A Call to Action

Children – The missing face of AIDS
Innovation for elimination of new HIV infections in children by 2015 and keeping mothers alive

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Presentation outline

• Context
• Global plan to elimination of mother to child transmission of HIV goals and targets
• Progress to date
• Challenges and innovative approaches
• WHO 2010 guidelines and update on B+
• Paediatric HIV care and treatment
• Conclusion
## Context: HIV and AIDS, 2011

<table>
<thead>
<tr>
<th><strong>ADULTS</strong></th>
<th><strong>Global Estimate</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of adults living with HIV</td>
<td></td>
</tr>
<tr>
<td>• Adults</td>
<td>34.2 million</td>
</tr>
<tr>
<td>• Women (15+)</td>
<td>30.7 million</td>
</tr>
<tr>
<td>• Women (15+)</td>
<td>15.0 million</td>
</tr>
<tr>
<td>Number of people newly infected with HIV</td>
<td>2.5 million</td>
</tr>
<tr>
<td>Number of people dying from AIDS-related causes</td>
<td>1.7 million</td>
</tr>
</tbody>
</table>

| **CHILDREN**                                                              |                     |
| Number of children under 15 living with HIV                               | 3.4 million         |
| Number of children under 15 newly infected with HIV                       | 330,000             |
| Number of children under 15 died from AIDS-related causes                 | 230,000             |
| Children who have lost one or both parents to AIDS as of 2011             | 17.3 million        |

Source: UNAIDS, Together We Will End AIDS, published/unpublished estimates 2012
A new Global Plan to eliminate new pediatric HIV infections by 2015 and keep mothers alive launched, HIV/AIDS HLM, NY in June 2011

- Goal is to reduce number of new child HIV infections by 90% and to HIV HIV related maternal mortality by 50%
- Reduce child related deaths by >50%

- Focuses on 22 countries with highest estimate of HIV+ pregnant women (sub-Saharan Africa + India)
Global Plan Targets

For Childbearing Women

Reduce new infections in women by 50%

For Women Living with HIV

Reduce unmet need for family planning among women to zero

For Pregnant Women Living with HIV

Provide ARVs to 90% of pregnant women to reduce MTCT to < 5%

Provide ART to 90% of pregnant women in need for their own health.

Provide ART to all HIV infected children.

Source: Countdown to zero: Global Plan towards the elimination of new infections among children by 2015 and keeping their mothers alive 2011-2015
More than 50% of HIV positive pregnant women in low- and middle-income countries received combination ARVs in 2011

Source: UNAIDS. Together we will end AIDS. 2012
Overall Target 1: Reduce the Number of New HIV Infections among children by 90% by 2015

Estimated new Pediatric Infections in Low and Middle Income Countries (LMICs)

<table>
<thead>
<tr>
<th>Year</th>
<th>Infections</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>430,000</td>
</tr>
<tr>
<td>2010</td>
<td>390,000</td>
</tr>
<tr>
<td>2011</td>
<td>330,000</td>
</tr>
<tr>
<td>2015 (Goal)</td>
<td>43,000</td>
</tr>
</tbody>
</table>

Country Contribution to 390,000 Paediatric HIV Infections in LMICs in 2010

- Nigeria: 29%
- DRC: 10%
- Uganda: 13%
- Malawi: 3%
- Kenya: 5%
- Mozambique: 6%
- India: 6%
- Tanzania: 6%
- Zimbabwe: 6%
- Ethiopia: 7%
- Other Priority Countries: 7%
- Other LMICs: 6%

Source: 1. UNAIDS. Together we will end AIDS. 2012
2. HIV/AIDS Response – Epidemic Update and Health Sector Progress Towards Universal Access 2011
Overall Target 2: Reduce the Number of HIV-associated maternal deaths to women during pregnancy, delivery and puerperium by 50% by 2015

Women dying from AIDS-related causes during pregnancy or within 42 days of the end of pregnancy in the 22 priority countries

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>42,000</td>
</tr>
<tr>
<td>2010</td>
<td>33,000</td>
</tr>
<tr>
<td>2015 (Goal)</td>
<td>21,000</td>
</tr>
</tbody>
</table>

22 priority countries contribution to 33,000 HIV-associated maternal deaths in 2011

- Nigeria: 20%
- South Africa: 12%
- Tanzania: 7%
- Mozambique: 7%
- Uganda: 7%
- Kenya: 7%
- Malawi: 5%
- India: 5%
- Zimbabwe: 5%
- Zambia: 5%
- Cameroon: 3%
- Cote D'Ivoire: 3%
- Ethiopia: 3%
- Ghana: 1%
- Chad: 1%
- Lesotho: 1%
- Burundi: 0.5%
- Swaziland: 0.5%
- Namibia: 0.5%
- Botswana: 0.5%

Source: UNAIDS. Together we will end AIDS. 2012
Almost a 40% reduction in new paediatric HIV infections between 2005 and 2011

Estimated number of new HIV infections among children (0-14 years), 2001-2011 and the target for 2015

- 2001: 550,000
- 2002: 540,000
- 2003: 430,000
- 2004: 330,000

2015 Target: 43,000

Percentage of Deaths Attributable to HIV among Children <5 Years; Selected Countries, 2000 and 2010

<table>
<thead>
<tr>
<th>Country</th>
<th>2000</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Africa</td>
<td>36%</td>
<td>28%</td>
</tr>
<tr>
<td>Swaziland</td>
<td>34%</td>
<td>23%</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>44%</td>
<td>20%</td>
</tr>
<tr>
<td>Lesotho</td>
<td>37%</td>
<td>18%</td>
</tr>
<tr>
<td>Botswana</td>
<td>48%</td>
<td>15%</td>
</tr>
<tr>
<td>Namibia</td>
<td>32%</td>
<td>14%</td>
</tr>
<tr>
<td>Malawi</td>
<td>16%</td>
<td>13%</td>
</tr>
<tr>
<td>Zambia</td>
<td>16%</td>
<td>10%</td>
</tr>
<tr>
<td>Mozambique</td>
<td>7%</td>
<td>10%</td>
</tr>
<tr>
<td>Sub-Saharan Africa</td>
<td>6%</td>
<td>4%</td>
</tr>
<tr>
<td>World</td>
<td>3%</td>
<td>2%</td>
</tr>
</tbody>
</table>


Paediatric ART Coverage, 2005-2011

- 2005: 6%
- 2006: 10%
- 2007: 13%
- 2008: 18%
- 2009: 21%
- 2010: 23%
- 2011: 28%

Note: ART coverage from previous years has been recalculated based on new estimates
Source: UNAIDS, Together We Will End AIDS, 2012
Implementation: what’s next?
Global Plan: Oversight Structure

GSG
UNAIDS and PEPFAR

GST Support Team

TA requests
Data requests

Resource & advocacy requests

High-level advocacy, resource mobilization, etc.

Countries

GSG POC

Country TWG & MOH

Data reports
TA tracking

Normative guidance

TA requests
M&E data

IATT
UNICEF and WHO

IATT Secretariat
MNCH Delivery Platform: Summary of bottlenecks Analysis, UNICEF 2012

% coverage (Country in East Africa)
Challenges and bottlenecks to reach the eMTCT targets!

**SUPPLY**
- Regimen choice and supply management
- Limited HR Capacity
- Limited lab capacity
- Loss to follow up
- Low quality of care

**DEMAND/ENABLING ENVIRONMENT**
- User Fees
- Limited community awareness & involvement
- Socio-cultural, economic barriers & beliefs
- High dropout rates

**OVERARCHING**
- M&E system
- Policy constraints
- Fragmented management & Coordination
- Budgetary constraints
Innovations to achieve EMTCT

✓ **Simplification of guidance** – moving from Option A/B to immediate treatment of all pregnant women living with HIV (B+)

✓ **Engaging men** – couples testing guidance; male engagement review

✓ **Point of care diagnosis** (CD4, EID, Vital load)

✓ **Mobile phone technology (SMS)** for transmission of results, clinic visit reminders and promoting adherence

✓ **Innovations in delivery of ARVs and incentives for seeking care, e.g. co-packaging**

✓ **Novel approaches that simplify services and integrate HIV and MNCH at the primary level of care**

✓ **Scaling up community-based approaches** to demand creation and service delivery

✓ **Innovative financing and social protection** approaches to ensure access

✓ **Bottleneck analyses tools** for planning and tracking progress
Current WHO guidelines for PMTCT and infant feeding (2010 and 2012 Update)

ANTENATAL
Early | Late
--- | ---
Pregnancy 10-25% 

Labor & Delivery 35-40%

POSTPARTUM
Early | Late
--- | ---
Breastfeeding 35-40%

<28 weeks | > 28 weeks
--- | ---
0-1 mo | 1-6 mos | 6-24 mos

Maternal therapeutic ART (AZT/TDF + 3TC/FTC +NVP/EFV)

AZT + Sd-NVP | Daily Infant NVP | Option A
--- | --- | ---
Maternal ART prophylaxis (AZT+3TC+LPV/r or EFV or ABC) | | Option B
Maternal ART for life (TDF/3TC/EFV) | | Option B+

Source: 1. WHO 2010 PMTCT Guidelines
2. WHO Programmatic Update 2012
<table>
<thead>
<tr>
<th>Country</th>
<th>Option A</th>
<th>Option B</th>
<th>High level Discussions</th>
<th>MOH approved</th>
<th>Implemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angola</td>
<td></td>
<td>Cote d'Ivoire</td>
<td>Zambia</td>
<td>Uganda</td>
<td>Malawi</td>
</tr>
<tr>
<td>Cameroon</td>
<td></td>
<td>Botswana</td>
<td>South Africa</td>
<td>Namibia</td>
<td></td>
</tr>
<tr>
<td>Chad</td>
<td></td>
<td>Burundi</td>
<td>Mozambique</td>
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<tr>
<td>Ethiopia</td>
<td></td>
<td>India</td>
<td>Kenya</td>
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<tr>
<td>Ghana</td>
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<tr>
<td>Lesotho</td>
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<tr>
<td>Swaziland</td>
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<tr>
<td>Tanzania</td>
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<tr>
<td>Zimbabwe</td>
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<tr>
<td>DRC*</td>
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</tr>
<tr>
<td>Nigeria*</td>
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</tbody>
</table>

* Piloting Option B in some regions
Main PMTCT regimens option B (number of patients = 4591)

- AZT+3TC+LPV/r: 48 (7
- AZT+3TC+NVP: 32 (6
- AZT+3TC+EFV: 4 (3
- ABC+3TC+LPV/r: 3 (2
- ABC+AZT+LPV/r: 2 (1
- Others: 10

WHO ART survey, 2011
Among HIV+ pregnant women who meet ART eligibility criteria, the majority receive AZT or D4T/3TC/NVP.
Option B+ Benefits

- Reduced infant HIV infection
- Increased maternal life expectancy
- Reduced transmission HIV negative male sexual partners

Malawi rationale

- HIV test the only condition for ART initiation... *allows for decentralisation* to lower level facilities
- Simple standard regimen for all, *one pill once a day*
- Clear public health message, *ART is for life*
- Avoidance of start, stop, start approach in a country with high fertility
- Makes breast feeding safe, single *breastfeeding message*
- Keeps mothers alive and healthy
- Prevents sexual transmission
Fundamental shift in thinking in delivery of PMTCT services

Before: Prevent mom from transmitting HIV to infant

Now: Entry point to chronic HIV care and treatment from which mom, infant, and partner benefit

SD-NVP (L&D)

Short course AZT from 36 weeks (ANC + L&D, postnatal tail)

Option A or Option B from 14 weeks (ANC, L&D, postpartum through the breast feeding period)

PMTCT = Maternal treatment + Maternal infant follow-up?

(overlapping treatment and MNCH continuum)
Different Cohorts Across Multiple Time Periods and Locations

- PREGNANCY COHORT FOR HIV+ PREGNANT WOMEN
  - Pregnancy – HIV Test – ARV – Birth -- BF

- ART COHORT FOR HIV+ PREGNANT WOMEN
  - ART Initiation --- Retention

- BIRTH COHORT FOR HIV EXPOSED INFANTS
  - Birth – BF -- ARV-- EID--- ART

- ART COHORT FOR HIV+ INFANTS
  - ART Initiation – Retention
Comprehensive MCH Services

Integrated MCH Service

Antenatal care
HIV testing
HIV Maternal ARV Prophylaxis
Maternity
Newborn Prophylaxis
Immunizations

HIV care and support
CD4 cell count testing
Antiretroviral therapy
Long term follow-up

Community
# Decision-Making Tools to Compare Effectiveness of Option A, B and B+

<table>
<thead>
<tr>
<th>Tool</th>
<th>Purpose</th>
<th>Key Components</th>
</tr>
</thead>
</table>
| 2010 WHO PMTCT ARV Guidelines and 2012 PMTCT Programmatic Update | Outlines changes and current thinking on ARVs for pregnant women as more countries adopt Option B/B+                                                                                                         | • Simplify and integrate PMTCT and ART programs  
Boy operational and programmatic advantages of Option B/B+  
• Assess country experiences to add to body of evidence |
| Business Case for Option B/B+ (UNICEF, BLC and CHAI)      | Presents results from cost-benefit analysis of Option A compared to Option B and Option B+                                                                                                             | Option B+ shows potential long-term cost savings and public health benefits:  
• Less cases of Peds HIV  
• ↓ transmission among serodiscordant couples  
• Secondary and tertiary care for HIV associated morbidity  
• Step by step guidance on what is needed to make it work |
| Key considerations guidance (UNICEF)                      |                                                                                                                                                                                                      |                                                                                                                                                  |
## Decision-Making Tools to Compare Effectiveness of Option A, B and B+

<table>
<thead>
<tr>
<th>Tool</th>
<th>Purpose</th>
<th>Key Components</th>
</tr>
</thead>
</table>
| Readiness Assessment Tool (PEPFAR)        | Key criteria and questions to assess health system readiness for move to Option B/B+ and guide national level decision-making process | • Political Commitment  
• Financial Considerations  
• Regimen Choice  
• Supply Chain  
• Human Resources  
• Community Involvement  
• M&E  
• Quality Management  
• Decentralization/Scale-up  
• Lab  
• Adherence Preparation  
• Retention  
• EID  
• Reproductive Health |
| Site Capacity Profile (EGPAF)              | Scores capacity of health facility to provide quality HIV services across 13 key areas | • Implemented in facilities in Côte d’Ivoire, Mozambique, Tanzania, and Zambia |

Percentage of HIV infected children in need receiving ART (2011)

- Chad: 8%
- Cameroon: 13%
- Nigeria: 13%
- United Republic of Tanzania: 14%
- Burundi: 14%
- Nigeria: 13%
- Cameroon: 13%
- Chad: 8%
Trends in pediatric age distribution at ART initiation (2005-2010)

DNA HIV Testing of HIV exposed infants at 6-8 weeks of age (2010)

- In 2010, 65 countries provided data up from 54 countries in 2009 and

- 28% (24% – 30%) of infants were reported to have been tested for HIV with DNA PCR within the first two months of birth, compared to 6% [5%- 7%] in 2009.

Source: UNAIDS. Together we will end AIDS. 2012
Overview of Early-Infant Diagnosis (EID)

- Survival rates for HIV+ children who do not initiate ART -

Over 40%

DNA PCR

Rapid Test

Survival rates for HIV-positive children who do not initiate ART
CHER: 76% Reduction in the Risk of Death with Immediate (Arms 2 & 3) Compared to Deferred (Arm 1) HAART

Most deaths occurred within first 6 months (i.e., before age 10 months)

Patients at risk

<table>
<thead>
<tr>
<th>Time to Death (months)</th>
<th>Month 0</th>
<th>Month 3</th>
<th>Month 6</th>
<th>Month 9</th>
<th>Month 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm 1</td>
<td>125</td>
<td>104</td>
<td>72</td>
<td>44</td>
<td>22</td>
</tr>
<tr>
<td>Arm 2 &amp; Arm 3</td>
<td>252</td>
<td>213</td>
<td>145</td>
<td>99</td>
<td>52</td>
</tr>
</tbody>
</table>

P = 0.0002
# Paediatric HIV treatment Recommendations

**WHO 2010**

<table>
<thead>
<tr>
<th>Adults</th>
<th>Children</th>
<th>RCT Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>When to start</td>
<td>&quot;Test &amp; Treat&quot; all infants (up to age 2 years) irrespective of CD4 or clinical stage</td>
<td>CHER</td>
</tr>
<tr>
<td>&lt;350 CD4 cells or WHO clinical stage 3/4</td>
<td>Early HIV diagnosis and early ART reduced early infant mortality by 76% and disease progression by 75%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What to start with</th>
<th>In children &lt;2 years who are exposed to NNRTIs during PMTCT, use 2 NRTIs plus LPVr as first line ART</th>
<th>P1060 Cohort 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use 2NRTIs plus an NNRTI as first line</td>
<td>In young children &lt;3 years exposed to sdNVP for PMTCT, starting ART with a NVP-based regimen resulted in twice as much failure as PI-based therapy</td>
<td></td>
</tr>
</tbody>
</table>
Viral Load and EID Product Pipeline

- Liat
- Alere NAT
- SAMBA VL
- NWGHF EID
- WAVE 80 EOSCAPE
- NWGHF VL
- SAMBA EID
- CAVIDI AMP
- Gene Xpert
- Micronics
- Biohelix
- Lumora

* Estimated — timeline and sequence may change

Pediatric Antiretrovirals: simplified dosing formats and analysing their adverse events

CHAPAS-1 trial
PK sub-study 2007 → FDA licensing

CHAPAS-2
LPV/r liquid vs tablets vs sprinkles PK study

CHAPAS-3
Looking at specific toxicities in children

d4T vs AZT vs ABC

Source: Dr Gibb for the Chapas Trials
Main first line regimens among children (number of patients = 370651)

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Frequency (%)</th>
<th>Number of countries with the regimen (n=41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>d4T+3TC+NVP</td>
<td>34.9</td>
<td>31</td>
</tr>
<tr>
<td>AZT+3TC+NVP</td>
<td>20.7</td>
<td>39</td>
</tr>
<tr>
<td>d4T+3TC+EFV</td>
<td>15.6</td>
<td>30</td>
</tr>
<tr>
<td>AZT+3TC+EFV</td>
<td>7.2</td>
<td>36</td>
</tr>
<tr>
<td>3TC+ABC+EFV</td>
<td>6.6</td>
<td>10</td>
</tr>
<tr>
<td>3TC+d4T+LPV/r</td>
<td>5.9</td>
<td>10</td>
</tr>
<tr>
<td>Others</td>
<td>9.0</td>
<td></td>
</tr>
</tbody>
</table>

WHO ART survey, 2011
**IATT optimized paediatric ARV list for programme procurement**

<table>
<thead>
<tr>
<th>Optimal</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Optimal</strong></td>
<td></td>
</tr>
<tr>
<td>ABC+3TC – Abacavir (60mg) + Lamivudine (30mg) DISPERSIBLE SCORED FDC TAB</td>
<td></td>
</tr>
<tr>
<td>AZT+3TC+NVP – Zidovudine (60mg) + Lamivudine (30mg) + Nevirapine (50mg) DISPERSIBLE SCORED FDC TAB</td>
<td></td>
</tr>
<tr>
<td>AZT+3TC – Zidovudine (60mg) + Lamivudine (30mg) DISPERSIBLE SCORED FDC TAB</td>
<td></td>
</tr>
<tr>
<td>d4T+3TC+NVP – Stavudine (6mg) + Lamivudine (30mg) + Nevirapine (50mg) DISPERSIBLE SCORED FDC TAB</td>
<td></td>
</tr>
<tr>
<td>d4T+3TC – Stavudine (6mg) + Lamivudine (30mg) DISPERSIBLE SCORED FDC TAB</td>
<td></td>
</tr>
<tr>
<td>ABC – Abacavir (60mg) DISPERSIBLE SCORED TAB</td>
<td></td>
</tr>
<tr>
<td>DDI – Didanosine (125mg) EC CAP</td>
<td></td>
</tr>
<tr>
<td>DDI – Didanosine (200mg) EC CAP</td>
<td></td>
</tr>
<tr>
<td>DDI – Didanosine (25mg) BUFFERED CHEW TAB</td>
<td></td>
</tr>
<tr>
<td>EFV – Efavirenz (200mg) SCORED TAB</td>
<td></td>
</tr>
<tr>
<td>*LPV/r – Lopinavir/Ritonavir (80 + 20 mg /ml) FDC ORAL LIQUID</td>
<td></td>
</tr>
<tr>
<td>LPV/r – Lopinavir/Ritonavir (100/25mg) FDC TAB</td>
<td></td>
</tr>
<tr>
<td>NVP – Nevirapine (50 mg) DISPERSIBLE SCORED TAB</td>
<td></td>
</tr>
<tr>
<td>AZT – Zidovudine (50mg/5ml) ORAL LIQUID (use should be reserved for PMTCT only)</td>
<td></td>
</tr>
<tr>
<td>NVP – Nevirapine (50mg/5ml) ORAL LIQUID (use should be reserved for PMTCT only)</td>
<td></td>
</tr>
<tr>
<td><strong>Limited Use</strong></td>
<td></td>
</tr>
<tr>
<td>3TC – Lamivudine (50mg/5ml) ORAL LIQUID</td>
<td></td>
</tr>
<tr>
<td>ABC – Abacavir (20mg/ml) ORAL LIQUID</td>
<td></td>
</tr>
<tr>
<td>*d4T – Stavudine (1mg/ml) ORAL LIQUID</td>
<td></td>
</tr>
<tr>
<td>*ddl – Didanosine (2g or 4g) POWDER FOR ORAL SOLUTION (10mg /ml)</td>
<td></td>
</tr>
<tr>
<td>*RTV – Ritonavir (80 mg/ml) ORAL LIQUID</td>
<td></td>
</tr>
<tr>
<td>RTV – Ritonavir (100 mg) HEAT STABLE TAB</td>
<td></td>
</tr>
<tr>
<td>ATV – Atazanavir (100 mg) CAP</td>
<td></td>
</tr>
<tr>
<td>ATV – Atazanavir (150 mg) CAP</td>
<td></td>
</tr>
<tr>
<td>DRV – Darunavir (100mg/ml) ORAL LIQUID</td>
<td></td>
</tr>
<tr>
<td>DRV – Darunavir (75mg) TAB</td>
<td></td>
</tr>
<tr>
<td>DRV – Darunavir (150mg) TAB</td>
<td></td>
</tr>
<tr>
<td><strong>Non-Essential</strong></td>
<td></td>
</tr>
<tr>
<td>d4T/3TC – Stavudine (12mg) + Lamivudine (60mg) DISPERSIBLE FDC TAB</td>
<td></td>
</tr>
<tr>
<td>d4T/3TC/NVP – Stavudine (12mg) + Lamivudine (60mg) + Nevirapine (100mg) DISPERSIBLE FDC TAB</td>
<td></td>
</tr>
<tr>
<td>AZT – Zidovudine (100mg) CAP</td>
<td></td>
</tr>
<tr>
<td>AZT – Zidovudine (60mg) TAB</td>
<td></td>
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<tr>
<td>d4T – Stavudine (15mg) CAP</td>
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<tr>
<td>d4T – Stavudine (20mg) CAP</td>
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<tr>
<td>ddl – Didanosine (100mg) BUFFERED TAB</td>
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<tr>
<td>ddl – Didanosine (200mg) BUFFERED TAB</td>
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<tr>
<td>ddl – Didanosine (50mg) BUFFERED TAB</td>
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<tr>
<td>EFV – Efavirenz (30mg/ml) ORAL LIQUID</td>
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<tr>
<td>EFV – Efavirenz (50mg) TAB or CAP</td>
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<tr>
<td>EFV – Efavirenz (100mg) CAP</td>
<td></td>
</tr>
<tr>
<td>EFV – Efavirenz (200mg) NON-SCORED TAB or CAP</td>
<td></td>
</tr>
<tr>
<td>fAMP – Fosamprenavir 50mg/mL SUSPENSION</td>
<td></td>
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<tr>
<td>TIP – Tipranavir 100mg/mL SOLUTION</td>
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</tbody>
</table>

*Formulation requires cold-chain for transport and or storage in the home and is not adapted for resource limited settings where refrigeration is not available
Proposed Recommendations on dosing and ratios for ATV/r and DRV/r formulations for children

1. Pending approval of ATV/r in younger children, the PAWG recommended the development of a FDC for children containing ATV 100mg and RTV 33mg – a 1/3 strength adult tablet.

2. Pending approval of DRV/r in younger children, the PAWG recommended the development of a FDC for children containing DRV 240mg and RTV 40mg.

3. These ratios and dosing approaches should be validated in paediatric PK studies.

Proposed Recommendations on NVP lead-in dosing in young children

1. Recommend full dosing NVP as an alternative to lead-in dosing in children under 3 years of age starting NVP-based treatment

2. Review results of P1103 as soon as these are available to determine the strength of these recommendations.

3. In the interim, recommend further viral load and PK studies on CHAPAS 1 stored samples.

Proposed Recommendations around TDF FDC formulations for children

1. Develop dual TDF/3TC FDC for paediatric use – either by scoring adult tablets if feasible or by manufacturing a child specific tablet containing TDF 75mg and 3TC 75mg (1/4 scale down of adult).

2. Develop triple TDF/3TC/EFV FDC for paediatric use – either by scoring adult tablets if feasible or by manufacturing a child-specific tablet containing TDF 75mg and 3TC 75mg EFV 150mg (1/4 scale down of adult).

3. Develop dual TDF/FTC FDC for paediatric use by manufacturing a child specific tablet containing TDF 75mg and FTC 60mg (this is not a scale down of the adult formulation).

4. Develop triple TDF/FTC/EFV FDC for paediatric use by manufacturing a child specific tablet containing TDF 75mg FTC 60mg and EFV 150mg (this is not a scale down of the adult formulation).

Proposed Recommendations around LPVr formulations for children

1. When regulatory approval for LPV/r sprinkles is obtained - advocate for programmes to replace syrup with sprinkles.

2. Dosing schedule proposed for LPV/r sprinkles outlined in table 1 and will be confirmed by the results of CHAPAS 2.
Pediatric advocacy toolkit: For improved pediatric HIV diagnosis, care and treatment in high HIV prevalence countries and regions
d4T use in 1st line has been progressively phasing out...

Fast d4T phase out*:
✓ Kenya ↓21%
✓ Mozambique ↓91%
✓ South Africa ↓51%
✓ Swaziland ↓33%
✓ Uganda ↓89%
✓ Ukraine ↓25%
✓ Vietnam ↓20%

Slow d4T phase out*:
✓ Cameroon ↓10%
✓ China ↓10%
✓ Ethiopia ↓6%
✓ Malawi ↓2%
✓ PNG ↓7%
✓ Tanzania ↓13%
✓ Zimbabwe ↓2%

* Reduction rate during the 2009-2010 period

WHO ARV survey, 2011
Conclusion: Future Direction

- Innovations to simplify regimen platforms and technologic and programmatic approaches to allow integration of PMTCT/ART in maternal child health services at the lowest levels of care

- Innovations to expand early HIV testing and treatment of infants before 2 months of age

- Find new ways to collaborate with community groups and structures to enhance support to women and their families to maintain good adherence and retention in care and treatment
Thank you