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Protocol

Knowledge, Attitudes, Behavior, Acceptance, and Hesitancy in Relation to the COVID-19 Vaccine among Pregnant and Breastfeeding Women: A Systematic Review Protocol

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Abstract: A new coronavirus, SARS-CoV-2, was identified at the end of 2019. It swiftly spread all over the world, affecting more than 600 million people and causing over 6 million deaths worldwide. Different COVID-19 vaccines became available by the end of 2020. Healthcare workers and more vulnerable people (such as the elderly and those with comorbidities) were initially prioritized, followed by the entire population, including pregnant and breastfeeding women. Despite the safety and efficacy of COVID-19 vaccines, a certain level of skepticism was expressed, including among pregnant and breastfeeding women. There were several reasons for this reluctancy, among them, fear of side-effects for both women and fetuses. Nevertheless, acceptance, as well as hesitancy, were time, country and vaccine specific. This review will collect available evidence assessing knowledge, attitudes, behaviour, practice and acceptance/hesitancy of pregnant/breastfeeding women in relation to the COVID-19 vaccination. The PubMed/MEDLINE, Scopus and EMBASE databases will be consulted. A predefined search strategy that combines both free text and MESH terms will be used. The systematic review will adhere to the PRISMA guidelines and the results will be reported in both narrative and summary tables. A meta-analysis will be conducted if data are available.

Keywords: pregnant women; lactating; breastfeeding; COVID-19 vaccine; acceptance

Citation: Gianfredi, V.; Berti, A.; D'Amico, M.; De Lorenzo, V.; Castaldi, S. Knowledge, Attitudes, Behavior, Acceptance, and Hesitancy in Relation to the COVID-19 Vaccine among Pregnant and Breastfeeding Women: A Systematic Review Protocol. *Women* **2023**, *3*, 73–81. https://doi.org/10.3390/women3010006

Academic Editors: Claudio Costantino and Maiorana Antonio

Received: 28 December 2022
Revised: 16 January 2023
Accepted: 16 January 2023
Published: 20 January 2023

1. Introduction

Vaccine hesitancy is a complex phenomenon that is listed as one of the ten threats to global health by the World Health Organization (WHO) due to the consequent decrease in vaccination coverage [1]. Several definitions of vaccine hesitancy have been proposed. The WHO defines vaccine hesitancy as a delay in the acceptance or refusal of vaccines despite their availability. Dubè et al. considered vaccine hesitancy to comprise a spectrum, with active demand for vaccines or their complete refusal at the two ends and vaccine-hesitant individuals in between [2]. However, heterogeneities in attitudes/practices/knowledge exist, with some people refusing some vaccines but agreeing to take others, or some others delaying or accepting vaccines but being unsure to do so. In addition, Peretti-Watel et al. defined vaccine hesitancy as a complex decision-making process influenced by several contextual factors [3]. On this basis, in 2015, the Strategic Advisory Group of Experts on Immunization (SAGE) Working Group on vaccine hesitancy developed a theoretical model named the 3Cs to explain the complexity of vaccine hesitancy and its determinants [4]. The 3Cs refers to the three main factors: *complacency*, *convenience* and *confidence*. From 2015 to the present, the 3Cs model was revised based on the outcome of literature reviews and theoretical considerations [5]. The new 5Cs model is based on five psychological antecedents of vaccination: (1) *confidence* in the safety and efficacy of vaccines and trust in the system and providers that deliver them, (2) *complacency*, reflecting a low-perception of the risks linked to the vaccine-preventable disease and the consequent belief that the vaccination is not necessary; (3) *constraints*, physical and psychological barriers that cause vaccination to be perceived as inconvenient, threatening the

conversion of vaccination intention into actual behavior; (4) *calculation*, the active effort in searching for information about risks and benefits of vaccination, though this commitment is not always associated with the ability to understand studies and data; and (5) *collective* responsibility, defined as "the willingness to protect others by one's own vaccination by means of herd immunity. The flipside is the willingness to have a free ride when a sufficient number of other people are vaccinated".

The 3C or 5C models provide a framework within which vaccine hesitancy/acceptance can be analyzed. In this respect, many studies have been conducted to date to better understand factors associated with vaccine hesitancy/acceptance. These factors include sociodemographic factors, such as ethnicity, age, sex, education, and employment; factors that depend on geographic or social context, such as accessibility and cost; the safety and efficacy of a new vaccine, lack of information or vaccine misinformation; and more personal factors, such as individual responsibility and risk perceptions and trust in health authorities and vaccines [6].

Among sociodemographic factors, pregnancy or breastfeeding represents a crucial period in which women seek information that will guide health decisions in relation to themselves and the unborn child. The safety of the unborn infant has been suggested to be the primary driver of decision-making during pregnancy [7]. In this context, exploring the knowledge, behavior and practice of vaccine acceptance/hesitancy among pregnant/breastfeeding women is important to plan counseling/education actions. This is particularly apposite considering the COVID-19 pandemic and the ensuing availability of new vaccines. A growing body of evidence suggests that COVID-19-related morbidity and mortality has been higher among pregnant women compared with age-matched non-pregnant individuals [8]. However, the novelty of the type of vaccines used, as well as the paucity of data about long-term effects (safety and efficacy) of the COVID-19 vaccine among the general population and pregnant/breastfeeding women, might impact on vaccination acceptance [9]. Emerging data from the Center for Disease Control and Prevention suggests that there has been no increase in side-effects or complications among pregnant women vaccinated against COVID-19 [10]. Considering data on the safety and efficacy of COVID-19 vaccines, public health programs have prioritized pregnant women as a high-risk group for COVID-19 infection and its complications. However, a certain level of vaccine hesitancy is commonly observed among pregnant women [11]. Moreover, pregnancy represents a time during which women, and the related family, are looking for information that can guide their own health choices and those of the unborn child [12]. Considering the above, the novelty of the COVID-19 vaccines, and recognising that vaccine hesitancy is vaccine-specific and depends on the socio-cultural background, we designed a systematic review and meta-analysis protocol with the purpose of better understanding the mechanisms underlying COVID-19 vaccine hesitancy among pregnant/breastfeeding women. Specifically, we aimed to assess the knowledge, beliefs, attitudes, barriers and facilitators relating to acceptance/refusal of the COVID-19 vaccine. Understanding the mechanisms underlying vaccination hesitancy is key to the design, testing and implementation of interventions that can improve vaccine acceptance and coverage in routine and outbreak settings.

2. Experimental Design

This systematic review protocol was developed based on The Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2015 guidelines, as extended for systematic review protocols (PRISMA-P) [13]. The review protocol was developed, shared among the authors, and submitted to the journal in advance, prior to commencing the review. The review will be conducted in accordance with the Cochrane Collaboration [14] and the results will be reported based on the PRISMA 2020 guidelines [15]. Moreover, if the necessary data are available, we will proceed with statistical pooling and a meta-analysis will be performed. The latter will be carried out and documented in accordance with the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) guidelines [16].

Research Question

The purpose of the systematic review (potentially with meta-analysis) is to answer the following questions: (1) What is the level of knowledge regarding COVID-19 vaccination among pregnant/breastfeeding women? (2) What are the facilitating/barrier factors associated with pregnant/breast-feeding women's acceptance/hesitancy to receive COVID-19 vaccine?

3. Materials and Equipment

3.1. Information Sources

A comprehensive, structured electronic search will be developed based on the research questions and conducted by checking three different scientific databases: PubMed/MEDLINE, Excerpta Medica Database (EMBASE) and Scopus. The electronic search will be conducted in the three databases during the same day by two different authors. If any discrepancy in records identification occurs between the two authors, it will be solved through discussion with a third (senior author) involved in retracing all the steps taken and checking for errors. The literature search will be supplemented by a review of the reference lists of included articles and, if available, by screening the reference lists of relevant similar reviews published previously in international scientific journals, consistent with previous research [17]. In addition, experts in the field will be contacted to potentially retrieve any additional relevant articles, as previously performed [18].

3.2. Search Strategy

A comprehensive and specific search strategy will be developed, combining medical subject headings (MeSH) and free text words. The search strategy will be defined according to the population, exposure, and outcome (PEO), as suggested by the Cochrane Collaboration [14]. We will first develop a search strategy for PubMed/MEDLINE. Then keywords and search terms will be adapted for use in the other two bibliographic databases. The Boolean operators AND and OR will be appropriately and logically combined in order to build the search strategy. The search strategy will be based on the following terms: (P) pregnant and breast-feeding women (and synonyms); (E) COVID-19 vaccination (and synonyms); and (O) knowledge, attitude, and practice (including factors associated with acceptance/hesitancy) regarding the COVID-19 vaccination (and synonyms). The specific search strategy will initially be created by a health specialist with extensive experience in conducting systematic reviews. Susequently, the search strategy will be adjusted based on input from the project team. The search strategy for PubMed/MEDLINE that will be adopted in the review is reported in Table 1.

Table 1. Search strategy developed in PubMed/MEDLINE.

Dataset	Search Strategy
PubMed/MEDLINE	"Breast Feeding"[Title/Abstract] OR "Pregnant Women"[Title/Abstract] OR "Maternal Behavior"[Title/Abstract] OR "Breast Feeding"[MeSH Terms] OR "Pregnant Women"[MeSH Terms] OR "Maternal Behavior"[MeSH Terms] OR "Postpartum Period"[MeSH Terms] OR "lactating"[Title/Abstract] AND ("attitude"[Title/Abstract] OR "knowledge"[Title/Abstract] OR OR "attitudes"[Title/Abstract] OR "behaviour"[Title/Abstract] OR "hesitancy"[Title/Abstract] OR "acceptance"[Title/Abstract] OR "barrier"[Title/Abstract] OR "barriers"[Title/Abstract] OR "behavior"[Title/Abstract] OR "behaviors"[Title/Abstract] OR "behaviour"[Title/Abstract] OR "behaviours"[Title/Abstract] OR "literacy"[Title/Abstract] OR "willingness"[Title/Abstract] OR "fear"[Title/Abstract] OR "facilitator"[Title/Abstract] OR "facilitators"[Title/Abstract] OR "determinant"[Title/Abstract] OR "determinants"[Title/Abstract]) AND ("COVID-19 Vaccines"[MeSH Terms] OR "2019-nCoV Vaccine mRNA-1273"[MeSH Terms] OR "BNT162 Vaccine"[MeSH Terms] OR "COVID-19 Vaccine"[Title/Abstract] OR "COVID-19 Vaccination"[Title/Abstract] OR "COVID-19 Vaccines"[Title/Abstract] OR "COVID-19 Vaccinations"[Title/Abstract] OR "Coronavirus Vaccine"[Title/Abstract] OR "Coronavirus Vaccines"[Title/Abstract])

4. Detailed Procedure

4.1. Inclusion/Exclusion Criteria

Studies will be selected based on the inclusion/exclusion criteria described below, defined according to the PEO strategy, along with additional information related to the study design, language, and time-span. Original population-based observational studies assessing the knowledge, attitudes and practice of pregnant or breastfeeding women in taking/refusing COVID-19 vaccination will be included in the review. By observational studies is implied all cross-sectional, case-control or cohort (prospective and retrospective) studies. Only English language, peer-reviewed articles published in international scientific journals will be considered. All articles published between 2019 and the date of the review's conclusion will be considered eligible for inclusion. The systematic review's exclusion criteria include the following: studies not performed among humans or that were conducted on a different population (for instance, the general public, women in general, parents or only mothers of children older than one year, and children's caregivers in general); studies combining data with different and multiple outcomes, or assessing different outcomes not listed in our inclusion criteria (for instance, articles assessing the efficacy, serology, immunology, safety, and development of the COVID-19 vaccine in pregnant or breastfeeding women); articles assessing acceptance/hesitancy/refusal against vaccines other than COVID-19; articles not written in the English language and those not published in peer-reviewed international journals; non-observational studies, e.g., trials (randomized or non-randomized controlled trials); and, lastly, non-original research papers, including reviews or meta-analyses, articles with no quantitative information or details, and non-full-text papers (e.g., letters to the editor, conference papers, commentary notes, expert opinions, abstracts). There will be no restrictions based on the type of setting, such as community-based or hospital-based populations.

4.2. Selection Process

All the retrieved studies will subsequently be downloaded to the EndNote software (EndNote® for Microsoft, Redmond, WA, USA, 2020). Duplicates will be removed using an automatic function in the EndNote software, followed by a manual check by one of the authors. The remaining articles will then be assessed for eligibility, firstly based on the title and abstract, followed by their full text. Two authors will independently undertake the two-step screening process by applying the inclusion/exclusion criteria detailed above. If any doubt or disagreement should arise during the two screening steps, this will be solved through a direct comparison between the views of the two authors. If divergences still persist, a final arbitrator will settle any disagreements over inclusion. Reviewer authors will be blind to the journal title, authors, and their institutions/affiliations. However, to increase agreement between the two reviewer authors, a pilot assessment will be conducted on 20 randomly selected retrieved articles [19]. Repeated articles and multiple publications from the same study will be excluded and all the reasons for exclusion will be reported. The results of the selection process will be detailed at each stage and reported using the PRISMA flow diagram.

4.3. Data Extraction

The data extraction process will be performed in duplicate by two reviewer authors. A standardized and pre-defined Excel (Microsoft Excel® for Microsoft 365 MSO, USA, 2019) spreadsheet will be used to extract data from the included studies [20]. The spreadsheet will initially be piloted on one-third (or no more than five, depending on the total number) of included articles to increase consistency between the two reviewer authors [21]. The following information will be extracted from each article included: author name, study period, country where the study was conducted, study settings, main characteristics and the study population's number, study completion rates (attrition), tool(s) used to assess the outcomes, number of items, whether the tool(s) was/were validated or not, manner in which the questionnaire was administered, recruitment methods, outcomes of interest,

outcomes definition, main results, and funds and conflicts of interests, if any. Vaccine coverage will also be recorded, if available.

Nevertheless, recognising that outcomes of interest are composite measures, we will extract data directly as reported in the original articles even if unvalidated instruments are used to assess the outcomes. Furthermore, despite a general consensus on the definition of vaccine hesitancy/acceptance, no unequivocal tool or operationalization method is in place to evaluate it [22]. Rather, several instruments and statistical methods are commonly used. In light of this, we anticipate substantial variation in the methods used to report results. For this reason, when available, we will also extract methodological information, such as whether the tool was validated or not and the statistical analysis undertaken. Lastly, if studies report data using risk estimates, for instance, odds ratio (OR), risk ratio (RR) or hazard ratio (HR), we will collect the maximally adjusted data, along with the list of variables used for the adjustment [23].

The data collected will support the assessment of the study quality and will be used for data synthesis.

4.4. Quality Assessment

The risk of bias of the included studies will be independently assessed by two reviewers. Disagreements between the reviewers will be discussed and resolved by consensus. However, insights from a third reviewer will be sought if necessary. The Joanna Briggs Institute (JBI) quality assessment tools will be used to assess the potential risk of bias in each included article [24]. We opted to use the JBI tools due to the availability of separate checklists for each study design (e.g., cross-sectional, case-control, and cohort studies) [25]. The JBI tools are based on eight items that explore seven different domains: (i) participant selection, (ii) setting definition, (iii) ascertainment of the exposure; (iv) validity of condition measurement; (v) identification of confounders and dealing strategy, (vi) ascertainment of the outcome, and (vii) appropriateness of the statistical analysis [24].

Assessed papers will be categorized based on their methodological qualities by applying a scoring system available in [11]. Specifically, for each of the eight items, four options are allowed: Yes, No, Unclear and Not applicable. We will assign 2 points for yes, -2 points for no, -1 point for unclear and 0 points for not applicable. The total score could range between -16 and 16. Articles scoring from -16 to 4 will be classified as low quality, articles scoring from 5 to 9 as moderate, and articles scoring equal to or more than 10 (and up to 16) as high quality.

5. Expected Results

The quantitative and qualitative results of the literature will be presented using descriptive tables. As previously performed [26], a narrative description of the main characteristics of the study (for instance, the study design, study period, country where the study took place), the population characteristics (for instance, the age of the women and their status), the methodology (for instance, the manner in which the survey was administered, if the tools were validated), and the outcome, will be obtained from the included studies. This description will help to identify similarities and differences among the studies. The main results will be presented with reference to the 5C model and synthesized using a narrative approach [5].

A pilot exploration of how many results will result was conducted on PubMed/MEDLINE (13 January 2023). A total of 184 records were identified.

5.1. Quantitative Analysis

If at least two studies report data for the same outcome using OR, RR, or HR and their 95% confidence interval (CI), then we will proceed to pool data through meta-analysis. When two or more studies report estimated risks (OR, RR or HR) for a specific factor, both random and fixed effects models will be used to calculate the pooled effect size. The pooled effect size will be reported as the OR with a 95% CI. We will assess the heterogeneity of

the studies using both the chi-square test and the I^2 statistic, as previously performed [27]. Heterogeneity will be classified into four categories based on the I^2 value (higher: $I^2 > 75\%$, moderate = I^2 ranging between 75% and 50%, low = I^2 ranging between 50% and 25%, and low = $I^2 < 25\%$). Publication bias will be assessed via visual inspection of the funnel plot and by means of the Egger regression asymmetry test, with statistical significance set at $p < 0.10$ [28]. If there is any publication bias, the trim and fill method will be performed [29]. All analyses will be conducted using Prometa3® software (Internovi, Cesena, Italy).

5.2. Subgroup and Sensitivity Analysis

If the necessary data are available, the analysis may be stratified according to the subjects' characteristics (e.g., pregnant or breastfeeding women), the country where the study took place and, lastly, the methodological quality of the studies (e.g., only including moderate/high methodological quality studies).

6. Ethical Considerations

This is a systematic literature review of the available literature using already published data. No interventions are planned, nor will there be any direct data collection from humans/animals. For these reasons, no ethical approval is required. The results of our review will be disseminated among academia, policymakers, healthcare professionals and the general public. For detailed information dissemination, scientific presentations at national and international congresses and conferences, peer-reviewed scientific publications, and posts on both academic and generalist social network platforms will be used.

7. Discussion

The current review will offer a comprehensive overview of the existing literature on the knowledge, attitudes, behaviour, acceptance, and hesitancy regarding the COVID-19 vaccine among pregnant and breastfeeding women. Although previous reviews have focused on knowledge, attitudes or behaviour in accepting/refusing vaccines, in general, the current review will focus on specific vaccines for COVID-19, which largely differ from other type of vaccines [30]. The differences include, first and foremost, the availability of several vaccines developed by numerous pharmaceutical companies (for instance, seven different vaccines were approved and authorised to be marketed in Europe) [31] that may increase uncertainty among individuals. Despite the fact that all these vaccines showed satisfactory levels of safety and efficacy in clinical trials [31–34], they were all administered to the general public, albeit with different indications [31]. This could cause people to be uncertain about vaccine preferences, which may raise doubts regarding vaccination [35]. Some vaccines share the same technology, while others were developed using different approaches. The first COVID-19 vaccines approved were those using viral mRNA (for example, those from Pfizer and Moderna). Subsequently, recombinant, adjuvanted vaccines (for example, those from Novavax), inactivated, adjuvanted vaccines (for example, from Valneva), and, finally, those using recombinant DNA technology (for example, from Janssen) were developed and approved [31]. Secondly, COVID-19 vaccines were the first mRNA vaccine administered to humans, which may have contributed to fear of long-term side-effects [36]. Thirdly, due to the novelty of the virus and its rapid global spread, there was an urgent need for safe and effective vaccines. For this reason, many efforts were made to expedite the testing and licensing of the vaccines. Consequently, the public could also have been affected by fear of poorly executed experimental trials and possible unknown side-effects [37]. Additionally, during the COVID-19 pandemic, the general public and pregnant/breastfeeding women directly experienced fear of the disease itself, fear not commonly perceived for other "old" vaccine-preventable diseases for which the vaccination programmes are known to have prevented millions of cases, dispelling the fear of the disease itself and leaving, instead, room for fear of possible, albeit rare and mostly non-serious, vaccine adverse effects [38]. Last, but not least, the great volume of information

(and even disinformation) readily available, especially on the internet and social networks, the so-called infodemic, has a substantial impact on vaccination acceptance [38–40].

The ultimate aim of the current review is to shed light on this still evolving area of research on the assumption that the results could help in understanding the barriers and facilitators of COVID-19 vaccine acceptance among a specific vulnerable sub-population. Pregnant women have a higher risk of severe complications from COVID-19 compared to non-pregnant women of reproductive age [41]. According to a large study conducted by the Centers for Disease Control and Prevention, pregnant women affected by COVID-19 have a higher risk of intensive care unit admission, invasive ventilation, extracorporeal membrane oxygenation, and death than non-pregnant women of reproductive age [8]. In light of this, and the associated high burden, it is of utmost importance to understand the reasons for hesitancy towards or acceptance of COVID-19 vaccines with the ultimate purpose of raising the vaccination rate among pregnant/breastfeeding women.

Some potential limitations of our work should be acknowledged. First, we will only be including articles written in English. This may exclude potentially relevant articles written in other languages, for instance, Chinese, the language of the country where the virus originally appeared. Moreover, we recognize the heterogeneity of outcomes, although this is a methodological weakness directly attributable to the content of the original studies published in the literature. However, the approach taken will enable us to assess a large number of studies, offering a broad overview of the phenomenon.

Despite the above-mentioned limitations, we conclude that our findings may be useful for both healthcare professionals and policy makers, as they can assist healthcare professionals in guiding pregnant and breastfeeding women through the decision-making process associated with receiving the COVID-19 vaccine [42–45]. Similarly, our findings could inform public health policies with respect to future vaccine communication strategies.

Author Contributions: Conceptualization, V.G.; methodology, V.G.; writing—original draft preparation, V.G., A.B., M.D. and V.D.L.; writing—review and editing, V.G. and S.C.; supervision, V.G. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

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