REVIEW OF COMMITMENTS ON HIV DIAGNOSTICS AND MEDICINES

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WHERE ARE WE?
2016-2020 strategy had two commitments for children: We missed them both
Peak of mortality of untreated, HIV-infected infants

- Mortality of untreated, in utero-HIV-infected infants peaks at two to three months of age.
- Approximately 35% die by 12 months of age and 52% by 24 months of age.

- 60% of HIV-exposed infants received an infant test within the first two months of age in 2019.
- Only 53% of HIV-positive children under 15 years of age were put on antiretroviral treatment in 2019.

Source: Bourne AIDS 2009
Improved identification and monitoring through collaboration

- More efficient case-finding
- Increased funding and commitment
- Streamlined regulatory
- Integrated diagnostic systems
- Better, more transparent pricing

Overall needs for collaboration on diagnostics and case-finding
High-level diagnostic solutions

- Consistent, transparent pricing
- All-inclusive pricing
- Clinical indeterminate range
- Service level agreements
- Support procurement and operations
- Support competitive, healthy market
- R&D

Suppliers

- Integrated, efficient system
- Multiplex technologies
- Streamline regulatory
- Enhanced case-finding
- Case finding and scale-up

Countries and partners

- Community/Civil Society
- Support national regulatory agencies
- Guidelines, PQ, regulation
- Post-market surveillance guidance
- Additional guidance for key interventions

Donors

WHO
Diagnostics Summary

• **R&D**
  • Better, more transparent, consistent all-inclusive pricing to increase access

• **Regulatory**
  • Prioritize fast track national regulatory approvals
  • Extend development of CRP schemes to expedite regulatory approvals

• **Case Finding**
  • Scale up appropriate infant diagnostic technologies, through system mapping and integration
  • Prioritize effective, evidence-based case finding strategies

*Sustained funding, strong leadership, and effective coordination is necessary for all components*
ART Coverage and Viral load suppression far behind adults

• Use of index family tracing among adults on treatment to get all CLHIV on ART

• Better regimens needed for VLS
Treatment R&D -- Focus on what’s next

NORMATIVE UPDATES
Revision of global guidelines, EOI and EML to fully reflect new approvals and changing landscape

ACCELERATION ON PRIORITY PRODUCTS
A number of priority products in the PADO list have been falling behind and require acceleration.

ACTION on PROMISING ARVs
Apply key principles for acceleration to new ARVs in the pipeline.

NEW PAEDS TECHNOLOGIES
Investigate and match new technologies with existing gaps.

WHO, GAP-f partners

IMPAACT, Unitaid, CHAI, MSD, Gilead

Unitaid, CHAI, Gilead, IMPAACT

Unitaid, PENTA, IMPAACT, CHAI, Gilead, J&J, Aurobindo, Mylan, MacLeod
PROACTIVELY PLANNING FOR CHANGE to INTRODUCE & SCALE-UP NEW PRODUCTS

“Yes, introduction of new products has historically taken time and availability has been a problem but it doesn’t have to be that way.”

1. NEW OPTIONS AVAILABLE
   Pediatric DTG anticipated to be available in 2021. Timeline for 4-in-1 (ABC/3TC/LPV/r) and 3-in-1 (ABC/3TC/DTG) is to be confirmed.

2. CURRENT STATUS OF OPTIMIZATION
   Ongoing optimization efforts should not be delayed because better products are anticipated.

3. TRANSITION PLANS
   Transition plans should include pediatric DTG for ALL children. Initial prioritization may include CLHIV new on treatment or failing current regimens. Right-sizing stock/order volume of pediatric LPV/r should start now.

4. TOXICITY MONITORING
   Set up active toxicity monitoring to ensure we scale up safely new products, without becoming a barrier to rapid implementation.

“Each country will need to develop a national transition plan which is tailored to the context and capacity of the HIV programme but the goal should be the same: get better formulations to children and their families.”
Reliance-based facilitated pathways

- Encourage use of the WHO and SRA Collaborative registration procedures, CRP-lite piloted for 2 products
- Make better use of sub-regional collaborative regulatory approval processes
- Target countries NRA to participate in SRA assessment (e.g. EU Art. 58, Swissmedic MAGHP)
- Submission in parallel to target countries and SRA (e.g. dolutegravir 5 mg)
- NRAs and WHO PQ to prioritize review/expedited review for the key paediatric HIV and TB Medicines (as per PADO/EOI lists)
- Make best use of available data, end requirements for local clinical trials when sufficient PK and safety data exists
### HOW TO DO MORE TOGETHER (1/2)

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<th>Best Practices</th>
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| **National Governments, including Ministries of Health and Regulatory Authorities** | - Streamline the regulatory process for pediatric DTG, including timely product registration  
- Accept WHO guidance and swiftly update national pediatric HIV treatment guidelines to allow for the use of DTG in CLHIV who are 4+ weeks of age and weigh 3+ kilograms  
- Carefully forecast anticipated need of pediatric DTG and adjust orders of pediatric LPV/r accordingly |
| **WHO**                                                                 | - Provide additional guidance and support implementation on post-market surveillance and quality assurance to manufacturers, countries, and national regulatory authorities. |
| **Manufacturers**                                                       | - Foster transparent communication with major buyers as to pediatric ARV production volumes and timelines of pediatric DTG and other critical pediatric ARV products  
- Rapidly communicate stock shortages with major buyers and work on joint mitigation strategies. |
## HOW TO DO MORE TOGETHER (2/2)

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<td><strong>Donors</strong></td>
<td>• evaluation or implementation studies <strong>NOT a barrier to timely uptake of pediatric DTG</strong></td>
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| **Implementing Partners**        | • **Support demand creation for optimal pediatric treatment regimens**  
                                        • Support the **prompt role out of pediatric DTG**  
                                        • Tackle the **stigma and discrimination** in  
                                        • Advocate for the **elimination of user fees** from  
                                        • Deliver through **new models like DSD**                                                                                                             |
| **Faith Based Organizations**    | • **Collaborate and coordinate community mobilization, education and outreach**  
                                        • Provide **health, social & spiritual support services** and integrate into the national system.                                                                                       |
| **Civil Society and Community**  | • **Throughout all areas of the collaborative work**                                                                                                                                                           |
What are the next steps?

- Vatican working group will send back a clean version of the commitments to you COB Monday 9th Nov

- Request that all your comments and updates for inclusions are returned by COB Friday 13th Nov

Why?

- Plan to release the updated 2020 Vatican Action Plan on World Children’s Day – 20 November
THANK YOU
NOW IT’S TIME TO ACT!

• **95,000 AIDS-related deaths** among children in 2019.
  • Two-thirds of those deaths were in 21 focus countries

• **850,000 children living with HIV not accessing treatment**,
  • 65% are ages 5-14 years

• **COVID-19** adds another challenge
  • ACCELERATE mitigation strategies and innovation!

• **Faith partners** (religious leaders and faith-based organizations) remain CRITICAL VOICES AND ACTORS FOR CHILDREN in the HIV response,