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RESEARCH GROUP: PERINATAL AND OBSTETRIC MEDICAL DEVICES: SOLUTIONS FOR EQUITY (PROMISE)

IDENTIFYING BIASES (Work Package 3)

Determine potential biases in medical devices, as identified through the landscape mapping device use and gathering perspectives.

WP3a: Rapid review of device performance and access

Methods:

We will use the outputs of WP1 and existing work to generate a list of medical devices encountered in pregnancy and the immediate neonatal period.

We will use rapid review techniques to outline existing evidence for bias in i) device performance and ii) device access, using primary literature searches where this has not already been undertaken, summarising the findings from previous reviews where they exist (updating searches to include most current studies and examine study registries). We will work with a dedicated information specialist (Nia Roberts, Bodleian Library) to design comprehensive searches for evidence quantifying bias.

- Inclusions – papers which have examined bias in use, design, performance or interpretation in the identified medical devices in antenatal or immediate postnatal care within the United Kingdom or countries with similar healthcare contexts if no papers exist from the UK.
- Exclusions: non-English language papers

While we will prioritise peer-reviewed publications due to the need for rapid evidence generation, if there is no peer-reviewed evidence retrieved, we will consider including grey literature. Search outputs in the form of title and abstract will be screened by one team member with any uncertainties discussed with a second team member. Full papers will be reviewed by 2 members of the team for formal inclusions.

Analysis:

Quality assessment will be performed for systematic reviews, cohort papers, diagnostic accuracy studies and clinical trials using the tools recognised by the Cochrane collaboration [28]. We will summarise the findings of included papers by device. While we anticipate that this will mainly be a narrative summary, if there are multiple papers using similar approaches to evaluate bias in the same device, we will perform meta-analysis. We will work with our PPI advisors to explore how best to present these results to allow our range of stakeholders to easily grasp the findings.

WP3b: Prioritisation of evidence and gap analysis

We will use patient and clinician perspectives and the findings from our review of existing evidence to generate a priority list of devices for discussion in our expert panel. In order to do this most objectively we will ultilise our expertise in formal consensus procedures [29, 30]. We will produce a report detailing the devices where more evidence is needed.

This work package will employ a modified and rapid Delphi consensus procedure to identify and prioritise devices where evidence of bias is most significant. The participants will include our Patient and Public Involvement (PPI) group and the Scientific Advisory Board (SAB), ensuring a diverse range of perspectives are represented. We have commitments from Prof Shakila Thangaratinam (Deputy Executive Dean of Institute of Life Course and Medical Sciences, University of Liverpool); Prof Asma Khalil (Professor of Obstetrics and Maternal Fetal Medicine at St George's Hospital) and Prof Jacqueline Dunkley-Bent (International Confederation of Midwives, and former Chief Midwifery Officer in England), Sadia Haqnawaz (lay member, member of Baby Lifeline Family Voices Group).

We will include a neonatologist and will liaise with the recently established NIHR National Collaborative Advisory Group on Health of Women, through its working group on LifeSciences including data, digital and devices stream to recruit a device regulatory expert.

Methods:

We will undertake iterative rounds to build consensus among the panel. In the first round, we will present the long-list of medical devices identified from Work Packages 1 and 2 and the existing evidence on bias, along with qualitative data on patient and clinician perspectives. We will prioritize devices where i) the clinical impact of the bias is most significant for maternity outcomes ii) the patient impact of the bias is most significant, derived from the experiences we hear in our qualitative interviews in terms of anxiety created and iii) where the evidence of bias is most clear from existing literature. Following each round, results will be aggregated and shared with the panel to refine rankings in subsequent rounds until consensus is reached.

Sample:

The Delphi panel will consist of 15-20 members, including representation from our PPI group (5-7 members), clinical experts (obstetricians, midwives, neonatologists), biomedical engineers, and medical device regulators (8-10 members). This diverse composition will ensure that both clinical and lived experiences are integrated into the prioritisation process.

Analysis:

Consensus will be defined as at least 70% agreement on the prioritisation of devices across the three key criteria. Where consensus is not reached after three rounds, we will hold a final roundtable discussion to address areas of disagreement, using facilitated dialogue to identify common ground. Data will be analysed quantitatively for ranking, and qualitatively through thematic analysis of open-ended responses, to ensure all nuances of bias and impact are captured.

Output:

The final output will be a report detailing the following: o A list of up to 20 medical devices where bias is most significant, categorised by clinical impact, patient experience, and strength of evidence.