CLINICAL GUIDELINES PROGRAM
NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE | HIV • HCV • STIs • SUBSTANCE USE • LGBTQ+ HEALTH

New York State Good Practices to Prevent Perinatal HIV Transmission

Updates, Authorship, and Related Resources

Date of current publication	June 26, 2023
Intended users	Clinicians who provide medical care for pregnant patients with HIV
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Development process	See Supplement: Guideline Development and Recommendation Ratings
Related NYSDOH AI resources	**Podcast** • Viremic—Cases in HIV

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Contents

Recommended Guidelines

The Perinatal Transmission Prevention Guideline Committee of the New York State Department of Health AIDS Institute (NYSDOH AI) Clinical Guidelines Program recommends that clinicians who provide medical care for pregnant patients with HIV follow the Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States published by the U.S. Department of Health and Human Services (DHHS).

In addition to supporting the comprehensive DHHS recommendations, this committee also encourages clinicians in New York State to follow the good practices outlined below.

Note on "experienced" HIV care providers: The NYSDOH AI Clinical Guidelines Program defines an "experienced HIV care provider" as a practitioner who has been accorded HIV Specialist status by the American Academy of HIV Medicine. Nurse practitioners (NPs) and licensed midwives who provide clinical care to individuals with HIV in collaboration with a physician may be considered experienced HIV care providers if all other practice agreements are met; NPs with more than 3,600 hours of qualifying experience do not require collaboration with a physician (8 NYCRR 79-5:1; 10 NYCRR 85.36; 8 NYCRR 139-6900). Physician assistants who provide clinical care to individuals with HIV under the supervision of an HIV Specialist physician may also be considered experienced HIV care providers (10 NYCRR 94.2).

→ KEY POINT

- Clinicians in New York State can call the Clinical Education Initiative (CEI Line) to speak with an experienced HIV clinician regarding maternal/fetal exposure. The CEI Line is available 24/7 by calling 866-637-2342 (press "2").

◊ LINKS TO CLINICAL RECOMMENDATIONS

Key topics covered in the DHHS guideline Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States include the following:

- Prepregnancy Counseling and Care for Persons of Childbearing Age With HIV
- Infant Feeding for Individuals With HIV in the United States
- Antepartum Care for Individuals With HIV

◊ LINKS TO CLINICAL RECOMMENDATIONS

- Special populations:
  - Hepatitis B Virus/HIV Coinfection
  - Hepatitis C Virus/HIV Coinfection
  - HIV-2 Infection and Pregnancy
  - Early (Acute and Recent) HIV Infection
- Intrapartum Care for People With HIV
- Postpartum Follow-Up of People With HIV

Antiretroviral Therapy

Do not interrupt antiretroviral therapy: Consistent adherence to antiretroviral therapy (ART) is essential to the maintenance of an undetectable HIV viral load in pregnant patients with HIV and is the best way to prevent perinatal transmission of HIV. Toward that end, this committee stresses that ART not be stopped or paused at any time antepartum, intrapartum, or postpartum, including any time when a patient has been directed to take nothing by mouth.

Any interruption in ART may increase the risk of perinatal transmission of HIV. Transmission rates as high as 18% have been reported when ART is interrupted in the third trimester [Galli, et al. 2009]. Continuing the baseline ART regimen intrapartum maximizes virologic suppression and reduces the risk of developing resistance to medications.

For clinical recommendations, see the DHHS guideline sections:

- Prepregnancy Counseling and Care for Persons of Childbearing Age With HIV
- Antepartum Care for Individuals With HIV
- Intrapartum Care for People With HIV

Continue ART postpartum: Good practice in discharge planning post-delivery includes making sure that the new parent has antiretroviral medications at home and has been counseled to avoid interruptions. HIV-associated clinical complications are reduced with the use of postpartum ART [Currier, et al. 2017]. For recommendations, see the DHHS guideline section Postpartum Follow-Up of People With HIV.

Syphilis Testing in the Third Trimester

Requirements: New York State Public Health Law requires that clinicians obtain serologic screening for syphilis for pregnant patients at the first prenatal visit and at delivery (cord blood testing). Syphilis screening between 28 and 32 weeks gestation is mandated by New York City. Effective May 3, 2024, New York State will require third trimester syphilis screening for all pregnant patients.

Recommendations: The NYSDOH AI recommends universal opt-out syphilis screening during the third trimester, preferably between 28 and 32 weeks gestation.

The incidence of primary and secondary syphilis among women has increased by 243% in the past 5 years in New York State [NYSDOH 2023]. Consequently, the number of cases of congenital syphilis is rising, with an increase from 29 cases in 2020 to 41 cases in 2021 [NYSDOH 2023]. Early third-trimester syphilis testing at 28 weeks is an additional opportunity for identifying syphilis and initiating treatment to reduce the risk of congenital syphilis. When diagnosed, syphilis is treated with penicillin G in collaboration with the local health department (see CDC: Syphilis Treatment Guideline, including Syphilis During Pregnancy).

HIV Testing for Sex Partners

Encourage HIV testing for sex partner(s): This committee encourages clinicians to recommend HIV testing for sex partners of pregnant patients. During the first prenatal visit, when a clinician provides counseling about HIV and other health conditions, the clinician can suggest that a patient's sex partner(s) undergo testing for HIV. The same suggestion can be made if a patient reports having new sex partners during pregnancy. Any sex partner who injects drugs is at particularly high risk of acquiring HIV [ACOG(b) 2018]. Knowledge of sex partner HIV risk factors may be limited, as these individuals are not patients of the clinician. HIV testing of all sex partners would provide the most comprehensive evaluation to limit perinatal transmission. If a pregnant patient's sex partner tests positive for HIV, initiation of ART will benefit the individual with HIV and will reduce the risk of sexual transmission. Barrier protection and pre-exposure prophylaxis (PrEP) may also be recommended for partners who test negative for HIV. Growing evidence suggests that involving partners in HIV treatment and prevention efforts during pregnancy can help decrease the risk of perinatal transmission [Takah, et al. 2017].

Method of Delivery

Vaginal delivery with HIV viral load <1,000 copies/mL: Clinicians are strongly encouraged to perform HIV RNA testing within 4 weeks of a patient's expected delivery date. If an HIV viral load <1000 copies/mL is detected, then a vaginal delivery as detailed in the DHHS guideline section Intrapartum Care for People With HIV is recommended, and intrapartum intravenous zidovudine may be considered if HIV viral load is between 50 and 999 copies/mL. Invasive fetal monitoring is best avoided in such individuals, with cesarean delivery reserved for the standard obstetrical indications.

Scheduled cesarean with HIV viral load ≥1,000 copies/mL: If a pregnant patient's HIV viral load is ≥1000 copies/mL in the 4 weeks before delivery, a scheduled cesarean delivery is recommended [ACOG(a) 2018]. If there is no documented HIV RNA level within 4 weeks of delivery, cesarean delivery may be preferred in some cases, especially if the patient reports a lack of adherence to ART during pregnancy or has missed prenatal visits. Cesarean delivery is considered appropriate practice in such cases because this mode of delivery has been associated with a decreased risk of perinatal HIV transmission [Andiman, et al. 1999]. Without documented evidence of HIV viral suppression close to the time of delivery, there is a lack of reassurance that vaginal delivery would be a safe alternative to cesarean delivery. In pregnant patients who have a history of nonadherence with medical care, and particularly with ART, the potential for perinatal HIV transmission cannot be ignored, and a planned cesarean delivery before the onset of labor may be strongly considered. Clinical recommendations are provided in the DHHS guideline section Intrapartum Care for People With HIV.

Infant Feeding

A culturally sensitive, patient-centered approach to counseling about infant feeding that is evidence based and addresses patient and infant health and a patient's values and desires is best to facilitate shared decision-making. When counseling a patient with HIV about infant feeding, discussion of alternatives to breastfeeding/chestfeeding, i.e., use of formula or pasteurized banked milk, that eliminate the risk of postnatal HIV transmission to the infant is advised. These replacement feeding methods are appropriate for patients with HIV who are not on ART or do not have a suppressed viral load, and clinicians can counsel such patients about the decreased risk of transmission (less than 1%) through breastfeeding/chestfeeding when viral suppression is achieved and maintained through consistent use of ART.

When a patient with HIV is on ART and has a sustained undetectable viral load and chooses to breastfeed/chestfeed, it is important for the care team (pediatric, adult, and obstetric) to support the patient's decision. In such cases, the clinician can emphasize that adherence to the prescribed ART regimen reduces the risk of HIV transmission to the infant and that exclusive breastfeeding/chestfeeding up to age 6 months is preferable to feeding with a combination of breast milk and formula (mixed feeding). In addition to other small case reports from resource-rich settings, an evaluation of 10 infants who were exclusively breastfed/chestfed by mothers with HIV in the United States, there were no cases of infant HIV transmission [Yusuf, et al. 2022].

Infant PrEP practices vary in the context of breastfeeding/chestfeeding. It is good practice for clinicians to consult an expert in pediatric HIV regarding the use of PrEP in infants being breastfed by a parent with HIV. Proposed harm reduction techniques

beyond PrEP include exclusive breastfeeding/chestfeeding (as opposed to concurrent use of formula) and flash-heat treatment of expressed breast milk [Levison, et al. 2014].

See the DHHS guideline section Infant Feeding for Individuals With HIV in the United States for complete evidence-based recommendations.

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Supplement: Guideline Development and Recommendation Ratings

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
Developer	New York State Department of Health AIDS Institute (NYSDOH AI) Clinical Guidelines Program
Funding source	NYSDOH AI
Program manager	Clinical Guidelines Program, Johns Hopkins University School of Medicine, Division of Infectious Diseases. See Program Leadership and Staff.
Mission	To produce and disseminate evidence-based, state-of-the-art clinical practice guidelines that establish uniform standards of care for practitioners who provide prevention or treatment of HIV, viral hepatitis, other sexually transmitted infections, and substance use disorders for adults throughout New York State in the wide array of settings in which those services are delivered.
Expert committees	The NYSDOH AI Medical Director invites and appoints committees of clinical and public health experts from throughout New York State to ensure that the guidelines are practical, immediately applicable, and meet the needs of care providers and stakeholders in all major regions of New York State, all relevant clinical practice settings, key New York State agencies, and community service organizations.
Committee structure	• Leadership: AI-appointed chair, vice chair(s), chair emeritus, clinical specialist(s), JHU Guidelines Program Director, AI Medical Director, AI Clinical Consultant, AVAC community advisor • Contributing members • Guideline writing groups: Lead author, coauthors if applicable, and all committee leaders
Disclosure and management of conflicts of interest	• Annual disclosure of financial relationships with commercial entities for the 12 months prior and upcoming is required of all individuals who work with the guidelines program, and includes disclosure for partners or spouses and primary professional affiliation. • The NYSDOH AI assesses all reported financial relationships to determine the potential for undue influence on guideline recommendations and, when indicated, denies participation in the program or formulates a plan to manage potential conflicts. Disclosures are listed for each committee member.
Evidence collection and review	• Literature search and review strategy is defined by the guideline lead author based on the defined scope of a new guideline or update. • A comprehensive literature search and review is conducted for a new guideline or an extensive update using PubMed, other pertinent databases of peer-reviewed literature, and relevant conference abstracts to establish the evidence base for guideline recommendations. • A targeted search and review to identify recently published evidence is conducted for guidelines published within the previous 3 years. • Title, abstract, and article reviews are performed by the lead author. The JHU editorial team collates evidence and creates and maintains an evidence table for each guideline.
Recommendation development	• The lead author drafts recommendations to address the defined scope of the guideline based on available published data. • Writing group members review the draft recommendations and evidence and deliberate to revise, refine, and reach consensus on all recommendations. • When published data are not available, support for a recommendation may be based on the committee's expert opinion. • The writing group assigns a 2-part rating to each recommendation to indicate the strength of the recommendation and quality of the supporting evidence. The group reviews the evidence, deliberates, and may revise recommendations when required to reach consensus.

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
Review and approval process	• Following writing group approval, draft guidelines are reviewed by all contributors, program liaisons, and a volunteer reviewer from the AI Community Advisory Committee. • Recommendations must be approved by two-thirds of the full committee. If necessary to achieve consensus, the full committee is invited to deliberate, review the evidence, and revise recommendations. • Final approval by the committee chair and the NYSDOH AI Medical Director is required for publication.
External reviews	• External review of each guideline is invited at the developer's discretion. • External reviewers recognized for their experience and expertise review guidelines for accuracy, balance, clarity, and practicality and provide feedback.
Update process	• JHU editorial staff ensure that each guideline is reviewed and determined to be current upon the 3-year anniversary of publication; guidelines that provide clinical recommendations in rapidly changing areas of practice may be reviewed annually. Published literature is surveilled to identify new evidence that may prompt changes to existing recommendations or development of new recommendations. • If changes in the standard of care, newly published studies, new drug approval, new drug-related warning, or a public health emergency indicate the need for immediate change to published guidelines, committee leadership will make recommendations and immediate updates and will invite full committee review as indicated.

Table S2: Recommendation Ratings and Definitions		
Strength	**Quality of Evidence**	
A: Strong B: Moderate C: Optional	1	Based on published results of at least 1 randomized clinical trial with clinical outcomes or validated laboratory endpoints.
	*	Based on either a self-evident conclusion; conclusive, published, in vitro data; or well-established practice that cannot be tested because ethics would preclude a clinical trial.
	2	Based on published results of at least 1 well-designed, nonrandomized clinical trial or observational cohort study with long-term clinical outcomes.
	2†	Extrapolated from published results of well-designed studies (including nonrandomized clinical trials) conducted in populations other than those specifically addressed by a recommendation. The source(s) of the extrapolated evidence and the rationale for the extrapolation are provided in the guideline text. One example would be results of studies conducted predominantly in a subpopulation (e.g., one gender) that the committee determines to be generalizable to the population under consideration in the guideline.
	3	Based on committee expert opinion, with rationale provided in the guideline text.