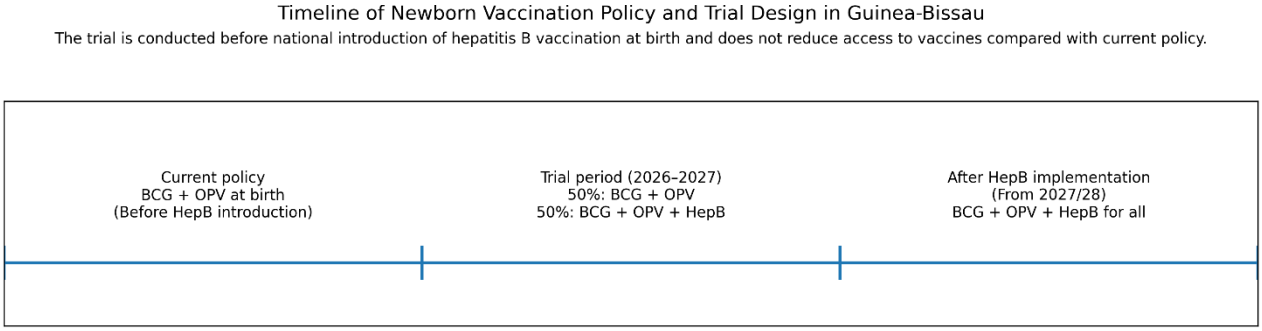
Frequently Asked Questions (FAQ)

Planned Hepatitis B Vaccine Study in Guinea-Bissau

This document provides factual information about the planned hepatitis B vaccine study in Guinea-Bissau, including study design, ethical considerations, and collaboration. The full study protocol and additional background materials are available at www.bandim.org.



Does the study withhold the hepatitis B vaccine from some children?

No. All children participating in the study receive the same vaccines they would otherwise receive under Guinea-Bissau's current national immunization policy. No child receives fewer vaccines because of participation in the study.

What is the current national immunization schedule in Guinea-Bissau?

Under Guinea-Bissau's current national immunization policy, newborns routinely receive BCG and oral polio vaccine (OPV) at birth. Hepatitis B vaccine is not currently given at birth in Guinea-Bissau. At present, hepatitis B vaccines are administered at around 6, 10 and 14 weeks of age, as part of the pentavalent vaccine.

Is maternal screening for hepatitis B currently implemented in Guinea-Bissau?

No. Guinea-Bissau does not currently have a universal maternal screening program for hepatitis B. Maternal hepatitis B status is therefore unknown for most women at the time of delivery, which reflects the existing standard of care. The study does not change this situation.

Why is a randomized design being used?

The study is designed to evaluate health outcomes before the introduction of hepatitis B vaccination at birth by the Guinean government (anticipated in 2028). Randomization during the period prior to the introduction of the new policy allows for more reliable evidence generation while remaining fully within the existing standard of care.

What about mothers who are hepatitis B positive and the risk of mother-to-child transmission?

Based on previous surveys, it is estimated that a proportion of mothers - possibly ~15% - may be hepatitis B positive. If a mother is known to be hepatitis B positive, her child will not be enrolled in the study and will be vaccinated according to clinical recommendations. For most mothers, hepatitis B status is unknown, which reflects the current national standard of care. Importantly, because half of all newborns in the study will receive hepatitis B vaccination at birth, the study will reduce the overall number of infants exposed to mother-to-child transmission compared with the situation in the absence of the study.

Is the study linked to US policy decisions regarding hepatitis B vaccination?

No. The study idea came up in 2024, the concept was developed in spring 2025, and the first funding commitment was secured from Pershing Square Foundation in June 2025 - well before subsequent policy decisions in the US. There is no causal or strategic link between the study and U.S. vaccination policy decisions.

Did CDC, Kennedy, or other political actors influence the study design or conduct?

No. The study was developed independently. Funders have had no role in the design, conduct, analysis, interpretation, or publication decisions.

Has the study received ethical approval?

Yes. The study has undergone ethical review and received the required approvals from relevant authorities.

Why study possible non-specific effects of vaccines?

Non-specific effects of vaccines - effects beyond protection against the target disease - have been studied and discussed in the scientific literature for more than three decades. Understanding these effects, whether positive, negative, or neutral, is important for strengthening the evidence base for vaccine policy and public trust.

Why is it important to generate evidence before introducing a new vaccine policy?

Yes. Vaccines are among the most widely used public health interventions, and policy decisions affect millions of children worldwide. While hepatitis B vaccine is highly effective in preventing hepatitis B infection, its effects on overall child health have not been evaluated in a randomized trial. When policies are introduced without such evidence, decisions must be made in the absence of complete information. From an ethical perspective, generating robust evidence - when it can be done without reducing the existing standard of care - is important to ensure that vaccination policies are as safe and beneficial as possible. This study aims to contribute such evidence.

Does this study aim to question or undermine confidence in vaccines?

No. The purpose of the study is to strengthen the scientific evidence base that underpins vaccine policy. Careful evaluation of vaccine effects - including non-specific effects - has been part of vaccine research for decades and is essential for maintaining public trust and ensuring that vaccination policies are as safe and effective as possible.

Is the trial run solely by Danish researchers?

No. The trial is conducted through the Bandim Health Project, a nearly 50-year-long collaboration between research institutions in Guinea-Bissau and Denmark. The project is embedded in Guinea-Bissau and operates in close partnership with national health authorities.

What is the role of Guinean researchers in the study?

Guinean researchers play a central role. A core mission of the Bandim Health Project is local research capacity building, including training Guinean scientists at Master's, PhD, and postdoctoral levels. Research questions, study design, data collection, analysis, interpretation, and dissemination are all conducted collaboratively.

Who owns the data and how will authorship be handled?

Data are managed within the framework of the Bandim Health Project and in accordance with agreements with national authorities in Guinea-Bissau. Data access, analysis, and publication follow established collaborative governance structures. Authorship reflects scientific contributions and includes Guinean researchers, in line with international guidelines and long-standing practice.

How does the study align with principles of ethical and equitable global health research?

The study is conducted within existing national health policies, has received ethical approval, and is based on a long-term local partnership rather than short-term external intervention. Shared decision-making, transparency, capacity building, and local relevance are central.

Where can I find more detailed information?

Additional information, including access to the full study protocol and background materials, is available at **www.bandim.org**.