Hepatitis B Birth-Dose Trial in Guinea-Bissau

This table summarizes recurring public claims about the hepatitis B birth-dose trial in Guinea-Bissau and provides factual clarifications based on the published protocol, ethics approvals, and national vaccination policy. Its purpose is to support accurate, evidence-based discussion.

Public / Media Claim	**Corrected / Contextualized Statement**
"Kennedy Plan to Test a Vaccine in West African Babies"	The study is **not politically initiated**. It is an **investigator-initiated academic trial**, developed independently prior to recent U.S. policy debates, and conducted through a long-standing Guinea-Bissau–Denmark research partnership.
The study is U.S.-driven, politically motivated, or influenced by RFK Jr. or vaccine-sceptic funding	The study is **investigator-initiated and scientifically independent**. The research question predates recent U.S. political developments and builds on long-standing research into the broader health effects of vaccines. **Funders have no role** in study design, conduct, analysis, interpretation, or publication decisions.
The study tests whether hepatitis B vaccines work	The protective effect against hepatitis B infection is **already well established**. The trial evaluates **overall health outcomes,** including broader effects, which **have never been tested in a randomized study**.
The study is already enrolling infants	The study **has not yet started participant enrollment** and remains subject to ongoing ethics and regulatory processes.
Researchers are "taking advantage" of Guinea-Bissau's lower standard of care	The study is conducted in **Guinea-Bissau because this is where the intervention will be implemented and where evidence is most relevant**. There is a **widely recognized global need for more high-quality clinical research conducted in African settings**, and this trial helps address that gap through the **Bandim Health Project's nearly 50-year partnership** with Guinean institutions, with **Guinean researchers in central leadership roles**.
The study violates ethics by not offering the global birth-dose standard	There is **no universal requirement** that clinical trials must provide interventions **not yet implemented in national policy**. Evaluating **realistic, locally relevant policy options** is widely considered ethically appropriate. As of recent WHO reporting, **only a minority of WHO AFRO countries** have implemented a universal hepatitis B birth dose.
Half of infants are "not given the vaccine" until six weeks	**No child receives fewer vaccines than under current national policy.** All children receive routine vaccines; **half receive an additional hepatitis B birth dose** they would not otherwise receive. The study will **improve the timeliness and coverage of BCG and oral polio vaccination for participants,** as vaccines are provided on all weekdays, including holidays, and during occasional national stock-outs.

Public / Media Claim	Corrected / Contextualized Statement
The study puts infants at risk	The study does **not reduce any child's access to recommended vaccines or standard care.** It operates under approved ethical and safety monitoring frameworks.
Researchers ignored maternal screening	**Maternal screening was considered from the outset.** It was not included due to **scientific, ethical, logistical, and feasibility considerations**, including relevance to national policy, counseling requirements at delivery, and potential impact on recruitment and study power.
"One in five people in Guinea-Bissau lives with hepatitis B"	Available data suggest **lower prevalence among women (~15% in a decade-old survey)**, likely **declining** due to infant vaccination and blood-screening programs. Not all infected mothers transmit infection to their infant, and **vertical transmission is not the dominant route** in Guinea-Bissau.
Media coverage implies very high infant risk from delayed birth dose	While prevention is important, the **magnitude of vertical-transmission risk is overstated** in public reporting. This does **not negate prevention benefits**, but it **affects the scale of risk being portrayed**.
The study is primarily conducted by Danish researchers	The trial is conducted through the **Bandim Health Project**, with **Guinean scientists playing central roles** in design, implementation, analysis, and dissemination.
The study did not receive proper ethics approval	The study **received ethics approval from Guinea-Bissau's National Ethics Committee** on November 5, 2025 (approval number 036-CNES-INASA-2025). Under Danish regulations, **ethics committees in Denmark do not review protocols for studies conducted entirely outside Denmark**.
The trial repeats unethical HIV placebo trials	The comparison is **not equivalent**. Unlike those trials, **no child in this study receives less care than the national standard**, and **some receive additional protection**.
The study reflects disregard for African lives	The study's purpose is **the opposite**: **to strengthen evidence for health policies affecting African children**, based on **locally generated data, long-term partnership, and a commitment to research equity in global health**.