Evaluating Scale-up of the CRADLE Vital Sign Alert device in Sierra Leone - Adaptive Implementation Strategies to enable early detection of obstetric emergencies

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Background:

The CRADLE Vital Sign Alert is an easy-to-use, accurate device that measures blood pressure, pulse and shock index with an incorporated traffic-light early warning system, alerting the user to obstetric emergencies. CRADLE and its training package was associated with reduced rates of maternal death (RR 0.37 [95% CI 0.25 to 0.55], p<0.0001) and eclampsia (RR 0.56 [95% CI 0.41 to 0.67], P<0.0001) when introduced into an urban centre, garnering political buy-in for scale-up to half of Sierra Leone (2020/21).

Funding has been awarded from NIHR Global Health Research Group (CRIBS) to determine the impact, adoption and sustainability of national scale-up into routine maternity care. We aim to assess fidelity of the intervention in rural contexts and feasibility of scale-up in similar LIMC settings.

Methods:

A randomised effectiveness-implementation type 2 trial in stepped-wedged design is being undertaken to evaluate the intervention across eight rural districts via:

1. Primary clinical outcome (composite of maternal death, eclampsia, hysterectomy and stillbirth measured per 1,000 deliveries)

2. Secondary clinical outcomes assessing impact on obstetric complications and maternity referral patterns

3. Process evaluation of intervention implementation using the RE-AIM framework (including offline mobile phone GPS to measure reach)

4. A mixed-methods exploration of contextual factors and mechanisms of action including clinical care escalation

5. Implementation Strategies using the PRISM framework.

Results:

Preliminary findings from pilot scale-up to half of the county informed implementation strategies to adapt CRADLE rollout for national health system integration and uptake. Strategies include expansion of the CRADLE training package to obstetric emergency training, adaptations to stakeholder engagement and sustainability planning; partner programme integration; as well as targeted consultations with healthcare workers to aid community engagement and mitigate multidisciplinary dynamics.

Discussion:
This trial will demonstrate the potential impact of CRADLE on reducing neonatal and maternal mortality and morbidity in low-resource settings. It is anticipated that its relatively low cost and easy integration into existing health systems will be of significant interest to local, national and international health policy-makers offering strategies for rural and global scale up to enable early detection of obstetric emergencies in low-resource settings.

Trial registration: ISRCTN94429427. Registered April 2022.