost and technical sophistication
 - Available in some countries (e.g. South Africa, Botswana)
 - Uncertainly on availability and utility of viral load where drug choices are limited
 - Early detection of failure
 - Promote adherence
- Where available, centralized testing systems mainly in operation
- Sample stability limited for certain platforms
 - Require processing in lab within hours of collection
 - PPT tubes and dried blood spot options allow stabilization of specimens and extension of transit time
- Manual, semi-automated and automated platforms in operation
- Cost
- Sample volume

Viral Load

- Where viral load will be used, a combination of centralized and decentralized testing may be most effective
- Data needed on long-term clinical utility of viral load
- Reduced prices, simpler technology
 - monitoring guidelines may consider viral load on the basis of clinical utility as well as cost
 - Recently reduced prices (Clinton Foundation)
 - » \$60-100/test to \$14-18/test including instrumentation
 - » Further reductions likely
- Ultimately, viral load volumes will be lower than CD4 count testing

Public ART Viral Load Scale-up



Questions