PrEP in Pregnancy:

Because Every mother deserves the tools to protect herself and her baby

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Objectives

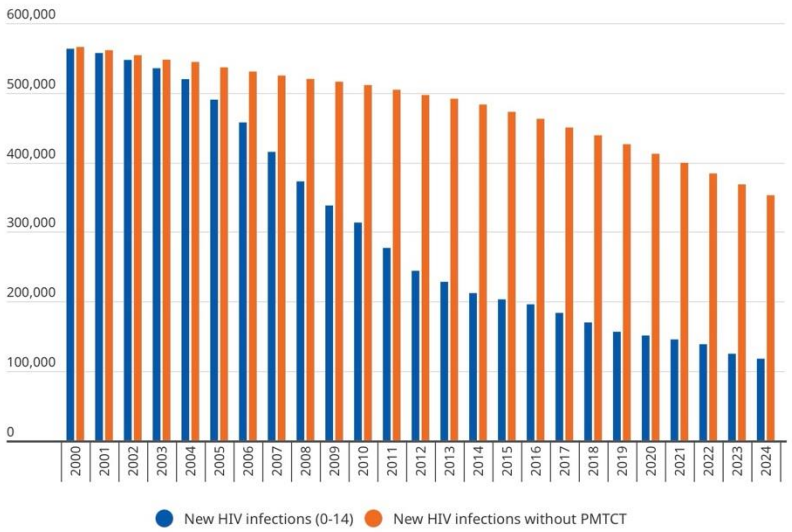
1. Explain what is PrEP and why it matters in pregnancy and breastfeeding?
2. Examine safety, efficacy, and implementation challenges of PrEP in maternal health contexts.
3. Encourage dialogue among clinicians, programme managers, and policymakers on adopting preventive strategies.
4. Identify pathways for integrating PrEP into Caribbean EMTCT programmes and maternal health systems.

EPIDEMIOLOGY

PMTCT Progress 2000-2024

Due to the impact of prevention-of-mother-to-child-transmission, about 4.4 million new paediatric HIV infections were averted between 2000 and 2024

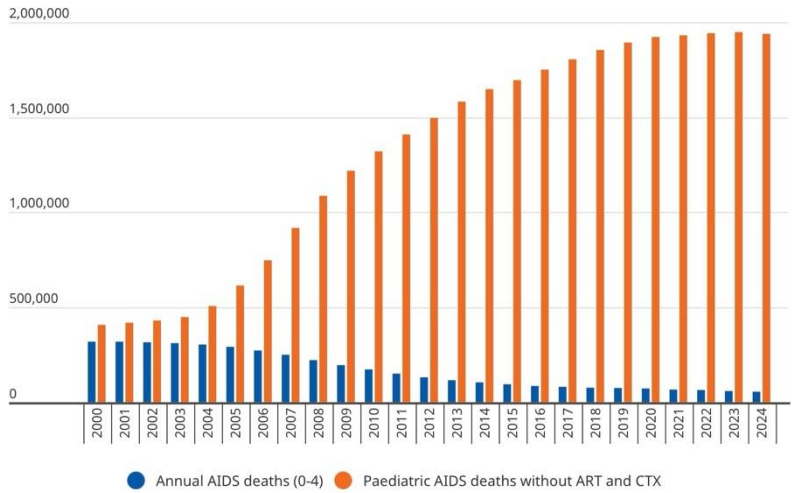
Impact of PMTCT on new child HIV infections, 2000-2024



Source: UNAIDS 2025 estimates.

Due to the impact of antiretroviral and cotrimoxazole treatment, nearly 2.1 million paediatric AIDS-related deaths have been averted between 2000 and 2024

Impact of ART on Paediatric AIDS-related deaths, 2000-2024



Source: UNAIDS 2025 estimates.

Global estimates for adults and children | 2024

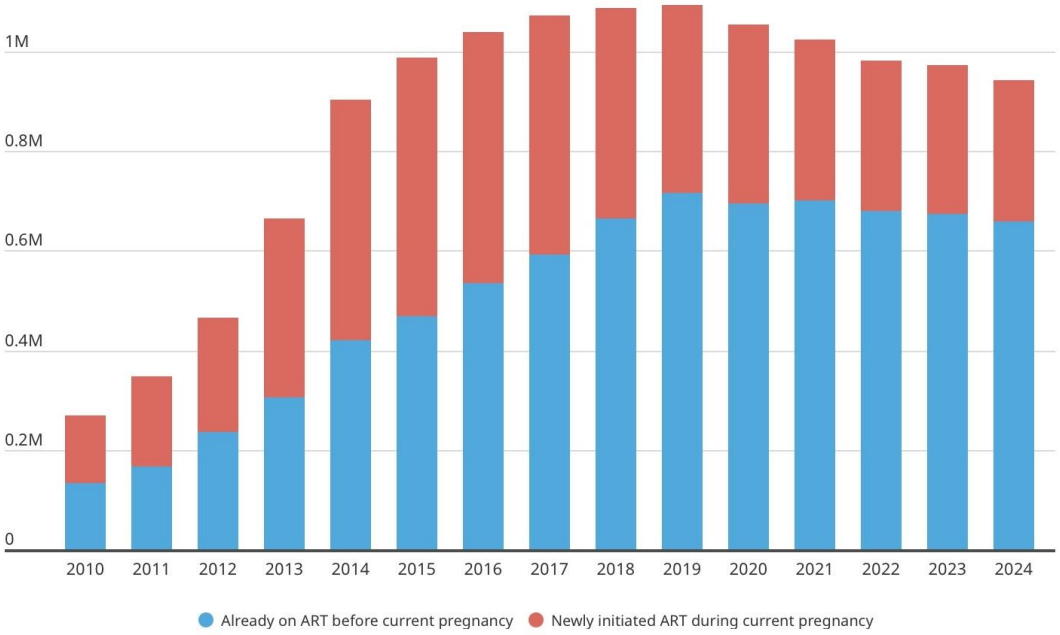
People living with HIV	**40.8 million** [37.0 million–45.6 million]
New HIV infections	**1.3 million** [1.0 million–1.7 million]
New HIV infections < 15 years	**120,000** [82 000–170,000]

About 3600 new HIV infections (adults and children) a day | 2024

- About 50% are in sub-Saharan Africa
- About 300 are among children under 15 years of age
- About 3300 are among adults aged 15 years and older, of whom:
  - 1600 are among women
  - 1000 are among young people (15–24)
  - 570 are among young women (15–24)

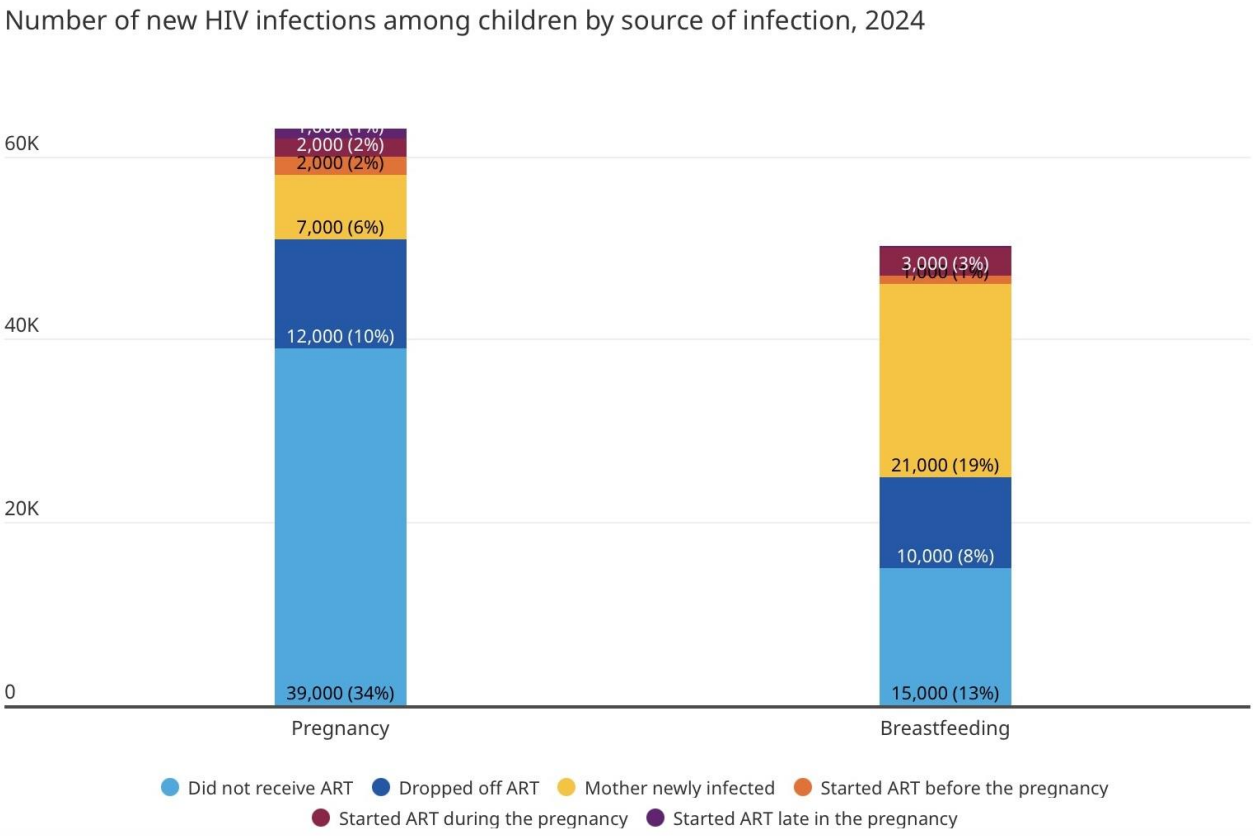
There have been gains in recent years to ensure that women who are not already on lifelong antiretroviral treatment before their current pregnancy are newly and timely initiated to prevent mother-to-child transmission

Pregnant women already on antiretroviral therapy (ART) for prevention of mother-to-child-transmission (PMTCT) before current pregnancy compared to those that started ART for PMTCT during current pregnancy, 2010-2024



Source: UNAIDS 2025 estimates.

New HIV infections in children

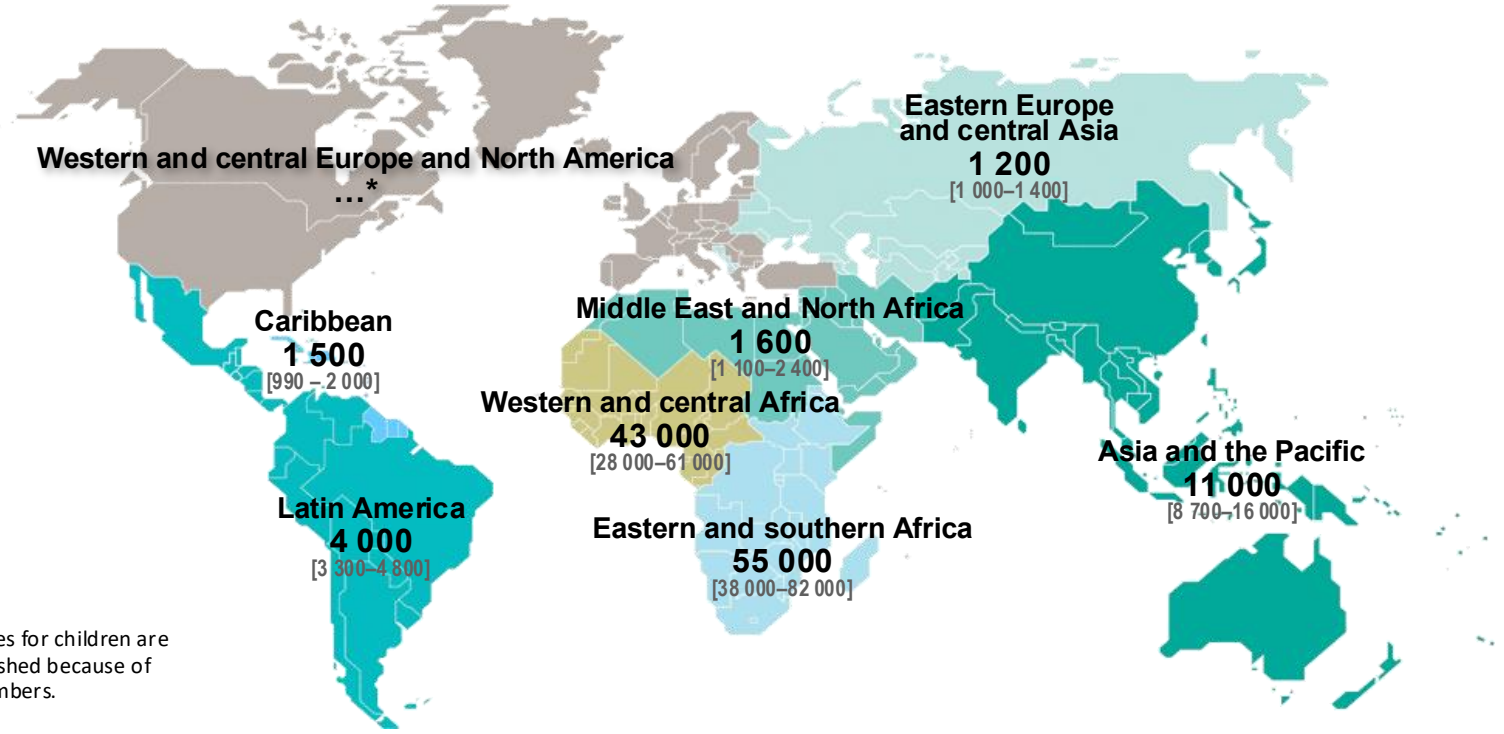


Source: Global AIDS Monitoring and UNAIDS 2025 estimates

Latin America and the Caribbean

HIV Estimates 2025

Estimated number of children (<15 years) newly infected with HIV | 2024



*Estimates for children are not published because of small numbers.

Total: 120 000 [82 000–170 000]

Source: UNAIDS 2025 epidemiological estimates

PMTCT Coverage

31,000

Pregnant women living with HIV

58%

Pregnant women living with HIV receiving ARVs for PMTCT (2030 Target is 95%)

17%

Mother-to-child HIV transmission rate, including perinatal and postnatal infections (2030 Target is 5%)

Source: UNAIDS 2025 Estimates – UNICEF | for every child

unicef

PRE-EXPOSURE PROPHYLAXIS

PrEP

What Is PrEP?

PrEP is the use of antiretroviral medications by people without HIV to protect themselves from getting HIV

PrEP is recommended for adults and adolescents weighing at least 35 kg (77 lb) who are at risk of getting HIV

Injectable PrEP

Cabotegravir (CAB) 600 mg (3ml) im injection (brand name Apretude®)

Lenacapavir (LEN) 463.5mg (1.5ml) injection sc

(brand name: Yeztugo®)

Oral PrEP

Emtricitabine (F) 200 mg in combination with tenofovir disoproxil fumarate (TDF) 300 mg (F/TDF – brand name Truvada® or generic equivalent)

Emtricitabine (F) 200 mg in combination with tenofovir alafenamide (TAF) 25 mg (F/TAF – brand name Descovy®)*

*F/TAF is not approved for use by women or other people who could get HIV through receptive vaginal sex

PrEP Side Effects and Safety

Side Effects	F/TDF (oral PrEP)	F/TAF (oral PrEP)	CAB (injectable PrEP)	LEN (injectable PrEP)
Start-up Syndrome	- <10% of patients - Headache, nausea, abdominal discomfort lasting <1 month[1]	- <10% of patients - Headache, nausea, abdominal discomfort lasting <1 month[1]	- No reported start-up syndrome[1]	No reported start-up syndrome
Kidney Safety	- Small decrease in creatinine clearance - Resolves after stopping drug[2]	- Less risk of kidney-related side effects[3]	- No reported risk of kidney-related side effects[1]	- No reported risk of kidney-related side effects[1]
Bone Safety	- Small decreases in bone mineral density - Not associated with fractures[4]	- No reported bone safety issues[1]	- No reported bone safety issues[1]	- No reported bone safety issues[1]
Injection Site Reactions	- N/A	- N/A	- Pain, tenderness, local skin swelling - Typically, mild/moderate, brief[5]	Lumps or nodules, pain, swelling, redness, itching, bruising, or hardening of the skin at the injection site.

CLINICAL EVIDENCE UPDATE | 2025-2026 Data

PrEP Safety & Efficacy in Pregnancy

Comparative Analysis of Key Options

Oral TDF/FTC

STANDARD OF CARE

>90% Protection

CLINICAL STATUS

Preferred First-Line

NIH Perinatal Guidelines 2024

KEY EVIDENCE

- High efficacy for receptive vaginal sex with adherence.
- Robust long-term safety data in pregnancy & breastfeeding.
- No adverse infant outcomes linked to exposure.

Recommendation: Continue if pregnancy occurs.

Cabotegravir LA

LONG-ACTING INJECTABLE

Superior Efficacy

CLINICAL STATUS

Supported Continuation

WHO 2025 Guidelines

KEY EVIDENCE

- HPTN 084 OLE & Botswana data show reassuring outcomes.
- Very low breastmilk transfer; minimal infant drug exposure.
- No new HIV infections in exposed pregnancies.

Recommendation: Shared decision-making; do not discontinue.

Lenacapavir

TWICE-YEARLY INJECTABLE

High Potency

CLINICAL STATUS

Approved for Use

FDA / WHO (IAS 2025)

KEY EVIDENCE

- PURPOSE 1: Maintained protective levels without dose adjustment.
- Minimal infant exposure (~2% relative to maternal blood).
- Birth outcomes comparable to oral PrEP and background rates.

Recommendation: Effective option; minimal dosing burden.

Why PrEP Matters for EMTCT

Heightened Vulnerability:

- Pregnant and lactating people disproportionately vulnerable to HIV
  - Many incident infections and transmissions occur during pregnancy and breast feeding.
  - Biological factors may increase susceptibility
  - Social and behavioural factors may increase exposure to HIV

Driving Vertical Transmission:

- Acute maternal infection = high viral load
- Elevates risk of transmission

Synergy with EMTCT Targets:

- PrEP in ANC and Postnatal care works alongside other prevention strategies to close the gap in our elimination efforts.

PrEP & Pregnancy

PrEP could complement established HIV prevention strategies for pregnant and breastfeeding women as part of a comprehensive package to reduce HIV infections among women and transmission from mothers to infants

The existing safety data support the use of PrEP in pregnant and breastfeeding women who are at continuing substantial risk of HIV infection.

QUESTION #1

1

- Which of the following statements about LA-Cabotegravir is false:
- 1)It has no reported start-up syndrome
- 2) It has no reported bone safety issues
- 3) It causes weight gain especially in females.
- 4) It is safe to use in pregnancy and breastfeeding.

Case DJ/AP

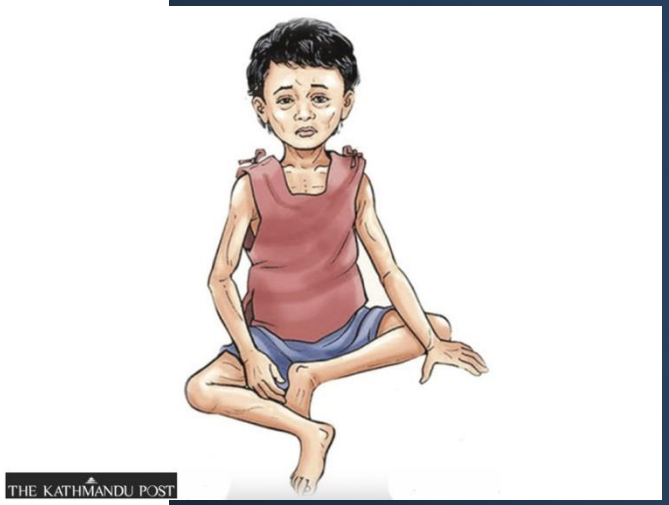
- DJ – 28 year old mother
- Uneventful pregnancy: HIV: neg. x2, RPR: non-reactive x 3
- Delivered term neonate, svd, no complications
- Presents for 6 week postnatak check up
  - No complaints, no concerns

Case DJ/AP

- No complaints. Normal physical exam x2
- Breastfeeding encouraged
- Social htx: Lives alone with infant – partner works in the mining sector, visits every 4-6 months- no other partner.
- No smoking, no alcohol use, no condom use

Case DJ/AP

- Mother attends well baby clinic regularly
- Infant vaccinated
- Developing well
- Diet: Exclusive bf x 6/12
- Introduction of solids and cereals after 6/12
- Breast milk until 22 months
- Infant weight: Plateaued from 18-20 months
- LOA: 21/22months
- Weight Loss: 27months



Case DJ/AP

- HIV rapid test positive x2
- VL: 1.3M
- CD4: not available
- TB : negative

Who is eligible for HIV PrEP?

- All sexually active adults and adolescents should receive information
- All HIV- pregnant women should receive information at every ANC visit
- HIV negative – no signs of Acute HIV infection
- Discordant couples:
  - Not on Tx/ not virally suppressed/unknown VL/-partner request
- STI within previous 6/12
- Multiple sexual partners
- Inconsistent condom use with multiple partners

Who can Prescribe PrEP

- Primary Health Care Provider
- STI Clinic Prividers
- HIV clinic providers
- RN/ Midwife

- **Making PrEP part of primary care can improve access for all who could benefit, and help address disparities**

When can you start PrEP

- **Same day intiation**
  - Client is ready
  - HIV-
  - No signs of AHI
  - Labs are drawn
  - Confirmed means of contact
- **Same day may not be appropriate for**
  - Patients with a possible very recent HIV exposure but no signs of AHI (consider nPEP)
  - Patients with a htx of renal disease
  - Patients unable to understand PrEP requirements (adherence, follow-up visits)
  - No means of contact

Initial Visit

- HIV Test
- Assess for PEP – potential exposure with 72 hrs
- Assess for Acute HV infection
- Counseling/Adherence
- Labs: Screen for Hep B + C
- STI screening
- Kidney funtions: Creatinine – eGFR
- Pregnancy Test
- Update vaccines – Hep B/HPV

QUESTION #2

2

- For which of these patients is PrEP inappropriate?
- 1) A man who has sex with men who reports inconsistent condom use
- 2) A heterosexual woman in a long-term monogamous marriage who asks for PrEP
- 3) A heterosexual man with multiple sex partners of unknown HIV status
- 4) A female patient with an acute STI
- 5) None of the above

Ongoing Assessments for Patients Using **Oral PrEP**

At least every 3 months:

- Repeat HIV testing and assess for signs or symptoms of acute infection
- Provide a prescription or refill authorization of daily oral PrEP medication for ≤90 days
- Assess and provide support for medication adherence and risk-reduction behaviors
- Screen sexually active people for STIs:
  - Syphilis
  - Gonorrhea
  - Chlamydia
- Respond to questions and provide new information

At least every 6 months:

- Monitor eCrCl for patients who had an eCrCl <90 mL/min when they started oral PrEP
  - Monitor more frequently or perform additional tests if there are other threats to kidney safety
- Assess interest in continuing or discontinuing PrEP

At least every 12 months:

- Monitor eCrCl for all patients continuing on PrEP medication
- For patients using F/TAF, monitor triglyceride and cholesterol levels and weight
- Screen heterosexually active people for chlamydia, even if asymptomatic

Centers for Disease Control and Prevention, US Public Health Service. *Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 update—a clinical practice guideline*. Published December 2021. Accessed January 20, 2023. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Ongoing Assessments for Patients Using **Injectable PrEP - CAB**

At visit 1 month after initial injection:

- Test for HIV and assess for signs or symptoms of acute infection
- Administer CAB injection
- Respond to new questions
- Provide medication adherence and behavioral risk-reduction support

At each bimonthly visit:

- Test for HIV and assess for signs or symptoms of acute infection
- Administer CAB injection
- Respond to questions and provide any new information
- Discuss the benefits of persistent CAB for PrEP use and adherence to scheduled injection visits

At least every 6 months:

- Screen heterosexually active people for bacterial STIs

At least every 12 months:

- Assess desire to continue PrEP
- Screen heterosexually active people for chlamydia, even if asymptomatic

Centers for Disease Control and Prevention, US Public Health Service. *Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 update—a clinical practice guideline*. Published December 2021. Accessed January 20, 2023. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Ongoing Assessments for Patients Using **Injectable PrEP - LEN**

Visits are every 6 months +/- 2 weeks:

- Test for HIV before administration of injection

At each 6 monthly visit:

- Test for HIV – confirm negative status before injection
- Assess for signs or symptoms of acute infection
- Assess injection site – pain, nodules hardening
- Confirm timing
- Administer LEN injection
- Respond to questions and provide any new information
- Discuss the benefits of persistent LEN for PrEP use and adherence to scheduled injection visits

At least every 6 months:

- Screen sexually active people for bacterial STIs

At least every 12 months:

- Assess desire to continue PrEP
- Screen heterosexually active people for chlamydia, even if asymptomatic

Centers for Disease Control and Prevention, US Public Health Service. *Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 update—a clinical practice guideline*. Published December 2021. Accessed January 20, 2023. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

INTEGRATING PREP INTO MATERNAL HEALTH

PrEP as part of EMTCT Programs

Global Alignment

- Helps international efforts to reduce pediatric HIV cases and improve maternal health outcomes.

Risk Mitigation

Community Outreach:

Safety and Efficacy of PrEP in Pregnancy and Breast Feeding

- Efficacy: Studies have established that PrEP effectively reduces the risk of HIV transmission in pregnant women
- Safety: Clinical trials show a favorable outcome for both mother and inant when PrEP is used correctly
- Guidance: Ongoing monitoring and adherence are important to ensure safety and maximum efficacy of PrEP use in Pregnancy.

Barriers to Implementation

Ethical and Cultural Considerations

- Decision Autonomy:
  - Ethical dilemmas often arise in respecting a mother's autonomy while ensuring both her and the baby's health are prioritized in PrEP discussions.
- Cultural Stigma
- Partner Dynamics

The Opt-Out Approach

- Offer PrEP at every ANC/PNC/Adolescent Health Clinic – normalize prevention
- Same day start if possible
- Counseling:
- Follow –up visits: Align visits with ANC visits
- Support System: Reminders, pillboxes,
  - Task –shifting, community refills.

QUESTION #3

Poll 3

- **Which of the following statements is true?**
- 1) Only oral PrEP medications are safe to give to a breastfeeding mother.
- 2) PrEP can only be prescribed by an infectious disease or HIV specialist
- 3) PrEP medications are generally well tolerated, and side effects are typically mild to moderate, manageable, and temporary
- 4) PrEP should only be prescribed for MSM and TG women.

RECOMMENDATIONS AND ADVOCACY FOR PREP IN PREGNANCY

Recommendations

- Update National Guidelines to include PrEP in pregnancy
- Clinical Practice: Standardize Protocols
  - Culturally acceptable
  - Safety Monitoring
  - Counseling
- Product Choice: Oral Vs Injectable

Recommendations

- Health Systems:
  - Capacity Building
    - Training programs
  - Resource Allocation
  - Strengthening Infrastructure
- Monitoring and Evaluation

Advocacy for Evidence-Based Innovations

- **Research emphasis**
  - Highlight clinical studies and data that validate PrEP's efficacy in preventing HIV infection during pregnancy as a critical tool for EMTCT .
- **Community education**
  - Promote awareness campaigns to encourage public acceptance of PrEP as a safe, evidence-supported intervention for pregnant women at risk of HIV.
- **Data-driven decisions**
  - Leverage real-world evidence to influence policies and dispel misconceptions about PrEP in maternal and child health programs.

Expected Outcomes

- Increased Awareness
- Practical Integration
- Strengthened Advocacy
- Regional Consensus

Cost & Impact

- Can you put a cost on a child's life?
- Preventing one pediatric HIV case saves a lifetime of ART costs

Key Take-Home Messages

- Pregnancy is a high-risk period
- PrEP is safe and effective
- EMTCT needs prevention

Call to Action

- CLINICIANS: OFFER PREP

- PROGRAMS: PILOT & MONITOR

- POLICYMAKERS: ENABLE SCALE-UP

Key References

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- • WHO. Technical brief: Preventing HIV during pregnancy and breastfeeding.
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