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Physiological Burden Associated with the Use of Filtering Facepiece Respirators (N95 Masks) during Pregnancy

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Abstract

Objective: The purpose of this study was to review the available literature regarding the physiological burden imposed on pregnant women by their wearing filtering facepiece respirators.
Methods: A medical literature search was conducted using MEDLINE (1996–2008) for English language articles, bibliographies of retrieved articles, electronic references from medical and governmental agency sources, and selected textbook articles.
Results: Two hundred thirty-four articles from the medical literature and 267 electronic references were retrieved, of which 51 articles from the medical literature, 25 electronic references, and 2 textbook articles were selected for data acquisition.
Conclusions: Very little rigorous scientific data exist on the physiological burden associated with the use of filtering facepiece respirators by pregnant women, and no definitive conclusions can be reached at this time. Although studies are warranted, they may be difficult to undertake because of health concerns and potential liability associated with the use of pregnant women in medical research. Computer modeling that incorporates features of pulmonary function in pregnancy might offer an alternative to human studies. Filtering facepiece respirators developed to meet the respiratory limitations of pregnant wearers might offer a universal design that would improve the comfort and tolerability for all users. Alternative strategies that limit the pregnant woman's contact with potentially infectious agents (e.g., job reassignment, working from home) may have to be employed in certain circumstances.

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Introduction

Pregnant women infected with influenza virus are at increased risk of morbidity and mortality,[1,2] and there is concern that the same could be true for other pathogens, such as the causative agent of severe acute respiratory syndrome (SARS).[3] In response to increasing concerns about the potential for an influenza pandemic, issues related to the care and protection of pregnant women during such an event, including the use of respiratory protection, have been highlighted recently.[4] Recommendations have been made for respiratory protection following natural disasters, such as floods and hurricanes, that are associated with mold and microbial growth that can be associated with significant respiratory symptoms (e.g., rhinitis, asthma exacerbation).[5,6] National Institute for Occupational Safety and Health (NIOSH)-certified filtering facepiece respirators (FFR), the most frequently used example of which is commonly (though incorrectly) referred to as the "N95 mask" (Figs. 1, 2, and 3), have been identified as one component of an overall strategy to help reduce the spread of influenza virus by the U.S. Occupational Safety and Health Administration (OSHA) and the Centers for Disease Control and Prevention (CDC).[7,8] FFRs are generally recommended over surgical masks (Fig. 4) for respiratory protection because, although the latter provide protection against large droplets, they do not provide an adequate facial seal and frequently do not have filtration characteristics equivalent to those of FFRs.[9] However, there is little reliable information or guidance regarding the use of FFRs during pregnancy.[7,10,11] Further, there are numerous inconsistent or contradictory statements about this topic. For example, a Canadian worker safety guideline[12] from the province of Alberta's Department of Employment, Immigration, and Industry stipulates that "pregnant workers with lower than normal pulmonary function should be carefully assessed as to their fitness to use respirators because of concerns that the diaphragmatic elevation during pregnancy and the increased oxygen demand of pregnancy produce a trend toward the likelihood of respiratory fatigue while

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FIG. 1. N95 filtering facepiece respirator. (Courtesy of Moldex, Culver City, CA.)

FIG. 2. N95 filtering facepiece respirator with exhalation valve. (Courtesy of National Institute for Occupational Health and Safety.)

FIG. 3. Surgical N95 filtering facepiece respirator. (Courtesy of Inovel, Culver City CA.)

wearing some respirators,"[12] whereas another guideline[13] from the same agency, addressing the medical assessment of respirator users, does not mention pregnancy. Pregnant physicians have been counseled to use FFR for protection from tuberculosis,[14] and it has been suggested that infection control practices, including respiratory protection, do not differ markedly between pregnant and nonpregnant healthcare workers (HCW).[15] A study investigating the medical evaluation of respiratory protective device users noted pregnancy to be the most common reason for denying medical clearance for respirator use, although this was not based on concern for adverse effects associated with respirator wear.[11] Some consumer advocates have advised pregnant women to refrain from the use of N95 FFR altogether.[16] Given these disparate views and recommendations, this study was undertaken to review the existing literature on the use of respirators by pregnant women.

Materials and Methods

A computerized literature search was undertaken using MEDLINE (1966–2008) for relevant articles using the search terms, pandemic influenza and pregnancy, influenza and respiratory protective equipment, SARS and pregnancy, gas masks and pregnancy, and estrogen/progesterone and respiratory function. Bibliographies of selected articles were also searched for relevant articles. A web-based search of relevant electronic references was performed using the same aforementioned search terms, and selected textbook articles were referenced. Articles selected for inclusion in the review were those that included information on the use of any type of respiratory protection (e.g., FFRs, surgical or medical masks,

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FIG. 4. Surgical mask. (Courtesy of Centers for Disease Control and Prevention.)

gas masks) during pregnancy, articles dealing with the respiratory physiology of pregnancy, and references related to government agency regulations pertaining to respiratory protection. A total of 234 articles from the medical literature were retrieved along with 267 web-based relevant articles and chapters from two textbooks.

Results

A total of 78 sources served as the databases for this study, including 51 articles from the medical literature, 25 electronic references from medical and governmental agency sources, and 2 textbook chapters. There were very few peer-reviewed articles specifically addressing the issue of respiratory protective equipment use by pregnant women, and there was a predominance of electronic references about this topic and associated issues.

Magnitude of the issue

The exact number of U.S. women who routinely use respirators in the course of their employment is unknown, but 60% of the female population are employed and account for 46% of all U.S. workers.[17,18] Approximately 3.3 million U.S. workers in private firms use respirators in the course of their employment.[19] Among the 4.3 million nurses and nursing aides in the United States, a proportion of whom use N95 FFR on a routine basis, 92% are women,[20] and many are in the childbearing age group.[15] Because of the current nursing shortage[21] and the increased work demands that may arise from novel emergent events, such as an influenza pandemic, pregnant nurses may not be able to avail themselves of the usual option of transfer to clinical areas that would offer less risk of infection. The current (presumed) significant number of women N95 FFR users in the working environment, coupled with the anticipated increased FFR use among all women during an influenza pandemic, underscores the potentially significant number of pregnant women who might be using FFR in such a setting.

Prior experience with respiratory protection in pregnancy

There are very limited data about the use of respiratory protection devices during pregnancy. A report describing the obstetrical delivery of two women wearing gas masks during a missile attack in Israel observed that there was no apparent effect on maternal or fetal oxygenation.[22] An Israeli study of the effect of tight-fitting, full facepiece gas masks worn by 48 women between 32 and 42 weeks of gestation (half of whom were in active labor) reported no significant change (>5% decrease) in maternal oxygen saturation and no fetal heart rate abnormalities on concomitant cardiotocography between baseline values and those measured after 30 minutes of gas mask wear. Maternal tachypnea (mild, but statistically significant) was observed and thought to be related to the increased dead space of the gas mask.[23,24] During the SARS outbreaks, an obstetrical unit in a Toronto hospital successfully instituted the use of N95 FFR for all patients during the entire duration of hospital stay (including labor) and reported that no pregnant woman contracted SARS; however, there was no discussion of N95 FFR-related issues (e.g., tolerability, comfort, compliance).[25] Another report during the Toronto SARS outbreaks mentioned the use of "masks" by participants in Lamaze birthing classes, but no details of their wear were provided.[26] Pregnant HCWs during the Toronto SARS outbreaks reported that wearing N95 FFR for any length of time caused increased fatigue that was, at times, extreme.[27]

N95 FFR impact on respiratory dynamics of pregnancy

The respiratory system undergoes a series of physical and physiological changes during pregnancy that are an adaptation to the increased metabolic burdens of gestation and parturition. Respirator use impacts human respiratory physiology to variable degrees, but these effects on the gravida and fetus have not been examined in detail. Specific areas of concern include impact on nasal airway resistance, effect on pulmonary airway resistance, influence on lung volumes, oxygen saturation effects, increased carbon dioxide levels, respirator tolerance, and regulatory issues.

Discussion

Nasal airway resistance

Approximately two thirds of total airway resistance is derived from the nasal passages, and nasal patency is predominantly controlled by changes in nasal capacitance vessels.[28] Elevated levels of progesterone and estrogen during pregnancy bring about a vasorelaxant effect on blood vessels by modulating calcium channel activity in the plasma membrane of vascular smooth muscle[29,30] so that blood vessels in the nose become progressively more dilated and engorged (capillary congestion). Associated edema of nasal tissues may occur by leakage of plasma from these engorged vessels[31] or as a result of the general increase in interstitial fluid volume that occurs with pregnancy.[32] Pregnancy-related overactivity of the parasympathetic nervous system, one feature of which is to regulate glandular secretion, causes hyperplasia and

hypersecretion of respiratory tract mucous glands that further decrease the caliber of nasal air passages.[33]

The combination of increased nasal blood vessel capacitance, mucosal edema, and excess secretions leads to varying degrees of nasal obstruction that is experienced in 5%–32% of pregnant women and is termed rhinitis of pregnancy.[28,32] The natural respiratory path at rest is nasal, resulting in a number of beneficial effects on inhaled air (e.g., conditioning [humidification, warming], filtration, transport of nitric oxide from the sinonasal unit to the lungs [induces vasodilation]).[31,34–36] The nasal congestive symptoms of rhinitis of pregnancy could make it difficult to tolerate an N95 FFR; however, there are pregnancy-safe nasal decongestant therapies (e.g., nasal washing with physiological saline solution,[31] nasal corticosteroid aerosols,[32] pregnancy-approved antihistamines) that might diminish nasal congestion sufficiently to enable tolerance to the respirator (pregnant women should always contact their health practitioner prior to use of any medication-related decongestant therapies). A theoretical concern is that both the increased mouth breathing associated with rhinitis of pregnancy[37] and the switch from nasal to mouth breathing that is a feature of respirator use[34] may cause the loss of more water vapor,[36] which can lead to increased breathing resistance due to blockage of the respirator's pores.[38] This might require more frequent change of N95 FFR.

Pulmonary airway resistance

Despite the increase in intraabdominal pressure caused by the enlarging uterus, maximal inspiratory and expiratory pressures do not change significantly during pregnancy. Elevated levels of progesterone and estrogen induce hyperpolarization of respiratory tract smooth muscle cell membranes by increasing the cell membrane permeability to potassium, causing a decrease in available calcium required in sufficient quantity for muscle contraction. This antagonism of muscle contraction results in bronchial smooth muscle relaxation and associated bronchodilation of medium and large airways that serve to maintain normal, prepregnancy airway resistance,[39–41] including unaltered peak expiratory flow rates.[42]

NIOSH, the U.S. agency responsible for respirator certification, has established N95 FFR breathing resistance limits of 35 mm and 25 mm H_2O pressure, respectively, for exhalation and inhalation (tested at a constant airflow of 85 L/min, which reflects a high work activity) that should impose a minimal physiological burden to the average user.[43] Support for this premise is found in a study of the physiological burden of wearing an FFR while treadmill exercising at 50% maximum oxygen consumption (50% Vo_2max), which reported low mean inhalation and exhalation resistances (−12 mm, +11.9 mm H_2O pressure, respectively).[44] Similarly, the controversial suggestion of use of a surgical mask as an outer barrier over an N95 FFR (because of the possibility of cross-contamination with respirator reuse) to increase the life of the respirator in the event of decreased availability during an influenza pandemic causes minor additional increases (±10%) over baseline N95 FFR breathing resistance, which should also be well tolerated.[45] For individuals who have difficulty with the breathing resistance offered by an N95 FFR, use of an exhalation valve-equipped model may be beneficial, although this allows for dissipation of respiratory pathogens from infected persons.

Lung volumes

Upward displacement of the gravid uterus causes a 4-cm elevation of the diaphragm, but lung volumes are, for the most part, well preserved in pregnancy because of compensatory increases in the transverse and anteroposterior diameters of the chest and flaring of the ribs.[46,47] Although some individual components of lung volumes are diminished in pregnancy (e.g., functional residual capacity, expiratory reserve volume, and residual volume are progressively decreased up to 20% at term[47] due largely to a 35%–40% decrease in chest wall compliance, increased abdominal mass raising the diaphragm, and low-to-normal expiratory muscle strength[46]), the minute volume increases in pregnancy. Progesterone sensitizes the respiratory center of the brain to carbon dioxide through either a direct stimulatory effect or an increase in the gain of the respiratory center chemoreceptors,[46] thereby causing a 40% increase in minute volume over baseline values while maintaining an essentially normal respiratory rate.[48] This boost in minute volume, without an accompanying increase in breathing rate, is brought about by an augmentation in tidal volume that is primarily attributable to enhanced rib displacement.[49] Relaxin, a polypeptide hormone that is increased in pregnancy, causes progressive relaxation of the ligamentous attachments of the ribs, thereby allowing greater lateral movement of the ribcage (flaring) and an increase in the thoracic circumference of approximately 5 cm, both of which enhance pulmonary excursions and expansion.[49,50] The increase in breathing resistance brought about by the use of some respirators can lead to a decrease in tidal volume and hypoventilation.[51] Although the breathing resistance offered by N95 FFR is low,[43] its effect on tidal volume is unknown at present. This is an important issue because the pregnancy-related loss of residual volume (which serves as an oxygen reservoir) increases the risk of hypoxia from hypoventilation,[46,47] and any respirator-related hypoventilation theoretically could also offset the progesterone-induced hyperventilation and lead to increased carbon dioxide retention.

Oxygen saturation

The increase in minute volume results in the uptake and exchange of more oxygen (O_2) and resultant higher arterial partial pressure (Pao_2 100–105 mm Hg) than in the nonpregnant state.[46] This higher Pao_2 reflects the greater metabolic demands of pregnancy (e.g., uterus, fetus) and the 50% increase in the O_2 cost of maternal breathing.[41,46] The impact of wearing an N95 FFR on O_2 levels has received limited scrutiny. O_2 levels within N95 FFR were noted to be decreased (i.e., 17.1%) over ambient levels during a study of respirator fit testing (OSHA considers atmospheres with O_2 concentrations <19.5% to be oxygen deficient[52]), but no significant change (i.e., <1%) was noted on the subjects' O_2 saturation.[10] In a NIOSH nonhuman study using an automated breathing and metabolic simulator that simulates human metabolism, minute ventilation, and human sinusoidal breathing waveforms, similar decreases in within-N95 FFR O_2 levels (i.e., 16.8%) were reported.[53] Patients wearing N95 FFR during dialysis treatment averaged a 9 mm decrease in Pao_2 over baseline values.[54] A recently completed study noted hypoxemia in HCW wearing N95 FFR while performing clinical duties.[55] Israeli researchers reported no changes in O_2 saturation during short-term (<2 hours) wearing of full-facepiece, negative

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pressure gas masks (20 cm H_2O breathing resistance) by women in advanced stages of pregnancy (32–42 weeks), half of whom were in active labor.[23]

A recently described modification of an N95 FFR, which allows supplemental O_2 to be administered through the respirator while not compromising filtration efficacy,[56] offers an interesting approach to individuals who might exhibit a decrease in O_2 levels while wearing a standard N95 FFR; however, this modification is not NIOSH approved. The ISO-O_2 oxygen mask, an N95 FFR respirator that incorporates an O_2 supply into the respirator, is approved for use by Canadian health authorities and is currently undergoing U.S. Food and Drug Administration (FDA) evaluation.[57] Australian health officials have recommended that suspected cases in an influenza pandemic requiring supplemental O_2 administration use nasal O_2 prongs (cannulae) or a nonrebreather O_2 mask, either of which should be covered with a surgical mask[58] (bearing in mind that surgical masks offer considerably less respiratory protection to the wearer than an N95 FFR[59]).

Carbon dioxide levels

The lower arterial carbon dioxide ($Paco_2$) levels noted during pregnancy (26–34 mm Hg) are the result of the increased minute volume that allows for more gaseous exchange at the alveolar level. Concomitant increased renal excretion of bicarbonate, to counteract the lowered $Paco_2$, leads to a compensated respiratory alkalosis. The lower $Paco_2$ is thought to provide a diffusion gradient from the maternal blood (the transfer of fetal CO_2 [normal 45–50 mm Hg] across the placenta is thought to require a $Paco_2$ difference of approximately 10 mm Hg between fetal and maternal circulation[60]) that facilitates the fetus's ability to eliminate CO_2 from aerobic metabolism and develop at physiological $Paco_2$ values.[41,48] There is limited human research with respect to the effects that wearing an N95 FFR has on CO_2 levels. One study of HCW (nonpregnant) wearing N95 FFR reported increased $Paco_2$ levels, but the results have not yet been published.[55] Elevated within-respirator CO_2 concentrations (i.e., 2.8%) were reported for subjects wearing N95 FFR,[10] thereby suggesting the possibility of entrainment of greater than normal amounts of CO_2 (ambient $CO_2 = 0.5\%$). Similar findings of elevated within-respirator CO_2 levels (i.e., 3.6%) were reported for N95 FFR in a nonhuman study.[53] Prolonged use of an N95 FFR, leading to increased breathing resistance (e.g., due to accumulated water vapor), could potentially increase within-respirator CO_2 levels, inasmuch as increases of 3–18 mm H_2O pressure can cause a 3% increase in end-tidal CO_2 levels.[61] Entrainment of air with elevated CO_2 concentrations is an important issue, given that maternal breathing of air mixtures containing 2%–5% CO_2 for 15–30 minutes has been shown to cause increased fetal respiratory rates and vasodilation.[62–64] The use of exhalation valve-equipped N95 FFR could serve to decrease within-respirator CO_2 levels, but at the cost of airborne dissemination of respiratory pathogens during exhalation. Use of a surgical mask as an outer barrier over such respirators might prevent dissemination of some of the pathogens expelled via the exhalation valve, but this combination is not currently NIOSH approved.[51]

Respirator tolerance

The ability of individuals to tolerate the extended wearing of an N95 FFR varies widely. Although a recent study documented an average of 1-hour use of N95 FFR by HCWs that was associated with a 68% comfort rating,[65] prolonged wearing of respiratory protection (as during the SARS outbreaks) has been shown to be associated with greater discomfort and less tolerability by a majority of HCWs.[66] Issues include physiological impact (e.g., facial warmth, breathing resistance) and psychosocial effects (e.g., communication difficulties, claustrophobic effects).[43] The issues of comfort, tolerability, and psychological impact have not been evaluated for the working population who may have to wear FFR for prolonged periods in pandemic or epidemic situations; however, researchers at the Veterans Administration recently completed a study (not yet published) addressing this issue in HCWs.[67] One study[68] noted that upward of 10% of the general population may be intolerant of respirators because of associated psychological issues (e.g., claustrophobia, anxiety) that, of themselves, can impart a sense of dyspnea. During the second and third trimesters, as many as three quarters of pregnant women experience the so-called dyspnea of pregnancy, a sensation of difficulty getting a deep breath, air hunger, or a sense of increased effort that accompanies the pregnancy-related increase in minute volume,[46] which may be related to awareness of the increased muscle effort required to generate increased tidal volumes, altered chest wall proprioceptors, or associated anemia.[37,41,69] Use of an N95 FFR could aggravate this sensation and negatively impact respirator use. Desensitization programs designed to gradually acclimate users to respirators have had some success in military circles.[70] Also, it may be that such issues as professional altruism (e.g., use of N95 FFR by pregnant HCWs during the SARS outbreaks[27]) and maternal safety concerns and selflessness toward the fetus (e.g., use of gas masks by pregnant women during wartime chemical attacks[22] and SARS outbreaks[25]) induce pregnant women to overcome the negative physical and physiological aspects of respirator wear.

Regulatory issues

Although respirator certification in the United States is the purview of NIOSH, the FDA grants approval of NIOSH-certified N95 FFR with special features for use in surgical venues (surgical/N95 FFR). The FDA does not test surgical N95 FFR or surgical masks but relies on data (i.e., fluid resistance, filtration efficiency, differential pressure, flammability) supplied by the manufacturer to grant approval as a medical device.[71] From a U.S. regulatory perspective, the OSHA CFR 1910.124 regulation governing respiratory protection in the workplace does not ask about pregnancy in its mandatory medical questionnaire.[11]

Leakage into the breathing zone while wearing an N95 FFR can occur (1) through the filter media itself, (2) at the face/N95 FFR interface, and (3) from other components of the respirator (e.g., exhalation valve); the combined leakage is termed total inward leakage.[72] Optimal protection from an N95 FFR requires that the respirator selected fits the wearer appropriately so as to minimize leakage at the face/N95 FFR interface. To ensure optimal N95 FFR fit and selection for workers who are required to wear respirators, annual fit testing (a qualitative or quantitative assessment of a respirator's performance on the wearer[73]) is mandated because studies have shown that fit testing is associated with improved respiratory protection.[74] OSHA also requires repeat fit testing if there

have been significant physical changes that might affect respirator fit (e.g., significant change in dentition, severe facial deformity, >20-lb. weight gain in <1 year[74]). Although pregnant women who are not required to wear a respirator as a condition of work would not have to undergo fit testing to wear an N95 FFR, the protection afforded might not be optimal. OSHA Respiratory Protection Standard provision 1910.134 (c) (2) describes the provisions for voluntary respirator use in the workplace.[75] Also, because average weight gain during pregnancy is >20 lb and increased body mass index (BMI) associated with weight gain has been shown to affect facial measurements that are used in fit testing,[76] it is possible that an appropriate fit-tested respirator selected in early pregnancy might not be adequate in the latter stages of pregnancy (if there is facial weight gain). Lastly, because the hood apparatus used in qualitative respirator fit testing has been shown to house increased CO_2 concentrations and decreased O_2 levels that could be potentially harmful to the pregnant woman,[10] it may be prudent to employ only quantitative respirator fit testing during pregnancy.

Conclusions

The issue of respiratory protection for pregnant women is an important one, but, unfortunately, there is little guidance available based on sound scientific data. Many of the issues raised in this review have not been adequately researched and resolved for the general public, let alone the pregnant woman. The dearth of reports on this topic and the increased risk to the pregnant woman and her fetus associated with some respiratory pathogens underscore the pressing need for research. Because of general prohibitions against the use of pregnant women in research (out of concern for the health of the mother and fetus, as well as legal concerns), guidelines for the use of respiratory protective equipment in pregnant women will have to be developed from scientific data derived from nonpregnant wearers. It may be possible to develop computerized mathematical modeling using pregnancy-related pulmonary function data.[77] Lastly, it may be that for some pregnant women who are intolerant of respiratory protective equipment, alternative measures (e.g., job reassignment, working from home) may have to be used to limit exposure. Ongoing human studies at NIOSH's National Personal Protective Technology Laboratory are investigating the effects of N95 FFR on ventilation, O_2 saturation, CO_2 retention, and breathing resistance.[78] It is anticipated that the results of these studies will lead to the development of amelioration strategies for negative features of N95 FFR that might impact pregnant women. Ultimately, it may be that FFRs developed to meet the respiratory limitations of pregnant wearers might offer a universal design that could improve the comfort and tolerability for all users.

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Disclosure Statement

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