

N95 Filtering Facepiece Respirator Use during Pregnancy: A Systematic Review

Jared T. Roeckner, MD¹  Nevena Krstić, MS, CGC¹ Bradley H. Sipe, MD¹ Sarah G. Običan, MD¹

¹Division of Maternal Fetal Medicine, Department of Obstetrics and Gynecology, University of South Florida, Morsani College of Medicine, Tampa, Florida

Address for correspondence Sarah Običan, MD, Division of Maternal Fetal Medicine, Department of Obstetrics and Gynecology, University of South Florida Morsani College of Medicine, 2 Tampa General Circle, Suite 6053, Tampa, FL 33606 (e-mail: sobican@usf.edu).

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Abstract

Objective This study was aimed to systematically review the use of filtering facepiece respirators, such as N95 masks, during pregnancy.

Study Design A comprehensive search for primary literature using Medline, Embase, Scopus, Web of Science, and ClinicalTrials.gov was conducted from inception until April 2020 to find articles reporting outcomes of pregnant women using filtering facepiece respirator (FFR). Studies were selected if they included the use of FFR in pregnant women and reported an outcome of interest including physiologic changes (heart rate, respiratory rate, pulse oximetry, and fetal heart rate tracing) or subjective measures (thermal or exertional discomfort or fit). The Newcastle-Ottawa Quality Assessment scale was used to assess the risk of bias. The main outcome was to describe the physiologic changes in pregnant women compared with nonpregnant women. Due to the small number of studies and heterogeneity of reported outcomes a meta-analysis was not conducted. Results of the studies were synthesized into a summary of evidence table.

Results We identified four studies, three cohort studies and one crossover study, comprising 42 women using FFR during pregnancy. Risk of bias was judged to be low. Studies were consistent in showing no significant increase in maternal heart rate, respiratory rate, oxygen saturation, and fetal heart rate between pregnant and nonpregnant women using N95 FFRs for short durations. Repeat fit testing was not supported for women gaining the recommended amount of weight during pregnancy. No evidence was found to reach conclusions about prolonged N95 FFR use in pregnancy.

Conclusion Limited duration N95 FFR use during pregnancy is unlikely to impart risk to the pregnant women or her fetus.

Keywords

- ▶ N95
- ▶ filtering facepiece respirators
- ▶ pregnancy
- ▶ physiology of pregnancy
- ▶ fit testing

Key Points

- Limited N95 use unlikely to impart risk to pregnant woman/fetus.
- Prolonged N95 use in pregnancy is unstudied.
- Repeat fit testing in pregnancy likely unnecessary.

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In December 2019, the government in Wuhan, China, confirmed treating dozens of patients for a new viral illness. The culprit, a newly identified severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2), rapidly became a pandemic infecting over 3 million people at the time of the writing of this article. Health care systems and health care workers (HCWs) worldwide have been affected, none so intimately as the HCWs needing limited personal protection equipment, including N95 filtering facepiece respirators (FFR). In some countries, up to 75% of the health sector workforce is female and of those approximately 10% are pregnant at any one time.¹⁻³

The surgical mask, first utilized by a German surgeon in 1897, was originally implemented to minimize transmission of the surgical teams' oropharyngeal bacteria onto the patient's open wounds; and it quickly became the standard of care in operating rooms.^{4,5} In the era of air and blood borne viruses, masks have taken on the dual role of protecting the HCWs and patients. Concerns over severe viral pathogens causing SARS, Middle East respiratory syndrome (MERS), avian flu, and SARS-CoV-2 have increased the need for respiratory protection for HCWs. While surgical masks protect against viruses with droplet transmission of large respiratory particles (>5- μ m diameter), it is not the optimum protection among viruses spread by inhalation of particles (<5 μ m) evaporated from larger respiratory droplets. In these clinical scenarios, the use of an N95 FFR or equivalent is warranted.^{6,7}

Pregnancy results in significant physiological changes in the respiratory system that may impact N95 FFR safety and utility. Notable lung function changes include an increase in tidal volume, minute volume, and respiratory rate resulting in a decrease in plasma carbon dioxide (CO₂).⁸ Oxygen (O₂) consumption is increased by 20% due to increasing metabolic needs. Inspiratory and expiratory reserve, as well as residual volume decrease.⁹ In addition, there is edema of the respiratory tract and nasal congestion. N95 FFR use may increase discomfort and worsen these physiologic changes which may affect the fetus. Knowledge about the use and safety of N95 FFR is imperative in the pregnant population particularly in current times of increased mask use.

The increasing need for PPE in a pandemic has made it clear that there is not enough information on the extended use of N95 mask in HCWs and there is less information regarding their use in pregnancy. Thus, we performed a systematic review to gather and synthesize evidence relating to the use of N95 FFR during pregnancy.

Sources

This systematic review was preceded by a prospectively written protocol (PROSPERO registration no.: CRD42020179284) and was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.¹⁰ Institutional review board approval was not required. A search of published literature from database inception to April 24, 2020 was conducted with Medline, Embase, Scopus, Web of Science, and ClinicalTrials.gov ([Supplementary Material 1](#), available in the online version). A three-step search strategy was applied. First, a limited Medline search was conducted by a

medical librarian (AH) to obtain key words contained in the title and abstract and the index terms describing the article. Second, a search using the identified keywords and index terms was done across all included databases. Third, the reference list of all identified articles and reports was searched for additional studies. The key words "N95" and "pregnancy" were searched independently, as well as in conjunction, with the following keywords: "filtering facepiece respirator," "mask," and "physiological burden" ([Supplementary Material 2](#), available in the online version, for full search strategy).

Study Selection

Any study reporting outcomes among pregnant women using FFRs was identified and selected. Study selection was performed in a method similar to that described by Bramer et al.¹¹ All study designs were considered for inclusion if the study assessed one or more of the following outcomes: heart rate, respiratory rate, blood pressure, pulse oximetry, temperature (body temperature or facial temperature), transcutaneous CO₂ and O₂ saturation, and fetal heartrate monitoring. Studies reporting subjective measures related to mask usage including fit, comfort, perceived exertion, or surveys of opinions about mask usage in pregnant women were also considered. French-, English-, and Spanish-language studies were included, and studies were not limited to HCWs. Article references were screened for additional sources. Articles on non-N95 surgical mask use in pregnancy and articles not including pregnant women were excluded.

The primary outcome was a description of any possible changes in the physiological burden among pregnant women using FFR. Secondary outcomes included a descriptive summary of tolerability, fit, and perceptions related to FFR use. N95 FFR was defined as any type of filtering facepiece respirator. Blood pressure, pulse, respiratory rate, temperature (body temperature or facial temperature), transcutaneous CO₂ and O₂ saturation, and fetal heartrate monitoring were defined based on the study definition. Thermal discomfort and perceived exertion were obtained using the Frank Scale of Perceived Thermal Comfort or Borg Rating of Perceived Exertion, respectively.

Each study was scored for quality by two authors (J.R., B.S.) who employed the Newcastle-Ottawa Quality Assessment scale.¹² The Newcastle-Ottawa Quality Assessment scale is a risk of bias assessment tool that judges studies on three broad perspectives: the selection of the study groups, the comparability of the groups, and the ascertainment of the outcome of interest.

Data collected from each study were extracted onto a premade form and included first author, publication year, study design, language, number of pregnant and nonpregnant study participants, gestational age, type of FFR used, definitions for the outcomes of interest, and reported outcomes. The synthesis aimed to organize existing evidence into a clinically meaningful presentation of N95 FFR use in pregnancy. Results were organized into a summary of evidence table and described qualitatively. Owing to the small number of studies and heterogeneity of reported outcomes, a meta-analysis was not appropriate and quantitative estimates of pooled effects were not generated.

Results

The literature search identified 174 articles. After review of titles, abstracts and 16 full-text articles were screened for inclusion. Four articles including 42 pregnant women using FFR were selected for inclusion in the systematic review (→ Fig. 1). Included studies consisted of three observational cohort studies^{13–15} and one crossover study.¹⁶ Publication years ranged from 2014 to 2015 and all publications were in English. We did not encounter publications describing outcomes for non-HCWs. The gestational age of pregnancy ranged from 13 to 35 weeks. Study characteristics can be seen in →Table 1. The same cohort of women was used for three of the four studies with each study reporting different outcomes.^{13–15} The New-Castle Ottawa Assessment scale showed that most of the studies had a low risk of bias scoring eight of nine possible points (→Supplementary Material 3, available in the online version, for detailed scoring). The studies reported outcomes on various physiological parameters, on subjective variables of thermal and exertional discomfort, and on fit testing during pregnancy (→Table 1). Duration of testing was limited to a maximum of 1 hour and

exertion consisted of walking on a treadmill or riding a stationary bicycle.

All studies were consistent in the finding that N95 FFR use among pregnant women was not associated with increases in heart rate, respiratory rate, fetal heart rate, or O₂ saturation. Perceived thermal and exertional discomfort were not different between pregnant and nonpregnant participants. N95 FFR use was associated with increased transcutaneous CO₂ during exercise (increase 31.3–33.3 mm Hg, $p = 0.04$).¹³ A cross-over study¹⁶ showed decreased tidal volumes (relative change 23%; 95% confidence interval [CI]: 10.5–33.5%, $p < 0.001$), lower minute ventilation (25.8%; 95% CI: 15.8–34.2%, $p < 0.001$), and increased expired CO₂ (8.9%; 95% CI: 6.9–13.1%, $p < 0.001$), in pregnant women wearing N95 FFR compared with not wearing a mask.

To determine the impact of pregnancy on respirator fit testing, Roberge et al compared the facial measurements of pregnant women to those of nonpregnant controls matched for height.¹⁴ Pregnancy weight gain was estimated using the Institute of Medicine weight gain recommendations.¹⁷ Authors concluded that gestational weight gain within the recommended range did not significantly impact the facial

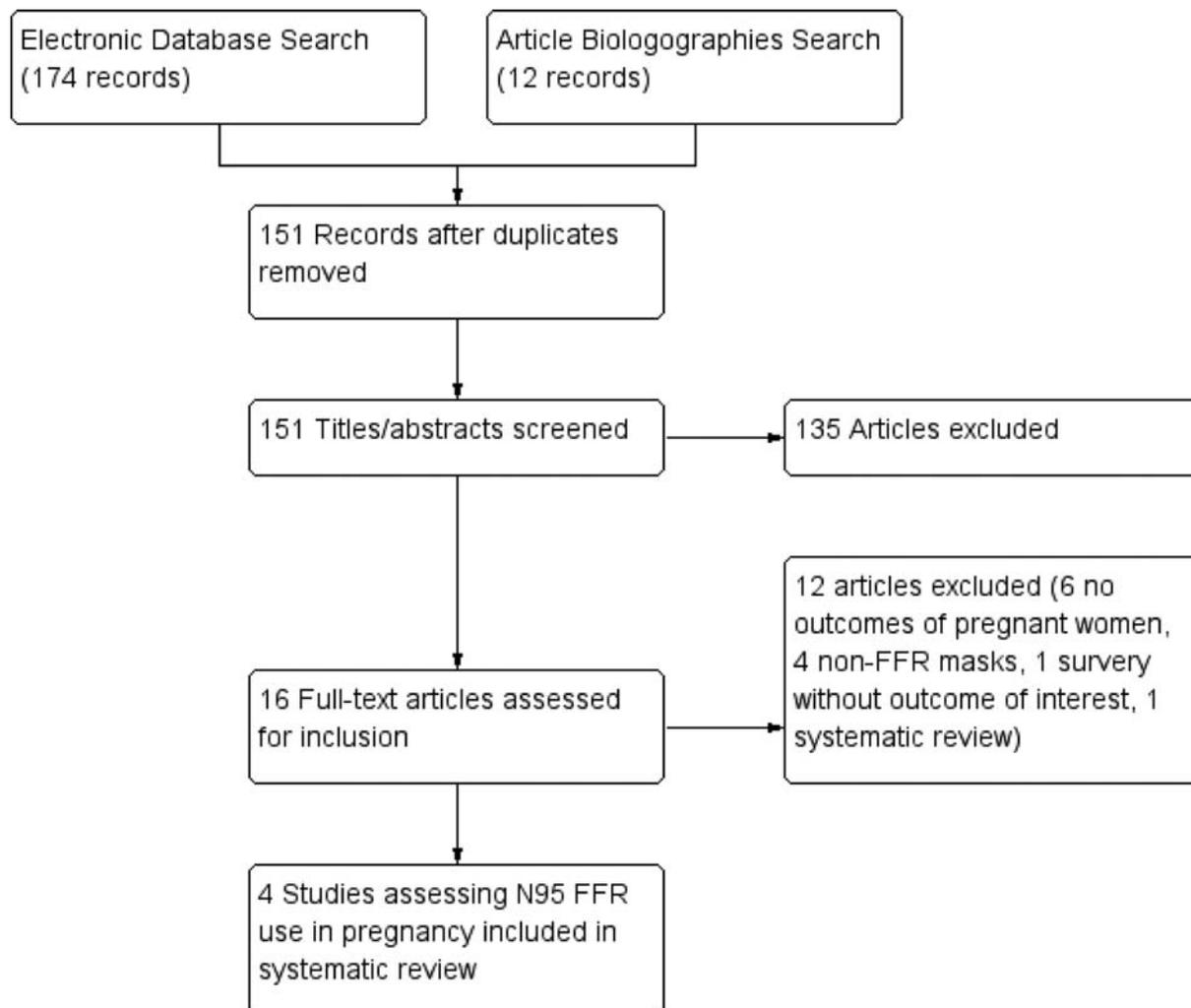


Fig. 1 Flow diagram of study selection process. (→Supplementary Material 4, available in the online version, has full-text citations with reasons for excluded studies). FFR, filtering facepiece respirator.

Table 1 Included studies

Author (year)	Study design	Pregnant versus nonpregnant	N95 FFR used	GA range (wk)	Outcomes measured	Exposure duration and intensity	Key finding(s)
Roberge ¹³ (2014) ^a	Prospective cohort	22/22	3M 9210; Moldex 2200, 2201	13–35	Objective: RR, temperature (chest, aural), HR, TcpCO ₂ , SpO ₂ , FHR Subjective: FSPC, BRPE	1-hour 20-minute standing 20-minute bicycle (60 cycles/min at 50 Watts resistance) 20-minute sitting upright	No differences in RR, HR, SpO ₂ , TcpCO ₂ , temperature, FHR, exertion or thermal discomfort between pregnant and nonpregnant cohorts
Kim ¹⁵ (2015) ^a	Prospective cohort	16/16	3M 9210; Moldex 2200, 2201	13–35	Objective: HR, BP, MAP, TPR, SV, CO, SpO ₂ , TcpCO ₂ , FHR Subjective: BRPE	1-hour 20-minute standing 20-minute bicycle (60 cycles/min at 50 Watts resistance) 20-minute sitting upright	No difference in HR, TPR, SV, CO, SpO ₂ , TcpCO ₂ , FHR between pregnant and nonpregnant women Increase in diastolic BP and MAP, and exertion in all subjects with N95 use
Tong ¹⁶ (2015)	Crossover	20 (all pregnant)	3M N95 material covering outlet of Hans Rudolph mask	27–32	Objective: VO ₂ /CO ₂ , HR, RR, TV, VE, FeO ₂ /CO ₂ , FietO ₂ , FietCO, FHR Subjective: BRPE	50 minutes 10-minute rest 15-minute treadmill (3 MET) 25-minute rest	No difference in HR, RR, oxygen saturation, lactate level, exertion, or FHR in pregnant women with and without mask Decrease in TV, VE, expired O ₂ with mask Increased expired CO ₂ with mask
Roberge ¹⁴ (2015) ^a	Prospective cohort	15/15	3M 9210; Moldex 2200, 2201	13–35	Objective: 13 cephalofacial anthropometric measurements in pregnant women matched to nonpregnant women with same height	Facial measurements quantitative fit testing	Pregnant workers who follow Institute of Medicine weight gain recommendations are unlikely to have an increase in cephalofacial dimensions that would mandate additional fit testing

Abbreviations: BP, blood pressure; BRPE, Borg's rating of perceived exertion; CO, cardiac output; FeCO₂, forced expired CO₂; FeO₂, forced expired O₂; FFR, filtering facepiece respirator; FHR, fetal heart rate; FietO₂/CO₂, forced inspired end-tidal O₂/CO₂; FSPC, Frank's scale of perceived (thermal) comfort; GA, gestational age; HR, heart rate; MAP, mean arterial pressure; MET, metabolic equivalent; RR, respiratory rate; SpO₂, pulse-derived oxygen saturation; SV, stroke volume; TcpCO₂, transcutaneous partial pressure of carbon dioxide; Temp, temperature; TPR, total peripheral resistance; TV, tidal volume; VCO₂, volume of carbon dioxide; VE, minute ventilation; VO₂, volume of oxygen.
^aStudies included the same cohort of women.

measurements ($p = 0.85$) and pregnancy did not appear to necessitate additional fit testing.

Discussion

The four studies identified in this review, consisting of 42 pregnant women, provide limited evidence that N95 FFRs use in pregnancy is likely safe for short duration as evidenced by absence of changes in maternal heart rate, respiratory rate, O₂ saturation, and fetal heart rate. Pregnancy-associated weight gain within the Institute of Medicine recommendations does not appear to necessitate additional fit testing. No conclusion can be reached about prolonged N95 FFR use in pregnancy and further work is needed clarify possible changes in tidal volume and increases expired CO₂.

The studies reviewed suggest that limited duration N95 use in pregnant women results in a minor impairment of gas exchange that does not ultimately lead to notable physiologic changes to the mother or fetus. The cross-over study by Tong et al found N95 mask use is associated with increased forced expired CO₂ (FeCO₂) concentration and decreased forced expired O₂ (FeO₂) concentration, suggesting a trend toward increased aerobic metabolism.¹⁶ However, there was no noted physiologic effect on the participants as evidenced by normal and unchanged fraction of inspired O₂ (FiO₂) and fraction of inspired CO₂ (FiCO₂) when wearing a N95 mask. Similarly, the cohort studied by Roberge et al and Kim et al failed to demonstrate significant physiologic changes related to N95 mask use in the pregnant population as evidence by unchanged pulse derived O₂ saturation (SpO₂) and transcutaneous CO₂ levels in their patients while standing or sitting.^{13,15} Roberge et al did show an increase in transcutaneous CO₂ levels over time during exercise among pregnant and nonpregnant patients wearing N95 FFR.¹⁴ It was theorized that the increase in CO₂ was due to rebreathing of higher CO₂ levels related to CO₂ retention in the dead space created by the mask; however, Tong disputes this argument given that the total CO₂ intake was decreased due to decreased minute ventilation.¹⁶ Additionally, while studies are limited, the increase in CO₂ over short duration is not expected to pose an increased risk to the developing fetus unless the levels are at a high-enough concentration to lead to more significant physiologic changes or loss of consciousness in the pregnant woman.¹⁸

While the slight increases in CO₂ found in these studies failed to have a significant physiologic impact on the pregnant participants, it is unclear if this would hold true with prolonged use of the N95 masks. Although most studies on mask usage in HCWs are limited to short durations, reviews of health care working conditions during the 2003 SARS epidemic illustrate the common practice of prolonged mask usage.^{19–21} The key question is “what is the maximum allowable time that pregnant women should wear a N95 FFR, particularly if she is an HCW?” In a 4-hour simulation of moderate breathing using N95 FFRs in a nonpregnant population, there was a 3% increase in inhalation and exhalation resistance which the authors stated would not significantly increase breathing resistance.²² Additionally, in nonpregnant HCWs, prolonged use of N95 FFR for 12-hour shifts

was associated with increased transcutaneous CO₂ levels greater than those seen in the studies included in this review; however, these levels failed to reach the clinical definition of hypercapnia.²³ An observational study of 53 nonpregnant surgeons using surgical masks showed decreased O₂ saturation and increased pulse with operations lasting more than 3 hours.²⁴ Though our review suggests that gas exchange changes associated with N95 FFR use are similar in magnitude in the pregnant and nonpregnant population, it is possible that the effects elicited by prolonged use may have a greater physiologic impact on the pregnant woman. Further studies are therefore needed to elucidate the clinical significance, if any, of prolonged N95 mask use on pregnant women, with particular focus on the effects of increasing CO₂ levels.

In a recent survey, 87% (89/102) of nursing students supported the statement that pregnant HCWs should be prioritized to receive N95 masks during a pandemic.²⁵ Despite evidence supporting the need to stockpile FFRs and articles exploring the cost of such measures,^{26,27} shortages of N95 FFRs will continue prompting prolonged use, reuse, mask-over-mask covering techniques, and additional creative solutions. A study of 48 pregnant women ranging from 32 to 42 weeks of gestation which included 24 women in active labor, showed that wearing a gas mask for 30 minutes did not change pulse oximetry and fetal heart rate measurements.²⁸ No significant differences in heart rate, breathing rate, tidal volume, minute volume, and transcutaneous CO₂ and O₂ saturation were observed with application of the surgical mask placed over a N95 FFR for 1 hour in a cohort of 10 nonpregnant HCWs.²⁹ Exertion and comfort scores were not significantly impacted by the additional surgical mask placed over the N95 FFR. Additionally, when used alone, surgical masks did not alter several physiological parameters in a cohort of 20 nonpregnant HCWs.³⁰ Surgical masks were as effective as N95 FFR in the outpatient setting for the prevention of influenza and other respiratory infections in a large, cluster-randomized clinical trial.³¹ As there is less resistance in surgical masks than N95 FFRs, surgical masks should be equally, if not better tolerated by pregnant women, although prolonged use of surgical masks also needs further validation.

While we found limited data on N95 FFR comfort in the pregnant population in this review, extrapolation from the body of FFR literature in the nonpregnant population is informative. Multiple studies outline the discomforts of wearing N95 FFRs including increase in temperature,^{32–34} humidity and facial irritation,³⁵ itchiness, headaches,³⁶ acne,³⁷ and increased work of breathing.^{38,39} Thermal discomfort and facial irritation may lead to additional mask adjusting and face touching, which could minimize the effectiveness of the respirator. In a survey conducted on psychosocial impacts of 2013 SARS outbreak, in addition to concerns regarding personal and family's health, approximately 85% (1,710/2,001) of HCWs noted that wearing a mask was particularly burdensome, most frequently due to physical discomfort.⁴⁰ Despite these drawbacks, research suggests that N95 FFRs are generally well tolerated. Improvements to the FFRs are underway and new designs may ameliorate some of these complaints.^{41–43}

Outside the scope of the studies reviewed but of interest to the pregnant population is the potential teratogenicity of materials utilized in personal protective equipment. The filters used in modern National Institute for Occupational Safety and Health (NIOSH) certified N95 FFR and surgical masks are primarily composed of polypropylene fibers, while the shell is composed of polyester, the nose foam of polyurethane, the straps from thermoplastic elastomer, and the nose clip of aluminum.⁴⁴ Because these materials are chemically inert and do not release, or otherwise result in exposure to a hazardous chemical, manufacturer-provided information, indicating inhalation or ingestion of the components is not expected to increase health risks to the user under normal use conditions. These materials are not considered to be hazardous by Occupational Safety and Health Administration (OSHA). There is no data regarding polypropylene, polyurethane, and polyester effects on human pregnancy. In circumstances where decontamination for reuse of N95 FFRs may be necessary, effects of the particular decontamination agent would need to be assessed. While not specific to pregnant women, a study noted that amounts of decontaminants retained by the FFRs treated with seven different energetic, gaseous and liquid chemical disinfectants were small enough that exposure to wearers is expected to be below the permissible exposure limit⁴⁵; therefore, these would likely pose minimal risks to a developing fetus due to minimal exposure.

Limitations and Strengths

Limitations of our review include the small number of studies. As three of the four identified studies used the same cohort of pregnant women and the outcomes varied between studies, meta-analysis of the results was not judged to be appropriate. One study¹⁶ approximated N95 FFR use by placing mask material over the outlet of a Hans Rudolph mask which may alter the respiratory dynamics. In study of fit testing,¹⁴ the mean body mass index (BMI) for both cohorts was 24 kg/m² and the method of estimating gestational weight gain had limitations. Studies varied in exercise methods and duration. Duration of use was only studied for 60 minutes limiting the applicability to the “real-world” pandemic conditions experienced by HCWs. Additionally, most studies were conducted under laboratory settings and may not reflect risks and outcomes in actual clinical or hospital setting. None of the studies provided evidence for the frequency or duration of breaks nor did they provide guidance for pregnant women with comorbidities as the cohorts were composed of healthy pregnant women. Strengths of the current review include use of a comprehensive search strategy with the aid of a librarian trained in systematic reviews, detailed review of references from selected articles, and systematic review registration.

Conclusion

This systematic review of N95 FFRs in pregnancy suggests that limited-duration use is unlikely to impart risk to the

pregnant women or her fetus, providing some reassurance to pregnant HCWs during the current coronavirus 2019 pandemic. There is a clear need for more research on the safe duration of N95 FFR use in pregnancy. While N95 FFR use can be bothersome, proper use affords the best protection from respiratory viruses and its usage should be encouraged.

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Conflict of Interest

None declared.

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