Clinical Trials in Global Health 3

Advancing maternal and perinatal health through clinical trials: key insights from a WHO global consultation

Teesta Dey, Mariana Widmer, Arri Coomarasamy, Shivaprasad S Goudar, Mabel Berrueta, Estela Coutinho, Myriam El Gaaloul, Ruth R Faden, A Metin Gülmezoglu, G Justus Hofmeyr, Marian Knight, Smaragda Lamprianou, Anna C Mastroianni, Flor M Munoz, Olufemi T Oladapo, Martina Penazzato, Françoise Renaud, Claire L Townsend, Mercedes Bonet

Pregnant and lactating women have long been excluded from participation in clinical research. This exclusion has resulted in the absence of high-quality evidence on the effectiveness and safety of medical products (medicines, vaccines, and other biological or biomedical products) during pregnancy and lactation, and fragmented health policies and practice recommendations. Based on the discussions at the inaugural WHO Global Clinical Trials Forum in November, 2023, a rapid review of key global, regional, or national ethical and regulatory documents, and previous expert consultations, this paper aims to summarise obstacles and suggest opportunities for appropriate inclusion of pregnant and lactating women in clinical trials. The main challenges identified relate to issues of: trial design; inconsistent interpretation and implementation of ethical, regulatory, and legal guidance; high costs of trials and low return on investments; insufficient research capacity and funding opportunities; misinformation; and insufficient community engagement. Appropriate inclusion is necessary and possible through: multi-stakeholder coordination; alignment with governance bodies to streamline ethical, regulatory, and legal processes for trial conduct; advocacy to prioritise investments in research; stronger focus on capacity strengthening; and good participatory practice that includes women and communities. A paradigm shift towards more inclusive and integrated research methodologies is urgently needed. This shift extends beyond pregnancy to transform the overall trial ecosystem and prioritise the health and wellbeing of all women and their infants everywhere, to truly achieve equitable access to health and innovations and leave no one behind.

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UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, Department of Sexual and Reproductive Health and Research, WHO, Geneva, Switzerland (T Dey PhD, M Widmer MSc, O T Oladapo MD, M Bonet PhD); **Institute of Metabolism and Systems Research, University of Birmingham, Birmingham, UK** (A Coomarasamy MD); **Women's and Children's Health Research Unit, KLE Academy of Higher Education and Research** (S S Goudar MD); **Jawaharlal Nehru Medical College, Belgaum, Karnataka, India** (S S Goudar); **Institute for Clinical Effectiveness and Health Policy, Buenos Aires, Argentina** (M Berrueta MD); **European Foundation for the Care of Newborn Infants, Munich, Germany** (E Coutinho MSc); **Medicines for Malaria Venture, Geneva, Switzerland** (M El Gaaloul PharmD); **Johns Hopkins Berman Institute of Bioethics, Johns Hopkins University, Baltimore, MD, USA** (R R Faden PhD, A C Mastroianni JD); **Concept Foundation, Geneva, Switzerland** (Prof A M Gülmezoglu PhD); **Department of Obstetrics and Gynaecology, University of Botswana, Gaborone, Botswana** (G Justus Hofmeyr MD); **Effective Care Research Unit, University of the Witwatersrand, Johannesburg, South Africa** (G Justus Hofmeyr); **Department of Obstetrics and**

Introduction

Globally, the annual number of pregnancies has increased to 250·4 million according to the latest estimates.[1] Yet, progress made to reduce maternal and perinatal deaths has stagnated in the last decade,[2–4] and mortality and life-threatening complications remain unacceptably high.[2,5]

Pregnancy-specific complications, such as haemorrhage, hypertensive disorders of pregnancy, and maternal sepsis, account for most of the maternal deaths and near misses of maternal deaths.[5,6] These conditions can be prevented and treated with quality maternity care and quality-assured medical products. Women might also need medical products to manage common conditions during or after pregnancy, such as anaemia, hyperemesis, reflux, pain,[7–9] or other conditions not specific to pregnancy, including non-communicable diseases and non-obstetric infections. Moreover, the use of medical products during pregnancy and lactation might reduce the risk of adverse perinatal outcomes (eg, related to preterm birth[10] or infectious diseases).[7,11,12]

Little attention has been paid to the historical under-representation of pregnant and lactating women in clinical research and development of medical products. Indeed, research and development (R&D) efforts for pregnancy-specific conditions have been slow, resulting in only two new drugs being developed in the past 30 years.[13] Pregnant women are also often excluded from research on non-pregnancy-specific conditions, even in the context of health emergencies.[14–16] This practice restricts the collection of evidence on the effectiveness and safety of medical products for use during pregnancy and lactation. Furthermore, trials tend to focus on short-term outcomes, neglecting the broader effect of pregnancy on women's health throughout their life course, including future fertility, future pregnancies,

Key messages

- Pregnant and lactating women are often under-represented in clinical trials, which leads to insufficient data on the safety and effects of medical products (medicines, vaccines, and other biological or biomedical products). This under-representation contributes to fragmented maternal health policies and practice, as well as exacerbating gender, social, and geographical inequalities.
- Key challenges preventing the inclusion of pregnant and lactating women in clinical trials include trial design issues, varying interpretations of ethical and regulatory guidance, financial constraints, inadequate research capacity, and community participation.
- A global shift towards more inclusive research is paramount to achieve better and equitable maternal and perinatal health outcomes. This change requires a coordinated, multi-stakeholder approach to streamline ethical and regulatory processes, boost investments, enhance research capacity, and foster community engagement.

Gynaecology, Walter Sisulu University, East London, South Africa (G Justus Hofmeyr); **National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, Oxford, UK** (M Knight DPhil); **Department of Pediatrics**(F M Munoz MD) **and Department of Molecular Virology and Microbiology, Baylor College of Medicine, Houston, TX, USA** (F M Munoz MD); **Pharmacovigilance Team, Regulation and Prequalification Department, Access to Medicines and Health Products Division, WHO, Geneva, Switzerland** (S Lamprianou PhD); **Research for Health Department, Science Division, WHO, Geneva, Switzerland** (M Penazzato MD); **Department of Global HIV, Hepatitis and STI Programmes, WHO, Geneva, Switzerland** (F Renaud PharmD, C L Townsend PhD)

Correspondence to: Dr Teesta Dey, UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, Department of Sexual and Reproductive Health and Research, WHO, Geneva CH-1211, Switzerland **deyt@who.int**

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morbidity, and long-term effects on the child's health and development.[17,18]

The absence of high-quality evidence and understanding on potential benefits and harms of medical products for women and their offspring often results in fragmented health policies and care recommendations. Most approved drugs do not have safety information on use during pregnancy. Moreover, product information for patients is often overly conservative when presenting potential risks and benefits.[19,20] All of these factors place the burden on the health provider and the woman to judge the risks and benefits of taking drugs and therapies with minimal or non-specific information for decision making.[20] Consequently, pregnant and lactating women might receive suboptimal management options, resort to the use of medications off-licence, or use medicines without any evidence of efficacy and safety during pregnancy and lactation.[13,17,20] Ultimately, the absence of evidence not only compromises efforts to implement, scale up, and sustain effective and safe interventions to improve maternal and perinatal outcomes, but also exacerbates gender, social, and geographical inequalities affecting women's health and wellbeing.[13,17,18]

Based on discussions initiated at the WHO Global Clinical Trials Forum in 2023, this paper describes development and obstacles related to the appropriate inclusion of pregnant and lactating women in clinical trials for medical product development. The paper also provides possible solutions towards a more equitable global clinical trial ecosystem for improving maternal and perinatal health.

Summary of evidence and expert consultations

From Nov 20 to Nov 21, 2023, WHO held the first WHO Global Clinical Trials Forum, bringing together a diverse clinical, academic, and policy community to advance sustainable global clinical trial infrastructure.[21] Meeting participants discussed the improvements needed for strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination, as mandated by the World Health Assembly Resolution WHA75·8 adopted in May, 2022.[22] The consultation focused on how to transform clinical trial practices by promoting interconnectedness and equity and standardise the inclusion of under-represented populations including pregnant and lactating women as well as children,[23] among others, to advance their health outcomes and wellbeing.

Within the broader meeting, WHO convened a working group on pregnant and lactating women to identify challenges and formulate solutions for the appropriate inclusion of these populations in clinical trials. An initial list of obstacles and solutions was developed and emerging common themes were identified by consensus. Outputs of this initial discussion were presented at the WHO forum and further refined by the authors after the forum. These discussions complement broader consultations to shape the upcoming WHO guidance for best practices for clinical trials.

To inform discussions of the working group, a rapid review of documents related to the inclusion of pregnant and lactating women in clinical trials was completed (appendix pp 1–6), including: a review of global ethics and good clinical practice documents; a review of documents from national and regional regulatory authorities; and a targeted search of publicly available reports and meeting proceedings from international, regional, and national expert groups and organisations, on any aspect of trial development and conduct. The review focused on documents published between January, 2000, and April, 2024, to capture contemporary perspectives on the issue. Although disease-specific documents were considered (eg, on epidemics, pandemics, and HIV), the emphasis was placed on broader support for enhancing clinical trial participation across various health conditions during pregnancy and lactation. The identification of relevant documents was enriched through expert outreach and screening of references. Successful initiatives providing resources for accelerating research in pregnant and breastfeeding women are described herein.

Clinical trials were defined as health intervention studies involving human participants who were pregnant or lactating. We set the scope to any stage of R&D of new medical products (medicines, vaccines, and other biological or biomedical products) or the investigation of pre-existing products for use in pregnancy or during lactation. We also acknowledged the broader spectrum of design, health intervention, purpose, and setting that could be assessed in clinical trials. The interventions could address pregnancy-specific conditions, conditions not resulting from pregnancy but affecting pregnant and lactating women, and conditions affecting the offspring (embryo, fetus, or infant). The working group recognised that pregnancy and lactation periods are intimately linked but also noted distinctions in conducting clinical research during these periods, for example in study designs, ethical and legal considerations on bodily autonomy, and additional paediatric requirements. Although it is important to consider the individual needs of the pregnant and lactating populations, this paper will focus on the shared obstacles and solutions that affect both. In this paper, the term pregnant women describes pregnant and recently pregnant women and adolescent girls (ie, postpartum [whether breastfeeding or not] or individuals who had an abortion or miscarriage). The term lactating women refers to individuals who are breastfeeding regardless of the age of their child. These terms are inclusive of people who have the capacity to become pregnant or breastfeed but identify as gender-diverse individuals.

Major obstacles to clinical trials during pregnancy and lactation

Challenges in the design of trials

Designing trials that include pregnant and lactating populations requires attention to unique considerations (figure). During pregnancy and lactation, the health and wellbeing of the mother and baby are inextricably linked, with interventions for one possibly affecting the other. Examining the possible benefits and harms to the mother–baby dyad is a complex process, often resulting in the invocation of the precautionary principle.[24,25] This principle leads to excessive caution to the risk of teratogeneity and maternal and fetal toxicity (risk sensitivity), at the expense of appropriately valuing the possible short-term and long-term benefits of an intervention to both the woman and the baby (benefit insensitivity). For the baby, it is crucial to consider the benefits of treatments alongside any possible risks of teratogenicity, toxicity, or severe or irreversible effects on long-term infant development. In relation to pregnancy, it is important to evaluate risks specific to gestational age, postpartum period, and lactation. Risk assessments also often do not consider the risks of not participating in a study or withholding the product from populations who could benefit from it. In this sense, risk assessments might be flawed if the assessments overlook the potential maternal benefit of the intervention and subsequent risks to the baby arising from an untreated maternal condition. Moreover, the need to consider distinct primary outcomes for both the woman and the baby could have implications for power and sample size calculations, frequency and duration of follow-up, and data collection (linkage of mother and infant, sources, and ascertainment).

Excluding or showing a causal association between a given medical product and teratogenic or toxicity effects is often very difficult if not impossible, due to factors such as delay between exposure and outcomes[20,26] and the infrequency of events, resulting in large number of observations needed to draw any meaningful conclusions. Long-term follow-up of the mother and baby might be required, which might not be possible for logistical and financial reasons, including loss of participants, insufficient financial incentive, and time limitation of the study. Thus, long-term follow-up might often be undertaken through safety surveillance during pregnancy, postpartum, and lactation once the medical product has been approved for the general population.[27,28] However, safety surveillance has its limitations, including the limited use of standardised definitions and outcomes, data collection based on unsystematic processes relying on caregiver or self-report only, poor harmonisation of surveillance approaches across countries to enable data comparison, and no integration with routine medical datasets to identify safety signals.[17,20,29]

In addition, pregnancy is not a static state, and the research must account for physiological changes and obstetric specific events that occur during and after this period. In trials, selecting the optimal dose and regimen can be challenging, especially when pharmacokinetics and pharmacodynamics of drugs during pregnancy are under-researched, and when the target for the intervention could be the mother, infant, or both.[29,30]

Ethical, regulatory, and legal challenges

Global ethical and good practice guidance supports different aspects of appropriate clinical trial inclusion and retention of women who are or might become pregnant, or who are breastfeeding (appendix p 3). This guidance includes guidelines from the Council for International Organizations of Medical Sciences, good clinical practice guidance from WHO, and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use including on type and timing of non-clinical safety and toxicology studies.[31–35]

A key issue is the variable understanding and the inconsistent interpretation and implementation of ethics and good practice guidance across settings, where calls to action for inclusive trials seem no longer sufficient.[36–38] Ethics committees are often seen as too conservative, applying diverse assessments of what constitutes

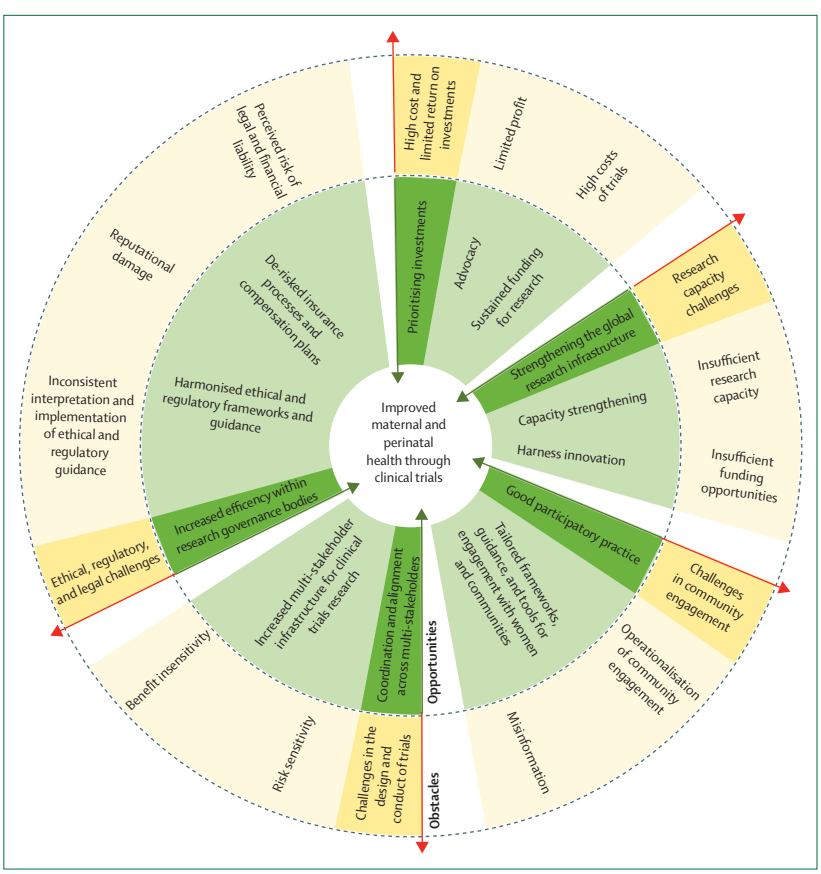

Figure: **Major obstacles to clinical trials during pregnancy and lactation and key opportunities to accelerate generation of high-quality evidence for improved maternal and perinatal health**

minimal risk or minimal evidence required for risk evaluation. Sometimes the diversity in their assessments is dependent on their experience and expertise.[18,39] In some contexts, such as during epidemics, the challenges to inclusion of pregnant women in clinical trials are further exacerbated despite existing guidance and evidence on increased adverse pregnancy outcomes.[16,40,41]

Some regulatory agencies in high-income countries have long promoted the importance of research involving pregnant and lactating women (appendix p 4);[42–49] their guidance addresses the conduct and requirements for preclinical studies, labelling, and post-authorisation safety surveillance. However, regulatory oversight and approval complexities can inhibit industry's interest to bring maternal medical products into the market.[26,39] Research governance and approval processes are often unclear and ever-changing, sometimes with little coordination or alignment across settings. Navigating these processes is complex due to increasing bureacracy, delays and costs. Additionally there can be significant demoralisation related to obtaining timely approval. All these factors mentioned could possibly delay or deter the initiation of essential research.[19,50]

Including pregnant and lactating women in clinical trials has an increased perceived risk of legal and financial liability and reputational damage.[17,26,51,52] Perception of liability is rooted in a poor understanding of risks, absence of expertise in maternal health research, challenges with participant recruitment, costs, and societal significance of preventing foetal harm.[51] Perceived liability risk leads to extended negotiation processes to reach costly insurance coverage agreements for clinical trials that include pregnant women. A 2024 survey[51] of reported legal cases in the USA found little if any evidence of liability resulting from clinical trials involving pregnant or lactating participants. The survey did, however, identify substantial evidence of liability arising from post-authorisation product use by pregnant women and little evidence of liability in case of use by lactating women, which could likely be mitigated through inclusive and well designed clinical trials.

Cost and little return on investments

Market dynamics play a major role in prioritising research and development efforts.[19,26,39] Medical products intended solely for pregnant and lactating women tend to have a small market and bring low profits for manufacturers. Pregnancy is a self-limiting period with a narrow time window for use of any medical product. Additionally, the highest burden of maternal mortality and morbidity is in low-income and middle-income countries (LMICs), where high development costs, initial prices of new medicines on the market, and poor existing infrastructure for delivery, might limit access to the medical products, despite their necessity. Therefore, the return on investment in either developing a new medical product or investigating the safety of existing products in pregnancy or lactation might not be sufficiently high to incentivise research sponsors to enter the market or sustain production levels.[53] Profit expectations are also lower during the development of new medical products for pregnancy-specific conditions compared with testing pre-existing drugs in pregnancy. For example, magnesium sulphate, used to prevent and treat eclampsia, is rarely globally manufactured because its low cost leaves little profit-based incentive for pharmaceutical companies to produce it.[53] Medical products approved for use in adults are often used off-licence in pregnant and lactating women (eg, misoprostol),[13] without industry and sponsors needing to conduct any additional research.

Conducting clinical trials involving pregnant and lactating women can also be inherently expensive. Such trials might bear additional costs due to the need for robust evidence to address concerns surrounding unlikely teratogenicity and toxicity risks, additional indemnity costs during product development, and extended timelines to ensure short-term and long-term follow-up of safety outcomes of the mother–baby dyad.[17,26,39]

Research capacity challenges

Capacity to conduct research involving pregnant and lactating women is low. Although some maternal health research infrastructures exist, few have the capacity to conduct high-quality clinical trials in LMICs.[16] Large trial infrastructures not specialised in maternal health might not have the expertise to include or access pregnant or lactating participants. Low investment in maternal health research hampers the capacity to conduct clinical trials.[17,26] Institutional review boards might not have experience dealing with ethical issues related to research in pregnant and lactating individuals, as they might not routinely include these groups, possibly overlooking the need for justifications regarding exclusion, or failing to consider the benefits to pregnant women and risks of not conducting the research.[18,50]

Funding opportunities necessary to generate data concerning pregnant women are scarce.[54,55] As of February, 2023, less than 1% of biomedical research grants were provided for maternal conditions.[56] Maternal health research funding comes mainly from donors, national research agencies, and private non-governmental organisations, with little direct funding from industry for R&D on new products.[26]

Challenges in community engagement with research

More awareness and community mobilisation on issues related to R&D and use of medical products during pregnancy and lactation are needed.[17,20,55] Engagement of women, families, and communities is particularly important and has gained traction. However, operationalising participant and community involvement in co-design, co-implementation, and co-dissemination of clinical research has several challenges. Pregnant and

postpartum women are often not viewed as patients, and are therefore not always aware of opportunities to be involved in health and medical research. Within communities, there is misinformation surrounding the inclusion of pregnant and lactating women in clinical trials.[17,18,20] Although some women seem to be open to and supportive of participating in clinical trials, many will be more reluctant due to the absence of agency in decision making, social or cultural norms, or concerns of potential harm to their offspring.[57]

Key opportunities to accelerate generation of high-quality evidence for improved maternal and perinatal health

Coordination and alignment across stakeholders

Cross-sector coordination, collaboration, and knowledge sharing between key stakeholders, such as researchers, health workers, regulators, industry, ethicists, insurers, funders, women, and communities, to harness each stakeholder's skill set and mandate is paramount.[17,20,26,51,52,58] Creating partnership structures and harmonising practices, processes, and pathways for clinical trials and regulatory approvals in pregnancy and lactation at both national and global levels is crucial. This strategy must promote innovative approaches for engagement across all phases of product development, from preclinical studies to post-marketing surveillance. Furthermore, partnerships should ensure equitable post-trial access to safe and effective medical products. For instance, a private–public collaboration between industry and WHO facilitated advancements in enabling access to heat-stable carbetocin for prevention of postpartum haemorrhage for the public sector in LMICs at an affordable price.[59] New efforts to galvanise maternal health R&D through partnerships should build on existing successful cross-sector collaborations, including public–private partnerships in maternal health[26,27] as well as from other disease areas, such as infectious diseases[36,60] and paediatric medicines.[23]

Increased efficiency within governance research bodies

There is an urgent need to change approaches and the presumption of exclusion to one of inclusion of pregnant women in clinical trials. Such strategies could provide guidance for conducting safety reviews, interpretation of non-clinical developmental and reproductive toxicology models, and provision of documentation on the rationale for excluding pregnant women to prevent inappropriate exclusion or discontinuation in trials.[17,18,20,38,46] These guidance documents could also cover appropriate informed consent and requirements for extension of follow-up for women who become pregnant during a trial.

Guidance and tools are needed to support protocol development and review processes that foster the inclusion of pregnant and lactating participants in trials and ensure appropriate assessments of benefits and risks for the mother–baby dyad, including the risks of inaction.[18,20,39,58] For example, the Antiretrovirals in pregnancy research toolkit provides access to guidance, study materials, and standardised endpoint definitions to facilitate the inclusion of pregnant and lactating women in trials of interventions for HIV, sexually transmitted infections, and hepatitis.[61]

Regulatory agencies should provide clear, harmonised guidance on licensing requirements for market authorisation. Regulatory authorities in high-income countries have already developed a shared vision and proposed solutions to ensure access to safe medicines during pregnancy and breastfeeding.[62,63] The upcoming International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guidance is expected to establish a globally accepted framework and best practices to enable the inclusion and retention of pregnant and breastfeeding individuals in clinical trials.[64]

Other frameworks, such as population-specific investigation plans, could be applied to maternal health to ensure the necessary data are collected for regulatory purposes.[13,17,65,66] These data could be required to be available for pregnant and lactating women at the time of the first registration of a new product. Mechanisms should also be developed to gather emerging safety information on existing medicines and to update product information on safety, dosing, and effectiveness.[17] This initiative would require functional and innovative post-marketing surveillance systems, including active surveillance and integration with routine health information systems.[20] Another way would be to leverage existing systems for routine surveillance of maternal and perinatal outcomes to support safety surveillance of maternal vaccines and drugs.

Appropriate medico-legal approaches, reduced-risk insurance processes, and compensation plans would be needed to address possible financial, legal, and reputational concerns that come with researching the mother–baby dyad. Diverse co-insurance, pooled insurance schemes, and compensation systems used in other areas of health care to distribute and reduce insurance costs, mainly between industry, research sponsors, and governments could be considered.[13,17,18,26,39,51,52] Collaboration with insurance and legal agencies is crucial to develop insurance pathways tailored to protect participants and empower their inclusion in research.[17,26] For example, one suggested solution is the government-funded research grants that would cover the costs of purchasing clinical trial insurance.[51] As more and better quality data are generated, risk assessment is expected to become better informed, which will reduce uncertainty and insurance costs.

Prioritising investments in maternal health

The low and inconsistent funding for research involving pregnant and lactating women is concerning especially

on the backdrop of stagnating progress on maternal morbidity and mortality. Funders have an opportunity to increase efficiency, coordinate investments, contribute to capacity for health research, and prioritise focus on poorly served areas such as maternal health. Indeed, some governments and funders have lately committed to advancing investment in maternal health and women's health research more broadly.

In a context of restricted resources, it is essential to optimise the use of funds available. Success includes building consensus on research priorities, fostering collaboration between funders, sharing information on past and future investments, establishing accountability mechanisms to monitor spending against investment targets, and curating a portfolio of prioritised projects alongside mechanisms to link funders to these projects.[67] For example, product target profiles have been developed to guide development of new medical products for prevention and treatment of pre-eclampsia and preterm birth, and preferred product characteristics for respiratory syncytial virus and group B streptococcus maternal vaccines. An up-to-date review of the maternal health R&D pipeline would also inform research funding.[13] Funders might need to also target new investments, including early preclinical and pharmacokinetics and pharmacodynamics studies, clinical trials of adequate size to assess the safety in pregnancy, and active post-marketing surveillance of safety in pregnancy.[38]

Coordinated multi-stakeholder and cross-sector advocacy, communication, and risk management campaigns are necessary to mobilise support, dispel misconceptions, and improve access to information on the benefits of including pregnant and lactating women in trials for health-care providers, women, and their communities.[19,26,58] Strong advocacy for the prioritisation of maternal health is needed to stimulate resources and secure sustained funding and prioritisation from donors, research councils, and industries.[13,26] In addition to targeting policy makers and funding agencies, advocacy campaigns should focus on empowering women and communities to advocate for their own health needs and rights. Establishing a global network of champions for this issue would be necessary to elevate the importance of inclusion of pregnant and lactating women in research studies and raise global awareness about challenges and potential solutions through key messages and events.

Strengthening the global research infrastructure

Strengthening the global infrastructure for research in pregnancy and lactation should focus on enhancing the overall capacity to conduct research in pregnancy and lactation within the broader trial ecosystem, particularly in LMICs, for improved maternal and perinatal health outcomes. Large international clinical trials networks can provide the required infrastructure and maximise the inclusion of under-represented populations.[21] This global research infrastructure could be achieved by continuously strengthening and capacitating a maternal health global research network with well functioning global hubs and sentinel or regional sites. Examples of such initiatives in LMICs include the International Maternal Pediatric Adolescent AIDS Clinical Trials Network[38] and The Global Network for Women's and Children's Health Research.[68] Any training developed to implement guidance on improved design of clinical trials should include specific considerations for inclusion of pregnant and lactating women.

Innovative methods offer the possibility for better assessment of the safety and efficacy of interventions in both pregnant women and their offspring. These strategies include new methods for assessing foetal wellbeing and placental function, predicting potential effect of anatomical and physiological changes during pregnancy on a medicine's pharmacokinetics, and accelerated timelines of preclinical studies.[29,30,65,69] Capacity building should also ensure that innovative research methodologies can be applied to diverse types of studies, including developmental and reproductive toxicology models, placenta studies, lactation studies, genetic technologies, pharmacokinetic modelling, artificial intelligence and computer simulations, parallel or adaptive trials, as well as leveraging existing clinical and health information systems and real-world evidence.

Good participatory practice

Good participatory practice is fundamental for effective engagement of stakeholders, including patients and their communities.[70] Stakeholder sensitisation to emphasise the benefits of appropriate participation in research is key to combat misinformation. Strategies should aim to build community literacy on the inclusion of pregnant and lactating women in trials.[50,57] Providing clear, reliable, and easily understandable information can help alleviate concerns and encourage informed participation in research. Engagement with patient advocates can bring additional perspectives and play a crucial role in mitigating challenges related to benefit insensitivity. Tailored practice guidance, considering cultural norms and accessibility barriers for community engagement and research, along with defined roles for patient and advocacy groups in the process is key. Meaningful engagement should also facilitate development of trusted, evidence-based sources of information on effects and safety of use of medical products for pregnant women and health workers.[17]

Conclusions

It is imperative to expedite progress for appropriate inclusion of the needs and interests of pregnant and lactating women in clinical trials and the research enterprise, generally. A shift in paradigm towards more inclusive research methodologies is essential to ensure that clinical trial findings apply to a broader demographic, thereby enhancing public health interventions'

effectiveness and safety. This shift extends beyond trials to transform the overall ecosystem and prioritise the health and wellbeing of pregnant and lactating women ensuring access to effective, safe, and quality-assured medical products. Setting the foundations for a more equitable clinical trial ecosystem that considers the needs of women, during and beyond pregnancy, is paramount to truly achieve equitable access to health care and innovations and leave no one behind.

Contributors

MBo, TD, and MW conceptualised the study. AC, SSG, MBe, MEG, RRF, AMG, GJH, MK, ACM, FMM, and MP were members of the WHO convened working group on pregnancy and lactating for the WHO Global Clinical Trials Forum. TD prepared the first draft of the paper. All authors participated in the development of the study, writing, and approved the final version of the paper. All authors had access to all the data in the study and had final responsibility for the decision to submit for publication. MBo, TD, and MW have accessed and verified the data.

Declaration of interests

EC has received payments for expert testimonies from European Foundation for the Care of Newborn Infants (EFCNI) and University of Edinburgh; support for attending meetings and travel from EFCNI; and is a member of the Parent & Patient Advisory Board of EFCNI. AMG is the Executive Director of Concept Foundation; has received a grant from Bill & Melinda Gates Foundation entitled Accelerating Innovation for Mothers, coordinating a range of activities including maternal health products pipeline analyses and developing target product profiles. GJH has received royalties from Maternova. MK is a member of the WHO Technical Advisory Group on Development of Guidance on Best Practices for Clinical Trials. ACM has received grants awarded to Johns Hopkins University from the US National Institute of Health (NIH) and Wellcome Trust; and support for travel from The National Academies of Sciences, Engineering, and Medicine, and WHO. FMM has received grants awarded to Baylor College University from NIH and US Center for Disease Control and Prevention for COVID-19 vaccines and respiratory viruses in pregnant women and children, and from Pfizer and Gilead for COVID-19 research projects in children; is a member of Moderna's Vaccine and Pfizer's and Meissa's (respiratory syncytial virus vaccines) Data Safety Monitoring Boards; and has received consulting fees from Sanofi, AstraZeneca, Merck, and GSK. All other authors declare no competing interests.

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