

Fetal movement trials: where is the evidence in settings with high-burden of stillbirths?

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BJOG Commentary

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Fetal movement (FM) is a sign of fetal life and wellbeing that is felt by the pregnant woman, and reduced FM is known to precede stillbirths(1,2). Therefore, healthcare providers may advise women to monitor and report if their babies' movements are fewer than usual. In high-income countries (HIC), there has been a renewed interest in FM with a recent wave of large-scale randomised controlled clinical trials investigating its potential to reduce stillbirths. The My Baby's Movement trial in Australia/New Zealand, and the Mindfetalness trial in Sweden investigated the effects of intervention aimed at increasing women's awareness of FM (3,4). The British AFFIRM trial investigated the effects of an FM awareness package coupled with a standardised management protocol (5). The ongoing CEPRA study in the Netherlands, UK and Australia and aims to evaluate Cerebro Placental Ratio as an indicator for delivery in women with reduced FM (6). None of the completed trials, however, found significant reductions in stillbirths. Moreover, they showed conflicting results on some potential harmful consequences, such as increased rates of obstetric interventions. In this commentary, we reflect on these trials through a global lens, and we urgently call for more trials – but this time in settings suffering the majority (98%) of the world's two million annual stillbirths.

Importantly, the global applicability of these HIC trials is questionable. They were conducted in settings where women are aware of the importance of reduced FM and are empowered to access highest standards of care. The contextual realities of pregnancy care are vastly different in low- and middle-income countries (LMICs) where antenatal care and health education are substandard. Women lack health information to self-monitor and report reduced FM. Furthermore, antenatal clinics are often overcrowded and understaffed, with lack of supplies, clinical guidelines, and adequate training of health workers. Recent estimates show stillbirth rates as high as 22 per 1000 per total births in Sub-Saharan Africa, compared to less than 3 per 1000 in HICs (7). Given the downward trend of stillbirths reported in all the HIC trials, it is possible that the completed trials may be demonstrating a lack of *evidence* rather than a lack of *effectiveness*. We hypothesise that involving women in their care, through training on how to monitor their baby's movement and when and how to respond coupled with strengthening healthcare workers' respect and response to women's concerns

on reduced FM, is a low-cost intervention with potential to significantly reduce stillbirths in high-burden LMICs.

Surprisingly, high-quality studies from LMICs that have assessed the effect of FM interventions on perinatal deaths are lacking (2). Of note, the authors of the above-mentioned trials did not consider the well-known major differences in clinical context globally as a limitation while discussing the generalisability of their findings. In fact, the latest My Baby’s Movement trial was not even published open access, limiting access to less privileged clinicians, researchers and policymakers (4). This lack of a global perspective on the international health crisis of preventable stillbirths is an epistemic injustice and a missed opportunity (8). We are concerned that the results of the above trials could prematurely prompt policies discouraging the use of FM awareness among pregnant women(9). It is thus crucial that the lack of generic applicability of these trials’ findings are stressed, and that their high-resource contexts are considered when developing global clinical guidelines and future research priorities. Notably, it has been seen too often how the unbalanced evidence production from HICs has had unintended harmful influences on clinical practice in LMICs (10). For instance, it appears that the breech trials from HICs have led to policy change also in LMICs with increased use of caesarean section in case of breech presentation. However, the risk ratios of vaginal breech births versus caesarean sections differ dramatically between high-resource and low-resource settings with lower surgical safety in LMICs (11,12).

The prevailing constraints in LMICs should stimulate innovation and creativity to design low-cost solutions that strengthen three areas 1) FM awareness and monitoring; 2) diagnosis to identify babies truly at risk, and 3) care provision protocols of pregnant women with reduced FM to improve perinatal outcomes. While such strategies or their evidence base are often lacking in LMICs, there is some evidence about possible low-cost diagnostic approaches to assess fetal risk following reduced FM: for example, measuring maternal blood pressure, fetal heart rate, and fundal height(13), or antenatal (hand-held) ultrasound to detect and monitor high-risk pregnancies. Measuring fetal blood flow in Doppler ultrasound studies has also been useful particularly in detecting growth restriction (6,14). Involving women and health workers in studies will ensure consideration of health-system constraints and allow these to be embedded in the design, implementation, and evaluation of any new intervention. If proven effective, this will increase the chance of seamless integration of the intervention into existing care, positive perceptions by providers and pregnant women- and not increase the burden on already overwhelmed healthcare workers.

Unfortunately, maternal perception of FM is still too often the *only* signal of complications in the absence of regular high-quality antenatal checks(15)– and there are possibly many babies’ lives lost by ignoring this danger sign. Given the burden of need and the context-specific realities that determine interventions’ effectiveness, we hope these recent waves of FM trials will continue into LMICs to investigate if and how FMawareness coupled with context-tailored management protocol can reduce stillbirths.

Contribution to Authorship

NH conceived and wrote the first draft. JB, NM, BSD and MJR contributed to subsequent drafting of the manuscript. All authors revised the commentary for important intellectual content and approved the final version to be published and agree to be accountable for all aspects of the work.

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Reference

1. Bekiou A, Gourounti K. Reduced Fetal Movements and Perinatal Mortality. *Mater Sociomed.* 2020;32(3).
2. Hayes DJL, Smyth R, Heazell AEP. Investigating the significance and current state of knowledge and practice of absent or reduced fetal movements in low and lower middle-income countries : a scoping review. 2019;3:1–12.
3. Akselsson A, Lindgren H, Georgsson S, Pettersson K, Steineck G, Skokic V, et al. Mindfetalness to increase women’s awareness of fetal movements and pregnancy outcomes: a cluster-randomised controlled trial including 39 865 women. *BJOG An Int J Obstet Gynaecol.* 2020 Jun 1;127(7):829–37.
4. Flenady V, Gardener G, Ellwood D, Coory M, Weller M, Warrilow KA, et al. My Baby’s Movements: a stepped-wedge cluster-randomised controlled trial of a fetal movement awareness intervention to reduce stillbirths. *BJOG An Int J Obstet Gynaecol.* 2022 Jan 1;129(1):29–41.
5. Norman JE, Heazell AEP, Rodriguez A, Weir CJ, Stock SJE, Calderwood CJ, et al. Awareness of fetal movements and care package to reduce fetal mortality (AFFIRM): a stepped wedge, cluster-randomised trial. *www.thelancet.com.* 2018;392.
6. Damhuis SE, Ganzevoort W, Duijnhoven RG, Groen H, Kumar S, Heazell AEP, et al. The CErebro Placental RAtio as indicator for delivery following perception of reduced fetal movements, protocol for an international cluster randomised clinical trial; the CEPRA study. *BMC Pregnancy Childbirth.* 2021 Dec 1;21(1).
7. Hug L, You D, Blencowe H, Mishra A, Wang Z, Fix MJ, et al. Global, regional, and national estimates and trends in stillbirths from 2000 to 2019: a systematic assessment. *Lancet.* 2021 Aug 28;398(10302):772–85.
8. Bhakuni H, Abimbola S. Epistemic injustice in academic global health. *Lancet Glob Heal.* 2021;9:e1465–70.
9. Walker KF, Thornton JG. Encouraging awareness of fetal movements is harmful. *Lancet.* 2018 Nov 3;392(10158):1601–2.
10. Maaløe N, Ørtved AMR, Sørensen JB, Sequeira Dmello B, van den Akker T, Kujabi ML, et al. The injustice of unfit clinical practice guidelines in low-resource realities. *Lancet Glob Heal.* 2021;9(6):e875–9.
11. van Roosmalen J, Meguid T. The dilemma of vaginal breech delivery worldwide. *Lancet.* 2014;338(9932):
12. Sobhy S, Arroyo-Manzano D, Murugesu N, Karthikeyan G, Kumar V, Kaur I, et al. Maternal and perinatal mortality and complications associated with caesarean section in low-income and middle-income countries: a systematic review and meta-analysis. *Lancet.* 2019 May 11;393(10184):1973–82.
13. Housseine N, Rijken MJ, Weller K, Nassor NH, Gbenga K, Dodd C, et al. Development of a clinical prediction model for perinatal deaths in low resource settings. *eClinicalMedicine.* 2022 Feb;44:101288.

14. Ali S, Kawooya MG, Byamugisha J, Kakibogo IM, Biira EA, Kagimu AN, et al. Middle cerebral arterial flow redistribution is an indicator for intrauterine fetal compromise in late pregnancy in low-resource settings: a prospective cohort study. *BJOG An Int J Obstet Gynaecol*. 2022 Feb 4;
15. World Health Organization. WHO recommendations on antenatal care for a positive pregnancy experience [Internet]. 2016 [cited 2020 Jul 30]. Available from: https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/anc-positive-pregnancy-experience/en/

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