

Therapeutics Scientific Committee Meeting



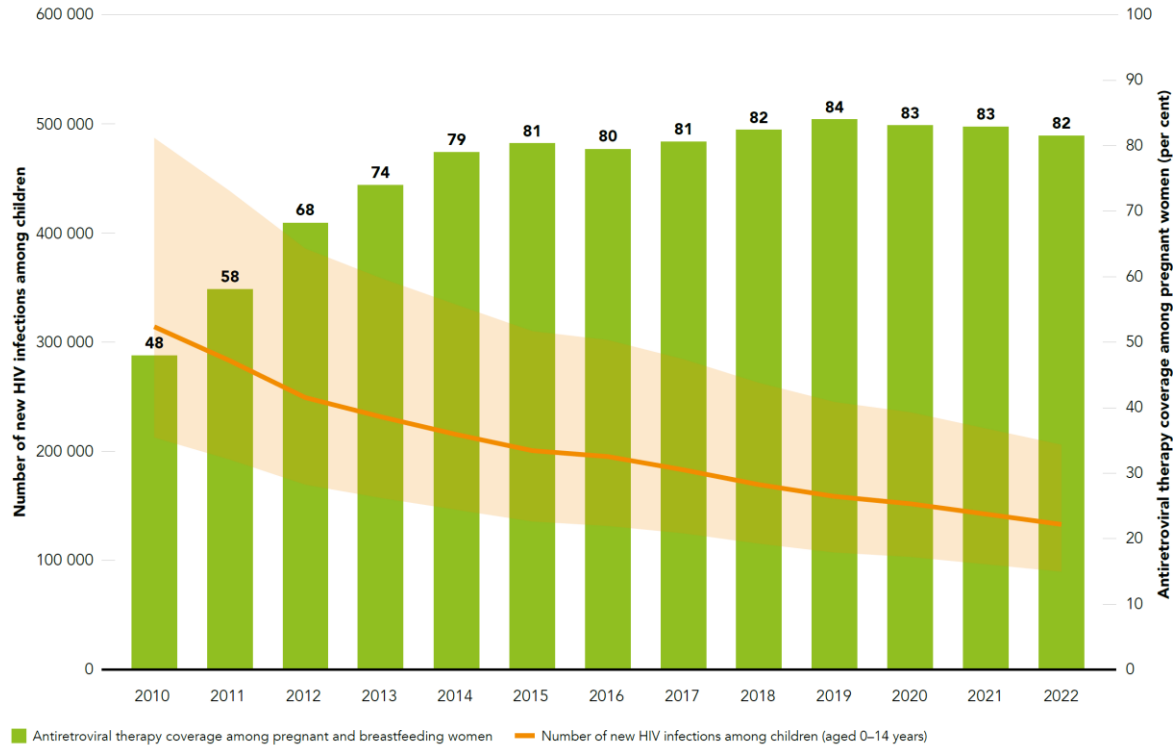
IMPAACT

International Maternal Pediatric Adolescent
AIDS Clinical Trials Network

Monday, October 23, 2023
10:30 AM – 12:30 PM EDT

ANNUAL MEETING
2023

Maternal ART coverage and new infections in children in 2022

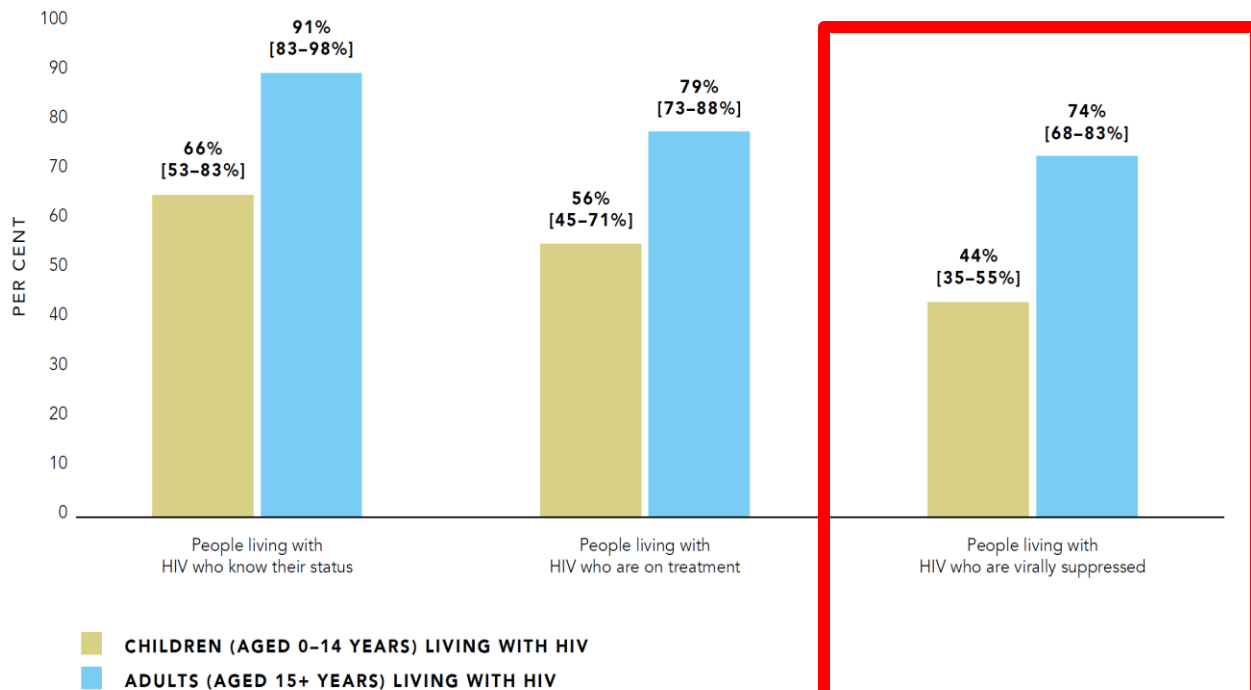


Source: UNAIDS epidemiological estimates, 2023 (<https://aidsinfo.unaids.org/>).

- **Progress is remarkable but flattening**
- **130,000 new child infections in 2022**

Source: UNAIDS epidemiological estimates, 2023 (<https://aidsinfo.unaids.org/>)

Treatment cascade outcomes in children with HIV still lag far behind adults



Critical gaps:

- Diagnosis
- Treatment coverage
- Treatment outcomes

And in the management of children presenting late with advanced disease

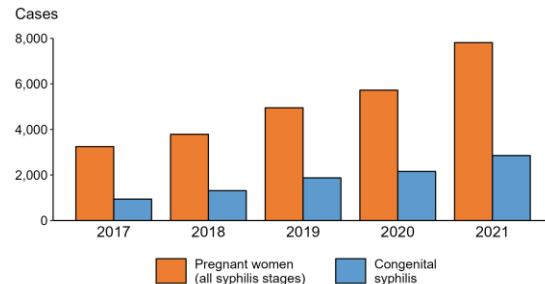
Our populations face other infectious burdens



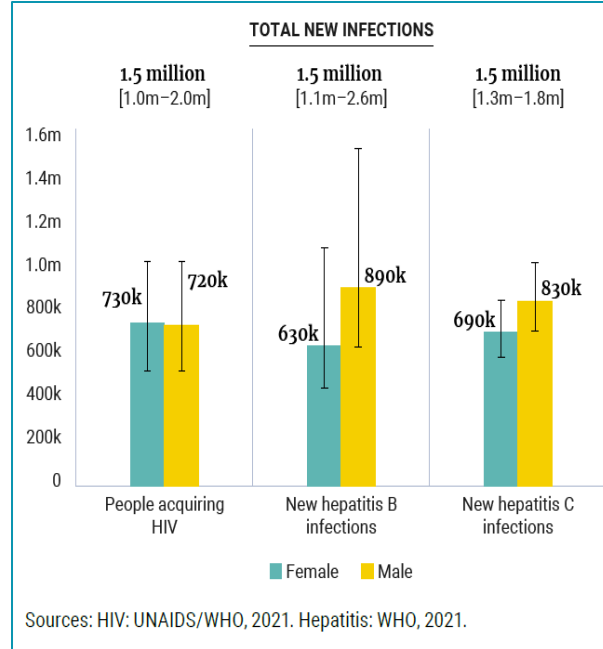
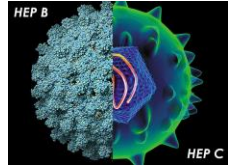
- ▶ SARS-CoV-2 affecting pregnant women and their children

- ▶ Syphilis
- ▶ 7.1 million adults 15 and 49 years old acquired syphilis in 2020, globally

Syphilis rates rising in the USA



Hepatitis Viruses

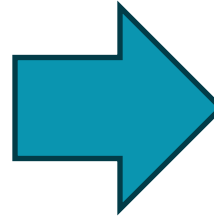


Updating our mission ...

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Treatment Scientific Committee

- ▶ Accelerate the evaluation (PK, safety, antiviral efficacy), licensure and optimal use of potent and durable ARVs for pregnant people and infants, children and adolescents with HIV.



*Mid-term
external
review
March 2023*

2023 and forward ...

“Therapeutics” Scientific Committee

- ▶ Continue to advance HIV treatment with focus on long-acting agents and pregnancy
- ▶ + *address other HIV-associated infections*

Agenda

Therapeutics Scientific Committee Meeting
Monday, 23 October 2023
10:30 AM EDT – 12:30 PM EDT

Start Time	Topic	Presenter
10:30	Welcome and Update on New “Therapeutics” Agenda	Ted Ruel
10:40	Update from CS 5035 <i>Pharmacokinetics of Benzathine Penicillin and Ceftriaxone in Pregnancy</i>	Jason Zucker
10:50	Empiric Treatment for Cytomegalovirus (CMV) and Tuberculosis (TB) in Children with HIV and Pneumonia	Pablo Rojo

Dolutegravir (DTG) has arrived!

Where are we now and what is next?

11:00	Overview of DTG Global Rollout Among Pregnant People and Children	George Siberry
11:20	Patient Perspectives on the DTG Rollout	Thabo Makete & Aisha Nakitto
11:30	Increasing Second-Line ART Options for Children with HIV in Africa: Week-96 Efficacy/Safety Results of the CHAPAS-4 Randomised Trial	Mutsa Bwakura-Dangarembizi
11:40	What have we learned about DTG resistance in from the ODYSSEY trial?	Alasdair Bamford
11:55	Frequency and Mechanisms of DTG Resistance: Lessons from P1093 and IMPAACT 2010/VESTED	Ceejay Boyce
12:10	Panel Discussion	All DTG presenters
12:25	Wrap Up	Ted Ruel & Mo Archary
12:30 PM	Adjourn	

Therapeutics Scientific Committee Membership

Chair & Vice Chair: **Ted Ruel** and **Mo Archary**

At-large Members			LOC Members	NIH Members
Linda Barlow-Mosha	Brookie Best	Carolyn Bolton Moore	Katie McCarthy	Renee Browning
Edmund Capparelli	Diana Clarke	Lee Fairlie	Sharon Nachman	Gretchen Buckler
Liz Lowenthal	Mark Mirochnick	Jorge Pinto	Veronica Toone	Ellen Townley
Andy Wiznia			Michael Whitton	Dwight Yin
				Franklin Yates

SBS Core	CAB Members	LC / DMC Member	SDAC Members
Rivet Amico	Aisha Gava	Hely Adisetiyo	Sean Brummel
Rachel Kidman	Thabo Makete	Barb Heckman	Kristin Baltrusaitis

Acknowledgments

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Session Rules

- ▶ **Save questions** for the discussion section at the end.
- ▶ **Maintain confidentiality of content**
 - ▶ Many presenters are including confidential “first presented” data. Please do not record slides or share information beyond this meeting. We plan to distribute slide decks - redacted for confidential material - after the session.
- ▶ Please silence phones and take needed leave discreetly

