Achieving the 3rd 90 in PEPFAR-supported countries: What will it take? Is it enough?

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Division of Global HIV and TB
Centers for Disease Control and Prevention

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Disclosures

- I work for CDC but PEPFAR pays my salary
What is the Global Goal for HIV?

The HIV/AIDS SDG Goal: Control the HIV Pandemic by 2030
90/90/90 by 2020 and 95/95/95 by 2030

The global strategy to achieve these objectives:
FAST TRACK STRATEGY

PEPFAR’s role is to support the above in the most effective and efficient manner possible to ensure the above can be sustained
Defining Epidemic Control
Global elimination goals

- Reduce annual new infections to 500,000 (incidence <1%) by 2020 and to 200,000 (incidence < 0.5%) by 2030.
  - 2020: 90-90-90 (73% viral suppression)
  - 2030: 95-95-95 (86% viral suppression)
KEY 2020 Fast Track Targets

90% of which Aware of their HIV status

90% of which On HIV treatment

90% Virally suppressed

30 million people on treatment

Fewer than 500,000 new HIV infections annually

Source: UNAIDS data 2017
The impact of Fast-Track

New HIV infections in low- and middle-income countries

AIDS-related deaths in low- and middle-income countries

- **Business as usual (no scale-up)**
- **Fast-Track results (rapid scale-up)**
Cote D’Ivoire

41% HIV Treatment Coverage

Source: AIDSINFO, UNAIDS 2017
Malawi

66% HIV Treatment Coverage

Source: AIDSINFO, UNAIDS 2017
Achieving Epidemic Control
Progress toward 90/90/90 in Adults

Figure 1 — Progress to 90-90-90 in Adults

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Age Groups (years)
- Aware of HIV Status
- Treated
- Virally Suppressed
Achieving Epidemic Control
Progress toward 90/90/90 in Adults

Figure 1 – Progress to 90-90-90 in Adults

- Swaziland: 15+ (2016)
  - Aware of HIV Status: 85%
  - Treated: 87%
  - Virally Suppressed: 92%
- Lesotho: 15-59 (2017)
  - Aware of HIV Status: 77%
  - Treated: 90%
  - Virally Suppressed: 88%
- Zimbabwe: 15-64 (2015)
  - Aware of HIV Status: 74%
  - Treated: 87%
  - Virally Suppressed: 86%
- Malawi: 15-64 (2015)
  - Aware of HIV Status: 73%
  - Treated: 89%
  - Virally Suppressed: 91%
- Zambia: 15-64 (2015)
  - Aware of HIV Status: 67%
  - Treated: 85%
  - Virally Suppressed: 89%
- Uganda: 15-64 (2017)
  - Aware of HIV Status: 66%
  - Treated: 88%
  - Virally Suppressed: 83%
- Tanzania: 15-64 (2017)
  - Aware of HIV Status: 52%
  - Treated: 91%
  - Virally Suppressed: 88%
Eswatini (Swaziland): Close to 90-90-90 yet incidence at 1.36%
What’s driving incidence?
Eswatini viral suppression by age bands
What’s driving incidence?
Or is the 3rd 90 inadequate to reduce incidence towards epidemic control levels?

3rd 95
(86% viral suppression)
### Viral load suppression at the community level after 15 years

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<th>Aged 15-64</th>
<th>Aged 15-24</th>
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<tr>
<td><strong>Swaziland</strong></td>
<td>68%</td>
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Viral Load Suppression among PEPFAR OUs by Age

Overall 95% Target Suppression
Namibia PHIA results

NAMPHIA key preliminary findings (ARV-adjusted estimates) among adults ages 15 to 64:

- **HIV incidence**: 0.36% (Women 15-24: 0.99%)
- **HIV prevalence**: 12.6%
  (1.0% for children ages 0 to 14)
- **Viral load suppression**: 77.4%
- **90-90-90**: 86.0% of PLHIV ages 15 to 64 in Namibia report knowing their status, 96.4% of those individuals self-report being on ART, and 91.3% of that group are virally suppressed

Source: https://phia.icap.columbia.edu/countries/namibia/
PEPFAR Strategy for achieving epidemic control

- 90-90-90 cascades targeted by sex and 5 year age bands
- Focus efforts on populations with greatest gaps:
  - Men
  - Younger women
  - <15 yo
- Maximize viral suppression among PLHIV successfully linked to ART initiation
  - ART optimization
  - Retention strategies
  - Increased access to routine viral load monitoring
PEPFAR: Remarkable Expansion of lifesaving services with flat budgets

Expansion through efficiencies

Expansion through 6-7B in pipeline

PEPFAR Bilateral Budget in $Millions
ACHIEVING THE THIRD 90
Achieving the 3rd 90: ART optimization

- Aggressive transition to Dolutegravir-containing fixed dose combinations
- TLD for the following populations:
  - 1st-line ART initiators (and re-initiators)
  - ART continuations with viral suppression (or unknown VL)
  - First-line ART failures
  - 2nd-line ART continuations
  - 2nd-line ART failures

Near universal use of a fixed dose combination with greatest tolerability and high barrier to development of resistance will achieve maximum population levels of viral suppression
## Safety and Efficacy of DTG and EFV600 in 1st line ART (summary 2018 WHO Sys Review & NMA)

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Reference: Steve Kanters, For WHO ARV GDG, 16-18 May 2018
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80-90 (per 1000) excess cases of non-viral suppression at 96 weeks predicted with EFV600

Reference: Steve Kanters, For WHO ARV GDG, 16-18 May 2018
1. A DTG based regimen may be recommended as a preferred first-line regimen for people living with HIV initiating ART *(conditional recommendation)*
   - Adults and adolescents *(moderate-certainty evidence)*
   - Women and adolescent girls of childbearing potential *(very-low-certainty evidence)*
   - Infants and children with approved DTG dosing *(low-certainty evidence)*
Achieving the 3rd 90: ART optimization

- Aggressive transition to Dolutegravir-containing fixed dose combinations
- TLD for the following populations:
  - 1st-line ART initiators (and re-initiators) ✓
  - ART continuations with viral suppression (or unknown VL) ✓
  - First-line ART failures ?
    - Rapid change to standard 2nd line with first VF
  - 2nd-line ART continuations ✓
  - 2nd-line ART failures ?
    - Consideration for third-line or switch back to standard PI-based 2nd-line with first VF
% of Adult ART Patients per Country on ARV Regimens, at the end of the COP18 TLD Transition (pre June, 2018 WHO/PEPFAR Revised Guidance)

- % on TLD
- % on TLE or TEE
- % on LNZ
- % on All other Regimens

- Based on submission of original TLD supply plans for PEPFAR work planning in February, 2018. Table does not include Ethiopia, Vietnam, or Uganda NMS, as supply plans for these programs were not submitted. Botswana was also excluded, given that their supply plan only includes current and future patients on DTG-based regimens.
As part of a program aimed to prevent mother-to-child transmission of HIV, outreach workers in Francistown, Botswana, staged a skit in a supermarket parking lot. MALCOLM LINTON

Troubling questions remain about whether a popular HIV drug causes birth defects

By Jon Cohen | Jul. 24, 2018, 6:15 PM
% of Adult ARV Patients per Country on ARV Regimen at the end of the COP 18 TLD Transition (per revised TLD Supply Plans, submitted in June/July 2018 – Post DTG Safety Notice)
Achieving the 3rd 90: ART optimization

- Reality Check: We are uncertain as to the true measure of NTD risk or even whether there is a risk of NTDs at all.
  - Many believe that this will be resolved early next year (release of data followed by updated WHO guidelines release) but prolonged uncertainty is quite likely.
  - Should we wait until next year or proceed despite the uncertainty?

- Two academic groups have modelled outcomes in women and children with implementation of DTG vs EFV-based ART in women of childbearing potential (Dugdale 2018; Phillips 2018).
  - Both models indicate that providing DTG-based ART for all HIV-positive women, including those of childbearing potential, resulted in lower mortality than providing them with EFV-based ART, and that the reduction in mortality significantly exceeded the potential increase in neonatal mortality should the increased risk of an NTD be confirmed.
Forum on the risks of preconception dolutegravir exposure

Supported by Grants from the Bill and Melinda Gates Foundation and the PENTA Foundation

FAQs for Dolutegravir & Women of Childbearing Potential: Interim Considerations
Proportion (%) of Individuals that initiated ART with DTG (2017) versus EFZ (2016-7) with VL<50 cp/mL since the begging of treatment: A real life observation

Source: Ricardo Diaz
Achieving the 3\textsuperscript{rd} 90: ART optimization

- Can we achieve the 3\textsuperscript{rd} 90 (or 95) in the absence of a single fixed dose regimen for >90% of PLHIV?
  - Are we entering an era of complicated algorithms along with increased informed patient choice?
    - What about regimen switches when suppressed/doing well?
    - Can our systems be capacitated to handle these layers of complexity in time?
- What should be the ideal approach to TLD in the era of uncertainty regarding risk?
  - For women of child-bearing age/potential:
    - Opt-out (TLD as default)
    - Opt-in (EFV as default)
- What is the role for TAF/L/D?
## 2018 WHO Guidelines Update - First line ART Regimens

### First line Regimens for Paediatric Populations

<table>
<thead>
<tr>
<th></th>
<th>Neonates</th>
<th>4 weeks – 6 years</th>
<th>6 – 10 years</th>
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</thead>
<tbody>
<tr>
<td><strong>Preferred</strong></td>
<td>AZT + 3TC + RAL(^1)</td>
<td>ABC + 3TC + DTG(^2)</td>
<td></td>
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<tr>
<td><strong>Alternative</strong></td>
<td>AZT + 3TC + NVP</td>
<td>ABC + 3TC + LPV/r</td>
<td>ABC + 3TC + RAL(^1)</td>
</tr>
<tr>
<td><strong>Special circumstances(^4)</strong></td>
<td>AZT + 3TC + LPV/r</td>
<td>ABC or AZT + 3TC + EFV(^3)</td>
<td>AZT + 3TC + NVP</td>
</tr>
</tbody>
</table>

\(^1\) For the shortest time possible until a solid formulation of LPV/r or DTG can be used

\(^2\) For age and weight groups with DTG-approved dosing

\(^3\) From 3 years of age

\(^4\) In cases where no other alternative is available
Instructions for administering RAL granules

Step 1: Get ready
Step 2: Fill a clean glass with water
Step 3: Fill the blue syringe with water
Step 4: Check for air bubbles
Step 5: Add the 10mL of water to the mixing cup
Step 6: Add ISENTRESS to the mixing cup
Step 7: Mix ISENTRESS and water
Step 8: Check your prescription
Step 9: Choose the syringe you need
Step 10: Measure ISENTRESS
Step 11: Check for air bubbles
Step 12: Give ISENTRESS to your child
Step 13: Clean up
Pediatric ARV market is small but complex

95 adult patients → All ages & weight bands → One pill, once-a-day

5 paediatric patients → Multiple ages and weight bands → Multiple formulations and regimens
Achieving the 3rd 90: ART optimization

- HIVDR surveillance in the era of TLD--key questions:
  - What is the pattern and prevalence of HIVDR when persons fail TLD?
    - 1st-line
    - 2nd-line
    - Adolescents with significant ART experience
  - What is the impact of pre-existing NRTI mutations when switching to TLD?
  - For countries hesitant to offer TLD to women who may become pregnant what is the prevalence of NNRTI resistance in that population?

- Sentinel cohorts vs. nationally representative data?
  - Sub-populations are important
  - Research cohort data is very useful!

- Avoid defining our response to the global threat of HIV drug resistance by the sources of the data but instead by the quality and utility of the data generated from all sources!
Achieving the 3rd 90: Retention Strategies

- Population friendly service delivery models
  - Men’s clinics
  - Evening and weekend clinic hours
  - Decreased frequency of clinic visits
  - Multi-month prescribing
  - Community-based drug distribution
  - Rapid tracing of defaulters
  - Adolescent-friendly services
Improving Adherence & Retention: Community Adherence and Support Groups in Mozambique

Ariel Adherence Clubs: Increasing Retention in Care and Adherence to Life-Saving Antiretroviral Therapy among Children and Adolescents Living with HIV in Tanzania

Improving Access to HIV Treatment Services through Community Antiretroviral Therapy Distribution Points in Uganda

Improving Patient Antiretroviral Therapy Retention through Community Adherence Groups in Zambia

Improving Retention and Viral Load Suppression Rates: Scale-Up of Adherence Clubs for Stable Antiretroviral Patients in Cape Town, South Africa

Source: https://www.pepfarsolutions.org
Achieving the 3rd 90: Retention Strategies

- New definition of TX_Curr (current on ART)
  - Patients who have not received ARVs within four weeks of their last missed drug pick-up should not be counted
- New indicator to track defaulters (TX_ML)
  - Number of ART patients with no clinical contact since their last expected contact
The graphic below describes the indicator flow in more detail:

1. Positive HIV Test
   - Initiation on life-long ART
     - ART Adherence and Retention
       - Maintain Viral Load Suppression

2. Patient Tracing
   - Attempt to contact patient via phone or SMS
     - Attempt to locate patient at home or in the community
       - Patient with no clinical contact since their last expected contact
         - Routine data review meetings at the district-level

3. Patient Outcome Determined to be:
   - Died
   - Undocumented "Silent" Transfer
   - Attempted to trace patient (unable to locate)
   - Did not attempt to trace patient
Achieving the 3rd 90: Increased access to viral load monitoring

- PEPFAR supports rapid viral load scale up to full coverage by the end of 2019 for most countries
  - Defined as ≥ 1 VL per person on ART per year
- Revised indicator for VL suppression
  - Greater emphasis on documentation of viral load result in the chart
  - Indicator now collected quarterly rather than annually
Viral Load Coverage

\[
VL \text{ eligible} = TX_{\text{CURR}} - (FY17Q3 \ TX_{\text{NEW}} + FY17Q4 \ TX_{\text{NEW}})
\]

<table>
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<tr>
<th>Country</th>
<th>FY17 TX_CURR</th>
<th>VL Eligible</th>
<th>FY17 TX_PVLS Result (D)</th>
<th>% VL Coverage Achieved</th>
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<td>Mozambique</td>
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*VL eligible = TX_CURR - (FY17Q3 TX_NEW + FY17Q4 TX_NEW)
# Viral Load Coverage and Suppression

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<tr>
<th>Country</th>
<th># of PLHIV</th>
<th>FY17 TX_CURR</th>
<th>VL Eligible</th>
<th>TX_PVLS, D</th>
<th>TX_PVLS, N</th>
<th>% Suppression</th>
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<th>95% Target Suppression</th>
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<td>Zambia</td>
<td>81%</td>
<td>75%</td>
<td>59%</td>
<td>49%</td>
<td>41%</td>
<td>41%</td>
<td>37%</td>
<td>85%</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>62%</td>
<td>75%</td>
<td>59%</td>
<td>49%</td>
<td>41%</td>
<td>41%</td>
<td>37%</td>
<td>85%</td>
</tr>
</tbody>
</table>

*VL eligible = TX_CURR - (FY17Q3 TX_NEW + FY17Q4 TX_NEW)
Viral Load Coverage and Suppression

**VL eligible** = TX_CURR - (FY17Q3 TX_NEW + FY17Q4 TX_NEW)

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*VL eligible = TX_CURR - (FY17Q3 TX_NEW + FY17Q4 TX_NEW)*
Sites targeted for intervention to improve viral suppression

9% of PEPFAR sites reported 100% TX_PVLS and 77% of PEPFAR sites reported TX_PVLS at ≥ 90%

Represents 44 sites. These sites will be targeted for improved viral suppression outcomes.
Challenges in viral suppression among children <15

27% of PEPFAR sites reported 100% TX_PVLS among peds but 59% reported TX_PVLS at < 90%
Challenges in viral suppression among young people 15-24 yrs

28% of PEPFAR sites reported 100% TX_PVLS among 15-24 year olds but 72% 15-24 were receiving care at sites with reported TX_PVLS at < 90%

Represents 104 sites. These sites will be targeted for improved viral suppression outcomes.
Viral load cascade-Uganda

- 89% of people on ART receiving VL test at 12 mo
- Only 21% of people with one VL >1000 receiving second VL

12% with VL >1000
- 21% with VL >1000
- 11% with NO 1st VL DONE
- 79% with first VL >1000 but NO 2nd VL DONE
- 50% with 2VL >1000 but NO Switch

Courtesy of Christine Watera, UVRI
Achieving the 3rd 90: More work to be done

- Improved approach to enhanced adherence monitoring
- Further study of impact of viremia clinics and other population-specific service delivery models
- Address the issue of LLV
- Strengthening supply chain
Effectiveness of Interventions for Unstable Patients on Antiretroviral Therapy in South Africa: Results of a Cluster Randomized Evaluation (Fox et al, Tropical Med Int Health, Oct 2018)

• Cluster randomized trial comparing EAC to standard of care
  – No impact of EAC on viral suppression noted at 12 months with extremely low uptake of 3 month repeat viral loads
Conclusions: 3rd 90

- Present levels of viral suppression, while certainly representing a remarkable achievement, are likely inadequate to have the desired impact on incidence in countries with high burdens of HIV infection
  - This reality must be considered when balancing the risks and benefits of treatment options for infants, children, adolescents and adults.

- To achieve 86% viral suppression among PLHIV (95-95-95) and thus true epidemic control, significant programmatic improvements guided by timely review of local data will need to take place over the next few years
  - Governments and their partners need to be the drivers of these improvements regardless of availability or source of needed resources
Acknowledgements

- PEPFAR ART optimization Short Term Task Team
- Colleagues at CDC Atlanta and country offices
- The Resistance Workshop Organizing Committee and the Southern African Clinician’s Society
- Ambassador Deborah Birx
Thank You!
We are poised to make the impossible possible