

# First mass reactive vaccination campaign against Hepatitis E: main results of observational studies

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## Introduction

Hepatitis E was first identified in the 1990s, but major epidemics date back to the 1950s. There is no specific treatment, and it can be fatal especially for pregnant women, causing spontaneous abortion and stillbirths. In 2011, the first vaccine was made available, and in 2015, the WHO recommended its use during epidemics, including for pregnant women. However, several major epidemics occurred without vaccine use. The first mass reactive vaccination took place in 2022 at the Bentiu camp in South Sudan, alongside operational research.

## Methodology

We assessed vaccination feasibility and acceptance through coverage surveys and conducted focus group discussions on acceptance. We monitored adverse events following immunization (AEFI) for pharmacovigilance. To assess safety in pregnancy, we monitored the pregnancy outcomes of all women identified as pregnant during the vaccination campaign through a census. Despite the significant efficacy shown in a phase 3 clinical trial after three doses, we aimed to evaluate the vaccine's efficacy in South Sudan during an epidemic after administering two doses through a case-control study.

## Results

Coverage of at least one dose of the Hecolin vaccine after three rounds was estimated at 86% (95% CI: 84-88), with no cases of severe AEFI. Focus groups revealed strong concern about hepatitis E and high confidence and demand for the vaccine. An emulated target trial showed a relative risk of foetal loss between vaccinated and unvaccinated pregnant women at 1.1 (95% CI: 0.7-1.8). Vaccine effectiveness after two doses was estimated at 88.3% (95% CI: 53.8-97.6) using a test-negative design.

## Discussion

We found high vaccine coverage, good acceptance, and demand from the population. There was no evidence of increased risk of foetal loss among vaccinated pregnant women. Despite the small number of cases, the reduced dose regimen appeared effective in reducing disease risk in this highly exposed population.

Studies from the first mass reactive vaccination against hepatitis E demonstrated high coverage and acceptance, no safety issues among pregnant women, and good effectiveness after two doses.

