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WHO consultation on the use of broadly neutralizing antibodies for postnatal prophylaxis against the vertical transmission of HIV

Meeting report, 22–23 May and 25 November 2024

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Contents

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Acronyms

ARV	antiretroviral
ART	antiretroviral therapy
BCG	bacillus Calmette–Guérin
bNAbs	broadly neutralizing antibodies
COVID-19	coronavirus disease 2019
HVTN	HIV Vaccine Trials Network
IMPAACT	International Maternal Pediatric Adolescent AIDS Clinical Trials (Network)
RSV	respiratory syncytial virus
UNAIDS	Joint United Nations Programme on HIV/AIDS

Background

Despite progress in expanding access to antiretroviral therapy (ART) for pregnant women living with HIV globally, vertical HIV transmission continues to occur with an increasing proportion of new infections occurring in the postnatal period *(1)*.

Thus, there is an urgent need to identify strategies that provide more effective protection throughout the risk period, and especially in the postnatal period.

The provision of antiretroviral (ARV) drugs to infants as postnatal prophylaxis remains a key tool for eliminating peri- and postnatal HIV transmission. However, there is now preliminary evidence and rapidly growing interest in using antibody-mediated protection to provide an extra layer of protection during periods of maternal viraemia throughout the postnatal exposure period *(2)*. An array of neutralizing monoclonal antibodies have now entered clinical trials, and newer, more potent and longer-lasting options covering a broader array of HIV variants are in advanced phases of development.

Formulations and dosing information for ARV drugs are still limited for neonates and young infants, and a consultative process convened by WHO and the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network in 2021 called for urgent action to ensure that novel drugs and strategies are investigated among neonates as soon as possible *(3)*. The consultation recognized that broadly neutralizing antibodies (bnAbs), especially in combination, may have a role in preventing vertical HIV transmission during breastfeeding through passive immunization, in addition to having potential to reduce viral reservoir burden as part of strategies to find a functional cure for infants who acquire HIV perinatally. In 2021, WHO also convened the fifth meeting on paediatric antiretroviral drug optimization to establish medium- and long-term priorities for developing HIV drugs for children *(4)*. In addition to identifying future ARV drug formulations and molecules that have potential to be used in postnatal prophylaxis, including long-acting agents, the group also gave priority to investigating and developing bNAbs as a key research priority for the HIV community. Further, 2022 marked the year that WHO released preferred product characteristics for monoclonal antibodies for HIV prevention that included postnatal prophylaxis for infants*(5)*.

Given both the urgent need to address gaps in the vertical transmission cascade and the evolving landscape of antibody-mediated strategies to prevent or control HIV, WHO hosted a consultation to review the current evidence on using bNAbs for neonates and infants and to identify gaps in evidence that will be required to issue normative recommendations on their use as an adjunct to current standards of care for preventing vertical HIV transmission. This included considerations regarding feasibility of delivery, acceptability to end users and how it affects equity.

Building on growing momentum from multiple stakeholders *(6)*, the aim of this consultation was to convene a multidisciplinary group of stakeholders, including researchers, clinicians, representatives from country programmes, nongovernmental organizations, funding agencies and civil society to review the current status of development, data gaps and anticipated challenges to inform the development-to-scale-up pathway of passive immunization strategies using bNAbs for preventing vertical HIV transmission.

Objectives

The objectives of the consultation were:

- to review the current pipeline for bNAb(s) use to prevent vertical HIV transmission, and the status of ongoing research, including anticipated timelines for completing and disseminating the results;
- to define potential use cases for infant postnatal prophylaxis strategies to prevent vertical HIV transmission, using passive immunization, including target population and optimal delivery models in a public health system;
- to discuss evidence gaps and inform efforts to generate high-quality data to inform future WHO guidelines on using passive immunization strategies to prevent vertical HIV transmission; and
- to develop a shared roadmap that can be used to track and communicate progress on developing passive immunization strategies to inform policies and guidelines.

Methods

About 40 participants (Annex 1), including HIV researchers, clinicians, programme managers and other stakeholders, attended the two virtual meetings held on 22–23 May 2024 and 25 November 2024 (Annex 2).

The agenda included brief plenary presentations to provide updates or a summary of evidence informing the consultation, followed by plenary discussion guided by key questions. Work group sessions were also organized to enable in-depth discussions of specific issues to be considered for drug optimization. Conflict-of-interest declarations were collected for all participants and closely reviewed by WHO staff. None of the conflicts of interest declared were judged significant enough to prevent participation and contribution to the discussion.

Proceedings

The global response to HIV has made significant progress toward eliminating vertical transmission, yet new paediatric infections continue to occur.

The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates highlight the urgent need to better target interventions across the cascade of care to eliminate HIV vertical transmission and optimize HIV prevention for infants *(1)*. Despite the availability of effective prophylaxis based on ARV drugs, programmatic gaps, implementation challenges and biological vulnerabilities leave many infants at continued risk of acquiring HIV during the breastfeeding period. Addressing these gaps requires refocusing the research agenda, accelerating product development and preparing health systems to evaluate and adopt novel approaches. In this context, the speakers and consultation participants were asked to review ongoing work to advance the optimization agenda for postnatal prophylaxis and the rationale and use case of postnatal prophylaxis based on bNAbs and to draw lessons from other diseases that have already considered policy development of monoclonal antibody–based interventions for children.

Building on previous efforts to advance the research agenda

The participants reviewed some of the past and ongoing WHO efforts to advance the research agenda and innovate postnatal prophylaxis for HIV. Since 2021 WHO, together with global partners in the Global Accelerator for Paediatric Formulations network and beyond, has implemented a stepwise strategy to strengthen the evidence base for new infant prevention modalities. This involved four key steps, advanced across four dedicated technical consultations. First, multistakeholder dialogue was directed to understanding existing gaps in implementing the standard of care, with specific programmatic consideration across epidemiological scenarios to identify optimal characteristics for more streamlined and effective postnatal prophylaxis strategies *(7)*. Second, attention turned to specific approaches – including candidate agents, technologies, treatment durations and delivery scenarios *(8)*. Third, a priority list of candidate agents was developed, aligned with technologies that can feasibly deliver them and accompanied by an assessment of existing data gaps *(4)*. Finally, these considerations fed into identifying optimal study designs to evaluate these new strategies in ways that generate rigorous yet programmatically relevant evidence. The immediate output of this process was the establishment of a postnatal prophylaxis task team mandated to address the critical how-to question: how to optimally evaluate new postnatal prophylaxis strategies in real-world contexts. The proposed solution was a pragmatic platform trial designed to assess the efficacy and effectiveness of emerging interventions *(9)*. This platform trial would use a contemporaneous standard-of-care comparator arm, applying Bayesian methods to enhance interpretability and efficiency. Randomization would occur at the level of the individual infant–mother pair, with follow-up through the breastfeeding period up to 24 months of age. Trials would be anchored in research hubs across multiple countries, especially those with large populations, high HIV prevalence and experience conducting clinical trials while being implemented through networks of satellite trial centres.

Rationale for investigating bNAbs

The group moved to acknowledge and review how within this broader research agenda, bNAbs represent one of the most promising innovations. The rationale for their investigation is compelling. Infants require protection from the moment of birth and continuing throughout the breastfeeding period, which represents a discrete window of vulnerability. Prophylaxis during this period would be time-limited, avoid daily administration of ARV drugs and potentially reduce risk of vertical transmission secondary to maternal viral non-suppression, potentially reducing the number of infants acquiring HIV and requiring lifelong treatment.

Recent technological advances now enable antibodies to be produced that are capable of neutralizing a wide range of circulating HIV variants. Several candidate antibodies have already demonstrated acceptable safety profiles and dosing parameters among newborns. Administration routes such as subcutaneous and intramuscular injections make delivery feasible in low-resource settings, avoiding the need for intravenous infusion–based infrastructure. Importantly, a proof-of-concept study has shown that neutralizing antibodies can indeed prevent HIV acquisition *(10)*.

The field of monoclonal antibodies more broadly is evolving rapidly, with regulatory frameworks, manufacturing standards and procurement mechanisms advancing in parallel. However, WHO policies must extend beyond the narrower evidence required for regulatory approval, ensuring that products can be translated into public health programmes that are effective, sustainable, equitable, affordable, acceptable and suitable for the target populations and health systems. To guide product development, WHO has therefore published preferred product characteristics for monoclonal antibodies for HIV prevention, establishing benchmarks for efficacy, safety, formulation, dosing and integration with maternal and child health services *(5)*.

Lessons from other infectious diseases

Important lessons can be drawn from the field of rabies prevention, in which monoclonal antibodies have been developed to address the supply limitations of blood-derived rabies immunoglobulin. Rabies continues to cause over 40 000 deaths annually, with more than 29 million courses of post-exposure prophylaxis administered each year. Because of cost, pre-exposure prophylaxis with vaccine is reserved for high-risk groups, and post-exposure management remains the global priority. Historically, supply constraints in human- and equine-derived rabies immunoglobulin posed barriers to access, since production is lengthy and prone to disruption.

In response, WHO initiated a project in 2002 to accelerate the development of rabies monoclonal antibodies. Regulators approved the first product in 2016, with additional products following, so several products are now available. These new tools, manufactured in India and China, are easier to produce, available at costs comparable to equine rabies immunoglobulin and included in the WHO Model List of Essential Medicines and WHO Model List of Essential Medicines for Children since 2021. WHO updated immunization policy recommendations in 2018 to encourage their use when available. Nevertheless, challenges remain, especially regarding WHO medicines prequalifications, since these monoclonal antibodies first need approval by a WHO listed authority creating a barrier for UN agency procurement. This experience illustrates both the potential of monoclonal antibodies to transform public health practice and the regulatory barriers that must be addressed to ensure access. These lessons underscore the importance of anticipating manufacturing scale-up, regulatory alignment and equitable distribution from the outset.

Other experiences can be drawn from the development of respiratory syncytial virus (RSV) monoclonal antibodies, which were developed to address an unmet need in preventing severe RSV infection among infants in their first RSV season and very young children at high risk during their second RSV season. Passive immunization for RSV has progressed from early serum-based products to modern long-acting monoclonal antibodies. The first product, RSV-immunoglobulin intravenous, provided protective levels of neutralizing antibodies and significantly reduced the number of high-risk infants acquiring lower respiratory infections but required large intravenous doses. It was replaced by palivizumab in the late 1990s, a monoclonal antibody targeting antigenic site II of the RSV F protein that was far more potent, safer and easier to administer as monthly intramuscular injections, although its high cost and monthly administration limited global use.

The field has since advanced toward long-acting, highly potent monoclonal antibodies that overcome the limitations of earlier serum and monthly-dose monoclonal antibodies, with a single intramuscular dose achieving protection over the entire RSV season. In 2024, WHO reviewed and recommended long-acting RSV monoclonal antibodies for preventing RSV infection that are now being used in some high-income and upper-middle-income countries. However, despite manufacturing efficiency that makes the cost of goods relatively amenable to large-scale, affordable supply, current market prices remain a major barrier to widespread use, especially in low- and middle-income countries. Although current pricing remains a barrier to widespread global use, the entry of additional products into the market and continued advances in manufacturing are expected to drive prices down in the longer term.

Highland children in Viet Nam
© WHO / Loan Tran

Service delivery and country context

For bNAbs to be sustainable and effective, delivery should be integrated into existing maternal, newborn and child health or immunization platforms rather than delivered as standalone interventions on standalone platforms. These systems provide established, trusted and efficient channels to reach mothers and infants while enabling synergy with HIV elimination, immunization and early infant diagnosis programmes through shared logistics and monitoring.

Integration can expand reach and lessons have been learned from past efforts to introduce new interventions, such as hepatitis B birth-dose vaccination, maternal tetanus immunization and coronavirus disease 2019 (COVID-19) vaccination. These lessons include integration into existing services, coordination across siloed programmes to ensure coordinated service delivery, setting priorities to avoid removal from an integrated package because of competing priorities, attention to supply chain management to avoid fragmented or interrupted supplies and inclusion into data systems to ensure monitoring and evaluation. These should be integrated in a way that does not increase the burden on the health-care workforce. In many low- and middle-income countries, established immunization platforms focus on healthy children and provide a feasible delivery system. Aligning the delivery of bNAbs within the distinct workflows of well-child visits and the immunization platform will require harmonized scheduling into national immunization programmes and their reporting systems. Further, systems for cold chain, stock management and financing – traditionally designed for vaccines – may need to be adapted for biologics such as bNAbs.

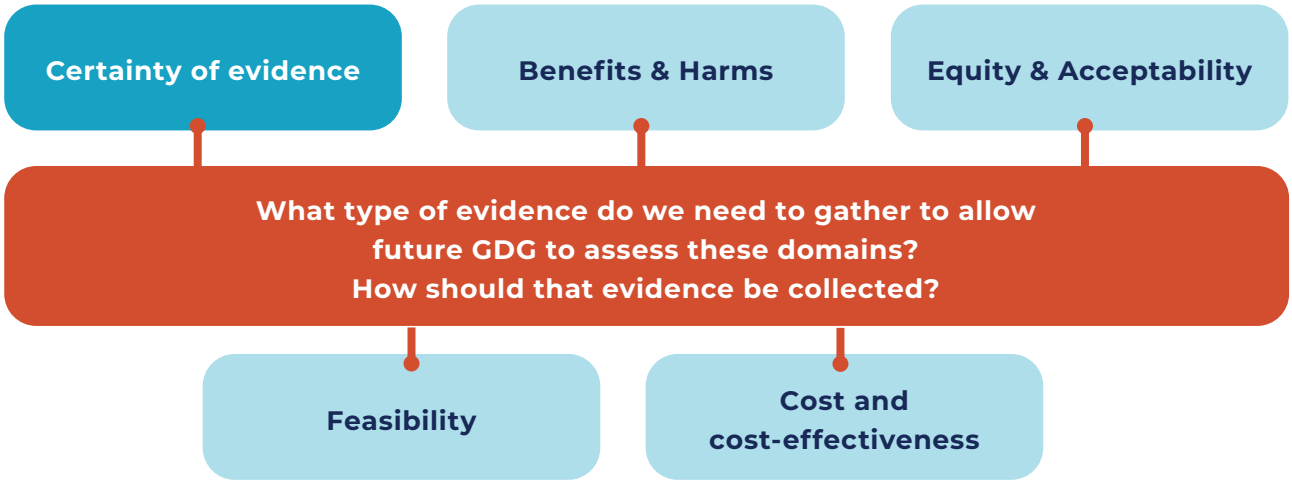
Community engagement is equally critical. Introducing new biologics can produce hesitancy if caregivers do not understand their purpose, underscoring the need for clear communication and involving community health workers. A community working group has convened to develop community messages and to establish a roadmap for partnership with communities to strengthen understanding of the potential role of bNAbs for preventing vertical transmission. This platform can be leveraged to support ongoing collaboration with communities throughout the clinical development and introduction processes for future interventions based on bNAbs *(11, 12)*.

Country contexts will shape delivery models: settings with mature prevention of vertical HIV transmission and immunization systems may integrate bNAbs more readily, whereas others with concentrated epidemics or weaker infrastructure may require targeted approaches. Implementation science will be central to identifying effective, equitable and sustainable models through phased roll-outs and real-world evaluation.

Developing guidelines

WHO's role in guiding the adoption of new technologies requires adhering to rigorous principles of guideline development *(13)*. The processes must be explicit, transparent and multidisciplinary, involving diverse expertise and perspectives. Scope, objectives and audiences must be clearly defined, with full assessment of key domains such as: benefits and harm, equity, acceptability, feasibility and cost–effectiveness (Fig. 1). The recommendations must be actionable, grounded in the best available evidence and accompanied by an explicit rationale, including assessments of certainty and strength. These standards ensure that policy guidance is credible, implementable and aligned with WHO's mandate to support Member States.

Figure 1. Domains informing how WHO develops guidelines



Overall, speakers contributing to the consultation outlined how the path toward postnatal prophylaxis based on bNAbs reflects both an opportunity and a challenge. By aligning research priorities, designing pragmatic trials, learning from other infectious disease fields and preparing for integration into maternal and child health services, the global community can generate the evidence needed to inform WHO guidance and national policies. If bNAbs are proven safe, effective, acceptable, cost-effective and feasible, they could become a transformative addition to the HIV prevention toolkit, helping to close the remaining gaps in the cascade for eliminating vertical HIV transmission and protect the next generation from HIV infection.

Rwanda: Accessing primary healthcare to strengthen Universal Health Coverage
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Key findings and discussion

Summary of the pipeline for bNAbs and research progress

Clinical trials are underway begun to establish the foundations for using bNAbs among infants and children. The table in Annex 1 illustrates the key paediatric trials as of November 2024 (when the second phase of the WHO consultative process took place) with a few updates by mid-2025. In summary, early-phase broadly neutralizing antibody trials include the following.

- IMPAACT Network
  - A Phase 1 P1112 trial investigated the safety and pharmacokinetics of three bNAbs (VRC01, VRC01LS and VRC07-523LS) administered subcutaneously in different doses to different groups of HIV-exposed newborn infants (some breastfeeding) to prevent vertical HIV transmission (Table 1).

Table 1. Phase 1 P1112 trial

Dose group	*n*	Dose
1	13	20 mg/kg subcutaneously X1 VRC01
2	13	40 mg/kg subcutaneously X1 VRC01
3	13	40 mg/kg subcutaneously for initial dose, 20 mg/kg subcutaneously monthly for VRC01 for at least six months (24 weeks) and no more than 18 months (72 weeks) while breastfeeding
4 Cohort 1: no-breastfeeding infants 4 Cohort 2: Breastfeeding	10 10	Single dose of VRC01LS at birth subcutaneously: If <4.5 kg: 80 mg If ≥4.5 kg: 100 mg Second dose of 100 mg VRC01LS subcutaneously at week 12 if infant has not completely stopped breastfeeding
5 Cohort 1: no-breastfeeding infants 5 Cohort 2: Breastfeeding	10 10	Single dose of VRC007-523LS at birth subcutaneously If <4.5 kg: 80 mg If ≥4.5 kg: 100 mg Second dose of 100 mg of VRC07-523LS subcutaneously at week 12 if the infant has not completely stopped breastfeeding

- A Phase 1/2 P2008 trial investigated the effect of one broadly neutralizing antibody with ART on HIV DNA concentrations among infants younger than 12 weeks living with HIV who initiated ART no less than 14 days earlier (see the table in Annex 1).
- The P1115 trial includes VRC administration at birth in one study arm for high-risk infants registering for an analytical treatment interruption trial. Those with perinatal HIV progress to continue treatment and analytical treatment interruption after meeting stringent criteria. Possibly not relevant here, although the bulk of babies do not have HIV and transition back to the standard of care postnatal prophylaxis.

- South African Medical Research Council's:
  - A Phase 1 PedMAb1 trial investigated the use of two bNAbs among HIV-exposed newborn infants (Table 2).

Table 2. PedMAb1 trial

Arm	*n*	Dose
1	8	CAP256V2LS 5 mg/kg subcutaneously within 96 hours of birth
2	8	CAP256V2LS 10 mg/kg subcutaneously within 96 hours of birth
3	8	CAP256V2LS 20 mg/kg subcutaneously within 96 hours of birth
4	8	VRC07-523LS 20 mg/kg subcutaneously within 96 hours of birth
5	8	VRC07-523LS 30 mg/kg subcutaneously within 96 hours of birth
6	8	CAP256V2LS 60 mg + VRC07-523LS 90 mg within 96 hours of birth
6b	8	If still breastfeeding: CAP256V2LS 120 mg + VRC07-523LS 120 mg at 12 weeks

- A Phase 2 SAMBULELO trial investigated the use of one broadly neutralizing antibody among newborns living with HIV:
  - group 1: 65 newborn HIV-exposed infants: 80 mg of VRC07-523LS subcutaneously within 72 hours of birth and, if still breastfeeding, 100 mg of VRC07-523LS subcutaneously at three months after birth;
  - group 2: 44 newborn HIV-exposed infants: placebo subcutaneously within 72 hours of birth and, if still breastfeeding, placebo subcutaneously at three months after birth;
  - group 3: 10 newborn infants living with HIV: 80 mg of VRC07-523LS subcutaneously within 72 hours of birth; and
  - group 4: 10 newborn infants living with HIV: placebo subcutaneously within 72 hours of birth.

Beyond safety and dosing, the Tatelo study represents a landmark in paediatrics. As the first broadly neutralizing antibody study to include an analytical treatment interruption of ART among children while administering the bNAbs VRC01LS with 10-1074, it provided important proof-of-concept evidence of using bNAbs for treating children who initiated ART before seven days of age. Notably, in the Tatelo study, 44% of participants sustained viral suppression for 24 weeks after ART interruption. Although this is preliminary, this signal underscores the potential role of passive immunization in maintaining viral control and reducing dependence on lifelong ART in selected groups of children.

No specific public information was available on the Neo broadly neutralizing antibody study planned by the LIFE study consortium, which remains in planning or early conceptual stages.

These trials represent essential steps toward the eventual use of antibody-mediated prophylaxis in the postnatal and breastfeeding periods and will help to establish practical delivery approaches for real-world settings.

Taken together, these studies highlight several considerations for the field.

- All available data confirm that the bNAbs tested so far have an acceptable safety profile for infants and children, with tolerability consistent across different trial contexts.
- Pharmacokinetics findings suggest that there are potentially feasible dosing strategies, although further optimization is needed for scale-up.
- Tatelo provides the strongest efficacy signal to date, showing that passive immunization may sustain viral suppression after ART withdrawal in a subset of children who initiated ART early.

Several evidence gaps remain. Larger, controlled efficacy trials involving infants are urgently needed to confirm the protective potential of bNAbs during the breastfeeding period. Longer-term follow-up will be required to assess the durability of protection, immunogenic effects and the risk of viral resistance. Finally, operational research is essential to evaluate the feasibility of integrating bNAbs into existing postnatal prophylaxis programmes, including optimal delivery platforms, health system capacity and acceptability to caregivers.

In conclusion:

The current body of evidence demonstrates promising safety and pharmacokinetics profiles and provides encouraging signals of efficacy, but substantial further work is required, including expansion into Phase 2 and 3 trials. Expanding trial populations, extending follow-up and embedding operational feasibility studies into future trials, including the planned IMPAACT 2048/HVTN 145 trial (see table in Annex 1), will be critical to building the evidence base needed for future WHO guidance and policy adoption.

Potential use cases identified and target populations

The potential use cases for bNAbs in postnatal prophylaxis can be considered along a continuum of target populations. The most immediate application is among HIV-exposed infants at high risk, such as those born to mothers with unsuppressed viral load at delivery, late presentation to antenatal care or acute infection in the peri- or postpartum period. In this scenario, bNAbs could serve as a critical tool to reduce transmission risk during the early weeks of life. A second, broader application is among all HIV-exposed infants, regardless of maternal risk status, to provide consistent protection throughout breastfeeding and simplify programmatic delivery compared with stratified approaches. A third, longer-term scenario is providing prophylaxis to all infants in settings with high HIV prevalence, regardless of HIV exposure, which could enhance feasibility by removing the need for maternal HIV status disclosure or testing at the point of care, thereby reducing stigma and ensuring universal coverage. Evidence generation across these three use cases will be essential to determine where bNAbs offer the greatest benefit, how they can be integrated into existing maternal and child health services and what delivery models are most appropriate for diverse epidemiological and programmatic contexts.

Risk–benefit balance for postnatal prophylaxis based on bNAbs

As discussions advance towards potential clinical use and guideline development, assessing both the expected benefits and the possible risks is critical, drawing on emerging data and identifying the types of evidence required to inform policy recommendations.

In terms of benefits, the central question is whether bNAbs can effectively reduce HIV transmission in infants. Regulatory studies are expected to provide essential pharmacokinetic and efficacy data, but broader clinical evidence will be needed. The efficacy outcomes of greatest relevance will be those that directly demonstrate reduction in transmission, although validated surrogate markers may also be useful to inform early assessments. Unless WHO guidelines are revised to recommend prolonged postnatal prophylaxis through the breastfeeding period, comparative data will be required against both the absence of extended postnatal prophylaxis through the breastfeeding period and standard approaches based on ARV drugs. Ultimately, a Phase 3 randomized controlled trial, adequately powered for efficacy and designed to compare bNAbs against both the standard of care and long-acting prophylaxis based on ARV drugs, is likely to be necessary. To ensure relevance across global settings, these findings must also be generalizable across regions and viral subtypes.

The Phase 3 trial should focus on populations in which impact is most likely to be measurable, namely infants at high risk of acquiring HIV, which would also reduce the required sample size. Premature neonates, given their especially elevated risk, should also be included. In such trials, non-inferiority to ARV drug prophylaxis may be sufficient if safety, feasibility and acceptability profiles are otherwise favourable. Earlier phase studies can help refine these trials by exploring surrogate markers of efficacy, which may streamline the design of larger studies. Another critical step will be to define the minimal threshold of viral susceptibility required for inclusion in trials, with potential thresholds ranging from 75% to 90%, accounting for the optimal composition of broadly neutralizing antibody cocktails to be tested.

The risks associated with bNAbs are expected to be low, but systematic evaluation is still required. Standard adverse event monitoring in Phase 2 and Phase 3 trials will provide the foundation of safety assessment. Examining the potential impact of bNAbs on the infant HIV testing cascade will also be important, although no major concerns have been raised to date. Possible effects on routine childhood immunization responses represent another area of interest and should be explicitly assessed within Phase 3 studies. Even after introduction, active pharmacovigilance will remain an important component of monitoring, despite not being strictly necessary for policy change. Trial placement should also consider geographical variation in viral susceptibility, ensuring that findings and benefits remain relevant across diverse epidemiological contexts.

Although initial trials should concentrate on HIV-exposed infants at high risk, longer-term considerations include evaluating HIV-free survival after administration of bNAbs among all infants, regardless of maternal HIV status. Such an approach would simplify programmatic delivery and improve generalizability. Implementation research could assess this broader use once the Phase 3 results among high-risk HIV-exposed infants are available and demonstrate efficacy. In addition, comparisons should account for maternal prevention strategies, including pre-exposure prophylaxis (vaginal ring and daily oral or long-acting injectable options), which are increasingly recommended for high-risk postpartum women.

Accelerating evidence generation to fully ascertain risks and benefits will require innovative trial designs and close international collaboration. Adaptive platform trials may provide important efficiency, enabling smaller sample sizes and head-to-head comparisons with novel long-acting ARV drug options used by the mother–infant pair. Harmonizing endpoints across studies is also essential to facilitate synthesis and interpretation of the totality of available data to assess risk–benefit ratios. In the build-up to trial development, mapping viral susceptibility in countries with a high burden of HIV will be critical to inform trial site selection, ensure global relevance and optimize the assessment of risks and benefits. Further, developing a system to track the progress and characteristics of ongoing Phase 2 studies will further strengthen coordination of the evidence base and facilitate the assessment of risk–benefit ratios. Finally, timely sharing of results with WHO and its technical advisory groups, including the Global Accelerator for Paediatric Formulations, the Paediatric Antiretroviral Working Group and Paediatric Antiretroviral Drug Optimization, will be central to supporting early appraisal of risk–benefit ratios and guidance development.

In conclusion, the risk–benefit balance of bNAbs for postnatal prophylaxis is anticipated to be favourable, if efficacy and safety are confirmed in Phase 3 studies of high-risk infants. Strategic study design, optimal composition of the broadly neutralizing antibody cocktail, careful site selection, integration with maternal prevention strategies and ongoing global collaboration will be crucial to ensure that evidence is generated efficiently and in ways that are applicable across diverse settings. If these conditions are met, bNAbs may represent a transformative addition to the HIV prevention toolkit for infants worldwide.

Acceptability and equity

Acceptability encompasses the perceptions, attitudes and willingness of parents, caregivers, health-care workers, policy-makers and communities to use and deliver prophylaxis based on bNAbs. Acceptability influences uptake, adherence and programmatic success and requires deliberate generation of evidence across settings and populations.

Qualitative methods including desk reviews, focus groups and in-depth interviews, and human-centred design workshops can be used to facilitate a shared understanding of the role of bNAbs in preventing children from acquiring HIV. Such qualitative engagements have begun, spearheaded by International AIDS Vaccine Initiative, which is leading the CELEBRATE study, aimed at understanding the acceptability and feasibility of bNAbs for preventing infants from acquiring HIV, in collaboration with the Family Centre for Research with Ubuntu in Cape Town, South Africa, the South African Medical Research Council and the Uganda Virus Research Institute – International AIDS Vaccine Initiative HIV vaccine programme in Entebbe, Uganda *(14)*. Through qualitative engagements, users and the larger community can understand what bNAbs are, how they work and how they differ from vaccines and that they will not offer lifelong protection. These qualitative approaches can illuminate how communities, mothers and parents perceive bNAbs and can enhance their understanding to facilitate decision-making about their use to prevent vertical HIV transmission. Moreover, in-depth qualitative exploration with health-care workers and policy-makers can deepen their understanding so that they weigh the feasibility and benefits of the case for using bNAbs for children. Qualitative explorations could also identify the most effective communication tools and messages that convey information about bNAbs – their use case and how they differ from vaccines – clearly, simply and in culturally appropriate ways.

Acceptability also depends on the cost and service delivery burden associated with administering bNAbs on communities, parents, health-care workers and the health system. Costing and economic evaluations can help determine acceptability from a government and policy-maker perspective. Moreover, the number and timing of required visits and number of injections at each visit affect community, family and maternal convenience, acceptability and desirability. The cost, additional workload for health-care workers, facility readiness (including training, cold-chain storage and supply chain management) affect feasibility within the health system. The need for targeted or stratified approaches compared with universal administration adds another dimension: although targeted strategies may conserve resources, universal administration may be perceived as operationally simpler and less stigmatizing and thus may be more acceptable from a community and health-care provider perspective if eligibility is not associated with HIV infection risk. Exploring the acceptability of a birth dose is especially relevant, especially from the perspective of a health-care provider and the health system, since birth dosing aligns with existing immunization schedules (bacillus Calmette–Guérin (BCG) and hepatitis B), possibly facilitating acceptability to communities through strong facility-based delivery systems.

Lastly, the characteristics of the product will play a central role in shaping acceptability. Fewer and less frequent doses, stable formulations and simplified administration methods (such as prefilled or co-formulated syringes) are likely to be preferred. Thermostable preparations that reduce storage requirements would be advantageous, especially in low-resource settings. By contrast, complex reconstitution procedures or cold-chain dependence may reduce acceptability among frontline workers and health policy-makers.

Acceptability also intersects with equity and gender considerations. Delivery strategies must be mapped within the HIV prevention cascade and broader maternal, newborn and child health services to ensure a non-stigmatizing delivery platform, such as through the Expanded Programme on Immunization. Further, strategies should ensure equitable access to everyone in need, especially the most vulnerable groups or in the most vulnerable settings. It is essential to examine whether certain service delivery models create barriers for women or marginalized groups, or conversely, whether discreet or universal administration could help to mitigate stigma. The potential for increased or decreased risk of gender-based violence must be considered, especially if partners exert pressure on women to avoid or discontinue treatment postpartum or if women experience violence because their HIV status becomes known because their infants receive bNAbs.

Feasibility

Even after efficacy and safety are established, feasibility is an important consideration for introducing new health interventions, especially in cost-constrained settings as complex product characteristics and health system limitations both affect successful uptake and real-world implementation.

The feasibility of bNAbs as infant postnatal prophylaxis will need to account for both the technical characteristics and administration needs of bNAbs and the contextual and health system factors in which they will be deployed. These specifications, coupled with overall cost, will help to determine whether bNAbs are feasible at scale. The identification of the most optimal broadly neutralizing antibody or broadly neutralizing antibody combinations for use as postnatal prophylaxis should consider the variety of scenarios in which they may be used, giving priority to bNAbs with broad neutralization breadth to ensure effectiveness across the widest range of HIV variants that are anticipated to change over time.

The maturity of programmes along the path to triple elimination of HIV, hepatitis and syphilis provides important context: stronger, more integrated programmes will be better positioned to introduce bNAbs efficiently. In resource-constrained health systems in which infants at high risk for HIV infection cannot easily be identified, a more universal indication for bNAbs will likely be needed. Expanding the indication for bNAbs to all HIV-exposed infants, or to a general population, will minimize the complexity of clinical management and enable decentralized service delivery but may be prohibitively resource intensive. In concentrated epidemics or settings with fewer infants at risk, more targeted approaches could be used with fewer resources required for effective implementation.

Manufacturing capacity and flexibility and the diversity and number of bNAbs should be appropriately considered in developing implementation plans and timelines. Logistical factors such as supply reliability, number of bNAbs or combination products needed, storage requirements, shelf life and complexity of administration requirements will affect the feasibility of introducing and scaling the delivery of bNAbs, and resources for implementation will also need to be considered. This includes whether the supply chain for bNAbs can reliably distribute, store and dispense products at a decentralized level and in less specialized health-care facilities in which health-care workers may not have the necessary training or skills to administer this intervention.

Affordability and accessibility remain key determinants, especially in low- and middle-income countries, and feasibility should consider the cost–effectiveness and ability of health systems to sustain the delivery of bNAbs over the longer term without the disproportionate diversion of resources from other essential services.

Cost–effectiveness

The cost–effectiveness of bNAbs will be critical in determining the conditions under which they can be sustainably introduced and scaled-up in diverse epidemiological and health system contexts. Modelling to date has suggested that bNAbs could be cost-effective under a range of price points and willingness-to-pay thresholds *(15, 16)*. However, cost–effectiveness highly depends on the delivery scenario, intervention price, efficacy and the availability of alternative prevention options.

Future economic modelling should account for emerging long-acting ARV drugs such as long-acting cabotegravir and lenacapavir, which are being explored for use both for infants as postnatal prophylaxis and for mothers as prevention during pregnancy and breastfeeding. Cost–effectiveness analysis must therefore reflect real-world programmatic choices between bNAbs, ARV drugs and combinations thereof among mother–infant pairs (with the intervention targeting either the mothers or their infants).

In addition to system-level costs, patient-level costs and benefits must be considered. These include potential reductions in the long-term financial and quality-of-life burden associated with lifelong ARV drug use if vertical transmission is prevented. Conversely, the affordability of bNAbs for health systems and any out-of-pocket costs for families and other caregivers in different settings remain pressing concerns.

Cost–effectiveness analysis should be embedded in an equity and ethics framework. Decisions about targeted versus universal delivery strategies carry implications for fairness, stigma and human rights. Ethical considerations also extend to giving priority to supply and distribution to countries with higher unmet need. A rights-based approach is required to ensure that those most at risk are not excluded from access because of resource constraints.

Gender and social equity analysis should explore how economic pressures influence uptake and adherence and whether discretion in administration provides additional value. These analyses must also account for risks such as gender-based violence, which may arise when women face pressure not to disclose HIV-related interventions. Exploring complementary services for caregivers and integration into existing maternal and child health platforms may help to mitigate these risks while improving overall programme effectiveness.

Ultimately, the cost–effectiveness of bNAbs will rest on a combination of efficacy, duration of protection, dosing requirements, commodity and delivery costs, programmatic context, scale of intervention and impact on market size and corresponding economies of scale, alternative interventions and willingness to pay. Ongoing modelling and pilot studies will be necessary to refine these projections and support evidence-informed decision-making.

A mother and daughter share a moment with each other
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Conclusions and next steps

The evidence generated to inform policy development for postnatal prophylaxis based on bNAbs must first establish or confirm safety and establish efficacy for infants, including premature neonates, with well-defined viral susceptibility thresholds and comparative safety and efficacy data against ARV drug–based prophylaxis. Strategies to accelerate the investigation of safety and efficacy and to increase the efficiency of research efforts should include targeting high-risk HIV-exposed infants or infants born to mothers at high risk of acquiring HIV first and enable comparison with novel long-acting formulations among mothers or infants to maximize evidence generation across priority innovations and prevention options. Research on acceptability and equity is needed to understand the perceptions of caregivers and health-care workers, the burdens of service delivery and gender-related barriers to access, ensuring that interventions are both practical and rights based. Feasibility studies should evaluate how bNAbs can be integrated into existing maternal and child health platforms, supply chains and delivery systems across diverse epidemic, economic and service-delivery contexts. Finally, additional cost–effectiveness analysis is required to determine sustainability, incorporating intervention price, programmatic alternatives such as long-acting maternal ARV drugs, patient-level costs and the ethical implications of targeted versus universal approaches.

WHO has outlined a sequenced process to guide evidence appraisal, policy development and novel potential recommendations for infant postnatal prophylaxis. This WHO consultation focused on setting the foundation for structured and coordinated evidence generation on the use of bNAbs and on identifying additional evidence needs for future normative policy considerations. WHO will disseminate the proceedings to relevant stakeholders by publishing a meeting report and preparing a manuscript for peer-reviewed publication. A pipeline tracker will be developed to monitor ongoing and planned infant broadly neutralizing antibody studies. These products will provide a transparent basis for evidence appraisal and stakeholder engagement.

In parallel, WHO will undertake a formal review of postnatal prophylaxis recommendations based on the accumulated evidence. This process will include input from technical advisory bodies such as Conference on Antiretroviral Drug Optimization and Paediatric Antiretroviral Drug Optimization processes, ensuring that evidence is rigorously evaluated and aligned with global normative standards. Remaining questions to foster effective evidence generation and optimal research and development will be discussed, leveraging existing platforms for paediatric drug optimization such as the Paediatric Antiretroviral Drug Optimization process and its related activities undertaken in partnership with multiple Global Accelerator for Paediatric Formulations partners and external stakeholders.

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Annex 1. Summary of key characteristics of ongoing trials to assess the efficacy and safety of bNAbs for infants and children (as of May 2024)

Trial	Phase and design	Population	Sample size	Interventions	Objectives	Status	Key findings and outcomes
Paediatric HIV prevention trials: data collection completed as of October 2025							
IMPAACT P1112	Phase 1, open-label, dose-escalation	HIV-exposed uninfected new-born infants	79	VRC01: 20 mg/kg subcu-taneously, VRC01: 40 mg/kg subcu-taneously VRC01: 40 mg/kg subcu-taneously then monthly 20 mg/kg for 24–72 weeks subcutane-ously VRC01LS 80 mg or 100 mg at birth subcutaneously VRC07-523LS, 80 mg or 100 mg at birth subcutaneously	Safety and phar-maco-kinetics	Completed *(1)*	Antibodies were safe and well tolerated; pharmaco-kinetics profiles established

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1 All references accessed on 28 October 2025.

PedMAb1	Phase 1, dose-finding	HIV-exposed uninfected newborn infants	48	CAP256V2LS (arms 1–3) 5 mg/kg, 10 mg/kg 20 mg/kg subcu-taneously and VRC07523LS (arms 4–5) 20 mg/kg and 30 mg/kg subcutaneously CAP256V2LS and VRC07-523LS (60mg and 90mg subcutane-ously, respectively) at birth and 120mg or each broadly neutralizing antibody at 3 months	Safety and pharmaco-kinetics over 28 days	Protocol published	
SAMBULELO	Phase 2	HIV-exposed uninfected new-born infants and HIV infected newborns	109 HIV-exposed uninfected newborn infants and 20 infants living with HIV	VRC-07-523LS 80 mg subcutaneously at birth and if HIV-exposed un-infected new-born infants are still breastfeeding, then 100 mgsubcutane-ously at three months	Safety and pharmaco-kinetics	Began in Q4 2024 and still recruiting as of October 2025	–
Paediatric HIV prevention studies in planning stages							
IMPAACT 2048/HVTN 145	Phase 1, open-label possibly with a qualitative feasibility component	Breast-feeding infants	To be confirmed	VRC07523LS, ePGT121v1LS, PGDM1400LS subcutane-ously or in-tramuscular alone and combined, doses at birth and weeks 12 and 24	Safety and pharmaco-kinetics	In development	–
Paediatric HIV treatment trials: broadly neutralizing antibody and ART trials							
IMPAACT 2008	Phase 1/2, randomized	Infants younger than 12 weeks initiating ART no less than 14 days earlier	68	VRC01 40 mg/kg subcutaneously at enrolment, weeks 2, 6 and 10 with continuous ART versus ART alone	Safety, tolerability	Completed	Injection-site reactions common (≤ grade 2); no serious adverse events attributable to VRC01
Tatelo (IMPAACT 2042/2042 Plus)	Phase 1/2, multisite	Early-treated (before seven days of age) chil-dren with at least 96 weeks of ART	25	Four-weekly overlapping intravenous VRC01LS + 101074 with daily ART for eight weeks, then ART interruption if viral load <40 copies/mL until 24 weeks or viraemia >400 copies/mL versus ART alone	Safety, pharmaco-kinetics, antiviral efficacy, reservoir and immune response	Completed *(2042)*; 2042-Plus enrolling	44% main-tained suppression at 24 weeks off ART; no serious infusion reactions, or grade 3 or 4 events (including neutropaenia and anaemia) occurred

Annex 2. Participants

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Yogan Pillay	Gates Foundation, South Africa
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Martina Penazzato, WHO	
Françoise Renaud, WHO	
Erin Sparrow, WHO	
Nandita Sugandhi, WHO	
Marco Vittoria, WHO	

Annex 3. Agenda

	Day 1: 22 May 2024	Speaker
14:30–14:40	Welcome and Opening remarks	Meg Doherty, WHO
14:40–14:50	Introduction and meeting objectives	Nandita Sugandhi, WHO
14:50–15:00	Epidemiological update on HIV vertical transmission	Anna Yakusik, UNAIDS
15:00–15:10	WHO efforts to optimize and innovate approaches to postnatal prophylaxis	Martina Penazzato, WHO
15:10–15:20	Community perspectives on the potential of broadly neutralizing antibodies for infant postnatal prophylaxis	Elina Mwasinga, Coalition of Women Living with HIV and AIDS, Malawi
15:20–15:35	Overview of immunotherapeutic strategies for using broadly neutralizing antibodies as pre-vention for HIV	Jon Heinrichs, International AIDS Vaccine Initiative
15:35–15:50	Q&A	
15:50–16:00	Break	
16:00–16:15	WHO guidelines development: key domains and drivers of evidence appraisal	Nathan Ford, WHO
16:15–17:45	Paediatric study updates followed by Q&A • IMPAACT Network studies • PedMAb • SAMBULELO • LIFE STUDY 2.0 • Tatelo	Facilitator: Ameena Goga, WHO Betsy McFarland, IMPAACT Network Gabriella Scarlatti, Ospedale San Raffaele Philippe Van de Perre, University of Montpellier Arne Kroidl, University of Munich Roger Shapiro, Harvard University
17:45–18:00	Wrap-up	Nandita Sugandhi, WHO
	Day 2: 23 May 2024	**Speaker**
14:30–14:40	Recap of day 1 and introduction to day 2	Nandita Sugandhi, WHO
14:40–14:50	Anticipated delivery models and key implementation considerations	Eleanor Magongo, Ministry of Health, Uganda
14:50–15:00	Cost–effectiveness of using neutralizing antibodies in postnatal prophylaxis	Andrea Ciaranello, Cost–effectiveness of Preventing AIDS Complications, Massachusetts General Hospital

15:00–15:15	Considerations and lessons learned from other disease areas	Erin Sparrow Jones, WHO
15:15–16:15	Breakout discussions • Risk and benefits • Acceptability and equity • Feasibility • Cost–effectiveness	Facilitated by group chairs with rapporteurs
16:15–16:30	Break	
16:30–17:00	Report back from group discussion	Rapporteurs
17:00–17:50	Structured discussion	All facilitated by WHO
17:50–17:55	Summary and next steps for the group	Nandita Sugandhi, WHO
17:55–18:00	Closing	Meg Doherty, WHO
	Day 3: 21 November 2024	**Speaker**
14:00–14:05	Welcome and opening remarks	Meg Doherty, WHO
14:05–14:15	Introduction and brief recap of part 1	Nandita Sugandhi, WHO
14:15–14:30	Overview of new developments since last consultation	Martina Penazzato, WHO
14:30–15:30	Structured discussion (5min presentation + 10 for group feedback) • Efficacy and safety • Feasibility • Acceptability • Cost-effectiveness – What is the evidence that needs to be generated for consideration for future guidelines? – What are the next steps to facilitate the evidence generation that will be needed?	Martina Penazzato and Pablo Rojo Nandita Sugandhi and Shaffiq Essajee Ameena Goga and Lynda Stranix Chibanda Erin Sparrow and Sébastien Morin
15:30–15:50	Next steps: Broadly neutralizing antibody tracker review Paediatric antiretroviral drug optimization planning Consultation report Manuscript	Nandita Sugandhi and Martina Penazzato, WHO
15:50–16:00	Wrap-up	Nandita Sugandhi and Meg Doherty, WHO

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