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Title: Mpox (MVA-BN) vaccination in pregnancy. Perspectives and challenges in data collection in remote resource-constrained settings (PregInPoxVac)

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Background. Mpox is endemic in the Democratic Republic of the Congo (DRC), where pregnant women face an elevated risk of severe disease, foetal loss, stillbirth, and congenital infection. Despite evidence of Modified Vaccinia Ankara–Bavarian Nordic (MVA-BN) safety in adults and MVA-BN-Filo safety in pregnancy, mpox vaccination for pregnant women remains off-label and clinical data are lacking. To address this gap, PregInPoxVac is conducting a Phase 3, open-label trial to evaluate the safety and immunogenicity of MVA-BN in pregnant women in Boende, DRC.

Methods. PregInPoxVac enrolled 362 pregnant women aged 16–35 years in their second or third trimester, randomised (3:2) to receive a homologous two-dose MVA-BN regimen during gestation or within 72 hours postpartum. Immunogenicity is assessed by the neutralising antibody response at day 42. Safety and reactogenicity are evaluated using local and systemic adverse events, following the Brighton SPEAC and FDA guidelines, and maternal, foetal, and neonatal outcomes are assessed per WHO GAIA guidelines. Given the remote, resource-limited setting, we implemented practical strategies to address expected challenges; including limited literacy, incomplete adverse-event capture, and participant retention, alongside operational, logistical, and socio-cultural barriers. These included tailored material development, an ancillary care policy, community engagement and health system strengthening.

Conclusion. PregInPoxVac demonstrates that rigorous maternal vaccine research can be conducted in remote, resource-limited settings through context-adapted strategies. Beyond operational insights, it will provide the first prospective safety and immunogenicity data on MVA-BN vaccination during pregnancy, informing mpox vaccination policies for pregnant women and future vaccine trials in similar settings.

