Maternal sepsis prevention across urban and rural health facilities in Nigeria: findings from the AZIN-V cluster-randomised trial

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Background: Maternal sepsis remains an important cause of preventable maternal morbidity and mortality in low- and middle-income countries (LMICs). Access to quality maternal healthcare varies across urban and rural settings, yet evidence to guide context-appropriate interventions across these settings remains important. Generating evidence from diverse health facilities, including those outside major urban centres, is essential to informing maternal health strategies in LMICs.

Objective: To evaluate whether intrapartum oral azithromycin reduces maternal sepsis among women giving birth in health facilities across diverse urban and rural settings in Nigeria.

Methods: We conducted an open-label, cluster-randomised trial involving 48 health facilities across six Nigerian states, covering both urban and rural settings. A total of 5,040 women at 24 weeks' gestation or later, planning vaginal birth, were enrolled. Facilities were assigned to provide either a single 2 g oral dose of azithromycin during active labour or usual care. The primary outcome was maternal sepsis within 42 days postpartum. Intention-to-treat analyses accounted for clustering at facility level.

Results: Maternal sepsis occurred in 21/2,508 (0.8%) women in the azithromycin group and 25/2,503 (1.0%) in the usual-care group (adjusted odds ratio 0.79; 95% CI 0.42–1.48; p=0.469). Azithromycin did not significantly reduce maternal sepsis. Serious adverse events were comparable between groups.

Conclusion: In this multicentre trial spanning urban and rural health facilities in six Nigerian states, intrapartum azithromycin did not significantly reduce maternal sepsis. The findings provide evidence to guide maternal sepsis prevention across diverse healthcare settings and reinforce the importance of context-appropriate interventions and antimicrobial stewardship.