SCIENTIFIC DAYS 20 May 2026

MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

Delivering R21 vaccine through seasonal malaria chemoprevention: coverage and qualitative insights from cluster-randomised trials in Burkina Faso, Mali, and Chad

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Introduction

The IMVACS (Burkina Faso and Mali) and CoSAV-R21 (southern Chad) ongoing trials assess the efficacy and safety of integrating R21/Matrix-M vaccine with seasonal malaria chemoprevention (SMC). We describe coverage and preliminary qualitative results obtained from surveys conducted after the primary series of vaccination.

Methods

The IMVACS and CoSAV-R21 randomly assigned health areas in Burkina Faso (n=20), Mali (n=16), and Chad (n=26) to integrated or routine arms. In integrated arms, children aged 3–59 months (Burkina Faso, Mali) or 6–59 months (Chad) received seasonal vaccination synchronised with SMC (June/July–October 2025). In routine arms, children aged 5–36 months (Burkina Faso, Mali) or 6–11 months (Chad) were vaccinated following expanded programme on immunisation schedules year-round, starting in June 2025. SMC delivery was either door-to-door or fixed-point delivery. Post-SMC cross-sectional coverage surveys (November–December 2025) used simple random sampling in Burkina Faso and Mali (412 children per arm) and two-stage cluster sampling in Chad (803 children per arm). Caregiver interviews collected data on vaccine and SMC doses (via cards or recall) and reasons for missed doses. Qualitative interviews explored acceptability, feasibility, and vaccine hesitancy. CoSAV-R21and IMVACS are registered with Clinicaltrials.gov (NCT07038837, NCT06860178) and Pan African Clinical Trial Registry (PACTR202506716081750, PACTR202502765006598).

Ethics

The IMVACS protocol was approved by national ethics committees of Mali and Burkina Faso and by the MSF Ethics Review Board (ERB). CoSAV-R21 protocol (and INTEGREVAC protocol for qualitative component) were approved by national ethics committee in Chad and by the MSF ERB. Both protocols were also approved by the ethics committee of Liverpool School of Tropical Medicine.

Results

By 18 November 2025, 6,078, 12,905, and 39,672 children in Burkina Faso, Mali, and Chad received at least one vaccine dose in intervention arms, compared with 3,023, 6,983, and 2,894 in routine arms. First-dose vaccine coverage in intervention arms was 98.3% (96.4–99.2) in Burkina Faso, 94.4% (91.4–96.2) in Mali, and 95.4% (92.5–97.3) in Chad, with 96.6% (94.3–98.0), 80.7% (76.6–84.3), and 84.6% (80.4–88.1) completing the 3-dose primary series. In routine arms, first-dose coverage was 75.2% (69.5–80.1), 79.2% (73.5–83.9), and 57.0% (47.9–65.4), with 63.1% (56.6–69.2), 63.4% (56.8–69.6), and 48.6% (40.1–57.1) completing the series. Missed doses were predominantly attributed to caregiver/child absence and farming work in integrated arms, and lack of awareness about vaccine availability in routine arms. SMC coverage for at least three rounds was 98.5% (96.7–99.3), 76.5% (72.1–80.3), and 91.9% (88.1–94.7) in Burkina Faso, Mali, and Chad in intervention arms, versus 98.3% (96.4–99.2), 49.3% (44.4–54.1), and 86.5% (81.2–90.4) in routine arms. Survey limitations included low retention of vaccination cards and, in routine arms, incomplete data due to ongoing vaccination.

Conclusion

Integrating R21/Matrix-M with SMC achieved high vaccine coverage and low dropout while maintaining SMC coverage. This approach could maximise malaria prevention in highly seasonal areas. Further efficacy and cost-effectiveness analysis will guide broader implementation.

Conflicts of interest

All authors declare no competing interests.