



H.E. Dr. Jean Kaseya
Director General
Africa Centres for Disease Control and Prevention
Haile Garment Square
Addis Ababa, Ethiopia

CC: Commodore Quinhin Nantote, MD
Minister of Public Health of Guinea-Bissau
Av. dos Combatentes
Bissau, Guinea-Bissau

November 1st, 2026

Dear Dr. Kaseya,

On behalf of the Hepatitis B Foundation, the African Hepatitis B Advocacy Coalition (ABAC), the Coalition Against Hepatitis for People of African Origin (CHIPO), the Hepatitis B in Africa Collaborative Network (HEPSANET), Society on Liver Disease in Africa (SOLDA), and the **X** undersigned organizations, we write to strongly oppose the proposal by the Bandim Health Project, supported by the U.S. Department of Health and Human Services (HHS), to conduct a randomized controlled clinical trial of the hepatitis B birth dose in Guinea-Bissau.¹

We are deeply alarmed by the proposed study, which raises serious questions regarding its transparency, scientific justification, study design, and protocols. These concerns are further compounded by the ethical questions raised by withholding a well-established preventive intervention from select infants in a country that already bears a substantial burden of hepatitis B and hepatitis B-related hepatocellular carcinoma, or liver cancer.

Guinea-Bissau has one of the highest prevalence rates of hepatitis B in the world, with approximately 12% of adults estimated to be living with chronic hepatitis B.² The country also bears a significant burden of liver cancer caused by hepatitis B, ranking seventh among 49 sub-Saharan African countries in liver cancer mortality.³ Given this information, we question the scientific and ethical justification for a study that would withhold the hepatitis B birth dose from infants living in a country where hepatitis B is highly endemic.

Based upon the publicly available information, this study seeks to answer questions for which ample scientific evidence already exists. Existing evidence has established that there is no causal relationship between the hepatitis B birth dose and the identified concerns within the proposed study, including atopic dermatitis, neurodevelopmental disorders, or mortality.

Guinea-Bissau also has one of the highest infant mortality rates in the world, with approximately 42 deaths per 1,000 live births, meaning roughly 1 in every 24 infants dies before reaching one year of age.⁴ To search for a disproven association between a lifesaving vaccine and mortality in a country that already suffers from high infant mortality from known causes, while failing to address those causes, is morally reprehensible. Infants in Guinea-Bissau should not be asked to bear additional and potentially harmful risks when these scientific questions have already been answered. The birth dose is an established and highly effective intervention that protects infants at the most vulnerable point in their lives from this virus and is an essential component of global efforts to prevent hepatitis B transmission and its long-term consequences, including liver cancer.

Most recently, findings from the IMPACT-B study, published in *Clinical Infectious Diseases* in September 2026, provide compelling evidence from an African setting that timely hepatitis B birth-dose vaccination substantially reduces mother-to-child transmission. In this multicenter observational study conducted in Ethiopia, no hepatitis B infections were identified among 39 infants who received birth-dose vaccination alone or 217 infants who received birth-dose vaccination with hepatitis B immunoglobulin, compared with 15% of infants who received neither intervention at birth and became infected. Importantly, all infants included in the analysis completed the routine hepatitis B vaccination series, demonstrating that vaccination beginning at six weeks does not provide equivalent protection against early transmission.⁵

These findings reinforce earlier evidence from Ethiopia and the extensive international literature supporting the World Health Organization's recommendation for hepatitis B vaccination within 24 hours of birth,⁶ and although this is not yet the standard in Guinea-Bissau, there should not be an inequitable introduction to a life-saving intervention.

The aforementioned concerns are particularly significant given Guinea-Bissau's own commitment to strengthening hepatitis B prevention. The country formally committed to introducing the birth dose in 2024 and has already begun efforts to roll out the hepatitis B birth dose nationwide. The public health consequences of delaying hepatitis B birth-dose vaccination in Guinea-Bissau are substantial. Currently, hepatitis B three-dose vaccine coverage is estimated at 68%, while birth-dose coverage remains at 0%. Modeling projections from the Center for Disease Analysis Foundation (CDA) suggest that achieving 90% timely birth-dose coverage and 90% three-dose coverage beginning in 2027 could prevent approximately 58,300 acute and 20,300 chronic hepatitis B infections by 2050, compared with maintaining current three-dose coverage. Critically, delaying implementation by just one year, until 2028, is projected to result in an additional 4,500 acute and 1,500 chronic hepatitis B infections compared with implementation in 2027. These findings underscore the potential health consequences of postponing the introduction of an established, effective prevention strategy in a country already experiencing a substantial hepatitis B burden.

At a time when the country is working to make this lifesaving intervention widely available, efforts should support and strengthen that progress, not withhold protection from the country's most vulnerable populations.

Therefore, we urge the Africa Centres for Disease Control and Prevention to reject this clinical trial. A study involving human participants, particularly infants, demands a clear and compelling scientific justification for both the questions being asked and the methods used to answer them, and that has not been shown by the research proposal.

We strongly believe that scientific research involving humans must uphold the highest ethical standards, be grounded in clear scientific justification, and protect the health and well-being of those who participate. These obligations take on even more importance when research is conducted in communities already carrying a significantly disproportionate burden of a cancer-causing disease, and where access to proven preventive interventions remains limited to so many.

The communities most affected by hepatitis B should benefit from advances in scientific research, not bear unnecessary and preventable risks in pursuit of information.

We strongly urge the institutions involved to consider the scientific and ethical justification for the proposed study and to ensure that research conducted in Guinea-Bissau supports, rather than undermines, progress toward equitable access to hepatitis B prevention.

Sincerely,

Hepatitis B Foundation

African Hepatitis B Advocacy Coalition

Coalition Against Hepatitis for People of African Origin

Hepatitis B in Africa Collaborative Network

Society on Liver Disease in Africa

Center for Disease Analysis Foundation

Undersigned Organizations:

Citations:

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2. <https://www.globalhep.org/data-profiles/countries/guinea-bissau>
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5. Berhe N, Desalegn H, Mengistu H, Birhane D, Kebede B, Maru M, Girma F, Bekele D, Gure T, Yaid H, Abdi S, Shimakawa Y, Johannessen A, Nayagam S; IMPACT-B Study Team; the. Effectiveness of timely hepatitis B birth dose vaccination to prevent mother-to-child transmission in Ethiopia. *Clin Infect Dis*. 2026 Sep 24:ciag598. doi: 10.1093/cid/ciag598. Epub ahead of print. PMID: 42781776.
6. Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection. Geneva: World Health Organization; 2024. Licence: CC BY- NC-SA 3.0 IGO.