Safety of hepatitis E vaccination in pregnancy following the first mass reactive vaccination campaign in Bentiu, South Sudan

Robin Nesbitt, Epicentre, France

Background

Hepatitis E causes high mortality among pregnant women with case fatality risks of 10-25%, and adverse fetal outcomes. Hecolin® is a safe and efficacious vaccine against Hepatitis E, but there is an evidence gap on its safety in pregnant women. In 2015 the WHO recommended its use in response to outbreaks, including vaccinating pregnant women. The first mass reactive vaccination campaign against Hepatitis E was conducted in Bentiu including pregnant women and achieved high administrative vaccination coverage. We aimed to document pregnancy outcomes in a cohort of vaccinated and non-vaccinated pregnant women.

Methods

An exhaustive pregnancy census was conducted after the second vaccination round from 16 May to 30 June 2022 to recruit women who were pregnant between 1 January 2022 and the interview date. Women were recontacted a minimum of 28 days after expected delivery to assess pregnancy outcome. Categorization of the cohort according to timing of potential vaccine exposure in pregnancy and regression models to evaluate the association between at least one dose in pregnancy and pregnancy outcomes is ongoing.

Results

Of 20,674 women of childbearing age who consented for interview, 3,458 (16.7%) reported being pregnant since 1 January 2022. Women were a mean of 25.5 years old, had a median of 2 previous pregnancies (0-11), and 21 (0.6%) reported experiencing jaundice during their current pregnancy. Overall, 2723 (78.7%) women received at least one dose of Hecolin®. Access to delivery care was high, with 90% of women delivering in a health facility; 357 (10.3%) women reported a complication during delivery and 16 (0.5%) reported a caesarean section. According to interview, 3233 (93.5%) women had a livebirth, and 225 (6.9%) had a pregnancy loss, including 57 (1.6%) reported stillbirths, translating to a stillbirth rate of 17.6/1000 pregnancies, compared to the national estimate of 25.8/1000 pregnancies.

Conclusion

It was feasible to implement an observational study on the safety of vaccination in pregnancy alongside the first deployment of Hecolin® in a humanitarian emergency setting. Access to delivery care is reflected in the lower than national average rate of stillbirth in the camp. Results are expected to narrow the evidence gap on the safety of this vaccine in pregnancy.

A cohort study on the safety of vaccination in pregnancy was implemented alongside the first deployment of Hecolin® in a humanitarian emergency setting. Preliminary results show overall high coverage with at least one dose and access to delivery care among women in the cohort.