

PROTOCOL

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What are the ethical, legal, and social debates surrounding artificial womb technology? A scoping review protocol

Srishti Hukku^{1,2}, L. L. Wynn² and Angel M. Foster^{1*}

Abstract

Background Ectogenesis—the development of the fetus outside the human uterus—is generally attributed to British scientist J.B.S. Haldane as early as 1924. Although efforts to develop artificial womb technology have seen limited success, a number of recent advances suggest that human clinical trials may become possible. The objective of this scoping review is to identify the ethical, legal, and social debates that have emerged regarding the future prospects of artificial womb technology.

Methods We will use a pre-defined five-step framework to guide this scoping review. Our primary research question is: “What are the ethical, legal, and social debates surrounding AWT?” We will identify relevant peer-reviewed studies in which the full text is in English from electronic databases including Scopus, PubMed, JSTOR, Proquest, Medline, LexisNexis, Westlaw, HeinOnline, and DOAJ. We will employ a two-stage process to identify relevant articles by (1) searching for articles in databases using keywords and 2) conducting a hand search of the reference lists of all retrieved articles to find any relevant sources not indexed by these databases or keywords. Two independent reviewers will select articles by screening titles/abstracts followed by a full-text appraisal using standardized inclusion criteria. We will extract and synthesize the data and develop a narrative summary with accompanying tables and figures. The final output will adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Extension for Scoping Reviews checklist.

Discussion The scoping review will document evidence and gaps in the evidence of key areas of focus for academics, clinicians, scientists, legislators, and public policy decision-makers as they consider how to move forward with artificial womb technology. Given the novelty of this technology, we anticipate that we will identify significant gaps that may inform future research and promote a proactive approach to the modernization of legislation, regulatory frameworks, and existing policies and guidelines that may govern this technology.

Systematic review registration We have registered this scoping review protocol with OSF Registries: <https://doi.org/10.17605/OSF.IO/D8Q96>.

Keywords Artificial uterus, Artificial womb, Biobag, Ectogenesis, Scoping review

Background

Discussions about technological interventions with “natural” human childbirth are not a new phenomenon. Indeed, significant scholarship has emerged over the last 100 years on the possibility of “ectogenesis”—reproduction outside of the human body [2, 3, 4, 5, 6, 7, 8]. The first wave of debates on ectogenesis is generally attributed

*Correspondence:

Angel M. Foster
angel.foster@uottawa.ca

¹ Faculty of Health Sciences, University of Ottawa, 1 Stewart Street, Room 312B, Ottawa, ON K1N6N5, Canada

² School of Social Sciences, Macquarie University, Sydney, NSW, Australia



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to British scientist J.B.S. Haldane as early as 1924 [1]. Complete ectogenesis is a still-theoretical reproductive process that can occur through “the development of artificial wombs that can sustain fetuses to term without the need for women’s bodies” ([5], p. 337). In contrast to complete ectogenesis through artificial womb technology (AWT), partial ectogenesis is “the continued gestation of a fetus after it has been removed from a pregnant person’s womb” [9].

Although efforts to develop AWT have seen limited success, a number of recent technological advances suggest that the technology could potentially be developing towards translation to human clinical trials. In 2016, Dr. Alan Flake, a fetal surgeon at the Children’s Hospital of Philadelphia, led the team of researchers that successfully enabled partial ectogenesis through the “Biobag” to support the continued gestation of eight lambs [10]. This milestone represents the most advanced extracorporeal support system developed to date [10]. In 2019, Dr. Frans van de Vosse, Professor of Cardiovascular Biomechanics, and Dr. Guid Oei, Head of Perinatal Issues, and their respective teams received a €2.9M Future and Emerging Technologies grant to develop their own prototype of an artificial womb. This funding mechanism is supported as part of Horizon 2020, a European program “aimed at securing Europe’s global competitiveness” [11]. The researchers aim to have their artificial womb prototype ready for human clinical trials within the next 5–10 years [12].

While the aim of these and other research projects is to improve the outcomes and survival of premature human babies [10], these advancements in the development of AWT have spurred new and rapid debates regarding the future prospects of this technology, particularly in relation to complete ectogenesis for humans. Partial and complete ectogenesis could have significant impacts for how society perceives gender, kinship, and bodily autonomy and, as such, how AWT and other sexual and reproductive health technologies are regulated.

We conducted a preliminary literature search that revealed no existing scoping review protocols or finalized systematic/scoping reviews centered on AWT since the development of the Biobag. As a result, this scoping review will describe the state of the peer-reviewed literature on key domains of AWT debates. Our scoping review will identify key themes and research gaps such that academics, clinicians, and public policy decision-makers are able to determine where further research and discussion are required as this novel and potentially disruptive technology develops. This review therefore encourages and promotes a proactive approach to the modernization of legislation, regulatory frameworks, and existing policies and guidelines that may govern this technology [13–15].

Methods

Study design

To map the range of debates on AWT and identify gaps, our team from the University of Ottawa and Macquarie University will undertake a scoping review. The framework developed by Arksey and O’Malley [16] will guide our approach. Levac and colleagues (2010) expanded on Arksey and O’Malley’s framework [17], and we will incorporate some of these components into the study. This includes envisioning the intended outcome of the study to determine the purpose of the review, justifying decisions made and any resulting limitations, holding regular meetings between the researchers, and most importantly, treating the study as an iterative process. The final output will adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Extension for Scoping Reviews (PRISMA-ScR) checklist [18]. Accordingly, we developed this review protocol using the PRISMA-Protocols 2015 checklist (see supplementary file).

A scoping review is a defined, systematic, and rigorous process for rapidly gathering, analyzing, synthesizing, and conceptually mapping literature related to a specific topic or question [16, 19]. Scoping reviews do not require an assessment of the quality of assembled materials and as the body of literature under examination for this study is largely theoretical and speculative, such assessments will not be necessary [16]. The purpose of this scoping review is to summarize key debates in relation to ectogenesis and identify research gaps. As a result, this scoping review is considered a method in its own right, as opposed to forming one part of a larger systematic review [16]. Given the emerging nature of AWT and related debates, we believe a scoping review is the most appropriate approach, as the information has not been comprehensively reviewed and is diverse with respect to discipline and perspective.

Review question

This scoping review aims to respond to the following question: “What are the ethical, legal, and social debates surrounding artificial womb technology?”

Eligibility criteria

For this scoping review, we will engage only with English-language, peer-reviewed articles. The Biobag study was published in April 2017 which was a significant milestone in the contemporary history of AWT. We will focus on literature published from January 2016 through December 2025 (inclusive) to ensure that we capture debates happening immediately prior to the publication of the Biobag study.

Information sources

We will identify relevant studies from electronic databases including Scopus, PubMed, JSTOR, Proquest, Medline, LexisNexis, Westlaw, HeinOnline, and DOAJ.

Search strategy

Our search strategy will aim to locate peer-reviewed English-language publications. Inclusion criteria include:

- Published from January 2016 to December 2025
- Publications focused on ethical, legal, and social ramifications of artificial womb technology
- Publications that center on human ectogenesis

Exclusion criteria include:

- Publications in languages other than English, that were published outside of the date range, and/or those that were not published after a peer review process
- Publications that *solely* focus on the biological/scientific experimentation of embryos and/or produced scientific findings in relation to embryo culture conditions
- Publications focused on artificial reproduction within agriculture, literature, or other non-relevant domains

Study records

Data management

We will manage the references retrieved from the various electronic databases with Microsoft Excel[®]. Use of this management software will allow us to more easily find and extract duplicates and have a clear trail of the document screening process. Once we finalize the list of articles, we will download full-text versions and store them in an electronic cloud. This will enhance efficiency as the research is being conducted with researchers located in different countries.

Selection process

We will employ a two-stage process to identify relevant articles: (1) searching for articles in databases using keywords and (2) conducting a hand search of the reference lists of all retrieved articles to find any relevant sources not captured in the database or keyword searches. Two independent reviewers will select articles by screening titles and abstracts sequentially. Once this is complete, they will compare their lists of selected articles and delete any duplicates to create one list. If there are disagreements between the reviewers on which studies to include, they will discuss the differences and invite a third reviewer if they cannot reach a consensus. After

creating the title and abstract screening list, both reviewers will independently conduct a full-text appraisal of each article utilizing standardized inclusion and exclusion criteria outlined above. We will record and report the reasons for exclusion of full-text studies that did not meet the inclusion criteria for the scoping review. In sum, the two reviewers will compare their final lists of selected articles and discuss ultimate inclusion in the study until they reach consensus; a third reviewer will adjudicate disagreements.

Data collection process

Two reviewers will work independently to extract data and will chart the extracted data into a Microsoft Excel[®] spreadsheet (form). The reviewers will test the data extraction form with two articles. They will use the learnings from these test cases to modify and revise the data extraction form as required to ensure greater coherence. We will outline these modifications when we present the findings of the scoping review. The final paper will contain a PRISMA-ScR diagram showing the search, screening, and data extraction processes.

Data synthesis

We will present the data in a table or as a diagram in line with the aim of this review. We will also present the results of the final scoping review paper in a tabular format, followed by a narrative summary describing how the results relate to the aim of the review.

Discussion

Emerging sexual and reproductive health technologies, like AWT, have the potential to have profound impacts on how society understands gender, kinship, and bodily autonomy. This scoping review is part of a larger project that aims to understand public knowledge and perceptions of AWT.

Given the emerging nature of AWT and related debates, a scoping review is the best approach to capture the breadth and depth of current literature. This scoping review will identify key themes and research gaps with respect to current debates on AWT. We expect that the findings will provide a clear and in-depth analysis of current points of tension among those considering the future of AWT as well as identify areas for future research.

We anticipate that the results of this scoping review will be useful to a variety of stakeholders who have an interest in emerging assisted reproductive technologies. We will disseminate the results of this scoping review through a peer-reviewed publication and presentations at relevant conferences.

Abbreviations

AWT	Artificial womb technology
PRISMA-ScR	Preferred Reporting Items for Systematic Reviews and Meta-Analysis Extension for Scoping Reviews

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13643-025-02940-x>.

Supplementary Material 1.

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Authors' contributions

SH led the development of the scoping review protocol and led the writing of the manuscript. LLW and AMF provided guidance at all phases of the project's development and contributed to writing the manuscript. All authors read and approved the final manuscript.

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Data availability

Not applicable.

Declarations**Ethics approval and consent to participate**

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare they have no competing interests.

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Srishti Hukku, PhD(c), MPA of Kashmiri origins, is currently a cotutelle doctoral candidate in the University of Ottawa Population Health program and Macquarie University's Anthropology program. Srishti holds a Master of Public Administration from Queen's University and a Bachelor's degree in Political Science and Economics from McMaster University. Srishti's research focuses on sound public policy, sexual and reproductive health over the life course including 2SLGBTQ+ issues, and technology.

L. L. Wynn is a Professor in the School of Social Sciences (Discipline of Anthropology) at Macquarie University in Sydney, Australia. Lisa received her PhD from Princeton University's Anthropology Department, then subsequently held two postdoctoral research positions at Princeton's Office of Population Research and Center for Health and Wellbeing. Lisa's research focuses on gender, medical technologies, reproductive and sexual health, and their intersection with religion.

Angel M. Foster, DPhil, MD, AM is a Professor in the Faculty of Health Sciences at the University of Ottawa where she leads the Collaborative on Interdisciplinary Global Abortion Research and holds the 2024-2029 University Research Chair in Medication Abortion Studies. She received her DPhil from the University of Oxford, her MD from Harvard Medical School, and her master's and bachelor's degrees from Stanford University. Her research focuses on emergency contraception, abortion, and health professions education.