

Broadly Neutralizing Antibodies: A New Hope for Elimination of Vertical Transmission of HIV

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BACKGROUND

Progress in preventing vertical transmission of HIV has stagnated (Figure 1). In 2020, there were ~150,000 new HIV infections among children globally. The majority of new infections occurred through vertical transmission and fell short of the Joint United Nations Programme on HIV/AIDS (UNAIDS) 2020 targets. Preliminary research indicates that broadly neutralizing antibodies (bNABs) are potentially promising tools for prevention of vertical transmission of HIV.

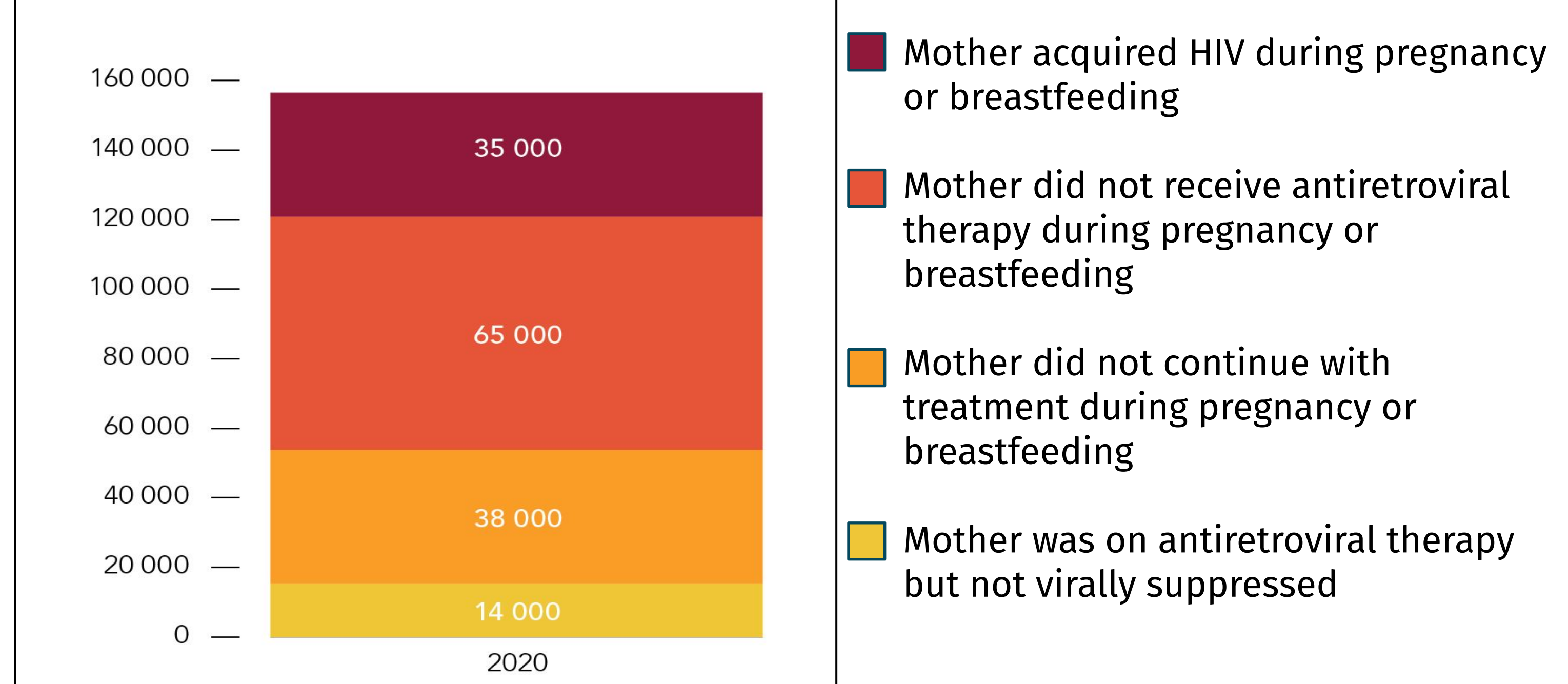
DESCRIPTION

In partnership with other global health organizations and implementing partners, USAID supported activities related to research, development, and preparation for future implementation of bNABs in low- and middle-income countries (LMICs) (Table 1). Given the recent advances in the safety, tolerability, and pharmacokinetic characteristics of bNABs, a strategic priority is to contribute evidence-based information on how bNABs might be optimally positioned to contribute to the elimination of vertical transmission in LMICs.

TABLE 1: Evidence Informing Decision-making around bNABs for Prevention of Vertical Transmission of HIV in LMICs.

Activity	Key Partners Involved	Brief Description/ Main Purpose
Health Economics Research Strategy	<ul style="list-style-type: none"> IAVI London School of Hygiene and Tropical Medicine (LSHTM) UNAIDS USAID 	Identify gaps in evidence and propose a priority agenda for health economics and modeling studies for biomedical HIV prevention over the next decade to inform critical decision-making junctures along the pathway from early development through implementation.
Cost-effectiveness of bNABs for HIV Prophylaxis for All Infants Born in High-burden Settings	<ul style="list-style-type: none"> Massachusetts General Hospital IAVI USAID 	Evaluate the clinical impact and cost-effectiveness of bNABs for infant HIV prophylaxis in Côte d'Ivoire, South Africa, and Zimbabwe.
Demand Forecasting	<ul style="list-style-type: none"> Avenir Health IAVI USAID 	Define the potential market for bNABs for infant prophylaxis to estimate manufacturing, scale and costs, and to inform clinical development strategy, commercial investment decisions, and eventual implementation planning.
Expert Consultations on the bNAB Use to Prevent Vertical Transmission	<ul style="list-style-type: none"> IAVI Individual stakeholders USAID 	Understand critical considerations, potential barriers, and enablers through expert consultations and two workshops to discuss strategies for the rapid development, access, adoption, and effective implementation of bNABs for infant HIV prophylaxis.
World Health Organization (WHO) Preferred Product Characteristics (PPC) for bNABs for HIV Prevention	<ul style="list-style-type: none"> WHO IAVI USAID 	Define preferred attributes for bNABs including for the prevention of vertical transmission to inform product development; Lay the groundwork for policy recommendations and WHO pre-qualification; Increase the understanding of the potential role of bNABs for HIV prevention in the global agenda.
Access Plan	<ul style="list-style-type: none"> IAVI USAID 	Define a strategy to ensure the affordability, availability, differentiated value proposition, and integration into health delivery systems of future bNAB products, to pave the way for accelerated access, including for infant prophylaxis indications.
Acceptability Studies	<ul style="list-style-type: none"> IAVI Y.R. Gaitonde Centre for AIDS Research and Education Centre for Sexuality and Health Research and Policy Humsafar Trust Final Mile USAID 	Understand the perspectives of potential end-users, service providers, and policy makers on the acceptability and feasibility of bNABs as HIV prevention products among populations of interest in India, as a starting point, and then expand studies to other locations.

Figure 1: New Vertical HIV Infections by Cause of Transmission, Global, 2020*



* 2020 Global AIDS Update, [UNAIDS](#)

LESSONS LEARNED

- The analysis indicates that several complementary streams of work must be implemented to overcome bottlenecks in advancing bNABs for prevention of vertical transmission.
- A robust business case, user-centric target product profile, and clear access strategy built upon learnings from these activities will be needed early in clinical development.
- The inclusion of bNABs for use in infants in the WHO-preferred product characteristic (PPC) of bNABs for HIV prevention has provided initial momentum for mobilizing the global health community to actively explore the potential of bNAB-based prevention products to reduce new vertical transmissions in LMICs.

CONCLUSIONS

- Willing partners within the global health community should continue prioritizing strategic activities to inform consideration of bNABs as a potentially integral tool to reduce vertical transmission and to understand the feasibility of bNAB implementation in LMICs.
- The goal of the historic four-decade-long journey to end the global HIV epidemic and eliminate vertical transmission will be reached only when we have a range of safe and effective prevention methods and have achieved comprehensive implementation of these methods worldwide.

The findings and conclusions in this poster are those of the authors and do not necessarily represent the official position of the U.S. Agency for International Development, the U.S. President's Emergency Plan for AIDS Relief, or the United States Government. This poster was made possible by the support of the American people through the United States Agency for International Development under the U.S. President's Emergency Plan for AIDS Relief.