

## Efficacy and safety of a new heat stable rotavirus vaccine (ROSE)

---

Amadou Matar Seck , Epicentre, Niger

### Background

Every year, rotavirus gastroenteritis causes about one-third of deaths due to diarrhea among children under 5 worldwide, most of which occur in sub-Saharan Africa. Infection can be prevented with a vaccine, but a global shortage of the vaccine and the need for cold-chain transport presents delivery challenges.

### Methods

We conducted a double-blind, randomized, controlled trial in Niger to evaluate the efficacy and safety of BRV-PV (Serum Institute of India, Pvt Limited), a live, oral, heat-stable rotavirus vaccine. Healthy infants received three doses of vaccine or placebo at 6, 10, and 14 weeks of age. Episodes of gastroenteritis were assessed through active and passive surveillance. The primary endpoint was vaccine efficacy from 28 days post-dose 3. Assuming a 2% attack rate, a 50% true vaccine efficacy, and 20% participant non-assessability, 117 cases (78 unvaccinated and 39 vaccinated) were required to establish 50% true vaccine efficacy. All serious adverse events, including intussusception, and adverse events were assessed using facility- and home-based surveillance.

### Results

Among the 3 508 infants included in the per-protocol efficacy analysis (1 780 in the vaccine group and 1 728 in the placebo group), there were 31 and 87 cases of severe rotavirus gastroenteritis in the vaccine and placebo groups,

respectively (2.14 and 6.44 cases per 100 person-years), resulting in a vaccine efficacy of 66.7% (95%CI 49.9–77.9). Similar efficacy was seen in the intention-to-treat analyses. There was no difference in the risk of adverse events (68.7% vaccine and 67.2% placebo) or serious adverse events (8.3% vaccine and 9.1% placebo), including death (n=27 vaccine and n=22 placebo). No child had confirmed intussusception.

### Conclusion

We found BRV-PV to protect against severe rotavirus gastroenteritis among infants. BRV-PV does not require refrigeration and represents an important option to prevent morbidity and mortality among the most vulnerable

Rotavirus gastroenteritis leads to about one-third of diarrheal disease deaths in children. We found BRV-PV to protect against severe rotavirus gastroenteritis among infants in Niger