**Footnote**

This was unfunded exploratory pilot work undertaken within the context of a funded study evaluating interventions to prevent second hand smoke exposure in pregnancy and in new mothers. The authors wish to thank Nicola Henderson and Dot Read and the Specialist Stop Smoking Advisors at Leeds NHS Stop Smoking Service for their assistance with the study and the support of Leeds NHS Stop Smoking Service and Leeds Community Healthcare NHS Trust.

**Abstract**

There is scant published evidence regarding electronic cigarette use during pregnancy and little is known in England, UK about smoking cessation services policy and type of advice given to women about electronic cigarette use during pregnancy. An internet survey of smoking cessation services in England, UK was conducted. A self-report questionnaire was administered to pregnant women accessing a smoking cessation service in England, UK. 36 out of 82 stop smoking services responded to the online survey. 60% reported they did not have a policy on the type of electronic cigarette advice they give pregnant women and 69% of services reported they advise pregnant women that electronic cigarette use during pregnancy is a personal choice. 29 out of 30 pregnant women approached completed the self-report questionnaire. 28% of women had considered or tried using electronic cigarettes, 76% were unsure about the potential harms of electronic cigarettes compared to smoking and 62% were unsure if women should even have the choice to use electronic cigarettes during pregnancy. There is uncertainty in smoking cessation services around the policy and practice of electronic cigarette use during pregnancy; robust information is lacking and pregnant women were uncertain about the relative benefits and harms of using them. Evidence from large, well-designed research studies on the outcomes, attitudes and safety of electronic cigarettes during pregnancy, particularly in community settings, is needed.

Key words: Electronic cigarettes; Pregnancy; Survey; Smoking.

**Introduction**

Smoking in pregnancy is a leading and potentially-preventable cause of foetal, obstetric and neonatal morbidity and mortality (U.S. Department of Health and Human Services, 2010). In England, UK smoking cessation services for pregnant women are provided in the community setting including community health centres, general primary care practice and in women’s homes by a variety of organisations including the National Health Service (NHS), local government public health teams and independent companies contracted by local health commissioning groups to provide smoking cessation services. In these variety of settings, smoking cessation advice is delivered by a variety of practitioners that includes specialist smoking cessation advisors, midwives and health visitors. Current clinical guidelines for smoking cessation in pregnancy issued by the National Institute for Health & Care Excellence (NICE) in England, UK recommend women use licensed nicotine replacement therapy (NRT) (National Institute for Health & Care Excellence, 2010). However, in randomised controlled trials of pharmacologic interventions for smoking cessation pregnant women have been found to have poor adherence to NRT treatment (Coleman et al, 2015).

Electronic cigarettes (ECs) also known as Electronic Nicotine Delivery Systems (ENDS) are increasing in uptake and popularity in the UK with current and former smokers as a smoking cessation or harm reduction tool (Brown et al, 2016; Dockrell et al, 2013). EC use, also widely known as ‘vaping’, has been described by the journal Nicotine and Tobacco Research as *“One of the most important innovations in people’s tobacco smoking habits”* (Nicotine & Tobacco Research, 2016). EC use has polarised international debate within public health bodies, the UK medical and public health profession, the ‘traditional’ media and social media platforms having widely disparate views regarding their use, regulation, efficacy and safety (Cressey, 2014). In parallel to these intense debate there is a growing body of research literature including some trial evidence addressing awareness, efficacy and safety of ECs in the general adult population, student and adolescent populations, but very little research in sub-populations, for example pregnancy (Pepper & Brewer, 2013).

Given the high profile debate around EC use in the UK (Wodak, 2016), it is likely that pregnant women in the UK who smoke may consider trying ECs during their pregnancy. In England UK, NICE collate the best available evidence for practitioners but make no recommendations regarding EC use during pregnancy in their smoking cessation guidance (National Institute for Health & Care Excellence, 2010) . However, there is scant published guidance for smoking cessation practitioners to draw on regarding EC use during pregnancy (McEwen & McRobbie, 2016; McEwen, 2015). There is a current paucity of published research evidence regarding the knowledge, attitudes and EC use during pregnancy and to date only a few small-scale studies conducted in the USA, which found there are misconceptions and knowledge gaps in pregnant women perceptions of EC use during pregnancy are available to inform practitioners (Ashford K et al, 2016; Fallin et al, 2016; Mark et al 2015; Kahr et al, 2015). This represents a significant evidential gap with regard to smoking cessation policy and practice, particularly as no published studies that assess EC attitudes, use and outcomes during pregnancy exist in the UK (Coleman et al, 2015). Pertinent questions therefore need to be addressed within the UK context as to what type of advice pregnant women receive from smoking cessation services about e-cigarette use and what pregnant women’s perceptions are of using ECs during pregnancy.

The exploratory work described here, was undertaken to: i) explore the policy and practice advice given to pregnant women about ECs by smoking cessation services in England, UK ii) explore use of and attitudes to ECs in a sample of pregnant women.

**Methods**

This study used intra-method mixing (Johnson & Turner, 2003). This variation of mixed methods technique employs a single method of data collection, in this instance the survey method, with a questionnaire designed to elicit both qualitative data in the form of free text comments and quantitative data in the form of closed questions.

A brief cross-sectional questionnaire administered via an online survey function was chosen as the optimum method to contact services across the whole of England. UK and collect information about the smoking policy and practice from individual smoking cessation services in a national survey intended to cover services across the whole of England, UK. Use of online survey method is increasingly common in terms of the ability to target the questionnaire responder, cover large geographical areas, and time and cost efficient to both the researcher and the participant responder (Wright, 2005; Eysenbach & Wyatt, 2002).

The contact details of 82 smoking cessation services in England, UK were identified using the web site [www.nhs.uk/smokefree](http://www.nhs.uk/smokefree), which contains basic contact information for services in different areas of the country. Regions in England were categorised using the main geographical areas e.g the London area, North East, North West, the Midlands and services were identified using the web site search function of main city names, locations and town postal (zip) codes within each geographical region. Services without an email address were contacted via telephone and asked to provide an email contact. The identified services were sent an introductory email between February to March 2016 with a user-unique web link and asked to complete a brief online survey regarding policy and practice related to EC use during pregnancy (see appendix 1). Services were asked to respond within 3 weeks. Services who did not respond by three weeks were sent one follow-up reminder email with a further seven days to respond.

A convenience sample (Battaglia, 2008) of 30 pregnant women were approached by a smoking cessation advisor in one specialist smoking cessation service in the North of England and were asked to self-complete an anonymised questionnaire between January to April 2015 to explore use and attitudes to EC use in pregnancy (see Appendix 2). Women were asked to return the completed questionnaire in a sealed envelope to their smoking cessation advisor at their next session, which was subsequently collected by the researcher. Women who said they thought there were disadvantages to using ECs in pregnancy were invited to respond to a directive free text question to provide women the opportunity to express their opinions regarding perceived negatives of EC use. Directive free text questions are considered an appropriate method to capture views considered relevant to survey respondents (Mackichan et al, 2010; Ong et al, 2006) allow respondents the opportunity to voice their opinions and corroborate answers to closed questions and are useful for eliciting reflection on key points and contextual information at the time a questionnaire is completed (O'Cathain & Thomas, 2004).

The Health Research Authority (HRA. hra.nhs.uk) online decision tool was used to determine if administration of surveys to study participants required ethical approval. The following HRA decision was received. “*Based on the information you have provided, our decision is that the project is not considered to be research and does not require review by an NHS Research Ethics Committee”*. A copy of the decision from HRA and the study documentation was sent to the local research governance director of the NHS Foundation Trust responsible for research activity in the smoking cessation service that agreed to participate in the study. Subsequent assessment of the study design and methods under local research governance process stated that the research did not require NHS governance approval and that the study could proceed under the definition of a service evaluation. Written informed consent was not sought from the participants as completion of an anonymised survey is assumed as implied consent (British Psychological Society, 2017; Royal College of Nursing Research Society, 2011).

Analysis

The surveys were designed to provide quantitative and qualitative descriptive data. Items in the surveys generating quantitative data were designed to provide only descriptive statistics. Proportions, mean and standard deviation were therefore used where appropriate to analyse the online survey, women’s questionnaire and the descriptive characteristics of the study sample (Field, 2005).

Free text comments were analysed by qualitative content analysis (Elo & Kyngäs, 2008) using the conventional content analysis method (Hseih & Shannon, 2005). Firstly, the comments were re-read multiple times in order to gain immersion in the data. Content-characteristic words in free text comments were identified and free text comments sorted into categories, from which emergent themes were identified. Use of exemplar comment is provided, as recommended for content analysis (Elo & Kyngäs, 2008; Hseih & Shannon, 2005) and these are provided with the descriptive text in the results. In order to contexualise the exemplar comment used for identified themes, respondents were identified according to two possible outcomes; pregnant women who tried an EC and pregnant women who did not try an EC. Exemplar comments are reported exactly as written by participants.

**Results**

**Online survey of smoking cessation services**

44% (36) of the services approached responded to the brief online survey. 35 responses had complete data. 60% (21) of services reported they did not have a local service protocol or policy in place to advise pregnant women about using ECs during pregnancy. 69% (25) of services reported that they advise pregnant women that using ECs during pregnancy is a personal choice, however of these services nine reported that they would recommend a licensed nicotine product in the first instance but would support personal choice to use an EC. 72% (26) of the services that responded described themselves as a Stop Smoking Service; 8% (3) Services with an NHS Foundation Trust; 8% (3) Health living/healthy improvement services; one service described itself as Public Health and two services did not state any service description. Of the 36 service that responded 10 services described themselves as a specialist service for pregnancy.

# The guidance most frequently cited by services to formulate advice to pregnant women about EC use was Public Health England (n=31 services) (<https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>), followed by voluntary organisations such as Action on Smoking and Health (ASH)(n=20 services), local smoking cessation service practitioner knowledge/experience (n=19 services), guidance from NICE smoking cessation guidelines (n=17 services), guidance from NHS Smoke Free (n=11 services), evidence from academic research journals (n=9 services) and evidence from professional/practitioner focused journals (n=5 services). Nine services reported that they also referred to other guidance from a specific training event /briefing about EC use in pregnancy from the National Centre for Smoking Cessation and Training (NCSCT). Only one service reported that they did not use any guidance to formulate EC advice for pregnant women.

**Pregnant women’s use and attitude to ECs**

29 of the 30 pregnant women who were approached by their smoking cessation advisor completed and returned the questionnaire.

All 14 of the women who reported that they currently smoked every day, most days or occasionally all reported that they were trying to quit smoking. The mean number of smoking cessation sessions attended at the time of questionnaire completion was 2.86 (Standard deviation 2.53).

Insert Table 1 here

Pregnant women’s e-cigarette use

Pregnant women reported their use of and attitudes to ECs.

Insert Table 2 here

69% (20) of women had tried an EC (even once) prior to pregnancy and 35% (10) women had considered using an EC since they found out they were pregnant. Of the ten women who had considered using ECs since they found out they were pregnant the most frequently endorsed reason for EC trial was ‘E-cigs may help me quit smoking’ (n=7 responses) and ‘E-cigs may help reduce cravings and withdrawal symptoms’ (n=6 responses).

28% (8) of the women had tried using ECs since they found out they were pregnant but of these women only two were still using an EC at the time they completed the questionnaire.

Pregnant women’s attitudes to EC use

Pregnant women reported uncertainty about the advantages and disadvantages of EC use in pregnancy and 52% (15) reported that they thought there might be disadvantages to using ECs during pregnancy. 62% (18) of women responded that they were ‘not sure’ if pregnant women should have the choice to use e-cigarettes to help them stop smoking. There was also uncertainty about the safety of EC use during pregnancy with 76% (22) of women reporting ‘don’t know’ as to whether using ECs during pregnancy was less harmful, more harmful or about the same as regular tobacco cigarettes.

A free text item at the end of the questionnaire invited women to comment about any perceived disadvantages to using ECs during pregnancy. Sixteen women provided a response describing their thoughts about perceived disadvantages of EC use during pregnancy. The themes of the comments centred around: i) ECs not being tested and uncertainty as to what chemicals ECs contained; ii) potential harm and effects of ECs on the baby; iii) not enough research and information about ECs.

“*untested in pregnancy, don't know if there’s any harm to baby”* [pregnant woman who did not try an EC after she became pregnant]

*“not tried and tested -don't know what the complications and effects will be”* [pregnant woman who did try an EC after she became pregnant]

# Discussion

This small-scale pilot work aimed to explore what type of policy, if any, and type of advice smoking cessation services in England give to pregnant women about EC use using an online survey and undertake small-scale exploratory work with pregnant women about their use and attitude to ECs using a self-complete questionnaire. The majority of smoking cessation services who responded were found to have no EC policy for pregnant women but reported they advise women that EC use is a personal choice during pregnancy. There was substantial variation between services in the type of guidance used to support advice. The most frequently cited document used to formulate advice was the guidance on ECs by Public Health England, however this guidance does not specifically cover EC use in pregnancy.

Women reported they had considered or tried using ECs since becoming pregnant; however they were uncertain about the potential advantages or disadvantages of EC use, women were unsure about the potential harms of ECs compared to smoking and unsure if pregnant women should have the choice to use ECs.

The decision to continue smoking throughout pregnancy is complex; pregnant women who find it difficult to quit, or, those who are unable to quit have few alternatives other than NICE recommended strategies. Alternative forms of nicotine delivery such as ECs are a novel approach, and may have the potential to represent an alternative option during pregnancy. However currently there is minimal evidence specific to pregnancy to guide the practice of all practice professionals who give smoking cessation advice and pregnant women on issues such as the outcomes and safety of EC use during pregnancy; this is particularly the case in the UK as to date there are no published studies relating to knowledge, perceptions, use and outcomes of EC use during pregnancy related to the pregnant women or to the foetus. Without the existence of large-scale outcomes studies, this currently makes the formulation of well-evidenced practice guidelines for health care professionals to follow difficult to achieve.

The data from this small sample of women suggests that women are uncertain about EC use in pregnancy and unsure about the safety of ECs and harm to the unborn baby. This finding corresponds with the small-scale research studies conducted in the USA that have found misconceptions and uncertainty regarding EC use in pregnancy (Ashford K et al, 2016; Fallin et al, 2016; Mark et al 2015; Kahr et al, 2015). This study therefore suggests pregnant women would be receptive to receiving more robust information about EC use in pregnancy from health care professionals. Briefings for smoking cessation advisors (McEwen & McRobbie, 2016; McEwen, 2015) advise that pregnant women who report using an e-cigarettes should be congratulated but the briefings stop short of making any robust recommendations in the face of pregnant women asking questions such as “are e-cigs safe in pregnancy?, will my baby be harmed?, do e-cigs help pregnant women stop smoking?”. However, the most recent (2017) advice created by the Smoking in Pregnancy Challenge Group (Smoking in pregnancy challenge group via smokefreeaction.org.uk) states “*because electronic cigarettes are relatively new, there is no evidence yet about the effects of longer term use. The risks to a foetus from exposure to vapour are unknown and are there are currently no reliable studies providing information in this context*”, which highlights the paucity of research to inform practitioners and uncertainty around EC use in pregnancy.

The data from this exploratory study highlights the uncertainty around EC use during pregnancy in smoking cessation services and in the light of the paucity of published research evidence some services are currently advising pregnant women that EC use is a personal choice. This is in contrast to evidence-based recommendations about most other aspects of health during pregnancy including diet, alcohol consumption, and exercise. This type of advice is often given in community settings and it would seem appropriate for community based services that have routine contact with pregnant women. For example, once more robust evidence is available from well-designed studies, all practitioners that give smoking cessation advice will be in a position to give more informed information on the benefits and potential risks of using ECs during pregnancy, particularly health visiting services could be in a unique position to deliver advice on e-cigarette use, particularly as the routine contacts span across the prenatal and postnatal period. The results of this small-scale work cannot inform practice at this time but highlights the need for large-scale research to inform practice guidelines and the advice offered by all professionals that deliver smoking cessation advice and use of ECs during pregnancy.

When considering the well-being of the foetus pregnant women should be offered evidenced-based information from well-conducted research studies by smoking cessation advisors in order for women to make an informed decision about EC use during pregnancy. However as previously stated large-scale studies have yet to be conducted and the potential importance of the safety of the foetus, as highlighted in the themes from the qualitative quotes in this work, is of concern to mother. There is currently ongoing work around the theoretical frameworks and behaviour change techniques as to how ECs should be offered to pregnant women and whether they will adhere to the use of ECs. However this work is as yet unpublished, and one can only assume that because it is difficult to draw generalisble conclusions from this preparatory work, the evidence cannot provide practice with sound recommendations at this time. Large–scale randomised mixed methods studies are required, however preparatory works prior to commencement of a large randomised trial of ECs in pregnancy take time to formulate the theoretical frameworks that underpin the delivery of the intervention, uptake and adherence to the intervention. Once practice guidance has been informed by large well-designed outcomes studies, given that community-based services such as health visiting teams in the UK are increasingly having routine contact with pregnant women, for example, the Early Start visit around 24-28 weeks gestation, the opportunity for health visitors to intervene and advise on smoking cessation and e-cigarettes appears highly advantageous; particularly as there may be some pregnant smokers who are potentially unlikely to engage with smoking cessation services.

Limitations

This small-scale study was limited by the number of services that were contacted and that responded to the survey email invitation. It is possible that not all of the stop smoking services available in England, UK were identified using thesearch facility on the [www.nhs.uk/smokefree](http://www.nhs.uk/smokefree) website, however there is no central NHS or government list currently available to identify country-wide stop smoking services. This indicates a potential difficulty in conducting research in this context, to undertake a national survey of the service characteristics of all country-wide stop smoking services in England, UK that provide smoking cessation advice to pregnant women. The work was also limited by the number of services that responded to the online survey. The website [www.nhs.uk/smokefree](http://www.nhs.uk/smokefree) is only able to provide basic contact details of service so unfortunately information about the structure and configuration of each service was not available, so it is not possible to compare the characteristics of services that did and did not respond to the online survey.

This exploratory work was limited to collecting the views of pregnant women using directive free text comments via a survey, so the qualitative results are not potentially transferable to other pregnancy population settings; but they do however give an indication of uncertainty in this sample of pregnant women, which corresponds with published small-scale USA studies. Future work using telephone or face-to-face semi-structured qualitative interviews informed by the issues identified in the results of this survey of pregnant women would help to explore the issues more fully and provide richer data. The work was only piloted in a small convenience sample of pregnant women and therefore self-selection bias is a limitation; a fully randomised controlled study design would account for selection bias, larger samples of women from smoking cessation services in other areas of the UK would be useful to either corroborate these findings and also may provide contrasting views, therefore obtaining multiple samples of pregnant women in future research studies are recommended to explore the issues of knowledge and perception of EC use more fully. In addition, the online survey and women’s questionnaire were administered at different time points, so there is the possibility that women from the participating service might answer differently if given different information by the service. It is difficult to speculate as to whether pregnant women would have answered differently given that the majority of services reported that their advice was that EC use is a personal choice during pregnancy and these responses were collected from services after the survey of pregnant women was conducted.

Gaining informed consent from participants using online-mediated survey method has been cited as a methodological limitation (Eysenbach & Wyatt, 2002), however more up-to-date considerations of consent procedures where participants completing a survey is classed as implied consent were utilised in this research (British Psychological Society, 2017).

Conclusion

This small-scale exploratory work provides an indication of the sources used to underpin the policies of smoking cessation services advising pregnant women on the use of ECs during pregnancy and an indication of the type of advice being given to pregnant women by advisors and practitioners in smoking cessation services with regard to vaping ECs during pregnancy in England, UK. In line with the limited published research on EC use and pregnancy, this exploratory works highlights the uncertainty that pregnant women feel around using ECs and the need for smoking cessation services and health care professionals to give pregnant women consistent, evidence based advice on EC use during pregnancy rather than the de facto option of no advice by stating that EC use during pregnancy is a personal choice. Research evidence is required from large, well-designed mixed-methods research studies on the safety, outcomes and acceptability of EC use during pregnancy to inform both pregnant women and best practice recommendations for all health care professional who deliver smoking cessation advice. Given that some pregnant smokers may be potentially unlikely to engage with smoking cessation services, health visitors are increasingly likely to have a high level of routine contact in the prenatal and postnatal period and therefore e-cigarette research would be advantageous in community settings to support community evidence-based public health practice.

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Table 1 Participant characteristics and self-reported smoking status (survey section 1 & 2)

|  |  |
| --- | --- |
| Mean Age (SD) | 28.34 (5.66) |
| Mean number of weeks pregnant (SD) | 18.4 (7.15) |
| Primagravida (%) | 34.5 |
| Number of children under 16 years  One  Two  More than two  Not applicable | 5  8  2  13 |
| Ethnicity white (%) | 86.2 |
|  |  |
| Self-reported smoking status | n |
| Current Smoking status  Everyday  Most days  Occasionally  Not at all | 11  2  2  14 |
| IF current smoking status =‘not at all’ smoking frequency before pregnancy?  Everyday  Most days  Occasionally | 13  0  1 |
| Tried to quit before pregnancy  Yes  No | 3  26 |
| Trying to quit now  Yes  No | 25  3 |
| Seriously thinking about quitting  Yes, in the next days  Yes, in the next 2 to 4 weeks  No  Not applicable | 7  1  3  15 |
| Cigarettes smoked in last 30 days  1 to five a day  6 to 10 a day  More than 10 a day  None  1-2 per week | 9  4  8  7  1 |
| What are you doing to quit  Stop smoking completely  Cut down the number of cigarettes smoked  Not applicable | 20  5  4 |
| How are you trying to quit  Using only nicotine replacement products such as nicotine patches, nicotine gum, lozenges  Using only counselling sessions with an NHS stop smoking advisor e.g FAB  Using nicotine replacement (patches/gum) **AND** counselling sessions with an NHS stop smoking advisor  Other – I have stopped smoking | 10  4  12  2 |

Table 2 Survey responses about e-cigarette use and attitudes (survey section 3)

|  |  |
| --- | --- |
| Heard of e-cigarettes  Yes  No | 29  0 |
| Ever tried e-cigarettes before pregnancy  Yes  No | 20  9 |
| Thought about using e-cigarettes since pregnancy  Yes  No | 10  19 |
| Reason might use an e-cigarette in pregnancy  E-cigs may help me cut down smoking  E-cigs may help me quit smoking  E-cigs may help reduce cravings or withdrawal symptoms  I can use e-cigs in public place where smoking’s not allowed  I can use e-cigs in addition to smoking cigarettes  Doesn’t contain harmful chemical  E-cigs would replace cigarettes  I didn’t know they were safe to use | 3  7  6  2  3  1  1  1 |
| Tried an e-cigarette since became pregnant  Yes, but I don’t use e-cigs anymore  Yes, and at the present time I still use e-cigs  No | 6  2  21 |
| Refills used with nicotine  Yes  Don’t know  Not applicable | 5  1  18 |
| If e-cigarettes used in last 30 days how often  Everyday  Occasionally  Not applicable | 1  3  20 |
| If e-cigarettes used since became pregnant, reasons for use  E-cigs are helping me cut down the number of cigarettes  Not applicable | 1  28 |
| Are there disadvantage to using e-cigarettes  Yes  No  Not sure | 15  4  10 |
| Should pregnant women have choice to use e-cigarettes  Yes  No  Not sure | 6  5  18 |
| Do you think that using e-cigarettes during pregnancy is  Less harmful than regular (tobacco) cigarettes, roll-ups etc?  More harmful than regular (tobacco) cigarettes, roll-ups etc?  About the same harm as regular (tobacco) cigarettes, roll-ups etc?  Don’t know | 3  3  1  22 |

Appendix 1

Dear [insert contact name],

I am a health services researcher at the University of York and I am undertaking some small-scale exploratory work around the information that smoking cessation services give to pregnant women about using electronic cigarettes during pregnancy. **[insert service name]** is one of over 80 services in England that I am approaching.

**I'd be extremely grateful if you would complete a very brief online survey about [insert service name] using the link below by [insert completion date] or please forward this email to the relevant person/s in your service/s dealing with smoking cessation advice in pregnancy.**

Consent to use the data for the purposes described above is taken as implied by completing the survey. Responses will be aggregated and individual’s will not be identified.

There are only **5 questions** to answer and the survey should take no more than 5 minutes to complete.

If you have any questions or have any problem with the link please do not hesitate to contact me via phone or email.

Many thanks in anticipation of your participation.

Thank you.

[insert unique-user web link to survey questions]

1. Please tell us the name of your service and your job title.
2. Do you have a local service protocol or policy in place to advise pregnant women about using e-cigarettes in pregnancy?
3. What advice does your service give pregnant women about using e-cigarettes during pregnancy?
4. What policies, advice or evidence has your service used when formulating any advice for pregnant women about using e-cigarettes during pregnancy