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Anticoagulation for pregnant individuals with cardiac conditions: A Systematic Survey Protocol

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ADMINISTRATIVE INFORMATION

Support - Heart & Stroke Foundation.

Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

Conflicts of interest - Rohan D'Souza reports grants from the Public Health Agency of Canada, Juravinski Research Institute, and Hamilton Academic Health Sciences Organization, International Vasa Previa Foundation, and the Perinatal Society of Australia and New Zealand and personal fees from Ferring, Sanofi and Pfizer outside the submitted work. He also holds a Tier-2 Canada Research Chair Award (#CRC-2021-00337). Other authors have no conflicts of interest to declare.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 July 2026 and was last updated on 28 July 2026.

INTRODUCTION

Review question / Objective The aim of this systematic survey is to describe what is known about anticoagulation regimens during pregnancy for individuals with cardiac conditions other than mechanical heart valves (MHVs) and the certainty of evidence behind clinical practice guidelines (CPGs) on the topic.

Rationale Pregnant individuals are at an increased risk of thromboembolic complications during pregnancy and the postpartum period due to gestational physiologic changes such as increased hypercoagulability and venous stasis (1-3). This risk is higher for pregnant individuals with pre-existing cardiac conditions including atrial fibrillation, heart failure with reduced ejection fraction, mitral stenosis, Fontan circulation, pulmonary hypertension and cyanotic heart disease (4) and may necessitate the need for anticoagulants during and after pregnancy (5). However, decisions regarding anticoagulation must balance between the benefits of preventing thrombosis and the risks of maternal bleeding, surgical and anaesthetic complications and perinatal adverse effects (6). Anticoagulation recommendations for these described cardiac conditions during pregnancy vary across institutions and regions (7) and rely mainly on expert consensus rather than high-quality evidence (8). Furthermore, many risk stratification tools used to guide the use of anticoagulation in the non-pregnant population are not validated in pregnant patients and may fail to capture pregnancy and post-partum specific considerations regarding thrombosis and bleeding (9). This systematic survey aims to synthesize the existing literature

and clinical practice guidelines to (a) determine what is known about the rationale, risks and benefits of anticoagulation for these conditions and (b) identify the evidence behind recommendations for prophylactic and therapeutic anticoagulation in pregnant individuals with cardiac conditions other than MHV.

Condition being studied Cardiac conditions including atrial fibrillation, heart failure with reduced ejection fraction, mitral stenosis, Fontan circulation, pulmonary hypertension and cyanotic heart diseases.

METHODS

Search strategy A comprehensive search strategy was developed in collaboration with a medical information specialist, in accordance with the Peer Review of Electronic Search Strategies (PRESS) guidelines (10). The search strategy included controlled vocabulary (medical subject headings/ Emtree) terms and keywords / free text terms related to anticoagulation, pregnancy, atrial flutter, atrial fibrillation, Fontan circulation, mitral stenosis, cyanotic congenital heart disease, and heart failure with cardiomyopathy (peripartum cardiomyopathy, noncompaction cardiomyopathy, Hypertrophic Cardiomyopathy) to retrieve relevant records. The search strategy was adapted for each database by using the appropriate controlled vocabulary and database-specific syntax. No limitations were applied regarding age, language, and publication year.

Participant or population Pregnant Individuals with the cardiac conditions including atrial fibrillation, heart failure with reduced ejection fraction, mitral stenosis, Fontan circulation, pulmonary hypertension and cyanotic heart diseases.

Intervention Any anticoagulant used for prophylactic or therapeutic indications in pregnant Individuals with the cardiac conditions of interest.

Comparator Not applicable.

Study designs to be included We will include both experimental and nonexperimental original research studies including randomized controlled studies, observational studies and case series as well as systematic reviews and meta-analyses of original research studies . Anticipating limited high-quality evidence for anticoagulation in the cardiac conditions of interest, we will also include commentaries, editorials, opinion papers, and narrative reviews and clinical practice guidelines. We will exclude single case reports unless they have been cited as the evidence justifying the use of anticoagulation in CPGs.

Eligibility criteria Studies and CPGs will be eligible, if they describe anticoagulation in pregnant individuals with cardiac conditions of interest. Although, we will include commentaries, editorials, opinion papers, and narrative reviews that may present rationales for the use of anticoagulation, these studies will be presented separately from original research studies and will not be included in assessing the certainty of evidence. If a single case report has been cited as the evidence justifying the use of anticoagulation in CPGs, we will appropriately down-rate while assessing the certainty of evidence. Articles on pregnant individuals with mechanical heart valves will be excluded as this is a unique condition with specific recommendations for therapeutic anticoagulation which has been extensively studied (11, 12).

Information sources The following databases were searched from inception to May 13, 2026 : Ovid MEDLINE, Ovid Embase , Ovid EBM Reviews – Cochrane Database of Systematic Reviews and Ovid EBM Reviews – Cochrane Central Register of Controlled Trials (CENTRAL). Turning Research into Practice (TRIP database) and the Guidelines International Network (GIN) database were also searched for the published guidelines on the topic. In addition, we also examined the reference lists of included studies and review articles to locate any additional studies that may have been missed in the initial search.

Main outcome(s) We will map the rationale, benefits, risks, and recommendations for prophylactic and therapeutic anticoagulation in pregnant individuals with cardiac conditions of interest. Outcomes will include the cardiac conditions addressed, anticoagulation regimens, recommendations from clinical practice guidelines, the certainty of evidence supporting each recommendation, and the evidence cited by guideline developers. An independent Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) assessment will be undertaken to evaluate the certainty of evidence related to each recommendation.

Additional outcome(s) Not applicable.

Data management All references and duplicate records will be managed and screened using Covidence systematic review software(13). Two reviewers will independently review the title and

abstracts to check inclusion and exclusion criteria. Any disagreements will be resolved by discussion or consulting a senior reviewer. Relevant studies will be reviewed in duplicate. The selection process will be depicted using a Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) Flow Diagram.

Quality assessment / Risk of bias analysis This systematic survey aims to synthesize the existing literature and clinical practice guidelines to determine what is known about the rationale, risks and benefits of anticoagulation for these conditions and identify the evidence behind recommendations for prophylactic and therapeutic anticoagulation in pregnant individuals with cardiac conditions other than MHV, rather than assessing the effectiveness of interventions. Therefore, a formal risk of bias assessment of included studies will not be conducted. Instead, the certainty of evidence supporting each recommendation will be independently evaluated using the GRADE approach.

Strategy of data synthesis We will extract data using a pre-piloted data extraction form. Extracted information will include year of publication; title; author names; journal; countries studied; study setting; study objective; name of cardiac condition; anticoagulation strategies; sample size; study period; study design; baseline characteristics and demographics of participants; cardiac, obstetric, and perinatal outcomes. Study reporting and presentation will be done in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses – Extension for Scoping Reviews (PRISMA-ScR) guidelines (14) and the synthesis without meta-analysis extension(15). The data will be synthesized narratively. Data will be stratified by cardiac conditions, anticoagulation regimen and study characteristics. The recommendations from each guideline will be tabulated as well as the stated certainty of evidence and the references cited in support of the recommendation. We will conduct a GRADE assessment (16) to independently review the certainty of evidence for each recommendation. Tables will be used to provide a descriptive summary of the key characteristics of the included studies, such as year of publication, the country, cardiac condition, sample size, study design, study period and baseline characteristics of participants. These tables may be organized by cardiac conditions. The associations of the regimen with the maternal and perinatal outcomes along with the strength of evidence will be presented separately. Figures will include PRISMA flowchart and visual summary of the results.

Subgroup analysis No subgroup analysis is planned.

Sensitivity analysis Not applicable.

Language restriction No language restriction were imposed in the search strategy.

Country(ies) involved The review will be carried out in Canada.

Keywords Anticoagulation; Scoping review; Pregnancy; cardiac condition; heart failure; atrial fibrillation; Fontan circulation; cyanotic heart disease.

Dissemination plans The results of the scoping review will be published in an open access academic journal with a global readership. The results will also be presented in national and international conferences (Cardiac and Obstetrics and Gynaecology).

Contributions of each author

Author 1 - Mohamad Chehab - Protocol development, title and abstract screening, full text screening, data extraction, and drafting a portion of the manuscript.
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