STUDY PROTOCOL

Pre-pregnancy and pregnancy cohorts: a scoping review protocol [version 1; peer review: awaiting peer review]

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V1 First published: 24 Aug 2021, 10:847
<https://doi.org/10.12688/f1000research.55501.1>

Latest published: 24 Aug 2021, 10:847
<https://doi.org/10.12688/f1000research.55501.1>

Open Peer Review

Approval Status Awaiting Peer Review

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Abstract

Introduction: Recent research in life course epidemiology has demonstrated the importance of evaluating how pre-pregnancy and pregnancy exposures affect later life developmental outcomes. While the fields of nutrition, non-communicable disease, and social epidemiology have examined a diversity of birth- and longer-term outcomes related to different exposures during pregnancy, little information exists on other types of exposures, including infectious, medication, and vaccine-related exposures. In this review, we describe completed or ongoing pregnancy and pre-pregnancy cohorts to assess gaps in the exposures and outcomes measured in these initiatives to inform future research investments.

Methods and analysis: We will apply the Arskey and O'Malley scoping review methodology and use the National Institutes of Health quality assessment tool for cohort studies. The systematic search strategy was developed and tailored for Ovid Medline and Embase, LILACs, and Web of Science with the assistance of an information scientist. We selected a scoping review rather than a systematic review methodology because this review is meant to provide a comprehensive overview of pregnancy and pre-pregnancy cohorts, rather than to focus on the findings from related research. The title-abstract and full text screening and data charting will be conducted independently by two reviewers. Discrepancies will be resolved by a third reviewer and results will be summarised in narrative form.

Ethics and dissemination: This scoping review summarizes findings from existing publications in peer reviewed journals and does not require ethics review. Findings will be disseminated through an open access publication.

Keywords

scoping review, pregnancy cohort, pre-pregnancy cohort, life course epidemiology

This article is included in the **Sociology of Health** gateway.

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Author roles: **Maxwell L:** Conceptualization, Data Curation, Funding Acquisition, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing; **Gilyan R:** Writing – Original Draft Preparation, Writing – Review & Editing; **Chavan SA:** Formal Analysis; **Al-Zumair M:** Formal Analysis; **Akter S:** Formal Analysis; **Jaenisch T:** Conceptualization, Funding Acquisition

Competing interests: No competing interests were disclosed.

Grant information: This scoping review is part of the RECODID project, which is funded by the EU Horizon 2020 research and innovation programme (grant agreement 825746) and the CIHR Institute of Genetics (grant agreement 01886-000).
The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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How to cite this article: Maxwell L, Gilyan R, Chavan SA *et al.* **Pre-pregnancy and pregnancy cohorts: a scoping review protocol [version 1; peer review: awaiting peer review]** F1000Research 2021, **10**:847 <https://doi.org/10.12688/f1000research.55501.1>

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Introduction

Pregnancy and pre-pregnancy cohorts are important for understanding the short- and long-term effects of a myriad of pre- and pregnancy exposures, including infectious disease, nutrition, medication, vaccine, illicit drug, environmental, behavioural, and socioeconomic exposures. Pregnant women are underrepresented in, or excluded from, most clinical trials, which underscores the need for observational data collected during pregnancy for understanding the effects of different types of exposures.

Exposures immediately prior to or during foetal development, as well as early in the post-natal period, are important considerations for childhood growth and development as well as the risk for disease later in the life course¹. For example, findings from the Avon Longitudinal Study of Parents and Children, a large cohort of pregnancies in the UK followed until 18 years of age, support an association between prenatal exposures such as maternal anxiety and certain medication use to the development of asthma in the child².

Study rationale and objectives

In this review, we will summarise information on existing pregnancy and pre-pregnancy cohort registries and platforms and provide a comprehensive map of the availability and coverage of pregnancy and pre-pregnancy cohorts in relation to populations, exposures, and outcomes. A scoping review of published pregnancy and pre-pregnancy cohorts and their findings will help researchers understand the resources that exist to explore perinatal exposures, and their association with development of chronic conditions and susceptibility to diseases. The scoping review will help inform efforts to harmonise participant-level data across ongoing or completed pregnancy and pre-pregnancy cohorts to facilitate further individual participant-level data meta-analyses. The mapping exercise will form the basis for a research agenda to set priorities for future investments in understanding proximal causes of short and long term adverse developmental outcomes or chronic conditions.

Information on biological specimen collection and availability will help researchers better utilize existing resources with a focus on understanding within-individual changes over time and the relation between maternal and child biological measures. For example, the 3D Cohort Study³ serves as a robust biological specimen repository with samples taken during pregnancy through to two years following birth, for the study of neonatal and childhood neurodevelopmental outcomes.

Methods

Scoping reviews may be used to map out broad concepts with the use of existing literature and help to identify more specific subject areas to be researched in a subsequent systematic review. The central questions addressed in this review are based on thorough assessment of relevant literature and expert feedback from the specific field of this study. Review questions might be subject to changes as needed based on the findings of the research. The approach undertaken in this review is the Arksey and O'Malley approach to scoping reviews and results will be presented in accordance with the PRISMA

Extension for Scoping Reviews guidance (PRISMA-ScR)⁴. In keeping with Levac, *et al.*'s guidelines for scoping reviews⁵, we will implement the following steps:

1. Clarify and link the purpose and research question (balancing)
2. Feasibility with breadth and comprehensiveness of the scoping process, using an iterative approach
3. Clarify approach to study selection
4. Clarify approach to data extraction
5. Qualitative thematic analysis, summarizing results, and clarifying policy, practice, and research implications
6. Stakeholder consultation to summarize results and facilitate research translation

This scoping review protocol was developed in keeping with the PRISMA-P guidelines⁶.

Stage I: Identifying the research question

The initial review questions were developed through consultation with the research team and feedback from key stakeholders who work with pregnancy and pre-pregnancy cohorts to ascertain the effects of infectious or environmental exposures during pregnancy.

Review questions

1. What pregnancy and pre-pregnancy cohorts exist?
2. What exposures do they measure prior to or during pregnancy?
3. What maternal, fetal, infant, child, or adult outcomes do they measure?
4. What samples do they collect from pregnant women, their partners, the fetus, the infant or child?
5. Do they share participant-level data and samples from their cohort? Where? What mechanisms are in place to facilitate access to that data?

Stage II: Identifying relevant studies

In order to identify studies relevant to the subject of this review, the following electronic databases will be searched: Ovid (Medline), Ovid (EMBASE), Web of Science, and LILACs. The proposed search strategies were developed in consultation with an information scientist and include a combination of text and MeSH terms, tailored for each database. Searches will be limited to published papers from the year 2000 to the time the search is run, to ensure all relevant studies related to exposures in pre-pregnancy and pregnancy cohorts are captured. The searches will not be further restricted by location or language of publication. The search strategy for each database is presented in [Table 1](#).

Stage III: Study selection and eligibility criteria

After implementing the search, citations will be exported to EndNote X9 for deduplication. The review process of the

Table 1. Tailored search strategy.

	MEDLINE (Ovid)	EMBASE (Ovid)	Web of Science	LILACS
1	(cohort\$ or longitudinal).ti.	(cohort\$ or longitudinal).ti.	TI=(cohort\$ or longitudinal).	(ti:((cohort* OR longitudinal))) AND ((ti:((pregnan* OR *pregnan* OR maternal))) OR (((maternal OR mother) near/4 exposure*))) AND (db:("LILACS"))
2	(pregnan\$ or \$pregnan\$ or maternal).ti.	(pregnan\$ or \$pregnan\$ or maternal).ti.	TI=(pregnan\$ or \$pregnan\$ or maternal)	PY=2000–2021
3	((maternal or mother) adj4 exposure*).ti,ab	((maternal or mother) adj4 exposure*).ti,ab	TI=((maternal or mother) NEAR/4 exposure*) OR AB=((maternal or mother) NEAR/4 exposure*)	
4	1 and (2 or 3)	1 and (2 or 3)	1 and (2 OR 3)	
5	exp animals/not humans.sh	exp animals/not humans.sh	TS=(animal model or animal* NOT human)	
6	4 not 5	4 not 5	4 not 5	
7	limit 6 to yr="2000 -Current"	limit 6 to yr="2000 -Current"	PY=(2000–2021)	

available literature will include an initial title and abstract screening and then a full text screening conducted independently by two reviewers. The screening process will be managed in Covidence systematic review software⁷. Disagreements in the title/abstract or full text screening will be resolved by consulting with a third reviewer.

Inclusion criteria

Included studies will be prospective, primary research studies published from 2000 until the time the search is run and will report on pregnancy and pre-pregnancy cohorts with any focus in any geography or language.

Exclusion criteria

Studies that do not report on pregnancy or pre-pregnancy cohorts and any type of research focusing exclusively on birth cohorts will be excluded. Retrospective chart reviews that do not prospectively enrol participants prior to or during pregnancy will not be included. Commentaries, editorials, systematic or scoping reviews, or other forms of non-peer reviewed, primary research will be excluded.

Stage IV: Charting the data

We will develop and pilot a data extraction and charting form to facilitate the descriptive synthesis of our findings prior to beginning the charting process. Key data that will be extracted from included studies are:

- Descriptive information for the pregnancy and pre-pregnancy cohorts (e.g., name, acronym, location, funding source, years active, participant enrollment criteria, source population, duration/frequency of follow-up)
- Demographic information related to enrolled participants, including socioeconomic factors
- Maternal exposures measured by the cohorts (e.g., social, environmental, and occupational factors)

- Infant and child outcomes measured by the cohorts (e.g., biological, social, and cognitive measures)
- Sample collection and availability by the cohorts (e.g., sample type, frequency, storage, and accessibility)

Data extraction and data charting will be completed independently by two reviewers in Covidence systematic review software⁷. The scoping review will use the [National Institutes of Health Tool](#) to evaluate the quality of included cohort studies. As part of this scoping review, we will conduct an informal search for platforms or repositories that harmonize and disseminate or solely host participant-level data and study-level metadata across pre-pregnancy and pregnancy cohorts.

Stage V: collating, summarising and reporting results

Results of the data charting process will be presented in a narrative form. Results of the systematic search will be reported in a PRISMA flow diagram.

Stage VI: consultation, patient and public involvement

The scoping review group will consult with external stakeholders in different domains of perinatal and life course epidemiology to develop recommendations related to the scoping review findings. Research findings will be shared publicly through a webinar and through the websites of partner institutions.

Ethics and dissemination

No ethical approval is required for this systematic review as only secondary data will be used. Findings will be presented in an Open Access publication and disseminated on the [ReCoDiD website](#).

Study status

Study status and timeline are presented in [Table 2](#).

Table 2. Study status at time of protocol submission and anticipated timeline.

Preliminary search	Completed
Pilot of search strategy	Completed
Implementation of search	Completed
Title-abstract screening	May 2021
Full text screening	June 2021
Development and piloting of data charting tool	June 2021
Charting the data	July 2021
Publication of results	August 2021

Conclusion

The importance of pre-pregnancy and pregnancy exposures on birth and later life developmental outcomes is an emerging field of research. Coordination between pregnancy and pre-pregnancy cohorts would facilitate cross-population inference and build a better understanding of how these exposures shape later life cognitive, behavioural, and developmental outcomes. In this scoping review, we summarise the structure and content of cohorts that provide prospective measures of pregnancy and pre-pregnancy exposures to provide a comprehensive evaluation of the information and samples available to help answer outstanding questions in life course epidemiology and to inform cross-cohort synthesis and future investments in related pregnancy and pre-pregnancy cohorts.

Data availability

Underlying data

No data are associated with this article.

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