Pregnant women's appetite for risk

Historically, pregnant and lactating women have been considered vulnerable groups, which is used as an ongoing justification for their exclusion from clinical trials. Melanie Taylor and colleagues (February, 2021)[1] argue that pregnant women, who already face increased risk of adverse outcomes from COVID-19, will be doubly disadvantaged if unable to access treatments due to a lack of safety and efficacy evidence. This concern extends to vaccinations, and a review of WHO-registered COVID-19 clinical trials found that all nine vaccine trials explicitly excluded pregnant women.[2]

In the UK, both pregnant and lactating women were initially excluded from receiving COVID-19 vaccines. A policy U-turn followed a month later and, although welcome, it confused clinicians and the public. Anecdotal evidence is emerging of pregnant women in the UK and the USA who are willing to be vaccinated.[3] These decisions could be influenced by an individual's personal risk assessment of high exposure to COVID-19, their underlying health conditions, or because they perceive that known benefits of vaccination outweigh theoretical risks. If the aim of excluding pregnant and lactating women from trials is to protect them and their babies from unknown harm, this is failing. Experimentation has merely shifted to the poorly controlled setting of real-world implementation.

In this real-world setting, a pertinent question is who should carry the experimentation risk? It is unclear whether responsibility lies with the pharmaceutical industry, which has historically avoided ownership of the problem. If not, risk lies between regulators or public health bodies producing immunisation guidelines, medical practitioners who must discuss risk–benefit decisions with patients (without data to inform this discussion), and pregnant women themselves. This risk shifting could lead to further inequities, variation in care, and vaccine misconceptions.

To facilitate ethical and just inclusion of pregnant women in clinical trials,[4] we support the 22 recommendations made by the PREVENT Working Group,[5] and propose a further two after observing the UK's COVID-19 vaccine rollout: (1) pregnant and lactating women must be considered separately (as in the recent WHO guideline), and receive tailored risk assessments and recommendations; and (2) women, families, and communities globally must be consulted about specific safeguards that would increase their ability and willingness to participate in clinical trials while pregnant or lactating.

The research community maintains a complacent and unsubstantiated assumption that pregnant women have a low appetite for risk. The COVID-19 pandemic has shown that default exclusion cannot continue, and we as a global research community must prioritise gender equity when producing evidence that underpins clinical recommendations.

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**Amy Vassallo, Kate Womersley, Robyn Norton, Meru Sheel*
avassallo@georgeinstitute.org.au

The George Institute for Global Health, University of New South Wales, Sydney, NSW 2042, Australia (AV, RN); NHS Lothian, Edinburgh, UK (KW); The George Institute for Global Health UK, Translation and Innovation Hub, Imperial College London, London, UK (KW, RN); National Centre for Epidemiology and Population Health, Research School of Population Health, ANU College of Health and Medicine, The Australian National University, Acton, Canberra, ACT, Australia

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