CTA Meeting on Paediatric ARVs

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Director
WHO HIV and Hepatitis Department
December 5th 2016
More than 80,000 children died of HIV in 2015.
We have committed with SUPER TRACK TARGETS!

Provide **1.6 million** children (aged 0–14) living with HIV with lifelong antiretroviral therapy by 2018.

[Reach 95% of all children living with HIV]
"Treat All" for children is happening

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Status</th>
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<tr>
<td>Recommend initiation threshold</td>
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<td>among children living with HIV in low- and</td>
<td></td>
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<td>middle-income and Fast-Track countries as per</td>
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<tr>
<td>MoH guidelines or directive (situation as of</td>
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<td>October 2016)</td>
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Map showing countries and regions with different initiation thresholds for children living with HIV, classified as follows:
- **Treat all**
- Recommending treat all later in 2016
- < 1 year
- < 2 years
- < 5 years (as per WHO 2013 guidelines)
- Other
- Data not reported

Fast-Track countries: 
- High-income countries
- Not applicable

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
Map Production: Information Evidence and Research (IER)
World Health Organization

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**BUT WE STILL NEED BETTER DRUGS**
Developing and delivering paediatric formulations through collaborative and coordinated action

Priority formulations are prioritised in the context of a public health approach.

Technical/research work is undertaken to support development of the priority formulations.

Priority formulations are included in optimal formulary for selection.

Priority formulations are reliably supplied to countries.

Priority formulations are procured via a pooled mechanism.
Developing and delivering paediatric formulations through collaborative and coordinated action

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LPVr 4-in-1: first line for under 3 years to address the lack of optimal formulations

**EFV triple:** first line 3-10 years to provide an FDC to maximise adherence and simplify procurement

**ATVr and DRVr:** use in 2\textsuperscript{nd} and 3\textsuperscript{rd} line formulations and overcome issue with separate administration of RTV

**NVP/AZT mg:** better dosage form to facilitate dosing for PnP

**RAL better formulation:** use in infants and young children to enable rapid introduction of INI for use in 1\textsuperscript{st} line regimen

**DTG single or FDCs:** identified as key drug to introduce INI in first line with potential for harmonisation across the full age spectrum

**TAF:** key drug for future use in 1\textsuperscript{st} line to minimise toxicity with potential for harmonization across the full age spectrum
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Paediatric HIV Treatment Initiative (PHTI)
But we need to be **FASTER**, **MORE EFFICIENT** and find **MORE SUSTAINABLE** ways to do this in the future!!
Paeds Drug Optimization

Key consultations have advanced the discussion on drug and formulations development for children and resulted in a more collaborative and coordinated action.

- Paediatric Conference on antiretroviral drug optimization 1 (PADO1)
- PHTI launch
- WHO 2013 Guidelines
- Paediatric Week 1:
  - PADO 2
  - PHTI
  - IATT
  - PAPWG
- PHTI stakeholders meeting
- 1st ILF roundtable
- 2nd ILF roundtable
- WHO Guidelines revised
- PADO2 list reviewed (no major changes)
- 3rd ILF roundtable
- CTA/ILF Meeting on Fast-tracking development of paediatric formulations
Evolving dialogue

• CTA bottle neck analysis highlighted in 2015 the need to think about alternative financing mechanisms
• EMA meeting on paediatric ARV formulations
• ILF roundtable (kick-off the conversation)
• High level meetings convened by Holy See promoted a closer collaboration with industry
• Bilateral conversations between CTA partners and
  – Regulators
  – Research networks
  – Industry
• CTA/ILF roundtable (Durban 2016)
The Global accelerator for Paediatric formulations

FAST-TRACKING DEVELOPMENT OF PAEDIATRIC ARVS

By Dr. Martina Penazzato
HIV Paediatric Advisor
HIV Department - WHO Geneva
The Global accelerator for Paediatric formulations

This is NOT a new initiative!

The Global accelerator is a collaboration framework supported by innovative financing mechanisms to fast track development of paediatric formulations.

This collaboration framework builds on existing efforts and aims to promote a faster, more efficient and more focused approach to paediatric formulation development.
Have a good meeting!