Overview of PEPFAR Approach to Infant Diagnosis

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Infant Diagnosis as Priority for PEPFAR

New priority area in 2006

- Previous focus on PMTCT coverage and scale-up (C&T, ARV prophylaxis, infant feeding)
- Joint activity of PMTCT/PEDS and Laboratory
- Unites 3 key areas:
  - M&E – effectiveness and impact
  - Clinical care – early treatment
  - Capacity building, national systems and planning

Current Ability to Support Infant Diagnosis

- All 20 PEPFAR countries have one or more laboratories with PCR capacity; most have proven research experience with a US university or other technical partner
- Several countries have well-developed local capacity (eg. S. Africa, Kenya)
- Approximately half have CDC laboratory assignees in-country; all will have active CDC lab back-up from Atlanta
- Most countries have active PMTCT/PEDS or laboratory PEPFAR grantees/ implementing partners
- *Goal: Unified plan of support and coordination*

Infant Diagnosis: 2 approaches

- Early diagnosis: 6 weeks – 6 (12) months
  - DBS DNA PCR
    - Standardized; commercially supported; QA/QC; practical approach to infant specimen collection, transport and handling; relatively low cost ($8-$12)
    - Good starting platform for more advanced technologies
  - Find infected kids early; counsel/ follow early negatives
  - Early standardized assessments of program effectiveness
- Final diagnosis: ≥ 18 months (12 m)
  - EIA rapid testing
  - Final triage decisions for care and treatment
  - Overall assessments of program effectiveness
- *Links between PMTCT and child health (HIV status on infant health card*

Central (HQ) Activities to Support Infant Diagnosis

- Infant diagnosis working group
- Consultation meeting July 2005
  - Strong support for country implementation
  - Roche Amplicor DNA DBS as initial standard
- Developing core package of support
  - Clinical and lab protocols, SOPs, QA procedures, training package and video, work with Roche favored pricing program
- Technical support to countries
- Work with international partners

Country Activities to Support Infant Diagnosis

- Country support projects for national implementation
  - Botswana, Rwanda, Nigeria, Uganda, Zambia, Kenya, Namibia, et al.
  - Work with countries with strong internal capacity (eg. S. Africa)
- Focus on quality national projects with regional networks, potential to expand
- Capacity-building and support with research labs
- Systems building: national monitoring, QA
- Ongoing assessments, lessons learned, program improvements

Operational Issues and Operational Research

- Comparison of methods
- Algorithms and efficiency
  - when to test?
  - confirmatory test?
- Improving follow up and integrating with EPI
- Use of rapid tests for screening after 9-12m
- Counseling with early testing and weaning

Goals for 2006

- Standardize rapid testing for exposed and symptomatic kids ≥18m
- Finalize PEPFAR guidance and support package for early infant diagnosis
  - DBS PCR testing
  - Rapid testing after 12-18m
- Country plans for infant diagnosis
- Functional programs and preliminary evaluations in 4-6 countries
- Support scale-up and expansion
- Intl support for HIV on child health card

CDC Infant Diagnosis Team

- Michelle McConnell and Amilcar Tanuri
  - *Thanks for starting program*
- Molly Rivadeneira and Chin-Yih Ou
  - Tracy Creek, Thomas Finkbeiner
  - Martha Rogers, Lydia Lu (coordinator)
  - John Nkengasong and lab team
  - Nathan Shaffer and PMTCT Team
- Expanding network of technical and implementing partners