Response to WHO Statement

14 February 2026

We welcome WHO's continued commitment to hepatitis B prevention and fully agree that the hepatitis B birth dose vaccine is effective in preventing mother-to-child transmission. That protective effect is well established and is not the subject of our study.

However, we respectfully disagree with WHO's characterization of the proposed randomized trial in Guinea-Bissau.

Constructive engagement with WHO

In January, we had a constructive meeting with WHO representatives to discuss the study design in detail. During that discussion, we explored potential design modifications, including the introduction of maternal hepatitis B screening within the trial framework.

While we carefully considered maternal screening during the design phase, it also raises important ethical and logistical challenges in this setting - including the ethical implications of identifying infected mothers without guaranteed access to antiviral treatment and long-term care in the health system. For that reason, it was not included in the original protocol. Nevertheless, we expressed openness to continued dialogue on this and other design elements.

We also discussed comparator options. A saline placebo was not included because the Guinean National Ethics Committee does not permit injectable saline placebo in newborns. We indicated openness to considering vitamin K as a comparator if deemed appropriate.

WHO representatives acknowledged that the trial could have important implications for future WHO policy considerations in this area. We remain open to further technical dialogue.

No child is denied existing care

The hepatitis B birth dose is not currently part of routine national practice in Guinea-Bissau. No child enrolled in the study would receive fewer vaccines than under current national policy. The study examines its introduction prior to planned nationwide rollout (currently scheduled for 2028).

The study is designed to evaluate the broader health effects of introducing this new policy in a randomized setting before universal scale-up. Research that evaluates the introduction of new policies before nationwide implementation is standard public health practice.

All children would receive hepatitis B vaccination at 6, 10, and 14 weeks, consistent with national guidelines. Half would receive an additional birth dose.

Because half of enrolled newborns would receive the birth dose, the trial would reduce - not increase - the number of infants exposed to potential mother-to-child transmission compared with the current situation, in which no newborns receive the vaccine at birth.

The study is conducted in an almost 50-year long Danish-Guinean collaboration. It has been reviewed and approved by the Guinean National Ethics Committee and would be conducted with parental informed consent.

The scientific question

The trial does not question the vaccine's efficacy against hepatitis B infection.

Its purpose is to evaluate broader non-specific health effects - positive, negative, or neutral - when hepatitis B vaccine is administered at birth together with BCG and oral polio vaccine. Where genuine scientific uncertainty exists regarding overall health impact in this co-administration contex, randomized evaluation is the appropriate method to resolve that uncertainty.

Policy relevance beyond Guinea-Bissau

Most countries in the WHO African Region have not yet implemented universal hepatitis B vaccination at birth. The policy question is therefore highly relevant not only for Guinea-Bissau, but for many African countries considering how best to implement WHO guidance in their specific context.

The birth dose is primarily intended to prevent mother-to-child transmission. In some settings, maternal screening with targeted vaccination of exposed newborns is an alternative strategy. When countries consider adopting universal birth dose vaccination, it is therefore scientifically and ethically relevant to assess whether universal administration confers overall net benefit compared with other approaches.

If this first randomized evaluation of overall health effects is not undertaken before nationwide implementation, important questions may remain unanswered - for Guinea-Bissau and for other countries in the region.

Commitment to dialogue

We respect Guinea-Bissau’s decision to pause implementation pending further technical review and welcome continued discussion.

Our objective is not to challenge hepatitis B vaccination, but to ensure that major policy introductions are guided by the strongest possible evidence. We remain committed to scientific rigor, ethical integrity, transparency, and collaboration with WHO and national authorities.

We believe that careful evaluation strengthens evidence-based decision-making and long-term trust in immunization programs.