



U.S.-Funded Hepatitis B Vaccine Trial Continues to Draw Criticism

A hep B vaccine study in Guinea-Bissau that is partially funded by the CDC raises ethical concerns.

February 16, 2026 By Eva Lorenz

The Centers for Disease Control and Prevention (CDC) awarded \$1.6 million to a team of Danish researchers for a hepatitis B virus (HBV) vaccine study in Guinea-Bissau to assess the impact of the immunization birth dose. Controversy has surrounded the West African trial; indeed, many public and health officials are worried about the ethical implications of withholding the vaccine from newborns.

On February 6, [House Democratic members of the Energy and Commerce Committee asked CDC director Jim O’Neill for more information](#) regarding the trial. On February 12, [World Health Organization \(WHO\) director-general Tedros Adhanom Ghebreyesus addressed the trial](#).

“Of course, a sovereign country can decide whatever they want, but as far as WHO’s position is concerned, it’s unethical to proceed with this study,” said Tedros during a press conference.

On February 13, [the WHO released a statement](#) outlining how withholding the vaccine in the proposed hep B vaccine trial is unethical.

The vaccine trial would randomize whether approximately 14,500 newborns in Guinea-Bissau receive a hep B vaccine dose at birth or at two months of age, [according to STAT](#).

[The Democratic House members asked O’Neill](#) for clarification on the status of the HBV trial, the study’s proposal and protocol, CDC’s communications with Guinea-Bissau’s Ministry of Health and documentation regarding the awarded grant.

“Deliberately withholding a proven vaccine that has saved millions of lives globally for the sole

purpose of examining theoretical, nonspecific side effects may constitute a major breach of scientific ethics,” wrote the Democratic members, “and using taxpayer dollars in such a study rather than using those dollars to provide proven, lifesaving vaccinations to babies is abhorrent.”

Vaccines can [prevent hep B infection](#) and its consequences. Antiviral treatment keeps viral replication under control, but it seldom leads to a cure. If left untreated, chronic [HBV](#) can lead to serious liver complications, including [cirrhosis](#) and [liver cancer](#).

At the end of 2025, the CDC [rolled back its recommendation that every child be vaccinated for hep B at birth](#). Instead, HBV immunization for newborns will be offered only for babies born to mothers who tested positive during pregnancy or whose mothers’ hepatitis B status is unknown. For other infants, the CDC recommends that the vaccine not be administered before a baby is at least two months old.

In Guinea-Bissau, chronic hep B infection is prevalent, affecting one in every five people, according to [a 2019 study](#). Approximately 90% of newborns exposed to HBV go on to develop chronic infection, and a quarter of these children die of liver cancer or liver failure related to their infection.

To learn more about the controversy surrounding the vaccine trial and the CDC’s changes to the hep B vaccine schedule, read “[CDC Advisers Vote Against Hepatitis B Vaccine for All Newborns](#),” and “[In Hepatitis B Vaccine Debate, CDC Panel Sidesteps Key Exposure Risk](#).”