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E-cigarette use in pregnancy: a human rights-based approach to policy and practice

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Abstract

The health risks associated with e-cigarette use in pregnancy are mostly unknown. Guidelines by the World Health Organization and national health agencies warn women against using e-cigarettes in pregnancy, however, in the UK, a recent multiagency guideline takes a different approach by not discouraging e-cigarette use in pregnancy. Furthermore, e-Voke™, an e-cigarette, has been approved for use in pregnancy in the UK. We analyze United Nations' human rights treaties to examine how they might inform best practice recommendations for e-cigarette use in pregnancy. These treaties oblige Parties to adopt policies that protect children's and women's right to health, appropriate pregnancy services, and health education. We argue that clinical practice guidelines related to use of e-cigarettes in pregnancy should consider both evidence and human rights principles, and ensure that healthcare providers and patients are given clear, accurate messages about the known and potential risks associated with e-cigarette use in pregnancy.

Keywords

e-cigarettes; education; pregnancy; human rights; tobacco

Introduction

Electronic cigarette (e-cigarette) use has proliferated in many countries (1). Recent studies suggest that some pregnant women are using – or seeking professional advice on using – e-cigarettes as an alternative to smoking in pregnancy (2-4). Lay perceptions on the safety of e-cigarette use in pregnancy appear to be mixed, with some believing that e-cigarette use in pregnancy is unsafe, others that quitting smoking without a form of nicotine replacement is

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unsafe, and others believing that e-cigarettes are not completely safe although safer than cigarettes (3-6). Based on reports from pregnant women, the professional advice received varies considerably, from recommendations to switch to e-cigarettes to ceasing all nicotine use (3).

National practice guidelines on e-cigarette use in pregnancy also show considerable variation in the recommendations made to healthcare providers and patients. The 2016 US Surgeon General report states that nicotine-containing e-cigarettes are unsafe for pregnant women (1). The US Centers for Disease Control and Prevention states that e-cigarettes, due to their unproven safety or efficacy, should not be considered safe to use in pregnancy (7, 8), and along with the US Preventive Services Task Force, states that e-cigarette use in pregnancy might damage the baby's lungs and brain and that e-cigarette flavors might be harmful (7, 9). The New Zealand Ministry of Health does not recommend e-cigarette use for smoking cessation, as e-cigarettes are classified as medicinal products in New Zealand and no e-cigarette has yet received regulatory approval (10). In Canada and Australia, there are no recommendations for e-cigarette use in pregnancy. Canadian practice guidelines do not reference e-cigarettes in relation to pregnancy, however they state that evidence on the safety of nicotine replacement therapy (NRT) in pregnancy is ‘limited’ (11). Australian practice guidelines make a similar statement (12).

In the UK, major public health organizations such as Public Health England and the Royal College of Physicians recommend e-cigarettes as part of an overall tobacco harm reduction strategy. In terms of e-cigarette use in pregnancy, a recent UK multiagency guideline (13) acknowledges that “We… don't know about any risks to unborn babies from exposure to [e-cigarette] vapour,” but recommends that: “if a pregnant woman chooses to use an electronic cigarette and if that helps her to stay smoke free, she should not be discouraged from doing so.”

In addition, the UK Medicines & Healthcare Products Regulatory Agency recently approved use of the ‘e-Voke™’ e-cigarette to aid smokers, including pregnant women, in smoking cessation (14). The approval was based on clinical studies of e-Voke™ which only examined efficacy in terms of nicotine delivery; no evidence was included on the short- or long-term health effects of e-Voke™ or comparisons with other forms of treatment, and no studies were done on the effects of e-Voke™ in pregnancy (14).

The lack of consensus speaks to the need for a common set of principles to support healthcare practitioners in navigating this issue. We posit that such principles already exist in the form of human rights: international ethical standards to which most countries are legally obliged to comply. Specific obligations are communicated in the Articles of various United Nations human rights treaties. These treaties have been analyzed in terms of their support of tobacco control measures more generally (15, 16), but to our knowledge have not been used in the context of e-cigarette use in pregnancy. We examine those Articles relevant to the issue of e-cigarette use in pregnancy, and discuss how they can guide a human rights-based approach to healthcare practice in this context.

Relevant human rights articles

Four United Nations treaties are relevant to the issue of using e-cigarettes to quit smoking in pregnancy (Table 1): the 1948 Universal Declaration of Human Rights (UDHR) (17); the 1976 International Covenant on Economic, Social and Cultural Rights (ICESCR) (18); the 1979 Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW) (19); and the 1989 Convention on the Rights of the Child (CRC) (20). States which are a Party to these treaties have a legal duty to meet the provisions of the treaties' Articles (Table 2).

ICESCR Article 12 reaffirms everyone's right to the highest attainable standard of physical and mental health, which also covers the healthy development of children and the prevention of diseases. Applied to the context of e-cigarette use in pregnancy, the ICESCR requires Parties to adopt policies and practices that prioritize the health of the baby *and* the mother, including the prevention of any future health conditions that may result from the mother's e-cigarette use.

CRC reaffirms the duty of Parties to protect children's rights and the duties of adults, particularly parents (CRC Article 18) and budget, policy and lawmakers (CRC Article 3) to consider the best interests of children. CRC also requires governments to support parents in making decisions in the best interests of their children (CRC Article 18). In relation to e-cigarette use in pregnancy, this means parents have a duty to protect the health of their child, and governments have a duty to support parents in doing so. CRC Article 24 makes these obligations more explicit stating that children have a right to “the highest attainable standard of health”, which also entails providing “appropriate pre-natal and post-natal health care for mothers…” and education and guidance for parents to help their children stay healthy (20).

Articles in the UDHR and CEDAW reaffirm women's right to appropriate services and education related to pregnancy. According to UDHR Article 25, motherhood and childhood are “entitled to special care and assistance” while CEDAW states that women have a right to appropriate services related to pregnancy (Article 12) and a right to educational information to support the wellbeing of herself and her family (Article 10) (17, 19). Thus women who are using (or considering using) e-cigarettes in pregnancy as an alternative to smoking should be given accurate, up-to-date information on the potential risks and efficacy as a smoking cessation aid of e-cigarettes, in the context of comprehensive evidence-based tobacco cessation treatment.

Current evidence on e-cigarette use in pregnancy

The scientific consensus is that a tobacco-free pregnancy is essential for a child's optimal development and that pregnant women who smoke or have recently quit should be routinely offered advice and psychosocial interventions for smoking cessation. However, there is currently no consensus on whether NRT should be given to pregnant women (21). NRT has demonstrated efficacy and safety in supporting quitting among non-pregnant smokers (22), but clinical trials on the safety and efficacy of NRT use in pregnancy have generated mixed results (23). According to a 2015 Cochrane Review, only one randomized clinical trial on

NRT use in pregnancy has followed infants after birth (up to age 2 years). The review, while acknowledging that NRT use may improve smoking cessation rates measured in late pregnancy, states that further research on NRT efficacy and safety is still needed before its use in pregnant women can be recommended (2). Thus, while NRT use might lead to better health outcomes for some pregnant women and their babies, this should not be recommended as a first-line option and, in respecting women's right to health-related educational information, the potential risks of using NRT in pregnancy – compared to quitting all nicotine use – should always be clearly communicated.

Current evidence on the safety of e-cigarette use in pregnancy is even more limited. E-cigarettes are not uniform products; their heterogeneity and fast product development makes the health effects of e-cigarettes difficult to assess. To date, no randomized clinical trials have been conducted on e-cigarettes in pregnancy (2). It is known, however, that most e-cigarette liquids contain nicotine, and that nicotine penetrates the placental barrier and accumulates in the fetus at levels similar or higher than in the mother (24). Nicotine is a potential teratogen: it has been linked to a range of adverse outcomes including preterm delivery, and in animal models, which are generally consistent with human studies of smokers and offspring, nicotine impedes the development of important neurobehavioral pathways and the lungs (25-27). For e-cigarettes, research suggests that embryonic tissue is more sensitive to cytotoxicity from e-liquid exposure than adult tissues (28). Consistent e-cigarette use in pregnancy has also been linked to colonic necrotizing enterocolitis, a potentially fatal condition in newborn infants (29). In regards to smoking cessation, it is also important to note that unlike NRT, there is evidence that e-cigarettes do not promote quitting, but rather lead to dual use and sustained smoking (30). For e-cigarettes, the Conference of the Parties to the WHO Framework Convention on Tobacco Control has released two reports, both of which state that the evidence is sufficient to warn pregnant women against e-cigarette use, specifically referencing the potential impacts on brain development that may result from fetal nicotine exposure (31, 32).

Towards a human rights-based approach

Within a human rights framework, there is an ethical and legal obligation to ensure that practice guidelines exist for important health-related matters in pregnancy, including tobacco and e-cigarette use. As with NRT, evidence has not yet conclusively shown that e-cigarettes are safe or effective to use in pregnancy. One may argue that e-cigarettes are probably less harmful than cigarettes to both mother and baby, and should be recommended as an alternative for pregnant women who cannot quit smoking using NRT. However, e-cigarettes contain potentially harmful flavors and other chemicals. Further, unlike NRT, there is no consistent evidence supporting e-cigarette use to facilitate smoking cessation and if this undermine a woman's attempts to quit smoking, it could result in net harm. Pregnant women should therefore be cautioned against using e-cigarettes at the very least and should be fully informed of the potential risks, to both mother and child, of using them in pregnancy. E-cigarette advocates may argue that pregnant women have a right to use e-cigarettes as an alternative to smoking on the basis that they have a right to benefit from scientific progress (ICESCR Article 15). This right may be engaged in the future, but only if e-cigarettes are

proven to be an effective smoking cessation aid in pregnancy and safe for both mother and baby.

To support women's rights, both healthcare providers and pregnant women who are considering using e-cigarettes should be given clear, accurate messages about the potential risks associated with e-cigarette use in pregnancy, and other options to quit, so that women can make informed decisions related to their own and their baby's wellbeing. In protecting the best interests of children, guidelines should err on the cautious side: children's right to health (CRC Article 24) and the duty to consider the best interests of children (CRC Articles 3 and 18) should continue to take precedent. Thus policymakers should continue to assess evidence of safety before implementing policies that promote e-cigarette use among pregnant women. During pregnancy, the provision of “appropriate services”, as called for by the UDHR and CEDAW, should always include access to comprehensive evidence-based smoking cessation treatment. The uninformed promotion of any product that may not be safe is inconsistent with these treaties, especially if the information given to pregnant women by these initiatives is potentially misleading.

Most guidelines, including the WHO guidelines have adopted this cautionary stance, recommending treatments with proven efficacy and safety. The UK guideline and approval of eVoke™ for use in pregnancy, however, are inconsistent with this position and do not draw on the same evidence as other guidelines. The UK guideline claims that nicotine is “relatively harmless,” a statement that does not mention studies which suggest that nicotine exposure in pregnancy harms the baby (13). These studies were also not referenced in the approval of e-Voke™ for smoking cessation in pregnancy, which only looked at the efficacy of nicotine delivery (14). The UK's approach might limit women's abilities to make informed choices on smoking cessation, and lead to health care professionals providing inconsistent information.

Conclusion

From an international human rights perspective, it is important to provide clear, evidence-based practice guidelines on e-cigarette use in pregnancy. Women have a right to health, appropriate pregnancy services and health education, and children have a right to the highest attainable standard of physical and mental health. Evidence on the safety of e-cigarette use in pregnancy is still emerging, but studies on the effects of nicotine in pregnancy already show that nicotine can harm the baby's development or result in other complications. From a human rights perspective, there is an ethical and legal obligation to clearly communicate these potential risks to healthcare providers and pregnant women who might use e-cigarettes as an alternative to smoking, and to support pregnant women in stopping smoking with safe, evidence-based treatments.

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Abbreviations

NRT	nicotine replacement therapy
UDHR	1948 Universal Declaration of Human Rights
ICESCR	1976 International Covenant on Economic, Social and Cultural Rights
CEDAW	1979 Convention on the Elimination of All Forms of Discrimination Against Women
CRC	1989 Convention on the Rights of the Child

Key message

From a human rights perspective, there is an ethical and legal obligation to communicate the potential risks and uncertainties associated with e-cigarette use in pregnancy to healthcare providers and pregnant women and to provide pregnant women with safe, evidence-based treatment.

Table 1
Brief description of relevant human rights treaties

Treaty	Description
1948 Universal Declaration of Human Rights (UDHR)	The UDHR was adopted in response to the experience of the Second World War, and articulates the fundamental rights to which all human beings are inherently entitled such as the rights to life, freedom from torture and non-discrimination.
1976 International Covenant on Social, Economic and Cultural Rights (ICESCR)	The ICESCR articulates universal human rights standards that apply to social, economic and cultural fields, such as rights related to labor, social progress, and standards of living.
1979 Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW)	The CEDAW articulates the rights of women, focusing in particular on women's right to non-discrimination and fields in which women have historically been stereotyped, mistreated or discriminated against, such as sex traffic, political life, labor and education.
1989 Convention on the Rights of the Child (CRC)	The CRC protects the rights of children, defined as individuals under age 18 unless legal age of majority is attained earlier under national law. It focuses on issues specific to children, such as custody and protection from exploitation.

Table 2
Relevant articles and text from United Nations human rights treaties

Article	Article Summary	Text of the Article
1948 Universal Declaration of Human Rights (UDHR)		
Article 25	Right to special care and assistance	"Motherhood and childhood are entitled to special care and assistance"
1976 International Covenant on Economic, Social and Cultural Rights (ICESCR)		
Article 12	Right to health	"[Everyone has a] right… to the enjoyment of the highest attainable standard of physical and mental health… [including] (a) The provision for… the healthy development of the child; … (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases …"
Article 15	Right to benefit from science	"[Everyone has a] right… To enjoy the benefits of scientific progress and its applications"
1979 Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW)		
Article 10	Right to education for the wellbeing of families	"[Women have] equal rights with men in the field of education and in particular… Access to specific educational information to help to ensure the health and well-being of families…"
Article 12	Right to appropriate pregnancy services	"Women [have a right to] appropriate services in connection with pregnancy, confinement and the postnatal period…"
1989 Convention on the Rights of the Child (CRC)		
Article 3	Best interests of children: budget, policy and law makers	"In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration…"
Article 18	Best interests of children: parents and governments	"States Parties shall use their best efforts to ensure recognition of the principle that both parents have common responsibilities for the upbringing and development of the child… The best interests of the child will be their basic concern."
Article 24	Right to health, a safe and clean environment, and appropriate health services	"[Children have a] right… to the enjoyment of the highest attainable standard of health…in particular…: (d) To ensure appropriate pre-natal and post-natal health care for mothers; (e) To ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health; … (f) To develop preventive health care, guidance for parents and family planning education and services."