The Eradication of HIV

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Introduction

- Children's Mercy Kansas City - Infectious Diseases APRN
- INMED Diploma in 2012
- Caring for PLWH since 2015
- Certified HIV Specialist through AAHIVM (2018)
- Advanced HIV/AIDS Certified Registered Nurse through HANCB 2023)

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Disclosures

- I will discuss non-FDA approved medication indications
- No relevant financial relationships with ineligible companies to disclose

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Objectives

- Describe how treatment of HIV infection can stop the transmission of HIV
- Verbalize how emphasis on stopping maternal to child transmission of HIV has significantly slowed pediatric infection
- Name medications used to prevent HIV through HIV PrEP
- Describe the social and legislative factors that hinder HIV prevention.

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Imagine a world.....

"It is possible to end AIDS by 2030 if countries demonstrate the political will to invest in prevention and treatment and adopt non-discriminatory laws." ~ UNAIDS Statement, July 2023.

"Embrace and celebrate the progress while not letting up the pressure until there is a cure." ~David Mixner, HIV/AIDS Activist

Image: ABCNews Live on X, 2022

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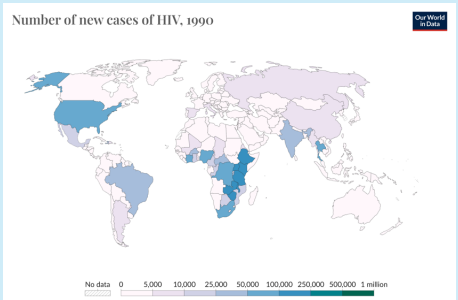

New Worldwide Cases of HIV infection in 1990: 2.06 million*

*all time high of 3.31 million new cases in 1997)

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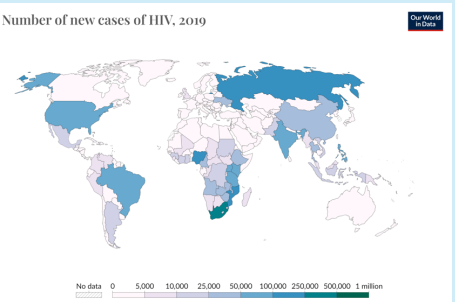

New Worldwide Cases of HIV infection in 2019: 1.99 million

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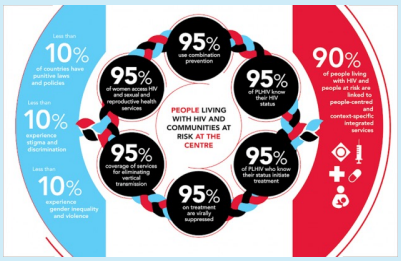
UNAIDS Global HIV Goals

In 2022, Global percentages:

- 86% diagnosed
- 89% taking ART
- 93% achieving viral suppression



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Ending the HIV Epidemic US Goals

Achieved through four initiatives:

1. Diagnose as early as possible.
2. Treat rapidly and effectively
3. Prevent new transmissions
4. Respond quickly to outbreaks

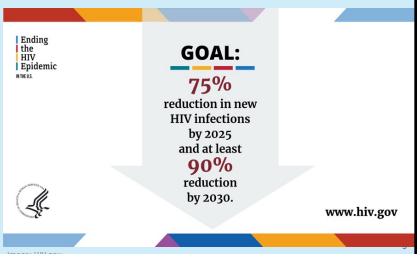

Image: HIV.gov

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HIV Eradication Toolbox

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HIV Prevention Timeline

- Late 1980's – HIV PEP first used following occupational exposures for health care workers
- 1990 – CDC First HIV PEP Guidelines
- 1991 – ACTG 076 – first study of MTCT launched using zidovudine (originally called AZT) commences
- 1993 – ACTG 076 shows IV zidovudine significantly reduces MTCT of HIV.
- 1994 – US Public Health Service first recommends zidovudine for pregnant women to reduce the risk of transmission
- 1997 – Case control study showed first evidence that single agent PEP could decrease transmission in humans.

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HIV Prevention Timeline

- 2001 – CDC Announces first *HIV Prevention Strategic Plan* with goal to cut new US infections in half by 2005
- 2005 – CDC created first guidelines for non-occupational PEP (nPEP)
- 2011 – Results of HPTN052 showed that early initiation of ART reduced transmission by 96% (TasP)
- 2014 – CDC issues first guidance for the use of Pre-exposure prophylaxis (PrEP)
- 2016 – U=U Campaign was started to highlight the findings of HPTN 052, START, and PARTNER, that undetectable Viral Load means HIV is not transmittable through sex.
- 2023 – First US guidance issued regarding HIV and Infant feeding

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Tool – HIV Testing

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HIV Testing as Prevention

- ~1.2 million people in the United States have HIV, including about 158,500 people who are unaware of their status.
- Nearly 40% of new HIV infections are transmitted by people who don't know they have the virus.
- Testing as recommended is the first step in preventing HIV transmission.

GET TESTED FOR HIV...

CDC recommends that **everyone** between the ages of 13 and 64 get tested **at least once** as part of routine care.

People with certain risk factors should get tested at least once a year.

Find an HIV testing site near you: **Locator.HIV.gov**

Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, CDC, June 2022

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HIV Testing as Prevention

The Role of HIV Self Testing in Ending the HIV Epidemic

Now is the time for bolder, more collaborative action.

HIV self-testing programs offer an innovative way to bridge gaps in access to HIV testing and **ensure that HIV testing is simple and more accessible for all.**

CDC cdc.gov/hiv

Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, CDC, June 2022

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HIV Testing as Prevention

WHAT IS THE WINDOW PERIOD FOR THE HIV TEST I TOOK?

Nucleic Acid Test (NAT)*	Antigen/Antibody Lab Test*	Rapid Antigen/Antibody Test†	Antibody Test‡
window period	window period	window period	window period
10-33 days	18-45 days	18-90 days	23-90 days

* Performed by a lab on blood from a vein.
† Done with blood from a finger stick.
‡ Most rapid tests and self-tests are antibody tests.

HIV Basics www.cdc.gov/hiv/basics

For more information, visit **www.cdc.gov/hiv/basics/testing.html**

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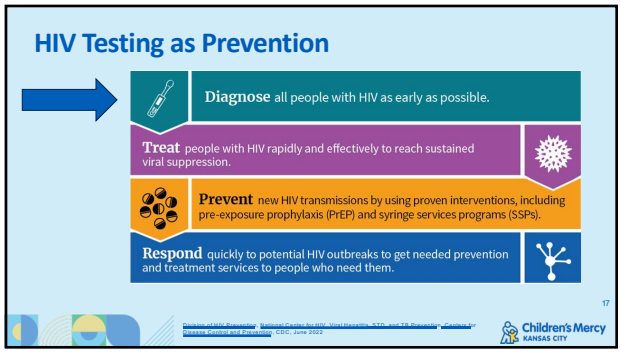
HIV Testing as Prevention
Diagnose all people with HIV as early as possible.
Treat people with HIV rapidly and effectively to reach sustained viral suppression.
Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).
Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.
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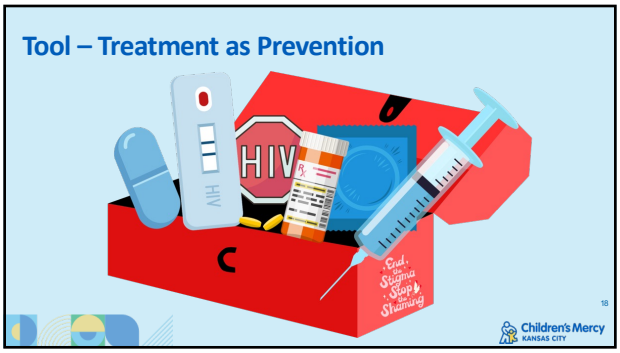
Tool – Treatment as Prevention
HIV
HIV
End the Stigma Stop the Shaming
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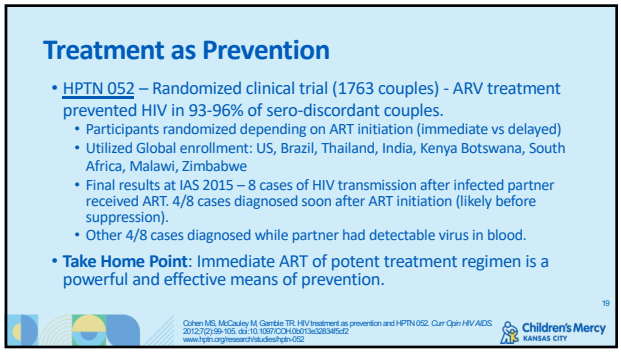
Treatment as Prevention
• HPTN 052 – Randomized clinical trial (1763 couples) - ARV treatment prevented HIV in 93-96% of sero-discordant couples.
• Participants randomized depending on ART initiation (immediate vs delayed)
• Utilized Global enrollment: US, Brazil, Thailand, India, Kenya Botswana, South Africa, Malawi, Zimbabwe
• Final results at IAS 2015 – 8 cases of HIV transmission after infected partner received ART. 4/8 cases diagnosed soon after ART initiation (likely before suppression).
• Other 4/8 cases diagnosed while partner had detectable virus in blood.
• Take Home Point: Immediate ART of potent treatment regimen is a powerful and effective means of prevention.
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Cohen MS, McCauley M, Gamble TR. HIV treatment as prevention and HPTN 052. Curr Opin HIV AIDS. 2012;7(2):99-105. doi:10.1097/COH.0b013e32834f5cf2
www.hptn.org/research/studies/hptn-052
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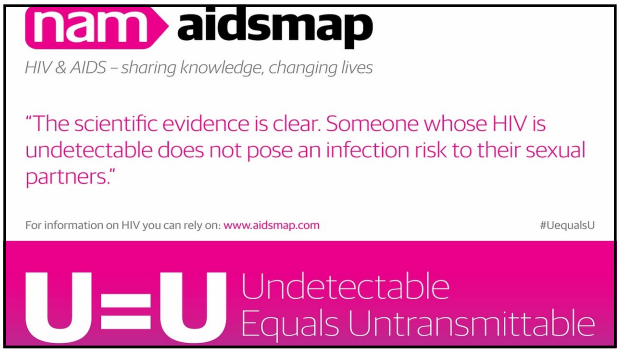
nam aidsmap
HIV & AIDS – sharing knowledge, changing lives
"The scientific evidence is clear. Someone whose HIV is undetectable does not pose an infection risk to their sexual partners."
For information on HIV you can rely on: www.aidsmap.com
#UequalsU
U=U
Undetectable
Equals Untransmittable

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Undetectable = Untransmittable

- Undetectable = Untransmittable (U=U)
  - "U=U means PLWH who achieve and maintain an undetectable viral load, by taking and adhering to antiretroviral therapy (ART) as prescribed **cannot sexually transmit** the virus to others."
  - Observation studies (PARTNER 1, PARTNER 2, Opposites Attract, HPTN 052)
    - No transmission when VL <200, + transmission other STI observed
- 2019 JAMA changed language from "effectively no risk" to "cannot transmit" based on a large volume of data.

Source: www.aidsmap.com/news/feb-2017/nam-endorses-undetectable-equals-untransmittable-uu-consensus-statement

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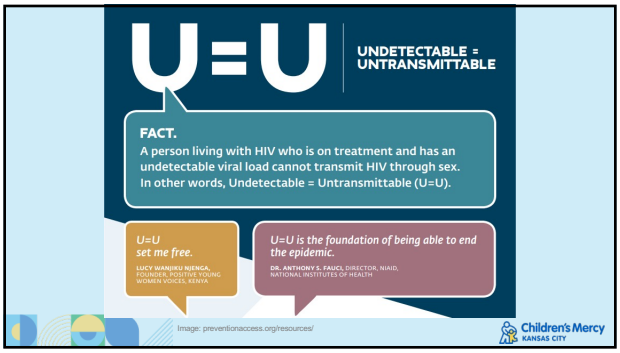

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Tool: Post-Exposure Prophylaxis

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HIV Prevention: nPEP

- PEP is for emergency situations where people have had substantial exposure to body fluids potentially containing HIV.
- nPEP is indicated for those at **substantial risk** of exposure from sex, IVDU, or sexual assault.
- PEP needs to be initiated within 72 hours.
- The sooner you start PEP, the better.
- Clinicians can call the **PEPline** (1-888-448-4911) for advice on managing occupational exposures to HIV.

WHAT IS PEP?

PEP (or post-exposure prophylaxis) involves taking anti-HIV drugs **very soon after** a possible exposure to HIV to **prevent HIV.**

Source: cdc.gov/hiv/basics/pep/about-pep.html; Image: HIV.gov

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HIV PEP: (Post-Exposure Prophylaxis

PEP 101

If you may have been exposed to HIV* in the last 72 hours, talk to your health care provider, an emergency room doctor, or your local health department about PEP right away. PEP can reduce your chance of becoming HIV-positive.

What Is PEP?

- PEP, or post-exposure prophylaxis, means taking medicines after you may have been exposed to HIV to prevent becoming infected.
- **PEP must be started within 72 hours (3 days) after you may have been exposed to HIV.** But the sooner you start PEP, the better. Every hour counts!
- If your health care provider prescribes PEP, you'll need to take it once or twice daily for 28 days.
- PEP is effective in preventing HIV, but not 100%. Always use condoms with sex partners and use safe injection practices.

Image: Centers for Disease Control

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HIV Prevention: PEP (occupational and not)

- In 1988, 2 uses (one at NIH in Bethesda and one in San Francisco) of occupational PEP led to utilization of zidovudine as effort to prevent HIV transmission.
  - In the name of employee advocacy, reservations regarding safety of the medications were overridden by the emerging, albeit limited, scientific information and by a desire to support the staff
- 1994 – Cardo, et al, had determined that the size of the inoculum from occupational exposures mattered, but also determined that PEP with ZDV led to an 81% reduction in transmission.
- Trials inoculating Macaques with Simian Immunodeficiency Virus showed successful prevention of transmission of virus when utilizing immediate ZDV as well as use up to 24 hours after inoculation.
- In 1997, occupational PEP case reports, combined with animal trials were extrapolated to eventually include nPEP for those with substantial risk as double-blind, placebo RCTs were unlikely to ever occur due to their ethical nature.

Chacko L, Ford N, Sbaiti M, Siddiqui R. Adherence to HIV post-exposure prophylaxis in victims of sexual assault: a systematic review and meta-analysis. Sex Transm Infect. 2012 Aug;88(5):335-41.

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HIV PEP – Substantial Risk of HIV

Type of Exposure	Risk per 10,000 Exposures
Parenteral	
Blood transfusion	9,250
Needle-sharing during injection drug use	63
Percutaneous (needle-stick)	23
Sexual	
Receptive anal intercourse	138
Receptive penile-vaginal intercourse	8
Insertive anal intercourse	11
Insertive penile-vaginal intercourse	4
Receptive or insertive oral intercourse	Low
Other	
Biting, spitting, throwing body fluids (including semen or saliva), sharing sex toys	Negligible

https://www.cdc.gov/hiv/risk/estimates/riskbehavior.html

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HIV nPEP Medications

Weight	Preferred Regimen
> 35 kg	Emtricitabine/tenofovir (200/300mg) tablet + dolutegravir tablet (50 mg)
28 – 34 kg	Emtricitabine/tenofovir (167/250 mg) tablet + dolutegravir tablet (50 mg)
22 – 27 kg	Emtricitabine/tenofovir (133/200 mg) tablet + dolutegravir tablet
14*– 22 kg OR unable to swallow tablets	Zidovudine (50mg/5mL syrup) 9 mg/kg PO BID (max. 300 mg/dose) AND Lamivudine (10mg/mL solution) 5 mg/kg PO BID (max. 150 mg/dose) AND Dolutegravir(PD)* (5mg soluble tab for oral susp): 20 kg: 30 mg once daily 14 to < 20 kg: 25 mg once daily

**DTG formulations are not interchangable.*
For pts < 14 kg, consider durable, INSTI-based HIV Treatment regimens.

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Tool: Prevention of MTCT

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Prevention of MTCT of HIV Infection

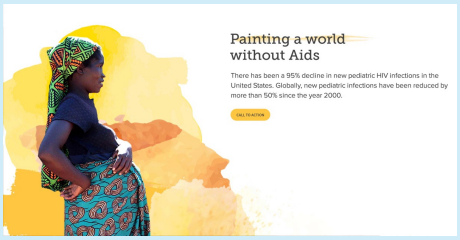

Image: Elizabeth Glaser Pediatric AIDS Foundation

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HIV Prevention: Maternal To Child Transmission

- Initial studies showed decrease in maternal to child transmission by providing mothers with ZDV.
- ACTG 076 landmark double-blinded placebo study showing that infants receiving 6 weeks of ZDV had transmission rate of 7.6% while the placebo group had 22.6% rate.

TABLE 1. MEDIAN PLASMA HIV-1 RNA LEVELS AT STUDY ENTRY, ACCORDING TO WHETHER MATERNAL–INFANT TRANSMISSION OF THE VIRUS OCCURRED.*

ASSAY AND STUDY GROUP	HIV-1 TRANSMISSION		NO TRANSMISSION		P VALUE
	NO. OF WOMEN STUDIED	MEDIAN (95% CI)	NO. OF WOMEN STUDIED	MEDIAN (95% CI)	
Reverse-transcription–PCR assay					
Zidovudine	12	19,330 (2100–108,310)	147	4650 (1340–8320)	0.01
Placebo	38	8,320 (4350–26,770)	130	5370 (2890–8770)	0.003
bDNA assay					
Zidovudine	10	2,620 (920–16,310)	136	2770 (1870–3900)	0.45
Placebo	31	4,680 (2200–11,130)	114	1850 (1540–2280)	0.008

*Medians are reported with nonparametric 95 percent confidence intervals (CI) as described in the Methods section. P values were calculated by the two-sample Wilcoxon test.

N Engl J Med 1996; 335:1621-1629
DOI: 10.1056/NEJM199611283352201

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HIV Prevention: MTCT

- All exposed infants should receive ARV drugs as soon as possible, preferably within 6 hours, after delivery.
- Nucleic acid tests (i.e. DNA and RNA PCR, RNA PCR assays) are required to diagnose HIV infection in infants aged <18 months
- If presumptive treatment is indicated, hemoglobin and neutrophil counts should be obtained at baseline. Infants found to have hematologic abnormalities may need to discontinue or switch ARV drugs, and consultation with an expert in pediatric HIV infection is advised.
- Discussion of safe infant feeding options should be provided

Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States. Department of Health and Human Services. 2023. Available at https://clinicalinfo.hiv.gov/en/guidelines/perinatal

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HIV Prevention: PMTCT - Botswana

"This groundbreaking milestone is a big step forward in ending AIDS on the continent and shows how visionary political leadership aligned with public health priorities can save lives. I look forward to other African countries also reaching this goal." - Dr Matshidiso Moeti, WHO Regional Director for Africa

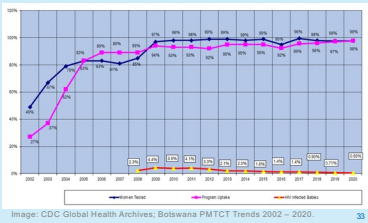

Image: CDC Global Health Archives; Botswana PMTCT Trends 2002 – 2020.

World Health Organization. World News, December 5, 2021.

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HIV Prevention: Maternal To Child Transmission

Level of Perinatal HIV Transmission Risk	Description	Neonatal ARV Management
Very Low Risk of Perinatal HIV Transmission	**Infants ≥37 weeks gestation when the mother—** •Is currently receiving and has received at least **10 consecutive weeks** of ART during pregnancy, *and* •Has achieved and maintained or maintained viral suppression (defined as at least two consecutive tests with HIV RNA levels <50 copies/mL obtained at least 4 weeks apart) for the remainder of the pregnancy, *and* •Has HIV RNA <50 copies/mL at or after 36 weeks and within 4 weeks of delivery, *and* •Did not have acute HIV infection during pregnancy, *and* •Has reported good ART adherence, and adherence concerns have not been identified.	ZDV for 2 weeks

Adapted from: Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States. Department of Health and Human Services. 2023. Available at https://clinicalinfo.hiv.gov/en/guidelines/perinatal

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HIV Prevention: Maternal To Child Transmission

Level of Perinatal HIV Transmission Risk	Description	Neonatal ARV Management
Low Risk of Perinatal HIV Transmission	Infants born to mothers who do not meet the previous criteria but who have a HIV RNA <50 copies/mL at or after 36 weeks gestation OR Premature infants (<37 weeks gestation) who do not meet criteria for high risk of perinatal acquisition of HIV	ZDV for 4 to 6 weeks

Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States. Department of Health and Human Services. 2023. Available at https://clinicalinfo.hiv.gov/en/guidelines/perinatal

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HIV Prevention: Maternal To Child Transmission

Level of Perinatal HIV Transmission Risk	Description	Neonatal ARV Management
High Risk of Perinatal HIV Transmission	Mothers who did not receive antepartum ARV drugs, *or* Mothers who received only intrapartum ARV drugs, *or* Mothers who received antepartum ARV drugs but did not have viral suppression (defined as at least two consecutive tests with HIV RNA level <50 copies/mL obtained at least 4 weeks apart) within 4 weeks prior to delivery, *or* Mothers with acute or primary HIV infection during pregnancy or breastfeeding (in which case, **breastfeeding should be immediately discontinued**).	Presumptive HIV therapy using either ZDV, 3TC, and NVP (treatment dose) *or* ZDV, 3TC, and RAL administered together from birth for 2 to 6 weeks; (if the duration of the 3-drug regimen is shorter than 6 weeks, ZDV should be continued alone, to complete a total of 6 weeks of prophylaxis)

Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States. Department of Health and Human Services. 2023. Available at https://clinicalinfo.hiv.gov/en/guidelines/perinatal

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HIV Prevention: Maternal To Child Transmission

Level of Perinatal HIV Transmission Risk	Description	Neonatal ARV Management
Presumed Newborn HIV Exposure	Mothers with unconfirmed HIV status who have at least one positive HIV test at delivery or postpartum, *or* Mothers whose newborn has a positive HIV antibody test	ARV management as described above for newborns with a high risk of perinatal HIV acquisition. Infant ARV drugs should be discontinued immediately if supplemental testing confirms that the mother does not have HIV.

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https://clinicalinfo.hiv.gov/en/guidelines/perinatal/management-infants-arv-hiv-exposure-infection?view=full

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So, what about infant feeding and HIV prevention?

What is the risk of transmission through breastfeeding?

There are no studies that have examined the risk of HIV transmission through breast milk in high-resource countries.

This is because these studies would be impossible to perform.

So all the research we have has come from low resource settings where breastfeeding is recommended for mothers living with HIV.

Overall summary of HIV transmission risk through breast milk:

Rates of HIV transmission through breast milk in women on antiretrovirals (ARVs) vary between studies but a WHO commissioned summary of all studies available at the time* reported an HIV transmission rate of:

1.1% with 6 months of breastfeeding

this means that on average for every 100 women living with HIV and taking ARVs that breastfeed their infants for 6 months, 1 infant will acquire HIV

2.9% with 12 months of breastfeeding

this means that on average for every 100 women living with HIV and taking ARVs that breastfeed their infants for 12 months, 3 infants will acquire HIV

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HIV Prevention: Safe Infant Feeding

- For decades, guidance has varied significantly between high-income and low-income regions
- The risk of HIV transmission through breastfeeding in high-income countries remains unknown because randomized, controlled trials of prevention of MTCT using combination ART **are not feasible**.
- 2016 WHO guidelines advised that, "in countries that have opted to promote and support breastfeeding" mothers should breastfeed exclusively for 6 months and may add complementary feeding from 6-12 months and may continue up to 24 months for mothers virally suppressed on ART.
- WHO also recommends in settings where this is promoted, shorter durations of breastfeeding are better than never initiating breastfeeding.

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World Health Organization, United Nations Children's Fund. Guideline: updates on HIV and infant feeding: the duration of breastfeeding, and support from health services to improve feeding practices among mothers living with HIV. Geneva: World Health Organization; 2016.

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HIV Prevention: Infant Feeding

- WHO guidelines balanced HIV prevention with other causes of child mortality. Countries could:
  - Offer ARV drug services and support breastfeeding
  - Avoid all breastfeeding to give infants the greatest chance of HIV-free survival.
- Systematic review data of multiple observational and experimental trials in Sub-Saharan Africa found a pooled postnatal transmission rate at 6 months of 1.1% in women (on ART from mid-pregnancy and breastfed their infant for 6 months).
- Breastfeeding provides numerous health benefits to the infant (reduction in asthma, gastroenteritis, AOM) and mother (reduction in HTN, DM2, breast and ovarian cancers).

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Graybill, L. A., Kasaro, M., Freeborn, K., Walker, J. S., Poole, C., Powers, K. A., ... & Mutale, W. (2020). Incident HIV among pregnant and breastfeeding women in sub-Saharan Africa: a systematic review and meta-analysis. *AIDS (London, England)*, *34*(5), 761.

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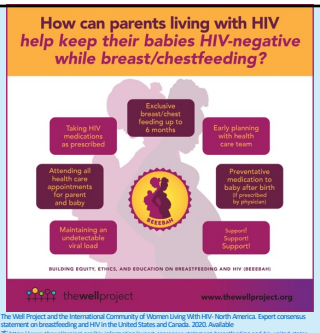
HIV Prevention: Infant Feeding



The Well Project and the International Community of Women Living With HIV- North America. Expert consensus statement on breastfeeding and HIV in the United States and Canada. 2020. Available at: https://www.thewellproject.org/sites/default/files/Expert_Consensus_Statement_on_Breastfeeding_and_HIV_in_the_United_States_and_Canada_2020.pdf

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HIV Prevention: Infant Feeding

New US guidance in Feb. 2023. What do the updated guidelines say?

1. The infant feeding options that eliminate risk of HIV transmission are formula or pasteurized donor milk.
2. Fully suppressive ART during pregnancy/breastfeeding decreases but does not eliminate transmission risk (described as < 1%).
3. Post-partum period is known to come with adherence challenges and additional support from a multi-disciplinary team (including lactation) is needed to ensure viral suppression.
4. Most studies were completed in resource limited regions—more information is needed for definitive guidance.
5. If breastfeeding is chosen, specific recommendations should be made.

Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States. Department of Health and Human Services. 2023. Available at: https://clinicalinfo.hiv.gov/en/guidelines/perinatal

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HIV Prevention: Infant Feeding

- The guidelines concluded that in the literature, most of the HIV transmissions occurred in the case of late ART initiation, or poor adherence or access to ARVs.
  - Mma Bana study – 500 mothers with 2 transmissions via breastfeeding (both with plasma and BM HIV RNA levels <50 copies).
  - Tanzania study of 186 mothers; 2 transmissions, 1 with high maternal VL 1 month after birth, 2nd when mother discontinued ART. No cases of transmission on mothers who remained suppressed.
- In all the SSA studies mentioned, maternal ART was initiated in the second or third trimester or postpartum. No studies have systematically evaluated the risk of HIV transmission through breastfeeding when maternal ART is started before pregnancy or in the first trimester and continued throughout breastfeeding.

1. Shapiro RL, Hughes MD, Ogwu A, et al. Antiretroviral regimens in pregnancy and breast-feeding in Botswana. *N Engl J Med*. 2010;362(24):2282-2294. Available at: http://www.ncbi.nlm.nih.gov/pubmed/20554983.
2. Luoga E, Vanobberghen F, Bircher R, et al. Brief report: No HIV transmission from virally suppressed mothers during breastfeeding in rural Tanzania. *J Acquir Immune Defic Syndr*. 2018;79(1):e17-e20. Available at: https://www.ncbi.nlm.nih.gov/pubmed/29787483.

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HIV Prevention: Infant Feeding

Infant ARVs during breastfeeding

- "There is no consensus on appropriate management of ARV prophylaxis for infants of individuals with sustained viral suppression who are breastfed."
- WHO recommends 6 weeks of NVP
- HPTN 046 showed the <1% post-natal transmission rate in the extended and shortened NVP arms.
- British HIV Association only recommends the 2 weeks of ZDV.

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Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States. Department of Health and Human Services. 2023. Available at: https://clinicalinfo.hiv.gov/en/guidelines/perinatal

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HIV Prevention: Infant Feeding

Newborns at Low Risk of HIV Acquisition During Breastfeeding		
Recommended Regimen	Recommended Duration	
ZDV	ZDV administered for 2 weeks	
Optional Extended Postnatal Prophylaxis for Newborns at Low Risk of HIV Transmission During Breastfeeding		
Optional Regimen	Optional Recommended Duration	
ZDV	ZDV administered for 4 to 6 weeks	
NVP	Birth to 6 weeks 6 weeks to 6 months 6 months to 9 months 9 months to 1-4 weeks post-ween	1.5 mL 2.0 mL 3.0 mL 4.0 mL

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Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States. Department of Health and Human Services; 2023.

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Tool: Pre-Exposure Prophylaxis

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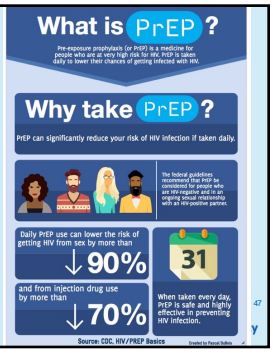
HIV Prevention: PrEP

- When taken as prescribed, Pre-Exposure Prophylaxis (PrEP) reduces the risk of getting HIV from sex by ~99% and IVDU by at least 74% (studied in TDF only).
- In now hundreds of clinical trials, adherence was the most important factor in HIV prevention.
- Time to maximum protection
  - **Receptive anal sex - 7 days** of daily use
  - **Receptive vaginal sex** and **injection drug use - 21 days** of daily use
  - No data for PrEP efficacy for insertive sex or injectable PrEP.



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CDC – PrEP Basics

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HIV Prevention: PrEP

- iPrEx Study (Grant, et al, 2010) – utilized FTC/TDF (emtricitabine/tenofovir disoproxil or Truvada) as part of comprehensive education for healthy sexual behaviors for MSM
  - Among those with detectable levels of the study drug and after adjustment for reported unprotected intercourse, the relative risk reduction was 95%
- Partners PrEP (Baeten, et al, 2012) – utilized FTC/TDF with 4758 enrolled heterosexual couples in Uganda and Kenya.
  - Study showed a 67% relative reduction in HIV-1 incidence for TDF and 75% for FTC/TDF.
  - HIV-1 protective effects of FTC/TDF and TDF were not significantly different (p=0.23), and both study medications significantly reduced HIV-1 incidence in both men and women.

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Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. N Engl J Med. 2012;367(5):399-410. doi:10.1056/NEJMoa1108524

Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med. 2010;363(27):2587-2599. doi:10.1056/NEJMoa1011205

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Efficacy Results from PrEP Clinical Trials

Clinical trial	Participants	Number	Drug	mITT ᵃ efficacy of % reduction in acquisition of HIV infection ᵇ		Adherence-adjusted efficacy based on TDF detection in blood ᶜ	
				%	(95% CI)	%	(95% CI)
iPrEx	Men who have sex with men (MSM)	2499	TVD*	42	(18-60)	92	(40-99)
Partners PrEP	HIV discordant couples	4747	TDF	67	(44-81)	86	(67-94)
			TVD*	75	(55-87)	90	(58-98)
TDF 2	Heterosexually active men and women	1200	TVD*	62	(22-83)	84	NS
Bangkok Tenofovir Study	IDU	2413	TDF	49	(10-72)	92	(2-91)
Fem-PrEP	Heterosexually active women	1951	TVD*	NS	-----	< 40%	-----
VOICE	Heterosexually active women	5029	TVD*	NS	-----	<30%	-----

a. Modified Intent to Treat
b. Excluded only those enrolled patients later found to be infected at randomization and those with no follow-up visit or HIV test
c. The percentage of reduction in HIV incidence among those with TFV detected in blood, compared with those without detectable TFV
*TVD = FTC/TDF

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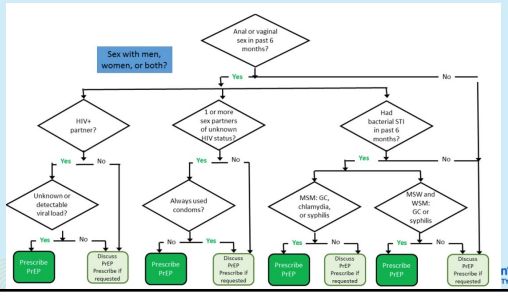
HIV Prevention: PrEP – who qualifies?



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HIV Prevention: PrEP

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PrEP Medications

- F/TDF- **Truvada®** - emtricitabine 200mg/tenofovir disoproxil 300mg
- 1 pill once daily
- Approved for **any** sexually active person or person who injects drugs weighing at least 77 lbs (35 kg) with eCrCl ≥ 60
- Most common side effects: headache, abdominal pain, weight loss
- FDA indication is for daily PrEP
  - 2-1-1 PrEP (not FDA Approved, but well studied)
  - IPERGAY Study - N Engl J Med 2015; 373:2237-2246 DOI: 10.1056/NEJMoa1506273

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HIV Prevention: PrEP Medications

- F/TAF - **Descovy®** - emtricitabine 200mg/tenofovir alafenamide 25mg
- 1 pill once daily
- Approved for men or transgender women engaging in anal intercourse and weighing at least 77 lbs (35 kg), eCrCl ≥ 30
- Not for use in receptive vaginal intercourse
- Most common side effect: diarrhea

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HIV Prevention: PrEP Medications

- CAB – **Apretude®** - cabotegravir 600mg injection every 2 months after initiation period
- Approved for adults and adolescents ≥35 kg
- Approved for men or women who are sexually active
- Most common side effect: injection site reactions, diarrhea, headache
- Tail effect

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Tool: Syringe Programs

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Tool: Syringe Programs

- Our nationwide opioid crisis is increasing risks of infections (like HIV) that are spread from shared needles.
- Over 2500 new cases of HIV each year are attributable to IVDU.
- SSPs are community-based prevention programs providing a range of health services, and a lifeline to those struggling with substance abuse.
- Comprehensive SSPs offer patients vaccinations and testing for diseases, referrals to treatment for substance abuse and infections, and sterile injection equipment to prevent the transmission of infectious diseases.

SYRINGE SERVICES PROGRAMS

SSPs are a safe, effective, and cost-saving way to **prevent the spread of HIV and HCV** through injection drug use.

HIV.gov

Source: HIV.gov; www.hiv.gov/federal-response/policies-issues/syringe-services-programs

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Tool: Syringe Programs

Scientists, including those at the Centers for Disease Control and Prevention (CDC), have studied SSPs for more than 30 years and found that comprehensive SSPs benefit communities.

Image: HIV.gov, SSP Program Infographic, July 2020

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Tool: Decrease Stigma and Harmful legislation

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HIV Prevention: Decreasing stigma and harmful legislation

- Societal and legal impediments that inhibit quality HIV prevention, care, treatment and support services and need to be removed.
- **Enablers** are indicators of a society that improve the effectiveness of HIV prevention, care, and stigma across the continuum.
- Success in one societal enabler (e.g. supportive legal environments) is very likely to influence another (e.g. reduced HIV stigma and discrimination).

- Societies with supportive legal environments and access to justice
- Gender equal societies
- Societies free of stigma and discrimination
- Coaction across development sectors*

- Strategic planning and information
- Communications
- Infrastructure
- Management and incentives
- Accountability

- Community-led
- Available, accessible, acceptable and quality
- Gender-responsive
- Integrated
- Differentiated delivery
- Demand creation through communications/advocacy
- Social protection programmes

Stangl AL, Pilakas T, Izazola-Licea JA, Ayala G, Beattie TS, Ferguson L, et al. (2022) Removing the societal and legal impediments to the HIV response: An evidence-based framework for 2025 and beyond. PLoS ONE 17(2): e0264249. https://doi.org/10.1371/journal.pone.0264249

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Tool: Decrease Stigma and Harmful legislation

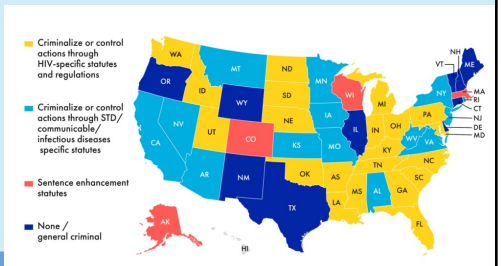

Image: 2023 State of HIV Stigma Report, GLAAD, Gilead and Compass Initiative. https://glaad.org/endhivstigma/2023/

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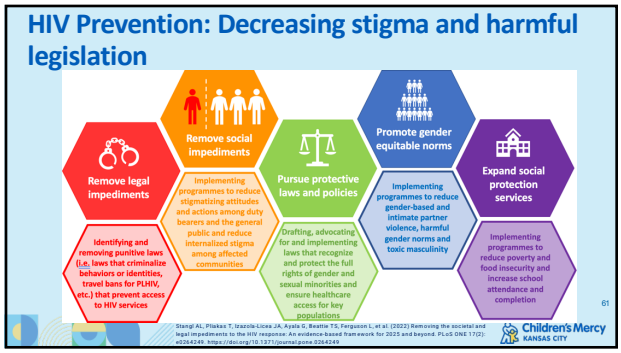
HIV Prevention: Decreasing stigma and harmful legislation
Remove social impediments
Promote gender equitable norms
Remove legal impediments
Pursue protective laws and policies
Expand social protection services
Implementing programmes to reduce stigmatizing attitudes and actions among duty bearers and the general public and reduce internalized stigma among affected communities
Implementing programmes to reduce gender-based and intimate partner violence, harmful gender norms and toxic masculinity
Identifying and removing punitive laws (i.e. laws that criminalize behaviors or identities, travel bans for PLHIV, etc.) that prevent access to HIV services
Drafting, advocating for and implementing laws that recognize and protect the full rights of gender and sexual minorities and ensure healthcare access for key populations
Implementing programmes to reduce poverty and food insecurity and increase school attendance and completion
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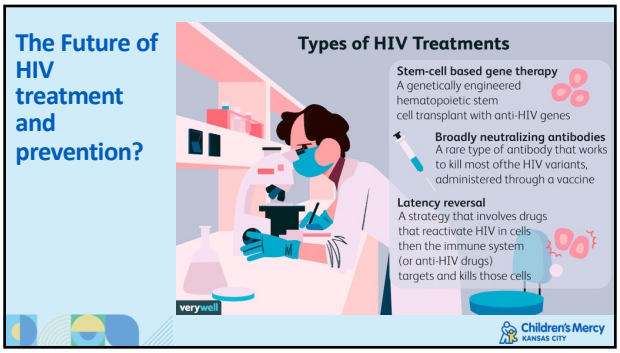
The Future of HIV treatment and prevention?
Types of HIV Treatments
Stem-cell based gene therapy
A genetically engineered hematopoietic stem cell transplant with anti-HIV genes
Broadly neutralizing antibodies
A rare type of antibody that works to kill most of the HIV variants, administered through a vaccine
Latency reversal
A strategy that involves drugs that reactivate HIV in cells then the immune system (or anti-HIV drugs) targets and kills those cells
verywell
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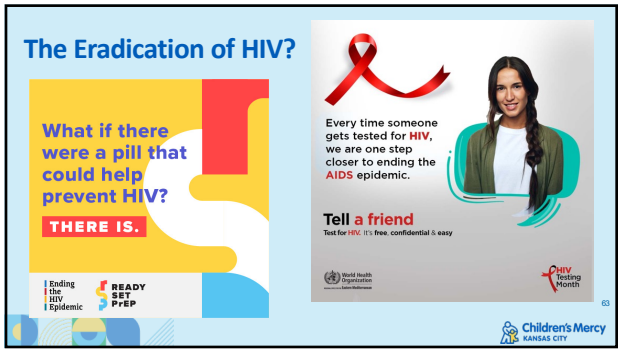
The Eradication of HIV?
What if there were a pill that could help prevent HIV?
THERE IS.
Ending the HIV Epidemic
READY SET PrEP
Every time someone gets tested for HIV, we are one step closer to ending the AIDS epidemic.
Tell a friend
Test for HIV. It's free, confidential & easy
World Health Organization
HIV Testing Month
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Thank You!
THE PATH THAT ENDS AIDS
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