Charting the Path to an HIV-Free Generation

Four research networks focus on HIV prevention and treatment for pregnant people and their infants and care for children born with HIV.

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The National Institute of Allergy and Infectious Diseases (NIAID) supports four research networks as part of its HIV clinical research enterprise. Every seven years, the Institute engages research partners, community representatives, and other public health stakeholders in a multidisciplinary evaluation of network progress toward short- and long-term scientific goals. This process takes account of knowledge gained since the networks were last funded and identifies essential course corrections based on the latest scientific and public health evidence. Subsequent NIAID HIV research investments build on the conclusions of these discussions.

Pregnancy, childbirth and the postnatal period are a key focus of NIAID HIV research and call for measures to support the health of people who could become pregnant as well as their infants. Biological changes and social dynamics such as gender inequality, intimate partner violence, and discrimination can increase the likelihood of HIV acquisition during all natal stages.

Of note, breastfeeding/chestfeeding is emerging as the predominant mode of vertical HIV transmission. NIAID is committed to optimizing HIV treatment and prevention options for people who might become pregnant, people who are pregnant and lactating, newborns, and young children who are still nursing or are living with HIV. Our goals are to offer safe, effective, acceptable, and accessible tools that provide evidence-based HIV prevention choices throughout the period of reproductive potential; prevent vertical HIV transmission to infants; and enable infants born with HIV to experience long periods of HIV remission or complete HIV clearance. We think these goals can be reached with discovery and development studies to advance biomedical interventions, and implementation science to rapidly introduce state-of-the-art interventions where they are needed most urgently.

In the current evaluation of our clinical trials networks, NIAID and other stakeholders are assessing novel interventions to interrupt the unacceptably high rate of new pediatric HIV diagnoses that persist in high burden countries. Recent research is rapidly expanding the evidence base for treatment for children and pregnant people with HIV, as well as biomedical prevention tools for pregnant people and people of reproductive potential who stand to benefit from their use. Some key advances include:

- Expanded evidence to support a cascade of multiple regulatory approvals making new therapeutic agents available to the youngest children with HIV;
- Demonstrated safety of prevention products and antiretroviral therapy (ART) throughout pregnancy, including long-acting cabotegravir for HIV pre-exposure prophylaxis (PrEP); the controlled-release vaginal ring for HIV PrEP; and integrase strand transfer inhibitor-based ART for viral suppression in people with HIV; and
- Rigorous examination of the potential of treatment initiation within hours of birth to enable ART-free HIV remission in children in a research setting.

Together, these advances open doors to improved tools for HIV prevention and treatment and help define remaining evidence gaps and research needs.

Biomedical research to accelerate evidence responsive to pediatric and perinatal needs

As noted above, a NIAID-sponsored clinical trial led by the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT), called IMPAACT P1115, found that four children surpassed a year of HIV remission after pausing ART. The protocol remains active with subsequent iterations of the trial in children receiving more advanced ART regimens and novel broadly neutralizing antibody-based therapy.

Further research is planned to identify biomarkers to predict the likelihood of HIV remission or rebound following ART interruption. Additional studies also are needed to better understand the mechanisms by which neonatal immunity and very early ART initiation limited the formation of latent HIV reservoirs to drive the original P1115 results.

Additional research priorities include developing early infant HIV testing assays that can promptly detect vertical HIV acquisition through breastfeeding/chestfeeding; wider examination of the safety and efficacy of presumptive ART pending an HIV diagnosis; administration of very early neonatal and pediatric formulations of the latest and future generations of long-acting ARVs for prevention and treatment and antibody-based therapy; and optimization of long-acting HIV treatment regimens to support health through periods of reproductive potential, pregnancy, and lactation.

Implementation science to strengthen delivery

Improving HIV prevention and care through reproductive years and intense early-life HIV intervention for infants will require an unprecedented level of reproductive health, prenatal, postnatal and pediatric HIV service integration. Several key clinical and operational questions warrant investigation through implementation science. The first is assuring availability of acceptable HIV testing modalities pre-conception, as well as universal HIV testing as part of

routine obstetric care, and then supporting access to a person's preferred PrEP method or ART based on HIV status.

For infants whose birthing parent has HIV, we need evidence-based models for offering very early point-of-care infant HIV diagnosis and treatment, including presumptive ART for infants exposed to HIV in utero pending confirmatory testing. We also need to understand how to better support continued engagement in care to maintain viral suppression for childbearing people with HIV through the end of the lactating period and life course. We will provide special consideration for the preferences of adolescent and young adult cisgender women who are disproportionately affected by HIV in high burden settings globally. Defining local and contextually appropriate adaptations of successful models will be paramount for successful uptake.

The research community plays an essential role in shaping NIAID's scientific direction and research enterprise operations. We want to hear from you. Please share your questions and comments at NextNIAIDHIVNetworks@mail.nih.gov.

About NIAID Clinical Trials Networks and Pediatric HIV

The IMPAACT Network examines prevention and treatment interventions for HIV, HIV-associated complications, and related pathogens in infants, children, and adolescents, and during pregnancy and postpartum periods. The Network is supported through grants from NIAID, with co-funding and scientific partnership from the NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development and the NIH National Institute of Mental Health. Three other networks—the HIV Vaccine Trials Network, HIV Prevention Trials Network, and Advancing Clinical Therapeutics Globally for HIV/AIDS and Other Infections—generate complementary evidence and provide research infrastructure where needed when rapidly evolving prevention and treatment science has implications for IMPAACT priority populations.

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