

Inclusion and participation of pregnant and breastfeeding women and people in non-obstetric clinical trials: a rapid scoping review

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Abstract

Background

Pregnant and breastfeeding women and people are often excluded from non-obstetric clinical trials. Exclusion sometimes provides immediate protection. It also causes subsequent population-level harms. The importance of inclusion is widely recognised. However, the rates of inclusion and participation are uncertain, as are the contexts in which pregnant and breastfeeding women and people might choose to take part, and factors which influence inclusion and participation. This rapid scoping review identifies and maps the evidence to fill these gaps.

Methods

We included research using any study design, published in English between January 2006 and July 2025, where the participants included women and people with experience of pregnancy or breastfeeding, or health care professionals or researchers working with them. We searched

MEDLINE, Embase, CINAHL, Google Scholar and Overton, selected websites and references. The most recent search was done on 3 July 2025. We embedded a Study Within A Review.

Results

We included 54 studies, most focused on the prevention or treatment of infectious diseases.

Thirteen studies assessed the proportion of trials which included pregnant women and people; this ranged from 0-8%. Three studies assessed the proportion of trials in which breastfeeding women are included; from 0.5-14%. Data on participation are sparse. 7-90% of participants in five studies considered themselves likely to participate in a non-obstetric clinical trial during pregnancy. Based on six studies we identified and developed four main themes relating to opinions and feelings about inclusion and participation; risk, evidence, culture and trust. We identified and developed six themes grouping factors that affect inclusion and participation from 25 included studies; need for research, fair inclusion, risk, early inclusion, financial concerns, and practical issues.

Conclusions

Addressing factors that influence inclusion in clinical trials is essential to support pregnant and breastfeeding women and people's access to evidence-based healthcare and to improve maternal and infant health outcomes.

Registration

<https://osf.io/4am6b/>

Keywords

Inclusion, participation, pregnancy, breastfeeding, clinical trials, public health, women's health, maternal health

Introduction

Rationale

Pregnant and breastfeeding women and people are often excluded from non-obstetric clinical trials (1). Exclusion from clinical trials sometimes provides immediate protection to pregnant and breastfeeding people, and their fetuses and babies. However, it also causes subsequent population-level harms, including deaths, for women and babies by creating an evidence gap in healthcare (2, 3). In the absence of inclusive evidence healthcare professionals sometimes withhold or withdraw likely safe and effective interventions (4, 5). In addition, pregnant and breastfeeding women and people sometimes refuse safe and effective treatment and healthcare professionals may prescribe interventions that cause harm (6-9).

The importance of inclusion is recognised by the World Health Organization (WHO), The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the World Medical Association, and our colleagues working in global health, many of whom have already made significant progress to improve women's health through inclusion in research (10-14). However, there is a perception among many researchers that pregnant women and people are unlikely to choose to participate in clinical trials (15). There are diverse factors across multiple levels and stakeholders affecting the inclusion and participation of pregnant and breastfeeding women and people in clinical trials (16, 17).

However, we do not know with precision, or across different contexts, the rates of inclusion and participation of pregnant people in non-obstetric clinical trials. We lack evidence on the contexts in which pregnant people might choose, or decline, to take part in non-obstetric clinical trials. We do not know which factors influence their inclusion (whether or not they have the choice to take part) and participation (what they choose). Globally-relevant, up-to-date and comprehensive evidence to provide this knowledge will enable the development of solutions to increase inclusion of, and choice about participation for, pregnant people in non-obstetric clinical trials. Increased inclusion and

participation in research will enable well-informed and clear messaging about potential benefits and harms of interventions; leading to improved health outcomes for pregnant and breastfeeding women and their babies (4).

This rapid scoping review aims to efficiently and systematically identify and map the available evidence to fill this gap. The findings will inform a subsequent programme of research to increase the inclusion of, and choice about participation for, pregnant and breastfeeding women and people in non-obstetric clinical trials.

Objectives

1. To identify the extent to which pregnant and breastfeeding women and people are included in, and/or participate in non-obstetric clinical trials.
2. To identify whether women and people with experience of pregnancy and breastfeeding, health care professionals and researchers believe pregnant and breastfeeding women and people should be offered the opportunity to choose whether to participate in non-obstetric clinical trials, or would choose to participate.
3. To identify factors influencing inclusion and participation of pregnant and breastfeeding women and people in non-obstetric clinical trials.

Patient and Public Involvement

We based the objectives of the review, in part, on questions raised by ongoing conversations with our Patient and Public Involvement (PPI) contributors. They advised us on our use of language relating to sex and gender, bearing in mind that not all pregnant women (sex) identify as women (gender), while some women prefer to be called women. We have described other researchers' participants and patients using the language those researchers used. We have ourselves used additive inclusive language to include women and people of different genders in our research, as well as acknowledge the impact of misogyny and sexism on women's health.

Methods

This review was conducted in accordance with the JBI methodology for scoping reviews, and reported following the PRISMA-ScR reporting guideline (18, 19).

Protocol and registration

The protocol for this review is registered at <https://osf.io/4am6b/> (20).

Framework for eligibility criteria

We used the Population, Concept, Context framework to construct our eligibility criteria.

Population

Women and people who are pregnant or breastfeeding, or have experience of pregnancy or breastfeeding, health care professionals who support women and people during pregnancy and breastfeeding, and researchers

Concept

Inclusion and/or participation in clinical trials

Context

All settings relevant to non-obstetric clinical trials

Eligibility Criteria

This review included published research and grey literature describing research using any study design, published from 1st January 2006 to 3rd July 2025, in English language. We selected rapid methods that were unlikely to lead to bias (21).

Inclusion criteria were that the research considered:

- pregnant or breastfeeding women and people
- in relation to their inclusion or participation in non-obstetric clinical trials

Exclusion criteria were:

- publications that did not describe research but presented opinion, commentary or discussion
- research relating only to inclusion in healthcare (rather than research)
- where pregnancy and breastfeeding were not primary factors relating to inclusion or participation in clinical trials

Information sources

We first carried out the searches from inception to 3rd October 2024, of Medline (OvidSP), Embase (OvidSP), CINAHL (EBSCOHost), Overton (<https://www.overton.io/>) and Google Scholar (<https://scholar.google.com/>). We used Google to search within websites of the UK Government, National Health Service (NHS), National Institute for Health and Care Research (NIHR), UK Research and Innovation (UKRI), Wellcome Trust, World Health Organization (WHO), European Medicines Agency (EMA), and Food and Drug Administration (FDA) on 21st October 2024. We updated the searches on 3 July 2025. We checked the references of relevant systematic reviews that were captured by this review.

Search

We searched the title, abstract, author keywords and subject headings for our key concepts of pregnancy and trial participation. We limited the search to 2006 onwards and English language. We exported the results to Endnote and excluded any pre-2006 publications. We exported the remaining references to Covidence for deduplication and screening. The full electronic search strategy is available at <https://osf.io/mpc5n>.

Selection of sources of evidence

Two independent reviewers carried out screening. They resolved disagreements through discussion or by involving a third reviewer.

Data Extraction

One reviewer extracted data and another independently verified this. They resolved disagreements through discussion or by involving a third reviewer. We created and pilot-tested a data extraction tool in Covidence.

We sought data on:

- study design
- research aims and objectives
- research methods
- participant characteristics
- dates, geographical locations and clinical settings of studies
- type of clinical trials
- number of trials including or excluding pregnant and breastfeeding women and people
- opinions of women and people with experience of pregnancy or breastfeeding, women, health care professionals, researchers, and the wider community
- factors influencing inclusion and participation

Analysis

Using publicly-available information about the studies, we adapted methods to assess and graph potential multiple-counting of trials including pregnant and breastfeeding women and people (22).

For objectives 1-2 we carried out a basic descriptive tabulation and analysis of the quantitative and qualitative data.

For objective 3 we undertook a basic qualitative content analysis using an inductive process of open coding to allocate factors influencing inclusion and participation to concepts (23, 24).

Study Within a Review (SWAR)

SWARs are a research method to test ways to improve systematic reviews and evidence syntheses, often embedded within a larger review. We embedded SWAR08 “Finding eligible studies efficiently” in this review (25, 26). To our knowledge this SWAR has been conducted once before (27). We tabulated the number of search results, eligible studies and sources of eligible studies.

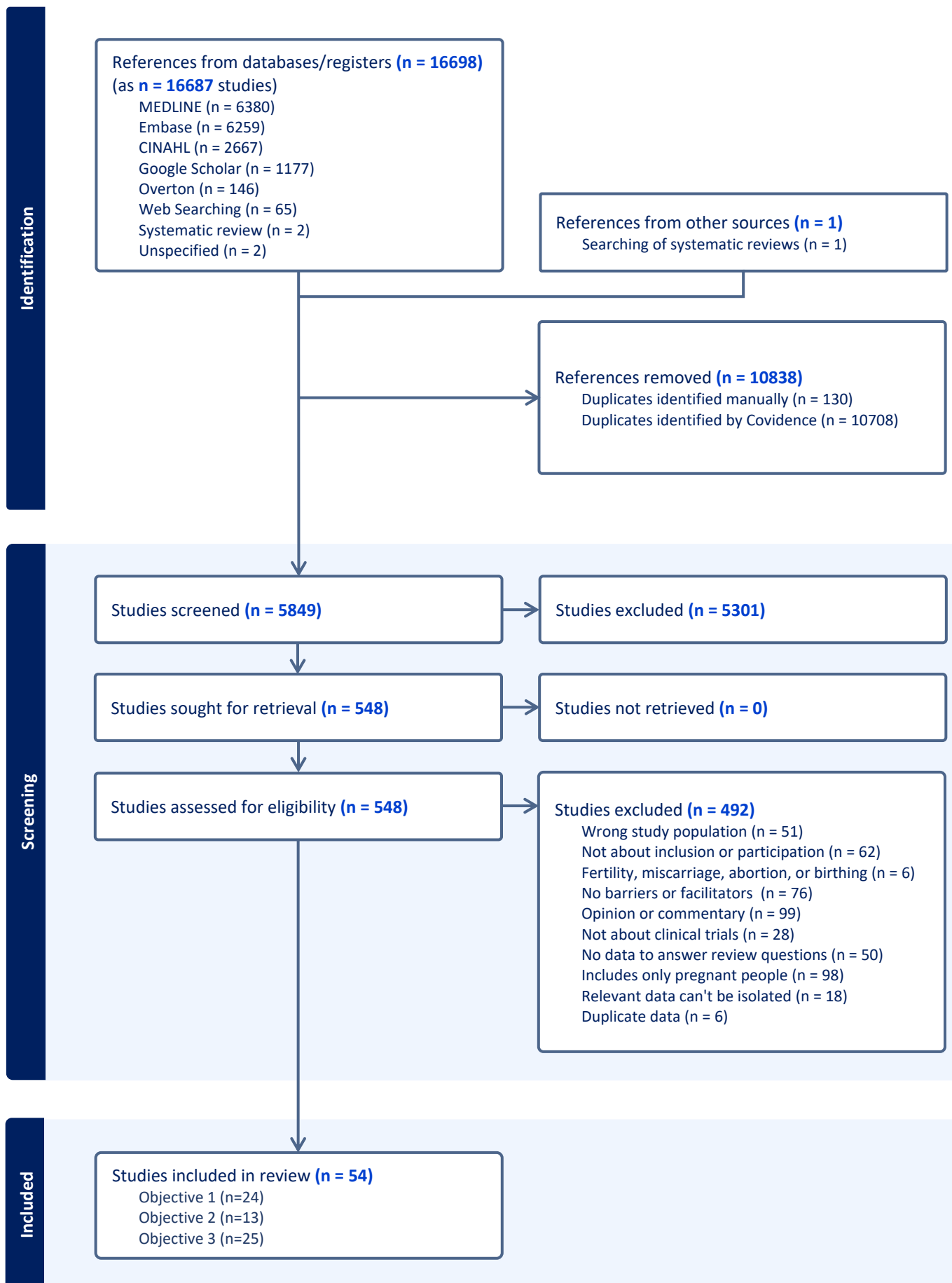
Patient and Public Involvement

We recruited PPI contributors through a community-based family centre, a primary school, and a pregnancy yoga group, to aid the design and interpretation of this review. We carried out individual interviews with five contributors and asked about their experiences of pregnancy, including their access to treatments, information about treatments, and participation in research. We also asked about their opinions of, and interest in, research to increase inclusion in research during pregnancy. We asked three contributors to review our results and the way that we had reported them. We have reported PPI following the GRIPP2 short form reporting checklist (28) .

Results

We included 54 studies, most of which focused on the prevention or treatment of infectious diseases (Figure 1).

Figure 1. PRISMA flow diagram



Rates of inclusion and participation for pregnant and breastfeeding women and people

Of 24 studies, 20 were systematic or semi-systematic reviews, of clinical trials registries, publications of clinical trials, or clinical trials supporting approved interventions, see Tables 1 and 2. Two were reviews with no clear methodology. Two studies were individual clinical trials. Two reviews focused on trials undertaken only in the USA; the other reviews did not limit the trials they included based on geographic location.

Table 1. Objective 1: Summary of included reviews

Study	Study Design	Search from	Search to	Search strategy	Clinical focus	Other focus
Rabinowitz 2022 (29, 30)	systematic	2000	2020	clinical trials registers	Crohn's, Ulcerative colitis	-
Bilinski 2025 (31)	systematic	2008	2023	clinical trials registers	All conditions	Post-Phase 1, US FDA-regulated, Drug interventions
Minchin 2023 (32)	systematic	2009	2019	clinical trials registers	H1N1 influenza, Middle East Respiratory Syndrome Coronavirus, Zika, Ebola	Phase II-III, Emergency vaccine trials
Shields 2013 (33)	Systematic	2011	2012	clinical trials registers	All conditions	Industry-sponsored, USA-based
Gomes 2017 (34)	systematic	2013	2016	clinical trials registers	Ebola	-
Duggal 2021 (35)	systematic	2014	2017	clinical review staff in the Office of New Drugs	All conditions	Biologics License Applications New Drug Applications
Westreich 2013 (36)	systematic	2015	2015	specific academic journals	HIV	-
Khaing 2025 (37, 38)	systematic	2015	2022	publication databases	Atrial Fibrillation Ablation	-
Harrilal Khan 2025 (39)	systematic	2015	2023	clinical trials registers	All conditions	Industry-funded, Phase III-IV
Mills 2021 (40)	systematic	2016	2021	clinical trials registers	Leukaemia, lymphoma	
McKenna 2017 (41)	un-systematic	2017**	2017**	***	TB	Phase III-IV treatment-shortening
Task Force on Research Specific to Pregnant and Lactating Women 2018 (42, 43)	un-systematic*	2017	2017	clinical trials registers	All conditions	USA-based
Jorgensen 2022 (1)	systematic	2017	2019	specific academic journals	All conditions	-
Salloum 2023 (44)	systematic	2018	2023	clinical trials registers	COVID, Ebola, Hepatitis B	Phase III and IV, Vaccine trials
Kons 2022 (45)	systematic	2020	2020	clinical trials registers	COVID	-
Green 2022 (46)	systematic	2020	2020	clinical trials registers	COVID	Treatment

Smith 2020 (47)	systematic	2020**	2020	clinical trials registers	COVID	-
Einav 2020 (48)	systematic	2020**	2020	clinical trials registers	COVID	-
Costantine 2020 (49, 50)	systematic	2020**	2020	clinical trials registers	COVID	-
Abbas-Hanif 2022 (51)	systematic	2020**	2021**	***	COVID	-
Metcalf 2024 (52)	systematic	2022	2022	clinical trials registers	Breast Cancer	-
Sliwinski 2025 (53)	systematic	2022	2022	Drugs@FDA website	All conditions	FDA drug approvals

* excluded from further analysis

** year estimated or inferred

*** no information available

Table 2. Objective 1: Summary of included clinical trials

Study	Study Design	Recruitment started	Trial	Countries where trials could recruit pregnant women and people
Vousden 2023 (54)	clinical trial	2020	Randomised Evaluation of COVID-19 Therapy	UK, Nepal, Indonesia
Malhalme 2023 (55)	clinical trial	2022	Staphylococcus aureus Network Adaptive Platform Trial	Australia, New Zealand, Canada, Israel, Singapore

Possible overlap (multiple-counting) of trials (some reviews may have included the same clinical trials) is tabulated in Additional Table 1.

Thirteen studies assessed the proportion of trials in which pregnant women and people were included (0-8%), 16 assessed the proportion that excluded pregnant women and people (66-100%) (table 3). Exclusion and inclusion were not explicit for 8 studies, accounting for between 1.5-32% of clinical trials. Four studies assessed the proportion of trials in which breastfeeding women and people were included (0-14%) or excluded (7 studies, 46-91%). Three further studies considered the exclusion of pregnant and breastfeeding women and people together (54-97%).

Table 3. Objective 1: Rates of inclusion of pregnant or breastfeeding participants in clinical trials

Study	Status	Total number of trials	Number of trials that include	% of trials that include	Number of trials that exclude	% of trials that exclude	Not specified
Rabinowitz 2022 (29, 30)	Pregnant and/or breastfeeding	146	-	-	80	54.8	-
Bilinski 2025 (31)	Pregnant	43821	23	0.1	33249	75.9	10549
Minchin 2023 (32)	Pregnant	80	4	5.0	76	95.0	0
Shields 2013 (33)	Pregnant	553	19	3.4	446	80.7	107
Gomes 2017 (34)	Pregnant	16	2	12.5	13	81.3	1
Duggal 2021 (35)	Pregnant	38	-	-	36	94.7	-
	Breastfeeding		-	-	35	92.1	-
Westreich 2013 (36)	Pregnant	25	2	8.0	20	80.0	3
Khaing 2025 (37, 38)	Pregnant and/or breastfeeding	147	-	-	42	96.6	-
Harrilal Khan 2025 (39)	Pregnant	3164	-	-	2140	67.6	1024
	Breastfeeding		-	-	1733	54.8	
Mills 2021 (40)	Pregnant	68	1	1.5	66	97.1	-
	Breastfeeding		3	4.4	57	83.8	-
McKenna 2017 (41)	Pregnant	8	0	0.0	8	100.0	0
Task Force on Research Specific to Pregnant and Lactating Women 2018 (42, 43)	Pregnant	4357	2	0.0	6!	0.1!	-
	Breastfeeding	4386	0	0.0	4**	0.1!	-
Jorgensen 2022 (1)	Pregnant	1333	13	1.0	937	70.3	383
	Breastfeeding		6	0.5	617	46.3	710
Salloum 2023 (44)	Pregnant	387	9	2.3	378	97.7	-
Smith 2020 (47)	Pregnant	163	3	1.8	-	-	-
Einav 2020 (48)	Pregnant	371	1	0.3	251	67.7	119

Costantine 2020 (49, 50)	Pregnant	376	1	0.3	>250	>66.5	-
Abbas-Hanif 2022 (51)	Pregnant	7*	0	0.0	7	100.0	-
	Breastfeeding		1	14.3	6	85.7	-
Metcalf 2024 (52)	Pregnant	1448	-	-	1026	70.9	-
	Breastfeeding		-	-	795	54.9	-
Kons 2022 (45)	Pregnant	585	-	-	438	74.9	-
	Breastfeeding		-	-	342	58.5	-
Sliwinski 2025 (53)	Pregnant and/or breastfeeding	56	-	-	30	53.6	-

* number of vaccines as denominator, rather than trials

** Difference in exclusion likely due to search methods lacking in sensitivity

Four studies provided data on participation of pregnant women, see Table 4. The two individual clinical trials reported the number of pregnant participants part-way through the trial (110 and <10) without a total number of participants enrolled. It is likely that two of the seven women described by Green et al., 2022 (46) are two of the 110 women by Vousden et al., 2023 (54).

Table 4. Objective 1: Rates of participation of pregnant or breastfeeding participants within clinical trials

Study	Study Design	Number of trials	Number of pregnant participants	% of participants
Jorgensen 2022 (1)	systematic review	13	*	0.7-3.4% of trial participants were pregnant
Green 2022 (46)	systematic review	10	7	*
Malhalme 2023 (55)	trial	1	<10	*
Vousden 2023 (54)	trial	1	110	7% of eligible pregnant women were recruited

* no data

Should pregnant and breastfeeding women and people be able to participate, and would they choose to?

Data were available from 13 studies for objective 2 (table 5). These used qualitative, quantitative, multi and mixed methods study designs.

Table 5. Objective 2: Summary of included studies

Study	Study design	Participants	Clinical focus	Other focus	Geographical locations
Palmer 2016 (56)	quantitative survey	women with or without experience of pregnancy	All conditions	Drug and vaccine	Canada
Goldfarb 2018 (57)	quantitative survey	pregnant women and women who recently gave birth	Zika	Vaccine	USA
Palazzani 2019 (58)	qualitative interviews and quantitative analysis	pregnant women and women who recently gave birth	All conditions	-	Germany
Jaffe 2019, 2020 (59, 60)	qualitative interviews	pregnant women and women who recently gave birth	Zika	Vaccine	USA
Trahan 2021 (61, 62)	multimethod quantitative and qualitative survey	health care professionals and researchers	COVID-19	-	Canada
Marban-Castro 2021 (63)	qualitative, phenomenology and grounded theory, and quantitative analysis	pregnant women and health care professionals	COVID-19	-	Spain
Anderson 2021 (64)	qualitative interviews	pregnant women	COVID-19	Vaccine	UK
Salami 2022 (65)	qualitative interviews	researchers	Lassa fever	Vaccine	Burkina Faso, Senegal, Ghana, Mali, Sierra Leone, Gabon, Republic of the Congo, Nigeria
White 2023 (66)	quantitative survey	community stakeholders	HIV	Prophylaxis	Botswana, Eswatini, Kenya, Malawi, South Africa, Uganda, Zimbabwe and USA
Jacobson 2024 (67)	quantitative survey	pregnant women and women who recently gave birth	All conditions	Drug and vaccine	USA
Quattrini 2025 (68)	mixed methods survey and interviews	pregnant women and women who recently gave birth	All conditions	New drug	Australia

Wood 2024 (69)	quantitative survey	general public	All conditions	-	USA
Salloum 2025 (70)	qualitative interviews and focus groups	pregnant women, general public and health care professionals	Ebola	Vaccine	Democratic Republic of Congo

Nine studies with quantitative elements focused on the opinions of women and people with experience of pregnancy, two on health care professionals, one on researchers, one on the general public, and one on community stakeholders (Table 6):

- A survey of women in Canada, with or without experience of pregnancy, considering drug and vaccine interventions, found 76% of pregnant women and women with experience of pregnancy strongly agree or agree that pregnant women should be included in clinical trials (56).
- Taken together, six studies (four using surveys, two using interviews, and one study based in phenomenology and grounded theory) found that in Canada, the USA, Germany, Spain and Australia, 7-90% of women with or without experience of pregnancy thought they were likely to participate in a clinical trial during pregnancy (56-58, 63, 67, 68).
- In a quantitative analysis of a study using phenomenology and grounded theory in Spain, with the context of Covid-19, researchers asked whether participants would take part in a clinical trial while breastfeeding; 14.3% of pregnant women would, 80% of health care professionals would (63).
- Another survey, of health care professionals and researchers in Canada, found that 72% of doctors believe that it is very or highly appropriate for pregnant women to be included in some Covid-19 clinical trials (61).
- One survey with participants in Botswana, Eswatini, Kenya, Malawi, South Africa, Uganda, Zimbabwe and the USA, found that the majority of community stakeholders agreed that pregnant women would accept the interventions required as part of a trial (66).
- One survey of the general public in the USA found that, although 68% of respondents agreed that including pregnant people in research is important, 55% though pregnant people should be excluded from clinical trials (69)

Table 6. Objective 2: Summary of quantitative analyses

Study	Question, statement or scenario posed by researchers	Response from participants	Participants ***	% of responses
Palmer 2016 (56)	I believe that when used appropriately, medications given in pregnancy can have a role in treating illness in women during pregnancy	Strongly agree or agree	110	80
	I believe it is important that women and their health care providers have information about the safety of medications during pregnancy			93
	I believe that if an experimental medication could help treat illness in a pregnant woman, she should be able to participate in a research study testing this medication if she wishes to			76
	I believe it is too risky for medications to be tested on pregnant women			24
	I would consider participating in a research study testing a medication during pregnancy			20
Goldfarb 2018 (57)	Prospective enrolment in an inactivated Zika virus vaccine trial while pregnant in an at-risk neighbourhood	Participate	128	68
	Continued enrolment in an inactivated Zika virus vaccine trial after falling pregnant during participation in a trial in an at-risk neighbourhood			65
	Prospective enrolment in a live-attenuated Zika virus vaccine trial while pregnant in an at-risk neighbourhood			19
	Prospective enrolment in a nucleic-acid Zika virus vaccine trial while pregnant in an at-risk neighbourhood			52
Palazzani 2019 (58)	Known but unapproved drug in case of illness	Yes	30	90
	New drug in case of illness			33
	Hormones for foetal growth			33
	Blood sample			80
	Research before abortion			23
Trahan 2021	Do you believe that it would be appropriate for pregnant women to be included in some Covid-19 clinical trials?	Very or highly	165	72
	How urgent is the need to include pregnant women in Covid-19 clinical trials?			67

(61, 62)	Do you believe it would be appropriate to include pregnant women in Covid-19 clinical trials involving repurposed drugs with a safety track record in pregnancy?	appropriate		85
	How comfortable would you be enrolling pregnant women in Covid-19 clinical trials involving experimental drugs otherwise thought to be safe during pregnancy?			86
Marban-Castro 2021 (63)	Would you participate in a clinical trial as a non-pregnant adult?	Yes	24 pregnant women 6 healthcare professionals	29
				67**
	Would you participate in a clinical trial during pregnancy?			17
				40**
	Would you participate in a clinical trial during breastfeeding?			14
				80**
White 2023 (66)	Would you participate in a clinical trial while pregnant in which hydroxychloroquine is the study drug?	Agree	~50	21
				80**
	Would you participate in a clinical trial while pregnant in which hydroxychloroquine is NOT the study drug?			21
				40**
Quattrini 2025 (68)	Participants will accept relaxed contraceptive requirements	Very likely or likely to participate	623	92
	Participants will accept injections during pregnancy			58
	You would accept injections during pregnancy			51
	Participants will accept injections during lactation			70
	Partners will object to injections during pregnancy and lactation			65
Wood 2024 (69)	Hypothetical 1 - new drug similar to safe drug already prescribed during pregnancy.	Agree	743	39
	Hypothetical 2 - new drug similar to existing drugs, small study in human pregnancy showing no harm.			24
	Hypothetical 3 - new drug similar to existing drugs well tolerated in pregnancy, hasn't been tested in human pregnancy, animal studies show the drug to have minor effects on fetal growth that resolved shortly after birth			12
	Hypothetical 4 - new drug to protect baby with evidence of harms to pregnant person			34
	Hypothetical 5 - new drug to protect pregnant person with evidence of harms to baby			7
(61, 62)	Pregnant people should be excluded from clinical trials*	Agree	743	55*
	The risks of including pregnant people in clinical trials outweigh the benefits*			53*
	Including pregnant people in research is important for providing evidence-based medicine			68

	Pregnant people should obtain partner consent prior to participation*			74*
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* Considering exclusion rather than inclusion

** Data relating to health care professionals

*** Unless specified, participants are women and people with experience of pregnancy

These items have been worded so that lower scores indicate greater support

Four main themes were found across the nine studies with qualitative elements. Six studies focused on the opinions of women and people with experience of pregnancy (58-60, 63, 64, 68, 70), four on health care professionals (59-63, 70), three on researchers (59-62, 65), and one on the general public (70)(Table 7). The four themes were:

Risk, or perception of risk:

- of the intervention to the fetus or the mother
- of the condition, particularly to the mother
- to the researchers, of liability, litigation, regulatory approval, potential participants and their families
- to the success of the trial itself

Potential harms of the interventions for the fetus were of paramount importance, less so than potential harms for the mother of the intervention or the condition. Participants may have overestimated the potential harms of the interventions while underestimating the potential harms associated with the conditions the interventions would potentially prevent or treat. Researchers perceived risks to their professional reputation and being able to undertake that specific research at all.

A lack of evidence of efficacy and safety:

- to support decision-making during pregnancy
- to balance potential harms and benefits
- to support testing the intervention

Women and people with experience of pregnancy, researchers and health care professionals highlighted the lack of evidence to support decisions about treatment, inclusion in research, and whether or not to participate in research.

Healthcare and research culture:

- of a lack of experience in prescribing and research during pregnancy
- of exclusionary research
- of not taking part in research during pregnancy

None of the participants in these studies were people who had participated in non-obstetric clinical trials whilst pregnant. Very few had experience of participation in obstetric research. Researchers and health care professionals had experience of exclusion of pregnant women being the default or assumed position.

Trust:

- in researchers

Women and people with experience of pregnancy described a lack of trust in the interventions being tested and the evidence of their safety, but had trust in the research process, and in researchers and health care professionals more generally.

Table 7. Objective 2: Summary of qualitative analyses

Study	Main area of questioning	Participants	Themes developed
Palazzani 2019 (58)	Participation in clinical research in general: Did the interview partner ever participate in clinical research? Would the woman participate in clinical research that tests a new drug for a certain disease from which she suffers? Would the woman participate in clinical research as a healthy participant that tests a new drug, involves blood taking, and for which she receives a financial reward? Participation in clinical research during pregnancy: What is the general opinion about clinical research involving pregnant women? Would the woman participate in certain types of clinical research? General issues on how to perform clinical research: Involvement of the partner, decision-making procedure, role of the researcher.	Pregnant women and women who recently gave birth	Drug Therapy During Pregnancy: The Restrictive Model
			Drug Therapy During Pregnancy: Deficiencies and Complications
			The Maternal-Foetal Relationship
			Decision-Making During Pregnancy
Jaffe 2019, 2020 (59, 60)	*	Pregnant women and women who recently gave birth	Evidence
			Risk
			Trust
Trahan 2021 (61, 62)	Do you believe that it would be appropriate for pregnant women to be included in some COVID-19 clinical trials? Do you believe it would be appropriate to include pregnant women in COVID-19 clinical trials involving repurposed drugs with a safety track record in pregnancy (e.g. hydroxychloroquine or lopinavir/ritonavir)? If not appropriate, please elaborate why: If yes, how urgent is the need to include pregnant women in COVID-19 clinical trials? If not urgent, please elaborate why: How comfortable would you be enrolling pregnant women in COVID-19 clinical trials involving experimental drugs otherwise thought to be safe during pregnancy (e.g.	Health care professionals and researchers	Potential harm to the fetus
			Lack of demonstrated efficacy of the drugs investigated
			Perception of low risk of severe maternal illness from Covid-19
			Fear of side effects for the mother
			Fear of litigation
			Culture of non-prescription in obstetrics
			Lack of experience with the investigational drugs
			Lack of understanding of the natural history of Covid-19

	hydroxychloroquine or lopinavir/ritonavir)? If uncomfortable, please elaborate why:		Unwillingness of pregnant women to be included in clinical trials Unwillingness of other members of the health care team to include pregnant women in clinical trials Burden of regulatory approval to include pregnant women in clinical trials Culture of exclusion of pregnant women Burden of recruitment for this specific population Fear of potential participants and their family Lack of eligibility among pregnant women Liability concerns Lack of infrastructure to include pregnant women in trials Relevance and feasibility of including pregnant patients in Covid-19 drug trials Ethical obligation to include pregnant women in clinical research
Marban-Castro 2021 (63)	Would you participate in a clinical trial to evaluate the effectiveness / safety of a drug? Why? And during pregnancy? Why? And in the specific context of the COVID-19 pandemic? Why? And if we tell you that the drug is hydroxychloroquine? Why? If it is another drug? Remdesivir? Dexamethasone? Under what circumstances would you agree to participate? And during breastfeeding? Why? [For health care professionals only] Would you recommend your patients to participate in a clinical trial? And during pregnancy?	24 pregnant women 6 healthcare professionals	Knowledge and uncertainties about COVID-19 and pregnancy Perceptions of disease severity and vulnerability Pregnant women's emotional state during the pandemic Barriers and facilitators to trial participation

	If there is another COVID-19 outbreak now or later, similar to the one in March April, would you change any of your answers?		
Anderson 2021 (64)	Should Covid-19 vaccines be tested on pregnant women?	Pregnant women	"I think they should be tested on pregnant women (but I wouldn't volunteer)"
	Personal willingness to participate in a Covid-19 vaccine trial		"That's a really tough question" – ethics of risk to the baby
Salami 2022 (65)	***	Researchers	"Hell no": Covid-19 vaccines should not be tested on pregnant women
			Would consider taking part in a vaccine trial if...
			Experience of sub-Sahara Africa investigators with pregnant women in clinical trials involving investigational agents
Quattrini 2025 (68)	Would you participate in this trial?	Pregnant women and women who recently gave birth	Barriers to the inclusion of pregnant women in Lassa virus vaccine clinical trials
			The enablers of including pregnant women in Lassa virus vaccine clinical trials
			Risk–benefit analysis
Salloum 2025 (70)	Que pensez-vous de la décision de l'essai d'exclure les femmes enceintes? S'il y avait un essai pour un autre vaccin à Boende, y participeriez-vous si vous étiez enceinte? [What do you think of the trial's decision to exclude pregnant women? If there were a trial for another vaccine in Boende, would you participate if you were pregnant?]	Women excluded from trial for pregnancy	Quality and type of evidence
			Trust
		Other community members who did not participate in the trial	Foetal safety is paramount
			Trust in the trial organisers
			Community trust and concerns
			Influence of past experiences

		Women excluded from trial for pregnancy	Marriage and parenthood options
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*Data not available

What are the factors influencing inclusion and participation of pregnant and breastfeeding women and people?

Twenty-five studies included data that we could use for objective 3 (table 8). These studies used a variety of designs, and most were published in or after 2016.

Table 8. Objective 3: Summary of included studies

Study	Type of evidence	Participants	Clinical focus	Other focus	Geographical locations
UNAIDS 2008 (71)	Review	health care professionals, researchers, key stakeholders	HIV	-	Not specified
Gupta 2016 (72)	consensus statements	health care professionals, researchers, community representatives	TB	Drug	Not specified
Krubiner 2016 (73)	expert consultation	health care professionals, researchers	HIV	-	USA, South Africa, sub-Saharan Africa
Task Force on Research Specific to Pregnant and Lactating Women 2018 (42, 43)	public consultation	Public	All conditions	-	USA
van der Zande 2017 (74)	interview and focus group	pregnant women, health care professionals	All conditions	-	Netherlands
Goldfarb 2018 (57)	quantitative survey	pregnant women, women who recently gave birth	Zika	Vaccine	USA
Nachman 2019 (75)	stakeholder engagement, expert consultation, workshop	health care professionals, researchers, key stakeholders, community representatives	HIV	Treatment and prevention	USA
Daly 2019 (76)	Interviews	Midwives	All conditions	-	Ireland
Vousden 2021 (54)	clinical trial	Researchers	COVID-19	Treatment	UK, Nepal, Indonesia
Trahan 2021 (61, 62)	multimethod quantitative and qualitative survey	Doctors	COVID-19	-	Canada
Marban-Castro 2021 (63)	phenomenology and grounded theory, interviews	pregnant women, health care professionals	COVID-19	-	Spain

Lyerly 2021, WHO 2021, Wickremsinhe 2018 (77-79)	stakeholder engagement, expert consultation, workshops	health care professionals, researchers, community representatives	HIV/co-infections	-	Botswana, Kenya, Malawi, South Africa, Switzerland, Uganda, UK, USA
Rose 2021 (80)	multimethod quantitative and qualitative survey	midwives, health visitors	All conditions	-	England
Krubiner 2021 (81)	stakeholder engagement, expert consultation, workshops	health care professionals, researchers, key stakeholders	Emerging epidemics	Vaccine	USA
van der Zande 2021 (82)	conceptual analysis	Researchers	All conditions	-	Netherlands
Malhalme 2023 (55)	clinical trial	Researchers	Staphylococcus aureus bloodstream infection	Treatment	Australia, New Zealand, Canada, Israel, Singapore
Salami 2022 (65)	interviews	Researchers	Lassa fever	Vaccine	Burkina Faso, Senegal, Ghana, Mali, Sierra Leone, Gabon, Republic of the Congo, Nigeria
National Academies of Sciences, Engineering, and Medicine 2023 (83)	workshop	Public	All conditions	-	USA
Penazzato 2022 (84)	stakeholder engagement, expert consultation, workshop	health care professionals, researchers, key stakeholders, women living with HIV	HIV	Drug	Worldwide
Jacobson 2024 (67)	quantitative survey	pregnant women, women who recently gave birth	All conditions	Drug and vaccine	USA
National Academies of Sciences,	expert committee consensus	researchers, key stakeholders, research participants	All conditions	-	USA

Engineering, and Medicine 2024 (85)					
Vidal 2024 (86)	systematic review	guidelines, recommendations	Oncology	-	Worldwide
Perman 2024 (87)	clinical trial	Researchers	Acute Care	Treatment	USA
Dey 2025 (14)	review, expert consultation	health care professionals, researchers, key stakeholders	All conditions	-	Worldwide
Serota 2025 (88)	policy analysis and interviews	Researchers	All conditions	Vaccine	USA

Hundreds of factors relating to inclusion were highlighted by the studies, we coded most to six key themes; the need for research, fair inclusion, risks, early inclusion, financial concerns, and practical issues (Figure 2). Most research into factors influencing inclusion and participation focused on factors perceived or experienced by researchers and health care professionals.

Figure 2. Objective 3: Themes identified by researchers

Need for research

- Perception that research including pregnant and breastfeeding women is unnecessary
- Rejection of interventions during pregnancy and breastfeeding
- Lack of agreed research agenda

Fair inclusion

- Pregnant and breastfeeding women are complex, complicated and logistically challenging
- Can be considered eligible for inclusion unless compelling reason for exclusion
- Culture of exclusion; regulatory authorities, ethics committees, funders, researchers, health care professionals and women
- Unclear who is responsible for fair inclusion

Risks

- Inadequate information on safety or efficacy of interventions
- Starting point is to maximise risk avoidance – “minimal risk”
- Acceptable levels of risk differ for women in different scenarios
- Considerations of risk focus on potential harms of the intervention to the baby
- Consider balance of potential harms and benefits of intervention and condition for mother and baby

Early inclusion

- Select interventions based on likely safety in pregnancy and breastfeeding
- Undertake developmental toxicity studies
- Undertake pregnancy and breastfeeding-specific pharmacokinetic and pharmacodynamic studies
- Undertake additional monitoring
- Excluding trials could plan for retention and follow-up of participants who become pregnant

Financial concerns

- Concerns about potential liability in case of harm
- Liability can be borne by some sponsors or governments
- Studies including pregnant and breastfeeding women can cost more to conduct
- Pharmaceutical companies perceive pregnant and breastfeeding women as unlikely to yield large returns on research and development investments

Practical issues

- Research needs to be convenient and supportive for pregnant and breastfeeding women
- Workloads can be onerous, with clinical work prioritised over research
- Expert involvement in design, methodology, implementation, governance and analysis
- Global collaboration and coordination can support infrastructure and capacity building
- Underpowering of subgroup analyses

SWAR08: Finding eligible studies efficiently

All sources yielded unique and eligible studies that were included in this review. MEDLINE contributed 43 of the 54 included studies, with Embase adding another five (table 9).

Table 9. Study Within a Review 08: Finding eligible studies efficiently

Source	Studies found		
	Unique eligible	Eligible	Total
MEDLINE	7	43	6380
Embase	5	39	6259
CINAHL	1	13	2667
GoogleScholar	3	27	1177
Overton	1	1	146
Web searching	2	2	65
References	1	1	Not calculated

Patient and Public Involvement

The feedback from five PPI contributors reinforced our interest in this project. We made changes to the way we described these results in response to the additional feedback from two PPI contributors. Changes included:

- clearer explanations of results in tables and their context
- comparison with rates of conceptions
- consideration of the absence of evidence relating to:
 - trials of interventions in conditions specific to women's health
 - conditions with higher prevalence, incidence or severity in pregnant women and people
 - different trimesters of pregnancy
 - complementary and alternative medicine
 - trust in pregnant and breastfeeding women and people to make healthcare decisions
- possible avenues for future research:

- consideration of researchers' motivations when pregnancy and breastfeeding were not mentioned explicitly
- assessment of the use of specific criteria to exclude pregnant and breastfeeding women and people

Our PPI contributors informed us that some studies were of less interest - for example, the opinions of the general public (included), or spouses on inclusion and participation (excluded) (69, 89). One PPI contributor expressed a hope that all members of our communities would be invested in a better future for our children but that not everyone could usefully guide research policy.

Discussion

This rapid scoping review has shown that most research to date into the involvement of pregnant or breastfeeding women and people in non-obstetric clinical trials has focused on the testing of vaccines and drugs in infectious diseases. Most studies were led by and included participants in the USA, Canada and Europe and most studies focused on globally-relevant infectious diseases, including several for COVID-19. Overall, pregnant and breastfeeding women and people are included in a small minority of non-obstetric clinical trials and explicitly excluded from a majority. Although exclusion may be appropriate for some clinical trials, it seems unlikely that is appropriate to exclude pregnant and breastfeeding women and people from such a large proportion of trials (10, 13, 90).

There is sparse data on rates of participation. There is almost no data on which additional underserved groups pregnant and breastfeeding women and people are part of, including minoritised ethnic groups, socio-economic status, or other health conditions.

There is a wide range in the proportion of women and people with experience of pregnancy who are likely to participate in a non-obstetric clinical trial during pregnancy. Likely rates of participation depend heavily on the context of the trial under consideration. Themes underpinning opinions and decisions include potential harms, a lack of evidence, research culture, and trust.

Hundreds of factors influencing inclusion and participation have been identified; these fit six key themes: the need for research, fair inclusion, risk, early inclusion, financial concerns, and practical issues. Often one factor could have been fitted into multiple interacting themes.

The focus we found, on infectious diseases in maternal health, is logical given that infectious diseases are a majority of the disease burden in low-income countries and maternal health conditions are the second leading cause of disability-adjusted life years (DALYs) among women of reproductive age (91, 92). However, there is substantial geographical variation in research and healthcare to minimise the impact of maternal health conditions (93). As non-communicable diseases are the majority of disease burden in high-income countries, we might have expected more research in different clinical conditions. Discussions with our PPI contributors highlighted the lack of information on whether researchers who did not mention pregnancy or breastfeeding in their eligibility criteria had deliberately included pregnant and breastfeeding women and people or had simply overlooked their existence in their patient population. Only two studies focused on conditions that are well-established to have higher rates of incidence or prevalence in women. No studies focused on conditions specific to women, or with higher rates of incidence or prevalence in pregnant women and people, for example, mental health, or autoimmune conditions, which our PPI contributors described as highly significant in their pregnancy experiences. There were no studies focused on non-life-threatening common conditions, for example, vulvovaginal candidiasis, or insomnia, that our PPI contributors described as highly significant in their pregnancy experiences. There were no studies looking at inclusion in studies of complementary and alternative medicine medicines, which our PPI contributors described as highly significant in their pregnancy experiences. These are unlikely to be useful targets for future research given that there is sufficient information to be confident that rates of inclusion in trials for non-communicable conditions are sub-optimal. In addition to improved inclusion in non-obstetric trials, more clinical trials focused on different aspects of perinatal health are essential to improve health outcomes for women (94, 95).

The COVID-19 pandemic has highlighted the lack of, and need for, the inclusion of pregnant and breastfeeding women and people in non-obstetric clinical trials, and several of the included studies were focused on COVID-19 research (96). The rates of inclusion and exclusion found by this study are consistent with other recent research (97-99), and enable a systematic overview of global and condition-agnostic rates of inclusion. Currently, guidelines for reporting research do not require, and few non-obstetric studies report, participant characteristics related to pregnancy and breastfeeding (100). An update to include these in guidelines for reporting of participants' key demographic, socioeconomic and health factors would enable researchers to assess how representative participants are of patient populations (101-103). This would also support an analysis of other dimensions of being under-served by research and inequities in health outcomes for pregnant and breastfeeding women and people (4, 104). Collected data on conceptions, or modelled estimates of unintended pregnancy incidence (including births, abortions, and miscarriages) could be used to support trialists to estimate what proportion of their potential participants are likely to be pregnant (105, 106).

The range of the proportion of pregnant women and people who considered themselves likely to participate in a non-obstetric clinical trial during pregnancy was wider and higher than might be assumed. The culture of exclusion may be driven more by health care professionals and researchers than by pregnant women and people; some of our PPI contributors have described to us their trust in researchers and health care professionals to only include them in studies where it is ethical and the potential benefits outweigh the potential risks. We do not know how willingness to consider participation would translate to actual participation. The historic exclusion of all women from clinical trials has led to a culture of exclusion by all stakeholders in the research process, including pregnant women themselves (107). However, when participants have more information about the risks of the condition under study, and these are higher, and the risks of the intervention to the fetus are better known, and lower, women are more likely to consider participation. Our PPI contributors highlighted that although trust in research, and trust in clinicians and researchers were identified as factors

influencing inclusion and participation, trust in women, and in pregnant women and people, were not identified as factors by any studies. This is in stark contrast to the responsibility placed on women and people to make decisions about healthcare interventions while pregnant or breastfeeding. To support informed decision-making future research should explore the impacts of evidence, communication and risks of non-participation on participation, considering the different potential harms and benefits at different gestational stages.

Based on the essential and extensive work of clinical trialists on research inclusion generally, and specifically of under-served groups, as expected, we found a large number of complex factors impacting inclusion and participation (16, 108-110). Opinion pieces or commentaries, which we excluded due to resource constraints, were included in a review with complementary findings and could provide useful insights into factors affecting inclusion and participation and possible solutions to support inclusion (17). Our PPI contributors highlighted an interest in the impact of different types of eligibility criteria used to exclude pregnant and breastfeeding women and people (for example, requiring the use of specific contraception, confirmation of post-menopausal status or verbal confirmation from the potential participant (16, 32, 45)). Future research to support inclusion will include an examination of the use of specific criteria and their impact.

Our review was limited to the English language; it may not be an accurate representation of pregnancy and breastfeeding experiences that are shaped by cultural and linguistic differences. We did not include studies that focused trials including only pregnant or breastfeeding women and people, these have been reviewed recently (16, 111).

Our implementation of SWAR08 indicates that we needed to search all of these sources to capture all the included studies. However, CINAHL, Overton and reference checking each contributed one unique study. Reducing the number of databases checked could be a pragmatic compromise for future reviews; this is consistent with methodological guidance from the Cochrane Rapid Reviews

Methods Group (112). Repeating this SWAR in future reviews could provide further evidence potential efficiencies.

Given the vast inequalities in research funding, the disproportionate amount of research led by high-income countries is unsurprising (113, 114). The experience of global health colleagues in infectious diseases and the immediate and clear link between evidence gaps and poor health outcomes for pregnant and breastfeeding women and people has empowered them to lead action on inclusion, hence the high proportion of research relating to infectious diseases. Our PPI contributors highlighted the tendency of the research to focus health care professionals and researchers, rather than women with experience of pregnancy. This may often be an appropriate study design but it does reduce the relative representation of women, and women and people with experience of pregnancy and breastfeeding, in the literature around their inclusion and participation.

We selected rapid methods to most efficiently capture studies of interest. The probability that using publication date restrictions, using data verification (rather than independent extraction), and including English language articles only is unknown but is unlikely to have had a significant impact on our findings (21). We chose not to carry out a full analysis or critical appraisal of the included studies because the three objectives for this scoping review were intended to identify key evidence and gaps, and inform a further programme of research (18). A key component of this programme is a targeted systematic review which will use methods that prioritise comprehensive evidence gathering and full analysis of one focused objective. The review studies that we used to inform objective 1 are likely to have some duplication in the clinical trials they include and we were unable to extract enough information from studies to assess the likelihood and size of any such duplication. However, rather than exclude studies with potential duplication, we have included them, and assessed whether duplication is possible, or not. We did not design our search to find all individual clinical trials reporting the participation of women and people who are pregnant or breastfeeding. We did

include data from individual clinical trials that focused on the participation of women and people who are pregnant or breastfeeding.

Some of the PPI contributors who informed this work are the founding members of a PPI Advisory Group on Maternal Health

https://www.phc.ox.ac.uk/ppi/getting_involved_as_a_public_contributor/PPI-Advisory-Group-on-Maternal-Health. Our group is diverse in demography, health factors, and pregnancy and parenting experiences. It is a stable and evolving group, with a keen interest in this field, and is an invaluable resource that continues to shape our research.

Conclusions

This rapid scoping review efficiently and systematically identifies and maps the available evidence to these knowledge gaps about the inclusion and participation of pregnant and breastfeeding women and people in non-obstetric clinical trials. It has shown that pregnant and breastfeeding women and people are explicitly eligible for a small minority of non-obstetric clinical trials and that there is very little information about whether or not they participate in such trials. Women and people with experience of pregnancy might be more likely than researchers expect to consider participation in non-obstetric clinical trials, especially if a condition has greater risks. Hundreds of factors influence inclusion and participation of pregnant and breastfeeding women and people in clinical trials; further research into these is our key priority.

Our PPI contributors reiterated that the exclusion of pregnant women and people from research does not avoid a problem, rather, it shifts the problem from researchers to individual clinicians and patients making decisions about healthcare. Addressing factors that influence inclusion in clinical trials is essential to support pregnant women and people's choices about participation in research, their access to evidence-based healthcare, and to improve maternal and infant health outcomes.

List of abbreviations

WHO – World Health Organization

ICH – International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

PPI – Patient and Public involvement

NHS – National Health Service

NIHR – National Institute for Health and Care Research

UKRI – UK Research and Innovation

EMA - European Medicines Agency

FDA - U.S. Food and Drug Administration

SWAR – Study Within A Review

DALYs - Disability-Adjusted Life Years

Ethics approval and consent to participate

This review did not have research participants, and did not need ethics approval or consent.

Consent for publication

Not applicable.

Availability of data and materials

The data that support the findings of this study will be made available for research that sets out to achieve aims specified in a methodologically and scientifically sound protocol approved by the University of Oxford Nuffield Department of Primary Care Hosted Research Datasets Committee (PrimDISC). Information regarding how to apply for access to these data should be directed to: primdisc@phc.ox.ac.uk

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

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HL - Formal Analysis, Investigation, Methodology, Writing – review & editing

LHH - Formal Analysis, Investigation, Methodology, Writing – review & editing

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