periFACTS® OB/GYN Academy
Obstetric and Fetal Monitoring Course
Case #1144

Date of release: May 1, 2014 **Period of Validity: May 1, 2014 through May 31, 2014**

About the Program
periFACTS® is a self-instructional program designed to assist obstetric healthcare professionals in the acquisition of the knowledge and expertise needed to provide quality care for childbearing women.

This online, enduring material has been developed from the content of the periFACTS Program, presented by the Department of Obstetrics and Gynecology at the University of Rochester School of Medicine and Dentistry in Rochester, NY.

Target Audience
This educational content is intended for obstetric care providers.

Learning Objectives
After completing the program modules, participants should be able to:

- Identify factors that place the maternal-fetal unit at risk and how they may present on the fetal heart rate tracing.
- Discuss the clinical assessment, including fetal heart rate interpretation, and nursing management of common obstetric problems.
- Recognize and discuss the physiologic factors affecting the maternal-fetal unit and how they may present on the fetal heart rate tracing.
- Present the National Institute of Child Health and Human Development's vocabulary and classification system for fetal heart rate interpretation.
- Describe components of fetal heart rate patterns: baseline fetal heart rate, variability, periodic and nonperiodic changes, and contraction patterns.
- Describe the role, responsibilities, and accountability of professional obstetric nurses and healthcare providers relating to electronic fetal heart rate monitoring care.
- Describe appropriate nursing and collaborative interventions based upon the assessment of case presentations and fetal heart rate monitor tracings.
- Discuss required assessment, drug options, dose, and evaluation of pharmacotherapeutic agents and their impact on the maternal-fetal unit and/or neonate.

Planning Committee and Author/Speaker Declarations
The planners and presenters of this CNE activity have disclosed no relevant personal or financial relationships with any commercial interest pertaining to this activity. Director: James R. Woods, M.D. Planning Committee: Tamara Eis, M.S., R.N., Kathryn Flynn, R.N.C., M.S.N.P., Carol Giffi, R.N.C., M.S.N.P., J. Christopher Glantz, M.D., M.P.H., and Shirley Warren, R.N., M.S.N.P.-BC. Authors: Deborah J. Ossip, Ph.D. and Scott McIntosh, Ph.D.

Planning Committee: Elizabeth Warner, M.D., declares: Spouse/Partner Consultant to Harter; Secrest; and Emory, LLP

No Commercial funds or sponsorships have been received to support this educational activity.

Continuing Nursing Education Accreditation

The University of Rochester Center for Nursing Professional Development is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

ANCC Nursing Contact Hours Provided
___ (____ EFM) (____ PHARM) contact hours will be provided upon reading this Article and successfully completing the corresponding Clinical Case Study. Successful completion requires reading the Article, achieving a minimal score of 80% on the Clinical Case Study, and completing the program evaluation.

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Current Subscribers

10,688 individual participants at 443 sites use the periFACTS® OB/GYN Academy. 159 nursing schools use periFACTS®'s Introduction to Fetal Heart Rate Monitoring Tutorial for student teaching.

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Minimum System Software Requirements

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Microsoft Windows 2000 or later
Internet Explorer (versions 8.0 through 10.0) or Mozilla Firefox (versions 25.0 and 26.0) or Safari (version 7.0) web browser
Google Chrome (version 32.0 and 33.0) web browser
Google Android Browser (1.6 or higher)
FlashPlayer (5.0 or later), QuickTime (6.3 or later), MediaPlayer (6.4 or later), or RealOnePlayer (2.0 or greater)
Adobe Acrobat Reader (5.1 or later)
Java VM 1.4 or later

MAC

MAC OS 10.2 or later
High-speed Internet connection recommended
Mozilla Firefox (25.0 and 26.0) or Safari (7.0) web browser with Flip4Mac plugin
FlashPlayer (5.0 or later), QuickTime (6.3 or later), MediaPlayer (6.4 or later), or RealOnePlayer (2.0 or later) or Flip4Mac
Adobe Acrobat Reader (5.1 or later)
Java VM 1.4 or later

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Obstetric and Fetal Monitoring Course

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May 2015 Topic: Substance Abuse in Pregnancy

Case #1144

E-CIGARETTES IN PREGNANCY
Discussion, Clinical Case Study, and Fetal Heart Rate Interpretation

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DRAFT

Learning Objectives for **periFACTS®** Cases #1144 and #1145: **In addition to the overarching Obstetric and Fetal Monitoring Course objectives**, upon completion, the learner also will be able to:

- Describe the basic function of an e-cigarette.
- Explain epidemiology of e-cigarette use.
- List potential adverse exposures and effects relevant to pregnancy and the developing fetus.
- Identify sources for interventions for tobacco cessation in pregnancy.
- Interpret R.S.'s fetal heart rate tracing.

INTRODUCTION

Cigarette smoking is the single most preventable cause of key adverse pregnancy outcomes (USDHHS, 2004, 2006, and 2014). In addition to reducing fertility and conveying long-term health risks to the mother, smoking during pregnancy increases the risks of ectopic pregnancy, placental abruption, miscarriage, preterm birth, low birth weight, stillbirth, and sudden infant death syndrome (SIDS). Children of mothers who smoked during pregnancy may develop respiratory illnesses, orofacial clefts, obesity, learning disabilities, and behavior problems. (Clifford, 2012; Dietz, 2010; Gaysina, 2013; Ko, 2014; USDHHS, 2004, 2006, and 2014; and Yochum, 2014). Family members also may experience adverse effects through exposure to secondhand smoke or to smokeless tobacco (USDHHS, 2006, and England, 2010). New tobacco products continue to appear, often with purported claims of safety or reduced risk. Electronic cigarettes are the most recent class of products to emerge, both nationally and globally.

WHAT IS AN ELECTRONIC CIGARETTE?

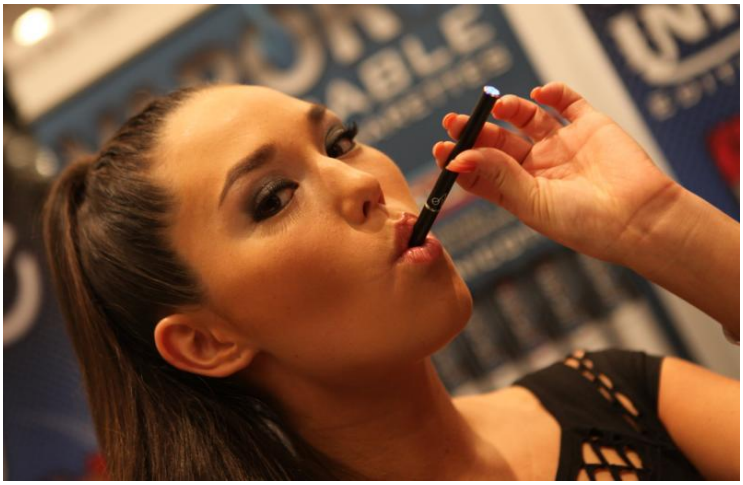
Electronic cigarettes, or e-cigarettes, are devices that do not require combustion for nicotine delivery. Instead, nicotine and other components are aerosolized for inhalation (Callahan-Lyon, 2012). E-cigarettes are the most popular subset of the broader category of electronic nicotine delivery systems (ENDS) that also include e-cigars, e-pipes, and e-hookahs.

E-cigarettes were launched in 2003 by Ruyan Technology in China, received their first international patent in 2007 (Bell, 2012), and by 2008 to 2009 were available globally. E-cigarettes include three basic components: a cartridge containing a liquid that typically includes nicotine dissolved in propylene glycol (PG) and/or glycerin/glycerol (generally of vegetable origin, VG) and a variety of flavorings, an atomizer that contains a heating element to vaporize the liquid, and a battery. Atomizers and cartridges may be combined into a "cartomizer." A sensor switch is activated when the user inhales, causing the heating element to aerosolize the solution in the cartridge to produce vapor that is inhaled into the lungs and exhaled as a vapor that resembles cigarette smoke. Users of e-cigarettes refer to this process as "vaping" (vs. smoking) and to themselves as "vapers." The liquid, known as "juice" or "e-juice," may contain differing strengths of nicotine (or no nicotine) and a variety of flavorings, such as chocolate, vanilla, butterscotch, cherry, pina colada, bubblegum, and others (note that all flavors except menthol are banned in the United States for use in combustible cigarettes). E-juices also may be made by local distributors and by users.

E-cigarettes may be disposable or refillable. First generation e-cigarettes resembled combustible cigarettes ("cigalikes"), whereas second- and third-generation e-cigarettes generally have larger capacity batteries, larger capacity tanks for e-juice, higher heating element temperatures, and adjustable resistance on the atomizer/cartomizer. These features of the newer generation e-cigarettes allow multiple options for user customization. The lack of quality control on the devices and e-liquids, combined with

user customization, result in wide variability in aerosol production, aerosol composition, nicotine delivery and, thus, potential risk (Bhatnagar, 2014, and Grana, 2014).

INSERT FIGURE 1 HERE.



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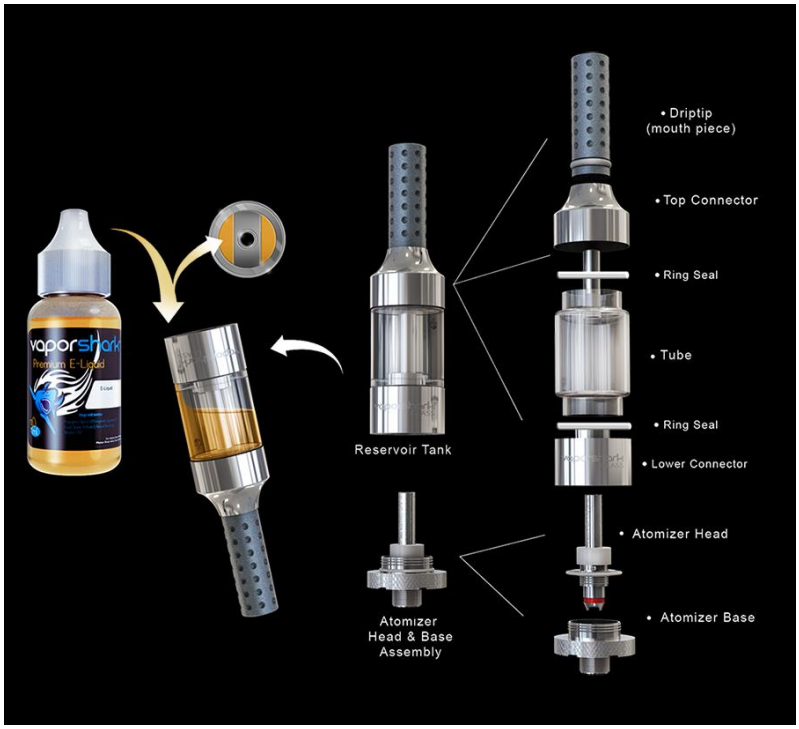

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As of January 2014, there were 466 brands of e-cigarettes and 7,764 unique flavors of e-cigarettes available (Zhu, 2014). All transnational tobacco companies now sell e-cigarette products (Chapman, 2014). None is regulated currently. In April 2014, the United States (U.S.) Food and Drug Administration (FDA) issued a proposed rule to extend its regulatory authority to additional tobacco products, including e-cigarettes (http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm394667.htm). Notably, the FDA deemed e-cigarettes to be tobacco products and, thus, subject to regulation consistent with other tobacco products. However, e-cigarette companies who say they intend to promote these products as smoking cessation aids will be required to use standard FDA approval channels for medications. The political and legal steps involved in the FDA ultimately obtaining regulatory authority over e-cigarettes are likely

to result in a lengthy process. In the interim, the e-cigarette market continues to grow while public health officials grapple with policy decisions and healthcare providers seek guidance in clinical interventions. On one hand, some researchers and advocates point to the potential harm reduction of e-cigarettes, citing literature indicating lower levels of many toxicants compared to combustible cigarettes. In contrast, others cite a range of risks of e-cigarettes, including presence of toxicants, per se (with some at levels comparable to those of combustible cigarettes), the potential for dual use of e-cigarettes with conventional cigarettes or other combustible products that obviates benefits, and the net public health damage if uptake of e-cigarettes occurs in those who would not otherwise try tobacco products, or in former cigarette smokers if e-cigarettes renormalize "smoking," and if smoke-free regulations exempt e-cigarettes (Chapman, 2014).

EPIDEMIOLOGY

Nearly half of adult (ages 18+) smokers and ex-smokers (47%) reported having tried e-cigarettes in the United States in 2013, with a 4% prevalence of regular use (Giovenco, 2014). Use was higher among young adults (18 to 44 years old) relative to older groups. It was also higher among, white non-Hispanics relative to non-whites, and unlike findings for combustible cigarettes, higher among those with some college education or more relative to those with high school or less education. In addition, the CDC reported a doubling of use among middle and high school students, from 3.3% in 2011 to 6.8% in 2012; of these, most were dual users of e-cigarettes and combustible cigarettes,

although 20% of middle school and 7% of high school students who ever used an e-cigarette were never smokers (CDC, 2013). The higher uptake among youth and young adults is consistent with marketing that specifically targets this group with social media campaigns and candy/fruit flavorings (Grana, 2014). Notably, this group includes women in childbearing years, suggesting that pregnant women may be a particularly vulnerable group for e-cigarette use. Also consistent with marketing messages, the most common reasons for trying e-cigarettes are for use in locations where smoking is prohibited, to reduce cigarette intake, for harm reduction, and for cessation of cigarette smoking (Grana, 2014, and Adkison, 2013). The four available clinical trials do not support the effectiveness of e-cigarettes as a cessation intervention (Grana, 2014).

HEALTH RISKS TO USERS AND NONUSERS

Health Risks to Users

Assessment of risk is complicated by the rapid development of new e-cigarette products, wide variation in composition of e-cigarettes even within the same product line, variability in purity of ingredients including nicotine, and discrepancies between levels of constituents (e.g., nicotine) reported on labels and actual levels (Grana, 2014 and Cameron, 2014). In addition, few studies are available specifically related to pregnancy or fetal development. Where available, these studies are summarized below. The remainder of the review includes findings with relevance to e-cigarette use or exposure in pregnancy.

Nicotine

E-cigarettes deliver nicotine (with the exception of zero nicotine formulations, some of which actually contain nicotine), which is a potential fetal teratogen. Research supports the role of nicotine in preterm delivery and stillbirth, and suggests an association with fetal growth restriction, congenital malformations, SIDS, and adverse effects on fetal lung and brain development (USDHHS, 2014). Blood levels of nicotine from e-cigarettes previously have been shown to be lower than levels from combustible cigarettes. However, more recent-generation e-cigarettes with larger capacity tanks and more powerful batteries that can produce higher temperatures for heating e-liquids may produce blood nicotine levels in vapors that are similar to those in cigarette smokers (Bhatnagar, 2014). The long-term effects of vaping aerosolized nicotine from e-cigarettes are unknown.

Nicotine refill cartridges can be purchased with varying levels of nicotine, some of which are sufficient to produce illness or death in infants and adults if ingested. The fatal dose of nicotine is approximately 30 mg to 60 mg in adults and 10 mg in children. A 5 mL vial of a 10 mg/mL nicotine solution contains a total of 50 mg of nicotine, and a comparable vial of a 20 mg/mL solution contains 100 mg of nicotine. If swallowed or absorbed dermally (for example, if the liquid accidentally spills on the skin), these would pose a high risk of acute toxicity or death (Cameron, 2014). Indeed, calls to U.S. poison centers for exposures to e-cigarettes have dramatically increased (CDC, 2014). Isolated cases

of deaths have been reported (Bhatnagar, 2014), along with a published case study of nicotine poisoning in a ten-month old infant who ingested a “small” amount of e-liquid containing nicotine (Bassett, 2014). The packaging of e-liquids that include cartoons, pictures, and appealing flavorings like lemonade likely increase the vulnerability of young children to ingesting these products (Bassett, 2014).

Other Toxicants and Potential Toxicants

Given the long time lag for development of tobacco-related illnesses, the ultimate health impact of e-cigarettes remains unknown. No studies of the impact of e-cigarettes on pregnancy outcomes have been conducted. However, studies of various components of e-liquid and vapor are available that have potential implications for pregnant women, although generally in non-pregnant samples.

Propylene glycol, a nicotine solvent commonly present in e-cigarette liquids, is considered by the FDA to be safe for consumption, but exposure can cause eye and respiratory irritation. Vaping an e-cigarette produces an immediate increase in airway resistance and a decrease in concentrations of FENO (fraction of exhaled nitric oxide), a standard marker of bronchial inflammation, potentially caused by propylene glycol inhalation or other components (Schober, 2014, and Vardavas, 2012). Further, the long-term effects of chronic inhalation may adversely affect the central nervous system, the spleen, and behavior (Grana, 2014).

A range of toxicants have been found in e-cigarette vapor, including carbonyl compounds (e.g., formaldehyde, acetaldehyde, acrolein, and o-methylbenzaldehyde), volatile organic compounds (VOCs, toluene, and p,m-xylene), tobacco-specific nitrosamines (TSNAs and NNN,NNK), and metals (e.g.,cadmium (Cd), nickel (Ni), and lead (Pb)). Although levels in e-cigarettes generally have been lower than in combustible cigarettes, most are higher than in the FDA-approved nicotine inhaler (Goniewicz, 2014). Carbonyls, such as formaldehyde, acetaldehyde, and acetone, may be present in e-liquids, or may be formed by decomposition of propylene glycol and glycerin (nicotine solvents commonly present in e-cigarettes) at high temperatures. Newer-generation, variable-voltage e-cigarettes allow users to adjust the voltage and, thus, the heat produced by the unit. Formaldehyde is classified as a Group 1 human carcinogen by the Agency for Research of Cancer (IARC) and acetaldehyde is classified as possibly carcinogenic (Group 2B); acetone is a mucous membrane irritant. A recent study reported a four- to 200-fold increase in formaldehyde, acetaldehyde, and acetone levels as voltage increased, with formaldehyde levels at the highest voltage comparable to levels found in combustible cigarette smoke (Kosmider, 2014).

Of particular relevance to pregnant women, a recent study demonstrated the cytotoxicity of multiple e-liquid refill solutions. Human embryonic stem cells and mouse newborn stem cells overall were more sensitive to the solutions relative to adult human pulmonary fibroblasts. These data suggest that e-cigarette exposure may pose particular risks for fetuses and newborns, and the authors hypothesize that the cytotoxic effects of some solutions could result in embryonic loss or developmental defects in

pregnancy. The cytotoxic effects observed were associated with chemicals used in the flavorings and not with nicotine, with the most potent effects observed being from a cinnamon formulation (Bahl, 2012).

E-cigarette aerosol contains fine and ultrafine particles, similar to those produced by combustible cigarettes (Bhatnagar, 2014). Exposure to fine and ultrafine particles from tobacco smoke can produce pulmonary and systemic inflammation and increase cardiovascular and respiratory disease and death risks; whether particles generated from e-cigarettes produce the same effects is unknown (Grana, 2014).

Finally, low levels of various metals (tin, silver, iron, nickel, cadmium, copper, and lead) have been detected in e-cigarettes and could be produced by the heating element. In addition, tin “whiskers” (crystals emanating from a tinned surface) have been produced from solder joints in some e-cigarettes. The toxicity of long-term inhalation of these metals is unknown (Bhatnagar, 2014, and Lerner, 2015).

HEALTH RISKS TO NONUSERS

Secondhand Vapor

Unlike cigarettes, e-cigarettes do not produce primary vapor from the tip of the product; however, exposure of nonusers does occur from the aerosol exhaled by users. Studies have shown that this aerosol produces a range of toxicants (e.g., formaldehyde,

acetaldehyde, isoprene, acetic acid, 2-butanodione, acetone, propanol, propylene glycol, polycyclic aromatic hydrocarbons, some metals, and nicotine) although generally at lower levels than observed with combustible cigarette smoke (Grana, 2014). Nevertheless, similar serum cotinine levels (a measure of nicotine uptake) have been found in subjects exposed to secondhand vapor compared to secondhand smoke (Flouris, 2013). In addition, the presence of any toxicants in secondhand vapor (even if lower than those in combustible cigarette smoke) produces a potential elevated risk for pregnant women. In addition, fine and ultrafine particles are present in secondhand vapor; adverse health effects have been demonstrated at very low levels of such particles and there is no lower threshold for harm (WHO, 2006).

Finally, concerns have been raised regarding the potential effects of third-hand exposure to nicotine through vapor. Third-hand exposure to tobacco smoke occurs when the deposit on surfaces from nicotine and other chemicals in secondhand smoke remain chemically active. They may form new toxicants not present in secondhand smoke and can be inhaled, absorbed dermally, or ingested. Third-hand smoke persists for months, likely longer, and currently, there are no known effective methods for cleaning or removing the toxicants (Matt, 2011). A recent study demonstrated that e-cigarettes resulted in third-hand vapor in the form of deposition of nicotine on various surfaces, and indicates the need for further research about the potential risks of third-hand exposure to the resulting carcinogens that may be produced by this nicotine that remains when the vapor has cleared (Goniewicz, 2014).

MARKETING AND BELIEFS

E-cigarettes are marketed widely through social media, as well on television and radio (where advertising for combustible cigarettes is banned). The most common marketing messages include that e-cigarettes are healthier (e.g., that they produce “harmless water vapor”), are less expensive and cleaner than cigarettes, can be smoked in places where combustible cigarettes are banned, and that they can be used for cessation (Grana, 2014a, and Grana, 2014b). These themes generally are cited by users as reasons for trying e-cigarettes (Grana, 2014a, and Adkison, 2013).

Specific to pregnancy, a single study was found in which 184 respondents indicated that they perceived e-cigarettes as less harmful than combustible cigarettes during pregnancy (Baeza-Loya, 2014). The authors suggest if this is a widespread belief, it may induce pregnant women to use e-cigarettes. For this current article, the authors (Ossip and McIntosh) conducted a nonrandom search of social media postings regarding e-cigarette use during pregnancy by entering the following search terms into Google: e-cigarettes and pregnancy; is it safe to smoke e-cigarettes in pregnancy; social media, e-cigarettes and pregnancy. Although most postings indicated caution in using these devices in pregnancy, there were favorable postings also. These postings reflect erroneous perceptions by a subset of pregnant women that e-cigarettes are less harmful during pregnancy relative to combustible cigarettes and that e-cigarettes without nicotine are safe.

A 2012 survey of obstetricians-gynecologists through the American College of Obstetricians and Gynecologists found that only 60% reported screening pregnant women for noncombustible tobacco products (including e-cigarettes) at intake. Regarding care providers' perceived health effects of e-cigarettes during pregnancy, 14% reported that they had no adverse effects, 29% reported that they have adverse health effects but are safer than cigarettes, 14% reported that the effects are the same as for cigarettes, and the remainder responded "didn't know" or did not respond. Approximately two-thirds indicated that they wanted to learn more about these products (England, 2014).

IMPLICATIONS FOR PROVIDERS

The evidence indicates that e-cigarettes are more than just "water vapor" and likely pose serious risks to the developing fetus. In addition, they expose nonusers to nicotine and a range of toxicants through second-hand and possibly third-hand vapor. Embryonic cells may be particularly vulnerable to toxicants in e-cigarettes. Toxicants and potential toxicants arise from nicotine and also independently from flavorings and other products' components (thus, even nicotine-free e-cigarettes cannot be classified as toxicant free). E-cigarettes have not been shown to increase cessation rates relative to other interventions. Uptake is highest during childbearing years, which make pregnant women a particularly vulnerable population. Although there is a need for additional research specifically focusing on the effects of e-cigarette use and exposure

during pregnancy, the current evidence base is sufficient to make certain recommendations for clinical care.

The American College of Obstetricians and Gynecologists provides tools for the obstetrician-gynecologist for routinely screening and treating tobacco use in all patients at all visits, and for appropriately coding for smoking cessation counseling (http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Tobacco-Use-and-Womens-Health; https://www.acog.org/~/media/Departments/Tobacco%20Alcohol%20and%20Substance%20Abuse/SCDP.pdf). Treatment is based on the 5As model (Ask, Advise, Assess, Assist, Arrange) for all patients, and on the 5Rs (Relevance, Risks, Rewards, Roadblocks, Repetition) for patients who are not ready to quit. Clinicians are encouraged to refer patients to their local free quitline (1-800-QUITNOW), some of which provide specific interventions for pregnant smokers, as well as to www.smokefree.gov, which provides web-based resources including free text messaging for cessation.

Based on the current review, the evidence supports the following additional points specific to e-cigarette use in pregnancy:

1. Clinicians should screen specifically for e-cigarette use in a unique question. Pregnant women tend to underreport smoking and tobacco use in general (USDHHS, 2014), and anecdotal evidence

suggests that e-cigarette users may not consider themselves to be tobacco users. Thus, embedding e-cigarette use under a broader question such as, “do you smoke or use tobacco; if yes, what do you use?” will miss e-cigarette users who do not self-identify as tobacco users.

2. Patients should be advised to completely quit using all tobacco (including e-cigarette) products AND to set and enforce 100% smoke-free home and vehicle policies that extend to e-cigarettes.
3. Obstetrician-gynecologists should support extending clean indoor air policies to e-cigarettes, as evidence suggests particular vulnerability of fetuses to e-cigarette exposure.
4. The evidence does not support the safety or effectiveness of e-cigarettes for smoking cessation in pregnancy.

The American Heart Association recently issued a policy statement on e-cigarettes (Bhatnagar, 2014), and the Tobacco Control and Smoking Cessation Committee of the International Association for the Study of Lung Cancer issued a statement for clinicians regarding e-cigarette use by cancer patients (Cummings, 2014). Development of such a policy on e-cigarettes for obstetrician-gynecologists could facilitate clinical decision-making around intervention for this key risk factor in pregnancy (England, 2014).

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