

PROMISE: Addressing Inequity in Maternity Medical Devices

Perinatal and Obstetric Medical devices: Solutions for Equity (PROMISE) is a NIHR Policy Research Programme-funded mixed-methods study running until 2027 led by a cross-disciplinary team at the University of Oxford. It aims to generate evidence on how biases in medical tools and devices may contribute to inequalities in maternal and neonatal outcomes, particularly for women and babies from ethnic minority communities. The programme is developing practical tools that can be used by regulators, commissioners, manufacturers and NHS organisations to identify and reduce inequities arising from maternity medical devices.

THE PROBLEM

Persistent inequalities in maternal and neonatal outcomes by ethnicity, deprivation, and migration status are well documented. Medical devices are present at every clinical decision point in maternity care. Yet their contribution to these disparities has neither been systematically measured nor well understood. Current device approval, procurement, and guideline processes rarely assess equity or bias explicitly. There is no existing evidence-based tool to do so.

WHAT PROMISE IS DOING

PROMISE is generating the evidence and practical implementation tools needed to ensure that maternity medical devices work equitably for all women and babies. This evidence is built on maternity service user experience and includes mapping, prioritising and investigating medical devices used across the maternity pathway through NHS maternity unit observations; interviews with health professionals and women; a national UKMidSS survey; systematic evidence reviews; and stakeholder engagement with clinicians, industry, policymakers and people with lived experience of maternity services.

A key anticipated output will be an Equity Impact Assessment Framework for Maternity and Neonatal Medical Devices that enables regulators, commissioners, manufacturers and NHS organisations to identify whether a maternity or neonatal device could contribute to inequitable care and to mitigate those risks. The framework considers the woman and her context through device performance, clinical use, offers and access, and structural factors, to concrete implications for practice, policy, and regulation.

WHY THIS MATTERS NOW

PROMISE is the first research programme in England to systematically examine how maternity medical devices may contribute to health inequalities across the entire maternity pathway. National attention is now focused on implementing practical solutions to improve safety and reduce inequalities in maternity care. PROMISE provides evidence and implementation tools that directly support this agenda:

- The final report of the Independent National Maternity and Neonatal Investigation, led by Baroness Amos, is due to be published on 30 June 2026. PROMISE provides an evidence-informed framework that could support implementation of recommendations relating to equitable use, evaluation and regulation of maternity technologies.
- The MHRA's draft Medical Devices (Amendment) Regulations 2026 are the most significant reform of Great Britain's medical device framework since Brexit, but do not include explicit equity requirements. PROMISE provides evidence to help address this gap, building on the Whitehead Review (2024).
- Reducing inequalities in maternity outcomes remains a national policy priority. PROMISE provides an evidence-informed framework that could support commissioners in procuring maternity technologies, NHS trusts undertaking equality impact assessments, and regulators considering equitable device performance.

NEXT STEPS

- Refine and test the Equity Impact Assessment Framework through a quasi-independent expert group (clinicians, MedTech, PPI) using a structured consensus process.
- Dissemination will include alignment with Amos review outputs and engagement with the MHRA guidance.

We welcome opportunities to collaborate on piloting and refining the Equity Impact Assessment Framework with regulators, commissioners, NHS organisations and industry partners, supporting implementation of the Amos Review recommendations and future MHRA guidance.

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