Rapid Point-of-Service Testing
A Public Health Perspective

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Centers for Disease Control and Prevention

17 September 2003
Hershey Medical Center
Keystone POCC – AACC Meeting

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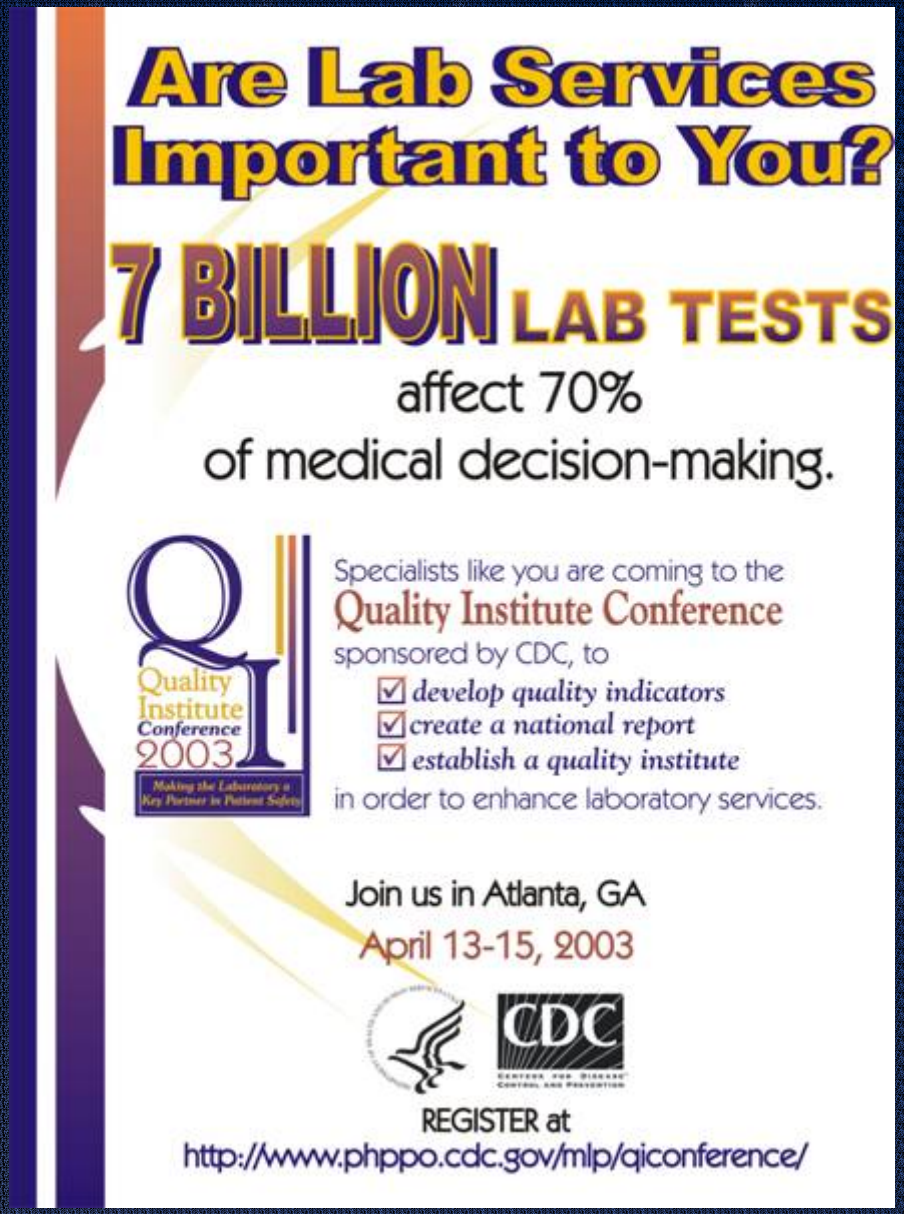
Mobile Cholesterol Testing in Sydney, Australia


Are Lab Services Important to You?
7 BILLION LAB TESTS
affect 70%
of medical decision-making.
Quality Institute Conference 2003
Making the Laboratory a Key Partner in Patient Safety
Specialists like you are coming to the
Quality Institute Conference
sponsored by CDC, to
☑ develop quality indicators
☑ create a national report
☑ establish a quality institute
in order to enhance laboratory services.
Join us in Atlanta, GA
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Managing Your POCT Program for Success – 2003

AUTHOR/EDITOR : Paula Santrach, MD (moderator), Charles Root, PhD; Christopher Fetters; Robert Christenson, PhD; Fred Apple, PhD; Larry Kricka, PhD, D Phil; Kent Lewandrowski, MD

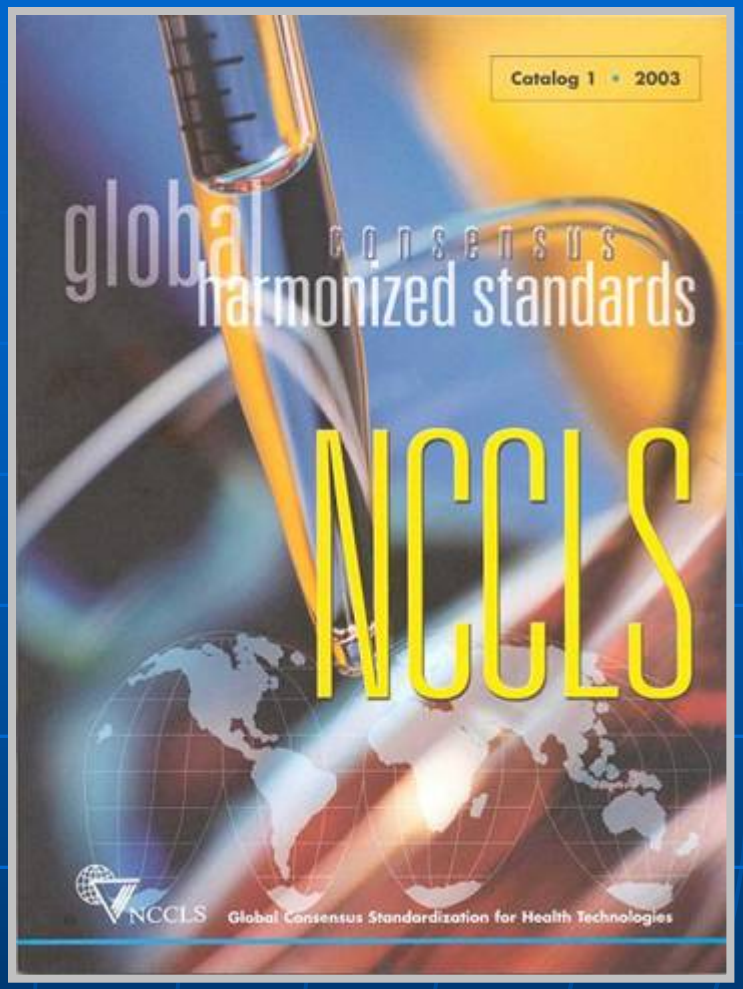
Top 10 Tips for Managing your Point-of-Care Testing Program-2003

September 17, 2003 2:00 p.m.-3:30 p.m. Eastern time

THE PRESENTERS

James Nichols, PhD
Medical Director, Clinical Chemistry
Baystate Health System, Springfield, MA

Mark Barglowski, MT(ASCP), MBA, Director of Laboratory and Respiratory Care Services
Providence St. Joseph Medical Center, Burbank, CA


Catalog 1 • 2003
global consensus
harmonized standards
NCCLS
NCCLS
Global Consensus Standardization for Health Technologies

NCCLS

NCCLS Area Committee on Point-of-Care Testing

- Committee formation in progress
- Chairholder-designate: Jeffrey A. DuBois, Ph.D., NOVA Biomedical Corporation
- Balanced area committee will serve as the NCCLS consensus body
- Significant number of attendees at recent POCT Planning Session

Major Themes

- Point-of-service (POS) testing is an integral part of health care services.
- Quality and access are the goals
- POS testing can provide much needed support to prevention programs (e.g., HIV/AIDS)
- Quality assurance is an essential element of POS testing, particularly infectious disease tests

CDC Waived Tests- Listed in Regulations

1. Dipstick/tablet reagent urinalysis (143)
2. Fecal occult blood (33)/gastric occult blood (1)
3. Ovulation tests (37)
4. Urine pregnancy tests (252 = 35% of all waived tests)
5. Erythrocyte sedimentation rate, nonautomated (4)
6. Hemoglobin (copper sulfate) (1)
7. Blood glucose devices (FDA-cleared for home use) (130)
8. Spun microhematocrit (5)
9. Hemoglobin single analyte instruments (2)

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Tests Categorized and Waived by CDC

From February 1992 until January 2000

- 25,708 test systems categorized
  (to date the total is 32, 032)

- 733 test systems (**includes 27 analytes**) approved for waiver *(to date the total is 1, 403 test systems)*
  - **612 specified by regulation (9 analytes/tests)**
  - **109 proposed rule 9/95**
  - **12 approved for home use**

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CDC Waived Tests Approved for Home Use

1. Bladder tumor antigen (1)
2. Catalase, urine (1)
3. Cholesterol (5)
4. Fructosamine (2)
5. HDL cholesterol (1)
6. Ketone, blood (1)
7. Prothrombin time (1)

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CDC Waived Tests
9/95 Proposed Rule

1. Amines (1)
2. Cholesterol (4)
3. Creatinine, urine (1)
4. Ethanol (2)
5. Fructosamine (1)
6. Glucose (2)
7. Glycosolated hemoglobin (3)
8. hCG, urine (1)
9. HDL cholesterol (1)
10. H. pylori (4)
11. H. pylori antibodies (13)
12. Hematocrit (2)
13. Inf mononucleosis (13)
14. Microalbumin, urine (3)
15. Nicotine (1)
16. Prothrombin time (4)
17. Strep A, rapid (14)
18. Triglyceride (1)
19. Vaginal pH (1)

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New Measurands Waived Since 2000

Examples-

- Amphetamines
- Cannabinoids
- Cocaine
- Follicle-stimulating hormone
- Opiates
- Phencyclidine
- Respiratory syncytial virus
- Human immunodeficiency virus type I antibody

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Rapid Tests for Infectious Diseases

- Chlamydia trachomatis
- Group A streptococcus*
- Helicobacter pylori*
- Herpes simplex
- Influenza A/B*
- HIV*
- Lyme disease (Borrelia burgdorferi)*
- Legionella pneumophila
- Streptococcus pneumoniae
- Others

*indicates CLIA waived test(s) available

Characteristics of Rapid Tests for Infectious Diseases

- Presumptive results with confirmatory testing required for some rapid tests
- Pre- and post-test analytic testing steps, e.g. safety, reporting
- Prevalence of disease has a significant effect on predictive value of test results

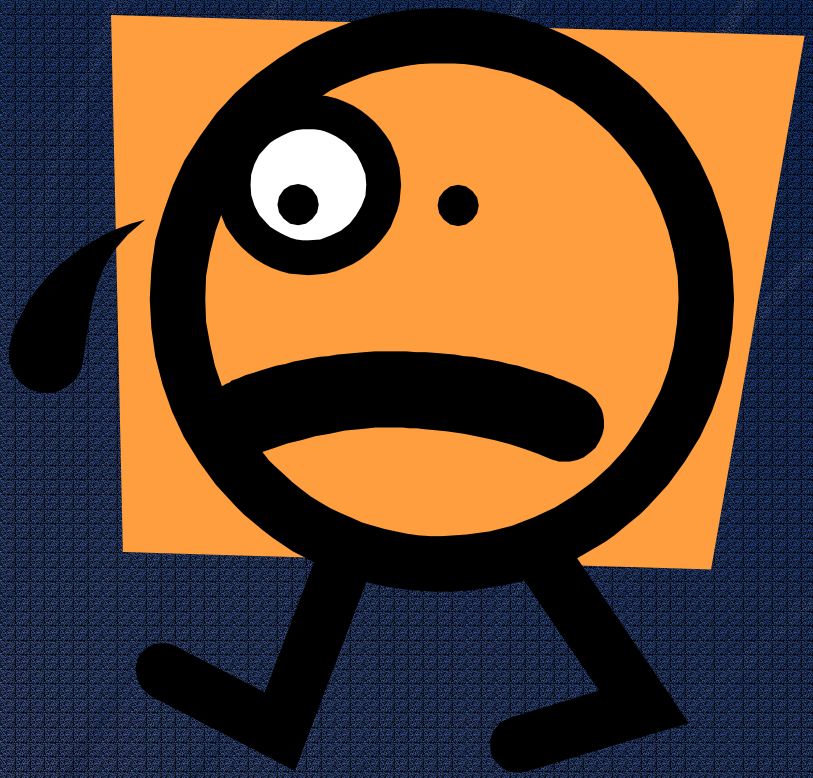
Examples of Diverse Facilities Conducting Waived Testing

- Adult day care centers
- Ambulances
- Blood banks
- Community, rural clinics
- Correctional facilities
- Environmental labs
- Fire departments
- Government – IRS
- Health fairs
- Home health agencies
- HMO's
- Industrial labs
- Insurance companies
- Medical foundations
- Mobile units
- Oral pathology labs
- Pharmacies
- Physician office labs
- Planned Parenthood
- Rehabilitation centers
- Research labs
- Schools/student health

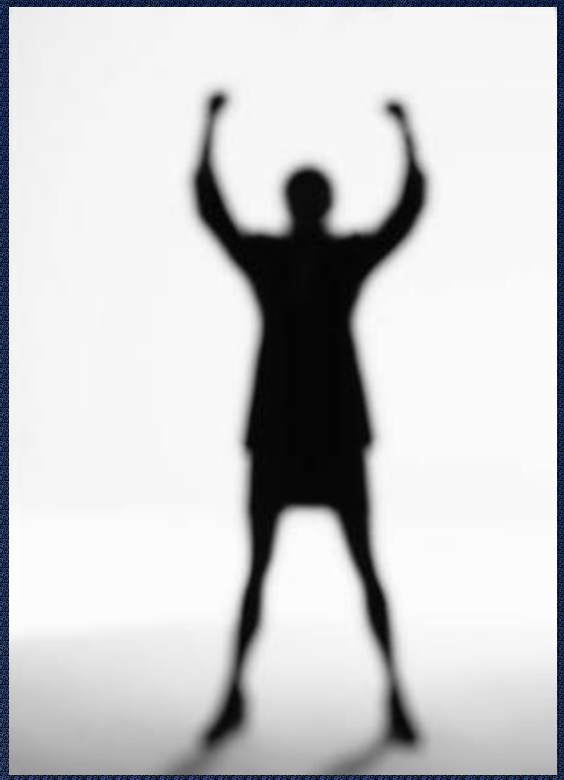
Ensuring Access to Testing Under CLIA

- Limited Public Health Testing Certificate – not-for-profit federal, state, or local government laboratories may conduct a menu of no more than 15 waived and/or moderate complexity tests at multiple sites per certificate (multiple limited public health testing certificates allowable)
- Mobile Testing Provision – a mobile van may conduct waived, moderate, or high complexity testing at an unlimited number of sites
- These provisions may be used in combination

ACCESS …or… QUALITY



ACCESS ---AND--- QUALITY



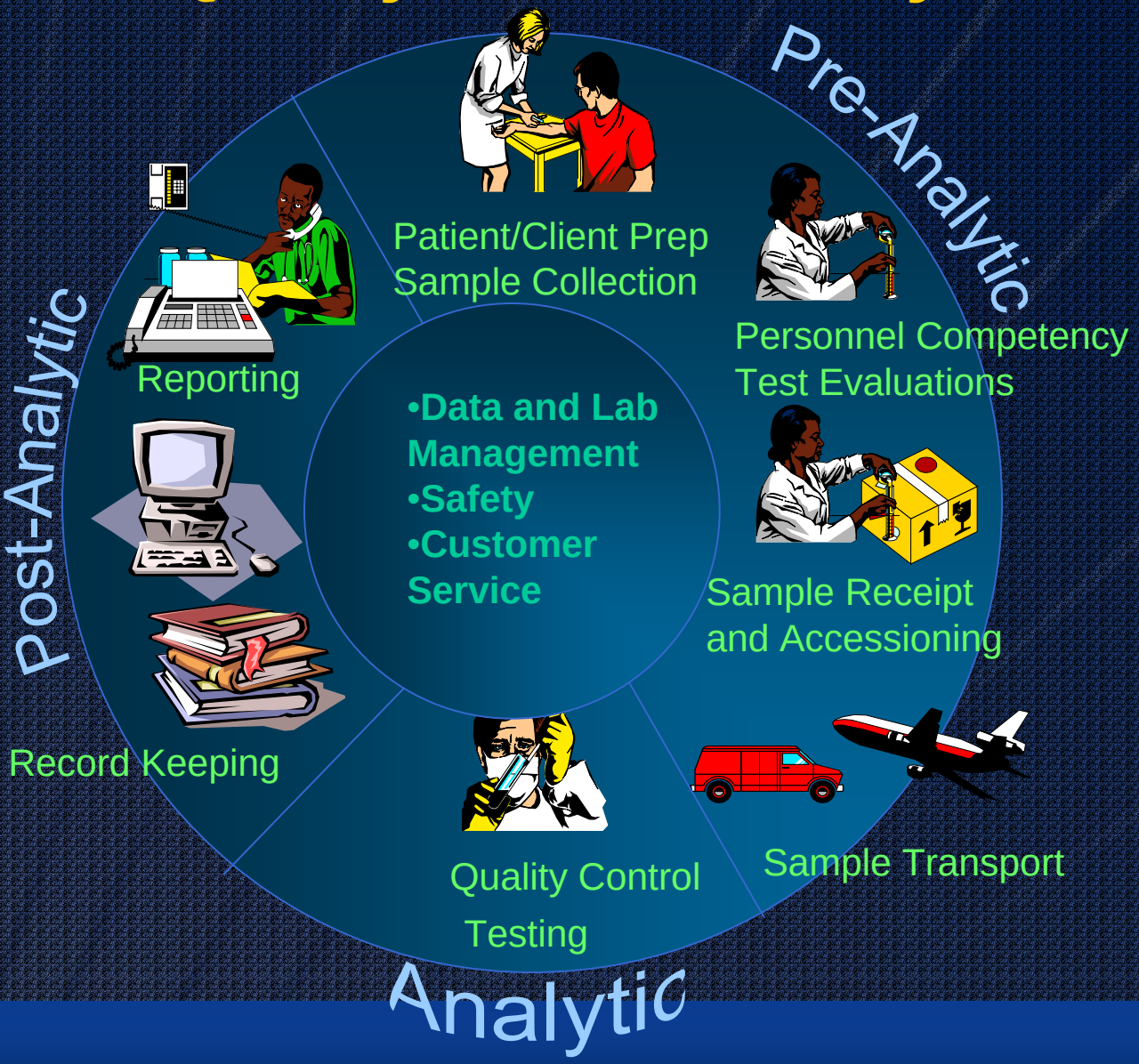
What Are the Consequences of Unreliable Testing?

- Medical errors
- Lack of confidence in testing by-
  - Doctors
  - Patients
  - Health program directors
  - Payers of services
- Waste of financial and human resources
- Legal and political consequences

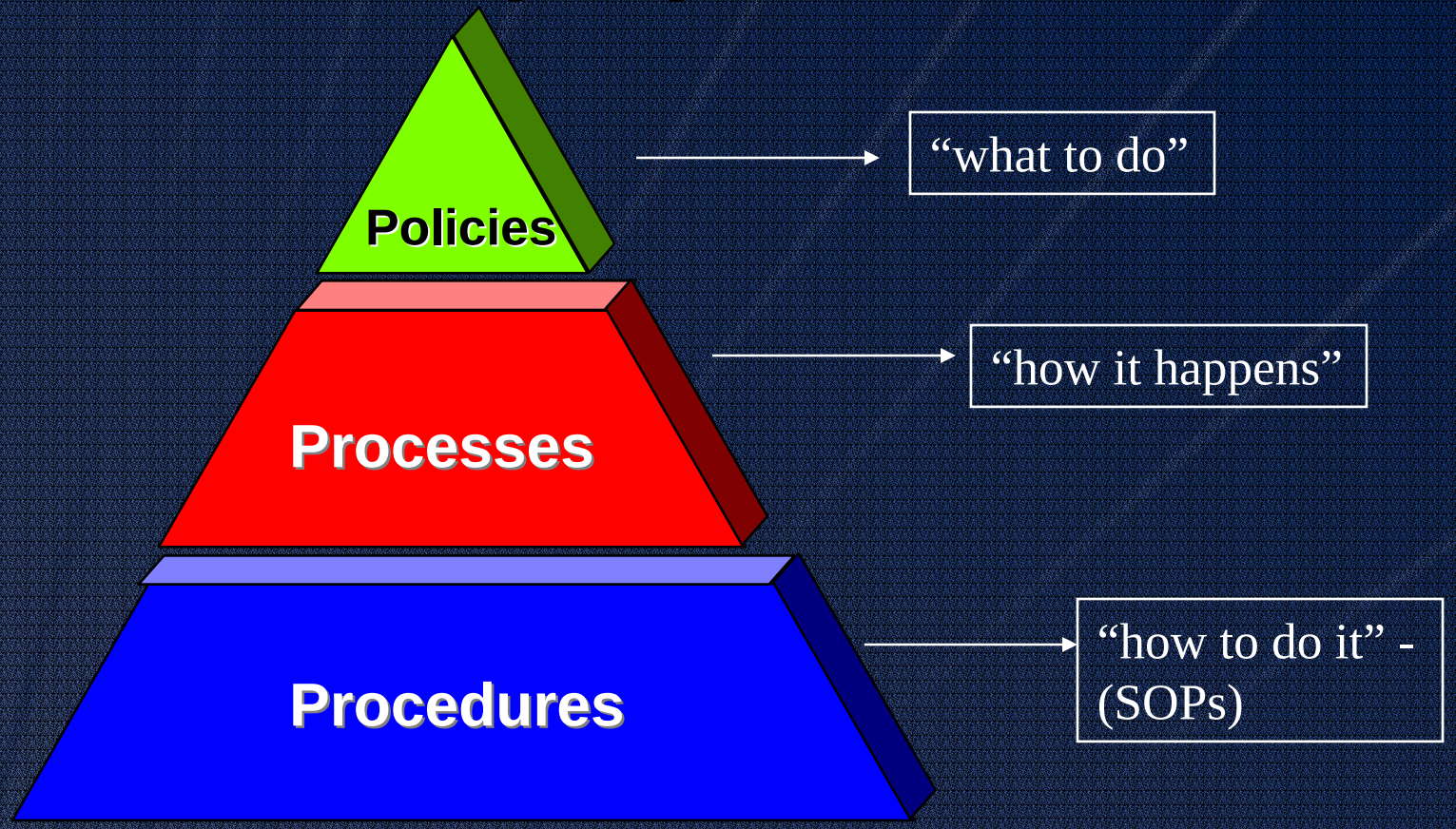
What are the Consequences of No Access to Testing?

- Delay in treatment
- Poor avoidable health outcomes
- Decrease in opportunity for prevention
- Disproportionate access to health services

The Quality Assurance Cycle



Quality System



CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

Laboratory Support for the GLOBAL AIDS PROGRAM(GAP)

The Laboratory Technical Support Unit of the Global AIDS Program (GAP), National Center for HIV, TB, and STD Prevention was established to improve laboratory capabilities for surveillance, prevention, and care activities in GAP countries.

Laboratory support for GAP will come from the National Center for Infectious Diseases (NCID/DASTLR), the Public Health Practice Program Office (PHPPO/DLS), and the Association of Public Health Laboratories (APHL). Our systematic approach will necessitate consultation with the host country and partners on programmatic needs.

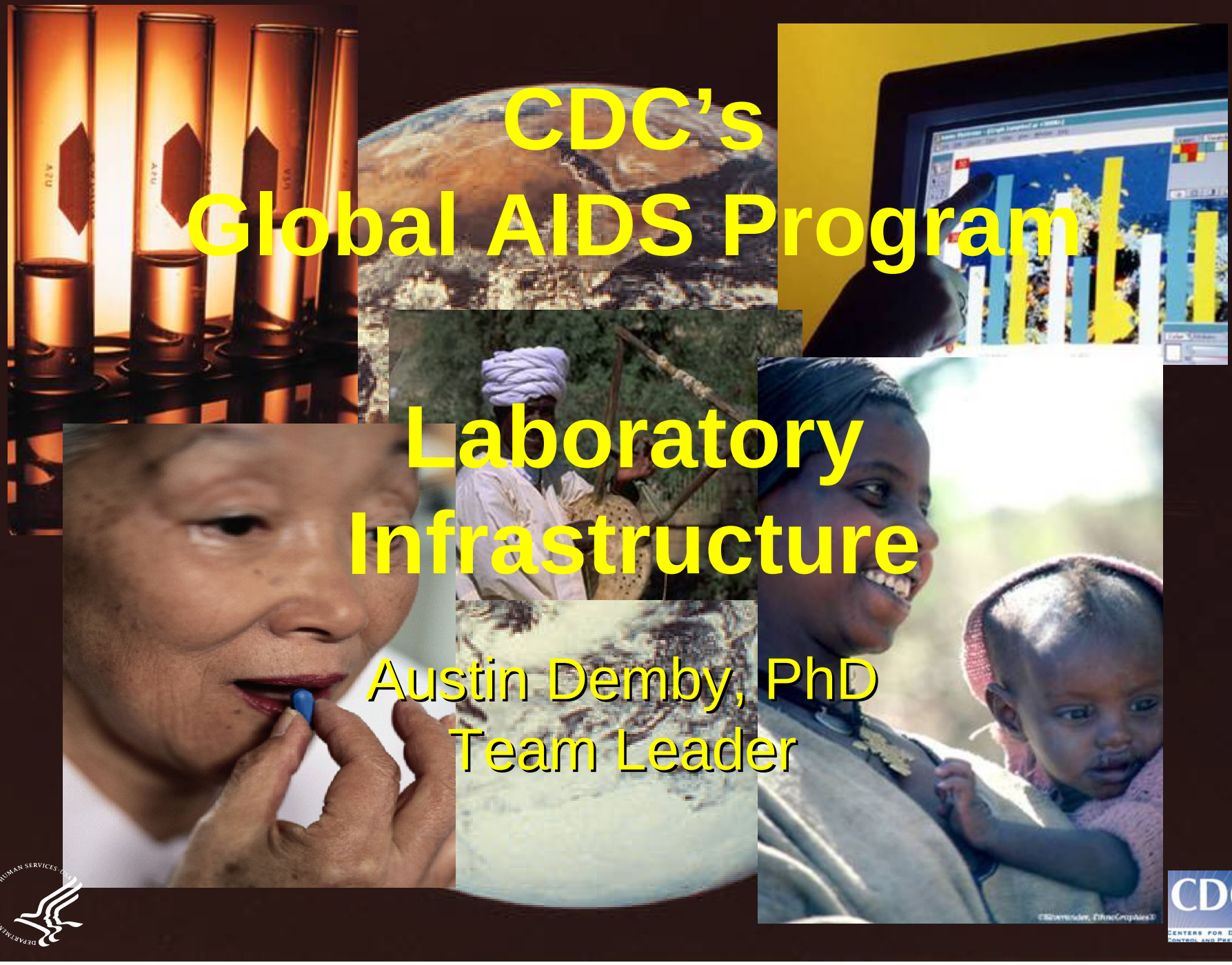
Specific activities include:

- coordinating technical and programmatic laboratory support from CDC and all partner organizations to GAP countries;
- reinforcing CDC technical capacity to respond to GAP country needs;
- consulting with partners to craft GAP laboratory policies based on best practices, and represent such policies to governmental, regional and international organizations;
- negotiating bulk procurement of reagents and supplies from which field directors may draw; and
- coordinating the assessment of new lab products or techniques and advising field directors on their utility.

GAP Contacts:

Austin Demby, Ph.D. Telephone: (404) 639-8258 Email: ADemby@cdc.gov

Peter Crippen Telephone: (404) 639-1972 Email: PCrippen@cdc.gov



CDC's Global AIDS Program

Laboratory Infrastructure

Austin Demby, PhD
Team Leader

GAP and the USG Collective Effort

- HHS (CDC, NIH, HRSA)
- State Department (USAID, Embassies)
- DOD and other USG agencies
- USG effort designed and implemented in partnership with:
  - Ministries of Health and other in-country institutions
  - CDC GAP Country Offices
  - Official NGOs working within GAP countries
  - International organizations (WHO, UN, Global Fund to Fight AIDS, TB, and Malaria, etc.)
  - Donor countries and organizations

CDC Global AIDS Program Mission

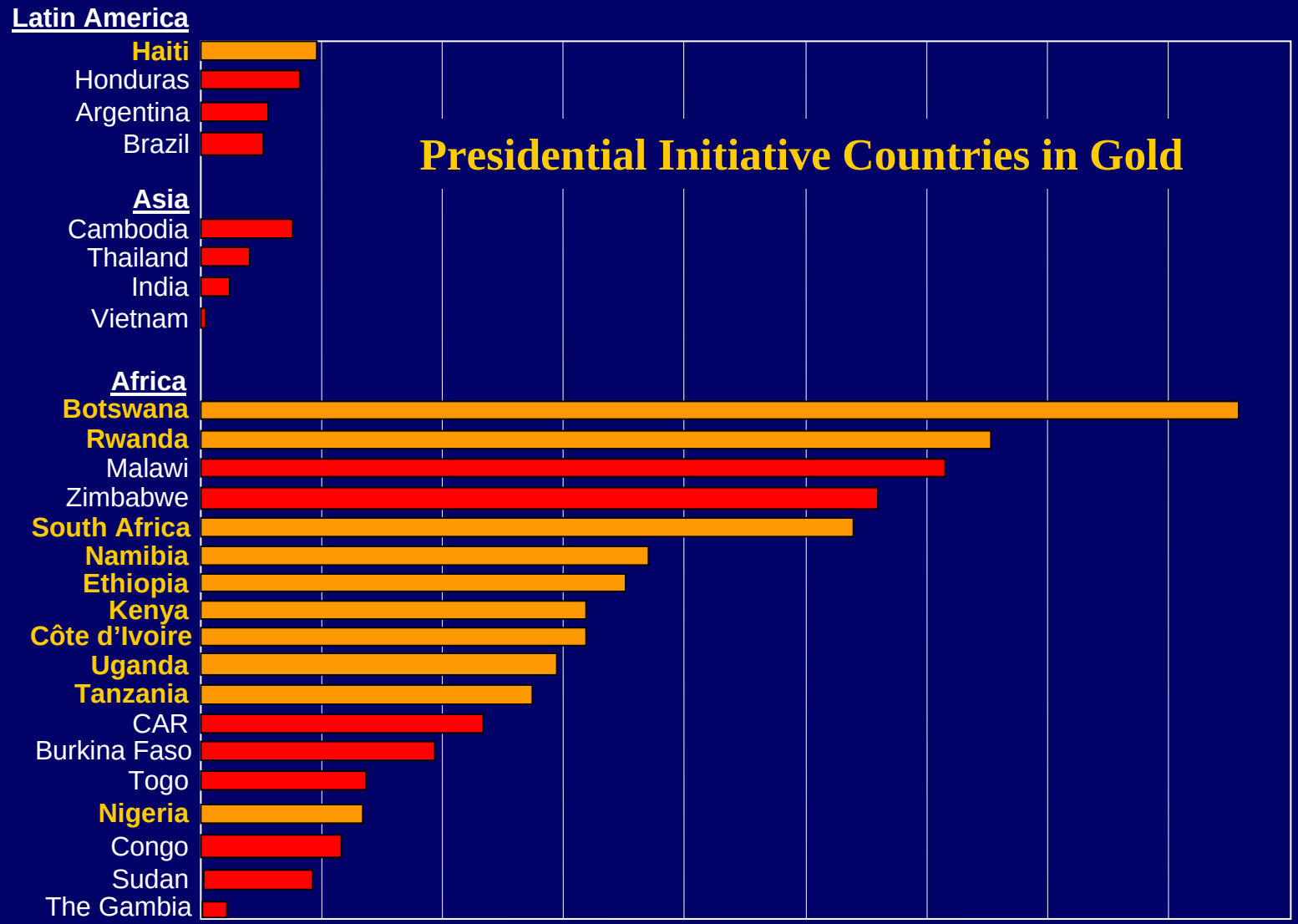
- GAP helps resource-constrained countries:
  - prevent HIV infection
  - improve treatment, care, and support for people living with HIV
  - build capacity/infrastructure to address the global HIV/AIDS pandemic
- GAP provides its assistance directly through CDC staff and through partnerships with governments, communities, and national and international entities

HIV/AIDS Burden: Year-End 2002

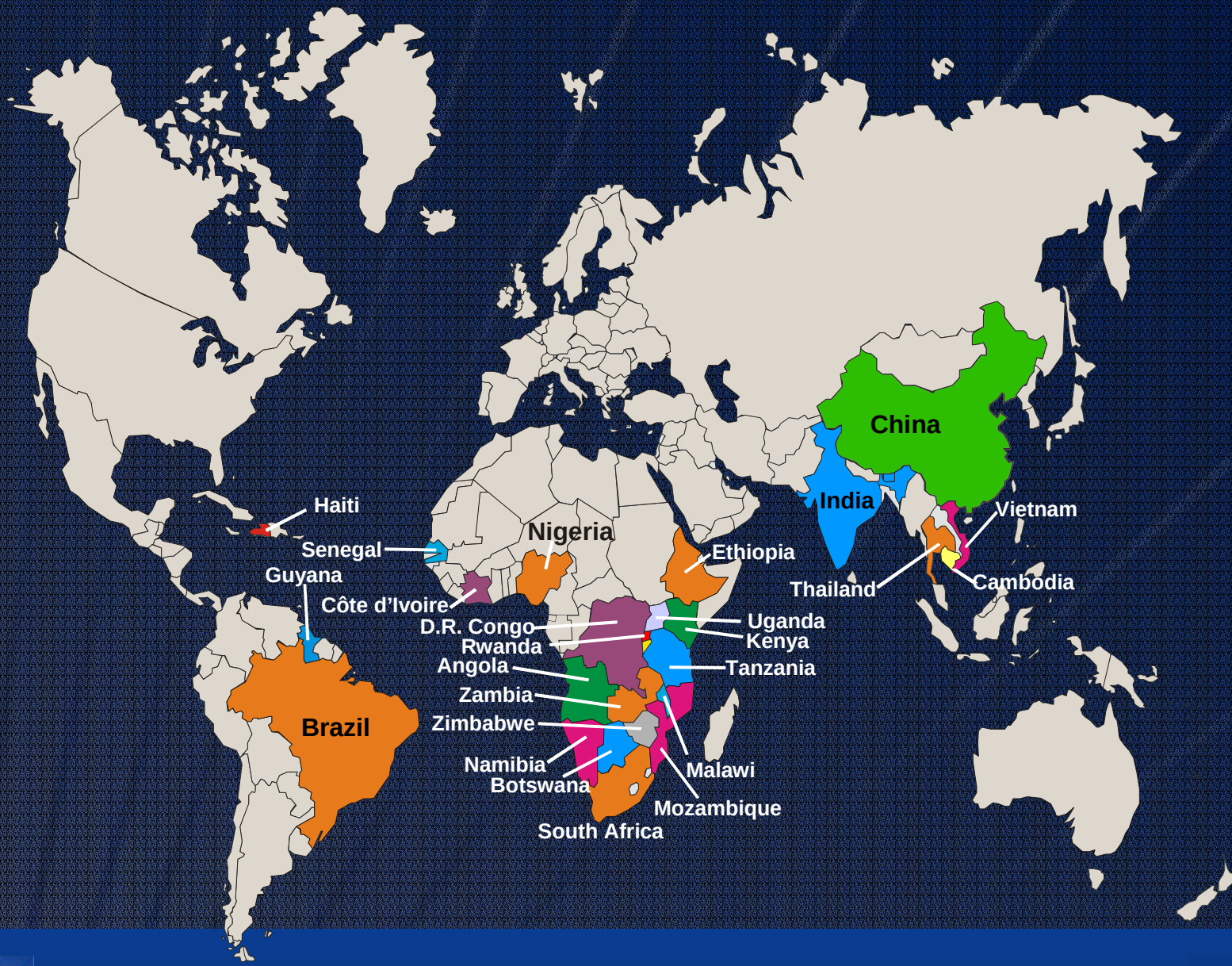
- Total estimated HIV-infected population worldwide: 42 million, 95% in the developing world
- Total HIV burden in GAP countries: 37 million
- >90% of all HIV-infected persons live in countries that have, or soon will have, a CDC Global AIDS Program presence

Source: UNAIDS, December 2002

Antenatal Seroprevalence in Selected Countries: 2000



GAP Countries 2003



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Major GAP Activities

- **HIV Prevention Programs**

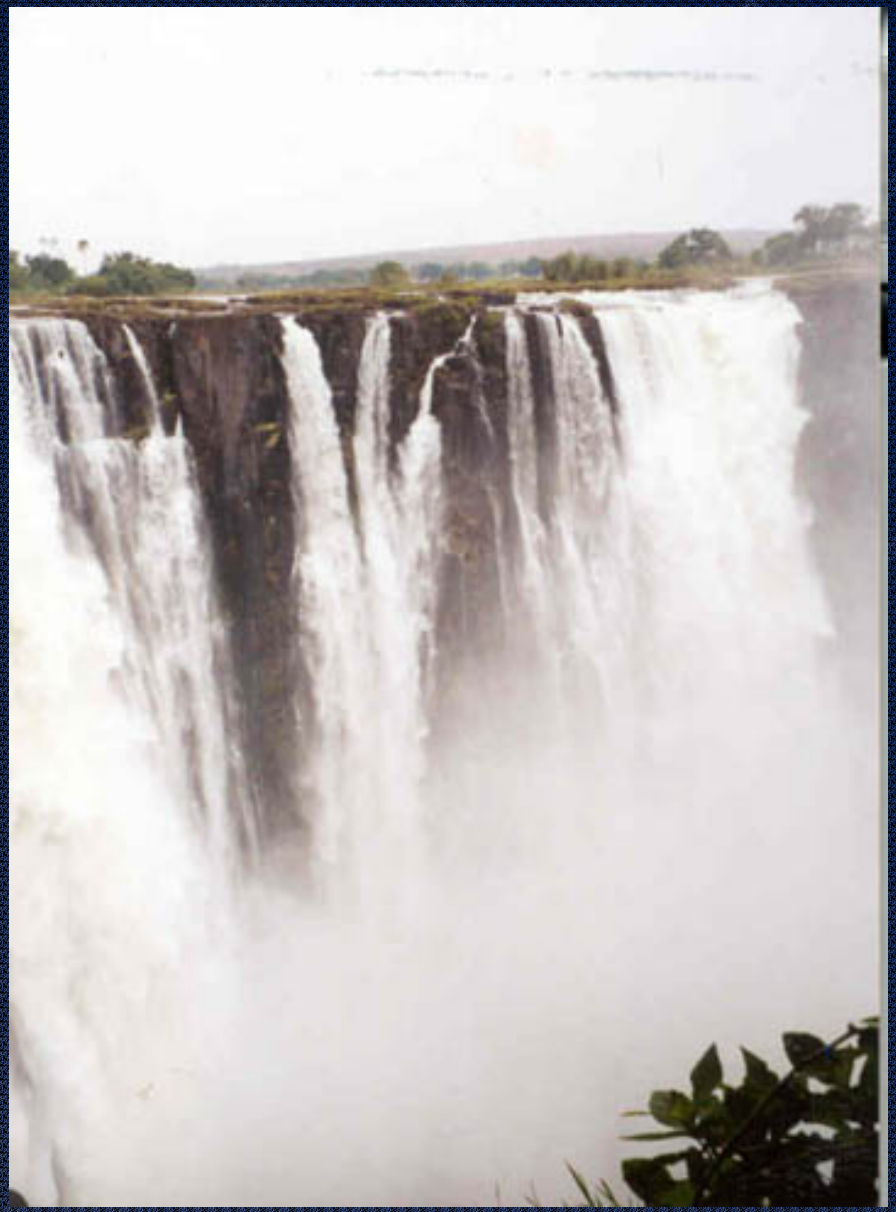
  Including behavior change (abstinence, delay, risk reduction), voluntary counseling and testing, prevent/treat other sexually transmitted infections, prevent mother-to-child transmission, blood safety

- **HIV/AIDS Treatment and Care Programs**

  Including diagnosis, prophylaxis and treating opportunistic infections, tuberculosis and HIV/AIDS, and operational research related to developing program models, standards and guidelines

- **Program Infrastructure**

  Including surveillance, operational research, informatics, training, laboratory support and monitoring and evaluation



Reality on the Ground - Lab

- Wide range of competencies
- Loss, sub-optimal distribution of trained personnel
- Need for quality standards
- Improved training needs for critical lab staff including laboratory management training
- Intermittent supply of reagents
- Congested and in some cases unsafe laboratory environment
- Fear that additional work load overwhelms weak laboratory system

Laboratory Infrastructure

- National Institute of Public Health a potential for national laboratory training and oversight
- Substantial government investment already in place
- Very capable though limited staff with vision for quality laboratory services

Laboratory Infrastructure (INSP)

- Facility currently grossly under-utilized

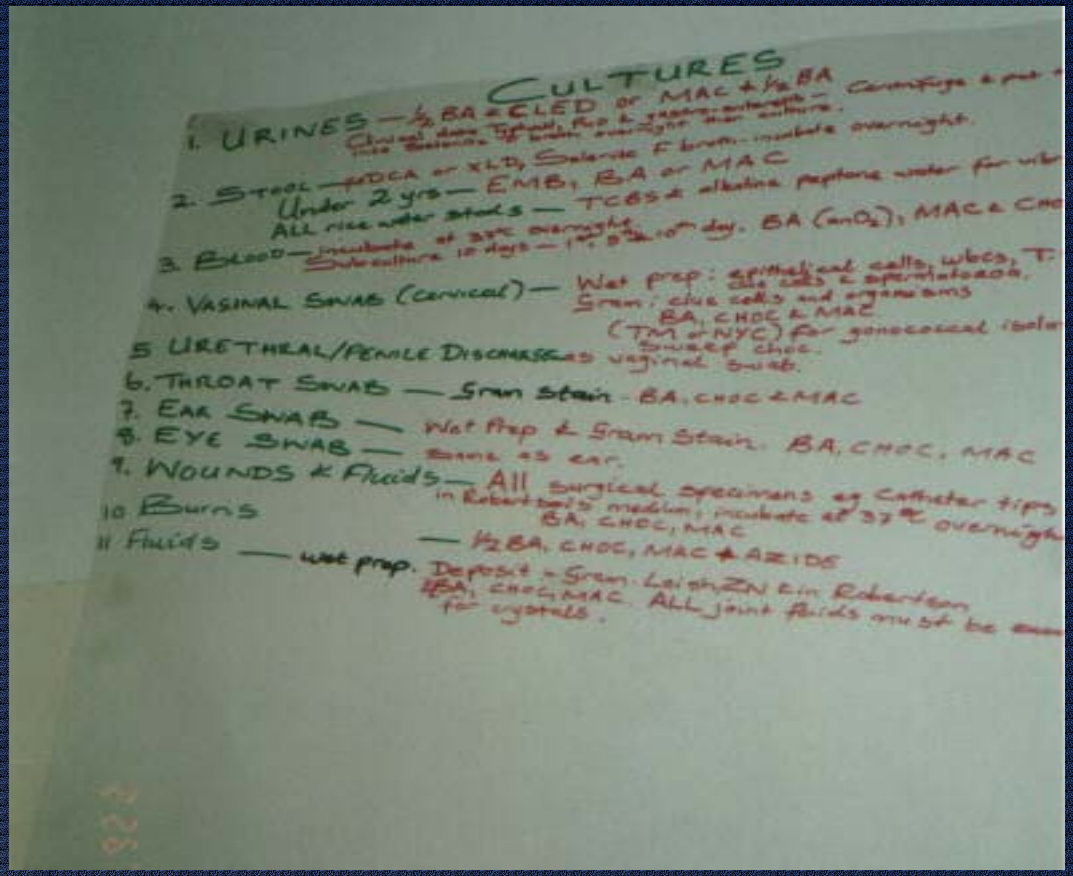
  In the process of installing:

  – 1 flow Cytometer, 1 Roche Amplicor viral load monitor, and 2 EIA systems – donated by an association of PLWA

Laboratory Technician at Remote Rural Site

Laboratory Ledgers

Procedures


CULTURES
1. URINES
2. STOOL
3. BLOOD
4. VAGINAL SWAB (cervical)
5 URETHRAL/PENILE DISCHARGE
6. THROAT SWAB — Gram Stain
7. EAR SWAB
8. EYE SWAB
9. WOUNDS & Fluids
10 Burns
11 Fluids — wet prep.

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

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Use of Rapid Tests

- **Programmatic priorities include: VCT, PMTCT , differential diagnosis, clinical assessment, rural blood services, and emergencies.**

- **Technical considerations include: need for rapid results, elimination of cold chain for both reagents and specimens, cost effectiveness in low volume labs, and simplicity of testing.**

HIV Testing in Kenya is Done on Site by a Trained Counselor, Supervised by a Laboratory Technician

- Two different, rapid, simple whole blood tests are used for every client
- Confirmed results in 15 to 20 minutes
- Tests used at present:
  - Abbott Determine
  - Trinity Biotech UniGold

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Critical Steps in Rapid Testing Implementation

- Policy Development
- Rapid Test Evaluation
- Training
- Quality Assurance

Zimbabwe HIV Rapid Testing Committee

Critical Steps in Policy Development

- Determine who makes policy
- Determine how policy is made
- Determine what drives policy development?
  - law,
  - financial leverage,
  - culture,
  - data supporting best practices…
  - politics
- If policies exist, are they followed?

Critical Partners in HIV Policy Development

- High Level Appointees in the Ministries of Health and Boards created by MOHs
- International Health and Standards Organizations (e.g., WHO, PAHO, CAREC, EU)
- National AIDS Control Boards
- Bilateral donors (e.g., DIFID, AMREF, USAID, CDC, GDZ, JICA, World Bank)
- Medical and laboratory scientists/leaders
- HIV counselors
- Nurses and midwives
- Hospital authorities
- Clients

HIV Testing Policy Questions

- What is the primary purpose for testing and are there ethical issues?
- Who will be tested?
- What will be done as an outcome of testing?
- How will testing be funded?
- What happens if financial and other program resources wane?
- Who can do the testing?
- Will training be provided?
- Which tests can be used?
- Who is responsible for purchase and inventory control?
- How will testing be audited?
- At the national level, who has authority & responsibility for QA?
- What is the role of laboratory directors (national, provincial, and district) in QA?
- Who makes, and will review, testing policies?

Consequences of Jumping Past Policy Development

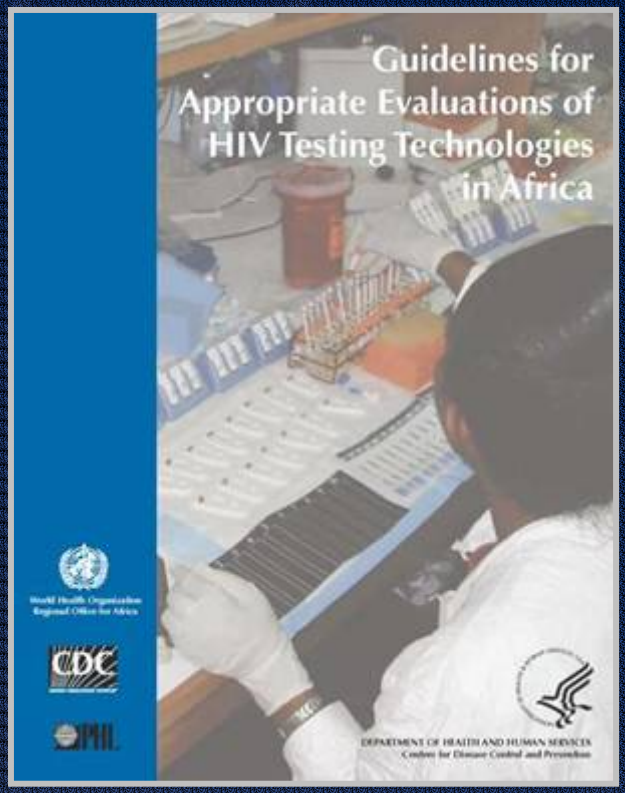
- Lack of buy-in with critical partners / players (e.g., government officials, medical staff, laboratory scientists, procurement officers)
- Without clear policy, processes and procedures can follow a hazardous path
- Loss of invested resources, time, and credibility

Protocols and Guidelines Serve as the Foundation for Processes & Procedures

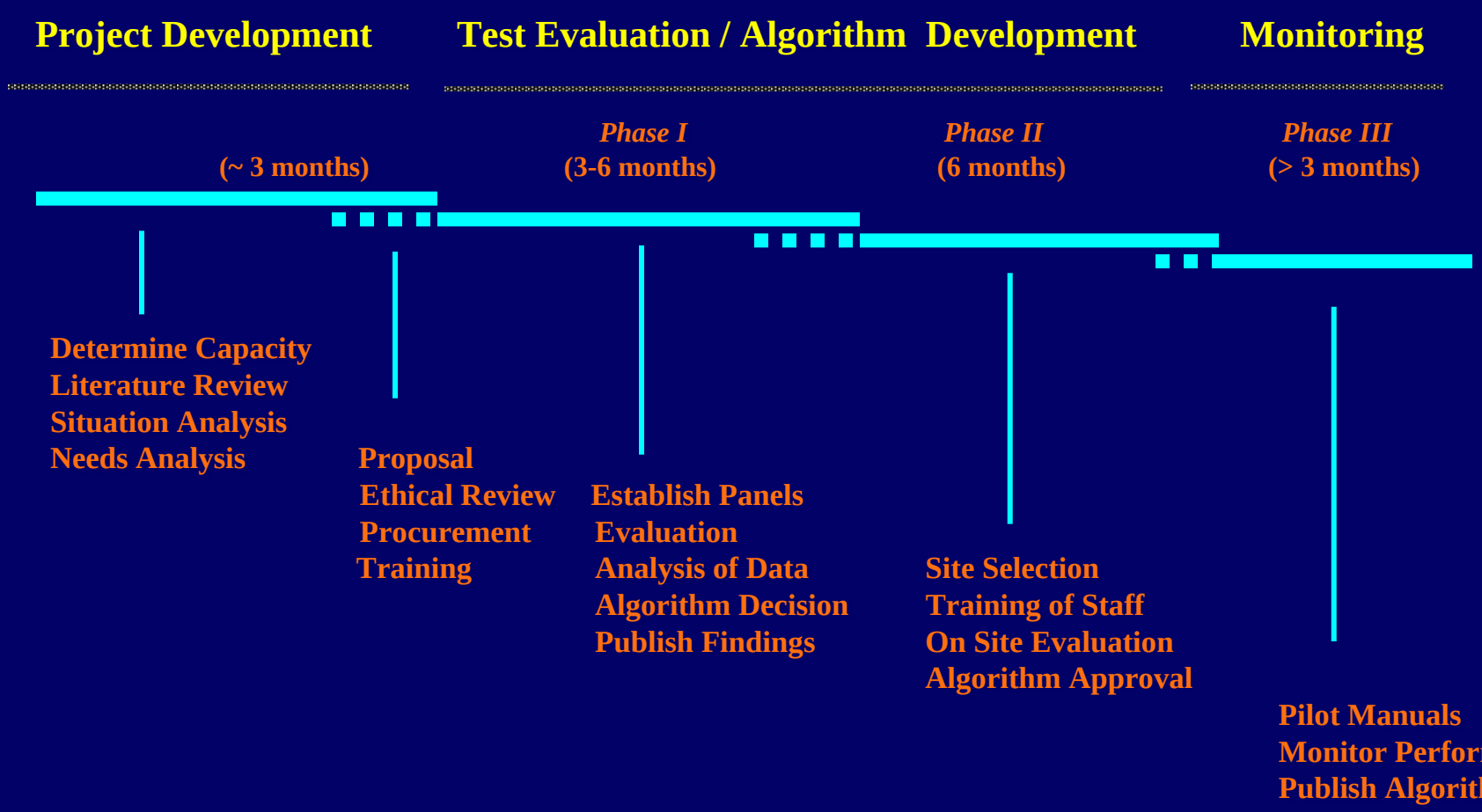
CDC and WHO-AFRO led development of Guidelines for Appropriate Evaluation of HIV Testing Technologies

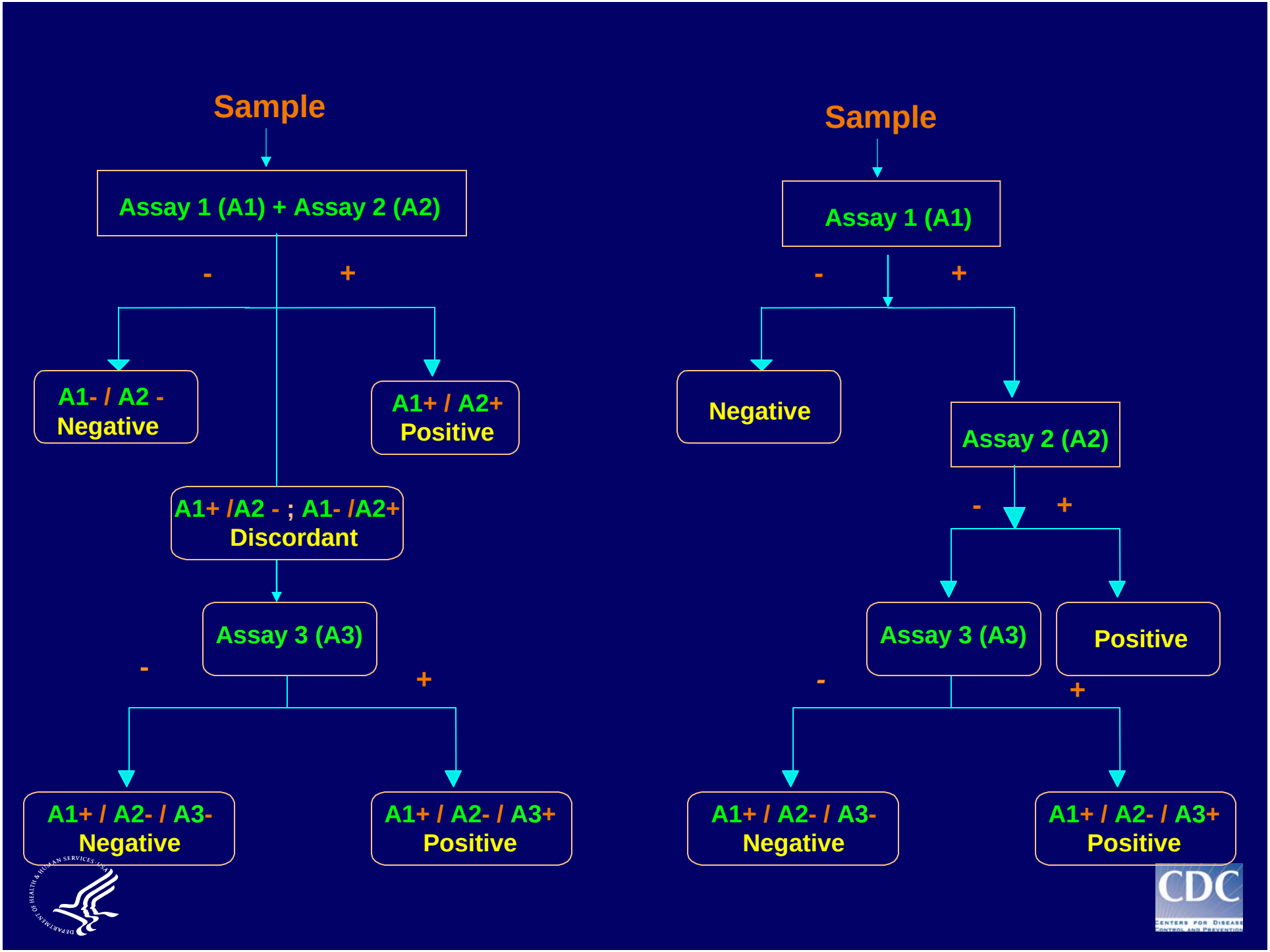
The Guidelines are an outcome of a Consensus Workgroup Meeting

- Harare, Zimbabwe
- (20) CDC, WHO, APHL, Regional Participants



TIMELINE


Project Development
Test Evaluation / Algorithm Development
Monitoring
(~ 3 months)
Phase I
(3-6 months)
Phase II
(6 months)
Phase III
(> 3 months)
Determine Capacity
Literature Review
Situation Analysis
Needs Analysis
Proposal
Ethical Review
Procurement
Training
Establish Panels
Evaluation
Analysis of Data
Algorithm Decision
Publish Findings
Site Selection
Training of Staff
On Site Evaluation
Algorithm Approval
Pilot Manuals
Monitor Performance
Publish Algorithm


Sample
Assay 1 (A1) + Assay 2 (A2)
-
+
A1- / A2 -
Negative
A1+ / A2+
Positive
A1+ /A2 - ; A1- /A2+
Discordant
Assay 3 (A3)
-
+
A1+ / A2- / A3-
Negative
A1+ / A2- / A3+
Positive
Sample
Assay 1 (A1)
-
+
Negative
Assay 2 (A2)
-
+
Assay 3 (A3)
Positive
-
+
A1+ / A2- / A3-
Negative
A1+ / A2- / A3+
Positive

Evaluation Methods

PANEL	EIA1	EIA2	STATUS	RT 1	RT 2	RT 3	Algorithm
296	N	N	N	N	N	N	N
297	N	N	N	N	N	N	N
667	P	P	P	P	P	P	P
16	P	P	P	P	P	P	P
660	P	P	P	N	N	N	N
506	N	N	N	P	N	N	N
668	P	P	P	N	P	P	P
1005	N	N	N	N	P	N	N

Study Sites = City A and City B
Raw dataset = 1022 records
Final Panel = 972 specimens (360 positives / 612 negatives)

Comparison of Rapid Testing ELISA Reference Labs

Test	n	Sensitivity	Specificity	PPV	NPV	Test Efficiency
Determine	**3034**	**100%**	**99.6%**	**97.9%**	**100%**	**99.6%**
Hemastrip	**3034**	**100%**	**100%**	**100%**	**100%**	**100%**
D & H combined	**3034**	**100%**	**100%**	**100%**	**100%**	**100%**

Zimbabwe
Settings for Use of Rapid HIV Test Kits

- Stand Alone VCT Services

Public Health Delivery System

- VCT for PMTCT – clinics & district hospitals –
- Clinical testing in District Hospitals
- Emergency testing following occupational exposure – Central & Provincial Hospitals –
- VCT services & mobile testing from District/Mission Hospitals

Rural Zimbabwe

Summary of Rapid Test Training in Zimbabwe

- Number of Courses held : 9
- Number of people trained : 194
- Training database established
- Participants trained in testing with Oraquick, Determine, Unigold, Virochek, Capillus, Hemastrip

Breakdown by profession

- Medical Laboratory Scientists 80
- Nurse/counselors 95
- Counselors 15
- Clinicians 4

Duration of training

Nurse counselor

- 2 days in laboratory setting +

1 month with daily support from a medical laboratory scientist

- First 50 specimens done by EIA before results are released to client by nurse counselor

Lab scientist

- 2 days

Training

- Conducted by experienced MLS from the National Microbiology Reference Laboratory with assistance from District or Provincial MLS
- On site and at the NMRL
- Standard Operating Procedure manuals used
- Standard training materials used – training CD and video (Determine& Oraquick)

Standard Curriculum Developed

- ✓ Type of kits and assay format
- ✓ Testing algorithm
- ✓ Use of rapid kits - setting
- ✓ Kits approved for use in Zimbabwe
- ✓ Confidentiality-code of conduct
- ✓ Quality Assurance – IQC and EQA
- ✓ Collection, Storage & Transport of DBS to the Reference Laboratory
- ✓ Reporting of Results
- ✓ Inventory Control & Storage of kits
- ✓ Pipettes & Items needed
- ✓ Premises or Site – general requirements for lab or clinic
- ✓ Practical in rapid testing

Practical Session

General (Demonstration)

- Separation of Serum and Plasma from the Cells
- Stability of Blood Samples
- Changes in Blood on Keeping
- Storage of Blood Samples
- Type of Blood to be Used
- Storage & dispatch of dried blood spots
- Reporting of results

Testing

- Testing from reference panel of serum, whole blood and plasma with all approved rapid HIV test kits
- Finger pricking
- Testing of trainer from finger prick if trainer willing
- Testing from finger prick if volunteers come forward
- Spotting whole blood onto S&S filter paper

Assessment

- Written Exam: 30 minutes.
- Practical exam: Each student is required to test a panel of 6 specimens.
- Certification.

Only students who pass will be awarded a certificate of competence in using the kits they were trained for.

Lab set up

Set up of Lab for Training

- Good lab set up prior to the practical is essential

ANC Clinic Attendees

Drawing Blood

On site training in Rapid Testing

Training

Training MLS

Assessment

Follow-up QA of the testing

- On-site Audits
- Dried Blood Spot Testing (reverse PT) – just starting
- Zimbabwe National Quality Assurance Program (PT program)

Comparison of Technical Difficulties Observed During Training

Nurse Counselors	Lab Scientists	Both Groups
Difficulty with volume concepts – 50ul		
		Adding the incorrect specimen volume to the kits.
	Difficulty doing a finger stick – Uneasy dealing directly with clients who come for HIV test.	
Mixing up buffers - Problem acute with nurse counselors. There is a need for manufacturers to label their buffers clearly especially Unigold		Mixing up buffers especially when testing in parallel
Hema- Strip problems Knocking over buffer +		
		Not observing universal precautions – leaving used lancets on bench
Contamination of buffer bottles – splash back!		

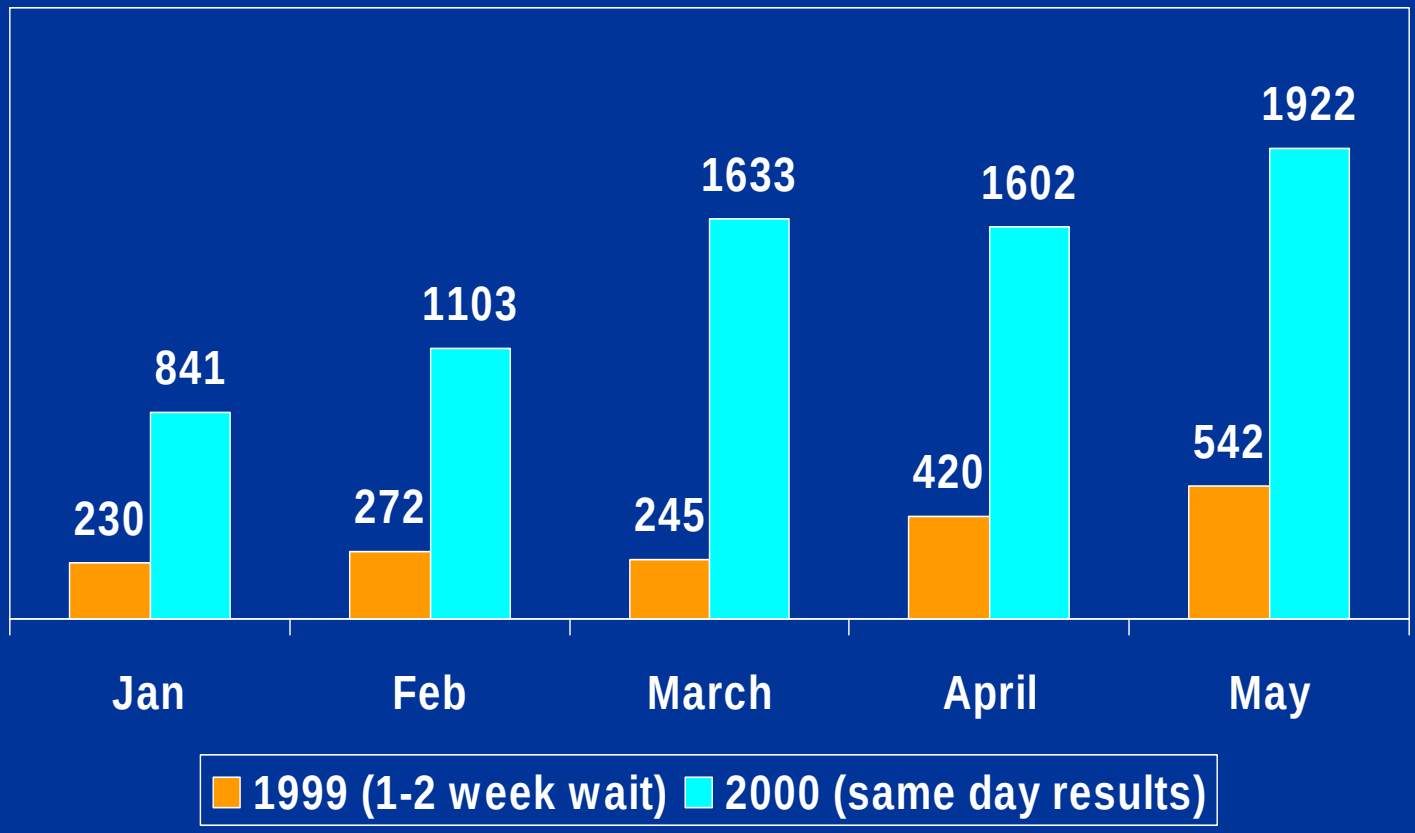
Technical difficulties observed during training

Nurse Counselors	Lab Scientists	Both Groups
Capillus Not putting sample into well area, having kit wrong side up!		
		Slopping blood on gloves. Putting wet DBS paper flat on bench = possibility of cross contamination

Lessons learned

- Order of training is very important – better for MLS be trained first.
- Nurse counselors can be easily trained to do rapid testing and give comparable results to that of MLS.
- A QA system should be in place
- The private sector must be included
- Nurse counselors need support from a MLS and be part of the lab network

Increase in Demand for VCT in Malawi with Same Day Results using Rapid Tests



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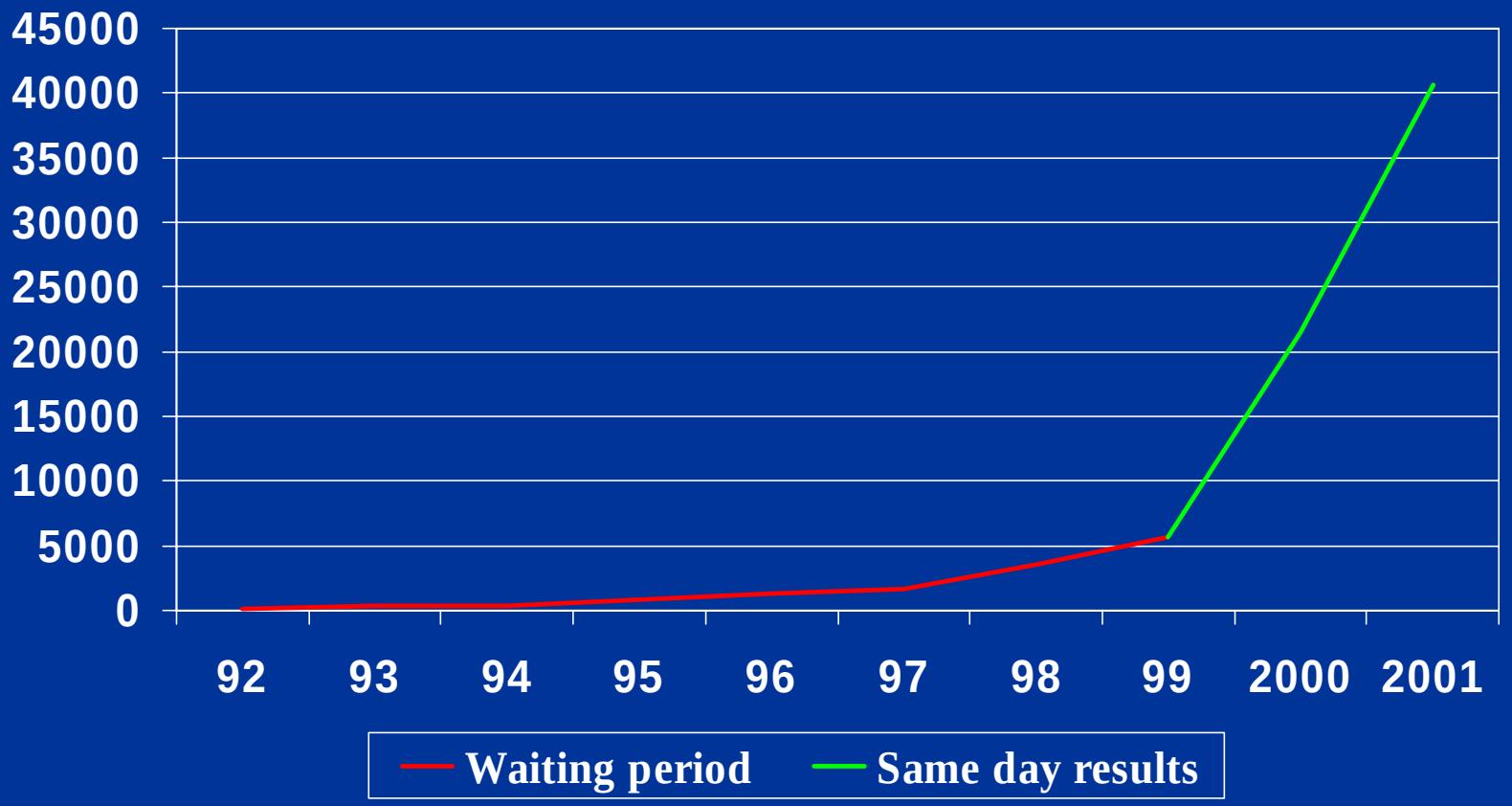
VCT Clients in Malawi: Waiting period versus same day results



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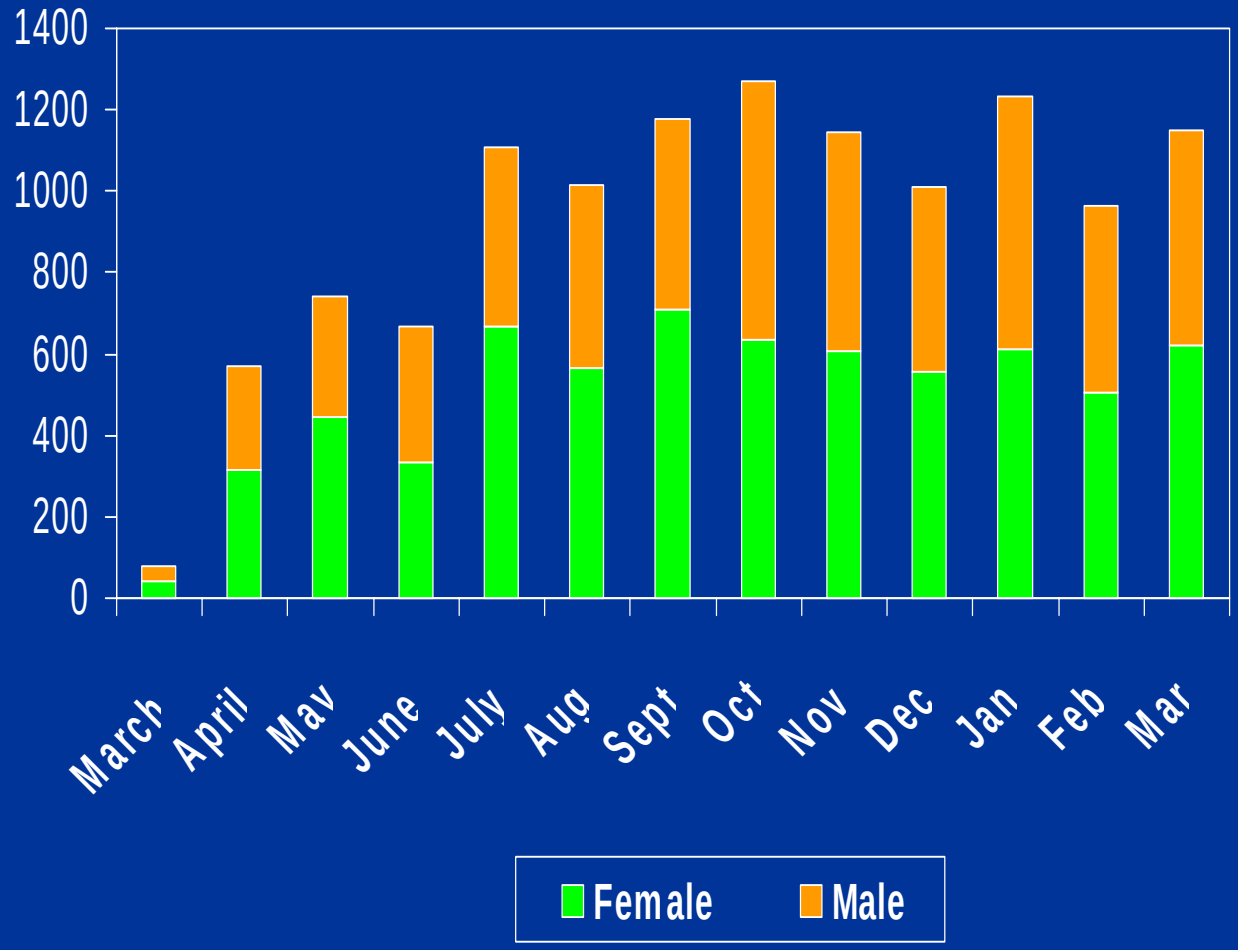
Rapid Increase in Utilization of VCT in Kibera, March 2001 – March 2002



- KICOSHEP served 12,157 VCT clients at 5 sites in the Kibera slum and at 17 medical camps

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EDWARD R. ROYBAL CAMPUS
1600

Advancing HIV Prevention: New Strategies for a Changing Epidemic

- Estimated 40,000 new infections annually
- Of 850,000-950,000 persons living with HIV, an estimated 180,000-280,000 (25%) are unaware of their status
- During 2000, of persons tested in CDC-funded sites and having positive tests for HIV, 31% did not learn their test results
- Many persons who do learn they are HIV-infected adopt behaviors that might reduce risk for transmitting HIV

MMWR April 18, 2003 / 52(15);329-332

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Four Key Strategies

- Make HIV testing a routine part of medical care
- *Implement new models for diagnosing HIV infections outside medical settings*
- Prevent new infections by working with persons diagnosed with HIV and their partners
- Further decrease perinatal transmissions

MMWR April 18, 2003 / 52(15);329-332

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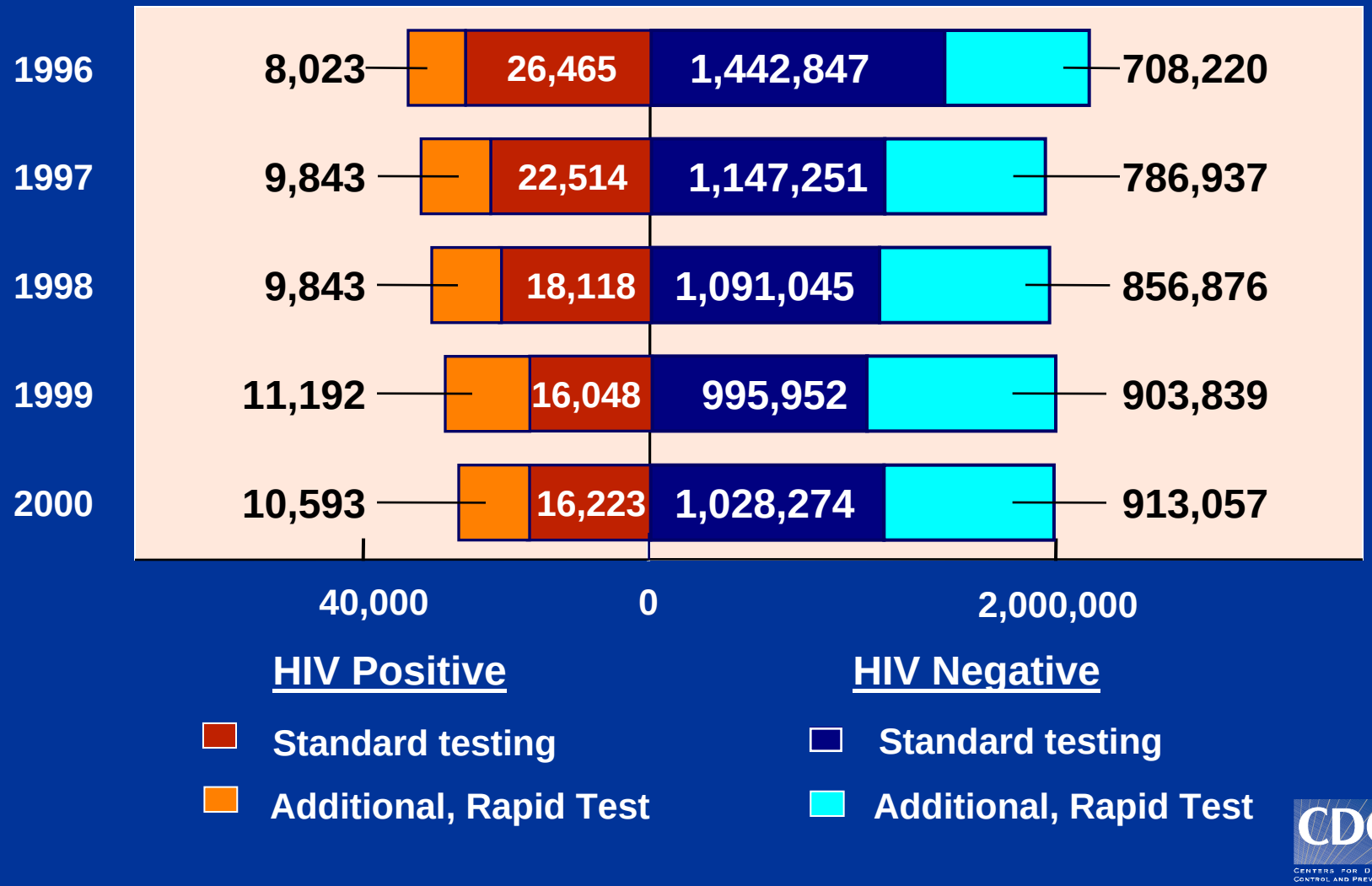
What if rapid HIV tests were used in all public testing sites?



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HIV Testing Algorithms

- Screening – (a) EIA testing (serum, plasma, oral fluid, dried blood spots, urine) or (b) Reveal Rapid Test (serum, plasma)
- Supplemental testing – if subsequent EIA repeatedly reactive perform Western blot or indirect immunoflourescence

- Screening – OraQuick Rapid HIV test (whole blood)
- Supplemental testing – (a) perform Western blot or indirect immunoflourescence

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Rapid HIV Tests Approved by FDA

- OraQuick Rapid HIV-1 Antibody Test
  - Orasure Technologies
  - Whole blood
  - CLIA waived
  - http://www.orasure.com

- Reveal Rapid HIV-1 Antibody Test
  - MedMira, Inc.
  - Serum, plasma
  - CLIA Moderate complexity
  - http://www.medmira.com

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CDC Activities Supporting Implementation of Rapid HIV Testing

- Rapid HIV test studies: www.cdc.gov/hiv/rapid_testing/index.htm#study
- Satellite Broadcast: Update on Rapid Testing for HIV - April 24, 2003
- Quality Assurance Guidelines for Testing Using the OraQuick Rapid HIV-1 Antibody Test www.phppo.cdc.gov/DLS/pdf/rHIV/QA_Guidelines_OraQuick.pdf

For additional information - http://www.cdc.gov/hiv/dhap.htm

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CDC Implementation Activities

- Training for CDC direct and indirectly-funded programs that will be using OraQuick
- Demonstration projects and evaluation
- Enrollment in CDC Model Performance Evaluation Program
  http://www.phppo.cdc.gov/mpep/enrollment.asp

For additional information - http://www.cdc.gov/hiv/dhap.htm

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RESTRICTIONS: Sale of the OraQuick® Rapid HIV-1 Antibody Test

- Restricted to clinical laboratories
  - That have an adequate QA program
  - Where there is assurance that operators will receive and use the instructional materials.
- OraQuick® is approved for use only by an agent of a clinical laboratory.
- Test subjects must receive the "Subject Information" pamphlet prior to specimen collection and appropriate information when test results are provided.
- OraQuick® is not approved for use to screen blood or tissue donors.

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Waiver Requirements

- Waived laboratories
  - **must register**
  - **not routinely inspected**
  - **exempt from CLIA standards**
  - **must follow instructions**
- Standards (personnel, PT, QC, and QA requirements) do not apply to waived testing
- Comply with all applicable state and federal laws

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Quality Assurance Guidelines For Testing Using The OraQuick Rapid HIV-1 Antibody Test

SAFER • HEALTHIER • PEOPLE™

Document Development

- Meeting of experts from CDC, FDA, DOD, CMS and those outside the federal government with expertise in rapid point-of-care testing, QA, HIV prevention programs, and private and public health laboratories

- OraQuick^{R}Rapid HIV-1 Antibody Test - first rapid HIV point-of-care test approved by FDA; granted CLIA waiver January 2003

Content of QA Guidelines

- Establishing a QA program
- Testing Personnel
- Process control
  - Before testing
  - During testing
  - After testing
- Documents and Records
- Troubleshooting

Establishing a QA Program

- Identify those responsible for managing the QA program
- Write procedures and make them available to all staff involved in testing
- Verify the testing process
- Ensure staff know how to perform processes and procedures
- Create mechanisms for communication
- Develop and implement mechanisms to ensure the site meets all applicable Federal, State, and other regulatory requirements.

Testing Personnel

- Qualifications
  - Sincerity and commitment
  - Literacy
  - Organizational skills
  - Decision-making skills
  - Communication skills

Testing Personnel (cont'd)

- Training
  - How to perform the test, including procedures performed before, during and after testing
  - How testing is integrated into the overall counseling and testing program
  - The importance of QA and the elements of the site's QA program
  - The use and importance of Universal Precautions/biohazard safety

Testing Personnel (cont'd)

- Competency Assessment
  - Before trainee performs testing alone, their ability to conduct tests should be demonstrated and documented
  - Assessment should be done periodically as determined by the testing site
  - Every task for which staff member is responsible should be evaluated
  - Supervisor or trainer should perform assessment

Process Control

Before Testing

Check storage & rm. temperatures daily

Check inventory / test kit lots, as needed

Receive testing requests

Give HIV/AIDS info to test subjects

Set up test area, label test device

External QC per manufacturer's and site's instructions

During Testing

Follow biohazard safety precautions

Collect finger-stick specimen

Perform the test

Interpret test results

After Testing

Clean up & dispose of biohazard waste

Give results to client

Document results

Collect, process, transport confirmatory test specimens

Manage confirmatory test specimens

Periodic external quality assessment

Documents and Records

- Temperature Logs
- External Control Result Logs
- Test Result Logs
- Specimen Transfer Log
- Training Checklist for ***OraQuick^{R}Rapid HIV-1 Antibody Test***
- External Assessment: Proficiency Testing and Other Mailed Evaluation Programs

Troubleshooting

Procedures:

- When to discontinue testing
- How to take corrective action
- How to document problems and actions taken
- How to verify the corrective actions taken addressed the problem

Upcoming CDC Training

- Target audience – CDC grantees who will be performing OraQuick testing
- Phase 1(Oct-Dec 2003) – Training delivered at ~24 venues around the country
- Team of counselor trainers and laboratory trainers deliver training
- State training coordinators, State laboratory directors, AIDS program directors, and CMS staff apprised of training
- Training limited to 25 participants

Upcoming CDC Training

- Training modules
  - Introduction to rapid HIV testing
  - Universal precautions & performing a fingerstick
  - QA of OraQuick rapid HIV testing
  - Providing information, prevention counseling, and test results
  - Practicum – integrating the course work
- Phase II – Begins January 2004

Closing Remarks

- POS testing provides additional opportunities to address current limitations for testing hard to reach populations and for access to testing in environments where conventional testing is limited
- The benefits of POS testing can be realized if testing is implemented within the context of a quality system
- POS testing works when all the critical partners are working together using their collective energy and talent

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