Overcoming Barriers and Identifying Solutions to Improve Access to Optimal Drugs in Resource-Limited Settings

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Children (<15 years) estimated to be living with HIV  |  2012

Total: 3.3 million [3.0 million – 3.7 million]

New HIV infections in 2012  260 000 [230 000 – 320 000]
Deaths due to AIDS in 2012  210 000 [190 000 – 250 000]
Paediatric ART

630,000 children received ART in 2012

Gap between need and coverage

(WHO, Global Report 2013)
Global evolution of main 1st line ART combinations (2006-2013) *

Evolution of the main children first line regimens, 2006-2012

*12 countries which have been followed since 2006 and have complete report in all years: Burkina Faso, Burundi, Cambodia, Cameroun, Ethiopia, Kenya, Lesotho, Namibia, Nigeria, Uganda, Zambia, and Zimbabwe
Evolution of main 2nd line combinations (2007-2013)*

*12 countries which have been followed since 2006 and have complete report in all years: Burkina Faso, Burundi, Cambodia, Cameroun, Ethiopia, Kenya, Lesotho, Namibia, Nigeria, Uganda, Zambia, and Zimbabwe.

Evolution of the main children second line regimens, 2006-2013

- ABC+3TC+LPV/r
- AZT+ddI+LPV/r
- ABC+ddI+LPV/R
- AZT+3TC+LPV/r
- AZT+ddI+EFV
- d4T+3TC+LPV/r
- TDF+3TC+LPV/r
- AZT+ABC+3TC+LPV/r
- AZT+ABC+3TC+LPV/r
- d4T+3TC+ABC
Challenges of paediatric ARV development and delivery

**Technical**
Safe, Potent, Palatable, Child-friendly, Heat-stable, Fixed-Dose Combinations

**Programmatic**
Forecast, Supply chain and Procurement

**Financial**
Small and fragmented Market
Return of Investment?
HOW to optimize paediatric ARVs and better shape the market?

- **PADO**
  - New drugs *mid and long* priorities
  - New formulations

- **EOI**
  - New drugs *short and mid* priorities
  - New formulations

- **Guidelines**
  - Existing drugs
  - Existing formulations

- **IATT formulary**
  - Optimized formulations for procurement
  - Minimum number of products to build regimens recommended by Guidelines

- **PAPWG**
  - Coordinated procurement of paediatric ARV
Industry perspective

- Developing FDCs are technically difficult
- Industry are often excluded from discussions
- Procurement is fragmented and better coordinated procurement is needed
- No reliable forecasts on paediatric needs and demands, with information about age range
- Lack of direction on desired paediatric profile (regimens, combinations, formulations)
- Industry are often excluded from discussions
- Information about target price would be valuable
So...what do we need to make this happen?

- Technical Barriers
- Programmatic Barriers
- Financial Barriers
Objectives

- Provide an overview of ongoing global efforts to address challenges in paediatric ARV development and delivery
- Initiate a dialogue with paediatric ARV manufacturers and partners on these efforts, and explore innovative solutions to address barriers
Agenda

09:00 – 09:30  Welcome and roundtable introduction  
Co-chairs: Shirin Heidari (IAS) and Martina Penazzato (WHO)

09:30 – 09:40  New paediatric treatment recommendations  
Martina Penazzato (WHO)

09:40 – 09:45  Q & A

09:45 – 09:55  IATT optimal paediatric formulary  
Marianne Gauval (CHAI)

09:55 – 10:00  Q & A

10:00 – 10:10  Paediatric ARV Procurement Working Group (PAPWG)  
Martin Auton (Global Fund)

10:10 – 10:15  Q & A

10:15 – 10:25  Overview of the Paediatric ARV Optimization Meeting  
Martina Penazzato (WHO)

10:25 – 10:30  Q & A

10:30 – 11:00  Break

11:00 – 12:50  Discussion on creative solutions to overcome barriers to development and delivery of optimal paediatric ARV formulations  
• What are the bottlenecks with paediatric ARVs?  
• What are some solutions to these bottlenecks?  
Facilitator: Shaffiq Essajee (CHAI)

12:50 – 13:00  Summary and closing  
Co-chairs: Shirin Heidari (IAS) and Martina Penazzato (WHO)