PEPFAR and Treatment 2.0

World Health Assembly
Treatment 2.0 Side Meeting
May 19, 2011

Charles Holmes, MD, MPH
Office of the US Global AIDS Coordinator
President’s Emergency Plan for AIDS Relief
Drug Optimization

• At a global-level:
  – Purchasing power to drive demand for ARV regimens with better profiles for TB, pregnancy, durability, toxicity and simplicity
  – Build on the work CHAI, UNITAID and others have done to ensure manufacturers are moving toward more efficient process chemistry and co-formulations

• At country-level:
  – Annual guidance to PEPFAR country teams encourages use of 2010 WHO guideline regimens and movement to FDCs; emphasizes support to national program guidelines committees
  – PEPFAR works with SCMS and other ARV procurement partners to ensure that suppliers are responsive to the needs of the national programs we support

Pillar 1: Drug Optimization
• PEPFAR believes that improvements in laboratory platforms and systems and use patterns are essential to improving the impact and efficiency of our programs

• Working with country teams to support national governments in the evaluation of basic packages of laboratory support that are needed and ensuring greater consistency in laboratory use across implementing partners.

• As part of tiered laboratory systems, PEPFAR sees value in careful adoption of POC diagnostics
Point-of-Care CD4 Testing

Available Now: Pima CD4 Assay

In Evaluation or soon to be in evaluation:

- Daktari
- Zyomax
- ZAHA! By Force Diagnostics

Pillar 2: Improving Diagnostics
PEPFAR Evaluation of POC CD4, Through CDC

**Quality Indicators:**

**Accuracy** - Comparison with other CD4 assays
- CD4 counts <500: $R^2 = 0.93$
- CD4 counts >500: $R^2 = 0.96$

**Bias** - Variation from other CD4 assays
- CD4 counts <500: 1 cell/μL
- CD4 counts >500: -15 cells/μL

**Precision** - Reproducibility (Average CV%)
- CD4 counts <200: 13.4%
- CD4 counts >200: 5.9%

Pillar 2: Improving Diagnostics

Source: John Nkengesong, CDC
Select PEPFAR Implementation and Field Activities
For POC CD4

• Tanzania: Protocol for validation of specimen type (venous vs finger-stick blood) and acceptance by healthcare worker performing testing
• Dominican Republic: Protocol for Quality Monitoring and acceptance by healthcare worker performing testing
• Supporting national governments in the development of plans that promote standards, guidelines and policy for the quality management and monitoring

Pillar 2: Improving Diagnostics
GeneXpert Implementation to date through Government of South Africa/PEPFAR Partnership

- **Pilot rollout phase 1 for evaluation**
  - 23 sites, 30 instruments in 9 provinces
  - 54 individuals trained
  - 10,423 samples processed to date nationally
- **Pilot will help facilitate costing, algorithm development, performance of instrumentation, future research and development**
  - Pilot EQA program developed

Source: Wendy Stevens, NHLS
Reducing Costs

- Cost savings in PEPFAR HIV treatment programs over time
- Addressing service delivery costs
- ARV price and delivery savings through PEPFAR
Declining HIV Treatment Costs under PEPFAR, 2004-2009

Note: Per-patient PEPFAR budget allocation is estimated as lagged treatment allocation divided by end-of-reporting of patients directly supported on ART by PEPFAR. Budget per result estimates may vary from site-level costing estimates.
Sample PEPFAR Expenditure Analysis Results: HIV Testing and Counseling. Driving Efficiency Through Better Information

Cost Per Client by Cost Category (2009 USD)

<table>
<thead>
<tr>
<th>Category</th>
<th>Mean</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Support</td>
<td>1.48</td>
<td>0.38-12.41</td>
</tr>
<tr>
<td>Operating</td>
<td>7.24</td>
<td>1.66-21.43</td>
</tr>
<tr>
<td>Investment</td>
<td>2.62</td>
<td>0.27-5.88</td>
</tr>
<tr>
<td>Total</td>
<td>11.34</td>
<td>2.63-32.82</td>
</tr>
</tbody>
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Distribution of Costs by Category

<table>
<thead>
<tr>
<th>Category</th>
<th>ALL Partners</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Support</td>
<td>13 %</td>
<td>5 % - 57 %</td>
</tr>
<tr>
<td>Operating</td>
<td>64 %</td>
<td>30 % - 84 %</td>
</tr>
<tr>
<td>Investment</td>
<td>23 %</td>
<td>2 % - 37 %</td>
</tr>
</tbody>
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Pillar 3: Reducing Costs

Note: Sample data from a single country. There are multiple sources of observed heterogeneity that may be assessed by local program managers.
Savings in ARVs

Number of Generic vs. Branded Drugs Procured (Monthly Packs 2005-2009)

<table>
<thead>
<tr>
<th>Year</th>
<th>Generic</th>
<th>Branded</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>2,415,125</td>
<td>17,358,069</td>
<td>88% Generic</td>
</tr>
<tr>
<td>2008</td>
<td>2,361,358</td>
<td>19,768,334</td>
<td>89% Generic</td>
</tr>
<tr>
<td>2007</td>
<td>3,335,474</td>
<td>8,994,218</td>
<td>73% Generic</td>
</tr>
<tr>
<td>2006</td>
<td>4,281,555</td>
<td>2,857,214</td>
<td>40% Generic</td>
</tr>
<tr>
<td>2005</td>
<td>5,269,384</td>
<td>1,034,911</td>
<td>16% Generic</td>
</tr>
</tbody>
</table>

* Monthly pack volume decreased in 2009 due to increased purchasing of fixed dose combinations

JAMA, 2010
Pillar 3: Reducing Costs

Source: SCMS
Adapting Delivery Systems

- Shifts toward lower level care delivery
- Integration of TB/HIV services
- Integration of PMTCT/MNCH services - new guidance
### Early Benefits of Lower-Level ART Delivery

**Site (# ART patients) | Model of care | % in care & responding | Average cost/ patient**
---|---|---|---
**South Africa (12 months after down-referral of stable patients)**
Thembha Lethu Clinic (7656) | Urban, hospital-based, well-resourced HIV clinic | 89% | $555 |
Crosby Clinic (1210) | Primary health clinic (down-referral site of hospital) | 95% | $504 |
**Zambia (12 months after treatment initiation)**
St. Francis’ Hospital (3305) | Rural, hospital-based HIV clinic | 77% | $366 |
St. Francis’ Makungwa Outreach (638) | Non-clinic location; hospital clinical team visits weekly | 79% | $289 |

• At the lower level sites:
  — Patient outcomes are as good as or better than at hospital-based sites
  — Costs are lower (9% in South Africa, 21% in Zambia)
  — Most of the savings come from lower fixed and staff costs and fewer lab tests

Pillar 4: Adapting Delivery Systems

Source: Sydney Rosen
TB/HIV Integration in Rwanda

• TB - One-stop service
  – Early HIV diagnosis
  – ART, CD4, clinical care, cotrimoxazole

• ART
  – TB screening with checklist
  – Rapid and accurate TB diagnosis

Pillar 4: Adapting Delivery Systems

Source: Greet Vanderbriel, ICAP Rwanda
PEPFAR Supports Strategic HIV-MNCH Integration to Improve PMTCT and ART Outcomes

- HIV care and treatment in MNCH settings increases ART enrollment
  - Swaziland: Enrolling women on ART in ANC services increased eligible women receiving ART from 5% to 45%. Pilot rolled out nation-wide
  - Zambia: Enrolling women on ART in ANC services more than doubled the proportion of eligible women starting treatment from 14% to 33%

Pillar 4: Adapting Delivery Systems  
Source: Elizabeth Glaser Pediatric AIDS Foundation
Integrating PMTCT, Maternal, Neonatal, and Child Health and Pediatric HIV Services (January 2011)

-PEPFAR Guidance on Integrating Prevention of Mother to Child Transmission of HIV, Maternal, Neonatal, and Child Health and Pediatric HIV Services (January 2011) [PDF version]
Community Mobilization

- Peer support to provide individuals with the comfort and information needed to be successful on treatment and PMTCT
  - PEPFAR supports partners and we’re beginning to see national adoption of best practices
- Mobilization of civil society
  - Working to support groups of PLWHA and most at risk populations, especially in concentrated epidemics to design systems to support access and rights
- Community support
  - Supporting affected individuals to map available care resources, support and education groups that improve adherence and encourage greater testing of partners and community members
Thank You!

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