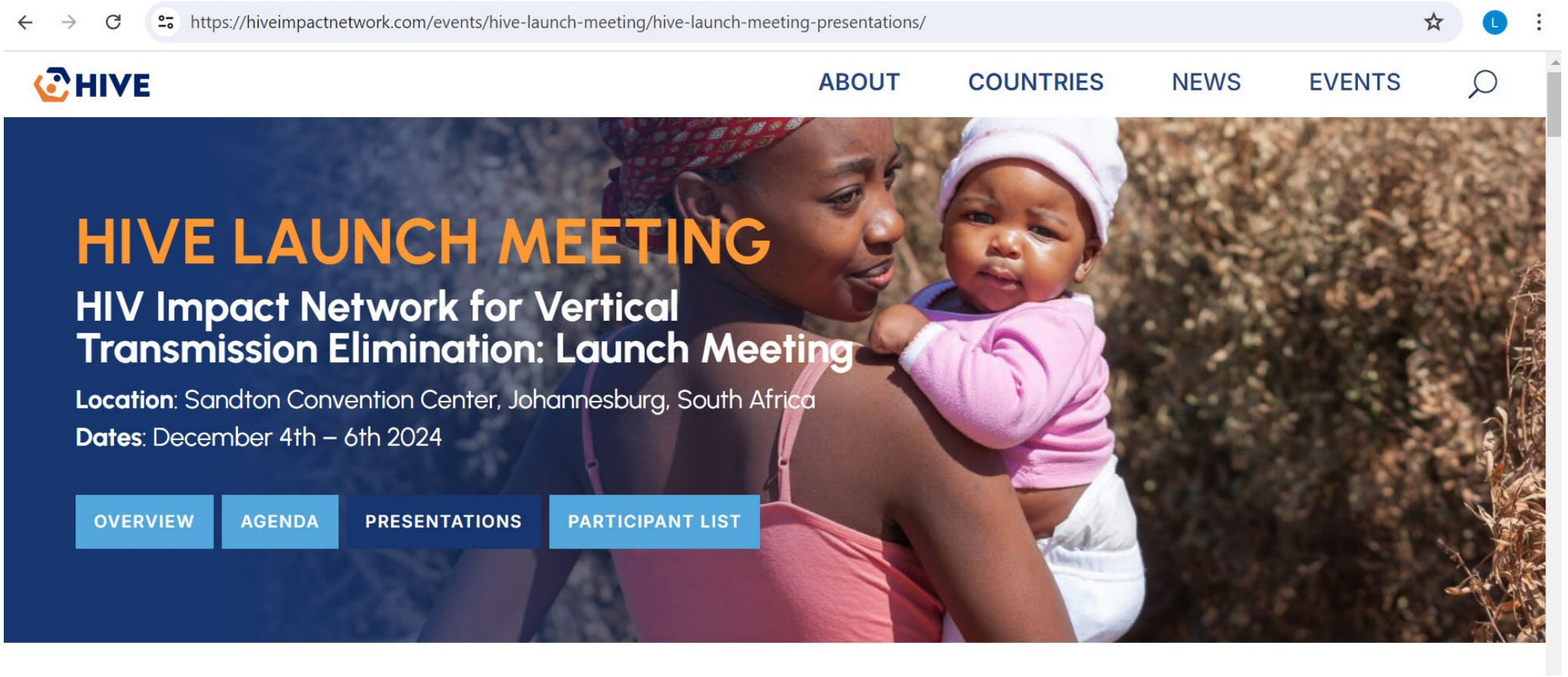
Session 5: Recap and Keynote

Slides from Meeting are available on HIVE website



HIV Impact Network for Vertical Transmission Elimination

Back to the Basics: Preventing New Pediatric HIV Infections and Keeping Mothers Healthy

Elaine Abrams

HIVE Launch Meeting | December 4-6, 2024
Johannesburg, South Africa

HIV Impact Network for Vertical Transmission Elimination

PATA

icap Global Health

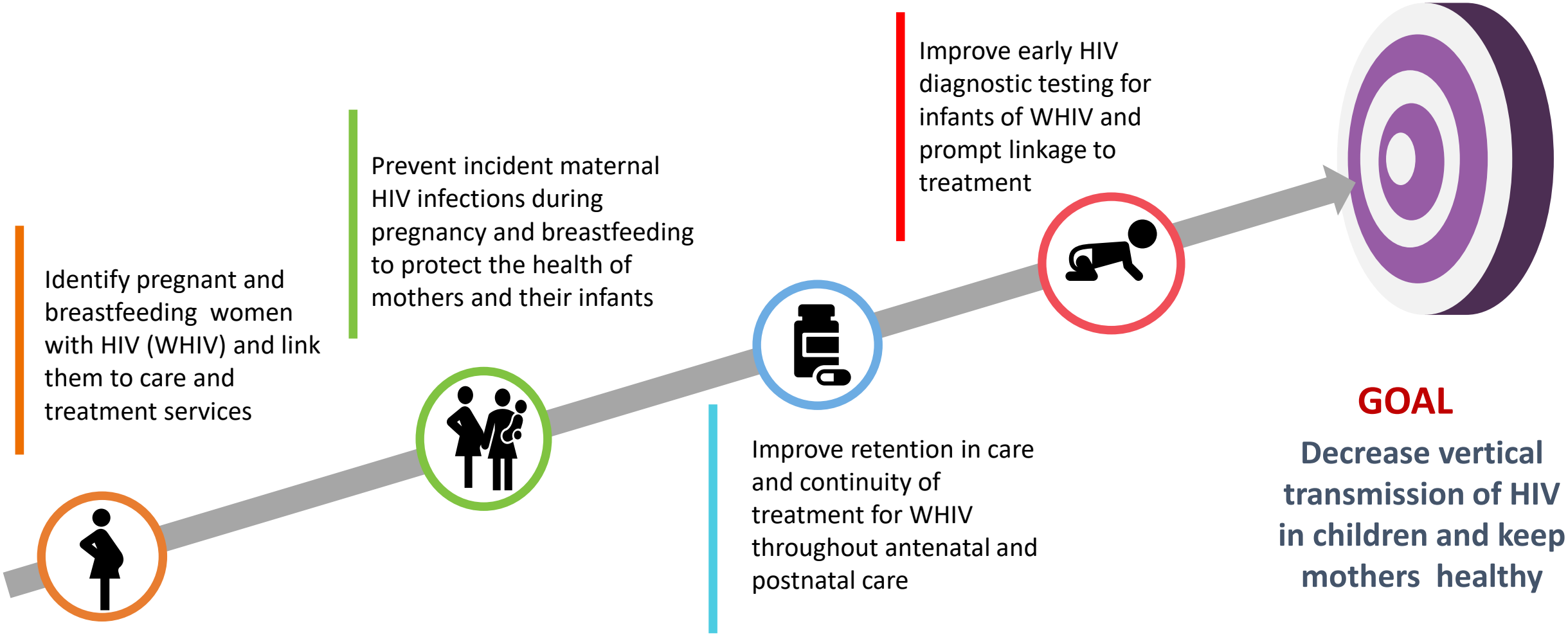
HIVE Project Goal and Objectives

Identify pregnant and breastfeeding women with HIV (WHIV) and link them to care and treatment services

Prevent incident maternal HIV infections during pregnancy and breastfeeding to protect the health of mothers and their infants

Improve retention in care and continuity of treatment for WHIV throughout antenatal and postnatal care

Improve early HIV diagnostic testing for infants of WHIV and prompt linkage to treatment



GOAL

Decrease vertical transmission of HIV in children and keep mothers healthy

Prevent incident maternal HIV infections during pregnancy and breastfeeding to protect the health of mothers and their infants

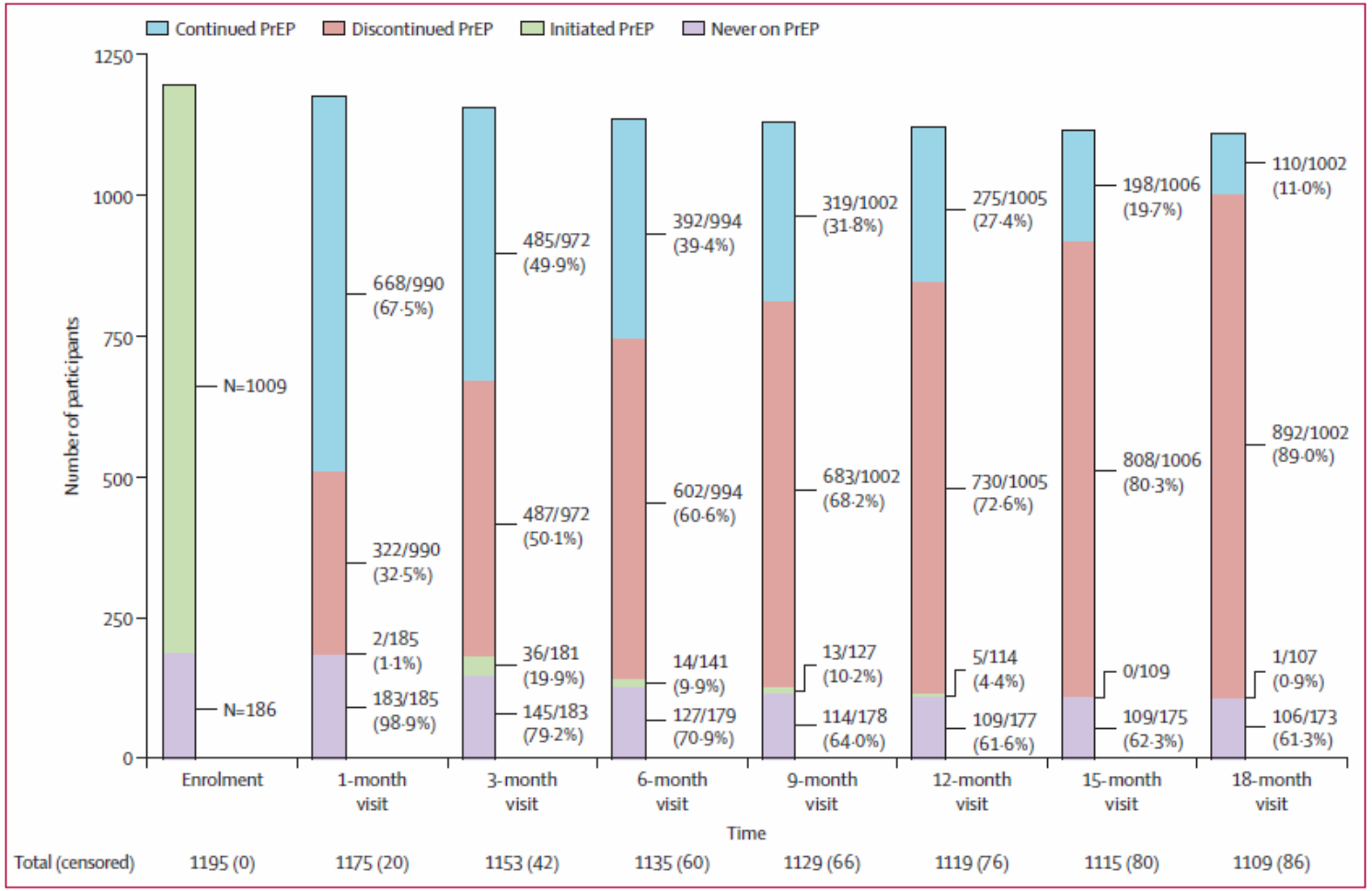
HIV Impact Network for Vertical Transmission Elimination

Pre-exposure Prophylaxis (PrEP) for PBFW

- **PBFW are at high risk for HIV acquisition**
- **Availability of new PrEP agents for PBFW has been delayed compared with the general populations. Traditionally, studies of new agents exclude PBFW due to safety concerns for the health of the pregnant woman and the fetus/infant.**
  - Historically there is a ten-year lag from when a new ARV is approved for use and when dosing and safety data are available for PBFW, if available at all.
  - Leading to additional delays in regulatory approval and global and national guidance.

Cascade of daily oral PrEP use in cohort of PBFW, PrEP-PP, Cape Town, SA, 2019-2023

Davey et al Lancet HIV 2024; 11: e746–55



Persistence:

50% discontinued by 3mo

68% discontinued by 9mo

80% discontinued by 12mo

Adherence:

DBS drug levels among 186 : 46% had drug detected, of whom 48% were low.

HIV Impact Network for Vertical Transmission Elimination

Daily oral PrEP in PBFW: barriers and challenges to uptake, persistence and effective adherence

- **Defining who is at risk**: large numbers of PBFW; universal vs risk stratified; PBFW risk perception; shifting risk across the pregnancy-postpartum timeline
- **Individual level barriers: young age,** pill burden, side effects, access to services, depression, fear of IPV,
- **Health system barriers: financial costs, poor access, multiple visits, frequent laboratory testing, negative HCW attitudes and beliefs, low HCW knowledge**
- **Stigma and discrimination**

Court et al, Global Health: Science and Practice 2024:12:6; Kinuthia et al Lancet HIV 2020; 7: e38–48; Davey et al Lancet HIV 2024; 11: e746–55

Dapivirine Ring (q28 days)

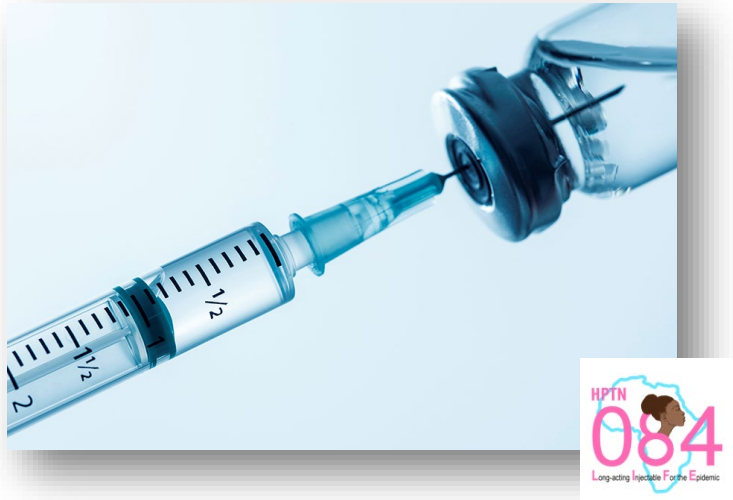
A dedicated program of safety studies across the pregnancy – breastfeeding timeline demonstrated **no differences in adverse pregnancy or birth outcomes** compared to the historical and contemporary background rates. Approval and availability varies by country.

Injectable CAB-LA for PrEP (q2 months)

Data from HPTN 084 OLE presented at AIDS 2024:

- Among 288 pregnancies with CAB-LA PrEP exposure at conception, 212 of whom continued CAB in pregnancy.
- CAB-LA was well-tolerated in pregnant women.
- CAB-LA dosing in pregnancy appears appropriate.
- **Maternal, pregnancy & infant outcomes with CAB-LA at conception appear similar to background rates in the community and with no CAB exposure**.

Several countries are including PBFW in CAB-LA programs.



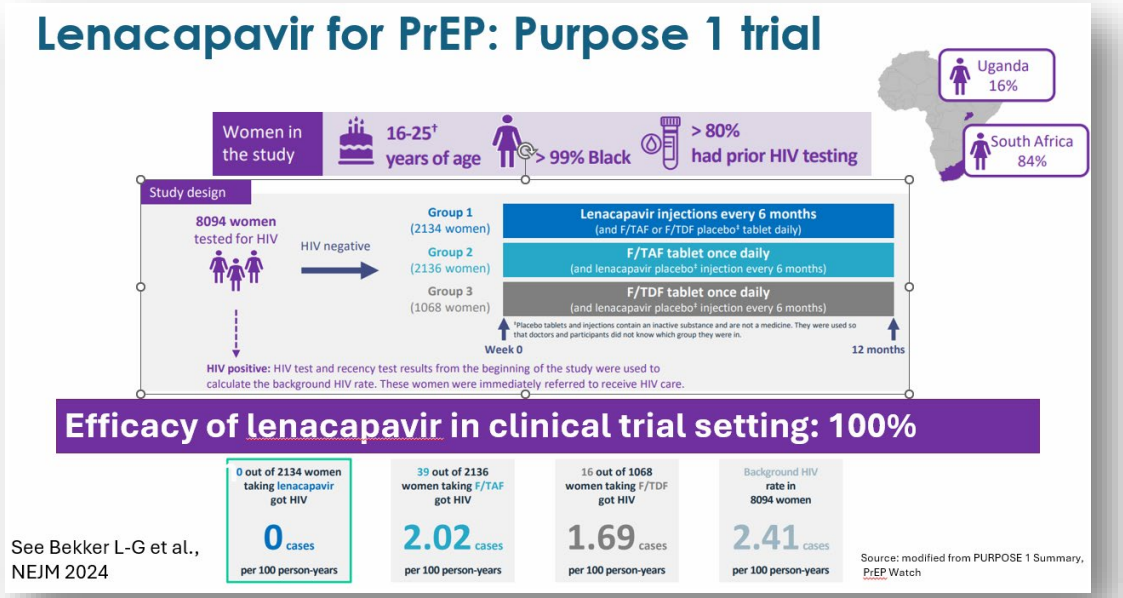
Lenacapavir for PrEP (q6 months)

510 pregnancies in 487 women (193 LEN, 219 F/TAF, 98 F/TDF); 277 pregnancy outcomes, 233 pregnancies still ongoing.

- Data on 105 completed pregnancy with LEN exposure at conception.

No significant differences in pregnancy outcome with LEN vs oral PrEP.

No signal of increased adverse pregnancy complications or birth outcomes with LEN.



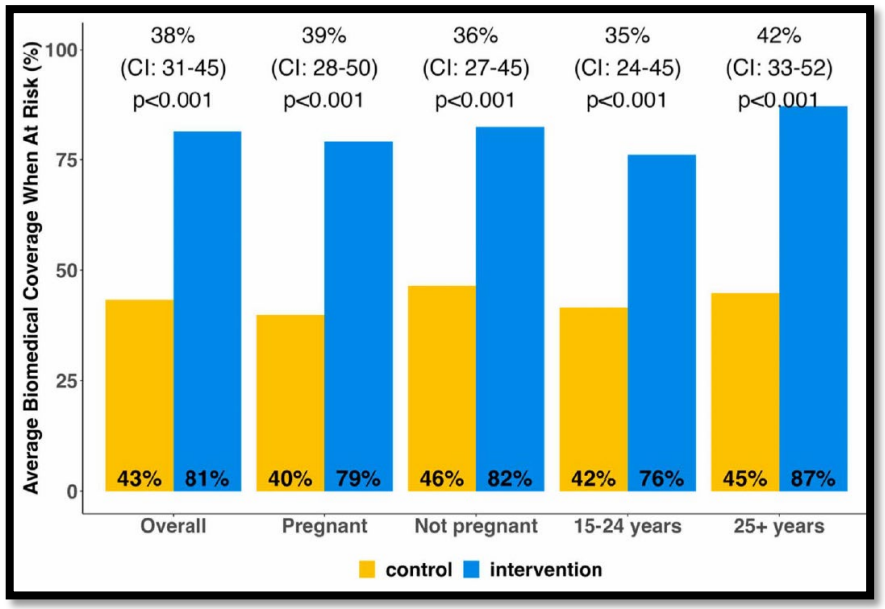
See Bekker L-G et al., NEJM 2024

HIV Impact Network for Vertical Transmission Elimination

Dynamic Choice HIV Prevention (DCP) at ANC and Postnatal Care Clinics

Kabami JAIDS: 95; 5,2024 ; Kamya MR Lancet HIV 2024; 11: e736–45

- **PBFW** at 4 public sector ANC clinics in rural Kenya and Uganda, 4/21-7/21
- The DCP intervention included
  - (1) structured client **choice** of biomedical prevention product, HIV test modality, and location of service delivery, with the option to switch between these choices over time
  - (2) **person-centered care**, including provider training, structured barrier assessment, counseling, and phone access to a clinician.
- **DCP significantly increased biomedical prevention coverage ~40% overall and during months at risk**
  - 81% in intervention, 43% in control



Effect of DCP on proportion of follow-up time with self-reported PrEP/PEP with coverage restricted to months with self-reported risk of HIV acquisition.

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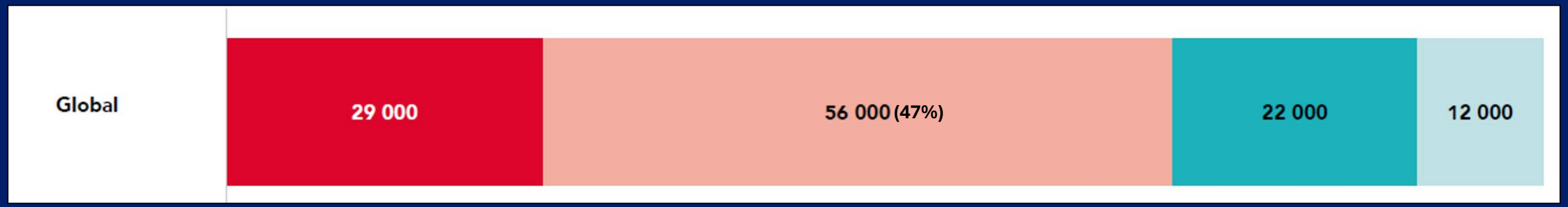
Identify PBFW women with HIV not engaged with the health system and link them to care and treatment services



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Barriers to identification of PBFW with HIV

- **HIV and ANC integration has been recommended and widely adopted for pregnant women starting with routine, opt-out HIV testing .**
- **PW obtaining ANC in non-conventional settings or in facilities without integrated HIV services have limited access to HIV testing.**
- **Retesting during pregnancy and the postpartum period to identify women missed during pregnancy or newly acquiring HIV infection have been difficult to implement.**
    - Systems and approaches to testing during the postpartum period are emerging (who, how often, where).

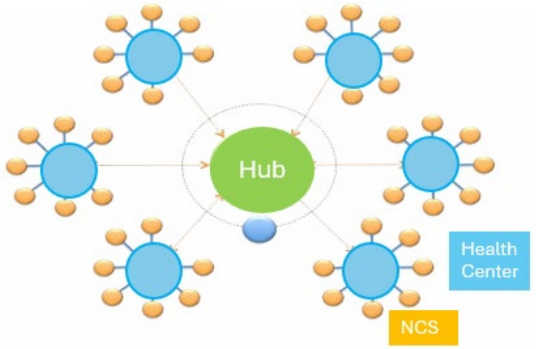
Faith-based congregational strategy: Baby Showers

HIV testing and results for pregnant women and male partners participating in Baby Shower events

	Females (n = 10,056)	Males (n = 6,187)
Individuals tested, n (%)	10,055 (>99.9%)	6,185 (>99.9%)
HIV positive, n (%)	724 (7.2%)	249 (4.0%)
Newly diagnosed, n (%)	274 (2.9%)	138 (2.3%)
Previously known, n (%)	450 (4.5%)	111 (1.8%)

Montandon et al PLoS ONE 2021 16(12): e0260694.

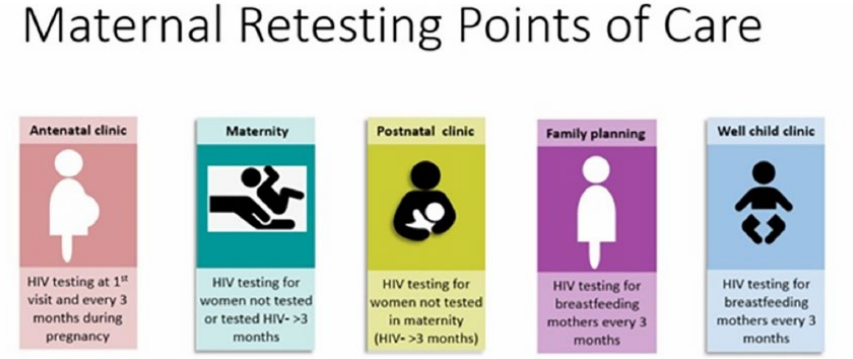
RISE Nigeria Community VTP Strategy



Many pregnant women access ANC services in non-conventional settings (NCS) such as traditional birth attendants, private midwives, prayer homes and primary health centers.

- **NCS were categorized according to skill level of the providers and center. Support included**:
  - Category 1: Received refresher trainings, tools, materials roving data entry clerks for reporting, mentor mothers for counselling and referral directory was provided easy referral.
  - Category 2: Roving community teams (nurse midwife, HIV counselors, data entry clerk, Mentor Mothers, patient referral directory.
  - Category 3: Mentor mothers for counselling, health assistant or support group from the facility, provided with patient referral directory.
  - RISE Nigeria data, 2023 (Taraba, Cross River and Akwa Ibom)
    - 77,587 pregnant women tested, **42,630 (55%) in the community**
    - 458 diagnosed with HIV, **178 (38%) in the community.**
    - 178 (100%) initiated ART **in the community**

HIV retesting in PBFW, Mozambique



Child Welfare Clinic	
Women retested	**39499**
Women tested HIV+	**397**
Percent HIV+	**1%**

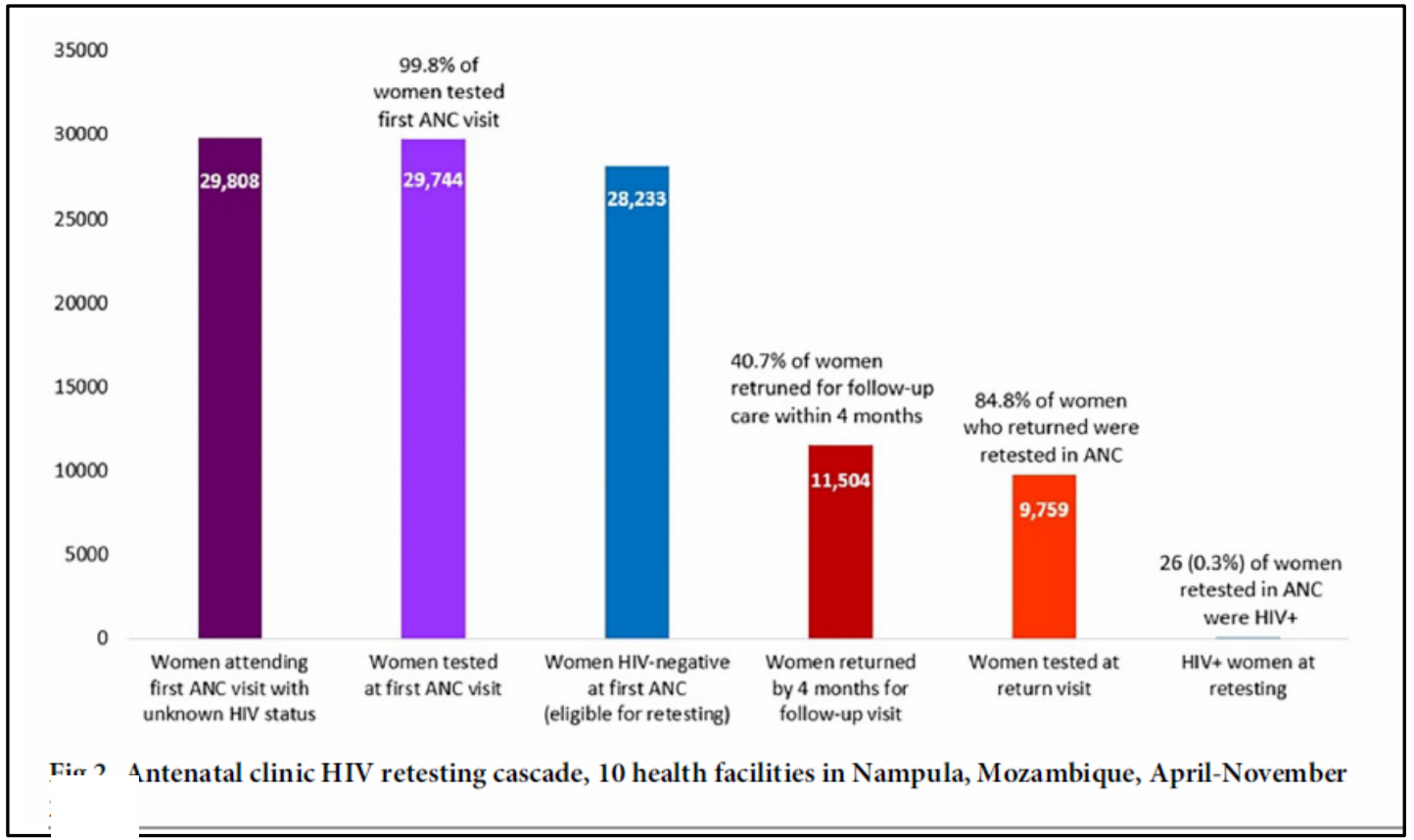


Fig 2. Antenatal clinic HIV retesting cascade, 10 health facilities in Nampula, Mozambique, April-November

Teasdale et al. PLoS ONE 18(3):e0283558.

Using HIV self-tests (HIVST) to expand testing of PBFW

Using HIVST, at home or in clinic, has the potential to reach greater numbers of breastfeeding women

- HIV-negative PW in ANC were enrolled (n=994); given **choice** to retest with home-based (HB)-HIVST or clinic-based rapid-diagnostic test (CB-RDT):
  - 33% HB-HIVST - Private, convenient, and offered flexibility in the timing of retesting
  - 67% CB-RDT -trust of providers to administer the test, convenience of clinic testing
- HIV-negative PBFW (n=400) were invited to choose between CB-HIVST and CB-RDT for repeat HIV testing.
  - 53% chose CB-HIVST – fear of needle prick

Drake et al, PLoS ONE 19(8): e0302077.Oyaro et al. JAIDS 2020 Aug 1;84(4):365–371

Improve retention in care and continuity of treatment for WHIV throughout antenatal and postnatal care

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Achieving a more nuanced understanding of engagement in care for PBFW

- **Not a uniform population**
  - PW newly identified with HIV and newly initiating ART (in ANC.)
    - Young age puts PW at greater risk for treatment interruptions
  - WHIV on ART becoming pregnant and entering ANC
    - Subject to same cycles of engagement and disengagement as the non-pregnant population -PWHIV with history of interruptions are at greater risk for future interruptions
    - Often already engaged in DART models of care
      - Consider how this impacts the VTP cascade -Linking mothers and infants; viral load monitoring; Infant postnatal prophylaxis (PNP)
- ***The transition from pregnancy to postnatal care is a particularly vulnerable moment along the VTP cascade***

Factors influencing transition out of VTP

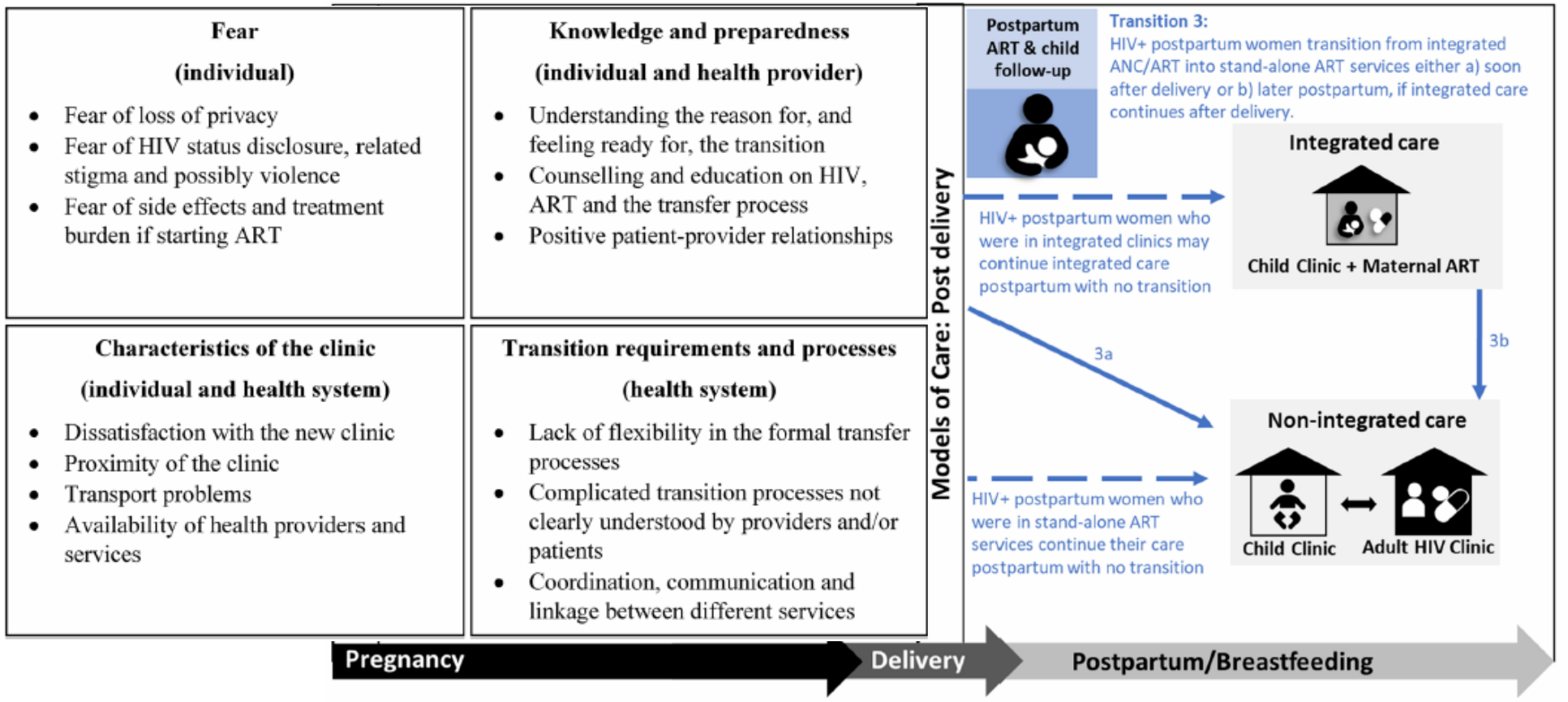
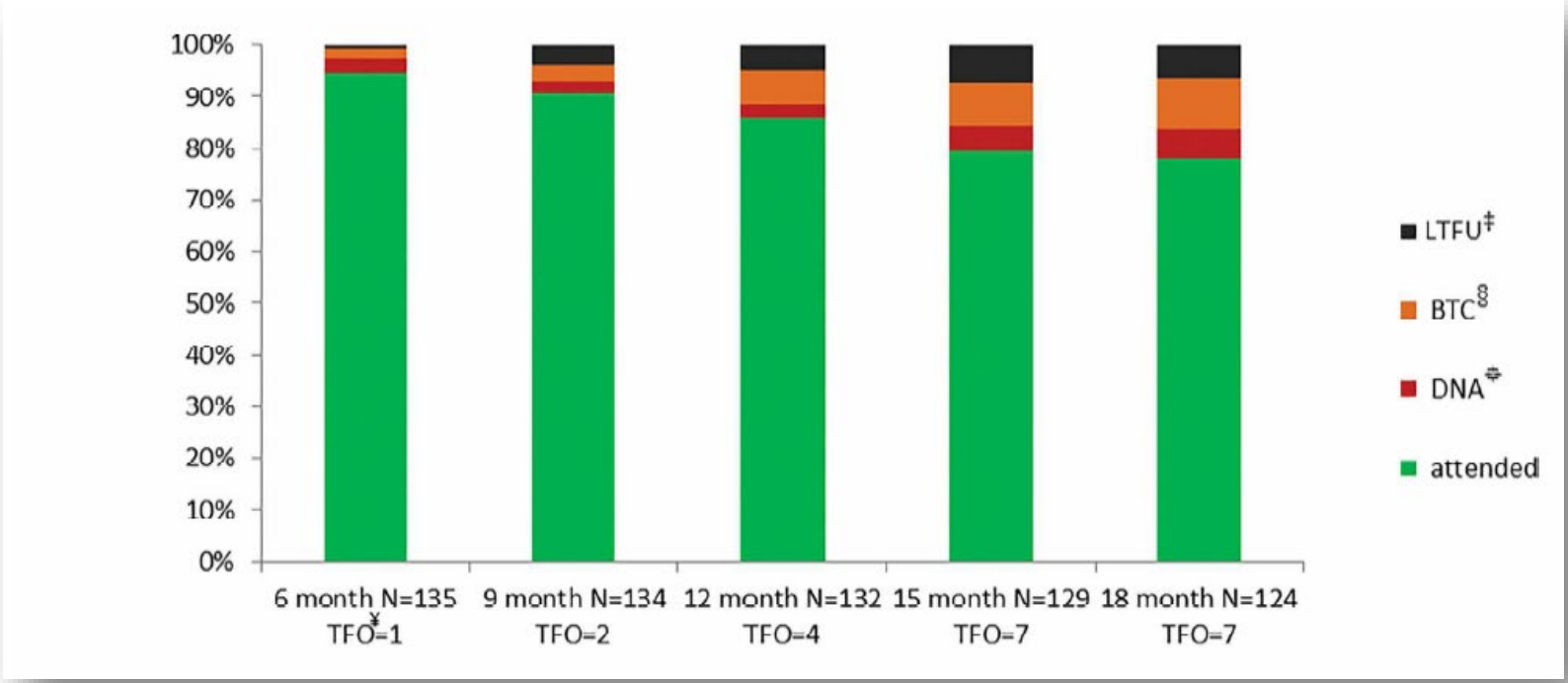


Figure 1. Transition points, models of care and timing of transition into and out of PMTCT for pregnant and postpartum women. Dashed lines represent continued care with no transition needed. ART, antiretroviral therapy; ANC, antenatal care.

Phillips TK et al, JIAS 2020, 23:e25633

Postnatal Clubs: Implementation of a differentiated and integrated model of care for mothers with HIV and their babies



Among 484 MIP recruited: 84% overall attendance, 95% VS, 98% EID uptake.

Nelson A, PLoS ONE 18911):e0286906

HIV Impact Network for Vertical Transmission Elimination

Person-centered interventions for VTP

To address the plateau in VT rates in Kisumu, Kenya, the FACES program implemented a 3-prong person-centered approach:

1. High risk clinics
2. Case management
3. Mobile app to support treatment engagement

Evaluated new pediatric HIV infections at 18-24 months and loss to follow-up

- VT declined from 4.9% in 2018 to 2.2% in 2021
- Loss to follow-up declined from 9.9% to 2.5%

Table 1. FACES intervention descriptions.

Intervention	Description
High risk clinic	We established targeted clinics days for women considered at risk of perinatal transmission or poor care engagement to enable multidisciplinary team review of cases and to provide social networking for adolescents. Women with any of the following characteristics were eligible: • Newly diagnosed with HIV in the current pregnancy or breastfeeding • Adolescents aged 10–19 years • Unstable support system (stigma within the household or family, recent migration from home, food insecurity) • Any viral load >200 copies/ml in the last 12 months • History of poor adherence prior to the current pregnancy • Any history of a treatment interruption greater than 30 days Package of services provided at "high-risk clinics" • Moms' Clubs for adolescents for peer support and safe and acceptable spaces for treatment interventions • Multidisciplinary review and patient management at every visit • Psychosocial and disclosure status reviewed at every visit by mentor mothers • Nutritional support
Case management	Case managers were charged with planning, obtaining, coordinating, and monitoring treatment needs of the individuals assigned to them. Case managers had at least a diploma in social science. Each followed roughly 10 individuals at any given time. The case manager provided the following support until the end of breastfeeding: • Developed treatment goals with individuals assigned to them based on their identified barriers • Developed an individual treatment plan which was reviewed regularly by the clinic team • Provided one-on-one psychosocial support where needed • Appointment tracking with phone reminders as needed
Mobile App	*Ushauri* is a mobile app for clinic use to support adherence, retention, and mother–infant pair tracking. The app was developed by mHealth Kenya and customized using feedback from user acceptance testing by FACES. The app included the following modules: • Digital appointment diary with automated same day alerts to case managers of any missed appointments • Automated appointment reminder messages sent 1 week before, 1 day before, and the morning of the appointment • Two-way text messaging with motivational messages to specific groups of individuals in care • Linked to medication pickup and clinical review to ensure completion of services

https://doi.org/10.1371/journal.pmed.1004441.t001

Odhiambo F, , et al. (2024) PLoS Med 21(8): e1004441

HIV Impact Network for Vertical Transmission Elimination

Improve early HIV diagnostic testing for infants with HIV exposure and prompt linkage to ART

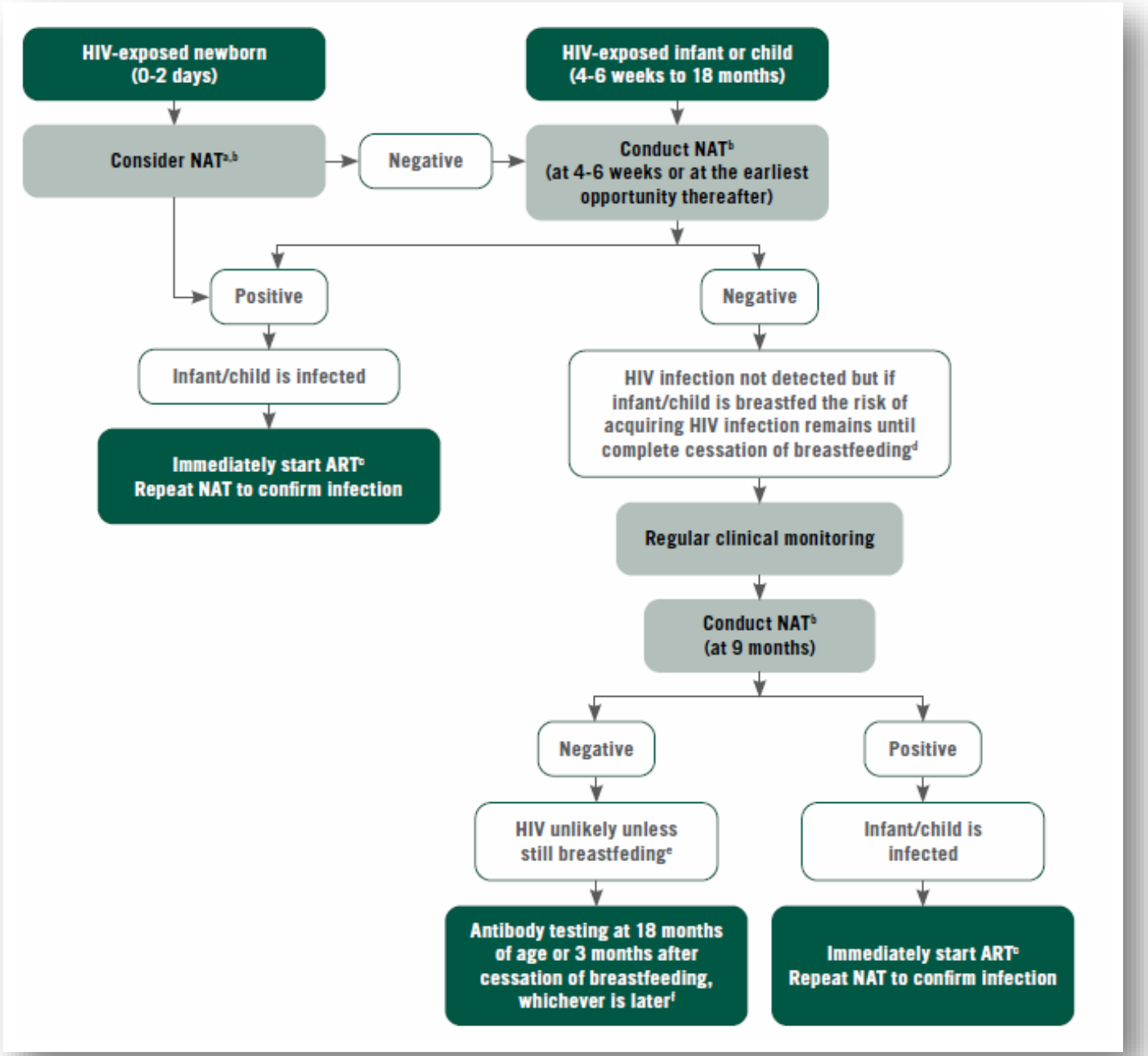
HIV Impact Network for Vertical Transmission Elimination

Early infant diagnostic (EID) testing, HIV-exposed infants (HEI) and postnatal prophylaxis (PNP)

- **High rates of disease progression in first months of life among infants with HIV infection, particularly those acquiring HIV in utero.**
- **Goal of EID, using a virologic nucleic acid test (NAT), is to identify the infant with HIV and initiate ART ASAP to prevent death and reduce disease progression.**
    - **Repeat virologic testing** must be done through the period of 'risk' to *diagnose* HIV infection acquired during breastfeeding.
    - Testing must also be done **after the period of 'risk'** to determine final infection status.
- **EID testing is a critical component of VTP strategy and the package of care for HEI.**
- **Antiretroviral PNP for HEI is an impactful and often neglected component of the VTP toolkit.**

HIV Impact Network for Vertical Transmission Elimination

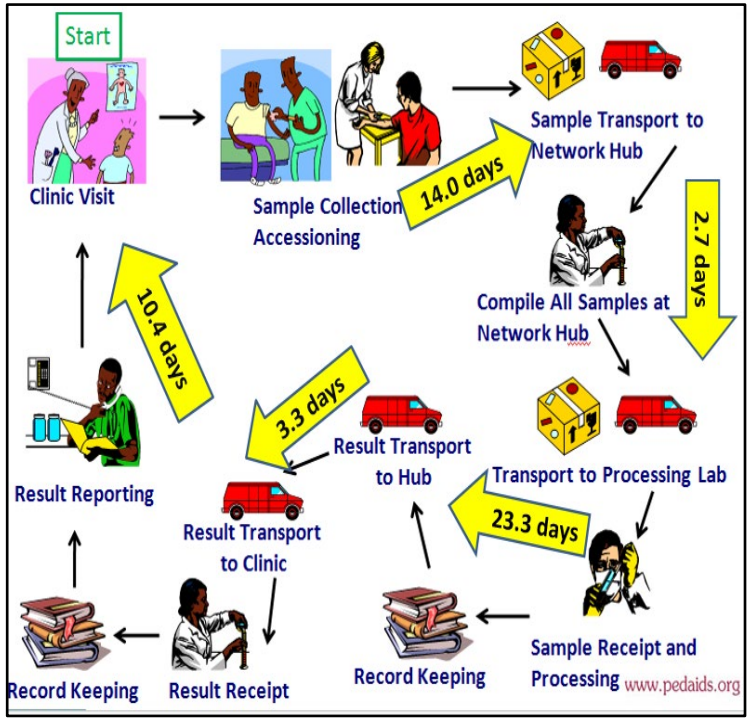
WHO testing strategy and algorithm for early infant diagnosis



WHO consolidated guidelines on differentiated HIV testing, 2024

Barriers and challenges to timely infant diagnosis

- **Retention in care for HEI through determination of final infection status is poor and poorly monitored.**
- **EID programs most often centered within VTP programs**
  - HEI unrecognized outside of VTP programs.
  - Mothers and infants generally not linked in EMR or other records.
- **EID requires *virologic testing* (vs RDT) that detects HIV nucleic acid**
  - Obtaining samples from babies, specialized laboratory testing
  - Inefficient systems with long turn around times (TAT) >60 days, to return results



EID Total TAT time: 61.7 days (CI = 55.3, 68.7)

Tiam A et al. PLosOne. 2017;12:e0184769

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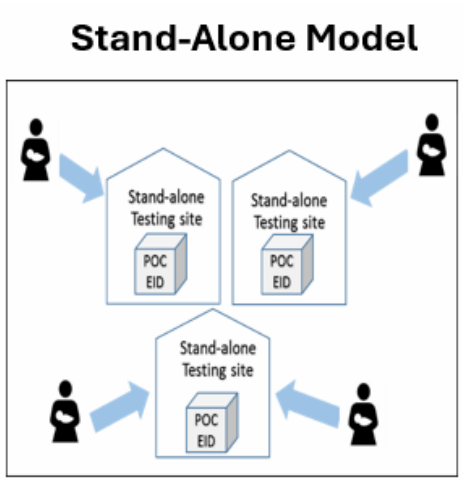
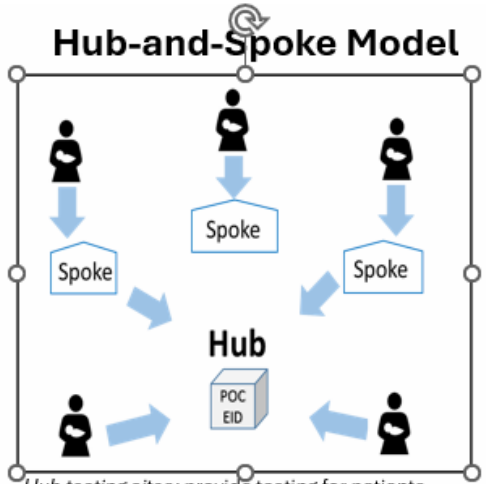
Point-of-Care (POC) EID improves child outcomes

Multiple studies and program experiences demonstrate improvements using POC for EID.

- Decreases TAT for EID results
- Increased rate of ART initiation for HEI testing HIV positive
- Decreases time to ART initiation
  - Higher proportion with same day initiation
- Stand-Alone and Hub-and Spoke Models both effective



Stand-alone testing sites (without spokes): Receive samples directly from clients and perform POC EID tests on site

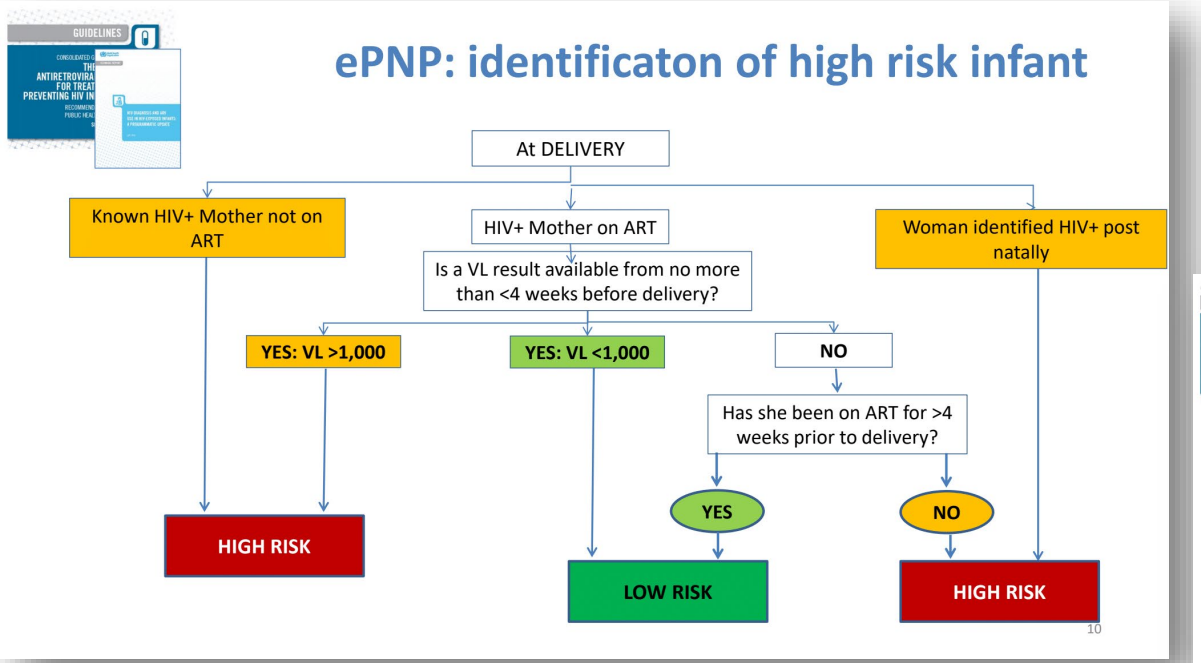


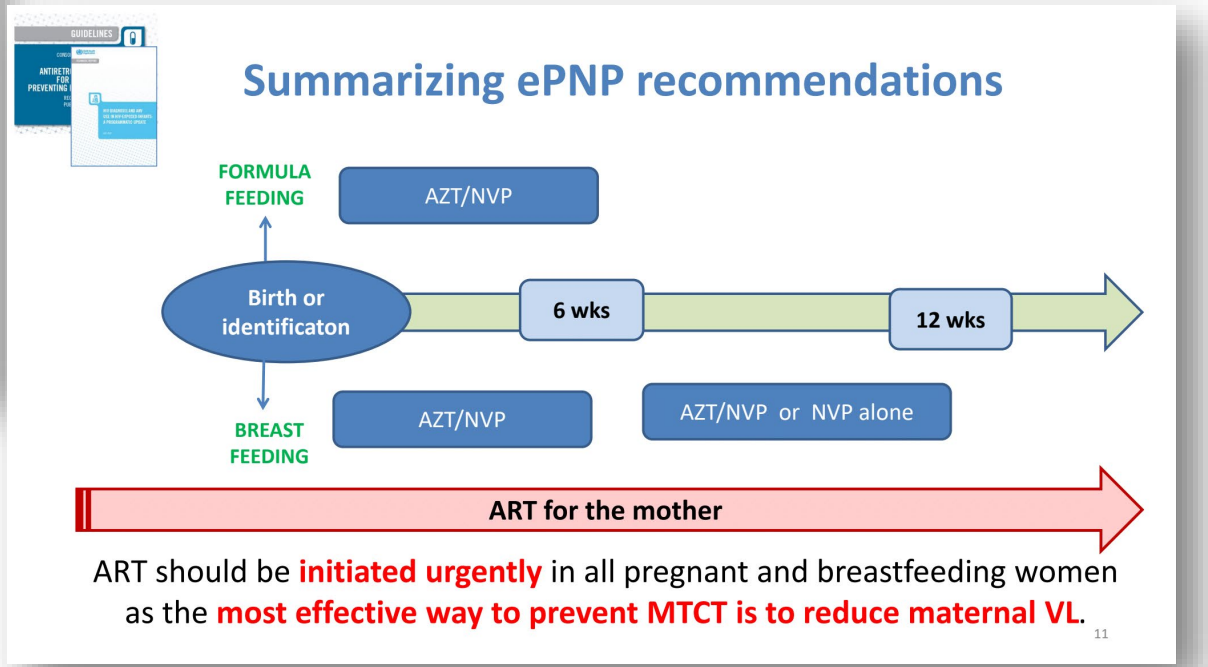
Hub testing sites: provide testing for patients at that site and for spoke sites; *Spoke sites:* regularly send samples to the hubs sites

Indicator	Stand Alone Sites (n = 28 sites)	Spoke Sites (n = 67 sites)
% of results returned to caregiver	99.5%	99.9%
Median turnaround time from blood sampling to caregiver receipt of results	0 days (range: 0-33 days)	2 days (range: 0-38 days)
Median turnaround time from receipt of results to initiation on treatment	0 days (range: 0-28 days)	0 days (range: 0-7 days)
% HIV-Infected children initiated on ART	88.5%	80.6%

UNITAID-EGPAF demonstration project

WHO guidelines provide a risk-based approach to postnatal prophylaxis

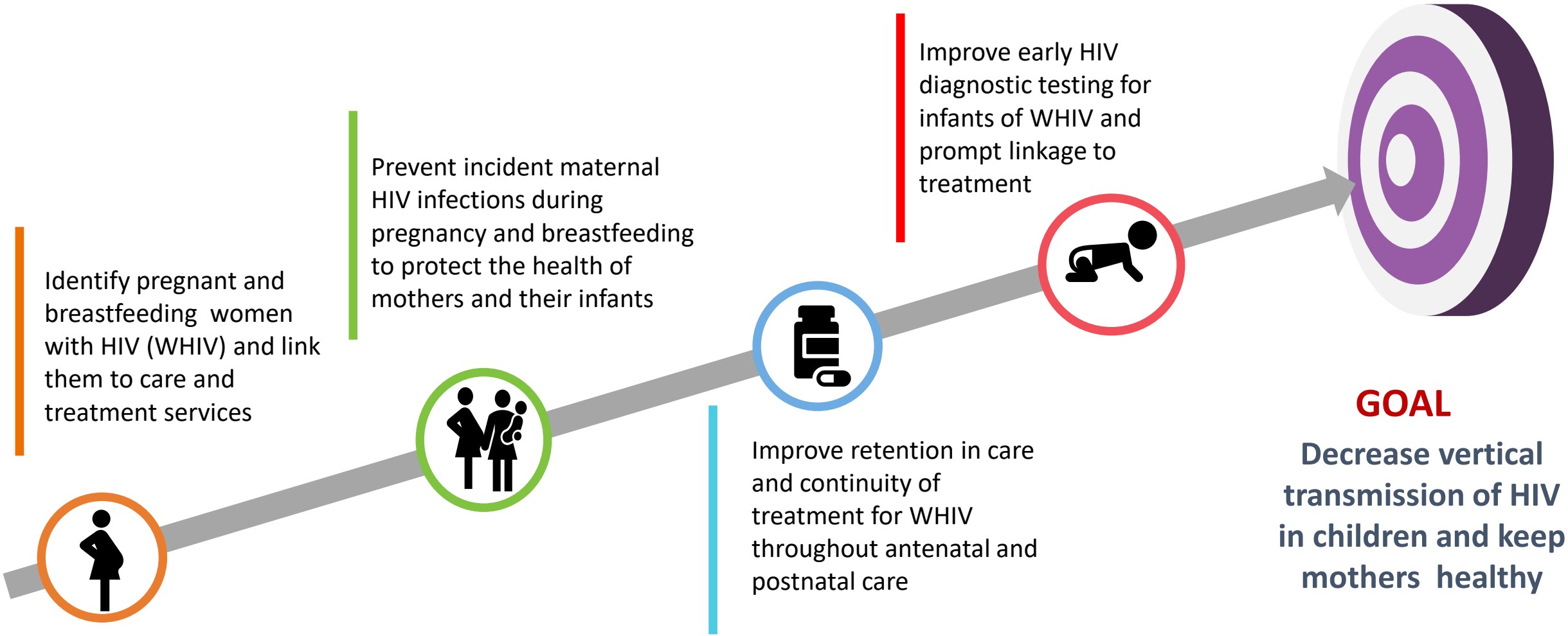




PNP – more questions than answers

- **Is risk stratification at birth feasible?**
    - Should all infants receive enhanced prophylaxis?
- **Is there added value to infant PNP during breastfeeding when mothers are receiving ART?**
    - All infants? Infants of mothers with viral suppression?
- **What is the optimal frequency of VL monitoring during breastfeeding**
- **Can we use DTG for PNP?**
- **MMD for PNP? Home-based EID?**
- **What do the mothers/carers say?**

Back to the Basics



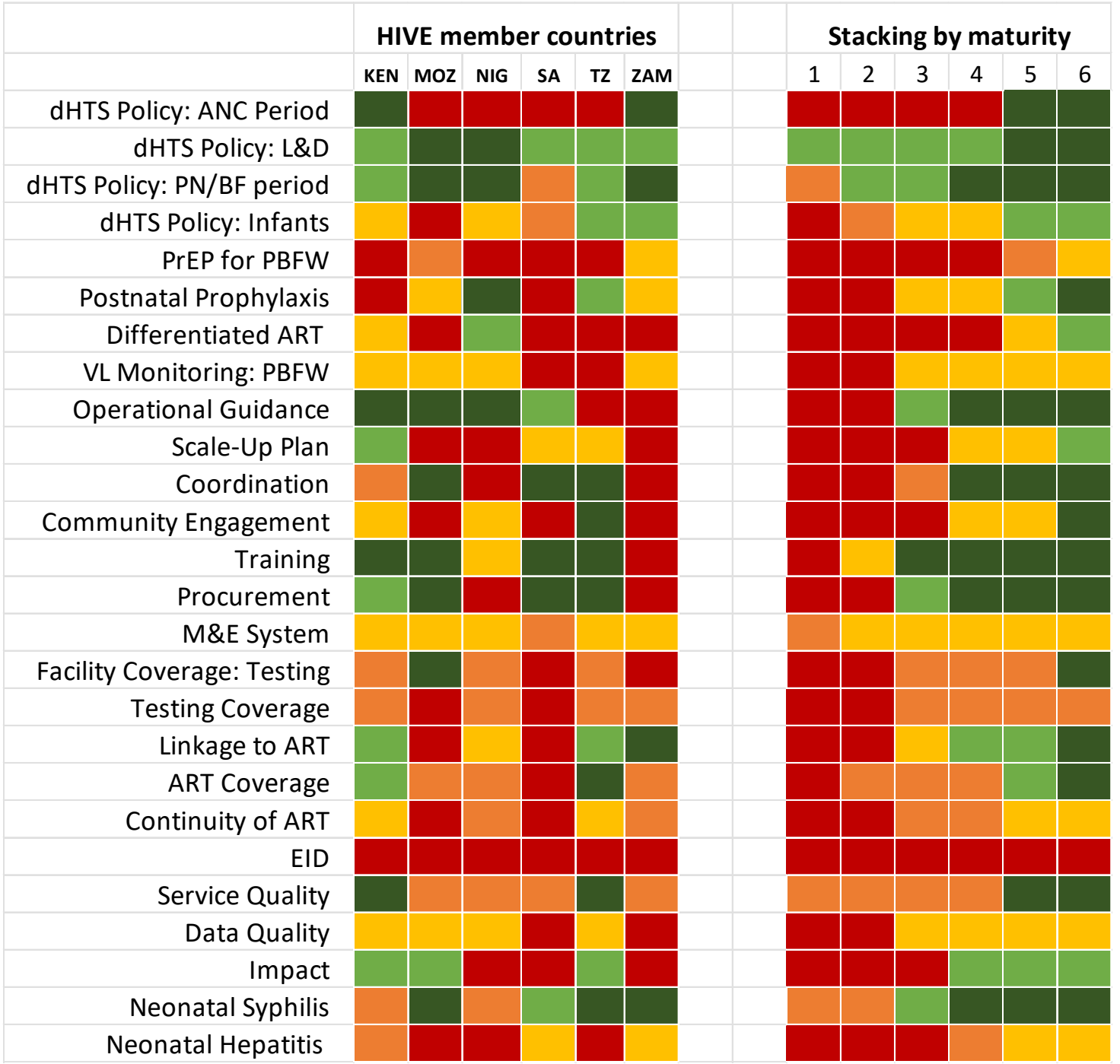
Thank You!

Session 6: Paired Country Breakout Session Instructions

HIVE Launch Meeting

December 4-6, 2024, | Johannesburg, South Africa

HIV VTE CMM Baseline Results 2024



Introduction

Aim: Pairing countries to discuss their CMM results

- Country to country exchange of lessons and best practices
- Sharing common challenges and brainstorming on solutions

Session Objectives:

- Discuss best practices and exchange lessons on CMM results in light green and dark green staging
- Share common challenges in red and orange staging and interventions to address the challenges
- Briefly discuss how countries will align new priorities from the gaps identified in their CMM results with global alliance action plans

HIV Impact Network for Vertical Transmission Elimination

Instructions

Session duration is 90 minutes

- Introduce participants, select one rapporteur from each country, review instructions, (**10 minutes**)
- Each country takes turn to present their CMM results, highlighting the most mature and least mature domains **(10mins)**
- The listening country selects 1-2 mature domains of the presenting country that is of interest to them and asks the country team to share their best practices in those domains, including any resources they can share. (3**0 minutes – 15mins for each country)**
- Both countries identify 1-2 domains with shared challenges and brainstorm on solutions to address the challenges (**30 minutes**)
- Develop your report back slides (**10mins**)

HIV Impact Network for Vertical Transmission Elimination

Instructions

- **Prepare one group presentation on the following using information shared by the countries in the group:**
  - 3-4 key strategies/interventions which have worked well in domains with dark green scores
  - 3-4 recommended interventions to address challenges in the least mature domains selected for brainstorming
  - 1- 3 priority actions/next steps for each country in alignment with global alliance action plans or to complement it.
  - Email your presentation to Laura at lmb2279@cumc.columbia.edu at the end of the session
- There will be no report back in the plenary room
- Slides will be posted on the HIVE website

HIV Impact Network for Vertical Transmission Elimination

Structure

Time	Groups	Location
8:30am - 10:00am	Group 1: Kenya and South Africa	Bill Gallagher
8:30am – 10:00am	Group 2: Tanzania and Zambia	Committee Room 4
8:30am – 10:00am	Group 3: Nigeria and Mozambique	Committee Room 5

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Session 6 Report Back

[Add country names]

Key successful strategies/Interventions for domains in light and dark green scores

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Key recommendations to address least mature domains

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Priority actions/next steps to complement GA action plan

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Thank You!

Reminder… We now have parallel sessions

- 7a: Strategies for Identification of Pregnant and Breastfeeding Women Living with HIV, Linkage to Treatment, and Retention in Care for Mother-Infant Care *(Committee Room 4)*

- 7b: Preventing HIV in Pregnant and Breastfeeding Women: PrEP Uptake, Strategies, and Impact *(Bill Gallagher Room)*

- 7c: M&E of Vertical Transmission Prevention (VTP) *(Committee Room 5)*

HIV Impact Network for Vertical Transmission Elimination