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E-cigarettes: an acceptable alternative to smoking for breastfeeding mothers?

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Philosophy

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ABSTRACT

Despite many women quitting smoking during pregnancy, the majority will return to smoking by 12 months postpartum. Smoking postpartum carries substantial risks of morbidity and mortality for both mother and baby. Breastfeeding is a protective factor against some of the risks associated with smoking. However, mothers who smoke are less likely to intend to breastfeed, initiate breastfeeding at birth, or continue breastfeeding, than non-smoking mothers. Current explanations for this association include a possible physiological mechanism, a coincidental association due to shared demographics, or a fear of harm.

E-cigarettes are an increasingly popular alternative to smoking, helping to prevent relapse in those trying to quit, and Public Health England, in an evidenced based review, estimate cite them to be at least 95% safer than smoking. While research has explored e-cigarette use during pregnancy, thus far, no study has considered how e-cigarettes may be being used in the postpartum period. Crucially, research has not explored if and how e-cigarettes are used by breastfeeding mothers. As e-cigarettes are likely to be far safer than cigarettes, with far fewer toxicants, they may be an appropriate alternative to smoking in the postpartum period. To explore possible future interventions using e-cigarettes to reduce postpartum smoking and increase the likelihood and duration of breastfeeding, research must first explore the acceptability and current use of e-cigarettes in relation to breastfeeding.

This thesis includes three studies. The first study aimed to explore whether an association between smoking and breastfeeding currently existed within a sample of UK mothers, independent of demographic factors. This study used data from the Pregnancy Lifestyle Survey, which recruited 750 current and recent ex-smokers, e-cigarette users and dual users (both smoking and e-cigarette users) who self-completed questionnaires in early pregnancy, late pregnancy and at 3 months postpartum. In late pregnancy, 63.5% of women intended to breastfeed, 46.35% initiated breastfeeding, and 17.68% of women were breastfeeding at 3 months. Older mothers were more likely

to initiate breastfeeding at birth ($p = 0.02$), and mothers with higher levels of education were more likely to intend to breastfeed ($p < 0.001$), initiate breastfeeding ($p < 0.001$) and be breastfeeding at three months ($p = 0.01$). Ex-smokers were more likely to intend to breastfeed ($p < 0.01$), initiate breastfeeding ($p = 0.04$) and be breastfeeding at three months ($p < 0.01$) than smoking/vaping mothers. When adjusted for age and education, smokers were less likely to breastfeed at birth (OR 0.48, 95% CI: .26 - .75), and at three months postpartum (OR .19, 95% CI: .09 - .37), compared to ex-smokers. Vapers were similarly less likely to initiate and intend to breastfeed, but this was not significant. A negative association between smoking and breastfeeding exists in the UK, irrespective of demographics. Interventions should consider the association is at least, in part, due to factors other than demographics. Due to only a small sample of vapers recruited, further research should explore the use of e-cigarettes and attitudes to vaping as a breastfeeding mother in more detail.

The second study used infodemographic methods to explore the use of e-cigarettes postpartum, and opinions towards e-cigarette use when breastfeeding. This study used data obtained from online parenting forums. The study identified four themes using a template approach to thematic analysis; use; perceived risk; social support; and evidence. Women were using e-cigarettes to prevent returning to smoking postpartum, many having started using them during pregnancy to quit smoking. In regards to breastfeeding, women varied on their opinions as to the acceptability of e-cigarettes. However, overall, women were generally positive about their use. Women viewed the risks of using e-cigarettes using direct comparisons to the risks of smoking; using e-cigarettes was seen as a positive behaviour to avoid smoking. Social support was an important part of the discussion; some women felt judged for using e-cigarettes, which was primarily related to the use of nicotine. Some women thought that the use of nicotine was evidence of bad mothering and a morality issue as well as a safety issue. A key finding was the sources of evidence women used and were looking for. Some women had accessed peer-reviewed scientific sources but had misinterpreted the results of the studies they quoted. Some women used non-scientific sources such as blogs and media articles to form both positive and negative opinions on vaping. Many

women felt there was not enough research on the long term use of e-cigarettes; this made them fearful that serious harm would be linked to e-cigarettes use in the future. One thing that united women who were both positive and negative about e-cigarette use were the shared opinion there wasn't enough advice and support for mothers who vaped and wanted to breastfeed. More advice and support needs to be available as part of usual care for women who do vape, to enable them to make informed decisions about breastfeeding their infants.

The third study used an online survey to explore further the themes identified in the second study. This study recruited 149 women who either smoked, vaped, or smoked and vaped and had an infant aged 18 months or younger using social media advertisements and links on parenting forums. The survey asked women about their experiences and opinions on smoking/vaping breastfeeding using open-ended questions that were thematically analysed. The survey also included Likert scales following PPI feedback. Three main themes were identified: smoking, vaping and breastfeeding behaviours; barriers and facilitators for breastfeeding as a smoking or vaping mother; and barriers and facilitators for using e-cigarettes (and not smoking) postpartum.

Women employed a series of behaviours to reduce perceived harm to their infant from breastfeeding as a smoker or vaper. For vaping mothers, this involved using only low or zero nicotine. Smoking and vaping mothers discussed maintaining a smoke-free home, ensuring the maintenance of proper hygiene, and timing feeds around their smoking/vaping behaviours. Vaping mothers reported being less cautious about vaping around their infants. Dual-use mothers reported vaping in the day and only smoking when they had either expressed enough milk they wouldn't need to feed their infant or when they had their partner home to care for the infant. Barriers and facilitators were not fixed and invariable. They included the mothers' beliefs on what was acceptable, the perceived safety of breastfeeding as a smoker/vaper, and access to social support. Barriers to breastfeeding as a smoker were often due to women's beliefs it was unacceptable and unsafe for them to breastfeed; this barrier was sometimes overcome by switching to vaping. However, a lack of support and advice from health care

professionals about vaping and breastfeeding was a barrier. Barriers to using e-cigarettes included previous use resulting in adverse events (such as a cough, or not successfully quitting smoking) and a lack of consistent (if any) advice from health care professionals. Facilitators included wanting to improve health, pregnancy, good social support, saving money and not having the smells associated with smoking.

Overall, women view e-cigarettes as acceptable for use when breastfeeding. Interventions should consider the use of e-cigarettes to prevent women from returning to smoking postpartum and improve confidence in breastfeeding. To support and encourage women to switch to vaping, training for health care professionals on the relative safety of e-cigarettes is required.

PUBLICATIONS AND CONFERENCE PRESENTATIONS

1.1 Published work from thesis

Johnston EJ, Campbell K, Coleman T, Lewis S, Orton S, Cooper S. Safety of electronic cigarette use during breastfeeding: Qualitative study using online forum discussions. *Journal of medical Internet research*. 2019;21(8):e11506.

1.1.1 Manuscripts in preparation

Johnston EJ, Campbell K, Orton S, Lewis S, Coleman T, Cooper S. Smoking and Vaping postpartum: results from an online survey about experiences, beliefs and infant feeding choices

1.2 Conference and seminar presentations

1.2.1 Oral presentations

Johnston EJ, Campbell K, Coleman T, Lewis S, Orton S, Cooper S. Infodemic methodology: using forum data to explore e-cigarette use in postpartum women. Midlands Health Psychology Conference, Coventry, May 2017

Johnston EJ, Campbell K, Coleman T, Lewis S, Orton S, Cooper S. Exploring the potential of e-cigarettes to reduce postpartum smoking, and increase UK breastfeeding rates. National Institute of Health Research, School of Primary Care Research Trainee Event, Oxford. September 2017

Johnston EJ, Campbell K, Coleman T, Lewis S, Orton S, Cooper S. Safety of electronic cigarette use during breastfeeding: Qualitative study using online forum discussions. National Institute of Health Research, School of Primary Care Research Trainee Event, Oxford. September 2018

Johnston EJ, Campbell K, Coleman T, Lewis S, Orton S, Cooper S. Safety of electronic cigarette use during breastfeeding: Qualitative study using online forum discussions. Division of primary care, University of Nottingham, Nottingham. March 2019

Johnston EJ, Campbell K, Coleman T, Lewis S, Orton S, Cooper S. Safety of electronic cigarette use during breastfeeding: Qualitative study using online forum discussions. Division of Epidemiology and Public Health, University of Nottingham. March 2019

Johnston EJ, Campbell K, Coleman T, Lewis S, Orton S, Cooper S. Infodemic research methods: a novel way of exploring novel phenomenon (e-cigarettes). School of Psychology, Stoke University, October 2019

1.2.2 Poster-oral presentations

Johnston EJ, Campbell K, Coleman T, Lewis S, Orton S, Cooper S. Exploring the potential of e-cigarettes to reduce postpartum smoking, and increase UK breastfeeding rates. Nicotine & Tobacco Harm Reduction Conference, Warsaw, June 2017

Johnston EJ, Campbell K, Coleman T, Lewis S, Orton S, Cooper S. Safety of electronic cigarette use during breastfeeding: Qualitative study using online forum discussions. Baby-friendly Initiative Annual Conference, Telford, November 2017

Johnston EJ, Campbell K, Coleman T, Lewis S, Orton S, Cooper S. Safety of electronic cigarette use during breastfeeding: Qualitative study using online forum discussions. Society for Research on Nicotine and Tobacco Conference, Munich, September 2018

Johnston EJ, Campbell K, Coleman T, Lewis S, Orton S, Cooper S. Safety of electronic cigarette use during breastfeeding: Qualitative study using online forum discussions. European Health Psychology Conference, Dubrovnik, September 2019

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I would like to thank my supervisors for their ongoing support, advice and academic expertise. Without their help, guidance, and experience, this thesis would not have been possible. I consider myself to have been very fortunate to have such an incredible and inspirational team of supervisors. I am very thankful that after stepping in as maternity cover, Dr. Katarzyna Campbell was willing to stay on board as a supervisor, her ongoing support has been invaluable. I would also like to express gratitude to my colleagues in the division for their support both personally and professionally. In particular, I would like to thank the smoking in pregnancy research team, and all of those in my office who were on hand to offer suggestions and guidance when needed, but most importantly moral support when things were hard. You taught me that research is indeed a collaborative effort, and that to struggle in the final stages of your PhD is entirely reasonable. I'd like to thank Master Mansfield, George, Nicky, and all others at the leadership academy for martial arts for helping me to maintain focus, manage frustrations and continue to become the best version of myself.

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DECLARATION

In study one, data analysed was from the Pregnancy Lifestyle Survey cohort. Cancer Research UK funded the original study, the Chief Investigator (CI) was Dr Sue Cooper from the University of Nottingham. The survey design and implementation involved co-investigators from the University of Nottingham, the University of London, the University of East Anglia, and the University of Stirling. For the first and second follow up surveys, I contributed questions relating to breastfeeding. In follow-up one, women were asked about their intentions to breastfeed. For follow-up two, one question asking about feeding intentions and three questions relating to breastfeeding behaviours were asked with pre-set answers to select from. A final question asked participants to rate how strongly they agreed or disagreed with a statement relating to a health belief. PPI insight was sought independently of the original study. The wording of additional questions on health beliefs changed in response to PPI feedback due to ambiguity. With this in mind, the initial wording of 'Mothers should not smoke tobacco cigarettes/ e-cigarettes and breastfeed' changed to 'mothers should not breastfeed if they smoke tobacco cigarettes/use an e-cigarette'. At the time of this study, this was the first time women have been directly asked about the use of e-cigarettes in relation to breastfeeding. All findings presented in study one are the result of my own work, with input from supervisors (particularly Dr Sarah Lewis).

Studies 2 and 3 were designed by me, including all protocols and ethics applications with support from supervisors. Data collection was managed by me, as was initial coding. A second coder was used to reduce bias. The survey and all questions were designed by me, although six Likert scales were added following PPI input. An independent company managed the advertisement for the study on social media – SMRS – but advert design and data collection were implemented and monitored by me, including liaising with parenting website moderators. Initial sorting and coding of the data was my own work, with support from a second coder to reduce bias. The results and interpretations are my own work.

GLOSSARY

APA	American Paediatric Association
BFHI	Baby Friendly Hospital Initiative
BPS	British Psychological Society
CI	Confidence Interval
CO	Carbon Monoxide
COPD	Chronic Obstructive Pulmonary Disease
ENDS	Electronic Nicotine Delivery System
GCSE	General Certificate of Education
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NNK	Nicotine-derived nitrosamine ketone
NNN	N-Nitrosornicotine
NRT	Nicotine Replacement Therapy
OR	Odds Ratio
PAHs	Polycyclic Aromatic Hydrocarbon
PHE	Public Health England
PLS	Pregnancy Lifestyle Survey
PPI	Patient and Public Involvement
RCM	Royal College of Midwives
RR	Risk Ratio
SIDS	Sudden Infant Death Syndrome
SOR	Summary Odds Ratio
TSNA	Tobacco Specific Nitrosamine
UK	United Kingdom
UN	United Nations
UNICEF	United Nations's International Children's Education Funds
VOCs	Volatile Organic Compounds
WHO	World Health Organisation

Chapter 1: Background

1.1 Smoking: overview

The smoke from cigarettes contains many chemicals that are harmful to both the smoker and those exposed to smoke via passive smoking. Minimal amounts of smoke exposure are needed to present a risk of harm [1, 2]. Tobacco smoke from cigarettes is a “*concentrated aerosol of liquid particles suspended in an atmosphere consisting mainly of nitrogen, oxygen, carbon monoxide and carbon dioxide*” [3]. When assessing the health implications of cigarette smoke, we must understand the chemical composition, the concentration of these chemicals, and the size of particles and charge [4]. The constituent particles in cigarette smoke are multi-compositional; they are compounds created via the pyrolysis, distillation and combustion of tobacco [4]. Tobacco-related constituents are discussed in detail in 1.4.1.

1.1.1 Health consequences of smoking

The health concerns associated with smoking are well documented since Doll & Hill first published a paper in 1950 [5] highlighting the link between smoking and carcinoma of the lung. Smoking remains one of the biggest, yet preventable, causes of cancer [6]. Smoking alone is responsible for an estimated 5-6 million deaths a year globally [7] – in the UK, roughly 77,000 deaths are expected per annum, and around 484,000 hospitalisations are likely to occur due to smoking-related health consequences [8].

Even with low-intensity smoking (< 10 cigarettes a day), the risk of all-cause mortality is elevated [9]. Particularly for women, the disease risk from smoking has a rate ratio (RR) of 1.77 (CI 1.40-2.24) for low-level smoking and a RR of 1.95 (CI 1.70-2.24) for higher-level smoking (≥ 20 cigarettes per day) [10]. Cigarette smoke can also inhibit the immune response [11, 12], increase the acute risk of respiratory infection [13] and chronic lung conditions [14]. The risk of cardiovascular/coronary disease also increases with smoking [15-17], particularly for women who may be more vulnerable to the effects

of tobacco smoking. Female smokers have a relative risk ratio of 1.25 (CI 1.12-1.39) of developing coronary heart disease compared to male smokers [18]. Smoking is also linked to an increased risk of several cancers [19]. A systematic review and meta-analysis reported the increased risk from smoking for lung cancer (RR = 8.96, CI 6.73-12.11), laryngeal cancer (RR = 6.98, CI 3.14-15.52), pharyngeal cancer (RR = 6.76, CI 2.86-15.98) cancer of the upper digestive tract (RR = 3.57 CI 2.63-4.84) and oral cancers (RR = 3.43, CI 2.37-4.94) [20]. The risk of developing breast cancer is also elevated for women who smoke (HR = 1.24, CI 1.07-1.42) [21]. Smoking can also be a cause/contributing factor to infertility in women [22] and impotence in males [23].

Smoking does not just have consequences for the smoker but to those exposed to smoke via 'passive smoking' [24]. Passive smoking is the inhalation of 'second-hand' smoke by a person other than the smoker. Children and those with chronic respiratory illnesses are particularly susceptible to the risks of second-hand smoke [25]. Children of smokers have increased risks of childhood morbidity and mortality [26]; this is described in more detail in 1.1.3.2.

1.1.2 Smoking in pregnancy

Smoking during pregnancy remains one of the single most significant preventable causes of foetal and infant morbidity [27]. Globally, smoking during pregnancy prevalence is around 1.7% (95% CI 0.0-4.5) and 8.1% (CI 4.0 – 12.2) in European countries though this varies significantly by country [28]. In the UK, around 10.6% of mothers in the UK are still smoking at the point of delivery. This varies from area to area, with rates as high as 27.8% in Blackpool and as low as 1.6% in Wokingham [29]. Smoking during pregnancy is associated with miscarriage, ectopic pregnancy, low birth weight, premature birth, stillbirth, and intrauterine growth retardation [30-33]. Infants of mothers who smoked during pregnancy are also at higher risk of sudden infant death syndrome as well as subsequent developmental and health-related consequences [32].

Smoking during pregnancy is highest amongst younger mothers who have lower educational attainment, lower levels of social support and come from lower socioeconomic backgrounds [34, 35]. For some women, the stresses related to

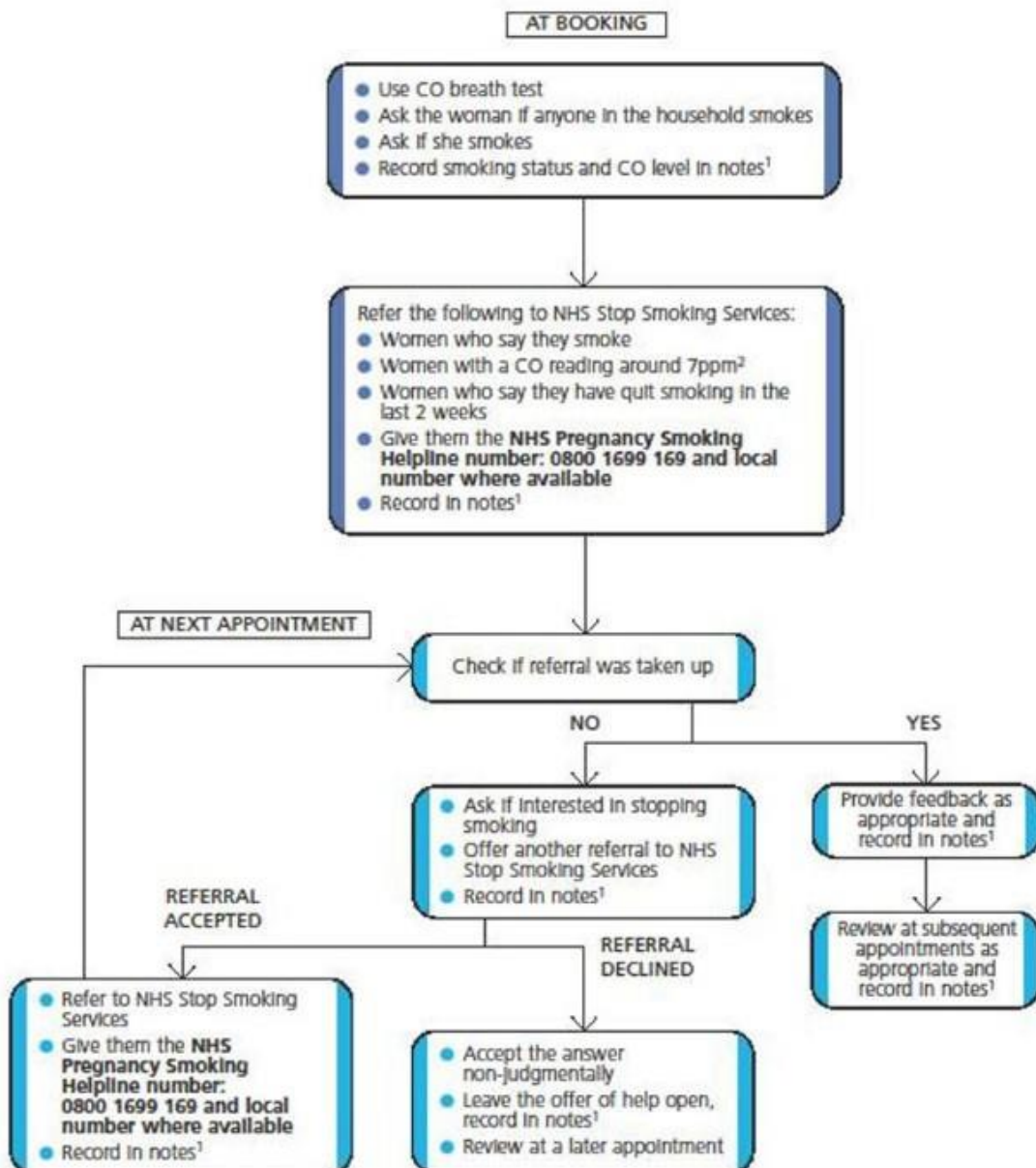
pregnancy and the broader context of their lives (such as socioeconomic disadvantages) are barriers to quitting smoking during pregnancy. Relationships may also be a barrier or facilitator for quitting smoking during pregnancy. Having a partner who smokes can reduce a woman's chances of successfully being smoke-free throughout her pregnancy, whereas having a supportive partner can improve a woman's chances of quitting smoking successfully. Relationships with healthcare professionals are also a key facilitator; women who receive smoking cessation counselling and feel supported, rather than judged, have a better chance of remaining smoke-free [36].

National Institute for Health and Care Excellence (NICE) guidance recommends a referral pathway for midwives to identify and support pregnant smokers. This involves discussions with women regarding their smoking status, carbon monoxide (CO) testing, and referring those in need of support to stop smoking services [37]. Women who smoke in pregnancy, and fail to quit with behavioural support alone, are recommended to use Nicotine Replacement Therapy (NRT) such as patches or lozenges, but to avoid other pharmaceuticals such as varenicline or bupropion while pregnant [38]. More recently groups such as the smoking in pregnancy challenge group, alongside bodies such as the Royal College of Midwives (RCM), has supported the use of electronic cigarettes for pregnant women trying to quit smoking [39].

Figure 1.1 NICE referral pathway

Recommendation 1: Referral pathway from maternity services to NHS Stop Smoking Services

Provide all women with information (for example, a leaflet) about the risks of smoking to her and the unborn child, including smoking by partners or family members. Address any concerns she, her partner or family may have about stopping smoking. Tell partners and family members about NHS Stop Smoking Services.



¹ Preferably the patient handheld record.

² Lower level (e.g. 3 ppm) may apply for light/infrequent smokers. Note: higher level might apply if prior exposure to other sources of pollution, e.g. traffic fumes, leaky gas appliances.

1.1.3 Smoking postpartum

1.1.3.1 Epidemiology of smoking postpartum

Postpartum relapse refers to women who stopped smoking immediately before or during pregnancy, resuming smoking within one year of giving birth [40, 41]. Qualitative research on smoking in pregnancy identifies concern for the baby's health and the desire to be a responsible mother as the primary motivators for the decision to quit and maintain abstinence [42].

The percentage of women who quit smoking during pregnancy is not well reported. However, a recent cohort study identified around 43% of women smoking at least three months before pregnancy have quit smoking by 26 weeks gestation; this figure drops slightly to 41% at 34-36 weeks gestation [43]. Although many mothers spontaneously quit during early pregnancy and wish to remain abstinent [44], around 44% will resume smoking within six months of giving birth [45, 46], and approximately 75% will return to smoking within 12 months [47]. A recent systematic review suggests that by six months postpartum the proportion of women returning to smoking is 43% (CI = 16-72%) from pooled data of studies that did not biochemically-verify smoking status, and 74% (CI = 64-82%) for pooled studies that did biochemically-verify smoking status [48].

1.1.3.2 Health effects of smoking postpartum

Smoking relapse postpartum exposes the infant to potential morbidity and mortality. Young children are more susceptible than adults to the harms of passive smoking, particularly as their respiratory system is still immunologically immature [49]. A meta-analysis examining the risk of lower respiratory tract infections in infants found the odds ratio (OR) for an infant developing a lower respiratory tract infection was 1.58 (CI 1.45-1.73) if the mother smoked postnatally. The same review found any household smoking increased the risk of the infant developing bronchiolitis (OR 2.51, CI 1.96-3.21) [50]. A further meta-analysis found an increased risk of wheezing (OR = 1.70, CI 1.24-2.35) and asthma (OR = 1.85, CI 1.35-2.53) in infants ≤ 2 years whose mothers smoked [51].

As well as respiratory health effects, a meta-analysis identified that maternal smoking postnatally was associated with an increased risk of sudden infant death syndrome (OR = 1.97, CI 1.77-2.19) [52]. Other meta-analyses have concluded that maternal smoking increases the risk of middle-ear infections (OR 1.62, CI 1.33-1.97) [53], and invasive meningococcal disease (OR = 2.26, CI 1.54-3.31) [54]. Parental smoking is also a predictor of adolescent smoking; a meta-analysis identified that any parental smoking significantly increased the risk of the child smoking (OR 1.72, CI 1.59-1.86), this is particularly significant if the mother smoked (OR 2.19, CI 1.73-2.79) [55].

Parents who smoke may be given tips by health care professionals or can find advice online, on ways to reduce the risk to their child from tobacco smoke exposure. These include only smoking outside of the house, removing outer-layer clothing immediately after smoking, washing hands before picking up their baby and avoiding smoking close to the time they feed or pick up their infant as smoke continues linger for 2-3 hours after smoking [56]. Although all parents are advised to avoid bed-sharing, due to the increased risk of Sudden Infant Death Syndrome (SIDS), smoking parents are especially encouraged to never bed share/co-sleep with their infants [57]. Smoking mothers are also advised to breastfeed as breastmilk can offer some protective factors for the infant from the harm of cigarettes [58, 59].

1.1.3.3 Why women return to smoking postpartum

Factors associated with a higher risk of relapse are similar to those associated with smoking in pregnancy. A recent systematic review found that the most significant predictors for postpartum relapse were; being less well-educated, younger, living with a household member who smoked, being multiparous, experiencing higher levels of stress, depression or anxiety, not breastfeeding, only intending to quit throughout pregnancy, and having low confidence about remaining abstinent [60]. This review encompassed 39 studies; the quality of these studies overall was insufficient for any particular factor to allow for a meta-analysis, however, the majority of the studies were graded as high quality.

A thematic synthesis of qualitative studies exploring postpartum return to smoking identified factors affecting relapse and barriers and facilitators to relapse prevention around five key themes; beliefs, social influences, motivation, physiological factors, and identity [61]. In this review, which included 16 studies (reporting the views of 1031 women), barriers and facilitators are context-dependent. They have the capacity to help or hinder remaining smoke-free during the postpartum period. For example, the motivation for quitting smoking may have been dependent on pregnancy (protecting the unborn baby from harm). For some women that motivation is no longer present once the baby is born, whereas others are motivated to remain smoke-free to avoid second-hand smoke exposure to the infant. The authors noted the themes of most importance were often misinformed beliefs [61], such as smoking as a way of mediating stress. This review also highlighted how pivotal the transition to motherhood is for smoking cessation; stress and lack of sleep resulting from new-born behaviour was a barrier to remaining smoke-free, although for some women the mothering role was a protective factor against relapse. This transitional theme was related to identity, where some women felt smoking was integral to their 'old life' before motherhood [61].

Similarly, an earlier review [36] found social relationships reinforced identity; for some women, their immediate social circle had an expectation the mother would quit smoking during pregnancy but resume smoking postpartum. This review [36] also highlighted how barriers and facilitators for remaining smoke-free were not fixed and invariant.

Both reviews [36, 61] highlighted social influences and relationships as being important barriers and facilitators to smoking cessation in the postpartum period. For example, women whose partners smoke or are generally unsupportive of their quit attempts are more likely to report returning to smoking in the postpartum period. In contrast, good support and health care professionals who are supportive and non-judgemental can help mothers to remain smoke-free. Both reviews offer an insight into what may help or hinder women's attempts to remain smoke-free postpartum. However, it should be noted the later review [61] only included American/Canadian studies, which may not apply to the UK due to differences in health care systems.

Ethnographic research also suggests that smoking cessation is linked to both gender and class [62]. For example, historically gender roles place the health of women as a lower priority [62]. This research also suggests that ambivalence towards social mobility was directly related to ambivalence towards smoking cessation. In working class communities there are inequalities in the dissemination of health literature and unequal opportunities for smoking cessation, this leads to smoking as a social norm [63, 64]. Therefore smoking is more acceptable and, as a consequence, more prominent during pregnancy amongst working-class communities [65]. This may explain why lower educational attainment and SES are associated with smoking in the postpartum period.

1.1.3.4 Relapse prevention interventions

Relapse prevention refers to interventions that aim to reduce the risk of now-abstinent smokers returning to smoking.

Behavioural interventions

Behavioural interventions have focused on counselling, education and self-help materials. One systematic review of behaviour change techniques to prevent return to smoking postpartum identified 32 trials, six of which reported long-term effectiveness [66]. The review highlighted that the most beneficial interventions include problem-solving, information about health consequences, information about social and environmental consequences, social support, reducing negative emotions, and instructions on how to perform a behaviour. Although long term effectiveness of some behavioural interventions were identified in this review [66], another systematic review published the same year did not find evidence to support the efficacy of behavioural interventions in pregnancy (RR= 1.05, CI 0.99-1.11), or postpartum (RR= 1.02, CI 0.94-1.09) [67]. This systematic review considered relapse prevention techniques amongst the general population but included a sub-analysis of 8 pregnancy, and 15 follow-up postpartum studies that were all behavioural interventions [67].

The behavioural interventions reported in this review [67] ([68-73]) included face to face counselling throughout pregnancy and postpartum with additional materials [68, 69] and a follow-up video about the benefits of remaining smoke-free [69]. The addition of leaflets and materials wasn't sufficient to reduce relapse rates [68]. There was some success with using a video prompt, although this effect decreased over time [69]. One study using motivational interviewing showed no effect in reducing relapse [70]. The final postpartum intervention in this review included both face to face and telephone counselling [71], but again there was no observed difference between the treatment and control group. Within this review, 15 studies followed up in the postpartum period; these had no significant effectiveness at reducing postpartum relapse (RR 1.02, CI 0.94-1.09).

Self-help materials are somewhat effective in reducing the risk of returning to smoking postpartum. Brandon et al. [72] used the 'forever free' booklet; an in-depth booklet, including educational information about tobacco dependence plus cognitive and behavioural strategies to manage cravings. The books were given throughout pregnancy and postpartum. Participants were randomised into two groups; treatment group who received the 'forever free' booklet and a control group who received usual care. Participants were then followed up at 1, 8 and 12 months postpartum and paid for their participation. The treatment group were significantly less likely to return to smoking at eight months postpartum compared to the control group (OR = 1.27, CI 1.04-1.56); however, no significant differences were observed at 1 and 12 months postpartum. Household income acted as a moderator for this effect; for households with an annual income of less than \$30,000 the treatment group was significantly less likely to return to smoking at eight months (OR = 1.48, CI 1.09-2.00, $p=0.012$) and at 12 months (OR= 1.58, CI 1.17-2.14, $p <0.01$). No significant differences were observed for household incomes more than \$30,000 per annum. As women from lower socioeconomic backgrounds are more likely to return to smoking postpartum [41, 46], the results of this intervention are promising. However, there were no a priori predictions regarding a moderating variable meaning this post hoc test requires replication. It should also be noted that of the 594 women involved in this study, biochemical verification of self-

reported smoking status was only performed on 22 local women as the study was conducted via mail. Previous research has suggested that biochemical results are inconsistent with self-reported behaviour in up to 26% of cases [74]. This study was also under representative of racial and ethnic minority women, who are more likely to smoke in the postpartum period [41, 46].

One study recruited an ethnically diverse sample of women with a household income of less than \$30,000 per annum [73]. This study used Motivation and Problem Solving (MAPS); a holistic approach to aiding and maintaining behaviour change based on motivational interviewing and social cognitive relapse prevention theories. In this trial 251 women were randomized into either MAPS or usual care groups. They attended assessment visits at 30-33 weeks pregnant, eight weeks postpartum, and 26 weeks postpartum and were compensated for their time with gift cards and small items such as nappies. All participants were given self-help materials, with the MAPS group receiving additional telephone counselling. When adjusted for age, race, education and partner's smoking status, the treatment was somewhat effective at reducing the risk of relapse (OR = 1.60, CI 1.00-2.58), although this only just reached statistical significance and decreased over time. In this study, smoking status was biochemically validated at 8 and 26 weeks postpartum; however, continuous abstinence was self-reported.

Financial Incentives

Four studies identified used financial incentives to remain smoke-free in the postpartum period [75-78]. Two studies were combined with other approaches to preventing relapse; self-help materials [75], and social support [77]. All studies used incentives through pregnancy and followed on with incentives postpartum.

Only one of the studies had a control group for comparison, Heil [78] found that offering vouchers based upon biochemically verified abstinence significantly increased the likelihood of smoking abstinence from pregnancy, to 12 weeks postpartum (24% abstinent compared to 3% of the control group, $p= 0.006$).

The use of financial incentives postpartum combined with self-help materials, has shown effectiveness for reducing relapse rates up to 12 months postpartum [75], compared to care as usual. As part of a quasi-experimental study, women were given self-help materials and counselling monthly and asked to complete a CO breath test at each visit; if the test were negative, the women would receive the incentive to remain smoke-free. This study found voucher incentives were most effective when combined specialist cessation counselling and extended postpartum visits, compared with less intense cessation counselling and usual visits (OR = 4.60, CI 2.80-7.57).

Previous research has combined financial incentives (\$50 a month for biochemically verified quits) with social support [77]. This study found that the treatment group, which included a self-appointed peer support person who would also receive the same financial incentives for validated quits, were more likely to remain abstinent from smoking at two months postpartum ($p < 0.001$). Higgins et al. [76] added to this by offering a contingent voucher for biochemically verified smoking abstinence, and a non-contingent voucher regardless of smoking status. This study examined whether the effects of an incentive-based intervention would persist beyond the two months postpartum found by Donatelle et al. [77]. It was observed that the contingent based voucher conditions were still statistically effective ($p < 0.0001$) at reducing relapse rates at 24 weeks postpartum.

Apart from the Heil study [78], there are no control groups within financial incentive studies. In Gadomski et al. [75] and Donatelle et al. [77], all conditions resulted in higher levels of postpartum abstinence than the usual levels of abstinence postpartum observed. In contrast, Higgins et al. [76] observed similar levels of abstinence to that of usual care in the non-contingent voucher group. There is a need for randomised control trials with control groups of usual care to fully assess the effectiveness of incentive-based studies. As incentive-based studies are often combined with self-help materials and counselling, it is difficult to assess the true impact of the incentive versus the combined intervention style. Overall there are significant limitations to these findings. As such, they should be viewed with a degree of caution.

Health care professional led

The systematic review mentioned above [67] also included a health care led intervention [79]. In a randomised trial, health care professionals involved in the usual care of pregnant women were given training on how to tailor smoking cessation counselling to women based on their current stage of behaviour change [79]. There was significantly less risk of returning to smoking (biochemically validated) within 1 month postpartum (OR = 3.01, $p = 0.04$); by 3 months postpartum, there was still a small effect, but this was not significant (OR = 1.91, $p = 0.65$). The initial results observed during the first month postpartum are promising. However, previous research shows that the majority tend to relapse after 1 month [40]. The power of this study is reduced in comparison to individualised randomisation due to controlling for the clustering of women in the health centers. It does, however, suggest interventions that are successful during pregnancy do not persist over time in the postpartum period. It's also worth noting that this study did not report the confidence intervals relating to the odds ratios; this makes the full effectiveness challenging to ascertain.

Further research using health care professionals, educated midwives on how to deliver smoking cessation advice. Midwives distributed self-help materials for women, including a video on the benefits of remaining smoke-free [80]. Compared to a control group (who received treatment as usual) women were significantly more likely to achieve continuous abstinence from smoking at 6 weeks postpartum ($n=286$, OR = 6.25, CI 1.16-33.61), however, due to logistical issues smoking status was self-reported. Originally urine samples were collected to verify smoking status, but due to a problem with transportation, the majority of samples were lost, so smoking status was not biochemically verified for the majority of participants. At 6 weeks postpartum, only 7 urine samples were tested, this may have led to self-report biases, and these results should be viewed with caution. Previous research has shown that midwifery-led interventions are acceptable and well adhered to, although again, reduction in postpartum relapse rates only persists up to 1 month postpartum [81].

Pharmaceutical

The use of other pharmaceuticals has not been widely studied with postpartum women. Nicotine replacement therapy (NRT) is a method used to quit smoking that may consist of lozenges, transdermal patches or inhalation products. Of the two studies identified that considered NRT in the postpartum period, it was found to be unsuccessful at maintaining cessation [82, 83]. To date, studies concerning NRT and postpartum cessation exist only as extensions to pregnancy studies.

While there is no pharmaceutical evidence for postpartum relapse, a systematic review of relapse prevention techniques amongst the general population, that included 81 studies (69,094 participants) with randomised abstainers, showed extended pharmaceutical use could be effective at preventing relapse [67]. This was particularly evident for varenicline (RR= 1.23, CI 1.08-1.41) and rimonabant, an anti-obesity drug now withdrawn due to serious psychiatric side-effects, (RR= 1.29, CI 1.08-1.55). There was some evidence for the effectiveness of extending NRT with unaided abstainers (RR= 1.24, CI 1.04-1.47), but this was inconsistent with NRT for hospital inpatients (RR= 1.23, CI 0.94-1.60) and assisted abstainers (RR= 1.04, CI 0.77-1.40) [67]. NRT combined with bupropion was also not significantly successful in reducing relapse (RR= 1.18, CI 0.75-1.87), nor was bupropion on its own (RR= 1.15, CI 0.98-1.36).

Although not tested in a postpartum population, a meta-analysis found there was no substantial evidence to suggest one pharmaceutical drug, bupropion, is harmful to take during pregnancy [84], and thus may be safe for postpartum women. Bupropion is an anti-depressant that is licensed for smoking cessation use in the United Kingdom since 2000. It works as a smoking cessation aid by inhibiting dopamine reuptake [85] and has proven to be effective in many trials, helping around 20% of smokers to quit [86-88]. However, a review of relapse prevention techniques amongst the general population did not find evidence of bupropion's effectiveness at preventing relapse (RR= 1.15, CI 0.98-1.36), even if combined with NRT (RR= 1.18, CI 0.75-1.87) [67].

Although the use of pharmaceuticals is an effective method of quitting smoking [67, 89], pharmaceuticals are primarily used to quit smoking, rather than prevent relapse.

Follow-on interventions

Most postpartum relapse prevention interventions are follow on interventions from pregnancy interventions. Some interventions have shown potential for reducing smoking in pregnancy using cognitive behavioural therapy (CBT), social support, counselling and self-help materials, but have shown no effectiveness in the postpartum period [90-98]. In a randomised controlled pilot study, pregnant smokers were asked to select an 'intervention supporter' (a female friend or relative to help them quit smoking and sustain cessation) [99]. In the intervention group, the supporter was to receive monthly contact to aid with counselling and support of the mother. Although the study showed an overall trend for biochemically validated abstinence at 3 months postpartum, this was not significant. Due to randomisation, the intervention group included a significantly higher proportion of multiparous and ethnic minority mothers compared to the control groups. Both demographics are associated with higher levels of smoking during pregnancy and higher levels of relapse [41, 46]. Fifty-two percent of the 'supporters' were also smokers, which may have impacted the results.

Interventions to prevent women from relapsing to smoking postpartum have included behavioural, cognitive, social, and incentive-based study designs. Overall there is still no intervention that successfully prevents women relapsing postpartum and sustaining that abstinence. Although incentive-based study designs do show more positive results for maintained abstinence, there are serious methodological flaws to take into account.

1.1.4 Summary

Smoking postpartum remains a public health concern, with a significant proportion of mothers continuing to smoke, or returning to smoking within the first 6 months postpartum. This poses serious health risks for both mother and child. Although interventions exist, they have not shown consistent success in reducing postpartum

smoking. Evidence suggests that self-help and financial incentives do show some effectiveness in reducing the risk of postpartum relapse. However, effectiveness is often not sustained long term, and there are issues such as relying on self-reported smoking status. Several risk factors of postpartum return to smoking exist, including whether a mother plans to breastfeed, and whether she initiates breastfeeding.

1.2 Breastfeeding: overview

Breastfeeding is the natural process of feeding an infant via lactation. Breastmilk may be given to the infant directly from the breast or expressed and fed via a bottle. In research, breastfeeding is divided into “never breastfed” (baby has only received formula milk from birth) or “ever breastfed.” Ever breastfed can relate to exclusive breastfeeding (just breastmilk without supplementary formula milk or solid foods), combination feeding (with supplementary foods/formula), or early cessation of breastfeeding (breastfed at birth but switched to formula milk.)

1.2.1 Health consequences of breastfeeding

Profound health benefits for both mother and baby are associated with any breastfeeding, although greater benefits are seen in infants who are breastfed exclusively and for a longer duration of time. Breastfeeding is known to reduce the risk of Sudden Infant Death Syndrome (SIDS). In a meta-analysis involving 18 studies the summary odds ratio (SOR) of SIDS for infants who received any amount of breastmilk for any duration was 0.40 (CI 0.44-0.69), and for breastfeeding for 2 months or longer the SOR was 0.38 (CI 0.27-0.54), compared to infants who had never been breastfed. When considering only infants who were exclusively breastfed for any duration, the SOR was 0.27 (CI 0.24-0.31) [100].

Breastfeeding is also known to protect against gastrointestinal illnesses [101], a breastfed baby is less likely to develop Crohns disease (OR=0.45, CI 0.26-0.79) or ulcerative colitis (OR= 0.56, CI 0.38-0.81) [102]. Breastfeeding is also a protective factor against the development of asthma (OR 0.78, CI 0.74-0.84) and wheezing illnesses

(OR 0.81, CI 0.76-0.87) [103]. A meta-analysis found that babies exclusively breastfed for 4 months or more were less likely to be admitted to hospital with any respiratory illnesses (OR 0.28, CI 0.14-0.54) [104]. Breastfeeding for 6 months or longer is also associated with a 20% lower risk of developing childhood leukaemia (OR= 0.80, CI 0.72-0.90) [105]. Research suggests breastfeeding is a protective factor against other childhood cancers, although the quality of this research is low and causality cannot be assumed [106].

Overall, infants aged 6-11 months who were not breastfed have a risk ratio (RR) of 1.76 (CI 1.28-2.41), and those aged 12-23 months have a RR of 1.97 (CI 1.45-2.67), for all-cause mortality compared to infants who received any breastmilk. The risk ratio is higher in infants aged 0-5 months and increases the more breastfeeding is reduced. A predominantly breastfed baby (a breastfed baby supplemented with formula milk) has a RR of 1.48 (1.13-1.92), a partially breastfed baby (a baby who is formula fed but receives some breastmilk) has a RR of 2.84 (1.63-33.9), and a baby who receives no breastmilk has a RR of 14.4 (CI 6.13-33.9) of all-cause mortality when compared to exclusively breastfed infants [107].

Breastfeeding also has health benefits for the mother; in a meta-analysis Chowdhury et al. calculated the relative risk of developing breast and ovarian cancer [108]. The results showed that ever breastfeeding was associated with a reduced risk of breast cancer (OR=0.78, CI 0.74-0.82) compared to never breastfed. This review found that the longer a mother breastfed, the more significant the reduction in risk. Mothers who breastfed for 6 months had an OR of 0.93 (CI 0.88-0.99), those who breastfed 6-12 months had an OR of 0.91 (CI 0.82-0.96) and those who breastfed >12 months had an OR of 0.74 (CI 0.69-0.79) when compared to women who had never breastfed [108]. For ovarian cancer, the OR for women who had ever breastfed, compared to never breastfed, was 0.70 (CI 0.64-0.77). As with breast cancer, the risk of developing ovarian cancer reduced the longer a woman breastfed for; for those who breastfed for <6 months the OR was 0.83 (CI 0.78-0.89), 6-12 months (OR 0.72, CI 0.66-0.78) and for >12 months (OR 0.63, CI 0.56-0.71) [108].

Low breastfeeding rates in the UK may have led to increased incidence of illnesses with significant cost implications for the National Health Service (NHS) [109].

1.2.3 Breastfeeding trends

During the 20th century, breastfeeding became less common in high-income countries, and amongst wealthier and better-educated women in middle-income countries [110]. The introduction of formula milk, an artificial breastmilk substitute, led to a societal opinion that breastfeeding was for the poorer and less sophisticated in society. Formula milk was perceived as a modern and sophisticated way of feeding an infant [111]. This enabled women to work outside the home with more ease, and as breasts became more sexualised, formula feeding became the norm [112].

Not breastfeeding can have health consequences for both mother and baby; thus, the Innocenti Declaration was adopted as a global goal in 1990 [113]. The declaration stated that all women should be supported and enabled to exclusively breastfeed from birth to at least 4 months (adjusted to 6 months in 2016). It affirmed that infants should continue to breastfeed for up to 2 years old, supplementary to solid foods and water from 6 months. The UN Convention for the Rights of Children also introduced a legal obligation for countries to promote breastfeeding, adopt working practices to enable working women to breastfeed and to reduce marketing practices that promoted biased information designed to influence women to adopt formula feeding [114]. In 1991 the Baby-Friendly Hospital Initiative (BFHI) was also established to support, promote, and establish breastfeeding within hospitals [115]. The BFHI has had a significant effect globally [116-118] but has had limited success in the UK [117].

The Infant Feeding Survey was (until 2010) conducted every 5 years to measure UK breastfeeding rates. The final Infant Feeding Survey showed that despite 81% of mothers initiating breastfeeding at birth, only 24% were still breastfeeding at 6 weeks postpartum, and by 6 months only 1% of UK infants are still breastfed. While the 2010 report [119] showed a 12% increase in breastfeeding initiation since 2005, by 12 weeks postpartum, the UK has the lowest breastfeeding rates globally (17%) [120]. By a year

old, only 0.5% of UK mothers are still breastfeeding compared to 23% in Germany, 56% in South America and 99% in Senegal [120]. More recently, Public Health England has continued to collect breastfeeding statistics but only at 6-8 weeks postpartum. The latest annual report identified 46.2% of mothers are still breastfeeding at 6-8 weeks postpartum (CI 46.1%-46.3%); however, this does not differentiate between exclusive breastfeeding and any breastfeeding. It is also important to note that of the 145 local authorities involved in the data collection, only 72 are included in the 2018/2019 report due to validation issues [121].

The differences between breastfeeding rates within the UK and other countries can be explained by cultural differences. The cultural experiences of breastfeeding drastically vary. For example in some cultures withhold breastmilk for the first 48hrs of life due to the belief that colostrum, the initial milk produced immediately after birth is 'dirty'. Despite this, women in these cultures are still committed to exclusive breastfeeding, for example in India 35% of infants had still not breastfed at 48hrs old, however by 1 month old 94% of infants were exclusively breastfed [122]. In some cultures, breastfeeding is expected, celebrated and supported; for example many countries still practice 'confinement' after birth, that is a period of time in which the new mother is expected to remain home, usually in bed, with very few visitors as she acclimatises to motherhood and focuses on breastfeeding her infant [123].

Within Western cultures breasts are often sexualised [112]; this can cause women to feel uncomfortable about feeding their infant outside of the house or in the company of others [124] [125] [126]. Research suggests that in the UK, breastfeeding is not seen as the social norm amongst women from lower SES areas. They report negative attitudes towards breastfeeding themselves and negative influences from friends and family about breastfeeding. Women also felt they had a lack of knowledge about breastfeeding and limited support from health care professionals [127].

1.2.4 Factors associated with breastfeeding

Previous research concerning breastfeeding rates has identified sociodemographic factors as being significant predictors of breastfeeding [128]. Maternal age is associated with both the initiation [129] and duration [130] of breastfeeding, with younger mothers less likely to breastfeed. Women over the age of 25 are more likely to breastfeed, and women under 25 have a RR of 2.33 (CI 1.33-4.05) of early cessation of breastfeeding [131]. Another study conducted in Scotland identified that the OR of a mother breastfeeding significantly increases by 1.05 (CI 1.02-1.08) per year of age [132]. The same study found that previously breastfeeding increased the odds of breastfeeding by 6.4 (CI 4.00-10.31) and living with a partner also increased the chances of a mother breastfeeding (OR= 1.92, CI 1.29-2.90) [132]. Marital status has been shown in previous work to be associated with breastfeeding, with single mothers less likely to breastfeed (RR= 1.46, CI 1.12-1.90) [130]. In a study focused on mothers from England and Wales, it was highlighted that lower socioeconomic status was associated with not breastfeeding, and breastfeeding for a shorter duration. They also identified lower educational attainment and lower household income, along with younger age, were associated with not breastfeeding and breastfeeding for shorter durations [133].

Ethnicity is also associated with breastfeeding, with lower breastfeeding rates observed within ethnic and racial minority groups [134]. However, there is conflicting evidence as to whether belonging to an ethnic/racial minority increases or decreases the likelihood of breastfeeding. Some research shows that first-generation immigrants are more likely to breastfeed than those who are second-generation [135]. In the United Kingdom, Pakistani, Bangladeshi, black Caribbean, and black African mothers are more likely to initiate breastfeeding, and continue breastfeeding at 3 months, compared with white mothers [136].

Smoking status is one of the most significant predictors of breastfeeding; women who smoke are less likely to intend to breastfeed, to initiate breastfeeding and are more likely to breastfeed for a shorter duration when compared to non-smokers [137-139]. In a study of 2323 women, smoking was found to be the strongest predictor of not breastfeeding in comparison to other sociodemographic factors [140]. It is suggested

that breastfeeding rates could be improved if women reduced or quit smoking cigarettes [137].

1.2.5 Interventions to increase breastfeeding

Interventions have focused on supporting women to initiate breastfeeding and maintain breastfeeding for as long as possible. When designing interventions to improve breastfeeding rates, there are three time points to consider; the intention to breastfeed during pregnancy, the initiation of breastfeeding at birth, and the continuation of breastfeeding after birth.

The Innocenti Declaration and UNICEF have focused on intervening from a policy and structural perspective. A review by Fairbank et al., (2000) suggests that while health sector initiatives can be effective at promoting the initiation and continuation of breastfeeding, these effects are only really seen within rural or low-income areas. This review also highlighted that the effectiveness of health sector initiatives were inconsistent across studies [141]. Therefore, interventions may be more effective if focused on an individual level.

One systematic review considering interventions to increase breastfeeding indicates that lay peer support combined with education and professional support was successful in improving the continuation of breastfeeding [142]. Lay peer support encourages other mothers who have breastfed or are trying to breastfeed to work with other mothers to support their breastfeeding journey. In this review, peer support was combined with professional advice from health care professionals and educational materials on the benefits of breastfeeding. Despite an improvement in the duration mothers' breastfed for, this review found no evidence for the efficacy of peer support with the intentions to breastfeed, nor the initiation of breastfeeding at birth. It may be that mothers who are already motivated to breastfeed benefit from peer support to overcome any barriers they face after the initiation of breastfeeding. Fairbank et al., highlighted that peer support was effective for increasing breastfeeding initiation and duration, but only amongst low-income families [141].

In a UK specific review, while professional support has shown to be significantly effective for any breastfeeding (RR = 0.89, CI 0.81-0.97), this is not significant for increasing exclusive breastfeeding. Conversely, the same review found lay support to be significantly effective at reducing the cessation of any breastfeeding (RR= 0.66, CI 0.49-0.89) but it was not significantly effective at increasing exclusive breastfeeding [143]. A UK specific review is useful for understanding the role professional support may have in increasing breastfeeding due to specifically low breastfeeding rates in the UK, and differences amongst global healthcare models.

A further review and meta-analysis by Sinah et al. (2015) [144] looked at how the effectiveness of interventions may be influenced by the setting in which it is delivered. This review looked at the initiation, exclusivity and duration of breastfeeding. Overall, when pooled, interventions increased breastfeeding initiation (RR= 1.25, CI 1.19-1.32), exclusive breastfeeding (RR= 1.44, CI 1.38-1.51), any breastfeeding (RR= 1.38, CI 1.28-1.50) and breastfeeding up to 23 months (RR= 1.61, CI 1.17-2.20). The review concluded that for all breastfeeding time points, interventions delivered concurrently in a combination of settings (hospital, home and community) were more effective than independent interventions delivered in a single setting. It should be highlighted, however, that there was a high degree of heterogeneity, even for subgroup analysis. Therefore it is difficult to determine whether the overall analysis of effects is due to the different intervention settings rather than the differences between the studies.

Haroon et al. conducted a systematic review and meta-analysis to look at the effectiveness of promotional interventions for breastfeeding [145]. The review included 63 randomised control trials and 47 quasi-experimental studies. The results indicated that educational interventions significantly increased exclusive breastfeeding rates at birth (RR= 1.43, CI 1.09-1.87), 1 month (RR = 1.30, 1.19-1.42) and between 1-5 months (RR= 1.90, CI 1.54-2.34). Educational interventions had no significant effect on predominant or partial breastfeeding. This review also found evidence that individual counselling was effective at reducing never breastfed (RR= 0.73, CI 0.55-0.96), and that group counselling was effective (RR= 0.57, CI 0.41-0.80), however, when combined there was no significant effectiveness [145]. Longitudinally, education, and

counselling were still effective at 6-12 months, increasing partial breastfeeding rates (RR= 1.19, CI 1.12-1.26) but not significant at increasing exclusive or predominant breastfeeding rates. This review evidenced the effectiveness of interventions early on; however, it showed limited success for breastfeeding beyond 6 months; this review concluded that overall, interventions were most effective for developing countries [145].

An editorial published in 2011 considered interventions conducted more recently; in the UK, none of the interventions tested in nine randomised controlled trials since 2000 found any significant improvement for breastfeeding [146], whereas international studies suggest interventions have effectiveness above usual care [147]. The editorial suggested that there are often methodological weaknesses in UK based intervention studies and that interventions delivered are often reductionist and not understanding of how complex breastfeeding may be. The editorial calls for more individualised and tailored interventions for UK mothers [146].

1.2.4 Summary

Breastfeeding is the healthiest infant feeding option for both mother and baby, with profound acute and long-term health benefits. Rates of breastfeeding declined globally in the 18th century, and despite recent global initiatives to increase breastfeeding having some effect, rates of breastfeeding in the UK remain low. While interventions have shown some success, they are often successful in improving 'partial' breastfeeding; these successes also have a minimal impact on the duration of breastfeeding. Various sociodemographic factors influence whether a woman breastfeeds or not. One factor related to whether a woman breastfeeds is her smoking status. Mothers who smoke are much less likely to initiate and continue breastfeeding.

1.3 Smoking & Breastfeeding: overview

Breastfeeding has been identified as a protective factor against returning to smoking postpartum, and research has identified that smoking may negatively impact whether a woman breastfeeds or not, and for what duration. Interventions to reduce smoking

postpartum are largely ineffective, and breastfeeding interventions have shown little if any, effect in the UK. As both smoking and not-breastfeeding can lead to serious health consequences for both mother and baby, combining support for both behaviours (rather than individually) may be more effective. This would depend on the strength of the association and more understanding of why this association exists.

The initiation and continuation of breastfeeding are positively associated with smoking abstinence in postpartum women [41, 148]. Research suggests that the intention to breastfeed acts as a precipitating factor for reducing postpartum relapse [139]. Research indicates the intention to return to smoking is the strongest predictor of the intention not to breastfeed, as well as mothers who smoke being more likely to wean from the breast early (< 3 months postpartum) [137, 140].

A meta-analysis in 2001 found that smoking mothers had an OR of 1.93 (CI 1.55-2.40) of not breastfeeding compared to non-smoking mothers [137]. After adjusting for maternal feeding intention, another meta-analysis identified that women who smoke during pregnancy have an OR of 2.5 (95% CI: 2.2-2.8) of not breastfeeding at 6 months compared to non-smoking mothers [139].

In a secondary analysis of data from a randomised controlled trial, women relapsing to smoking were more than twice as likely to stop breastfeeding (OR= 2.6, CI 1.5-4.7) than women who remained smoke-free, there was an even stronger association for women who relapsed to daily smoking (OR= 3.6, CI 2.1-6.4). Of the women who relapsed to smoking and stopped breastfeeding, 21.7% had stopped breastfeeding before relapse, 28.9% stopped breastfeeding and relapsed within a 2-week window, but the remaining 49.4% of women who relapsed stopped breastfeeding after they had resumed smoking [149]. Similar associations are found with women who smoke more than 10 cigarettes a day being more likely to stop breastfeeding by 10 weeks postpartum (RR= 2.32, CI 1.13-3.95) [150].

The reported association between breastfeeding and postpartum smoking status has led to the suggestion that including breastfeeding education may enhance current

smoking cessation interventions [151]. Research has shown that breastfeeding promotion can incentivise mothers to remain smoke-free [152].

Within the literature, there is a strong case for an association between smoking and breastfeeding; however, most studies are observational [41, 139, 140, 149-152]. While observational studies are useful for collecting data that is naturalistic, it negates the ability to assume causality. While these studies highlight there is indeed a strong association between smoking and breastfeeding, they do not explore how or why this association exists. There are three proposed explanations for why an association exists.

1.3.1 Proposed explanations

Although there is no known causation for the relationship between smoking and breastfeeding, three primary schools of thought exist; physiological, sociodemographic, and fear of harm.

1.3.1.1 Physiological mechanism

Prolactin and oxytocin are hormones released from the pituitary gland that stimulates the production of milk in postpartum women. This theory suggests that nicotine may suppress the production of prolactin and oxytocin, which in turn lessens milk production, causing the infant to nurse more frequently, and if milk volume is sufficiently reduced, restrict growth and weight gain. If this theory is correct, it will account for why fewer women breastfeed if they smoke.

Nicotine increases the release of dopamine, which in turn may inhibit the release of prolactin [153]; however, research has only been conducted with rodents and thus maybe not generalizable to humans. Some research examining the volume of breastmilk in humans did conclude smoking mothers produce lower quantities of milk than non-smoking mothers [154]. However, this research only involved 20 mothers and did not take into account the complex nature of milk production. For example, how regularly an infant feeds and how well they latch can determine how much milk the

mother produces. One study identified lower basal levels of prolactin in smoking mothers than in non-smoking mothers, but observed infant suckling induced acute increments in prolactin and oxytocin [155]. Some women do report insufficient milk as a reason for switching to formula feeding. However, research suggests that nicotine transfer may cause restlessness in an infant that may be perceived as hunger resulting from insufficient supply [156].

Although there is evidence that smokers have lower basal levels of prolactin, other studies have shown no relationship between plasma prolactin levels and the rate of milk synthesis; thus, the nicotine and milk production association is still uncertain [155, 157, 158]. In a further review of the physiological mechanisms that may account for the smoking/breastfeeding association, it was concluded that studies that reported a negative impact on prolactin either relied on studies of mice or did not account for poor lactation practices [157].

A review of epidemiological evidence considered the role of nicotine as a prolactin and oxytocin suppressant [138]. Six studies were included considering intentions to breastfeed, seven were included for breastfeeding initiation, and 10 studies were included for breastfeeding duration. The review concluded that smoking was consistently negatively associated with breastfeeding intentions, initiation and duration, even when confounding variables were accounted for; this finding was consistent across all study designs. Therefore a physiological effect was unlikely to explain this; as if the association were due to physiological effects, and we would anticipate no differences in the number of women intending to or initiating breastfeeding, we would only see differences in the duration of breastfeeding. Physiological effects cannot explain why smoking mothers are less likely to intend to breastfeed and why they are less likely to initiate breastfeeding at birth.

Overall there is little consistent evidence that nicotine has any detrimental physiological effect on the production of breastmilk.

1.3.1.2 Sociodemographic characteristics

Sociodemographic variables are associated with both smoking status and the likelihood of breastfeeding. Breastfeeding intention, initiation, and duration are related to maternal age, deprivation, and educational levels; younger mothers, those from deprived areas and those with lower levels of education are less likely to breastfeed [159, 160]. These same factors are also associated with smoking during pregnancy and postpartum [34]. Therefore this explanation for the association between smoking and breastfeeding would suggest it is not the behaviours themselves but merely a coincidental association based on shared characteristics.

To test this explanation, research has sought to examine the independent association of smoking and breastfeeding by adjusting for these factors. When these factors are adjusted for the association between smoking and breastfeeding exists independently [140] [139, 150]. In a study based using mothers from the UK, Donath et al., found women who smoked had an OR of 2.5 (CI 2.2-2.8) of not breastfeeding, but when adjusted for maternal age, education, socioeconomic status and breastfeeding intention the OR were reduced (OR = 1.5, CI 1.3-1.7) but still statistically significant [139], with smokers around 50% more likely to not breastfeed than non-smoking mothers. If a statistically significant association between smoking and breastfeeding persists even when sociodemographic characteristics are adjusted for, any association can be due to residual confounding by these and other associated factors. It's also worth noting that the association is likely to be a combination of mechanisms, rather than a given factor. The association cannot be explained purely by shared demographics.

1.3.1.3 Fear of harm

Mother's may consider smoking while breastfeeding to be detrimental to the infant's health, and therefore either do not intend to breastfeed, initiate breastfeeding, stop breastfeeding earlier than non-smoking mothers [161]. In a longitudinal qualitative study, it was identified that women who smoked postpartum believed this affected both the quality and the quantity of their breastmilk; the authors noted around 95% of the

women in their study thought smoking had a negative effect on the quality of breastmilk [162]. This is highlighted in previous work, where mothers feared the composition of their milk was compromised due to smoking [163, 164]. Women felt that smoking caused their milk to contain toxic components, and was therefore not safe. They believed that the taste of their milk was altered resulting in the baby not feeding correctly, and that the presence of nicotine would mean their infant was addicted [162]. This study also highlighted that women were concerned that the closeness necessitated by breastfeeding meant the infant wasn't just exposed to toxins via milk, but also from lingering tobacco smoke on the mother. Misinformation given by health care professionals validated this belief; some participants were told if their infant wasn't gaining enough weight, it was probably due to smoking depleting their milk supply. As well as misinformation, some women reported no health care professional had discussed smoking and breastfeeding with them, and due to the stigma they had felt unable to ask [162].

The NHS [166] report the benefits of breastfeeding even when smoking; despite these recommendations, women are still uncertain of the safety of breastfeeding while smoking [150].

1.3.2 Interventions for smoking and breastfeeding

There have been very few interventions that specifically target both smoking and breastfeeding for behaviour change [167-169].

In a randomised control trial, Philips et al. delivered an intervention combining support for both smoking cessation and breastfeeding within a Neonatal Intensive Care Unit (NICU)[169]. While both the control and intervention groups received encouragement to remain smoke-free and usual care breastfeeding support, the intervention group were also given more information on maternal-infant bonding and encouraged to frequently practice skin to skin holding (which promoted breastfeeding). Within the intervention group, 81% remained smoke-free, compared to 46% of the control group, and 86% were breastfeeding, compared to 21% of the control group by eight weeks postpartum

[169]. While this study showed that a combined intervention was effective, it was limited by its sample size; a priori power analysis estimated 128 mothers would be required for the study, yet only 54 women were recruited. This study also relied on self-reported smoking abstinence and CO monitoring once a week, which is not a reliable measure of smoking given CO would only be indicated if the mother had smoked within the last six hours. However, cotinine levels were checked at the end of the study (at eight weeks postpartum).

A randomised control trial in the Netherlands combined smoking cessation advice with breastfeeding advice as part of the VoorZorg programme; this consisted of between 40 and 60 home visits from specialised nurses throughout pregnancy and until two years postpartum [167]. This resulted in significantly lower rates of smoking during pregnancy and postpartum and well as significantly higher rates of breastfeeding when compared to usual care [167]. Although it should be noted this study relied on self-reported smoking abstinence rather than biochemical verification, this study also did not record whether women were exclusively or partially breastfeeding. There was also a high non-response rate from women in the control group which may have added bias to this study.

Another intervention reported by DiSantis et al. (2010) evaluated the effectiveness of a combined smoking and breastfeeding intervention against a smoking-only intervention. Although smoking was associated with a shorter duration of breastfeeding, the study found there were no differences in breastfeeding or smoking between the two intervention groups [168].

Although interventions combining both behaviours are minimal, there is evidence that a combined intervention can reduce smoking and increase breastfeeding rates and duration.

1.3.2.1 Potential interventions

The use of smoking cessation products among lactating women has not been extensively studied. The use of bupropion during the postnatal period has been reviewed in terms of transference to milk. Concentrations of the drug are higher in breast milk than in maternal plasma concentrations; however, accumulation does not occur in the infant [170]. One study concluded that bupropion should be considered to prevent postpartum smoking even if the mother is lactating [171]. However, we know from research concerning other drugs such as anti-depressants that the acceptability of taking medications is low amongst lactating women [172, 173]. Although one study found bupropion was deemed acceptable by lactating women as long as it was discussed with them during postnatal visits, however, this study did not look at the efficacy of bupropion use [174].

In a descriptive study looking at the attitudes, knowledge and practices of paediatricians in Pennsylvania, less than half of 296 physicians surveyed reported that breastfeeding was safe for smoking mothers [175]. In this study, physicians were asked five knowledge questions about smoking and breastfeeding. Only 21% of physicians were able to answer at least four correctly, and 27% answered none correctly. The lower the score on knowledge questions, the more likely a physician was to recommend formula feeding for smoking mothers [175]. The majority of the physicians involved in the study were also uncertain about whether it was safe to prescribe NRT or pharmaceuticals, such as bupropion, to lactating mothers [175]. Previous research also highlighted that physicians were less likely to recommend NRT to lactating mothers than pregnant women [176]. A recent review of the prevalence and risk of NRT during pregnancy and breastfeeding could not identify any studies concerning the use of NRT, or any potential health effects [177]. Research has found that using NRT does not influence the milk intake by a breastfed infant, and although high strength patches (21mg) show similar levels of nicotine in breastmilk to smoking 17 cigarettes a day. There is a significant reduction ($p < 0.05$) in nicotine present in breastmilk if medium dose (14-mg) or low dose (7-mg) patches are used [178]. Due to the absence of research in this area, the

only information available is in the form of narrative reviews. One such review considering myths around NRT use identified that NRT is likely to be far less harmful than smoking during breastfeeding as infants are not exposed to harmful cigarette smoke [179]. In a guide for health professionals on smoking cessation by the same author, it is recommended NRT should be offered to lactating mothers [180]. However, GlaxoSmithKline and Pfizer, pharmaceutical companies that produce NRT for consumer use, funded this review, which suggests a conflict of interest [179].

Although financial incentives have been used for both smoking cessation and breastfeeding promotion, currently no study has utilised financial incentives for both behaviours concurrently. A mixed-methods review to inform a trial design named the Benefits of Incentives for Breastfeeding and Smoking cessation in pregnancy (BIBS) outlined that incentive-based interventions with tailored components show promise for both smoking cessation and breastfeeding. Still, acceptability from both providers and women was low [181]. The efficacy of combined incentives to support smoking abstinence and breastfeeding remains to be seen.

A relatively new tool that some people have used for smoking cessation [182] is e-cigarettes. These are devices that create a similar sensation to smoking [183, 184] but are less harmful than combustible tobacco [188]. With the potential for harm reduction, this is a potential aid for mothers who smoke to breastfeed that has not yet been explored.

1.3.3 Summary

There is strong evidence of a relationship between smoking and breastfeeding intentions, initiation and duration. There is no substantial evidence that there is a physiological effect of nicotine on prolactin that would explain the strength of this relationship. There is evidence that women who smoke postpartum and women who do not breastfeed share similar demographics, although when these demographics are adjusted for it suggests there may be other mechanisms involved. The available literature supports the theory that the relationship between smoking and breastfeeding may be, at least in part, a psychological one, a fear of harm.

The fear of harm stems from a fear that toxic components of cigarette smoke will be passed to the infant via breastmilk. Women are told during pregnancy how harmful cigarette smoke can be to her unborn baby, and may use this information to inform breastfeeding choices. This is contradictory to advice from the NHS and APA who promote breastfeeding amongst smoking mothers to reduce the harm to the infant from smoking. What isn't currently known is how smoking might be related to breastfeeding in the UK. Recent research concerning smoking and breastfeeding is primarily from Turkey or the USA. Research also compares just smokers and non-smokers, so we are unable to say whether any identified relationship is due to individual differences or the behaviours themselves.

Interventions that promote change to both smoking and breastfeeding are minimal and limited by study design. Relapse to smoking postpartum persists in being a public health concern, which correlates with lower rates of breastfeeding, which is, in itself, a public health concern. A solution may be to offer an alternative method of nicotine delivery. An e-cigarette can create a similar experience to smoking but with reduced risk and may be an acceptable alternative.

1.4 E-cigarettes: an overview

An emerging product that may be useful for preventing relapse, and supporting cessation are e-cigarettes. E-cigarettes are Electronic Nicotine Delivery Systems (ENDS) [189]. E-cigarettes are handheld devices that produce an aerosolized mixture from a solution (e-liquid) typically containing concentrated nicotine, flavouring chemicals, and propylene glycol [190]. E-cigarettes come in many forms (e-cigarettes, e-hookahs, vape tanks, etc.), but generally consist of a flow sensor, battery, solution storage area, and aerosol generator [191]. The user draws a deep breath and inhales the vaporised liquid, an act known as 'vaping', creating a similar experience to smoking combustible tobacco. This may mean the user gains the bio-behavioural feedback they crave from cigarettes to appease their addiction [183]. Bio-behavioural feedback is particularly important for women. Research suggests women are less responsive to the interoceptive effects of nicotine [192, 193], and more sensitive to the sensorimotor

aspects of smoking [193, 194]. In an online survey Dawkins et al., (2013) found that women liked e-cigarettes because of the resemblance and similarity to a combustible cigarette and were more likely to agree they reduced cravings [195].

Nicotine is the principal psychoactive ingredient in e-liquids (although 0% nicotine 'e-juices' are available); thus, e-liquids can be highly addictive and toxic if ingested [196]. Some research suggests that as well as nicotine, there may be exposure to toxicants, carcinogens, and heavy metals via e-cigarette vapour [196-198]. The popularity of e-cigarettes has also caused disagreement within academics, and the public health community, as to whether they will serve as a tool to renormalize nicotine product use and act as a gateway to smoking combustible tobacco [199]. So far, most research suggests that this is not the case [187, 200, 201]. E-cigarettes are cited as being a useful quit aid for smokers looking to reduce or completely quit traditional cigarettes [187, 202-204]. Research concerning the safety of e-cigarettes is ever-growing, however evidence for long term safety is still minimal [205, 206], although Public Health England have reported that e-cigarettes are at least 95% safer than cigarettes [188].

1.4.1 Vapour versus smoke

There are over 2,500 chemicals in a cigarette; upon combustion, these are transformed into over 7,000 chemicals, including more than 70 known carcinogens. The process of combustion is a chemical reaction whereby the reactant molecules (tobacco and oxygen) are mixed and rearranged, becoming product molecules and concurrently releasing heat. This results in the thermal decomposition of tobacco, the result of which is the production of smoke; a mixture of gases and suspended particles [207, 208].

During combustion, the nitrogenous constituents of the tobacco leaf transform into tobacco-specific nitrosamines (TSNAs) [209]; the body metabolises these into carcinogenic compounds. High levels of formaldehyde are observed in cigarette smoke, particularly the first inhale, and trace metals are present [210].

With e-cigarettes, there is no combustion; instead, a heating coil causes a liquid formulation (known as E-liquid or E-Juice) to vaporise, which the user then inhales

[191]. E-cigarette aerosol is generated when the e-liquid reaches between 100-250°C within the liquid chamber [189]. The aerosol generated is composed of liquid submicron particles of condensed vapour which consists of water, nicotine, flavourings, propylene glycol, glycerol and other chemicals [211, 212].

There is a growing body of evidence of empirical data examining the safety and composition of e-cigarette vapour. Toxicity testing has evaluated the chemical nature of the vapour generated from e-cigarettes in comparison to combustible tobacco. Goniewicz et al. [213] generated vapours from 12 different brands of e-cigarettes, alongside the medicinal cessation product; a nicotine inhalator. Using a modified smoking machine, the researchers screened the resultant vapour for four groups of toxic or carcinogenic compounds: carbonyls, volatile organic compounds (VOCs), nitrosamines and heavy metals. Once extracted from the vapour, the selected toxicants were then analysed using chromatographic and spectroscopy methods. The researchers concluded there was evidence of some toxic substances existing in e-cigarette vapour. However, the levels identified were up to 450 times lower than the levels of those toxicants found in cigarette smoke (Table 1.1). They were also, in many cases, comparable to the medicinal product of a nicotine inhalator. A total of 4 carbonyls were found in e-cigarette vapour, a finding consistent across almost all of the e-cigarette brands. Identification of tobacco-specific nitrosamines was less consistent across all e-cigarette samples, with levels of NNN and NNK fluctuating in both presence and amount. Researchers also identified the presence of cadmium, nickel and lead in the e-cigarette vapour.

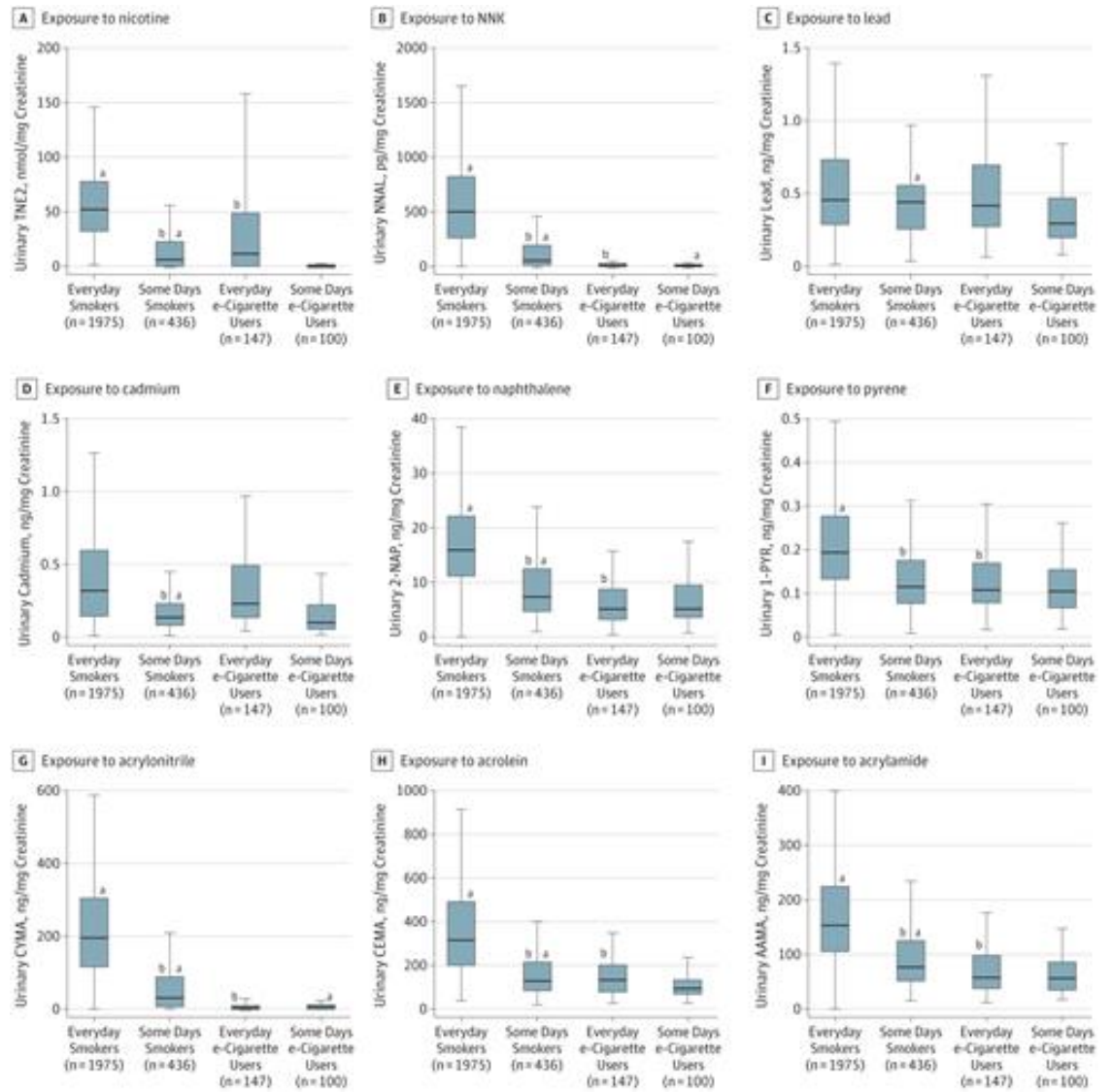
Table 1.1 Goniewicz et al., 2014

Toxic compound	Conventional cigarette (µg in mainstream smoke)	Electronic cigarette (µg per 15 puffs)
Formaldehyde	1.6–52	0.20–5.61
Acetaldehyde	52–140	0.11–1.36
Acrolein	2.4–62	0.07–4.19
Toluene	8.3–70	0.02–0.63
NNN	0.005–0.19	0.00008–0.00043
NNK	0.012–0.11	0.00011–0.00283
Cadmium	1.6-101	0.02–0.22
Nickel	0.1-0.78	0.11–0.29
Lead	3.9-32.9	0.02-0.57

This study supports findings from other studies [214-217] that e-cigarettes represent significantly less exposure to toxic compounds than cigarettes. There are also methodological concerns to consider; this study analysed vapour generated using a smoking machine in laboratory conditions usually used for researching tobacco. Inhalation differs between e-cigarettes and tobacco cigarettes so to create vaping conditions reflecting actual usage, topography ('puffing' behaviour) was measured amongst 10 e-cigarette users. From this it was assumed 'usual' topography involved a user taking 15 puffs on an e-cigarette which corresponded to 1 cigarette; for this study 10 series of 15 puffs were used to generate the vapour. The main limitation of this study is the use of a smoking machine that generates vapour in non-naturalistic conditions. This meant vapour generated might not reflect actual puff topography. Similar to issues observed in tobacco testing with smoke machines, research should consider these vulnerabilities [3].

A method of comparing the exposure to tobacco-related toxicants without artificially generating smoke is to compare biomarkers. Goniewicz et al. [218] conducted a population-based, longitudinal cohort study in the United States. This study used a cross-sectional analysis of biomarkers from exposure to tobacco-related toxicants in urine samples provided by 5105 adults who either smoked (n = 2411), vaped (n = 247), smoked and vaped (dual users) (n = 792) or never smoked or vaped (n = 1655). Fifty biomarkers were measured that fell into five classes of tobacco constituents: TSNA's, heavy metals, polycyclic aromatic hydrocarbons (PAHs), and VOCs. The study found that in comparison to exclusive smokers, exclusive e-cigarette users had similar concentrations of almost all heavy metals (except for cadmium) and some VOCs (toluene, benzene, and carbon disulphide), but had 93% to 98% lower levels of TSNAs (p <0.001). Cadmium biomarkers were 30% less in exclusive e-cigarette users (p= 0.02), and PAHs were 47% to 62% lower (p <0.001). Exclusive e-cigarette users also had 59%-97% lower concentrations of VOCs biomarkers compared to exclusive smokers (p <0.001). Exclusive cigarette users also had 10% to 36% lower concentrations of several biomarkers than dual users [218]. The levels of biomarkers for smokers, vapers, dual users, and never smokers/vapers are shown in Figure 1.2.

Figure 1.2 Toxicant biomarkers; Goniewicz et al., 2018



While this study [218] found evidence that conflicted with the earlier study [186] in terms of concentrations of heavy metals, it should be noted that heavy metals have long half-lives' [219]. The similar levels of heavy metals observed between exclusive vapers and exclusive smokers in this study may be due to previous exposure from tobacco smoking, as 93% of exclusive e-cigarette users in this study had previously smoked tobacco. This study also did not assess which generation of e-cigarettes participants used, and previous research has shown that different generations of devices can deliver different levels of nicotine and toxicants [220]. This study may be a more accurate measure of how toxicant levels with shorter half-lives may differ between smokers and vapers. However, relying on urine analysis does pose a limit in establishing whether biomarkers are specifically related to smoking/vaping rather than the result of other environmental sources, such as pollution [219].

The findings [218] are similar to an earlier longitudinal study [197]. In this study, 20 smokers (average 16 cigarettes per day) were recruited to switch to using an e-cigarette for two weeks. Urine samples were taken at baseline and tested for biomarkers of 13 major carcinogens and toxicants in cigarette smoke. The biomarkers were then measured after two weeks of e-cigarette use. This allowed for a more 'real world' view of potentially toxic exposure from e-cigarettes. Although 55% of the participants reported smoking as well as using e-cigarettes, there was still a significant decline in all biomarkers except for nicotine metabolites. Tobacco-specific nitrosamines, VOCs, and PAHs, were all significantly reduced, similar to previous research findings [186, 221]. The decline in biomarkers was decreased to similar quantities found in participants who quit smoking with no substitute e-cigarette [222].

Another cross-sectional study also measured biomarkers of tobacco-related toxicants [216]. This study looked at biomarkers of TSNA's and VOCs in the urine samples of exclusive smokers, former smokers who have used e-cigarettes exclusively for >6 months, former smokers using NRT exclusively, dual smokers and e-cigarette users,

and dual smokers and NRT users. Each group had 36-37 participants. Those who were long term exclusive e-cigarette users and those who were long term exclusive NRT users had substantially lower levels of biomarkers (from urine and salivary samples) for TSNA's and VOCs compared to those who used combustible tobacco. Exclusive e-cigarette users had around a 97% lower level of TSNA's than combustible tobacco, although significant reductions in TSNA's were not observed in dual-use categories. Dual-use also didn't have any significantly reduced levels of VOCs; however, exclusive e-cigarette users had the lowest levels of all the groups. This study is limited due to its cross-sectional design as we are unable to analyse a change in levels of carcinogens and toxicants over time, we cannot determine cause and effect.

Despite methodological differences, these studies are relatively consistent. Any toxicants identified are consistently found to be at significantly lower levels than those found in tobacco products, apart from nearly all heavy metals in [218] which, as explained, maybe due to residual contamination from prior smoking.

Compared with cigarette smoke, e-cigarette aerosol contains much less harmful components. Of those components identified, they are at much lower quantities than those found in cigarettes [186]. In a comparison study, cigarette smoke was found to have 1,500 times more potentially harmful/harmful constituents than e-cigarette vapour [223].

1.4.1.1 Potential health consequences of using E-cigarettes

There is evidence for improved health after switching from tobacco smoking to e-cigarettes with the suggestion that an increase in e-cigarette use amongst current smokers could reduce the disease burden of smoking-related cancers [224].

One of the primary, potentially harmful substances identified within e-cigarette vapour is formaldehyde, which can cause oxidative damage to DNA [225]. In animal research there is some evidence that exposure to e-vapour increases oxidative stress; when rats were exposed to e-vapour for four weeks increased levels of 8-hydroxy-

2'-deoxyguanosine (8-OHdG) which may be a biomarker for oxidative damage to DNA [226]. With *in vitro* studies, Thorne et al., [227] found that e-cigarette vapour was not mutagenic in contrast to cigarette smoke. Likewise, further *in vitro* research has found e-cigarette vapour generated using different flavoured liquids (with/without nicotine) does not have mutagenic, cytotoxic, genotoxic, or inflammatory effects [228].

The risk of respiratory illnesses from e-cigarettes cannot entirely be ascertained due to the length of time they have been available for use. There is some concern over the constituents of vapour that have the capacity to cause harm to the respiratory system. Recently there were fears e-cigarettes could cause 'popcorn lung' (bronchiolitis obliterans). The risk stemmed from the flavouring diacetyl [229] which is now banned from e-liquids. Aside from diacetyl, there are substances within e-liquids that could cause respiratory issues, or exacerbate existing conditions. Liquids containing nicotine can impair cystic fibrosis transmembrane conductance regulator function due to the downregulation of the $\alpha 7$ nicotinic acetylcholine receptors [230]. This is a risk factor for developing chronic obstructive pulmonary disease (COPD) [231]. *In vitro* research using mice epithelial cells also identified effects associated with COPD when exposed to nicotine-containing e-liquid, but no effect was observed in nicotine-free e-liquid [232]. There is also the risk from other constituents of e-cigarette vapour – for example, ultrafine particulate matter (<100nm) can induce an inflammatory response [233].

Further *In vivo* studies on mice have shown that e-vapour may be associated with pulmonary abnormalities. However, when compared with tobacco smoke, the damage was far less [234]. Research has shown that switching from cigarettes to e-cigarettes does reduce the number of COPD exacerbations [235] and an improvement in smokers with asthma [236]. Overall there is no conclusive evidence that e-cigarettes cause respiratory disease in users, but there is some (limited) evidence of the potential to exacerbate pre-existing lung conditions. This must be viewed in the context of smoking, which is known to be a causal factor COPD [237] and is strongly associated with asthma prevalence and severity [238].

Overall, despite inconsistency, specific components of e-vapour have the potential to induce mutagenesis; formaldehyde and acrolein are DNA-reactive, and there is evidence for oxidative stress. However, there is no conclusive evidence that e-cigarettes pose a specific risk to health. It can be concluded that the risk from e-cigarettes is higher than that of not vaping or smoking. Still, research shows that users of e-cigarettes are those who aim to quit or reduce smoking [239], therefore when considering the health consequences of e-cigarettes, we should view them in comparison with the relative risk from smoking combustible tobacco.

1.4.1.2 E-cigarettes: possible harm reduction tools?

In line with PHE recommendations, E-cigarettes can be used as harm reduction tools. Harm reduction refers to minimising the negative health consequences of smoking with the use of e-cigarettes. While e-cigarettes cannot be defined as 'safe,' they are a way of diminishing the harmful effects of smoking, without eliminating the smoking behaviour (in this case the hand to mouth action, the inhalation of a substance and exhale, and the presence of nicotine in some cases). Harm reduction using e-cigarettes isn't solely to reduce the impact of tobacco smoking on the smoker but to also prevent second and third-hand exposure to non-smokers. Currently, there is no long-term, epidemiological research that explores possible harm reduction from e-cigarettes, however, as there is no combustion, there is a lack of harmful toxins caused by pyrolysis.

As well as a reduction in biomarkers of toxicants [197, 218], carbon monoxide (CO) levels are also observed to reduce significantly (around an 80% reduction) in those who switch from smoking to exclusive e-cigarette use [197, 221, 240]. Using self-report measures, smokers who switch exclusively to e-cigarettes also report better breathing, less coughing, less sore throats, improved sleep patterns, improved taste, and an improvement in general health and fitness [241, 242]. Clinically, evidence of enhanced respiratory function is inconsistent; some research has found that there is an increase in flow-mediated dilation [243], whereas other research has found no significant differences in spirometric indexes [242, 244]. However, improvements are observed,

just not to a significant degree [215]. There is evidence that those with existing respiratory illnesses experience a reduction in symptoms when switching to e-cigarettes [235, 236, 245]. There is more considerable evidence for increased cardiovascular health when switching to e-cigarettes from smoking. Acutely, smoking combustible tobacco elevates diastolic blood pressure and heart rate significantly more than using e-cigarettes, and switching exclusively to e-cigarettes significantly reduces blood pressure [215, 224, 245]. Arterial hypertension is also shown to significantly improve in those who switch from smoking to e-cigarettes [246]. Further research by Polosa et al. (2016_b) has observed significant reductions in COPD exacerbations in smokers who switched to e-cigarettes [235].

Evidence also supports e-cigarettes being a harm-reductive approach to reducing second and third-hand smoke. While the homes of people who use e-cigarettes still show detectable levels of nicotine and particulates, these levels are 5.7 times lower than in the homes of smokers; the geometric mean (GM) of airborne nicotine were 0.13 $\mu\text{g}/\text{m}^3$ in e-cigarette households and 0.74 $\mu\text{g}/\text{m}^3$ in smoking households [247]. A systematic review by Hess et al., (2016) found that while passive vapour from e-cigarettes has the potential to cause adverse effects in those exposed, it is significantly less harmful than those exposed to passive smoking due to quantities of biomarkers identified [248]. Although nicotine is found in the homes of e-cigarette users [249, 250], there is no evidence of exposure to CO or VOCs [249]. However, research examining passive exposure to e-cigarette vapour is currently limited.

1.4.2 Smoking cessation

Research is ongoing to assess not only the safety of e-cigarettes but also the efficacy of them as smoking cessation aids. The Smoking Toolkit Study [251] has collected data on electronic cigarette use since 2011. E-cigarette use in the UK has remained stable since 2013, and while the use of e-cigarettes amongst never smokers remains negligible, the use amongst long term ex-smokers has increased. The majority of people using e-cigarettes in the UK are dual users, although ex-smokers use an e-

cigarette more frequently. Despite peaking in 2016, the proportion of smokers attempting to quit smoking with e-cigarettes has declined, which may be due in part to health and safety concerns reported in the media.

In a 2014 Cochrane review, McRobbie, Bullen, Hartman-Boyce, and Hajek [252] reported promising results as to the efficacy of e-cigarettes as a tool to quit smoking. The review aimed to examine the efficacy of e-cigarettes in helping people to achieve long-term abstinence from smoking and to examine the efficacy of e-cigarettes in helping people who smoke to reduce cigarette consumption by at least 50%. The Cochrane review also looked for evidence of adverse effects from e-cigarette use. This review used various databases including the Cochrane Tobacco Addiction Groups Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase and included records from 2004-2014. This review included randomized controlled trials in which current smokers were randomized to e-cigarette or a control group, and that also measured abstinence rates or changes in cigarette use at six months. The review also included cross-over trials and cohort follow-up studies that included at least one week of e-cigarette use for the assessment of adverse events. A total of 13 studies that measured abstinence continuously (with biochemically validated measures) and reductions in smoking dichotomously were included in to perform a meta-analysis. The results showed that those using e-cigarettes were more likely to remain abstinent from smoking at six months compared to those who used placebo products (RR=2.29, CI 1.05-4.96). Although no significant differences in this review were recorded between those who used NRT vs those who used e-cigarettes, confidence intervals do show an important difference (RR=1.26, CI 0.68-2.34). No significant adverse events were associated with e-cigarettes, although throat irritation was reported in some cases. Overall the efficacy of e-cigarettes as a tool for quitting smoking, and reducing cigarette consumption is promising, especially with no evidence of significant adverse events.

However, the authors did conclude that due to the small amount of data collected on what is still a relatively new product, these results are subject to minimal confidence rated 'low' by GRADE (Grading of Recommendations, Assessment, Development, and

Evaluations) standards [252]. A further review published in 2016 by Malas et al. [253] provided a qualitative synthesis on e-cigarette studies. The review concluded there was evidence of a positive relationship between smoking cessation and e-cigarette use. The review also supported the efficacy of e-cigarettes for reducing the desire to smoke and alleviating nicotine withdrawal symptoms. However, the GRADE standards were 'very low' to 'low' for cessation, and 'low' to moderate' for reduced consumption due to limited availability of research.

In 2019 Hajek et al. conducted an RCT testing the efficacy of e-cigarettes compared to NRT [254]. Unlike the earlier review, this RCT found that using an e-cigarette compared to NRT increased a person's chances of remaining smoke-free at one year (RR = 1.83, CI 1.30-2.58). They also found that at one year, 80% of the e-cigarette group were still using their device compared to just 9% of the NRT group who were still using NRT [254].

Other research has assessed self-reported smoking abstinence, and reduced cigarette consumption, amongst online populations. Abstinence at six months was reported by 31% of respondents and significant reductions in cigarette consumption amongst 66.8% of respondents [255]. However, there are limitations to this study due to the cross-sectional online study design and reliance on self-reported smoking status. Recent research has suggested that the daily use of e-cigarettes, compared to no use of e-cigarettes, is associated with a 77% increase in odds of prolonged cigarette abstinence (up to 2 years) [256]. However, these statistics should be viewed with caution as daily cigarette users accounted for only 3.6% of the original sample, and smoking status was not verified. Other research has suggested that e-cigarettes are at least as effective at reducing smoking as NRT (although not significant, the proportion of abstinent smokers was higher amongst e-cigarette users than NRT) and has fewer reported adverse effects [257]. Although this study was an uncontrolled pilot study, e-cigarettes have also been shown to reduce cigarette consumption by more than 50% in smokers not intending to quit smoking [258]; this has been shown even with nicotine-free e-liquids [202]. However, the dropout rate for these studies was high, so results may not be an entirely accurate representation. E-cigarettes are also shown to reduce smoking

amongst populations where smoking cessation is often challenging to address [259]. Research also suggests that e-cigarettes may prevent a return to smoking after quitting [260]; this may be due to e-cigarettes reducing the desire to smoke and when containing nicotine, helping to manage nicotine withdrawal symptoms [261, 262].

1.4.3 Use in pregnancy

Smoking in pregnancy harms foetal development and can lead to a myriad of problems, including morbidity and mortality, as discussed above. Due to the lower concentrations of toxins in e-cigarettes compared to tobacco smoke, e-cigarettes may be a harm reductive approach for women who are unable to, or unwilling to quit smoking. As well as the reduced toxins, there is no carbon monoxide when using an e-cigarette, which reduces the risk of harm to the developing foetus, a stance supported by the Royal College of Midwives [39]. The reduction in CO is an important factor to consider; exposure to CO during pregnancy causes hypoxia in the developing foetus which can lead to impaired brain development and intrauterine growth retardation (IUGR) [33]. Several chemicals within cigarette smoke are teratogenic – increasing the rate of miscarriage or congenital malformation [263].

Due to the relative novelty of e-cigarettes, research examining the potential effects on the developing foetus relies heavily on animal studies and the analysis of e-liquid/vapour constituents [230]. The majority of this research has focused on the role of nicotine and the potential teratogenic effects; possible damage to the lungs via $\alpha 7$ nicotinic receptors [264, 265], and brain development [266].

Although evidence available on the safety of e-cigarettes during pregnancy is minimal, the evidence of harm from smoking is clear (1.1.2). Whilst the nicotine within e-liquids is not a benign substance, evidence from the SNAP trial suggests there are no adverse events associated with nicotine use (from nicotine patches) to the developing foetus [267]. Therefore e-cigarettes are an opportunity to remove the harm posed by tobacco-related toxicants [230].

The perception of e-cigarette safety differs among pregnant women [268-270]. A large proportion of pregnant women do accept there are risks associated with e-cigarette use

in pregnancy, but these risks are lower in comparison to smoking during pregnancy [271-274].

1.4.4 Postpartum use

Research considering E-cigarette use in the postpartum period is currently limited. There is evidence that women are seeking information about e-cigarette use. However, they are also confused about the current evidence for e-cigarettes as a harm reductive tool, despite research suggesting this is so [186, 189, 197, 221, 235, 245, 275, 276]. A three-phase mixed methods study for designing an intervention to prevent a return to smoking in the postpartum period included qualitative data on the potential use of e-cigarettes postpartum to reduce relapse [277]. Phase one, a systematic review, highlighted the need for postpartum interventions to consider the use of e-cigarette use in the postpartum period due to a small body of literature [66]. During phase two of the study, qualitative data was collected using interviews, focus groups, and online versions of the questionnaire. This phase of the study aimed to gather multiple viewpoints from a purposive sample of pregnant and postpartum women who had stopped smoking for or during pregnancy about the need for a relapse prevention intervention. This included why an intervention is needed, who should deliver it, when it should be offered, and what format it should take. This phase also asked specific questions about e-cigarettes. Amongst other findings, it was identified that women wanted objective information about infant feeding and staying smoke-free, and advice on additional support available, such as e-cigarettes. This phase determined that advice and information on e-cigarettes were somewhat mixed. While women reported they were very wary of using e-cigarettes, they did identify that e-cigarettes were likely to be much less harmful than smoking tobacco [277]. This was, in part, due to concerns that e-cigarettes were a way of 'continuing' the addiction. There were also some concerns about the long term effects of e-cigarette use due to a lack of research. Women (and health care professionals) also highlighted the need for clear and precise information about using e-cigarettes, including which devices to use and advice of e-liquids. Crucially, both women and health

care professionals highlighted that information on breastfeeding and using e-cigarettes was thought to be completely unavailable [277].

Phase three of this study involved testing and retesting prototypes of the intervention [277]. Part of this was a box full of advice, information, and gifts. It was discussed that this box could contain a lapse prevention tool such as nicotine gum or e-cigarettes. While not every woman was receptive to using e-cigarettes as a prevention tool, participants did highlight they may be useful for women at risk of relapse to have access to alternatives they could turn to instead of cigarettes. Women did highlight that e-cigarettes would need to be presented with very clear information, particularly due to confusion regarding nicotine use postpartum. It was expressed by some women that knowing which device and concentration of nicotine to use could be too complicated for some women and result in them returning to smoking. This study highlights the need for clear and concise information about e-cigarette use postpartum [277].

One qualitative study has sought to understand women's perceptions of e-cigarette use postpartum [278]. This study found that overall, women were attracted to e-cigarettes due to claims they reduced harm. However, there was still a lot of uncertainty regarding potential health effects [278]. Some women were uncertain about the e-cigarettes due to the novelty of them. There was also evidence that for some women, e-cigarettes were often used in combination with cigarettes, and that using e-cigarettes exclusively did not always prevent relapse.

While some research considers postpartum e-cigarette use, this is very limited; only three papers (two of which were part of the same studies) [66, 277, 278] discussed postpartum use of e-cigarettes. In the three-phase study [277] the review highlighted the need for postpartum relapse prevention interventions to consider e-cigarettes, and that the lack of clear and concise information regarding their use postpartum is an issue for women. This study did not specifically focus on e-cigarette use postpartum but highlighted the need for more evidence, advice, and support [277]. The Medicaid study [278] found similarly mixed views on e-cigarette use and provided information on how postpartum women are primarily using them as well as cigarettes. However, this study

had a small sample size and only reflected the views of women in the US in receipt of Medicaid. Thus it's questionable how transferable this is to other women. Research considering postpartum e-cigarette use is in its infancy and more research is needed to provide a greater insight into the perceptions, opinions and usage of e-cigarettes postpartum.

1.4.5 Summary

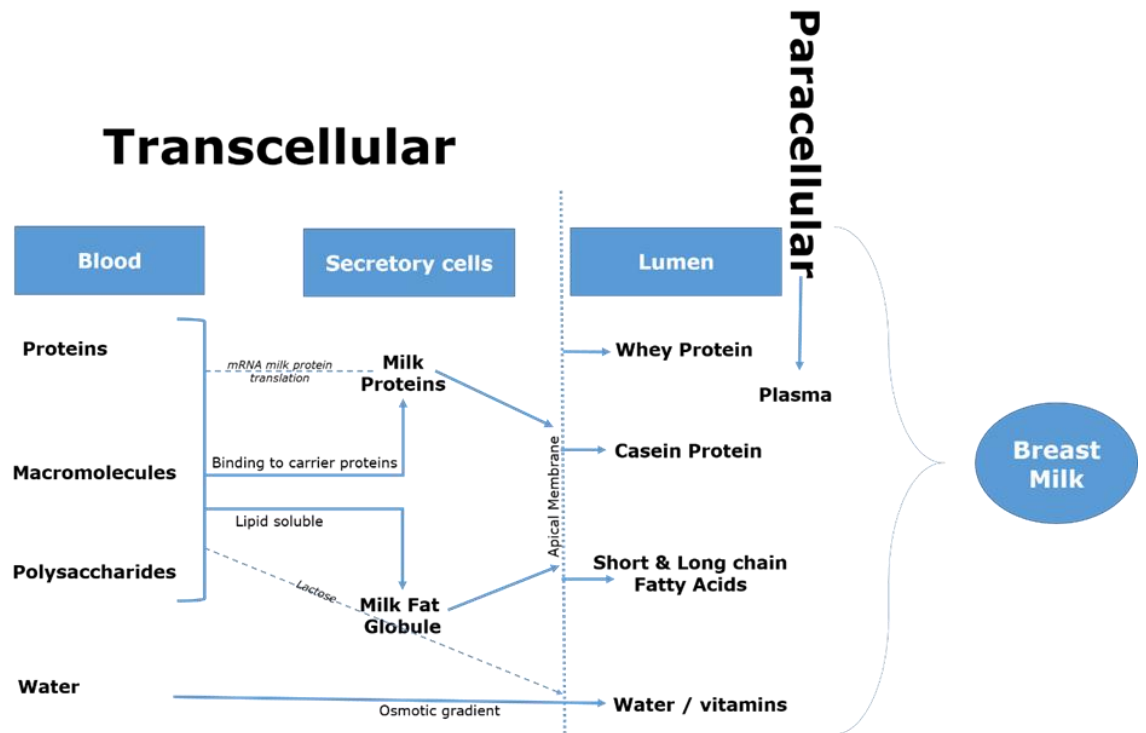
E-cigarettes are still relatively new and lacking long term epidemiological data. We do, however, have consistent data that shows carcinogens and toxicants found in tobacco smoke are either absent from e-cigarette vapour or are identified at significantly lower levels. Those carcinogens and toxicants identified within e-cigarette vapour still have the potential mechanisms to cause damage to health, particularly the respiratory tract. Despite this, risks from e-cigarette use should be viewed in comparison to those from tobacco smoke, as research shows e-cigarettes are predominantly used by ex-smokers, or smokers wishing to quit/reduce the number of cigarettes they smoke. E-cigarettes are more effective than usual treatment for smoking cessation, although not much long term evidence exists for this efficacy persisting. Those who use e-cigarettes can regulate their nicotine levels in line with their nicotine needs from smoking which may explain why e-cigarettes have been successful for smoking cessation even in those smokers who were not looking to quit smoking. While pregnant mothers who cannot or chose not to quit smoking are advised to use e-cigarettes, not much research has examined postpartum use of e-cigarettes. Of the work that has considered e-cigarette use postpartum, confusion and seeking further information are prevalent themes. E-cigarettes may be tools for reducing harm from tobacco smoking, but further research is needed to assess the acceptability of e-cigarettes postpartum. Currently, no data exist considering the use of e-cigarettes in relation to breastfeeding.

1.5 E-cigarettes and breastfeeding?

Currently, there is no research considering e-cigarette use and breastfeeding. Women's concerns regarding breastfeeding as a smoker (and the contamination of milk by tobacco-specific components) are not entirely unfounded. While it is safer for a smoking mother to smoke and breastfeed than smoke and formula feed, there is still exposure to harmful toxins that may transfer to the infant via breastmilk. This is due to the way breast milk is produced and secreted. It is important to understand the potential transference of smoke constituents to rationalise those concerns. Although toxicants identified in e-cigarettes are much lower than cigarettes (see 1.4.1), addressing how those toxicants may transfer into breastmilk, in comparison to cigarettes, may offer women the clear and concise information they want.

Galactopoiesis is the maintenance of lactation, including the hormones that regulate milk production and the milk being removed from the breast. There are four major secretory processes to produce milk (Figure 1.3); secretion via fat globule, secretion related to concentration gradients, pinocytosis (the movement of small particles into a cell, and then suspended within the cell in small vesicles) and exocytosis of immunoglobulins [279-281].

Figure 1.3- Galactopoiesis



1.5.1 Transference from inhalation to breastmilk and potential health consequences

Although relatively little is known about the movement of trace mineral and elements such as heavy metals into breastmilk, it is generally accepted that the most probable transportation of these elements is via binding to specific carrier proteins [281, 282]. The pharmacokinetics of nicotine-containing products into breastmilk depends mainly on the route of absorption, size of molecules, metabolic process, and distribution within tissues, lipid solubility, and excretion pathways [283]. Substances absorbed into the mother's bloodstream or stored in her bones and fats can reach the nursing infant if they can pass directly into the breast during active lactation [282, 284].

Within cigarette smoke and e-cigarette vapour, there are potential contaminants of breastmilk. The most well-known chemical found in cigarettes and e-cigarettes is nicotine, which has been shown to pass directly into breastmilk [285]. In a study examining cotinine (the metabolite of nicotine) levels in the urine of infants, babies who

were breastfed by smokers had cotinine levels ten times that of bottle-fed infants of smoking mothers, suggesting that infant exposure to nicotine is via breastmilk and not environmental smoke [286]. Despite concerns regarding infant exposure to nicotine, there remains no conclusive evidence as to whether it is harmful to the infant, however, with a half-life of 90 minutes [287] women can reduce the risk of infant exposure by smoking directly after a feed [285].

Some tobacco-related constituents are unlikely to pass into breastmilk due to molecular size; for example, formaldehyde [288] and acetaldehyde [289]. There is limited information on the likelihood of acrolein [290] or toluene transferring into breastmilk [291]; both have the potential to be transferred to milk, however, the quantities identified are minute.

N-Nitrosornicotine (NNN) is a group one carcinogenic present in tobacco products; around half of the NNN is released through burning the tobacco. Nicotine-derived Nitrosamine Ketone (NNK) is a pro-carcinogen (a substance that is not directly carcinogenic until it is metabolised); it relies on activation by enzymes or metabolic genes to exert its effects. Via an oxidative or reductive pathway, NNK becomes its metabolised carcinogenic form, NNAL (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone) [292]. Both NNN and NNK are transferred into the mother's milk via smoke inhalation [291, 293]. Research into e-cigarette vapour has concluded NNN and NNK are either not present in vapour, or present in vastly reduced quantities (>97% less) compared to cigarettes [186, 197, 218].

Heavy metals are also found in cigarette smoke; cadmium exposure is significantly increased in those who smoke [294, 295], and is known to transfer to breastmilk [296-300]. As a cumulative toxin with a long half-life (6-38yrs) [301, 302], infants exposed via breastmilk may not experience the effects of cadmium until adulthood, although early life exposure via breastmilk is significantly associated with infant oxidative stress [303]. Cadmium exposure can cause gastrointestinal problems, reproductive and fertility issues, and DNA damage [302]. Cadmium also mimics oestrogen increasing the risk of osteoporosis and breast cancer in exposed females, as evidenced by 'Itai-Itai' disease

[304]. Cadmium has been identified in e-cigarette vapour, but again in vastly reduced quantities; with levels in tobacco smoke ranging from 1.6-101 μ g per cigarette, and levels in vapour of 0.02-0.22 per 15 puffs [186].

Lead is also known to transfer to breastmilk [305]. This is a concerning component of cigarettes for breastfeeding mothers as young children are particularly vulnerable to the toxic effects [306]. The concentration of lead transferred to breastmilk in smokers varies throughout the lactation processes, with the initial colostrum having a higher concentration of lead. Research has identified this ranges from 13.3 ng/mL to 3.01 ng/mL throughout the feed [307]. There is already an increased exposure to the breastfeeding infant; during pregnancy and lactation as the increased turn over in bone releases stored lead into the blood [308]. High exposure to lead in children can lead to profound and irreversible adverse health effects [309]. The World Health Organisation state that even blood lead concentrations as small as 5 μ g/dL can result in long term mental and physical disabilities as a result [310]. Lower levels of exposure do not cause immediately apparent symptoms; however, as the levels of exposure increase, so do the spectrum of related injuries. The accumulation of lead in children can adversely affect Intelligence Quotient (IQ) [311] and behaviour; such as reduced concentration and anti-social behavioural disorders [309]. Physiological symptoms may include anaemia [312], hypertension, renal impairment, immunotoxicity, and toxicity of the reproductive system [313]. The accumulation of lead in the child's bones has a half-life that may span decades; therefore, the effects of childhood exposure may not be directly expressed until adulthood [314]. As with other heavy metals, lead has been identified within e-cigarette vapour (0.02-0.57 μ g per 15 puffs), but at vastly lower concentrations than cigarette smoke (3.9-32.9 μ g per cigarette) [186].

Tobacco-related toxicants that do transfer to breastmilk from smoking are found in minute quantities, however it is still safer for a mother to breastfeed if she smokes, than to not breastfeed. Those toxicants that are also found in e-cigarettes (apart from nicotine) are found in much lower quantities. Therefore breastfeeding mothers who use e-cigarettes can be assured that contamination of their milk due to these toxicants is

likely to be in extremely minute amounts (13.3 ng/mL- 0.16 ng/mL for heavy metals [307]) and unlikely to cause any health consequences for their child.

As well as reducing fears of milk contamination that may be a barrier for breastfeeding to some women, e-cigarettes may also reduce exposure to toxicants in those infants who are breastfed by a smoking mother.

1.5.2 Summary

There is currently no research that exclusively considers e-cigarettes and breastfeeding. While e-cigarettes contain some toxicants that are capable of transferring into breastmilk, these are extremely minute quantities that are unlikely to pose any acute or long term harm. E-cigarettes should be considered for breastfeeding mothers as a tool to abstain from smoking tobacco cigarettes.

Chapter 2: Rationale and research aims

2.1 Rationale

As discussed in Chapter 1, most women who quit smoking during pregnancy will return to smoking within 12 months postpartum. Smoking postpartum has clear health implications for both mother and child. Women who do smoke postpartum are less likely to breastfeed, which again has clear health implications for both. Thus far, few interventions aim to reduce relapse and increase breastfeeding. Of the small body of literature that exists, there is no proven effective, long term intervention that targets both behaviours in combination. Some women who return to smoking postpartum are concerned that toxicants in cigarette smoke may pass to the breastmilk and negatively affect their baby. Although some toxicants transfer to breastmilk, as they are only transferred in minute quantities, these are not known to pose any significant risk to the infants. However, some women are still reluctant to breastfeed. E-cigarettes deliver nicotine in a similar way to cigarettes and are used by smokers to quit or reduce their smoking, but have far fewer harmful toxicants than cigarettes. Using an e-cigarette could potentially further reduce any risk of transferred toxicants and be more acceptable to breastfeeding mothers.

Although previous literature has identified a relationship between smoking and breastfeeding, there is no recent research that explores this relationship within UK mothers. It is also important to establish if a relationship exists, whether any relationship is the result of shared demographics/characteristics (such as age/education) or another mechanism. Crucially, there is currently a gap in the literature that explores the relationship between smoking and breastfeeding within women who currently smoke, and women who are recent ex-smokers. There is also a clear gap in the literature for understanding how the introduction of e-cigarettes over the past decade may have influenced or affected the number of women smoking and breastfeeding postpartum.

Currently, no published work has explored whether women are using e-cigarettes while breastfeeding. There is a need to understand whether women are using e-cigarettes postpartum, and what may motivate, or be a barrier to their use. As e-cigarettes are very novel products, there may be specific challenges that these women face. Given e-cigarettes do not contain most of the toxicants present in cigarettes that may transfer to breastmilk, there may be differences, depending on their knowledge of e-cigarettes, in how women view their use during breastfeeding.

There is also currently no literature that considers the barriers and motivators that may impact the decisions mothers who vape make regarding whether or not to breastfeed. Research has also not explored the experiences of vaping mothers postpartum and how this may affect how they feed their babies. There is a need to understand whether using e-cigarettes to protect against a lapse in smoking is acceptable to new mothers and how acceptable they are to use as a breastfeeding mother.

Establishing the above issues would create the necessary background literature needed for developing possible future interventions using e-cigarettes, for reducing postpartum smoking and increasing the number of women breastfeeding in the UK.

2.2 Philosophical foundations & mixed methods approach

In health and social science research, there are two distinct research strategies; quantitative and qualitative [315, 316]. Both strategies are underpinned by different ontological and epistemological positions that exist on opposite ends of the spectrum [316]. A positivist philosophical approach is taken with quantitative research, rooted in the realist ontological perspective; the belief that reality is ontologically independent of human minds [317]. The positivist epistemology is based on objectivism; that facts exist objectively and are therefore discovered and not constructed, and the researcher is an independent observer [318]. Therefore there is an objective truth that exists and can be discovered. Positivism focuses on facts, causal relationships, and the falsification of hypotheses. This assumes that psychological and social phenomena can be studied using objective, scientific methods that result in context-free generalisations [317].

Qualitative research, on the other hand, has a relativist ontological position and is rooted in social constructivism and interpretivism [318]. In this epistemological stance, it is believed that reality does not objectively exist but is constructed from a person's interaction and shared social experiences, and thus, multiple-realities may exist [319]; therefore there is no 'truth', and indeed our understanding of what exists is constructed from our experience of natural phenomena. Rather than being concerned with the falsification of hypotheses, this approach is more concerned with gaining a deeper understanding of the human experiences related to the phenomena being investigated [320, 321]. Unlike positivism, this is underpinned by the epistemology of subjectivism. Rather than an objective observer, the researcher is an integrative part of the research [319, 320]. Therefore the understanding of the phenomenon studied is constructed based on interpretations of interactions between participant and researcher [316, 319, 320].

It may be argued that as these approaches come from such opposing philosophical positions, they are not compatible and should not be mixed [316]. However, research has recognised there are benefits to incorporating a flexible and mixed approach, which can counteract the limitations of using a singular approach arising from the limitations of each methodology [322]. For example, whilst quantitative research does attempt to account for context and environment, it is often in a controlled and limited way. This can mean that the complexities of the environment within which the phenomena occur are not fully considered, nor are the underlying motives, perceptions, and experiences that may underpin or influence how the phenomena is lived [322]. While qualitative research allows in-depth exploration of experiences, perceptions, and motivations, this approach is susceptible to methodological flaws such as researcher bias, low reliability, and the inability to generalise findings [316, 322]. Whilst qualitative research does attempt to reduce these limitations, such as the use of reflexive accounts and second coding, limitations persist. For this thesis, a stance of critical realism will, therefore, be taken. Critical realism is positioned between the positivist and interpretivist paradigms; it accepts there are objective realities but also recognises that our knowledge of the world is relative to who we are and how we acquire our understandings [323, 324]. The

position of critical realism lends itself well to methodological triangulation in research, where the objective is to increase confidence in findings via confirmation of a research question using two or more independent measures [325].

As described in the rationale, there is a need to explore any association between breastfeeding and smoking in the UK and the use of e-cigarettes postpartum. Collecting data in a quantitative format gives an overall, generalizable picture of the phenomenon. To then explore the opinions on breastfeeding in relation to e-cigarettes, and to further explore the experiences, barriers and facilitators for breastfeeding as a smoking mother, a qualitative approach is more appropriate. This is due to the need to explore the phenomenon in the context of the women's lived experiences, which are constructed by societal expectations and shared knowledge. It is important to ensure the methodologies complement one another and that equal importance is afforded to each study, regardless of data collection and analytic methods. Therefore as outlined by Singh [326], in this thesis, the philosophy and methodology were considered in a holistic context that integrates the overall research [326].

2.3 Aims of research

This thesis aims to explore how women use e-cigarettes during the postpartum period and how acceptable they are for breastfeeding mothers. This will involve exploring associations between smoking and breastfeeding in a sample of UK mothers. This thesis will aim to understand if, and how, e-cigarettes are currently being used during the postpartum period and how this may relate to breastfeeding. It will also consider what barriers or facilitators for switching to e-cigarettes are. It will be important to understand how women form their opinions on e-cigarettes and where they source evidence and advice. If women are using e-cigarettes, this thesis will also look at why they are using them, for example, are e-cigarettes being used as an alternative to smoking, as a cessation method or for some other reason?

Research objectives:

- To understand whether there is a relationship between smoking and breastfeeding within a sample of smokers, ex-smokers, and vapers
- To describe the characteristics of women who breastfeed, smoke and/or vape postpartum
- To explore women's current usage, understanding and opinions of e-cigarettes in relation to breastfeeding
- To explore the barriers and motivators to breastfeeding as a smoking/vaping mother
- To explore the motivators/barriers for using e-cigarettes, as an alternative to smoking, in the postpartum period
- To explore the acceptability of using e-cigarettes as a breastfeeding mother

2.4 Methods

The methods used to meet the aims and objectives outlined in 2.3 are detailed below. These will form three separate studies as part of the PhD, and the findings from all three studies will then be collated to answer the overall question posed: are e-cigarettes an acceptable alternative to smoking for breastfeeding mothers?

2.4.1 Study one: Determining the characteristics of women who smoke, vape and/or breastfeed: a quantitative analysis

To determine if smoking and breastfeeding are negatively associated, irrespective of socio-demographics and characteristics, data from the Pregnancy Lifestyle Survey will be analysed. Three surveys (early pregnancy, late pregnancy, and postpartum) will collect quantitative data about basic demographic information, smoking/vaping status, breastfeeding status, and health beliefs/opinions on smoking and/or vaping as a breastfeeding mother. This study will recruit smokers, vapers, dual users and women who have quit smoking during, or just prior to, pregnancy. Chi-squared analysis will be

used to test for associations, and logistic regression analysis will be used to explore any independent associations between smoking and breastfeeding. Copies of the questionnaires are found in appendix 3.1, 3.2 and 3.3. This study is described in detail in Chapter 3.

2.4.2 Study two: Is it safe to vape whilst breastfeeding? Postpartum women's opinions on e-cigarettes, using online forum discussions: a qualitative analysis

Online forum discussions from popular parenting websites will be analysed qualitatively to explore opinions, current use, knowledge, and sources of knowledge about e-cigarettes in relation to breastfeeding. Google searches will be used to identify discussions around vaping and breastfeeding, which will then be analysed using a template approach to thematic analysis. A template approach will be used as the original discussions were not created for the purposes of this research. Thus *a priori* codes will help to focus the analysis on answering the research question. The *a priori* codes are 'Using e-cigarettes postpartum'; 'health beliefs (e-cigarettes and breastfeeding)'; 'Opinions (on e-cigarettes)'; 'Information (seeking and giving)'; 'Evidence (sources)'. These codes will be modified and expanded through an iterative process, and new codes added as and when they emerge. The full details of this study are described in Chapter 4.

2.4.3 Study three: Smoking and Vaping postpartum – results from an online survey about experiences, beliefs and infant feeding choices

Qualitative online surveys will be designed and distributed to explore the motivators and barriers to breastfeeding as a smoking and/or vaping mother, motivators, and barriers to vaping postpartum and assess the acceptability of using e-cigarettes as a breastfeeding mother. The survey will be distributed using Facebook adverts and adverts on online parenting forums, recruiting between 80-120 women who are aged 18 years or above, who smoke and/or vape and have an infant aged 18 months or

younger. Responses will be analysed thematically; this study is described in detail in Chapter 5.

2.5 Reflexive statement for qualitative chapters

For qualitative research, the data is mediated through the researcher. Therefore the preconceived ideas and experiences of the researcher may introduce bias into the work. As per the consolidated criteria for reporting qualitative research (COREQ) guidelines [327], the personal characteristics of the researcher will be disclosed in this section, enabling the reader to understand the perspectives of the researcher while interpreting the results. As critical realism highlights the need to distinguish the subjectivity of the researcher, the beliefs and pre-existing biases of the researcher should be considered when interpreting the results [318, 328].

Characteristics of the researcher: I am a female mother of two children, aged 3 and 8 at the time of study two (Chapter 4) and aged 4 and 9 at the time of study three (Chapter 5). I have a BSc in Psychology, MSc in Health Psychology, and am nearing completion of a PhD conducted within the Smoking in Pregnancy Research Group at the University of Nottingham. The research group is situated within the UK, and the health authorities (Public Health England) stance on e-cigarettes is that using an e-cigarette is safer than smoking for people who are unable to quit unaided or quit using Nicotine Replacement Therapies and/or behavioural support. This stance could potentially influence the views of all the researchers on the team. I am an ex-smoker who, at the time of this research, is using an e-cigarette to remain smoke-free, as I had done for the previous three years. I grew up with one smoking household and one non-smoking household, in a high poverty area where smoking was normal behaviour. I began smoking at a young age, having been given cigarettes by an adult within my family. I struggled to quit smoking, except for when pregnant, although I returned to smoking at roughly nine months postpartum. At 21yrs old I was diagnosed with cancer of the bladder, I knew this type of cancer could possibly be linked to smoking, however even such an alarming health scare did not put me off enable me to quit. I breastfed both my children exclusively until 6 months, and alongside supplementary food and drink until they self-weaned at around

3yrs. When my eldest child was six months, I volunteered as a breastfeeding peer support worker for a period of four years. In the area I grew up breastfeeding was not the norm, and I did struggle with breastfeeding initially, particularly with being able to breastfeed in public.

With my own personal experiences, I was already aware of my reasons for returning to smoking postpartum. When my children reduced the amount of breastfeeds, they needed, going back to University/work and the associated stresses, and also that of being a young mother and wanting to maintain my identity within my friendship circle.

In my working life, I have worked in two industries that relate to this thesis. The first was as a marketing manager and consultant. I wrote, under a pseudonym, for two parenting forums that are both used within Chapter 4. This meant I already had a good working knowledge and understanding of how these forums operate. I had to ensure that when writing up the research for Chapter 4, I wrote it in a way that non forum users could understand. This involved expanding on all abbreviations. The second industry was working in palliative care, working with end of life patients. As part of this work I saw people with illnesses directly related to smoking; seeing patients suffering from respiratory distress and still attempting to smoke whilst attached to oxygen tanks really piqued my interest in smoking cessation research.

At the start of this research, my beliefs were that breastfeeding was crucially important regardless of whether a mother smoked or vaped and that e-cigarettes were a safer form of nicotine delivery. Being aware of my experiences and beliefs I found I had to be conscious of transferring my own experiences and opinions on to the data analysis process. Throughout the process, I attempted to give equal weight to views opposing those of my own. In both qualitative studies, I used a second coder to offset any personal biases.

The second coder for study two (Chapter 4) was Dr Katarzyna Campbell (KC) (PhD, MSc Health Psychology), a research fellow with the Smoking in Pregnancy Team at the University of Nottingham. KC has experience of qualitatively analysing forum data, and KC is a never smoker/vaper. For study three (Chapter 5) the second coder was Lucy

Phillips (LP) (MSc Health Psychology, BSc Psychology), LP is a research assistant with the Smoking in Pregnancy Team at the University of Nottingham with experience of qualitatively analysing data, who is a never smoker/vaper. Both second coders hold the belief that breastfeeding is best even if for a short amount of time, and believe smoking/vaping mothers should be encouraged to breastfeed but with adequate harm reductions such as not smoking/vaping directly before a feed.

Chapter 3: Characteristics of women who smoke, vape and/or breastfeed

3.1 Introduction

Chapter one has discussed the characteristics of women who breastfeed (1.2.4) and of women who smoke postpartum (1.1.3.3), but much of the recent literature on smoking in relation to breastfeeding concerns mothers in the USA [329] or Turkey [330]. What is not currently known are the characteristics of women who breastfeed, and those who smoke within the UK. To explore ways of reducing smoking postpartum, and increasing breastfeeding rates within the UK, we must first be able to describe the current situation, which includes the characteristics of women who smoke, breastfeed and/or vape.

As discussed in chapter one, smoking is reportedly negatively associated with breastfeeding (1.3). There are shared demographics that may explain the association (1.3.1.2); however, there may be alternative explanations (1.3.1.1 and 1.3.1.3). Whether there is an association which is independent of confounding factors such as age and education is unknown for the current UK situation. Hence there is a need to explore this with a sample of UK mothers.

As well as limited research on smoking and breastfeeding in the UK, there is currently no literature that considers the use of e-cigarettes. Research has begun to look at the use of e-cigarettes (or e-cig/vapes) during pregnancy [269, 278, 331-335], with some consideration for their use postpartum [270, 278]. However, the characteristics of mothers who use them and how this relates to breastfeeding behaviour is currently not known. Women's opinions toward using e-cigarettes when breastfeeding are also unknown. However, literature on women's beliefs and opinions towards smoking as a breastfeeding mother does exist [162].

In previous literature, most studies have been cross-sectional, including never smokers and those who haven't smoked for a long time [137, 139, 150]. Looking at longitudinal data on a group who have all smoked recently, just before or during pregnancy, provides the opportunity to look at predictors of their smoking behaviour in the

postpartum period, and is sufficiently large and recent to explore predictors of vaping as well. This data from pregnancy through to the postpartum period allows us to explore how this may relate to breastfeeding. Therefore this chapter will describe characteristics using a sample of smokers, recent ex-smokers and vapers in relation to breastfeeding, and explore health beliefs women may hold about smoking, using an e-cigarette and breastfeeding.

3.2 Aims

The overarching aim of this research is to be able to describe the characteristics of women who were part of the Pregnancy Lifestyle Survey cohort, from the birth of their infant to three months postpartum. Specifically, the aim was to:

- To describe the demographics of women who are breastfeeding
- To describe the demographics of women who smoke and/or vape
- To understand the relationship between breastfeeding and smoking in this population
- To test if this relationship is independent of demographic factors
- To explore for the first time breastfeeding behaviours in women who vape
- To describe the beliefs women have about smoking/vaping and breastfeeding

3.3 Methods

3.3.1 Study design and recruitment

This study was part of the 'Pregnancy Lifestyle Survey: a multi-centre longitudinal cohort survey of smokers, recent ex-smokers and vapers during pregnancy and postpartum' study. Women aged over 16 years old, who were 8-24 weeks pregnant, and attending National Health Service (NHS) hospital antenatal clinics between June and November 2017 were asked to complete a screening survey about their vaping and smoking status. Those who reported that they were recent ex-smokers (who had quit <3 months prior to pregnancy) or who currently smoked and/or vaped were invited to complete the full survey, plus two additional follow up questionnaires in late pregnancy and postpartum. This study looked at breastfeeding intentions and initiation, which were

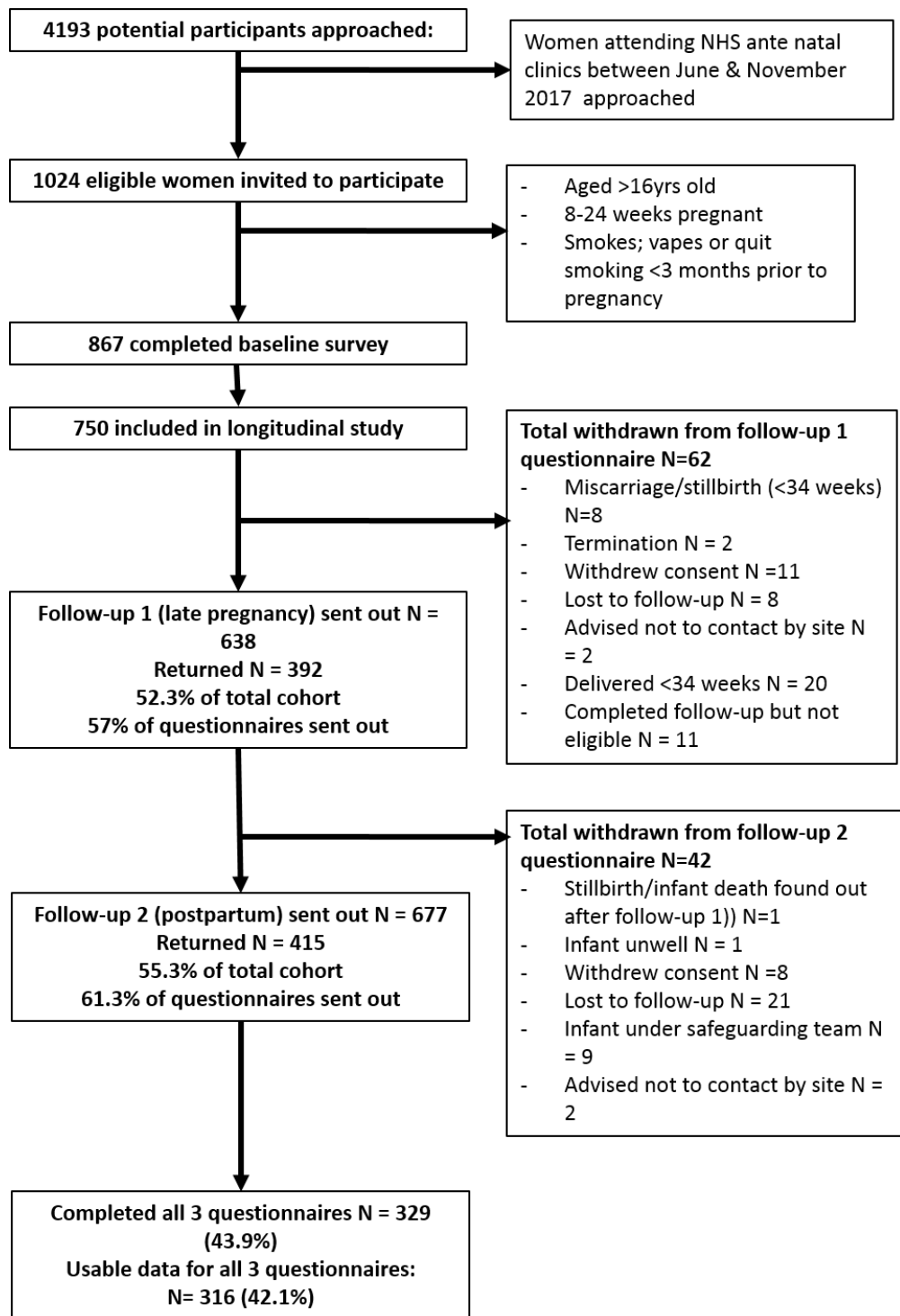
measured in the two follow-up questionnaires. A £10 high street shopping voucher was offered to women for completing each survey (a total of £30 if all questionnaires were completed).

Purposive non-probability sampling was used by selecting 17 hospital sites, with varying smoking in pregnancy rates, from across England and Scotland for recruitment. A research midwife/nurse systematically handed out a screening survey to all pregnant women attending various antenatal clinics (including specialist) at each site. Each hospital was asked to recruit approximately 44 women into the study. A unique identifier was given to women who completed the full survey after they gave contact details; these were cross-matched by a member of the research team to ensure each woman completed the survey only once.

Of the 3360 mothers who were eligible to complete the initial screening survey, 1024 were recent ex-smokers/current smokers and/or vaped. A total of 867 women completed the baseline questionnaire, 392 completed follow-up 1 (late pregnancy), and 415 completed follow-up 2 (postpartum) – full details of recruitment numbers are shown in Figure 3.1 **Error! Reference source not found..**

Follow-up questionnaires were sent by post at 34 weeks gestation, and three months postpartum; for women who provided an email address the survey made available online using JISC (formerly Bristol Online Survey Tools) and sent to them via a unique link. Participants were also sent an SMS as a prompt to enhance response rates. If a participant did not respond to the initial surveys sent out, a reminder was sent via post, text and/or email, and, if there was still no response, a member of the research team telephoned and offered the opportunity to answer all questions over the phone. Before sending out the follow-up surveys, hospital staff were contacted to check medical records for accurate delivery dates and to ensure questionnaires were not sent inappropriately to women whose fetus or infant had died.

Figure 3.1: Consort diagram



Adapted from: Bowker, 2020 (unpublished)

3.3.2 Ethics and funding

This work is part of the Pregnancy Lifestyle Survey, a study funded by Cancer Research UK, Tobacco Advisory Group Project (Grant number C53479/A22733). Ethical approval was granted by the South West Frenchay Research Ethics Committee, and a patient public involvement panel was involved in the study design. Full details of the original study are in the protocol [336] and Research Registry database [274].

3.3.3 Survey content and measurements

The first survey was divided into two parts: the screening survey and the full survey (baseline – appendix 3.1). The screening survey asked women about their gestation, age and whether they had previously completed the questionnaire. Women were then asked about their smoking (cigarette only)/vaping status; women were either current smokers, ex-smokers (stopped smoking more than three months prior to finding out they were pregnant) or recent ex-smokers (quit smoking less than three months prior to finding out they were pregnant). Women were also asked if they vaped (either used daily, or used occasionally), had never vaped (never heard of vapes, or heard of them but never tried) or were ex-vapers.

The full survey asked questions about women's views and experiences of e-cigarettes; this included future intentions about e-cigarette use and attitudes and acceptability of using e-cigarettes during pregnancy. Participants were also asked more detailed questions about their smoking behaviour, and demographic information was collected.

In follow-up 1 (FU1 – appendix 3.2) and follow-up 2 (FU2 – Appendix 3.3: Pregnancy Lifestyle Survey Follow-Up two 3.3), women were asked about their vaping at the time of the questionnaire, at the time of delivery, and the first three months after their baby's birth (FU2 only). The options were: not at all; only used once or twice; used occasionally, but less than weekly; used daily, but less than once a week; used every day. Women were then asked if anyone the woman knew felt they should use e-cigarettes either during pregnancy (FU1) or postpartum (FU2). Participants were asked about their

views, attitudes and acceptability of using e-cigarettes during pregnancy (FU1) or postpartum (FU2), and the safety of using them. This was measured using a 7 point Likert scale (ranging from strongly disagree to strongly agree).

Some of the reasons people give for using e-cigarettes in pregnancy (FU1) or postpartum (FU2) were listed, and participants were asked to select one from the list as being the most important reason for using e-cigarettes, and then asked to select any of the other reasons they felt were important. The same format was used with some reasons people may give for not using an e-cigarette during pregnancy (FU1) or postpartum (FU2). Participants were also then asked about their intended use of e-cigarettes in the future, and those who did use e-cigarettes were asked about their use, device type, e-liquid preferences, and reasons for use, satisfaction and comparison to e-cigarettes.

The questionnaires then focused on feeding intentions, and feeding practices (FU2), the options were; breastfeed only (from breast or expressed milk via bottle); formula feed only; combine breastfeeding and formula feeding; unsure. In FU2, further questions were asked relating to feeding, including how old an infant was when they last received any breastmilk (if formula feeding at the time of the questionnaire). Attitudes and opinions towards using e-cigarettes as a breastfeeding mother were measured with a 7 point Likert scale (ranging from strongly disagree to strongly agree).

Participants were then asked about their smoking status: not at all; occasionally, but not every day; every day, but cut down during pregnancy (FU1)/less than during pregnancy (FU2); every day, the same as before pregnancy (FU1)/same as pregnancy (FU2); every day, but more than before pregnancy (FU1)/ more than during pregnancy (FU2). In FU2 women were also asked about their smoking in the week prior to birth and for those who did smoke, how soon after birth did they have their first cigarette. Women were also asked about their future intentions to quit smoking, what support (if any) they would use to enable a quit attempt, and how many cigarettes they smoked.

Demographic questions asked about ethnicity, educational attainment, and the age participants left education.

3.3.3 Analysis

The primary outcome measures were; breastfeeding intentions and behaviour, and smoking/vaping status. Women were categorised as “never breastfed”: women who reported their infant never received any breastmilk, and “ever breastfed”: women who reported the infant had received at least some breastmilk. At FU2, women who reported any breastfeeding were classified as ‘breastfeeding’. Smoking and vaping status were categorised as “Ex-smoker”: women who identified they were neither smoking nor vaping, “Smoker”: women who reported smoking (daily or occasionally) but were not currently using e-cigarettes, “Exclusive vapers”: who currently used an e-cigarette but did not currently smoke, and “Dual users”: who currently used an e-cigarette (daily or occasionally) and also smoked cigarettes (daily or occasionally).

Maternal characteristics, smoking and vaping behaviour, breastfeeding (intention and initiation) were all analysed using descriptive statistics. Cross tabulations with Chi-Square statistics were performed using Stata/SE 16 to explore any differences in breastfeeding intention and initiation by demographic characteristics (age, ethnicity and education), and by smoking/vaping status. Multivariate logistic regressions were performed to assess the associations between smoking and breastfeeding, independent of significant demographic confounders. P values were deemed significant if they were less than 0.05.

3.4 Results

3.4.1 Missing data

At baseline (early pregnancy), a total of 750 women were included in the study; of those, 62 were withdrawn from the study (outlined in Figure 3.1), leaving 688 participants. Of the 688, 392 returned follow-up 1, a loss of 43%. Little's Test of Missing Completely at Random (MCAR) [337] was performed; the results suggest the data is not MCAR ($P < 0.001$). Individual tests examining missing variables showed that missing data were

associated with smoking status and educational levels at baseline; missing data at follow up 1 was more frequent amongst women who smoked at baseline, and women who held a GCSE level education. As missing data could not be assumed to be completely random, a listwise deletion method was used to manage missing variables [338].

In order to be included in the analysis, participants must have reported both their smoking and vaping status. For some breastfeeding variables, the total number of participants included differ due to whether data was reported for these variables; these are shown in Figure 3.2 and below Figure 3.3.

Figure 3.2: Follow-up 1 missing data

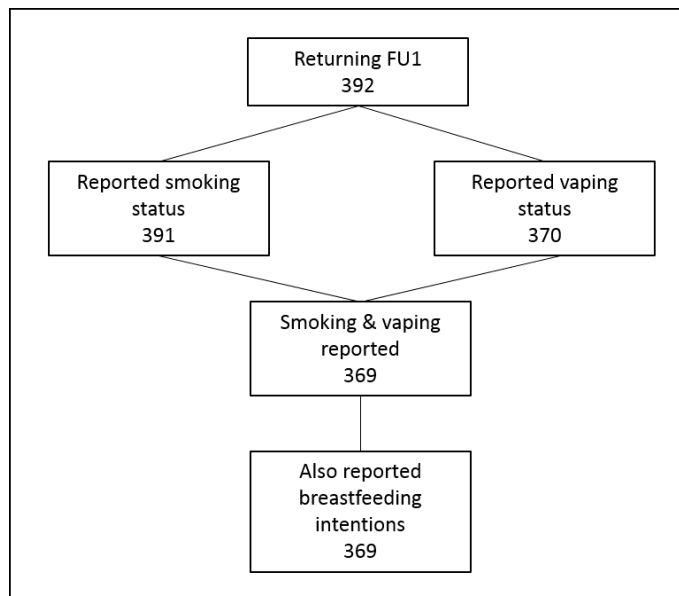
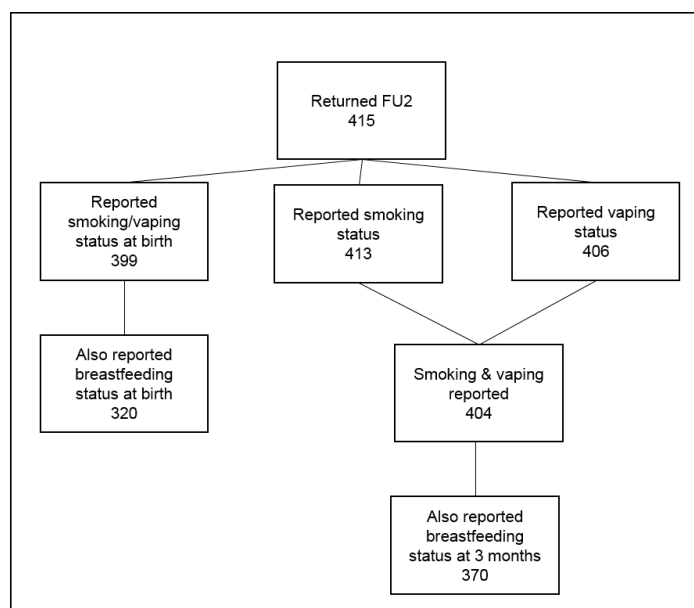


Figure 3.3 Follow-up 2 missing data



3.4.1 Demographic characteristics of women who breastfed

The demographic characteristics of the women at follow up 1 and 2 are presented in Table 3.1. Overall, at FU1 (34 weeks gestation), 63.5% of women intended to breastfeed, with 46.35% of women initiating breastfeeding at birth, by three months postpartum (FU2), only 17.68% of women were still breastfeeding. Older mothers were more likely to commence breastfeeding at birth ($p = 0.02$) and tended to be more likely to continue breastfeeding at three months ($p = 0.019$). Breastfeeding was also highest amongst mothers with greater levels of education, intention to breastfeed ($p < 0.001$), breastfeeding at birth ($p < 0.001$), and breastfeeding at three months ($p = 0.019$). Due to small sample sizes within most ethnicity categories, ethnicity was not included in this analysis.

In terms of smoking, vaping, and dual-use during pregnancy in relation to breastfeeding, ex-smokers were more likely to intend to breastfeed than smokers, vapers, and dual users ($p < 0.001$). Ex-smokers were also more likely to initiate breastfeeding at birth ($p = 0.04$) and were more likely to be breastfeeding at three months ($p < 0.001$).

Table 3.1 Baseline characteristics, and smoking status at FU1/FU2 according to breastfeeding behaviour

Demographics	Follow up 1		Follow up 2			
	N	Intend to breastfeed (n (%))	N	Breastfed at birth	N	Breastfed at 3 months
Age						
16-24	142	86 (60.0%)	120	44 (36.7%)	146	19 (13%)
25-34	199	131 (65.8%)	169	87 (51.5%)	191	36 (18.8%)
35 +	48	30 (62.5%)	42	23 (54.8%)	42	10(23.8%)
Total	389	247 (63.5%)	331	154 (46.5%)	379	67 (17.7%)
Missing	3		84		36	
<i>P</i> Value		0.602		0.024		0.178
Education						
None	49	19(38.8%)	41	10(24.4%)	45	7(15.6%)
GCSE	148	83(56.1%)	130	50(38.5%)	155	18(11.6%)
A level	94	69(73.4%)	79	42(53.2%)	92	16(17.4%)
Degree	92	73(79.3%)	77	51(66.2%)	82	23(28.1%)
Other	4	2(50%)	3	1(33.3%)	4	0(0%)
Total	387	246 (63.6%)	330	154 (46.7%)	378	64 (16.9%)
Missing	5		85		37	
<i>P</i> Value		<0.001		<0.001		0.019
Smoking Status						
Ex-smoker	145	111 (76.6%)	129	74 (57.4%)	88	33 (37.5%)
Smoker	173	98 (56.6%)	133	48 (36.1%)	198	20 (10.1%)
Vaper	17	10 (58.8%)	23	9 (39.1%)	32	8 (25.0%)
Dual User	34	18 (52.9%)	37	20 (54.1%)	52	4 (7.7%)
Total	369	237 (64.2%)	322	151 (46.9%)	370	65 (17.6%)
Missing	23		93		45	
<i>P</i> value		0.001		0.004		<0.001

^{1,2}

¹ Chi square tests for association between intention and initiation of breastfeeding, breastfeeding at 3 months, and demographics (at baseline) and smoking status (during pregnancy and postpartum)

² Percentages are given in rows

3.4.2 Demographic characteristics according to smoking/vaping status

The demographic characteristics, according to smoking/vaping status, are presented in Table 3.2. Although 39.3% of women in this cohort were ex-smokers/vapers during pregnancy, by three months postpartum, only 24.4% remained smoke/vape free. Age was not associated with smoking/vaping status. Mothers' education was related to smoking status such that mothers with higher educational levels were more likely to be neither smoking nor vaping during pregnancy ($p < .001$) and at three months ($p = .005$).

Table 3.2 Demographic characteristics according to smoking/vaping status

Demographic	Smoking / vaping at follow up 1				Smoking / Vaping at follow up 2			
	Total	Ex-smoker	Smokers	Vaper / dual users	Total	Ex-smoker	Smokers	Vaper / dual users
Age								
16-24	135	58 (40%)	62 (35.8%)	15 (29.4%)	153	42 (42.9%)	81 (37.7%)	30 (33.7%)
25-34	187	72 (49.7%)	87 (50.3%)	28 (54.9%)	204	45 (45.9%)	108 (50.2%)	51 (57.3%)
35 +	47	15 (10.3%)	24 (13.7%)	8 (15.6%)	45	11 (11.2%)	26 (12.1%)	8 (9.0%)
Total	369	145	173	51	402	98	215	89
Missing	23				13			
P Value	0.628				0.592			
Education								
None	42	8 (5.6%)	25 (14.6%)	9 (17.6%)	43	4 (4.1%)	26 (12.3%)	13 (14.3%)
GCSE	141	42 (29.1%)	79 (46.2%)	20 (39.3%)	157	34 (34.7%)	89 (42.0%)	34 (37.3%)
A level	90	39 (27.1%)	39 (22.8%)	12 (23.6%)	101	23 (23.5%)	54 (25.5%)	24 (26.4%)
Degree	90	54 (37.5%)	27 (15.8%)	9 (17.6%)	95	37 (37.7%)	41 (19.3%)	17 (18.7%)
Other	3	1 (0.7%)	1 (0.6%)	1 (1.9%)	5	0 (0%)	2 (0.9%)	3 (3.3%)
Total	366	144	171	51	401	98	212	91
Missing	26				14			
P Value	<0.001				0.005			

³

³ Percentages given in columns

		Smoking / vaping at follow up 1				Smoking / Vaping at follow up 2					
Demographic	Total	Ex-smoker	Smokers	Vaper	Dual users	Total	Ex-smoker	Smokers	Vaper	Dual users	
Age											
16-24	135	58 (40%)	62 (35.8%)	4 (23.5%)	11 (32.4%)	153	42 (42.9%)	81 (37.7%)	8 (22.9%)	22 (40.7%)	
25-34	187	72 (49.7%)	87 (50.3%)	13 (76.5%)	15 (44.1%)	204	45 (45.9%)	108 (50.2%)	24 (68.6%)	27 (50%)	
35 +	47	15 (10.3%)	24 (13.7%)	0 (0%)	8 (23.5%)	45	11 (11.2%)	26 (12.1%)	3 (8.6%)	5 (9.3%)	
Total	369	145	173	17	34	402	98	215	35	54	
Missing	23					13					
P Value		0.628					0.592				
Education											
None	42	8 (5.6%)	25 (14.6%)	2 (11.8%)	7 (20.6%)	43	4 (4.1%)	26 (12.3%)	7 (20%)	6 (10.7%)	
GCSE	141	42 (29.1%)	79 (46.2%)	7 (41.2%)	13 (38.2%)	157	34 (34.7%)	89 (42.0%)	11 (31.4%)	23 (41.1%)	
A level	90	39 (27.1%)	39 (22.8%)	4 (23.5%)	8 (23.5%)	101	23 (23.5%)	54 (25.5%)	6 (17.1%)	18(32.1 %)	
Degree	90	54 (37.5%)	27 (15.8%)	3 (17.6%)	6 (17.6%)	95	37 (37.7%)	41 (19.3%)	10 (28.6%)	7 (12.5%)	
Other	3	1 (0.7%)	1 (0.6%)	1 (5.9%)	0 (0%)	5	0 (0%)	2 (0.9%)	1 (2.9%)	2 (3.6%)	
Total	366	144	171	17	34	401	98	212	35	56	
Missing	26					14					
P Value		<0.001					0.005				

3.4.3 Smoking, Vaping & Breastfeeding

To test for the independent association between smoking/vaping status, and breastfeeding at birth, a logistic regression was performed to adjust for age and education. In the univariate logistic regression (Table 3.3) of the effect of smoking status on the outcome of breastfeeding at birth, those in the smoking category had a reduced odds of breastfeeding compared to those who were ex-smokers. Those who vaped also had reduced odds of breastfeeding, but this effect was not significant. Although adjusting for age and education does affect the strength of the association, Table 3.4 shows that women who smoke at birth have a 51% reduction in odds of breastfeeding at birth compared to ex-smokers (OR .480, 95% CI: .258-.890; P <0.001).

Table 3.3 Unadjusted logistic regression for smoking status and breastfeeding at birth

Breastfed at birth	Odds Ratio	Std. Error	Z	P	Confidence Interval (95%)	
Smoking status						
1. Ex-smoking	-	-	-	-	-	-
Smoking	.425	.121	-2.98	0.002	.243	.745
Vaping	.547	.2325	-1.01	0.310	.170	1.754
Dual Use	.589	.266	-1.17	0.242	.242	1.43

Table 3.4 Smoking status and breastfeeding at birth, adjusted for age and education

Breastfed at birth	Odds Ratio	Std. Error	Z	P	Confidence Interval (95%)	
Smoking status						
1. Ex-smoking	-	-	-	-	-	-
Smoking	.480	.151	-2.33	0.01	.258	.890
Vaping	.643	.416	-0.68	0.49	.181	2.287
Dual Use	.717	.347	-0.69	0.49	.277	
Educational level						
1. None	-	-	-	-	-	-
GCSE	2.175	.949	1.78	0.075	.925	5.116
A level	3.684	1.696	2.83	0.005	1.494	9.081
Degree	5.029	2.358	3.44	0.001	2.006	12.608
Age						
1. 16-24	-	-	-	-	-	-
25-34	2.228	.598	2.98	0.003	1.316	3.770
35+	2.538	1.025	2.31	0.021	1.150	5.599

As educational level was the only demographic to be significantly associated with breastfeeding and smoking status at three months postpartum, a logistic regression to check for an independent association between smoking and breastfeeding was performed adjusting for educational level. Smoking remains highly significant for the likelihood of breastfeeding at three months, even when adjusted for educational level (OR .190, 95% CI: .099-.367; P <0.001).

Table 3.5 Unadjusted logistic regression for smoking status and breastfeeding at 3 months postpartum

Breastfed at 3 months	Odds ratio	Std. Error	Z	P	Confidence Interval (95%)	
Smoking status						
1. Ex-smoker	-	-	-	-	-	-
Smoker	.187	.060	-5.19	<0.000	.099	.352
Vaper	.556	.257	-1.27	.205	.224	1.38
Dual user	.139	.078	-3.49	.000	.046	.420

Table 3.6 Smoking and breastfeeding status at 3 months, adjusted for education

Breastfed at 3 months	Odds ratio	Std. Error	Z	P	Confidence Interval (95%)	
Smoking status						
1. Ex-smoker	-	-	-	-	-	-
Smoker	.190	.063	-4.96	<0.000	.099	.367
Vaper	.568	.272	-1.18	.238	.222	1.45
Dual user	.157	.090	-3.24	.001	.051	.482
Educational level						
1. None	-	-	-	-	-	-
GCSE	.563	.286	-1.13	0.258	.208	1.523
A level	.823	.428	-0.38	0.708	.296	2.283
Degree	1.148	.593	0.27	0.790	.417	3.157

3.4.4 Health beliefs

Health beliefs, according to smoking category and overall, are presented in Table 3.7.

The following health belief statements were given to participants who were asked to state whether they disagreed, agreed or neither disagreed/agreed with the belief. The results suggest women believe vaping mothers should breastfeed more than they agree smoking mothers should, however mothers did not agree that using e-cigarettes when breastfeeding was safe. However responses, varied significantly by smoking status for beliefs on whether woman should breastfeed if she smokes ($p<.001$) or uses e-cigarettes ($p<.001$). Smokers were also less likely to agree that e-cigarettes were safer for breastfeeding than smoking ($p=.013$).

Table 3.7 Health beliefs by smoking status

Belief / Smoking status at 3 months	Total	Disagree	Neither	Agree
'Mothers should not breastfeed if they smoke tobacco cigarettes'	348			
Ex-smoker	91	25 (27.5%)	10 (11.0%)	56 (61.5%)
Smoker	181	98 (54.1%)	25 (13.8%)	58 (32.0%)
Vaper / dual user	34	15 (44.11%)	3 (8.8%)	16 (47.1%)
Dual user	45	21 (46.7%)	7 (15.6%)	15 (33.3%)
<i>P</i> value				<0.001
<i>Combined smoking categories</i>	355	162 (45.6%)	45 (12.7%)	148 (41.7%)
Mothers should not breastfeed if they use e-cigarettes	336			
Ex-smoker	91	41 (45.1%)	13 (14.3%)	37 (40.7%)
Smoker	180	123 (68.3%)	23 (12.8%)	34 (18.9%)

Vaper	34	31 (91.2%)	2 (5.9%)	1 (2.9%)
Dual user	31	21 (67.7%)	2 (6.5%)	8 (25.8%)
<i>P</i> value				.000
<i>Combined smoking categories</i>	343	222 (64.7%)	40 (11.7%)	81 (23.6%)
Belief / Smoking status at 3 months	Total	Disagree	Neither	Agree
Using e-cigarettes when breastfeeding is safe for the baby	316			
Ex-smoker	71	61 (85.9%)	5 (7.0%)	5 (7.0%)
Smoker	167	143 (85.6%)	14 (8.4%)	10 (6.0%)
Vaper	35	21 (60%)	4 (11.4 %)	10 (28.6%)
Dual user	43	38 (88.3%)	2 (4.7%)	2 (4.7%)
<i>P</i> value 4, 8.02				.091
<i>Combined smoking categories</i>	325	271 (83.38%)	25 (7.69%)	25 (7.69%)
Using e-cigarettes when breastfeeding is as safe for the baby as nicotine patches	324			
Ex-smoker	76	62 (81.6%)	9 (11.8%)	5 (6.6%)
Smoker	169	138 (81.7%)	18 (10.7%)	13 (7.7%)
Vaper	33	19(57.6%)	5 (15.2%)	9 (27.3%)
Dual user	46	41 (89.1%)	2 (4.3%)	3 (6.5%)
<i>P</i> value				.329

<i>Combined smoking categories</i>	331	266 (80.36%)	34 (10.27%)	31 (9.37%)
If a mother breastfeeds, it is safer for the baby if she uses an e-cigarette than if she smokes tobacco cigarettes	338			
Ex-smoker	78	40 (51.3%)	17 (21.8%)	21 (26.9%)
Smoker	180	123 (68.3%)	35 (19.4%)	22 (12.2%)
Vaper	35	12(34.3%)	10 (28.6%)	13 (37.1%)
Dual user	45	32 (71.1%)	5 (11.1%)	8 (17.8%)
<i>P</i> value				.013
<i>Combined smoking categories</i>	345	212 (61.45%)	67 (19.42%)	66 (19.13%)

3.5 Discussion

3.5.1 Key findings

Despite 63.9% of mothers intending to breastfeed, only 46.35% of women did initiate breastfeeding, and by three months postpartum, only 17.68% of mothers were still breastfeeding. Mothers who were older and/or had higher levels of education were more likely to initiate and continue breastfeeding. Age was not associated with smoking status; however, women with higher levels of education were more likely to remain smoke-free throughout pregnancy and the postpartum period. Those who did remain smoke-free were more likely to intend to, initiate, and continue to breastfeed compared to mothers who smoked and/or vaped. When taking in to account age and education, women who smoked and/or vaped were still less likely to intend to, initiate, or continue breastfeeding compared to those who remained smoke-free.

Overall many women held the opinion that smoking mothers should not breastfeed, although half of the women who smoked/vaped disagreed with this. Conversely, the

majority of women held the opinion that vaping mothers should breastfeed, and smoking women were more likely to agree vaping mothers should breastfeed, than smoking mothers should breastfeed. Despite this, 83% of women, including 60% of vapers, felt using an e-cigarette as a breastfeeding mother was not safe for the baby, and 80% believed nicotine patches to be safer. Overall the majority of women disagreed that it was safer for the baby if the breastfeeding mother vaped instead of smoked, which was contradictory to the earlier opinions, which were much more favourable of vaping than smoking. When looking at the responses to this question by smoking status, this contradiction may be explained by a higher percentage of smokers (who were the largest of the three groups) disagreeing. This question did have the highest 'unsure' responses, with around 20% of women being uncertain.

3.5.2 Strengths and limitations

This survey was the first of its kind to ask new mothers about their views and opinions on e-cigarettes and breastfeeding, as well as providing information on views and opinions of smoking and breastfeeding. By recruiting women at antenatal appointments target population was reached, and prospective longitudinal design enabled the follow-up of women at three separate time points.

This data did rely on self-reported smoking status, which has been previously shown to be inaccurate [339]. However, the validity of self-reported smoking is suggested to be more reliable when anonymous surveys are used [340], which may improve the reliability of the data collected in this study.

Unfortunately, only 44.8% of the full baseline sample returned FU 1. Little's test for MCAR showed that missing data was not completely random and further analysis showed that missing data was more frequently those who were smokers, and those with a GCSE education, at baseline. This may add bias to the analysis; however, overall, smokers were still the largest category in FU1 and 2, and GCSE level education was still the most prominent category for education. This will have impacted the prevalence of breastfeeding and smoking in both follow-up surveys. However, the

primary purpose of this research is to look at associations between smoking and breastfeeding, and associations tend to be less affected than prevalence.

Only a small proportion of the sample were exclusive vapers. This meant that for some of the analysis, dual users and exclusive vapers were grouped. There are likely to be differences between those women who exclusively vape and those who are dual users that could not be further explored within this data. However, it should be noted that currently, no literature exists that considers any vaping (exclusive or otherwise) in relation to breastfeeding and smoking. Still, the small sample sizes should be considered when interpreting the results. Small sample sizes may mean significant associations are missed. So the lack of a significant association between breastfeeding and vaping may be due to the small number of vapers, suggesting further research is needed. Despite the small sample size and unequal groups, this research is the first of its kind. It gives us novel data on e-cigarette use in the postpartum period, as well as a more recent data set of smoking and breastfeeding demographics.

3.5.3 Relation to prior work

The women in this study initiated breastfeeding at lower rates than most recent NHS Maternity statistics (2017-18); 46.5% initiated breastfeeding compared to a national average of 74% [341]. There is no recorded statistic for breastfeeding at three months within the NHS Maternity statistics. However, the final Infant Feeding Survey in 2010 [119] has statistics for four months postpartum, where 42% of mothers are still breastfeeding, compared to 17.7% in this sample at three months. The lower breastfeeding rates in this sample are likely to be due to the higher proportion of smokers. In this study 64.82% of mothers reporting smoking within the last 30 days at baseline (between 8-24 weeks pregnant), whilst the NHS Maternity statistics report smoking status at booking in appointment only, they recorded 14.8% of mothers smoking. In this sample, 46.9% of mothers were smoking in late pregnancy, compared to a national average of 10.8% mothers smoking at the time of delivery (1.6% - 27.8% range) [29]. The statistics for smoking in this study were going to be higher than the national average due to purposefully recruiting a sample of women who either smoked, vaped, or had quit smoking immediately prior to, or during early pregnancy.

With this in mind, when looking at just the ex-smokers in relation to breastfeeding, the figures are closer to the national average; 61.1% of ex-smokers initiated breastfeeding (compared to 74% national average) and 37.5% were still breastfeeding at three months (compared to 42 % at four months national average). Although these percentages are lower, they are much closer to the national average if smoking mothers are excluded from the sample. For smoking mothers, just 40% initiated breastfeeding, and by three months post-partum, only 10.1% were still breastfeeding. Regardless of smoking status, fewer women initiated breastfeeding than intended to breastfeed [342, 343]. This study did not consider why this may be, however previous research has identified that women who experience traumatic deliveries or have caesarean section deliveries are less likely to initiate breastfeeding at birth. This is due to insufficient milk supply, or the mothers need for recovery.

Previous studies have linked both age and education to smoking and breastfeeding status [47]. While our results show education is associated with smoking and breastfeeding status and age is associated with breastfeeding initiation, the logistic regression shows that when adjusting for these variables, the association between smoking status and breastfeeding is still significant. As this sample compares smokers/vapers/dual users to recent ex-smokers, conclusions can be drawn that are not afforded by other research that just compares non-smokers to smokers. This suggests that by changing the smoking/vaping behaviour, we may be able to increase breastfeeding intentions, initiation, and duration. There were no observable differences between smoking and vaping/dual-use mothers; however, this may be due to the small sample size of vapers in this study. There may be important differences between dual-use mothers and smoking mothers that, due to the novelty of e-cigarette research, have not been explored.

The belief that women should not breastfeed if they smoke is concerning; the NHS advises that women who smoke continue to breastfeed [58]. Breastfeeding can mitigate some of the risks to an infant who has a smoking parent [344-346], so despite the transference of smoke constituents into breastmilk, it is important that smoking mothers are not discouraged from breastfeeding. In this study participants were more likely to

agree that women who use an e-cigarette should breastfeed, than agree women who smoke should breastfeed, even amongst the smoking category. Prior studies have shown that overall smokers, non-users, dual-users and e-cigarette users perceived e-cigarettes as safer for bystanders (due to passive exposure) than smoking [347] which may account for the greater support for vaping mother's breastfeeding. Qualitative work has also shown that overall new mothers do perceive vaping to be safer around infants than cigarettes [270].

Despite the majority of mothers being more likely to agree that vaping mothers should breastfeed than smoking mothers, when asked if using an e-cigarette was safer for breastfeeding than smoking, the majority of women disagreed. This may be due to a larger number of smokers disagreeing with this statement, and as smokers were a larger group than ex-smokers and vapers/dual users, this may have skewed the results. When looking at these responses by smoking status, over half of vapers/dual users and half of the ex-smokers disagreed with this statement. In a narrative literature review of perceptions about e-cigarettes, the majority of studies suggested people perceived e-cigarettes to be less harmful than cigarettes. However, more recent studies within the review showed this perception had changed somewhat to e-cigarettes being perceived as equally harmful [347]. Within this review [347], it was identified that current smokers and non-vapers were more likely to perceive e-cigarettes to be more harmful than cigarettes. However, it was identified that different flavours of e-liquids influenced the risk perception, which we did not ask participants about in our study. Research involving women who had recently given birth also identified harm perceptions as a potential concern for mothers using e-cigarettes, citing more research was needed [270].

Participants in this study did not perceive e-cigarettes to be as safe as NRT (Nicotine Replacement Therapy). Although not much information exists on perceptions between e-cigarettes and NRT, one qualitative study did identify women who had successfully quit smoking and did not vape. This study reported women favour NRT in case of relapse, rather than e-cigarettes. Women viewed e-cigarettes as potentially leading back to smoking. Women who had never vaped or were ex-vapers also felt that NRT was more effective at supporting quit attempts than e-cigarettes [270].

3.5.4 Conclusion

This research shows that even when we account for certain demographic variables, smoking is strongly associated with whether a mother intends to breastfeed, initiates breastfeeding and for how long she continues to breastfeed. Overall, e-cigarettes are viewed more positively than cigarettes. However, we still don't fully understand what motivates women to use an e-cigarette, and what perceptions they have about e-cigarettes in relation to breastfeeding. Further research is needed to consider what may motivate some mothers to use a vape, and others not to. We must also explore the harm perceptions and health beliefs about e-cigarettes. Future research should consider a qualitative approach that explores these factors in greater detail.

Chapter 4: Is it safe to vape whilst breastfeeding? Postpartum women's opinions on e-cigarettes, using online forum discussions: a qualitative analysis.

4.1 Introduction

As discussed in chapter 1, maternal smoking and low breastfeeding rates are both significant public health concerns relating to the post-partum period, with health implications for both the mother and her child [101, 348-354].

Very little research thus far has examined the use of e-cigarettes amongst postpartum women; the research available has focused on the use of e-cigarettes in pregnancy. Therefore there is a need to understand the use of e-cigarettes in the postpartum period and how this may relate to breastfeeding. As seen in Chapter 3, women are using e-cigarettes during the postpartum period. While the data in Chapter 3 would suggest women who do use e-cigarettes breastfeed at similar rates to those who smoke, the sample size limits the value of this information. What was worth noting was that the participant sample as a whole (including smoking, vaping and ex-smoking mothers) were more likely to agree vaping mothers should breastfeed, than smoking mothers. This highlighted the potential for using e-cigarettes to reduce postpartum smoking, which may in turn improve UK breastfeeding rates.

For women not initiating breastfeeding (or stopping breastfeeding) due to fears that smoking may contaminate breastmilk, and the concern about passive smoking due to the proximity of breastfeeding, the belief that e-cigarettes are safer provides an alternative solution. As women are more likely to agree vaping mothers should breastfeed, the promotion of e-cigarettes for women who cannot, or do not, want to remain nicotine-free seems a sensible solution.

Due to the pressure on new mothers to appear as 'good mothers' [355-357], there may be a lack of representation of mothers who engage in behaviours that fall outside of this expected norm. This, along with the relative novelty of e-cig research in the postpartum

period, calls for an exploratory research design that reduces the influence of social desirability. With this in mind, an infodemic approach was used.

Infodemiology refers to a method of conducting health-related research using the medium of the internet [358]; it is used for health surveillance, promotion, and the tracking of health campaigns. With the increasing availability of the internet, infodemiology is a modern way of collecting data. Infodemiology is particularly useful for reaching 'hard to reach populations' [358]. When collecting data using new mothers, particularly when it relates to subjects that carry a burden of stigma (breastfeeding and smoking postpartum), an infodemic approach can access greater populations with fewer biases [358]. The use of infodemic methods is also advantageous when studying subjects that are relatively novel, such as e-cigarettes.

4.2 Aims

The overarching aim of this study was to explore the views of women present within online parenting forums on e-cigarette use during the post-partum period, specifically in relation to breastfeeding.

Specifically, this study aimed to:

- Explore beliefs about the use of e-cigarettes during the postpartum period
- Explore beliefs about the use of e-cigarettes by breastfeeding mothers
- Understand how, and where, women are getting the information to form these beliefs about e-cigarettes use
- Explore potential barriers and motivators to using an e-cigarette as a breastfeeding mother

4.3 Methods

4.3.1 Data Collection

As discussed, an infodemic approach was utilised for this research. Infodemiology allows for exploratory research of novel health related topics, and is particularly advantageous for stigmatised behaviours amongst 'hard to reach' populations [358]. Practically, infodemic research also allows for a wider range of opinions to be included in research; in this study parenting forums were used to provide opinions of many women across the UK [358]. Qualitative analysis of discussions on online parenting forums has been previously used to explore a range of context-specific behaviours, attitudes and beliefs [359, 360]; including the use of e-cigarettes (e-cigarettes) during pregnancy [269]. Plus, with the novelty of researching e-cigarette use in relation to breastfeeding, the lack of literature provides no framework for the design or implementation of other qualitative methods. This research involved collecting data publically posted to online parenting forums.

Inclusion criteria:

Due to varying guidelines between countries on e-cig use, only UK based forums were used. The eligibility for the inclusion of a thread (a continuous discussion on a forum) in the final analysis was:

- It was posted to a forum which is open to public use, without the need to sign up/log in to read posts – for ethical purposes
- It was posted to parenting forums not affiliated with vaping or tobacco companies – to reduce bias
- It contained a minimum of four unique contributors to the discussion – to ensure maximum transferability
- Discussions that included the mention of e-cigarette use/vaping and breastfeeding – in order to meet the aims of the research

Search strategy for data collection:

The keywords for e-cigarettes (Table 4.1) were combined using operator “AND” with keywords for breastfeeding, and searched using the search operator; a Google-based command to filter results; “site:sampleforum.co.uk” via Google search engine.

The use of search operators, or search parameter, involves a string of characters/phrases designed to narrow the focus of an online search. This was the most effective and thorough way to ensure relevant discussions were obtained, while ignoring forums owned by specific groups who may have competing interests, such as e-cig manufactures or tobacco companies. These sites were identified by screening of the URL name and home page.

Table 4.1 Keywords

Keywords (electronic cigarette)		Keywords (Breastfeeding)
E-Cig(s)	AND	Breastfeeding
E-cig(s)		BF (ing)
Electronic cigarette (s)		Nurse/Nursing
Vaping		Breastmilk
Vape (s)		Feeding

A total of 597 google results were returned using the above search terms; searches were then adapted to exclude ‘pregnancy’ and ‘TTC (trying to conceive)’ in line with the aims of the research. The threads used in the analysis were then transferred into NVivo11.

In the analysis, abbreviations within quotes were expanded in squared brackets, and the data source is identified by T (thread), and the numbered data set.

4.3.2 Ethical considerations

There are distinct ethical considerations when utilising forum data for research purposes, the main concern being the inability to gain informed individual consent. However, this was not deemed necessary as the data were publically posted on a large

forum [361-364]. The British Psychological Society (BPS) The BPS has published guidelines on internet-mediated research. This can be separated into four distinct sets of principles [365]; Respect for the Autonomy, Privacy and Dignity of Individuals and Communities, Scientific Integrity, Social Responsibility, and Maximising Benefits and Minimising Harm.

To maintain respect for participant's autonomy, privacy, and dignity (and that of the virtual community as a whole), only forums with a large number of members were used. This is because comments on large public forums are less identifiable than those on smaller, private online communities [366] (for this research, a large forum was defined as forums with over 1,000 members). Furthermore, all contributing users were randomly assigned a new name to protect their identity. Names of people, places, and institutions were removed from quotes, and quotations were corrected for spelling and kept brief to reduce the possibility of them being traced back to the original poster.

Maintaining a high degree of scientific integrity is vital when using forum data; the risk of researcher bias is one to be considered. For example, as the data has been created as part of a discussion not intended for research, the final results must reflect an analysis of the discussions, not merely the interpretation of the researcher and the pre-existing biases they may hold as a result of their research interests. To acknowledge this, a reflective journal was kept during data collection, the formation of *a priori* codes, and the construction of the coding template. A second coder was also used to independently analyse a portion of the data to reduce the risk of biases. The validity of the data remains an ongoing issue for any research utilising forum data; the ability to know for certain if the real person behind the online avatar is indeed a breastfeeding mother who smokes is not afforded to this type of research. Specific measures can be employed to reduce this risk; for example, in this study, data from any forums associated with e-cigarette or tobacco companies were not used, and all data collected was screened. Despite this apparent limitation, the benefits of using an infodemic approach for this research were deemed to far outweigh the limitations.

When considering social responsibility, it is important to consider whether the research procedures and dissemination of the research may disrupt or harm the virtual community as a group; i.e. a loss of anonymity. To minimise this, only data from publically accessible forums, where users are made aware during the initial sign up process that all posts are open to public access, were used [367]. Also, as the two parenting forums used in this research have been used in prior research [269], and both virtual communities have a newsletter and magazine for which comments and discussions may be published, the risk of harm to the virtual community was deemed to be minimal. Finally, with the health implications of smoking postpartum and low breastfeeding rates being a threat to the long and short term health of both mother and baby, the benefits of this research can outweigh the minimal risk of harm.

Ethical approval was obtained from the University of Nottingham Medical School Research Ethics Committee.

4.3.3 Analysis

Template analysis (a template approach to thematic analysis) was used to analyse the data, following the guidelines outlined by King [368, 369]. There are six stages to performing a template analysis; Familiarisation with the data – reading through the transcripts (or a subset of transcripts for larger studies); Preliminary coding with (if applicable) *a priori* codes; Initial coding template design; Application of the initial template to the data, allowing for modifications as and when they arise; Continued modification of the template through iteration; and Application of the final template to the full data set. When analysing large online support group datasets, template analysis is useful for comparing the perspectives of different contributors.

The use of *a priori* codes permits the analysis of the textual data that had been produced for 'a different purpose in a different context' [369]. The use of *a priori* codes can be used when there is the assumption that certain aspects of a research question should be focused on; for this research the data collected was not generated to specifically explore the research question, therefore, the *a priori* codes were used to focus the

analysis on addressing the needs of the research aims. The *a priori* codes in this study were: Using e-cigarettes postpartum, health beliefs (e-cigarettes and breastfeeding), Opinions (on e-cigarettes), Information (seeking and giving), and Evidence (sources). It is important to note that *a priori* codes are tentative and may be removed or redefined through iteration of the coding template. In line with the guidelines this initial template of *a priori* codes was used to code each transcript, with codes being continually modified or expanded, by Emily Johnston (EJ). After the last transcript was coded, a subset of transcripts was then coded by Dr Katarzyna Campbell (KC), one of the PhD supervisors with experience in qualitative analysis of online forum data, any disagreements were resolved via discussion allowing for final modifications and amendments until the coding and themes were finalised, a final version of the template was then used to re-code all transcripts (Table 4.2), and a mind map was also created to show integrative relationships and prevalence (appendix 4.1).

Table 4.2 Final coding template

1 st level		2 nd level	
Evidence	The sharing of evidence from various sources to support the argument for the use of E-cigarettes or the dis-use of them for breastfeeding mothers.	Anecdotal	Evidence is presented from personal opinions, or through the sharing of non-scientific articles. May include online sources which are not government certified authorities on health, or media stories
		Professional	Evidence is presented from scientific sources or from health professionals. It may be that the health professional quotes do not support the scientific knowledge, but will still be reflected here as an authority on health. Online sources such as NHS based sites will be included here, as well as academic citations.
		Lack of evidence	Asserting that conclusions cannot be drawn due to the lack of relevant evidence. This may include accepting recent evidence, but wanting long term evidence, or not accepting enough evidence to make an informed choice.
Social Support	Includes areas of support such as online groups, messages of support and the sharing of personal experiences of both smoking, quitting, remaining smoke free and relapse	Advice: seeking and giving	Asking for advice and recommendations as well as giving advice and recommendations. Unlike the evidence category this is based on personal opinion, experience or recommendation from others.
		Validation to use or not use	The behaviours and opinions of others validate a woman's choice to vape and breastfeed or choice not to. May cause divisions in the posters.
		Judgement	May be of self or of others – includes feelings of shame, embarrassment or concerns about the ability to be a good mother. May also include comments designed to shame mothers who vape or project own parenting ideals on to others regarding vaping and breastfeeding.
Breast Milk & transference	Discussions of the impact of smoking, vaping and NRT on breastmilk in terms of composition and what enters milk	Nicotine & infant health	May include health effects of nicotine on infants, or the presence of nicotine in milk.
		Reducing the risk	Mediating any perceived risks of breastfeeding a vaping by modifying vaping behaviour
		Vaping & breastfeeding Vs Smoking & breastfeeding	Comparing the two behaviours either as a way of justifying the use of one or arguing the safety of one.
Risk to health	Discussing the concept of 'risk' involved in using ENDS as a new mother. Discussions of the safety of e-cigarettes and potential health implications of use.	A justified risk	Balancing up the perceived pro's & cons of vaping and breastfeeding, or justifying the use of an e-cig in a way to still adhere to 'good mother' roles.
		Infant health	Discussions on possible positive or negative health implications of vaping as a breastfeeding mother on the infant.
		Mothers health	Includes health effects for the mother- positive and negative, as well as discussions around addiction
		Mediate the risk	Modifying behaviour or taking action to mediate any perceived risks that are non-specific to breastfeeding
Use	Exploring how women are using e-cigarettes and what the motivations are for use	Relapse prevention	E-cigarettes as a tool for reducing the risk of relapse to smoking
		Quitting	As a tool to quit smoking
		Motivation for use	Context-specific triggers for use and the concept of identity and choice
		Alternatives	Alternatives to vaping offered

4.4 Results

Of the eight parenting forums identified, two met the inclusion criteria.

Following the search method outlined, a total of 95 google results (discussion threads) were screened for inclusion; 39 were duplicate results and 46 did not meet the inclusion criteria, leaving a total of 10 results to be analysed (Table 4.3).

Table 4.3 Threads (T) for analysis

Thread number	Opening post title	Website	Sub-group heading	Comments
T1	Vaping whilst Breastfeeding?	Babycentre	Vapers Lounge	13
T2	Ecigarette and breastfeeding :(Babycentre	June 2016 Birth Club	6
T3	Smoking while breastfeeding?	Babycentre	September 2015 Birth Club	19
T4	Does anyone vape?	Babycentre	October 2015 Birth Club	10
T5	Today I am..	Babycentre	February 2015 Birth Club	48
T6	(AIBU?) To smoke an electronic cigarette whilst breastfeeding?	Mumsnet	Am I Being Unreasonable? (AIBU)	23
T7	(AIBU) To use the vape? For friend?	Mumsnet	Am I Being Unreasonable? (AIBU)	6
T8	(AIBU) To use electronic cigarettes even though I'm BF?	Mumsnet	Am I Being Unreasonable? (AIBU)	55
T9	(AIBU) To ask DH to stop vaping?	Mumsnet	Am I Being Unreasonable? (AIBU)	129
T10	(AIBU) To not give up smoking just yet?	Mumsnet	Am I Being Unreasonable? (AIBU)	39

Four main themes were identified within the transcripts: use, perceived risk, social support, and evidence.

Use (preventing relapse, quitting smoking & motivation for use):

Women were using e-cigarettes postpartum in a variety of ways and for a variety of purposes. Some reported using them to prevent relapse; describing cravings that

returned postpartum that were normally associated with specific triggers such as the demands of motherhood, mental health issues or relationship problems. Motivations for use were a separate subtheme, as motivations applied to those who had relapsed to smoking postpartum as well as those who had not relapsed (thus far), with women identifying this as a better alternative to smoking. Despite many women reporting going “cold turkey” throughout pregnancy, cravings were still experienced post birth which some women found could be alleviated by e-cigarette use:

'Before pregnancy I used to smoke roll ups but quit when I found out I was pregnant! But after giving birth I started craving badly so decided that rather than smoking again I would try e-cig.' Cressida, T2

Some women had used an e-cigarette to quit during pregnancy and continued use of an e-cigarette postpartum prevented them from returning to smoking. Others, however, did not manage to achieve abstinence during pregnancy or had already relapsed to smoking postpartum, whilst some had planned to return to smoking postpartum as they enjoyed smoking. The following quote highlights the experience of one woman who had already identified that she enjoyed smoking and didn't want to lose that experience, but found an e-cigarette to be a suitable alternative:

'I didn't want to quit, I liked smoking. Bought an e-cig and did 24hrs on it and thought well I can't go back to smoking now. That was 9 months ago and I haven't smoked at all' Sakina, T10

As identified above, women were able to identify what motivated them to seek out an alternative method of nicotine delivery. These were mainly related to the context specific issues attributed to new motherhood, such as lack of sleep, stress, loss of identity and relationship difficulties, as discussed below:

'She is going through a massively stressful time right now and struggling to cope. She borrowed her mum's vape and loved it, felt totally better and less stressed straight away.' Leah, T5

Perceived risk and strategies to mitigate risk (behavioural strategies, psychological strategies, physiological effects & environmental risks)

Although women were using e-cigarettes postpartum, they still had concerns regarding risk. However, this was mitigated by comparing to the perceived risks of vaping with the known risks of smoking:

'They are not unregulated, we know what's in them and they are at least 95% safer than tobacco.' Talitha, T6

Sometimes these were compared favourably and used to make assumptions on e-cigarette safety, such as the guidance on smoking and breastfeeding being used to argue the safety of vaping and breastfeeding:

'They say it's better for a smoker to smoke and breastfeed than not to breastfeed at all, so I should think the same applies to e-cigarettes.' Delilah, T4

However, there were also unfavourable comparisons, such as the health detriments of smoking being projected to vaping:

'I'm not an anxious or risk averse person, really. It's just the link between smoking and SIDS is so strong. What if you do continue to breathe out something for hours after vaping? If in twenty years they turn round and say vaping and co-sleeping causes x, and our baby had x?' Acacia, T7

Many of these comparisons were related to the nicotine content, for example the following forum user was advised it was OK for her husband to vape as he is not breastfeeding:

'The most harmful thing in e cigarettes is the nicotine. Unless your DH [dear husband] plans on doing the breastfeeding, it isnt going to harm your baby.' Daffodil, T7

There were also perceived risks associated with the physiological effect of vaping on breastmilk, with discussions on what was likely to transfer to the infant via breastmilk if the mother vapes. There were comments about 'unknown' substances that may be harmful if transferred to an infant, however the most commonly discussed concerns

were about nicotine, and the perceived health risks associated with passing nicotine to the baby. However, there were comments about 'unknown' substances that may be harmful if transferred to an infant. This concern was often mixed with judgement, the emphasis being that a good mother would not smoke or vape, for example:

'You're basically asking, "AIBU [Am I Being Unreasonable] to feed my baby small amounts of nicotine"? What do you think OP [opening poster]?' Tirzah, T6

Mothers were also informed their infant would develop an addiction to nicotine, in that the infant would *'feel like they want a fag'* and would suffer *'withdrawal'* from nicotine when breastfeeding ceased.

The concept of risk came with a variety of strategies to manage perceived risks. Behavioural strategies involved altering behaviours to reduce exposure to vapour for infants; these included only vaping outdoors or in a separate room, choosing low nicotine juice, or timing vaping around the infant's feeds to allow the maximum time to pass between vaping and the infant receiving inhaled components via breastmilk:

'I would recommend trying to time a vape after a feed rather than before so that you get the biggest gap possible between ingesting nicotine and then feeding the baby. That gives it the most chance to disperse from the milk.' Jemima, T6

Psychological strategies were also used; this involved justifying any perceived risk in a way that presented their choice to vape in a more favourable light, such as explaining that without vaping they would be stressed, which was worse for their baby. They also justified the perceived risks of vaping by comparing it to more accepted health behaviours, such as drinking coffee, as illustrated in the following quote:

'Nicotine is in the same drug classification as caffeine so its only as bad as anyone that drinks coffee and breastfeeds.' Helena, T2

As well as specific risks to infants via the breast milk, there were wider concerns for risks from the environmental exposure to vapour. This was mainly founded on the basis of the harm from passive smoking; women were concerned about the exposure to second hand vapour based on the known harm from second hand smoke:

'It's just not in my instincts to puff on a weird manmade contraption, full of unknown manmade synthetic substance, in close proximity to a new born baby. My instinct says that little one should get as natural untarnished breathing air as I can realistically provide.' Dahlia, T7

Social support (informational, emotional & instrumental)

While discussing risk on the forums, women were also seeking and giving support to one another about vaping. Social support was varied in nature. In many ways, the forum users offered positive social support to women who were vaping or considering an e-cigarette. There was informational support, such as giving advice on which products to use or how best to use an e-cigarette. Informational support was often guided by the woman's own experience of vaping, and included positive messages to support women, especially those, who were trying to quit smoking:

'Come over to the stop smoking section and we'll help you find one that works. Actually, come over anyway, you'll get lots of support and no judgement, whatever method you are using' Jael, T4

Emotional support came from supportive comments about posters' own and others, experiences of quitting smoking and the health benefits they experienced. Sometimes it came from reassurance a woman would not be judged for vaping. The following forum user discussed her partner's experience of vaping and how she viewed it positively:

'I would much rather see him vape than smoke and he no longer wheezes when lying down, he is much fitter and it's the first time he has gone longer than a week without smoking. I think he is coming onto three years now.' Bryony, T7

However, not all posts were positive and supportive; there were instances of harsh judgement of vaping mothers, or indeed a mother's harsh judgement of herself. There were accusations of not putting their infant's needs before their own and the insinuation that by vaping, they were somehow encouraging their child to learn unhealthy coping techniques:

'Why would anyone condone it? Very strange. She is teaching her son an unhealthy way of coping with normal life stress.' Tabitha, T6

The varying forms of support often led to a polarised divide amongst forum users with strong views amongst both those pro-vaping and anti-vaping.

Instrumental support was also identified, which included directing women to the best places to buy products or other forums to use for more information. This was also evident from those opposed to smoking who would direct women to alternative products/behaviours to remain smoke-free; including traditional NRT use, self-help materials or indeed more comical ways of both parents remaining smoke-free:

'Reward him with... I dunno. Doughnuts or something. I'd suggest BJs [oral sex] but then I remember how pregnant you are.' Xanthe, T7

Evidence (professional, non-professional, anecdotal, lack of evidence & mistrust/uncertainty)

This theme showed that women accessed a wide variety of sources of information to inform their arguments and opinions, and then interpreted and communicating their understanding of this evidence on forums (sometimes inaccurately).

Professional evidence came from academic articles or via professional websites such as the National Health Service (NHS) and Public Health England (PHE). This was often misinterpreted, particularly from those who were opposed to vaping. One example was an article available on the NHS website about 'popcorn lung'⁴, this was cited several times across transcripts, incorrectly, as evidence of e-cigarettes being harmful. A further example is the following poster, who hyper-linked a paper by Farsalinos & Polosa (2014):

⁴ 'Popcorn Lung' or Bronchiolitis obliterans is a rare fibrosing form of chronic obstructive lung disease that follows a severe insult to the lower respiratory tract 370. McEwen, A. and H. McRobbie, *Electronic cigarettes: A briefing for stop smoking services*. National Centre for Smoking Cessation and Training, 2016.

'If you want decent info on the risks and benefits of vaping this⁵ is a good place to start. You can access the whole paper for free if you create an account' Jael, T4

The most frequently quoted evidence was from non-professional sources; this included media articles such as blog posts and newspaper articles, but also linked to social media profiles and discussions. There were also examples of non-empirical sites, such as Wikipedia, being cited as sources of evidence against vaping, this was met with ridicule by some pro-vape forum users. The non-professional evidence was mostly quoted by those opposed to vaping, whereas those who were pro and anti-vaping equally shared professional evidence.

Anecdotal evidence was also shared by both pro and anti-vapers and appeared to be the most substantial form of evidence accepted by women. The women were often more responsive to the experiences and stories from other forum users than they were to other forms of evidence available, and these forms of evidence often appeared to be more persuasive:

'Anecdotally I can tell you that when my ExH [Ex-husband] vaped, our cats fled from the vapour and I hated the idea of him vaping inside near the cats. I'd be even more concerned about a baby.' Grace, T4

'I do, I feel so much better too, no coughs or colds. I am positive that e cigs are much much less dangerous than cigarettes and think maybe you're being a bit over anxious.' Jonquil, T7

As well as sharing, quoting and interpreting evidence, there was also a general discussion on the lack of evidence available about the safety of e-cigarettes. This was most often attributed to a lack of empirical evidence of the long term effects of vaping. Women were anxious to read information that related specifically to their situation, and talked about lack of evidence on vaping and breastfeeding, or vaping around young children.

⁵ <http://journals.sagepub.com/doi/abs/10.1177/2042098614524430>

'Everyone says that these things "must be better than real cigarettes..." ok, based on what evidence? Long term studies? The ones that haven't been done, you mean???'

Joy, T6

This lack of evidence specific to new mothers was also displayed in the final subtheme of mistrust and uncertainty. In the following quote, a forum user highlights the use of thalidomide in pregnancy, and how this was perceived as safe:

'95% safer, Not 100% safe then? Not that long ago the NHS also said Thalidomide was safe. Look how that ended.' Camelia, T7

This is evidence of women looking for evidence that relates to their specific circumstances; the comparison of a professional recommendation that resulted in infant harm. But it wasn't just mistrust at the science itself, but also the institutions that make the recommendations:

'And PHE [Public Health England] have been criticised for their supportive stance on e-cigarettes. They are very keen to get tobacco smoking down so I can see why they would be supportive.' Joy, T6

4.5 Discussion and conclusions

4.5.1 Key findings

This research is the first to describe how women are accessing information about e-cigarette use during the postpartum period. It is also the first evidence of women proactively using e-cigarettes to prevent relapse to cigarette smoking and aid smoking cessation, particularly as breastfeeding mothers. Women have concerns regarding potential risks of using an e-cig and utilise online forums to discuss these risks with other women. This type of forum provides both positive and negative social support.

The themes show that women are accessing information on e-cigarette safety and their use via multiple sources; both lay and professional. However, this information is not necessarily being interpreted correctly, or is met with a degree of mistrust and

uncertainty. There are conflicting opinions on the use of e-cigarettes while breastfeeding. This is mainly due to health concerns regarding what may be transferred from e-cigarette to breastmilk, as well as concerns second-hand vapour exposure.

4.5.2 Strengths and limitations

Online support groups provide specific benefits of virtual group membership compared to physical group membership. They are accessible 24-hours a day, 7-days a week, are free to join and participate in, lack geographical barriers and offer anonymity [371-375]. The public availability of online discussions provides rich data that is formed as part of an everyday discussion. With the anonymity that posting online affords a person, forum data is free from many of the social and research biases that may present in other qualitative methods such as interviews and focus groups. Online forum also offers a safe place to discuss sensitive topics or topics in which a person feels they may be judged [376] and has been used for discussions regarding smoking [377]. Accessing data from a virtual community offers the opportunity to analyse naturalistic data on a stigmatised issue without being influenced by research agenda; we are able to understand from an everyday perspective what women really think about e-cigarette use, what experiences they report and what particular issues that surround this are important to them.

The use of online support groups or 'forums' can also have potentially empowering effects on those who use them, providing health information, information sharing, and input for individuals to make health-based decisions [371]. The use of parenting forums is a valuable source of data on what women think about health-related risks and decision making [378-381].

There are limitations as to the use of online forum data; the very nature of this research forgoes the possibility of following up individual users or seeking clarification on the meaning of their words which increases the risk of bias during coding. It is also impossible to establish the validity of posts – i.e. to be completely confident that a user who identifies as a breastfeeding mother is in fact, a breastfeeding mother. The

transferability of these themes to the general postpartum population is limited due to a) the exclusive participation of forum users and b) all transcripts coming from only two parenting forums. There is also no way to establish the authenticity of the users on the forum entirely or whether they have connections within the e-cigarette or tobacco industry. We are also unable to follow up participants for clarification, longitudinal data or further research.

On the other hand, the use of online data has several strengths; discussions are free from the response bias that may be present within interviews, forum data provides a discourse that has been written to express and debate opinion for discussion, not for research. The use of forum data provides in-depth qualitative data; in other research, the use of a discussion analysis tool found that online interactions involving conflicting viewpoints promoted more discussion and critical thinking [382].

There should also be considerations for the dates of the threads included in this research, for example, some threads identified were produced in 2015. Given the popularity of e-cigarettes has increased in recent years [256] , and research has advanced, there may be opinions within these discussions that are outdated to the participants themselves. This research is novel in both subject matter and approach. Therefore, this research should be treated as an exploratory qualitative piece for which further research can be built upon. Thus far, this is the only piece of work that considers the motivators, barriers, and opinions of breastfeeding mothers using e-cigarettes postpartum.

4.5.3 Relation to prior work

This work has improved our understanding of how and why women use e-cigarettes in the postpartum. For the first time, we can understand and explore what evidence women are accessing to inform themselves about e-cigarettes and how this information is then interpreted. It also provides the first evidence of women perceiving their use of e-cigarettes postpartum to be preventative of smoking relapse. We are also able to understand better the concerns women have around the impact of e-cigarettes on infant

health. In particular, the misbelief that nicotine is the most harmful substance transferred to infants via a smoking mother's milk is sometimes an obstacle to the use of e-cigarettes postpartum.

Previous research has highlighted that some women perceive smoking to affect the quality of their breastmilk in a way which is detrimental to their infant's health [150, 162], despite the previous decade of recommendations from professional health bodies encouraging women who do smoke, to continue breastfeeding [166]. This current research helps us better understand the fears women have about e-cigarette use, most notably in relation to the perceived lack of consistent, evidence-based information about e-cigarette safety and the effects of nicotine transferring through breastmilk. By addressing these concerns, we could improve the acceptability of using a vape alternative for women who are breastfeeding and smoke, while minimising harm to the mother and infant and reducing her fears regarding her child's exposure to vape constituents via breastmilk.

Prior work using forum data considered e-cigarette use during pregnancy [269], with three distinct themes explaining how forum users debated the use of e-cigarettes while pregnant: quitting (nicotine) cold turkey is unsafe; vaping is the lesser of two evils; and vaping is not worth the risk, concluding that women perceive their addiction to cigarettes as more than just nicotine addiction and that the behavioural aspects of smoking are also important, hence the potential for e-cigarettes. In this research, there were similarities in postpartum views. Vaping being the lesser of two evils, was present within the evidence and perceived risk themes. The justification for using e-cigarettes was due to the relative safety of e-cigarettes compared to smoking. This was a motivating factor for using e-cigarettes; the concept of reducing harm for both mother and baby by using an e-cigarette instead of smoking. It also found within the perceived risk theme that some women viewed e-cigarettes as not worth the risk, for example in transcript 7 one woman asked '*If in twenty years they turn round and say vaping and co-sleeping causes x, and our baby had x?*'. This fear isn't completely unfounded, for example historically tobacco smoking was touted as a safe, even 'healthy' behaviour. For example, in response to concerns about detrimental effects of smoking in the 1930's- early 1950's

tobacco companies began financing reports from physicians on the health benefits of smoking [383].

As with the pregnancy forum discussions, postpartum forum discussions in our studies showed women displayed mixed views on e-cig safety. The majority of users accepted that e-cigarettes were 'probably' safer than cigarettes. However, there was skepticism and mistrust of the evidence for this, which acted as a barrier to using e-cigarettes. Health bodies such as PHE and the NHS were classed as biased due to their targets of reducing cigarette smoking, and comparisons were made regarding previous health recommendations that have since transpired to be detrimental. Women are accessing scientific journals to learn more about e-cigarettes; however, this is often mistranslated. News media stories are often shared amongst online groups if a headline is unusually provocative. Even when these stories were discredited, users felt that these fears must be based on something. Lack of evidence, or mistrust of the current evidence, appears to be a barrier for the use of e-cigarettes as a harm reduction tool during the postpartum period; this often gives rise to a thought process of 'better the devil you know.' This scepticism is not confined to e-cigarettes; previous research identifies some women believe nicotine replacement therapy patches to be harmful and smoking as preferable to these [384]. Evidence was cited from a variety of sources. Women who were opposed to vaping often cited media articles or unregulated sites, such as Wikipedia. This was often met with sarcasm and ridicule by those in favour of vaping. Likewise, those who cited scientific articles were often ridiculed for being 'too trusting' of large organisations, such as PHE, who some women felt were untrustworthy. Overall, personal anecdotes were exempt from this type of conflict.

Uncertainty regarding e-cigarette safety was a further barrier to use and often led to women discussing the concept of 'risk,' either in terms of comparison to smoking or in justifying the perceived risk. This individual assessment of risk is not unique to e-cigarette use and is attributed to a 'knowledge deficit' between professionals and the lay public [385]. The risk assessment formed by laypeople is complex and situationally influenced, and reflects their values [386], particularly relevant when considering the morality of motherhood and the negative attitudes some women hold towards vaping

while breastfeeding. For example, the negative attitude to government-backed advice on risk is assumed to be due to perceived exclusion from science-led and political decision-making [387]. With this in mind, involving women in discussions about e-cigarette use and safety within usual postnatal visits could help them make an informed choice on e-cigarette use.

This knowledge deficit could explain the reliance on unverified evidence from social media, news publications, or web content found within this study; these are written to inform a general population but are also written to be read with ease. This may explain why women are engaging more with this type of evidence. There is also a reliance on others for information; while women are seeking support and advice from health care professionals, they are also seeking advice from other mothers. It is unsurprising that new mothers would seek information that is easy to access and easy to read, but also the use of online forums provides anonymity. Therefore, despite judgment from other mums, the ability to remain anonymous while receiving or giving information offers some form of protection of self [388], the mother can still have perceived control over how those around her view her morally and ethically.

The concept of risk is a subjective one. While there was much discussion of risk, apart from discussions on nicotine, this risk was not defined. There were suggestions of harm drawn from media conclusions, but the risk was often discussed as a general term. Other lifestyle behaviours such as alcohol and caffeine consumption were commonly used to justify this 'risk' concept; the idea that if these behaviours were acceptable for mothers, then vaping was also acceptable.

The risk of nicotine exposure to the baby was one of the defined examples of risk. There were false attributions that nicotine caused SIDS. Women also expressed concerns about infants becoming addicted to nicotine, and therefore, being forced to experience withdrawal once breastfeeding ceased. There were also concerns that the use of e-cigarettes to manage the mother's mental health needs (such as stress) would lead to children who grew up exposed to unhealthy coping mechanisms. The exposure of infants to nicotine was also the subject of judgment; some women would argue that a

mother asking if it was OK to vape, was asking if it was OK to feed her baby nicotine. The nicotine becomes a deliberate exposure rather than a by-product of the breastmilk. This concern regarding nicotine acts as a barrier to the use of e-cigarettes postpartum. Harmful effects from nicotine are not fully understood but are likely to be minimal compared to the effect of other compounds, although it is accepted as an extremely addictive substance [389]. There are far more worrying compounds within cigarette smoke, which research suggests are either not present in e-cigarettes, or present at significantly lower levels [186]. There is still limited empirical data on the safety and composition of e-cigarette vapour. However, there have been some promising toxicity testing which has evaluated the chemical nature of the vapour generated from e-cigarettes. [186] Despite the identification of specific toxicants within e-cigarette vapour, these levels are <1% of the levels present in cigarette smoke. E-cigarettes, therefore, has potential as a harm reduction tool, as confirmed by the PHE report [188].

This research closely relates to the 'good mother' social construct [355], as shown with the justification of perceived risk, or the moralised stances against the use of any nicotine-containing products as a breastfeeding mother. The role of mother is one that is subject to historical and cultural experiences; social networks provide a framework within which to make sense of their experiences and responsibility that are culturally defined [390]. The use of an online forum varies slightly from this; bringing together women from various socioeconomic backgrounds, age, experiences and cultures to discuss breastfeeding. Therefore, the social constructions of a 'good mother' are more explicit, particularly for infant feeding [391]. A 'good mother' is synonymous with breastfeeding, without cultural or environmental context [355]. The justification of risk here is similar to mothers who justify smoking by claiming that it is for their baby's sake [392], i.e., the explanation that the baby should have a mother who isn't stressed or is more alert.

In terms of what motivated women to begin using e-cigarettes, women reported using them to either prevent relapse to smoking or to quit smoking after having already relapsed. Relapse (or perceived likelihood of relapse) was often triggered by the

demands of motherhood, perceived stress or the feeling of needing some 'me' time, similar to previous research on postpartum relapse [61]. Interestingly, some women are choosing an e-cigarette in response to what has previously been identified as reasons why women relapse to smoking traditional cigarettes; smoking for relief and nostalgia for their former self [393]. Although evidence is limited, it is suggestive that women who use e-cigarettes during pregnancy are still likely to relapse to cigarette smoking, with one qualitative study partly attributing this to a lack of professional consensus within healthcare on the safety of e-cigarettes [278]. Lack of consistent and transparent information from professional health sources is a significant barrier to e-cig use postpartum, an issue to be addressed given the success some women report using e-cigarettes to prevent smoking relapse.

4.5.4 Conclusions and implications

In conclusion, this study has shown women hold a mixture of views on the acceptability of vaping as a mother. Still, some women are using (or are interested in using) e-cigarettes in the postpartum period. They are seeking, and need, more reliable information to facilitate their use, especially when breastfeeding. The implications of this are that women are seeking to use less harmful alternatives to smoking, but are not able to access the information they require. Therefore there is a need for further research that explores the experiences of vaping and breastfeeding mothers in greater detail, to understand what motivates mothers to switch to vaping, and what may be a barrier to switching from cigarettes to vaping. As this research relied on forum data, an extension of this would be to directly ask women who do smoke/vape about what beliefs they hold about their smoking and vaping status, and what support or advice may have influenced these beliefs. With the evidence of judgment found within this work, it would be prudent to consider research that exclusively discusses the views of smokers and/or vapers.

Chapter 5: Smoking and Vaping postpartum – results from an online survey about experiences, beliefs and infant feeding choices

5.1 Introduction

From the previous research in Chapters 4 [394] and 3, it was identified that some women who breastfeed are also using e-cigarettes. Chapter 4 also identified there was a lot of confusion and misunderstandings amongst women about e-cigarettes, with some women opting to smoke cigarettes as they didn't feel they knew enough about e-cigarettes to use them. There was also evidence of judgement from non-smoking women about breastfeeding mothers who smoke or vape. While this study allowed us to gain some understanding of mothers' experiences of and views on vaping while breastfeeding and the challenges they might face, forum discussion analysis has several limitations. For example, the research was limited to the observation of existing conversations between members, this prevents being able to ask questions, clarify or explore specific themes in more depth. Therefore, to further our understanding of e-cigarette use, along with motivators and barriers to breastfeeding from the perspective of smoking/vaping mothers, an online survey was designed.

To understand the potential role of e-cigarettes in supporting mothers to initiate and continue breastfeeding, and to not return to smoking, we need to understand how perceptions of e-cigarettes compare with smoking in regards to impact on breastfeeding. We also need to understand what motivates one woman to choose an e-cigarette but another to continue smoking. We must also understand how women who smoke or vape feel about vaping and how acceptable they think it is to vape as a breastfeeding mother.

5.2 Aim

This research aimed to explore the experiences and beliefs about smoking or vaping while breastfeeding, from the perspective of new mothers who smoke or vape.

- What are the mother's experiences of being a smoker and/or a vaper postpartum?
- What views and beliefs do mothers who smoke and/or vape have about smoking and breastfeeding, and about vaping and breastfeeding?
- What support and information on breastfeeding do mothers who smoke and/or vape receive, and what support and information would they like to receive?
- What are the barriers and facilitators to switching from smoking to vaping

5.3 Methods

5.3.1 Ethics

All data collected were anonymised, and participants were not asked to provide any identifiable data. To help ensure privacy, participants were assigned a volunteer study identification number, upon analysis, women were randomly assigned names. Participants were advised that all research data and records would be stored for a minimum of 7 years after publication or public release of the work of the research. Participants gave informed consent by checking a box confirming they had read all the study information and were happy to proceed.

Ethical approval was given by the UoN Medical School Research Ethics Committee.

5.3.2 Study design

This cross-sectional study was an online questionnaire with open-ended questions was conducted throughout May and June 2019.

Understanding the time constraints many new mothers feel, and the stigma that may be attached to smoking, vaping and whether or not a mother breastfeeds, it was decided an online survey would be the best method of data collection. The demands of motherhood may be a barrier to participating in research. Sleep/feeding schedules, sickness, and maternal/parental leave ending have been shown to reduce the recruitment and retention of new mothers in research [395]. Smoking/vaping

postpartum is also a sensitive topic, with women reporting feelings of shame and judgement [392, 393], which may hinder recruitment. Online recruitment and participation is a convenient and confidential method of conducting research [396] which may increase the recruitment of new mothers to our study. By reducing participant burden and giving participants a more secure sense of confidentiality, we may reduce the risk of recruitment bias in our research [397]. Jisc (formerly Bristol Online Surveys) online survey platform was used to design and host the survey.

5.3.3 Recruitment:

Parenting forums (UK only)

A google search for online parenting support groups was conducted using a combination of the search terms “parenting” “new mother” “motherhood” (and related search terms) and “online support group” “online forum”, “online community”, “message board”. A ‘moderators’ information sheet (appendix 5.1) was designed, giving moderators of groups brief information on the study and requesting permission to recruit via their forums. An ‘invite’ was also designed (appendix 5.2 **Error! Reference source not found.**) to be posted into groups (with permission). This included brief information on the study and a link to the online survey. The following process was used.

Process:

- Contacted the ‘gatekeeper’ (i.e. website moderators and owners) first
- If permission was given, the forum was searched to understand if it consisted of one community forum or several groups within a forum
- Contacted administrators of groups (or community page) within the website for permission to post in individual groups
- If permission was given, posted the ‘invitation’ message to the group
- If allowed, the invitation message was kept visible in the group using ‘Bump’ (a common way of maintaining visible posts within a forum by commenting ‘bump’ on a post)

- If permission wasn't given to post in groups, the moderators were thanked for their time

Posts began on the parenting websites on May 15th 2019 and were 'bumped' weekly as per the guidance received by group administrators. Posts were not 'bumped' after 13th June 2019 as the recruitment numbers were met.

Facebook groups (UK specific)

Search terms such as "breastfeeding", "formula feeding" "parenting" "new mother" and "motherhood" were used to search Facebook for relevant groups. Parenting forums identified in the google search above were also searched for within Facebook, as it is common for forum users to move away from the forum and create Facebook groups for select others from the shared forum.

Process:

- Contacted the group administrator for permission to post (Appendix 5.1: Moderators message)
- If permission was given, the researcher introduced themselves to the group first and outlined the research
- Posted an invitation to take part in research (appending Invite)
- 'Bump' post once daily if permitted, or repost at intervals allowed by the administrators

Posts were made on the 15th May 2019, and a further post was allowed on June 5th 2019. Links to the survey were shared by the 'Mums & mums to be: research on smoking & quitting during & after pregnancy' Facebook group, run by the Smoking in Pregnancy group at the University of Nottingham, on 3rd June 2019 and received 16 shares.

Facebook advert (UK specific)

A Facebook advert ran for a period of one month (17th May to 17th June 2019). The advert was targeting women aged 18-47 who lived in the UK.

The advert (Figure 5.1) showed a picture of a new-born infant with the title ‘Smoking & Vaping postpartum’ with the headline ‘research exploring what it’s like to be a smoking or vaping mother – share your experiences.’

Figure 5.1 Facebook advert



A brief description of the research was also included, specifying that the research was interested in women with infants aged <18months. The advert was managed by SMRS, a digital marketing company, on a ‘pay per click’ basis with a budget of £500. The advert was delivered using algorithms to target potential participants at times of the day when they were most likely to be viewed, in line with the company’s knowledge and experience of running advertisements for the recruitment of mothers to research.

5.3.4 Participants

The target population for this study was mothers of infants aged under 18 months who exclusively smoked, exclusively vaped, or both smoked and vaped (dual users). As the regulations and popularity of e-cigarettes vary depending on country, only UK based forums and groups were included in this study.

The nature of this type of study and method of recruitment meant that while we could influence the type of participant recruited to the study through specific inclusion criteria, other aspects were more difficult to control for. For example, while it would be ideal to achieve a ratio of 50/50 recruitment smokers/vapers, there was an awareness that this might not be possible. The prevalence of smoking is much higher than the prevalence of vaping; thus, higher recruitment of smokers (than vapers) was anticipated. Using Jisc online surveys enabled the adaption of the screening questionnaire at a later part of the recruitment process in the event we struggled to recruit enough vapers; however, this was not necessary as our sample was relatively evenly split. Determining a sample size *a priori* for qualitative research is inherently problematic with no agreed framework [398]. To determine probable sample size, studies using similar recruitment methods were reviewed [399, 400]; these studies managed to achieve the quantity and quality of data suitable for qualitative analysis, such as thematic analysis, with around 100 participants. We, therefore, aimed to achieve similar numbers of 80-120 respondents, with the option to re-open the survey if data saturation was not achieved.

5.3.4.1 Inclusion / exclusion criteria

Before completing the questionnaire, women were asked a series of screening questions to ensure they met the inclusion criteria of the study:

Inclusion criteria:

Mother with an infant aged 0-18 months

Current smoker or vaper

UK resident

Aged ≥ 18 yrs

Able to give informed consent

Exclusion criteria:

Works/has worked for a tobacco or vape related industry or

Had immediate family who works for a tobacco or vape related industry

5.3.5 Questionnaire design

The survey began with a participant information sheet, and then a consent form with information on how to withdraw from the study. Women were then asked to either consent or not consent to take part. Women who did not consent were thanked for their time and proceeded no further with the survey (appendix 5.3). A screening survey was used to ensure women met the criteria for the study (appendix 5.4). Those who didn't meet the inclusion criteria were thanked for their time and unable to proceed with the study. Demographic information, such as age, parity, infant age, and marital status, was collected. Women were asked whether they smoked, vaped, or smoked and vaped; data were also collected on whether women had smoked/vaped during pregnancy. Women who didn't smoke/vape throughout pregnancy were asked when they first had a cigarette/vape postpartum. Information was collected on breastfeeding status; women were asked about their current breastfeeding status, and those no longer breastfeeding were asked how old their infant was when they last received any breastmilk.

Open-ended questions were asked about opinions on smoking and breastfeeding, and vaping and breastfeeding. Women were asked about any advice they had received (from health care professionals, friends or family) about breastfeeding as a smoker or vaper. Other open-ended questions asked about any experiences they had of vaping; for those who vaped (or had previously vaped) what had led them to try vaping, and those who smoked, and hadn't vaped were asked what would make them more likely to try a vape. Women were also asked what they felt would have helped them to breastfeed initially and for a longer duration.

This questionnaire was piloted with ten patient and public involvement (PPI) representatives, and with 10 participants. PPI feedback highlighted that some questions were difficult to understand, so the wording was amended. An additional six questions (three smoking, three vaping) with Likert scales were added to the questionnaire as a

result of PPI feedback. A full copy of the questionnaire is available in appendix 5.5. The questionnaire length was acceptable to PPI and took roughly 10 minutes to complete. When piloted with participants, the responses collected were relevant and met the aims of the study, so no further amendments were made to the questionnaire, and as per the ethics approval these ten responses were included in the overall analysis

5.3.2 Data Analysis

Descriptive tables of participant characteristics were generated, and box plots of responses to Likert scales were produced. The boxplot was created to show how views on acceptability and safety may differ between smoking and vaping.

Qualitative data were analysed using reflexive thematic analysis (TA), following the six-phase process outlined by Braun & Clarke [401]. In the reflexive TA approach, themes are defined as a pattern of shared meaning underpinned by a central concept or idea. While the six phases are sequential, TA is also a recursive process meaning these phases are not rules to follow rigidly. The six-phases in a reflexive thematic analysis are a series of conceptual tools that are designed to guide the analysis in a way that facilitates a thorough examination, understanding and engagement with the data.

1. Familiarisation with the data: The survey responses were read, and re-read until the researcher was familiar with the content.
2. Coding: Brief codes were attached to features of the data that may be relevant to the aims of this research. The entire dataset was coded within NVivo.
3. Generating initial themes: Codes and the respective collated data were examined to establish any significant patterns that could potentially be themes. Coded data was collated for each emerging theme.
4. Reviewing themes: The themes identified in phase 3 were then checked against the dataset to ensure they answered the research aims and were prevalent across data sets. During this phase, some themes were merged, some themes were split, and

subthemes began to emerge. Themes that were not prevalent or relevant to the research questions were discarded.

5: Defining and naming themes: A detailed analysis of each theme was developed that considered the particular focuses of individual themes, this evolved into a short narrative of each theme and each theme was given a name.

6. Writing up: The themes were written, including extracts from the data set, to tell the narrative of the data.

After phase five, a second coder (LP) was given a selection of transcripts to ensure coding was rigorous. As surveys are answered in different degrees of detail by different participants, responses were categorised into three groups prior to analysis; this ensured that for second coding, LP would have a selection of responses to code. These were grouped into category C (where a participant has answered primarily using minimal words and detail, usually less than one sentence), category B (where a participant has responded to the open-ended question with some detail, answers are primarily less than three sentences) and category A (where a participant has answered open-ended questions with detailed responses, primarily using more than three sentences). This categorisation did not affect the analysis overall, but it did allow the second coder to have a selection of data sets that were representative of the whole data set. The second coder was given six category C transcripts, six category B transcripts and, five category A transcripts. The overall number of transcripts by category were; 53 category C, 62 category B, and 38 category A. After coding half of the transcripts, a meeting was held between EJ and LP to discuss any issues within the coding that may have become apparent. At this stage, there were some misunderstandings about how two sub-themes differed from one another. After looking at the content and narrative of each sub-theme, it was decided that they were two distinct sub-themes, and a more detailed analysis of the sub-themes was written. After all coding was completed by LP, a further coding meeting was held during which any disagreements were discussed, and a consensus was reached.

5.4 Results

5.4.1 Characteristics of participants

The Facebook advert was seen 39,988 times, reaching 11,688 unique profiles. A total of 531 users clicked the advert, and so viewed the information sheet and consent pages. We are unable to say how many participants were recruited as a direct result of the Facebook advert, and how many came from online parenting forums. The majority of respondents completed the survey in the evening (between 20:00-23:00). The survey took, on average, 11 minutes and 23 seconds to complete.

A total of 168 participants responded to the survey, 14 did not meet the inclusion criteria, and one person did not consent to continue taking part, leaving a sample of 153 participants who completed the survey. Upon analysis, 4 participants had selected that they neither vaped, nor smoked and so were excluded from the analysis. A total of 149 women were included in the analysis. The characteristics of the participants are shown in Table 5.1.

Table 5.1 Characteristics of participants

Characteristics	N=149	
Median age of mother (IQR)	28.0yrs (6.0)	
Age of infant (n (%))	< 6mths	53 (35.6)
	≥6mths <12mths	59 (39.6)
	≥12mths ≤18mths	37(24.8)
Number of children	1	57 (33.3)
	2	43 (28.9)
	3	32 (21.5)
	4+	17 (11.4)
Marital status	Living with partner	122 (81.9)
	Not living with partner	9 (6.0)
	Single	18 (12.1)
Partner's smoking status	Smokes	48 (36.6)
	Vapes	29 (22.1)
	Dual user	22 (16.8)
	None smoker/vaper	32 (24.4)
	Total	131

5.4.1.1 Smoking, vaping and breastfeeding status

Smoking, vaping, and dual-use categories were evenly represented, the majority of women in this study had continued to either smoke, vape, or both throughout pregnancy (Table 5.2). The majority of women were not breastfeeding at the time of this survey; as we recruited women with babies from birth to 18 months, we asked mothers who were not breastfeeding at the time of this survey what age their infant last received any breastmilk. Just under half of our sample reported their infant had never received any breastmilk. Of those who had been breastfed at birth, the majority had stopped breastfeeding at <1 month (Table 5.3 **Error! Reference source not found.**).

Table 5.2 Smoking/vaping status

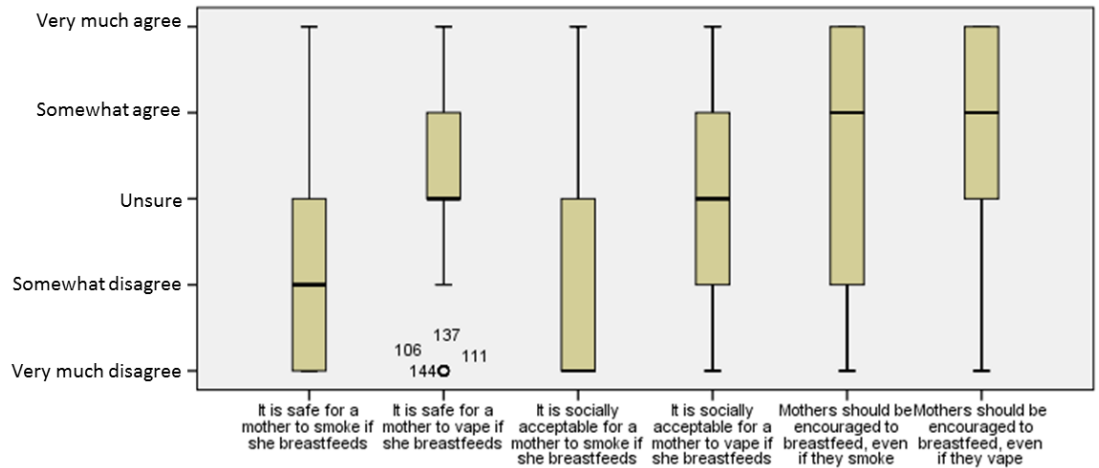
Smoke/vape status (n (%))	Pregnancy	Postpartum
Smoke	46 (27.5)	67 (45.0)
Dual	39 (26.1)	44 (29.5)
Vape	35 (23.5)	38 (25.5)
Didn't smoke/vape	34(22.9)	0 (0)
Total	149	149

Table 5.3 Breastfeeding status

Breastfed at time of survey		Age child last received any breastmilk (n (%))						
		Never	< 1 week	< 1 month	<2 months	<4 months	<6 months	>6 months
Yes	41 (27.5)							
No	108 (72.5)	45 (41.6)	17 (15.7)	21 (19.4)	9 (8.3)	6 (5.5)	6 (5.5)	5 (4.6)

5.4.2 Boxplot

Figure 5.2 Boxplot of safety and acceptability of breastfeeding as a smoking/vaping mother



Likert scales were added to the survey in response to PPI input, and this study was qualitative, so no *a priori* power analysis or sample size calculations were performed, these results should be viewed with caution. Women were asked whether they agreed or disagreed with three statements based on smoking and the same three statements about vaping; the results of these are shown in Figure 5.2, with the results for smoking and vaping presented side by side for each statement. Overall women were often unsure or disagreed that breastfeeding as a smoker was safe or socially acceptable. With vaping, women appeared to be unsure or in agreement that vaping as a breastfeeding mother was safe and socially acceptable. Women were primarily in agreement that mothers should be encouraged to breastfeed if they smoke or vape, although more women were likely to disagree with this statement for smoking mothers than disagree with this for vaping mothers. As outlined earlier, a quantitative analysis was not planned for this research; these findings indicate that further quantitative work is needed, but does provide some context for how women may view vaping and breastfeeding, and smoking and breastfeeding, differently.

5.4.3 Qualitative findings

Three main themes, with eight subthemes, were identified (Table 5.4):

Table 5.4 Table of themes

Themes	Subthemes
Smoking, vaping & breastfeeding behaviours postpartum	Reducing harm
Barriers and facilitators for breastfeeding as a smoking/vaping mother	Acceptability
	Safety
	Social Influences
Barriers and facilitators for switching to vaping, and maintaining smoking abstinence, postpartum	Experiences
	Motivations
	Comparisons to smoking
	Vape safety

5.4.3.1 Smoking & Vaping behaviours postpartum

Women described how they smoked/vaped as breastfeeding mothers. This included ways to reduce harm to the infant posed by smoking/vaping, but also how they altered their smoking/vaping to fit around their infant's needs. Dual-use mothers (women who both smoked and vaped) also discussed how they alternated between smoking and vaping to suit their baby's needs.

Reducing harm

Women discussed various techniques and behaviours they employed to reduce the risk to their infant from smoking and vaping. This included maintaining a smoke/vape free home, washing hands after smoking/vaping and for smoking specifically, removing an outer layer of clothing after smoking:

'I use an old dressing gown to go outside and smoke then take it off when I come inside so the smoke isn't sticking to my skin' Meg (Dual user)

Both women who smoked and vaped expressed concerns about the effects of nicotine passed on to the infant via the breast milk and described techniques they employed to minimise the risks. For example, some women timed their smoking/vaping around their baby's feeds to minimise the amount of nicotine their baby received:

'Smoke straight after a feed and avoid contact for as long as possible. I was told 3 hours is how long the nicotine stays in my milk. So I express milk and just do my best.' Eugenie (Smoker)

For vapers, reducing the nicotine level in their e-liquid was also seen as a harm reductive behaviour, with the ideal being to vape liquids without any nicotine:

'I vape 0mg nicotine so I can be sure that no harmful chemicals would pass over to the baby.' Constance (Vaper)

Women who were dual users often viewed vaping as a way of reducing harm. They discussed how they would alternate between smoking and vaping around their children's needs. For some women, this was occasional; they would usually vape unless they were feeling particularly stressed, or were out socialising with friends/having an alcoholic drink:

'I vape during the week and when regularly breastfeeding. I tend to have a cigarette if I have an alcoholic drink or at a weekend when I give my baby expressed milk.' Meena (Dual user)

For other women alternating between smoking and vaping was a daily occurrence, vaping was often used during the day, and smoking would generally be used in the evenings when the mother felt assured she would not need to breastfeed until morning. A few mothers reported they would struggle without their first cigarettes in the morning, so would smoke when they woke up, and then vape until their partner returned to help with the infant. Women also reported vaping until they had enough expressed breastmilk; they would then use it as an opportunity to smoke, knowing the infant had expressed milk that they felt wasn't contaminated by smoking. Many women had a set

routine for when they smoked and when they vaped, however, women would deviate from this schedule if they were stressed:

'I generally vape during the day and will sometimes smoke a couple of cigarettes in the evening once my partner returns from work and assists with the baby. Occasionally I will smoke one cigarette in the day if I am feeling stressed or if it is offered by a friend but never around my children' Sara (Dual user)

5.4.3.2 Barriers & facilitators to breastfeeding as a smoking/vaping mother

Acceptability, safety and social influences were all themes that could either be barriers to breastfeeding, or facilitators. Overall mothers tended to disclose more barriers to breastfeeding than vaping mothers.

Acceptability of breastfeeding as a smoking or vaping mother

The perceived unacceptability of breastfeeding as a smoking/vaping mother was a barrier to breastfeeding. The perceived unacceptability of breastfeeding as a smoking mother was particularly a barrier; women spoke about the 'smell' of cigarettes and how that would transfer to the baby and how it was 'selfish' to smoke and breastfeed. The perceived unacceptability of breastfeeding while being a smoker was prevalent amongst women who didn't smoke, and women who smoked but didn't breastfeed, and was often rooted in their beliefs of what a mother 'should' and 'shouldn't' do;

'It's wrong in every way ... a mother shouldn't be putting anything into her body that she wouldn't want her child to have simple' Hermione (Vaper)

Some women found breastfeeding while vaping to be also unacceptable, although this was less commonly expressed than the unacceptability of breastfeeding while smoking. Similar to smoking, this was linked to the beliefs of what mothers 'should' and 'shouldn't' do:

'Same as before... the mother's decision, not the babies therefore mothers shouldn't do it [vaping] whilst pregnant/ breastfeeding.' Elphaba (Vaper)

On the contrary, perceived acceptability of breastfeeding as a smoking mother could act as a facilitator; for some women breastfeeding as a smoker was seen as acceptable as it was a way of protecting the baby from the risks of smoking:

'No judgements better to breastfeed and smoke than not breastfeed because you smoke. I've got some strange funny looks myself but it's my choice not theirs' Meg (Dual User)

Perceived acceptability of breastfeeding as a vaping mother was also a facilitator for breastfeeding, women discussed how by vaping and breastfeeding a mother was 'making healthier choices' for her baby, and that a vaping mother who breastfed was doing the best by her infant:

'A mother is making a healthier choice by using an e-cigarette or vape as an alternative to smoking.' Amy (Vaper)

Acceptability would sometimes be context-dependent or conditional. Women would suggest breastfeeding as a smoker was not acceptable unless the mother was trying to quit or was experiencing stress/mental health difficulties. Some women would indicate that it was acceptable, but only if a mother took precautions:

'I think as long as precautions are taken so the baby is nowhere near the smoke, and the mother changes her clothes / covers her clothes whilst smoking and washes her hands afterwards it should not be a problem to breastfeed.' Opal (Vaper)

There were also examples of vaping and breastfeeding being acceptable conditionally. Some women suggested vaping should be treated like smoking (never around the

infant, washing hands, changing clothes). However, most centred on the nicotine content and strength; it was more acceptable for a vaping mother to breastfeed if she used zero or low nicotine liquids:

'If you vape nicotine I don't agree with it. If you're just vaping flavoured stuff carry on, who are we to judge?' Sherry (Smoker)

Women were more vocal about vaping and breastfeeding being acceptable. This was most often discussed in the context of smoking. The acceptability of breastfeeding as a vaping mother was often based on the unacceptability of smoking and breastfeeding:

'Vaping is a lot cleaner and smells a lot better than cigarettes but again I'd say handwashing and clothes changing is a must!' Galadriel (Dual user)

The acceptability of breastfeeding as a smoking or vaping mother varied; however, there were more expressions of acceptability amongst women for vaping than smoking. Overall opinions were often reduced to 'what mothers should/shouldn't do', or 'mother's choice':

'I think it's down to the Mother to decide to do it or not do it [smoking]. I know someone that smoked through pregnancy then quit when the baby was born to breastfeed and I know someone that quit once they found out they were pregnant to then start after the baby was born and breastfed.' Rosalie (Smoker)

The perceived safety of breastfeeding as a smoking or vaping mother

Concerns about safety and risk were a significant barrier to breastfeeding as a smoking/vaping mother. Concerns about nicotine and other smoke constituents getting into breastmilk made some women feel formula feeding was safer for their infants:

'Breast is supposed to be best but I don't think it counts if you smoke like when you're pregnant because if the smoke can go through the placenta then it can get in the milk. If you're going to breastfeed you shouldn't really smoke and I know friends who used bottles as it's safer. I stopped breastfeeding when I started smoking even though it's not much I still don't want to do it.' Belle (Dual user)

However, safety wasn't just limited to what may pass into breastmilk, but also from the skin to skin exposure and passive smoking due to the closeness needed to breastfeed:

'It is very dangerous to smoke whilst breastfeeding due to the toxins in your body and the skin to skin contact.' Raya (Smoker)

'You are still passing on second-hand smoke from your skin and hair and things after having a cig even if you smoke outside away from the baby' Skye (Dual user)

Safety concerns were primarily related to smoking, although, for some women, the risk of nicotine entering breastmilk from vaping was cause for concern. Women also felt the lack of research and evidence for vaping created safety concerns:

'My personal choice was to stop bfing [breastfeeding] as there wasn't much research as to what risks could be involved' Lauren (Dual user)

Women also compared the relative safety of vaping in comparison to smoking; this often involved discussion of 'toxins' and 'chemicals.' Predominantly, women discussed nicotine; this was a barrier for some women who felt that vaping with nicotine was as bad as smoking due to the nicotine content. However, many women discussed the lower levels of toxicants within vapour:

'They do not contain the chemical smoking does and if it's to aid in quitting smoking cigarettes then it must be better for both mother and child.' Tammy (Smoker)

Safety beliefs could act as a facilitator for breastfeeding if women believed that 'breast is best' regardless of smoking/vaping status. This was often due to the belief that breastfeeding protected against some of the risks associated with smoking. This was supported by the belief that breastmilk was nutritionally superior to formula milk:

'To add, for both I do believe that breastmilk will still always be the best option and more support should be out there so mothers will breastfeed. Regardless of the small nicotine content, it [breastmilk] will still always trump formula scientifically.' Kyra (Smoker)

Safety was often a facilitator specifically for vaping mothers to breastfeed. Mothers discussed how an e-cigarette was less harmful than a cigarette and therefore, safe for breastfeeding:

'I breastfeed and use an ecig right now. I feel that it can't be half as harmful as smoking cigarettes. It also contains less harmful elements so I have no issue with this.' Freya (Vaper)

However, for some women, there was not yet enough research on vaping for them to feel safe with breastfeeding as a vaping mother, particularly the lack of long term research:

'It's a difficult one as we don't yet know enough about the long term effects and negative health risks associated with vaping. I would be hesitant to vape and breastfeed.' Veronica (Smoker)

As with acceptability, often safety was a facilitator for vaping and breastfeeding because of the perception that smoking and breastfeeding was not safe. This comparison of smoking and vaping was commonly used to form an argument for the safety of breastfeeding as a vaping mother. Although safety concerns primarily focused on

smoking, the knowledge that breastmilk could protect against some of the risks associated with smoking facilitated smoking mothers to breastfeed.

Social Influences

Social influences included support, advice and judgement. Perceived judgement was a barrier to breastfeeding for women who smoke/vape. When asked 'what would make it easier for you as a smoking/vaping mother to breastfeed?' many women highlighted that people not being judgemental would help. Some highlighted how many mothers suffer from low mood after giving birth and may smoke to cope, suggesting that the judgements she gets may contribute to her feeling worse. It was recommended that this fear of judgment might impact women's choices when breastfeeding:

'You get a funny look if you do it [breastfeeding] outside anyway so you'd probably get more funny looks if you were doing it after a cig' Belle (Dual user)

'I do think people shy away from breastfeeding as standard because of "what people will think" so being a smoker/vaper may add to the stigma' Darcy (Vaper)

Some women who did smoke and breastfeed held negative judgements about themselves; referring to themselves as 'disgusting' and 'vile'. The fear of judgment was, for some women, more prominent than the fear of harm:

'I expressed my milk and still smoked didn't want to but was 8 weeks early. Only thing I don't like is mothers who are pregnant and smoke on the street. I did but only smoked in the back garden where no one could see me' Blanche (Dual user)

Although the perceived judgement was a barrier to breastfeeding for smoking/vaping mothers, women did feel there was a reduced stigma surrounding vaping, which may facilitate vaping and breastfeeding:

'I feel vaping during breastfeeding is more acceptable because it's not seen as such a bad thing, I'm also aware that the stigma around vaping is not as bad as smoking because of the fact that it's water vapour with nicotine and doesn't contain as many chemicals as tobacco and cigarettes.' Ola (Smoker)

As well as judgement, receiving no advice was also a barrier to breastfeeding. Women reported receiving little to no advice for both smoking and vaping in regards to breastfeeding, and this led to women being unsure:

'As a smoker nurses and midwives never suggested I should breastfeed and never brought it up. I'm not sure if this is because it is harmful or because they thought it was my choice.' Hayley (Smoker)

For some women, the fact they had quit smoking prior to, or during, pregnancy meant they received no advice on smoking/vaping during the postpartum period. Some women reported feeling guilty if they had smoked as a breastfeeding mother, others reported they had felt too guilty to ask for advice regarding breastfeeding:

'I also time my cigarettes between my feeds although I do admit I am somewhat ignorant to it because I feel guilty so don't want to ask, on the other hand, if more information was readily available I would have never resumed smoking' Maya (Smoker)

For many women, the only information they had received was related to pregnancy, not the postpartum period:

'I was told to quit whilst pregnant and advised there was a stop smoking clinic but no advice is given about smoking and breastfeeding even though I could have started smoking after the birth' Naya (Vaper)

Women tended to seek/receive advice from midwives, health visitors, friends, stop

smoking services and online groups however women expressed a wish for more factual advice, often feeling most advice was based on opinions rather than facts, this was particularly true for vaping mothers;

'I received little to no actually, factual literature about e-cigarettes and vaping in pregnancy or when breastfeeding. Mostly opinions, but no proven evidence.' Amy (Vaper)

For women who did receive advice/information, it wasn't always accurate or helpful. For some women, they were told to 'just quit' which they found to be dismissive. Other women received inaccurate advice that they found to be judgemental:

'I was told that if I smoked and breastfed that my health visitor would call social services.' Kim (Smoker)

Support and advice could also act as facilitators for smoking/vaping mothers to breastfeed if it was perceived as helpful and non-judgemental. Factual advice enabled women to make informed decisions about how to feed their infants, and being advised by a health care professional that it was safe to breastfeed if they smoked/vaped supported some women to breastfeed:

'When I had my baby I asked a Neonatal nurse about if it's okay to smoke and breastfeed (in my case pump) and she said it doesn't make a difference.' Esmerelda (Smoker)

Having these assurances from professionals helped women to feel they were doing the best for their babies, women were also told how breastfeeding would reduce risks to their baby caused by smoking which facilitated some women to breastfeed:

'I was advised that because I smoke, breastfeeding was the best way forward as it would reduce the risk of my baby getting respiratory illnesses such as asthma' Leah (Smoker)

Women also found advice on how to reduce harm further to be beneficial; the advice was often centred on reducing the risk of second-hand smoke such as smoking outside, washing hands, or removing outdoor clothing before feeding the baby. Some women were advised to time smoking around their baby's feeds. However, this was inconsistent; some women were told to smoke immediately after a feed and others, to smoke immediately before. The was always to reduce the amount of nicotine within the breastmilk:

'Midwives have told me it's [breastfeeding as a smoker] safe as long as you wash your hand afterward and brush your teeth. Also advised to try wait 10 minutes before breastfeeding' Cersei (Smoker)

Social influences came from a variety of sources; judgement and inaccurate advice and support were barriers for breastfeeding amongst smoking/vaping women. However, non-judgemental support and accurate advice facilitated women to breastfeed. Unfortunately, many of the women reported receiving little to no information or advice during the postpartum period.

5.4.3.3 Barriers and facilitators for switching to vaping and maintaining smoking abstinence postpartum

Barriers and facilitators for women switching from smoking to vaping and remaining smoke-free included Experiences, Comparisons to smoking, and Motivations.

Experiences

Women discussed their experiences of vaping; experiences could act as a barrier or

facilitator for switching to vaping and remaining smoke-free. Women who previously tried vaping but were now smoking found their prior experiences of vaping to be a barrier to trying again. Women discussed how they had used a vape to quit smoking but had been unsuccessful and were therefore unwilling to try again. For some women, it was that a vape did not satisfy the cravings they had. Many of the women who shared their experiences of being unable to quit smoking with a vape did highlight that they attempted to vape with no nicotine liquid which may explain why some women found it difficult to remain smoke-free:

'I couldn't quit or give up so I thought if I switched to 0% nicotine e-cigarettes it would be better than smoking, but it didn't completely work out. Whenever I try giving up or cutting back smoking I'll use my e-cigarette, sometimes for a number of days sometimes for weeks but always end up full-time smoking again.' Rosalie (Smoker)

As well as finding vaping didn't help them quit smoking, some women found overusing a vape to be a barrier. Women reported that during the time they did vape they realised they were less cautious than they were of smoking, so would regularly vape in the house. They also reported what they perceived to be overuse, finding that they would be vaping consistently throughout the day which they compared to the minimal time they spent going outside to smoke:

'I only smoke maybe 1-3 cigarettes per day. When I tried vaping, I found I was sucking on the thing all damn day.' Gertrude (Smoker)

Women also reported experiencing adverse events when vaping. These were mainly related to a sore/dry throat and a cough, although some women reported sickness as a side effect. Women who reported experiencing these events returned to smoking:

'I've tried e-cigarettes and find they are too harsh and cause me to have breathing problems so went back to cigarettes' Rosalind (Smoker)

Despite some adverse events, women also reported improvements socially, mentally, and physically when vaping, which acted as a facilitator. Some women reported vaping helped manage their stress levels while others talked about being able to still 'smoke' when out with friends or being able to use a vape around friends who didn't smoke:

'We're more sociable, energetic, less stressed in general and there's no horrible smoke smell lingering on our clothes! Obviously, the main benefit being that our family is no longer subject to cigarette smoke.' Darcy (Vaper)

Positive experiences of vaping were facilitators to remain smoke-free. A lot of women talked about vaping being a pleasant experience; they found the range of flavours appealing. The most common positive experience was not smelling like smoke, and in particular, they didn't want their infants to smell of smoke. Vaping was described as a 'cleaner' or 'fresher' experience. This facilitated switching to vaping for some women:

'I had a random thought, would my children remember me by the smell of cigarette smoke if I was to die tomorrow!' Maria (Vaper)

Motivation for use

Motivations for initially switching to vaping primarily wanted to quit smoking. For some women, this was to increase their chances of conceiving. For postpartum, this was due to not wanting their baby to smell of smoke. However, for the majority of women, this was explicitly related to quitting or cutting down on smoking during pregnancy. Successfully quitting during pregnancy was a facilitator for continuing to vape postpartum without returning to smoking:

'The hospital told me after examination that I had a threatened miscarriage and knew I needed to stop smoking immediately. Fortunately, my baby was fine and no reason was found. I felt quite unwell. After advice from smoking cessation, I switched to a

vape instead going from a 20 a day habit to zero within a day. I am now complete nicotine-free' Daisy (Vaper)

Switching to vaping during pregnancy was perceived as a way of reducing harm and 'doing what's best for baby'. Previously smoking through pregnancy caused health concerns for some women that they attributed to smoking; such as threatened miscarriage and previous low birth weight, this was a protective factor against returning to smoking postpartum:

'I personally smoked with my first child, she was born at full term but weighed 5lb14. My son I vaped all the way through my pregnancy and he was born a week early weighing 8lb15. I believe that smoking dramatically affects your child and birth weight, I also massively regretted it.' Cordelia (Vaper)

As well as pregnancy, health improvements in general motivated women to switch to vaping. For some women, it was seeing loved ones with smoking-related illnesses that prompted them to switch to vaping; for others, it was being diagnosed with a chronic condition or experiencing smoking-related health issues themselves:

'I stopped in 2014 when I was diagnosed with MS [Multiple Sclerosis], as cigarettes can exacerbate the disease. The nurse advised if I wanted to use nicotine replacement there were patients who used e-cigarettes to help quit smoking' Lucy (Vaper)

The cost of vaping was also attractive to women, although there were a few suggestions from women that help with the start-up cost (the device and liquids) would have enabled them to switch to vaping. Some women initially switched to vaping due to increased costs of cigarettes, and remaining on maternity pay or not returning to work motivated women to remain abstinent from smoking for economic reasons:

'I chose to quit smoking 5 years before I had my 1st child due to the prices of cigarettes

increasing. I bought a vape and since then have used my vape. I find it a much cheaper alternative and also I enjoy vaping.' Violet (Vaper)

Comparisons to smoking

As well as the cost of vaping versus smoking, women compared smoking to vaping in other ways. A barrier to switching to vaping was the belief that smoking and vaping were inherently the same behaviours that carried the same risk, and in some cases (albeit very few) vaping was seen as more harmful:

'I think my views about e-cigarettes and vaping are pretty similar to smoking, to be honest. The only thing I would add is that we know all the risks with smoking, but we don't really know everything about e-cigarettes and vaping yet.' Rosalie (Smoker)

Some women felt that by switching to vaping, they were not quitting smoking, just changing 'bad' habits:

'I wouldn't swap one bad habit for another' Viola (Smoker)

Conversely, a belief that smoking and vaping were very different behaviours could act as a barrier. Some women felt vaping didn't give them some of the perceived, positive benefits or experiences of smoking:

'I would [switch to vaping completely] if I felt like vaping had the same effects as smoking, I feel that smoking the actual cigarette isn't the only part of smoking that is satisfying compared to the vape, it's hard to get used to not having to roll or light a vape, I think that's part of the satisfactory process of smoking' Ola (Smoker)

Despite this, the majority of women felt that differences between cigarettes and e-cigarettes facilitated switching to e-cigarettes, as women perceived e-cigarettes sufficiently similar as an experience and way to reduce cravings, but at the same time

as a tool for harm reduction:

'Much better than smoking if unable to quit, much cleaner and healthier in the long run from personal experience' Cordelia (vaper)

Vape safety

Women also discussed vaping in terms of safety without comparing it to smoking. Believing vaping to be 'harmless' was a facilitator for vaping; some women felt vaping posed no risk to health and felt comfortable vaping around their children. Women simplified the ingredients of e-liquids to back up their opinions:

'I don't see an issue ...the same things in a vape minus nicotine are in ice-cream ... There's nothing harmful in a vape just 3 ingredients' Hermione (Vaper)

Although some women felt vaping was harmless, other women were less sure and remained uncertain about vaping. This acted as a barrier to switching to vaping:

'Unsure as I only vaped a small amount and did not like this. I don't think there are enough supportive evidence yet for this risk factor as vaping is fairly new.' Raya (Smoker)

Though this uncertainty was often due to the novelty of vapes; women felt there was not enough research of evidence to support their use which was a barrier to switching to vaping. Women discussed that no long term research on the effects of vaping was available:

'It's a difficult one as we don't yet know enough about the long term effects and negative health risks associated with vaping.' Veronica (Smoker)

When asked what would encourage them to try vaping, women who smoked often cited the need for further research and for the long term effects to be known. Some women felt that smoking was the better option as the risks were at least known:

'None tested no information I don't trust it!!..... Nope, not tested, I know the risks with smoking' Agnes (Smoker)

5.5 Discussion

5.5.1 Key findings

This study builds on the results in chapter 4 by directly asking women about their experiences and opinions of breastfeeding as a smoking or vaping mother. In a sample of 153 postpartum women who smoked (37.3%), vaped (30.7%) or smoked and vaped (32.0%), three main themes were observed; smoking, vaping and breastfeeding behaviour, barriers & facilitators toward breastfeeding as a smoking/vaping mother, and barriers & facilitators towards vaping postpartum.

This study shows that smoking is a barrier to breastfeeding due to acceptability and safety concerns and that some women use vaping to overcome this. Vaping is perceived overall to be safer and more acceptable for breastfeeding mothers. However, there are distinct barriers to switching to vaping.

Health care professionals have a pivotal role to play in increasing breastfeeding amongst smoking/vaping mothers. If mothers have access to relevant, clear, factual, and non-judgemental advice postpartum, they are better equipped and supported to breastfeed their infants, regardless of smoking/vaping status.

5.5.2 Strengths & limitations

There are limitations to this research; conducting online surveys means we cannot fully explore each woman's experience as we might do using interviews. There were some quotes where it would have been beneficial to have been able to explore these narratives at greater length and with more detail. We are also unable to verify that each

participant was indeed a smoking or vaping mother. However the anonymity of an online survey can also act as a strength, women can disclose experiences, behaviours, and opinions without fearing judgement, which as evident in the results is a concern for women when discussing this subject. There were also limitations in some responses; for example, while many women gave at least some detail in their answers, others responded with single words and, in some cases, emojis. However, this had been pre-empted, which was why a larger number of women were recruited than would typically be recruited for a qualitative study. A strength of this study is the recruitment strategy and flexibility of online surveys; while the aim was to recruit 80-120 participants over a 6-8 week period, 153 mothers were recruited within four weeks. This may be due to the flexibility of online research; mothers primarily took part in this research during the evenings when face to face interviews would not typically be conducted.

A limitation of this study was not conducting *a priori* power analysis for the Likert scale questions; these were added following PPI input, and as such, the study was not designed to include quantitative measures. The scales gave us some interesting data; however, this should be viewed with caution, and replication is needed to have confidence in the results.

5.5.3 Quantitative results: relation to prior work

In this sample, 69.3% of infants were breastfed at birth, similar to the national average of 74% [341]. However, by one month postpartum, only 44.4% of infants were receiving any breastmilk. This is similar to Public Health England's breastfeeding prevalence rates of 46.2% at 6-8 weeks postpartum [121].

Although we must be careful about what inferences we draw from the Likert scale results, they do suggest that more women view the safety of e-cigarettes while breastfeeding in a more positive light than they do smoking. This was also true for the social acceptability of vaping as a breastfeeding mother. Women viewed breastfeeding as a vaper more positively than did cigarettes. The acceptability of e-cigarettes in place of cigarettes is identified in previous research with the general population [195, 402].

Overall, women mostly agreed mothers should be encouraged to breastfeed regardless of whether they smoke or vape. However, women expressed disagreement with this for smoking mothers than they did for vaping mothers. This would suggest that perhaps women view vaping when breastfeeding to be safer and more socially acceptable than smoking, which is similar to research on vaping during pregnancy; e-cigarettes are seen as the 'lesser of two evils' [269].

5.5.3 Qualitative results: relation to prior works

Smoking, vaping and breastfeeding behaviours

Smoking, vaping and breastfeeding behaviours centred on how women managed their smoking and vaping around their infants regarding breastfeeding, this included the behaviours they put in place to reduce any harm or risk posed to the infant; both documented and perceived risks. These behaviours were often following the outlined advice for postpartum smokers; smoke only outside of the house, wear a protective layer of clothing to be removed after smoking and observe good hand hygiene [56]. Women applied this advice to vaping as well; many mothers who vaped treated vaping similar to smoking, and those who didn't vape highlighted that mothers who did should treat it the same as smoking. Some women were less cautious about vaping; they reported vaping meant they did not have to leave their baby. There were examples of women explaining that vaping helped them as new mothers because they could vape in the house, as opposed to going outside to smoke. This has been shown in prior research, where people hold the belief that e-cigarettes are safer in comparison to smoking, and therefore do not restrict their use in environments (such as homes or cars) as they would with cigarettes [403]. This was particularly evidenced in mothers who were dual users; they would talk about vaping during the day and only smoking when their partner returned from work to 'watch the baby'. For some dual users, smoking and vaping was alternated around the infants needs to nurse from the breast. Some mothers talked about exclusively vaping until they had enough expressed breastmilk to be fed to the infant via a bottle, before allowing themselves a cigarette. This was done in the expectation that no nicotine would be transferred into the breastmilk. Currently

organisations such as La Leche League advise mothers who do smoke, to smoke directly after a feed. Nicotine has a half-life in breastmilk of two hours, therefore to reduce the amount of nicotine present in breastmilk, a mother should aim to smoke no less than two hours prior to feeding [404, 405]. Concerns about nicotine were evident in many women's stories; women feared nicotine exposure to their infant via breast milk. Women who smoked or vaped nicotine talked about timing smoking/vaping around feeds, such as smoking/vaping directly after a feed to allow maximum time for the nicotine to leave their body before the next feed was due.

Fear of nicotine transference is evident in other bodies of work; Bogen et al., (2008) found only 2% of 204 American women felt the use of Nicotine Replacement Therapy (NRT) was acceptable for breastfeeding mothers because of the transference of nicotine via breastmilk [406]. Goldade et al. (2008) also highlighted how, for some women, it was concerns regarding nicotine transference that lead to the early cessation of breastfeeding [162]. In chapter 4, nicotine transference was also a significant concern for mothers postpartum [394]. While nicotine is not a benign substance, it is not the primary health concern when smoking. Infant exposure to nicotine via breastmilk is roughly 50 times less than maternal exposure [407]. Although nicotine has some hemodynamic effects and is highly addictive, it is the multitude of other toxicants within cigarette smoke that pose a serious risk to health [408]. Women who felt vaping while breastfeeding was safe highlighted this. They would talk about the harmful toxins present in cigarette smoke, the risk of second/third-hand smoke, and the dermal transference of tobacco-related toxicants during breastfeeding. For these women, smoking was a barrier to breastfeeding for which vaping overcame.

Barriers and facilitators for breastfeeding as a smoking/vaping mother

Barriers and facilitators for breastfeeding as a smoking or vaping mother were how the specific behaviour of being a smoking/vaping could both hinder and support breastfeeding. Whether this was a barrier or a facilitator depended on the individual notion of acceptability, perceptions of safety and the social influences of others

(including health care professionals).

Smoking and breastfeeding were sometimes discussed as being unacceptable, as reported in previous literature [406]. Women would talk about the rights of the infant; i.e. it's the mother's choice to smoke not the infants. This played into the notion that 'good mothers don't smoke' and 'good mothers breastfeed' [355-357, 409]; that a mother's job was to protect her infant from harmful things, and breastfeeding as a smoker negated this. Although some women found vaping to also be unacceptable for breastfeeding mothers, the majority of discussions were positive with vaping viewed as acceptable behaviour, as found in previous research [195, 402]. This is sometimes due to the perception that when vaping, a person is making an effort to quit smoking [200]. Women suggested that a mother was making healthier choices for herself and her baby by vaping, and not smoking. This again ties in with the 'good mother' principle that is intrinsic with breastfeeding [355, 409]; good mothers breastfeed their infants, so to overcome a barrier (smoking) with an alternative (vaping) in order to breastfeed is evidence of 'good mothering'. The acceptability of vaping may be very specific to the UK demographic, as the acceptability (overall) of vaping does vary by country [410, 411].

Acceptability of smoking or vaping as a breastfeeding mother was sometimes conditional. Overall most women agreed that it was acceptable to breastfeed as a smoker or vaper on the condition that basic hygiene was followed, and distance/timings were observed. For women who vaped specifically, acceptability varied depending on whether women used nicotine. For smoking, conditional acceptability was more nuanced. It was acceptable for a mother to smoke if she breastfed as long as she was trying to quit, not smoking would be detrimental towards her mental health, or that not smoking would cause undue stress. The belief that smoking postpartum is a tool to reduce stress has been identified in previous work [61] and was identified in Chapter 4 as a reason for the use of cigarettes and vapes [394] postpartum.

Contrary to this, some women asserted quite firmly that acceptability was a moot point;

a woman's decision to breastfeed, to smoke, or to vape was her choice and her choice alone. This ties in with feminist research that identifies infant feeding as a woman's choice needed to overcome the guilt and shame that are associated with infant feeding, regardless of the preferred method [409]. This was expressed in terms of a woman's right to choose what to do with her own body. Sometimes this was followed by the assertion that a mother intrinsically knows what is best for her baby with the phrase 'mother knows best.' This works with the principle that a mother is able to make informed choices by contextualising risk to ensure she does the best by her baby, which may or may not go against the information and advice of public health bodies [356]. The idea of 'mother knows best' has previously been identified in other work that looks at how mothers manage nutrition or their infants [412].

The perceived safety of breastfeeding as a smoking/vaping mother could be a barrier to breastfeeding. As discussed above, the fear that smoking resulted in breastmilk that was ultimately unsafe led some women to stop breastfeeding; similar to prior research that suggests women may stop breastfeeding in order to resume smoking [150, 413]. Some women perceived vaping as safer than smoking, which facilitated breastfeeding. There were discussions about the ingredients of vape juice being similar to that of ice cream, or soup. However, not all women agreed, for some vaping was just too novel a concept to risk, women reported that until long term studies existed, they would be reluctant to breastfeed as a vaper. While women accepted smoking was harmful, for some women, there was a general belief that at least smoking was an informed risk, whereas vaping remained an unknown risk.

The belief that 'breast is best regardless' was a facilitator to breastfeeding as a smoking or vaping mother. 'Breast is best' is a slogan that has been reported worldwide to women since the 1980s, as a way of increasing public awareness of the benefits of breastfeeding [414]. Women discussed how breastmilk was nutritionally superior to formula milk regardless of the mothers' smoking status and asserted that breastfeeding could negate some of the risks associated with smoking/vaping (such as the increased

risk of SIDs). This is in line with what the NHS state for new mothers [58], a stance supported by breastfeeding charities 'Laleche League' and 'breastfeeding network'. Not all women agreed, some women felt that it was safer to formula feed an infant if you smoked/vaped, which was a barrier to breastfeeding. Some women stated that no one should judge them for formula feeding when other women smoked and breastfed (the insinuation that the latter was worthy of judgement).

Judgement was a significant barrier for breastfeeding as a smoker/vaper. When asked what would make it easier for them to have breastfed, or have breastfed for longer, many women talked about judgement from others. Women discussed how breastfeeding in itself carried a lot of judgement; women felt judged if they didn't breastfeed but also judged if they were seen to be breastfeeding in public, an issue identified in previous work [415]. With the added fear that mothers also get judged for smoking, some women felt they would be judged more harshly if they were seen to be a smoking/vaping mother who breastfed. Some women also harboured judgement towards themselves, describing their smoking (in particular) as 'disgusting' or feeling like they had failed their baby, this is similar to the findings in chapter 4 [394]. Some women found relief from this self-judgement through breastfeeding, talking about their shame of smoking but their pride in breastfeeding. For others, they felt they had to hide the fact they either smoked or breastfed. There were no examples of self-judgement amongst women who vaped. The judgement also came from false information, for example one participant was told by family or friends that if she breastfed as a smoker, her health visitor would call social services. Women did get some positive encouragement from others; some women mentioned online communities where they received advice to breastfeed regardless of smoking or vaping. Vaping was often a way of negotiating social judgements; i.e. if a mother vaped, she was therefore making healthier choices (by not smoking) and could therefore be afforded the identity of a 'good mother'. For mothers who smoked, or who did not breastfeed, passing judgement on other mothers was a way of mediating the judgements they felt towards themselves. For example, some women spoke about the fact that other mothers drank alcohol and

breastfed, those mothers were therefore irresponsible and by making the decision to bottle feed this mother was protecting her baby from harm. In this research, the morality of motherhood became more of a complex spectrum of behaviours. Women could identify themselves as being a 'better' mother, despite engaging in behaviours that fall outside of the 'good mother' principles. This was because there would always be other mothers engaging in perceived 'less moral' behaviours.

Many social influences could be both a barrier and a facilitator for breastfeeding. For example, if a mother received encouragement and reassurance on safety from health care professionals, it could facilitate her to breastfeed. However, a large proportion of women did not receive any advice or information on breastfeeding as a smoker/vaper; this was particularly true for vaping. They found it challenging to find information about breastfeeding and vaping and often relied on advice about smoking to inform their behaviours. This was similar to the results in chapter 4 [394]; due to a lack of general consensus and advice women who vape adopt the advice given about smoking to inform their decisions regarding vaping.

Often women reported that they were not asked about their smoking status (having quit during pregnancy), and were too embarrassed to ask health care professionals about breastfeeding as a smoker or vaper. For some women, the fact it wasn't discussed with them led them to believe that they were not expected to breastfeed because of their smoking/vaping status. For vaping mothers, in particular, health care professional's lack of guidance was a barrier to breastfeeding. This is similar to research that has explored barriers and facilitators to using NRT or e-cigarettes during pregnancy; women who have positive discussions about e-cigarettes as safer than smoking with health care professionals report more confidence in using e-cigarettes [416]. Health professionals' influence, or lack of it, is an important factor to consider; many women mentioned that there was no advice being given on smoking and breastfeeding. This suggests that clinicians give little reassurance about smoking and breastfeeding, and thus women's concerns about this can go unchallenged.

Barriers and facilitators for vaping (and not smoking) postpartum

Although this study was primarily about the experiences and opinions surrounding vaping or smoking and breastfeeding, it's also important to understand why some women vape, and why others continue to smoke, given vaping could be a safer alternative [417] for mothers who do not quit smoking. The majority of women who vaped in this study indicated that their motivation for switching to vaping (from smoking) was pregnancy; either in preparation for pregnancy or after finding out they were pregnant. Some women had switched prior to pregnancy because of health issues, and some women had switched to vaping as they could no longer afford cigarettes while on maternity pay, as identified in previous research [270].

Experiences of using e-cigarettes could act as a barrier or facilitator depending on whether the experiences were positive or negative. Some women were reluctant to use e-cigarettes, having tried to quit smoking unsuccessfully with e-cigarettes in the past. Some women who had previously quit smoking with an e-cigarette reported over-using their device, such as spending a lot of the day vaping in comparison to what they perceived to be a relatively short time smoking cigarettes. Prior research has shown that vapers will regulate their nicotine levels regardless of the nicotine content in their e-liquid [211], so it may be that women were starting with a nicotine concentration too low to satisfy their cravings. One of the main barriers regarding experiences was adverse events. Women who had tried vaping and were reluctant to try again highlighted a sore throat or a cough. Some mentioned dizziness and nausea; these are all adverse events that have previously been associated with e-cigarette use [418]. Women reported that these adverse events disappeared once they resumed smoking. Positive experiences included feeling more energetic, no longer 'smelling' of cigarette smoke, feeling more sociable, saving money and successfully quitting smoking, this acted as a facilitator for women to continue to vape and not return to smoking.

Comparing smoking and vaping could also act as a barrier or facilitator. For some women, vaping was simply trading one 'bad' behaviour for another. The majority of

women described smoking and vaping as being different, which could be either a barrier or facilitator. For some, vaping was not a similar enough experience to smoking, and they missed other aspects of smoking, such as the lighting or rolling of a cigarette, which acted as a barrier to switching. For others, vaping was perceived to be different to smoking in a positive way which facilitated switching to vaping; this could be in terms of safety and social stigma, where women discussed feeling less 'guilty' when vaping. Overall the majority of women perceived vaping to be safer than smoking; some women felt they were safe to use, and a minority of women felt they were completely harmless. Despite the majority of women perceiving them to be safer than smoking, women still felt there is not enough research or evidence to be sure of the safety of vapes which was a barrier for switching to vaping from smoking.

5.5.4 Implications for practice and future work

While this research suggests that overall postpartum women see e-cigarettes as a safer alternative to smoking, and are more supportive of using e-cigarettes (than cigarettes) as breastfeeding mothers, there is a clear need for greater communication from health care professionals. Women are inundated with information on e-cigarettes from a variety of channels and are looking to health professionals to give them clear and concise guidance. Given the recent emergence of e-cigarettes, postnatal care should ensure that discussions around e-cigarette use are implemented within usual care, particularly in relation to breastfeeding.

Given the relative safety of e-cigarettes compared to cigarettes, their efficacy as a quit aid, and the greater acceptability of e-cigarette use for breastfeeding mothers, there is potential for interventions to consider utilising e-cigarettes for reducing postpartum smoking and increasing breastfeeding.

In order to trial e-cigarettes postpartum, the barriers to switching to vaping need to be considered. As women who had previously been unsuccessful in quitting smoking with an e-cigarette, smoking cessation services should consider providing information on regulating nicotine levels. For adverse events, it may be beneficial for new e-cigarette

users to be advised of the health impacts of smoking compared to these events, and be aware of alternative e-cigarette products for use.

5.5.5 Conclusions

In conclusion, there are various barriers and facilitators for breastfeeding as a smoking or vaping mother. However, women appear more favourable of breastfeeding as a vaper than a smoker. For some women, vaping was a way to overcome the barriers they faced as a smoking mother. There are still many misconceptions about smoking, vaping and breastfeeding, and a lack of information from health care professionals means women do not have the opportunity to discuss their worries. Clear and consistent guidance on breastfeeding as a smoker or vaper needs to be made available to all new mothers.

Chapter 6: Summary, implications, and directions for future research

6.1 Summary of findings in relation to objectives:

The overall aim of this thesis was to explore the use and acceptability e-cigarettes for breastfeeding mothers, and barriers and facilitators to their use postpartum:

1. To understand whether there is a relationship between smoking and breastfeeding within a sample of smokers, ex-smokers, and vapers.
2. Describe the characteristics of women who breastfeed, smoke and/or vape postpartum
3. To explore women's current usage, understanding and opinions of e-cigarettes in relation to breastfeeding
4. To explore the barriers and motivators to breastfeeding as a smoking/vaping mother
5. To explore the acceptability of using e-cigarettes as a breastfeeding mother
6. To explore the motivators/barriers for using e-cigarettes, as an alternative to smoking, in the postpartum period

This concluding chapter summarises the key findings of this research. It highlights the implications for future care and interventions that could use e-cigarettes to support those women who cannot, or do not wish to remain smoke-free postpartum, and consequently do not intend to initiate or continue breastfeeding.

6.1.1 Chapter 3, Study 1

The Pregnancy Lifestyle Survey (PLS) was a longitudinal survey of UK mothers, from early pregnancy to 3 months postpartum. The results showed that mothers who smoked were less likely to initiate breastfeeding at birth, and to continue breastfeeding at three months postpartum, compared to mothers who remained smoke-free.

Mothers who were older and had higher levels of education were also more likely to breastfeed, and a higher level of education was also associated with remaining smoke-free. When adjusting for age and education, smoking was still negatively associated with breastfeeding at all time points. The characteristics of mothers who vaped were similar to those of mothers who smoked, however small sample sizes of exclusive vapers made analysis difficult.

This study was limited by the sample size of exclusive vapers and the quantitative methodology. To explore the use of e-cigarettes postpartum, especially amongst breastfeeding mothers, qualitative research is needed that focuses explicitly on e-cigarettes and not cigarette use.

6.1.2 Chapter 4, Study 2

Women's views about e-cigarettes and breastfeeding were explored through infodemic methods. Infodemic research, as defined in Chapter 4, can be the analysis of how people search and navigate the internet for health-related information [358]. For this study, online forum discussions were analysed. Four main themes from ten discussion threads originating from two parenting forums were identified; use, perceived risk, social support, and evidence. Women appeared to be using e-cigarettes as an alternative to smoking; both to quit and prevent a return to smoking. Discussions suggested women generally believed that e-cigarettes were less harmful. However, opinions presented by forum contributors were divided; some believed that e-cigarettes were safe for breastfeeding mothers and others believed they were dangerous. This was sometimes due to concerns about the lack of long-term research about e-cigarettes or concerns about the trustworthiness of health bodies. Women reported accessing academic journals and other evidence from verified sources, as well as accessing non-verified sources (such as media articles) to form these opinions.

Infodemic research does not give the opportunity to ask questions of participants or explore specific themes in depth. To explore women's own experiences of vaping,

smoking, and breastfeeding, it was recommended that future work explore the themes identified in greater detail with participants. It was also recommended that postnatal care providers look to include discussions on e-cigarettes within usual postnatal care to ensure women's concerns are addressed.

6.1.3 Chapter 5, Study 3

An online survey was conducted with smoking and/or vaping mothers who had given birth within the last 18 months. Three main themes were identified; smoking, vaping & breastfeeding behaviours, barriers & facilitators for breastfeeding as a smoker/vaper, and barriers and facilitators for switching to vaping. Women reported changing their behaviour to reduce harm; this included creating a smoke-free home and, for dual users, alternating between smoking and vaping around their infants' feed. For some women, the act of smoking itself was perceived to be a barrier to breastfeeding. This was overcome by using an e-cigarette. Social influences such as the judgment of others and advice from health care professionals could act as barriers or facilitators to breastfeeding.

Mothers were more positive about the use of e-cigarettes when breastfeeding than they were about smoking. Generally, women were more likely to report that vaping as a breastfeeding mother was acceptable than smoking; although for some women, it was only acceptable if a woman vaped zero nicotine e-liquids. There were some concerns about the lack of long term research about vaping.

Wanting to remain smoke-free, and not being able to afford to smoke cigarettes were key motivators for vaping, and not smoking, in the postpartum period. There were also other motivators such as health, not smelling of tobacco, and avoiding second-hand smoke. Barriers to vaping included previously trying e-cigarettes and being unsuccessful at quitting smoking, overuse of e-cigarettes, or experiencing adverse effects of vaping. A major barrier to using e-cigarettes postpartum was a lack of advice about vaping available to new mothers, particularly concerning breastfeeding.

Future recommendations are the inclusion of discussions about switching to e-cigarettes during postnatal visits, and accessible information about their use and relative safety. Interventions should consider that e-cigarettes are, for the most part, more acceptable to breastfeeding mothers than smoking. However, barriers to switching to vaping should be minimised where possible.

6.2 Main findings across all thesis studies

The main findings of this thesis can be summarised as follows:

- Women in the UK who smoke postpartum are less likely to initiate breastfeeding and continue breastfeeding than mothers who have quit smoking.
- Women find smoking a barrier to breastfeeding because they are concerned the smoke will taint their milk, making it unsafe for their infant.
- Some women view smoking and not breastfeeding as evidence of 'bad mothering.'
- For some women, an e-cigarette can overcome these barriers, and women are more favourable about the use of e-cigarettes when breastfeeding than smoking.
- The majority of mothers believe e-cigarettes to be safer than traditional cigarettes.
- However, there are still barriers to switching to an e-cigarette; this is due to a lack of long term research and lack of (consistent) advice and support for breastfeeding mothers on using an e-cigarette.

Study 1 showed a negative association between smoking and breastfeeding. The results of this thesis suggest this association is, at least in part, due to a fear of harm. In study 1, smoking mothers were less likely to intend to breastfeed, which suggests the association is not physiological (i.e., the effect of nicotine on lactation hormones), study 1 also showed an association persisted even when age and education were adjusted for. In study 3, women discussed their fears and beliefs that smoking contaminated breastmilk and made it unsafe for them to breastfeed. Some women

highlighted stopping breastfeeding due to this fear, and there was a belief that formula milk was a safer option for smoking mothers, something identified in previous work [406]. Much of this harm related to concerns about nicotine, in studies 2 and 3 women reported a fear that nicotine transfers via breastmilk and is therefore harmful to the infant, similar to previous work [162, 406]. In study 2 and study 3 women talked about not only the health concerns of transference through breastmilk but the morality of it. The valued self-identity of being a 'good mother' was present in studies 2 and 3; the expectation was that a 'good mother' does not smoke but does breastfeed [355, 356]. In studies 2 and 3, the belief that a child could get addicted to nicotine via the mother's milk was also evidence of 'bad mothering'. The fear of harm from breastfeeding as a smoker was found to explain, at least in part, a negative association between smoking and breastfeeding; the very act of smoking was itself a barrier to breastfeeding.

In study 3, some women overcame this barrier by vaping; across all three studies vaping was shown to be more acceptable than smoking. While acceptability did vary between participants within every study, overall, the majority of women across all studies were more positive about e-cigarettes. This was due to the belief that when using an e-cigarette, a mother was making a concerted effort to quit/avoid smoking. This was a positive act, similar to findings in other research where e-cigarette use is seen a positive step towards being smoke-free [200].

The acceptability of e-cigarettes was primarily due to a comparison between smoking and vaping. E-cigarettes were determined to be safer than cigarettes with far fewer harmful constituents; this is in line with PHE's statements on vaping [417] and previous research examining e-vapour composition [196, 197, 216, 218, 276]. E-cigarettes were also generally seen as safer because they don't produce second-hand smoke. In study 2, women did raise some concerns about second-hand vapour. However, research suggests that second-hand vapour is only a source of nicotine exposure, not toxicant exposure [276]. One of the perceived benefits to vaping and breastfeeding was the ability to have skin to skin contact with the infant after vaping; women in studies 2 and 3 discussed concerns about the dermal transference of toxins from smoking during the necessary skin to skin contact for breastfeeding.

While the majority of women perceived e-cigarettes to be safer and more acceptable than smoking, there were barriers to switching to vaping. In studies 2 and 3, women reported concerns there was a lack of long-term research on the effects of vaping and highlighted there was no research on breastfeeding as a vaping mother. Of the research that was available to them, some women reported scepticism that supporting bodies, such as PHE, were untrustworthy and overly favourable of e-cigarettes because of their targets to reduce smoking. This is not unique to e-cigarettes, such as the mistrust of recommendations for vaccinations [419].

In studies 2 and 3, women highlighted the lack of information and advice for new mothers about e-cigarettes as a barrier. Some women felt the fact e-cigarettes were not discussed meant they were unsafe for use when breastfeeding. In contrast, others found they did not have the opportunity to discuss any fears and concerns about breastfeeding. A recent study has explored health care professionals' beliefs, attitudes, knowledge, and behaviour around vaping in pregnancy and postpartum [420]. This study identified that generally, amongst healthcare professionals, vaping was perceived as safer than cigarettes. Still, a lack of evidence, health and safety risks and regulatory issues were a cause for concern. Greater information and guidance about vaping is needed for health care professionals [420]. This is vital, as previous research on NRT and e-cigarettes use in pregnancy has identified that consistent messages from health professionals based on high-quality evidence, with clarity around safety concerning smoking, can improve the willingness to use harm reductive products [416]. In this thesis, women often managed their behaviours with e-cigarettes by relying on information given during pregnancy, or by applying information regarding smoking to their vaping.

6.3 Strengths and limitations

6.3.1 Quantitative work

In chapter 3, study 1 was the only purely quantitative chapter in this thesis. This inclusion of a quantitative chapter allows the generalisation of results to a broader population of UK mothers. However, there are limitations as this study was designed

for other research purposes. Questions relating to breastfeeding were only included in the two follow-up surveys, not the baseline survey, so we were unable to measure how intentions may have changed throughout pregnancy alongside changes in smoking behaviour. There was also no data collected about any interactions with health care professionals about breastfeeding as a smoker or vaper, which following the findings in chapters 4 and 5, would have been useful. Drop-out rates are also a limitation of this methodology [421] and do impact the validity of research [422]. Even when using a mixed contact method for non-responses (such as telephone and SMS prompts), responses are still generally limited [423]. In this study of the original cohort, complete data sets (both smoking and vaping status recorded) were only available for 49.2% and 53.9% at follow up 1 and 2, respectively. This may account for why age was not found to be associated with smoking status despite previous literature in Chapter 1 highlighting age to be a significant factor in whether a woman breastfeeds. The PLS also did not specifically aim to recruit an equal sample of e-cigarette users, which resulted in a small sample of exclusive vapers. For analysis, dual users and exclusive vapers were combined however there may be key differences between dual and exclusive users which means results pertaining to e-cigarettes users should be viewed with caution.

Chapter 5 also included some quantitative measures (Likert scales); however, as discussed within the chapter, this was ad hoc, and as such, no sample size or power analysis was conducted. These *a priori* tests are essential to minimise the risk of type I and type II errors [424]. This also meant that the results could not be separated to explore quantitatively any differences (or lack of) in opinions of those who smoked and those who vaped.

6.3.2 Qualitative work

Two methods of qualitative data collection, infodemic and surveys, were used for this thesis. The use of infodemic methodology allowed for the exploration of e-cigarettes and breastfeeding, a novel research question. The use of forum data permitted the analysis of naturalistic conversations, reducing research bias, and giving a voice within this research to women who may not have otherwise engaged in academic research.

This research method enabled the understanding of how and why women are using e-cigarettes postpartum and what opinions they hold on their use in relation to breastfeeding. The limitations of this research also relate to the strengths. Data is naturalistic and driven by discussion, and the absence of clearly asking research questions means data can be overly saturated with themes not relevant to the proposed question. The use of a template analysis mitigated this; the inclusion of *a priori* codes focused the analysis on answering the research question only. However, the use of *a priori* codes can also be controversial; it begs the question of whether the findings are a true reflection of what is presented in the data or a reflection of what the researcher expected to see in the data. The use of *a priori* codes is an example of deductive coding, which is more consistent within the critical realism framework [425].

A further limitation of this work was the date of the threads included. E-cigarettes have grown in popularity in recent years, and with the PHE report in 2018 highlighting the harm reduction benefits of e-cigarettes, it stands to reason that there may be a shift in the opinions of women who engaged in discussions about e-cigarettes in 2015. The very nature of this research removes the possibility of following this up to identify any changes in opinions and beliefs. It also raises the question as to the usefulness of this research, given the data collected may be 'out of date' in such a rapidly evolving field of study as e-cigarettes. With this in mind, this research should be considered exploratory, and whilst limitations are clearly present, this work lays down the foundations for further study. The research conducted in study 3 did corroborate the findings of study 2, suggesting that whilst opinions may have changed they have done so in a significant way.

Chapter 5, while not an infodemic piece of research, did rely on the distribution of surveys online. Therefore the sample of women within both qualitative chapters is confined purely to women who have access to the internet and are regular users of either parenting forums or social media platforms. An online approach was explicitly chosen to minimise the burden to participants who are in a transitional phase of life (new motherhood) and may struggle with alternative methods of research. It's also worth noting that, according to the Office for National Statistics (ONS), 99% of UK adults

aged 16-44 are internet users [426]. However, it is important to note that inequalities in the quality and access of the internet persist in line with socio-economic disadvantages in the UK, which should be taken into consideration [427].

A further limitation of study 3 is due to the nature of surveys; as surveys are completed anonymously and in writing, there are no opportunities for the researcher to explore points of interest or ask for clarification on discourse. For example, one participant had used emoji's to answer some questions which are open to varied interpretation. As a result, where some surveys were detailed and included lengthy sets of data, others were very brief, sometimes comprising of singular words. This was mediated by collecting data from a large group of women, ensuring there was adequate data to reach thematic saturation. Face to face interviews could further help obtain more in-depth data and allow for clarification of points raised; however, the loss of anonymity may prevent full disclosure.

The anonymity of study 3 also raises concerns about whether participants did meet the study criteria. For example, not speaking or being in front of the researcher means it cannot be said with 100% certainty that each participant was indeed a new mother who smoked or vaped. However, given the nature of this research required commitment of time, and some understanding of the issues surrounding breastfeeding as a smoking or vaping mother, this is likely to have been a minor issue. This was potentially more of a concern in study 2 due to 'internet trolls.' Internet trolls are people who deliberately interrupt communications online with either fake stories or harsh opinions [428]. However, research has suggested that on parenting websites, trolls are generally more of a source of entertainment. They tend to post provocative and fake opinions rather than engage in serious discussions [429]. Nevertheless, only threads with several unique contributors were selected to minimise this risk.

A limitation to both study 2 and 3 is the lack of awareness of the social and cultural contexts of the women involved in the study. For example, social norms relating to both smoking and breastfeeding are related to the environment a mother has lived in [136] [127], [62-64]. This is particularly important when considering e-cigarette acceptability

and use, as research suggests this too is influenced by the social and cultural environment a person lives in. For example, concerns about nicotine addiction amongst working-class smokers in the UK can act as a barrier to using e-cigarettes; smokers felt that switching to e-cigarettes using nicotine is similar to that of continuing to smoke due to the perception of addiction as a moral failure. There were also moral objections to spending money on e-cigarettes, and so choosing cheaper devices was a greater consideration than reducing health risks, as was choosing low nicotine juices [430]. This may have explained why some women involved in study 3 reported having previously used e-cigarettes and found them to be either unpleasant, or ineffective at satisfying their cravings. Thirlway (2016), identified differences in e-cigarette use and perceptions amongst working class areas in the UK. It was identified that e-cigarette use amongst working class families conflicted with hedonistic cultures. However an e-cigarette was often seen as functional in response to this, but only in male smokers [431]. In studies 2 and 3 women talk about the pleasurable experience of vaping, such as the different flavours smells. In hindsight, it would have been useful to have gained information on participant's areas of residence to explore any barriers that may have been socially and culturally specific.

Both qualitative studies used thematic analysis, although Chapter 4 used a variation of this, template analysis. Thematic analysis allows for both inductive and deductive analysis [432], and thus, this flexible approach was crucial to the overall thesis. Due to the novelty of this research area, a deductive approach with *a priori* codes was necessary to narrow the scope of the study and inform the future direction of the thesis. An inductive approach, as taken in Chapter 5, then allowed the thesis to understand better women's own experiences, barriers, and facilitators.

6.3.3 Overall strengths and weaknesses

This thesis utilised a mixed-methods approach, using quantitative and qualitative methodologies. Mixed methods approaches are comprehensive and can allow for research questions to be more efficiently answered [316]. This enables triangulation,

building a consensus through all findings, and can expand the scope and breadth of the questions posed [325]. Consideration of the findings across the methodologies described in section 6.2 of this thesis enabled a complete understanding of the acceptability of e-cigarette use as a breastfeeding mother, and how this may support maintaining a smoke-free status postpartum.

Across all three studies, smoking and vaping status were self-reported. Research suggests smoking is often underestimated when self-report measures are used [433], particularly in pregnancy [434]. This may have impacted some responses; for example, in Chapters 3 and 5, women were given options including 'I smoke, but less than before pregnancy' or 'I smoke, but less than when I was pregnant.' This may have been subject to underestimation based on social desirability factors, and retrospective memory. The use of anonymous online surveys does, however, appear to increase the reliability of self-reported smoking status [340].

A further limitation of this thesis overall is the lack of perspectives from a wider stakeholder group. This thesis only reported the views, opinions and experiences of mothers, whereas research suggests that the wider family network is important in the decisions a woman makes regarding smoking, vaping and breastfeeding. For example, having a partner who smokes, or abstains from smoking is directly related to whether a mother quits smoking during pregnancy, and whether she remains smoke free postpartum [435]. Evidence is also emerging that whether a partner vapes, or is supportive of vaping, is also somewhat related to whether a mother makes the decision to vape [270]. Breastfeeding is also supported if the mother is around other women who have breastfed, or comes from a family who are supportive of breastfeeding [436].

Other stakeholders include health care professionals, and whilst the women involved in this thesis discuss in detail their perceptions of the support, or lack of support, afforded to them by healthcare professionals, this thesis is unable to represent those professionals own experiences and opinions. This thesis would have been strengthened by the inclusion of a wider range of perspectives. However, given the exploratory nature of this research, it was felt that fully representing mothers own

experiences was a higher priority, providing an evidence base for future studies to include a wider stakeholder groups.

6.5 Triangulation of findings to inform future works/interventions

A theoretical framework did not guide this thesis, this was due to the novelty of the research question. To reduce biases, this research was treated as exploratory, where themes were guided by the data, rather than a framework. If a theoretical framework had been used to guide this thesis, the data generated would have provided a more robust evidence base for the future development of behaviour change interventions. Whilst this is a limitation of the thesis, it is negated by the wealth of information generated by taking an exploratory approach. Applying a theoretical framework was considered early on in the thesis process, however it was decided that due to the novelty of the subject, an exploratory approach would produce the necessary evidence base for future, more theory driven, research.

Throughout this thesis, a stance of critical realism was adopted. The research, being exploratory in nature, emerged to be more positivist; the assumption that there is an objective truth within the phenomena of smoking, vaping and breastfeeding. Critical realism is commonly known as the 'answer' to the epistemic fallacy; that our knowledge of the world cannot simply be reduced to our understanding of our knowledge of the world, and with this there is a flexibility in this approach. That positivism and constructivism are indeed a continuum, and although data may present as leaning more toward the positivist end of the spectrum, this 'truth' is presented within the context of motherhood throughout this thesis. For example, whilst the relationship between smoking and breastfeeding can be presented in an objective truth, this is within the context of the socially constructed 'good mother' principles.

Using this critical realism stance and a mixed-methods approach, the triangulation of the thesis chapters fits with the Theoretical Domains Framework (TDF) [437] and the Capability, Opportunity, and Motivation (COM-B) model [438]. The TDF and COM-B model provides a systematic and theoretical basis for changing, and better

understanding, behaviour [437]. The TDF includes 14 domains underpinned by psychological theory, which derive from 33 theories and 128 constructs. These domains include social factors (such as social support), individual factors (such as skills and knowledge), and environmental factors (such as access to resources) [437]. The TDF has been successfully used to identify the determinants of many health behaviours, including smoking cessation in pregnancy [439]. The COM-B model filters the TDF into three key domains that interact with one another to predict behaviour; a person's capability, opportunity, and motivation to change [438]. Using this framework helps to identify relevant intervention functions, based on a wide range of influences, that may support behaviour change. Therefore to affect a behavioural change from smoking to vaping, and from not breastfeeding to breastfeeding, the TDF and COM-B model can be used to inform future interventions and directions for further research.

To input the findings from this thesis into the COM-B/TDF domains, the findings across all three studies were entered into NVivo12©. From here, a simple coding template was formed based on the 14 TDF domains. Findings were coded depending on which domain they fitted, in the event a finding appeared to fit more than one domain, the finding was double coded. The coded findings were then filtered into the corresponding COM-B domain and noted as a barrier (B), a facilitator (F), or both (B/F). This is presented in Table 6.1, which was used to identify future research needs, implications for practice, and potential implications for future interventions.

Table 6.1 Triangulation of thesis within the COM-B & TDF

COM-B	Sources of behaviour	TDF Domain	Barrier (B) and facilitators (F) for breastfeeding as a smoker/vaper	Barriers (B) and facilitators (F) for switching to e-cigarettes
Capability	Psychological	Knowledge	Understanding that it is safer to breastfeed than formula feed regardless of smoking status (F)	Believing that e-cigarettes are safer than tobacco smoking (F)
			Holding the belief that smoking makes breastmilk unsafe for an infant (B)	Concerns about a lack of long-term research on potential health effects of e-cigarettes (B)
			Being unsure of the safety of e-cigarettes when breastfeeding (B)	Finding e-cigarettes to be a similar behaviour to smoking (B/F)
	Physical	Behavioural regulation	Being able to time breastfeeding around smoking/vaping needs (F)	Overusing e-cigarettes (B) Being less cautious with e-cigarettes than smoking i.e. vaping in the house (B)
		Physical skills		Being able to manage nicotine levels to suit their needs (F) Understanding how to use a vape (F)
Opportunity	Physical	Environmental	Accessing information online through social media and parenting websites (B/F)	Having access to and understanding scientific journals (F)
			Not having leaflets or advice available in healthcare settings (B)	Reading media articles on vaping (B)

Motivation	Social	Social influences	Feeling judged for breastfeeding as a smoker/vaper (B)	Seeing the health benefits of someone who has switched to vaping (F)
			Receiving positive support for breastfeeding as a smoker/vaper (F)	Experiencing judgement of vaping being 'the same' as smoking (B)
			Not receiving any advice on breastfeeding as a smoker/vaper (B)	
			Getting inconsistent advice on vaping and breastfeeding (B)	
	Automatic	Reinforcement		Saving money through switching to vaping (F)
				Not smelling of tobacco smoke (F)
				Feeling healthier through switching to e-cigarettes (F)
		Emotion	Feeling proud of breastfeeding regardless of smoking/vaping status (F)	Feeling they've accomplished 'quitting smoking' (F)
Reflective	Identity	Feeling that breastfeeding, regardless of smoking/vaping status was evidence of 'good mothering' (F)	Holding the identity of 'smoker' with a circle of friends (B)	
			Feeling that vaping maintains their smoker identity with friends (F)	
	Intentions	Planning to breastfeed (F)	Wanting to quit smoking (F)	
			Avoiding relapse (F)	

	Wanting to mitigate the harms of smoking to their infant (F)	Wanting to improve fertility (F)
		Not wanting to (or wanting their infant to) smell of tobacco smoke (F)
Beliefs about consequences	Believing there may be health consequences of vaping and breastfeeding in the future (B)	Believing e-cigarettes are as bad as (or worse than) smoking (B)
	Believing smoking would make their milk unsafe, and make their infant ill (B)	Believing that e-cigarettes will improve health (F)
		Believing that future research will indicate that vaping is dangerous (B)

6.6 Recommendations

Based on the triangulation of all findings within the COM-B/TDF (as outlined in Table 6.1), the following recommendations are made for research, practice, and future interventions.

6.6.1 Recommendations for research

One of the key limitations of this thesis was the lack of representation of vaping mothers in Chapter 3. As this study did not specifically aim to recruit vaping mothers, a larger-scale longitudinal survey recording smoking/vaping status at birth would provide a better picture of how popular vaping is amongst postpartum women. This would enable follow-up questions relating to feeding initiation and continuation, and allow exploration of similarities or differences between mothers who smoke, and mothers who switch to vaping. This could help inform future interventions, i.e., if mothers who switch to vaping are more likely to initiate and continue breastfeeding interventions should focus on helping smoking mothers to switch to vaping. However, if this research shows women initiate/continue breastfeeding similar to that of smoking mothers, interventions should focus more on education around the relative safety of e-cigarettes in the postpartum period.

A longitudinal study of this nature would also enable long term follow up to measure childhood outcomes of infants who are breastfed by mothers who vape. This could identify any concerns and change the direction of interventions, or it could provide the necessary data to overcome fears of future implications of vaping and breastfeeding, a barrier identified in this thesis. Further ways to increase confidence in the relative safety of e-cigarettes use when breastfeeding could also come from trials measuring levels of tobacco-specific/vape-specific constituents within the breastmilk of smoking/vaping mothers. This could provide the scientific evidence some women reported needing to increase confidence in the safety of e-cigarettes, compared to cigarettes.

A key theme across Chapters 4 and 5 was the lack of consistent if any, advice from health professionals about vaping and breastfeeding. This is a barrier that needs to be addressed to give postpartum women the confidence to switch to vaping if they cannot or are unwilling to stop using nicotine. In the early stages of this thesis, a protocol was designed to explore health visitor's beliefs and experiences around e-cigarettes and vaping (appendix 6.1). Semi-structured interviews with around 20 health visitors from across the UK were planned, and ethical approval was received. However, recruitment was a major obstacle to this study, with health visitors feeding back that they did not know enough about e-cigarettes and therefore did not wish to take part in research about e-cigarettes. While there were discussions about changing the recruitment strategy, the findings from chapter 4 indicated further work needed to explore postpartum women's own experiences and opinions before work was conducted with health care professionals. Research has since explored health care professionals' beliefs, attitudes, knowledge, and behaviour around vaping in pregnancy and postpartum [420]; however, this was not specifically tailored to ask about breastfeeding. Future research should consider interviews with those specifically involved in postpartum health care to assess attitudes, beliefs, and knowledge about vaping in relation to breastfeeding. From this, research should also consider the development of resources, training and information for health care professionals to enable those discussions with new mothers about e-cigarettes and breastfeeding. Although recruitment difficulties were encountered when considering the inclusion of health visitors in this thesis, the popularity and public conversations about e-cigarettes have rapidly evolved over recent years, and this may no longer be a barrier to participation in research. It may also be worth focusing on the breastfeeding aspect of the study rather than e-cigarettes since health visitors are targeted on improving breastfeeding rates. It may also be worth widening recruitment to include other health care professionals involved in postnatal care, such as GP's and midwives, due to success in another study [420].

Finally, research should seek to explore further the specific difficulties identified within this research for switching to vaping. Some women who had tried e-cigarettes reported

finding them 'difficult to get on with' and found a vape did not satisfy their nicotine cravings. Some of these barriers could be alleviated by having a better working knowledge of e-cigarettes and how to manage different nicotine strengths to achieve satisfaction. It may also help overcome the barrier of 'overuse' that women identified, as previous research has highlighted vapers will vape more to achieve their required nicotine levels, regardless of the strength they're using [211]. Within this thesis, ex-vapers were not specifically recruited or asked to expand on why they had returned to smoking; research should seek to explore this further.

6.6.2 Recommendations for practice

While further research is needed, some changes can be made to practice to facilitate mothers who smoke to switch to e-cigarettes and initiate/continue breastfeeding. Ensuring health care professionals are knowledgeable about the latest PHE guidance could lead to discussions with mothers who smoke about the relative safety of e-cigarettes. Updating information on smoking and breastfeeding to include the use of e-cigarettes, again highlighting the relative safety of them, could also facilitate switching to vaping and empower women to breastfeed. Health visitors and GP's could also be encouraged to discuss smoking with every new mother as part of usual care. This would open up a dialogue for women to discuss smoking and have their concerns addressed, and also allow women who are at risk of relapse to have a source of non-judgemental advice and guidance. As part of these discussions, health care providers could also take the opportunity to discuss the relative safety of e-cigarettes and provide women with more information for them to be able to make informed decisions.

6.6.3 Recommendations for interventions

The Medical Research Council (MRC) gives guidance on developing and evaluating new healthcare interventions. The original guidance (2006) [440] and framework (2008) [441] are due to be updated in 2020. The framework acknowledges that due to the

complexity of health interventions, a mixed-methods approach is advisable [441]. The MRC recommends following the development-evaluation-implementation process, which includes: developing an intervention, piloting and feasibility, evaluating the intervention, reporting the intervention and implementation of the intervention [440]. Due to the novelty of this research, further research is needed before an intervention can be designed and piloted. This thesis identifies barriers and facilitators for breastfeeding as a smoking/vaping mother and for switching from smoking, to vaping as shown in Table 6.1, which could be used to inform future intervention designs.

For example, health care professional's attitudes, support, and ability to give consistent advice are key facilitators for both breastfeeding and switching to e-cigarettes. Interventions should first aim to address any concerns that health care professionals have and address any training needs identified during further research. Future trials with postpartum women should include health care professional-led interventions.

Further barriers and facilitators in the COM-B also suggest that empowering women to manage breastfeeding around their smoking/vaping needs is important. Ensuring women are knowledgeable about how to time smoking around their infants' feeds could mitigate some of the risks to the infant. This may encourage more women to breastfeed; while this information has been available on NHS websites, women in these studies were still unaware or unsure of the recommendations.

To support women who smoke to switch to an e-cigarettes, education on how to use a vape and manage nicotine needs is important. Interventions should ensure women know how to correctly and safely use devices, and begin vaping with the right level of nicotine for their needs.

As myths about vaping are a barrier to their use, but positive experiences are facilitators, interventions could also consider highlighting positive stories of women who have quit smoking using e-cigarettes. Counteracting the negative media that e-cigarettes receive with positive stories that highlight facilitators such as 'not smelling of tobacco,' 'feeling healthier,' 'having more money,' and 'having more energy' could facilitate women who smoke to switch to e-cigarettes.

6.7 Closing remarks

This thesis presents data on e-cigarettes and breastfeeding for the first time. This data is triangulated from three studies that explored the use of e-cigarettes, the acceptability of e-cigarettes, and the barriers and facilitators for their use postpartum. From this, we are able to understand that women are using e-cigarettes postpartum in place of smoking and that the use of e-cigarettes can overcome some barriers that smoking mothers face when considering breastfeeding. While there are still barriers for switching to vaping that need to be addressed, e-cigarettes could potentially reduce the number of women who smoke postpartum and enable women to breastfeed who otherwise wouldn't have. Negative beliefs about e-cigarettes do persist, and are more evident within study 1, where the majority of participants were smokers. As any interventions will aim to support women who smoke to switch to e-cigarettes, this is a major barrier to overcome. Clear messages on reducing risk and dispelling myths about e-cigarettes are needed. This relates to a need to have clear and consistent messages on e-cigarette use within health care settings.

This area of research is in its infancy, and there is still more work to be done to address the feasibility and effectiveness of e-cigarettes postpartum. However, we now have evidence to show that e-cigarettes are acceptable to many postpartum women and are generally viewed as more acceptable than smoking.

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Appendices

Appendix 3.1: Pregnancy Lifestyle Survey Baseline



Trust LOGOs to be added

Researchers' use only

Participant ID number

		-				-			
Site number			Participant number				Initials		

Date returned

		/			/				
D	D		M	M		Y	Y	Y	Y

Researcher's initials

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Pregnant women's attitudes towards smoking and electronic cigarettes

BASELINE QUESTIONNAIRE
Final Version: 3.1
Version date: 27th June 2017

Dear Madam,

We are looking at ways to improve the health and lifestyle of pregnant women and their babies. We are therefore inviting ALL women who come to the antenatal clinic to answer a few questions. These include questions about smoking and electronic cigarette use, but we would like as many women as possible to answer the first few questions, even if you have never smoked or used e-cigarettes, so that we can see how common these are in *all* pregnant women.

Your answers to these questions will be used in our research, but will be anonymous and your name will not appear anywhere in our reports.

The questionnaire is optional and not related to your clinical care. Whether or not you decide to complete it, this will not affect the care you receive.

Thank you for reading this and for your help.

Best wishes

Dr Sue Cooper
Division of Primary Care, University of Nottingham
Nottingham NG7 2RD

Participant ID number

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SCREENING QUESTIONS

Your answers to the questions on this page and the next will determine whether you should complete the rest of the questionnaire. Please read the instructions carefully. Thank you.

S1 Have you completed this questionnaire before? (e.g. on a previous visit to the antenatal clinic or for a scan)

Yes

No

Don't know

If you ticked **Yes**, please **hand back the questionnaire** - you are finished – thank you. Otherwise please continue

S2 Approximately, how many weeks pregnant are you?

--	--

 weeks

Don't know

S3 How old are you?

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 Years of age

If you are:

- a) less than 8 weeks or more than 24 weeks pregnant, or
- b) you are under 16 years old

Then please **hand back the questionnaire** - you are finished – thank you. Otherwise, please answer the next 2 questions.

Participant ID number

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The next question is about electronic cigarettes, often called e-cigarettes.

They are also sometimes called e-pen, e-shisha, vape pens, vape mods, box mods or ENDS. E-cigarettes produce a vapour that looks like smoke but, unlike normal cigarettes, they are not lit with a flame and do not heat or burn tobacco. Here are some examples of what they look like:



S4 Please tick the box below next to the statement that best describes your use of e-cigarettes right now

- 1 I have never heard of e-cigarettes and have never tried them
- 2 I have heard of e-cigarettes, but have never tried them
- 3 I have tried e-cigarettes, but do not use them now
- 4 I have tried e-cigarettes and still use them, but not every day
- 5 I have tried e-cigarettes and still use them every day

S5 We would also like to know about smoking. Please tick the box below next to the statement that best describes your smoking right now

- 1 I have never smoked
- 2 I completely stopped smoking more than 3 months before finding out I was pregnant
- 3 I completely stopped smoking at some time in the 3 months before finding out I was pregnant
- 4 I completely stopped smoking after I found out I was pregnant
- 5 I smoke occasionally, but not every day now I am pregnant
- 6 I smoke every day, but have cut down during my pregnancy
- 7 I smoke every day, about the same as before my pregnancy
- 8 I smoke every day, and tend to smoke more than before my pregnancy

Participant ID number

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Have you ticked one or more of the coloured boxes in either question S4 and/or S5 above? If YES, please continue to read below.

If NO (you did not tick any coloured boxes in S4 or S5), please [hand back the questionnaire](#) - you are finished – thank you.

(If you are not sure whether you should be filling in the rest of the questionnaire please ask [\[the research midwife\]](#))

From your answers, so far, we are interested in finding out more about your views on e-cigarettes, smoking and pregnancy. We would be very grateful if you would read the following information sheet that gives more details about the study we are carrying out.

If you want to ask any questions either before or after you read this then please ask to speak to [\[the research midwife\]](#) who is [\[in the clinic waiting area\]](#).

After you have read the information sheet, if you are happy to continue, you can complete the questionnaire. Once you have finished this, we will give you a £10 gift voucher to thank you for your help.

PATIENT INFORMATION SHEET INSERTED HERE

Participant ID number

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YOUR VIEWS AND EXPERIENCE OF E-CIGARETTES

In this section, we would like you to answer some questions about your experience of and views on e-cigarettes – even if you haven't used them.

Some questions are for everyone and others are for particular individuals (e.g., those currently using e-cigarettes).

Everyone should answer A1 to A9 below. After that, please follow the instructions about which questions to answer. Thank you.

A1 How often did you use an e-cigarette or vaping device during each of the following times? (Please tick one box for each time period)

	Not used at all	Only used once or twice	Used occasionally, but less than weekly	Used less than daily, but at least once a week	Used every day
In the 3 months before you became pregnant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
In the first 2 months of your pregnancy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Now	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

A2 Does anyone you know *use* an e-cigarette? (tick as many as apply)

- Yes, my partner Yes, a family member or friend Yes, someone else I know No

A3 Do you know anyone who has used an e-cigarette *in pregnancy*? (tick as many as apply)

- Yes, a family member or friend Yes, someone else I know No

Participant ID number

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A4 Does anyone you know think *you* should use an e-cigarette in pregnancy instead of smoking cigarettes? (tick as many as apply)

- Yes, my partner Yes, another family member or friend Yes, a health professional (e.g., midwife, stop smoking advisor, GP)
 Yes, someone else I know No I have not discussed this with anyone

A5 We would like to know your views on using e-cigarettes in pregnancy.

Please indicate how much you agree or disagree with each statement below.

(Select one answer per row)

	Strongly disagree	Moderately disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Moderately agree	Strongly agree
E-cigarettes should be promoted to help pregnant women stop smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I'd be more likely to use an e-cigarette in pregnancy if a health professional recommended it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would feel comfortable using an e-cigarette in public while I am pregnant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would feel comfortable using an e-cigarette in public <i>after</i> having my baby	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E-cigarettes should only be used in the home or private places	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would take part in a research study that involved using an e-cigarette whilst I am pregnant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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A6 We would like to know your views on the safety of e-cigarettes in pregnancy.

Please indicate how much you agree or disagree with each statement below.

Select one answer per row

	Strongly disagree	Moderately disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Moderately agree	Strongly agree
Using e-cigarettes in pregnancy harms my baby	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using e-cigarettes in pregnancy is as safe as using nicotine patches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using e-cigarettes in pregnancy is much less harmful than smoking tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nicotine is harmful to my unborn baby	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E-cigarettes should only be available on prescription	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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A8 Below are some reasons people may give for **NOT** using e-cigarettes *in pregnancy*.

In the first column, please tick the reason that *you* think is the *most important*. In the second column, tick any other reasons that you think are important for not using e-cigarettes in pregnancy.

	Most important reason for NOT using e-cigarettes (tick one only)	Other important reasons for NOT using e-cigarettes (tick any you think are important)
Bad stories in the press or on social media put me off them	<input type="checkbox"/>	<input type="checkbox"/>
Family or friends tell me not to use them	<input type="checkbox"/>	<input type="checkbox"/>
They don't get rid of the 'smoking habit'	<input type="checkbox"/>	<input type="checkbox"/>
They don't get rid of nicotine addiction	<input type="checkbox"/>	<input type="checkbox"/>
They don't satisfy my cravings for cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
There isn't enough research on them	<input type="checkbox"/>	<input type="checkbox"/>
I'd be too embarrassed to use them	<input type="checkbox"/>	<input type="checkbox"/>
I'd rather try other ways to quit smoking, such as nicotine patches	<input type="checkbox"/>	<input type="checkbox"/>
I'm worried about side effects	<input type="checkbox"/>	<input type="checkbox"/>
I get different messages from different people so I'm confused	<input type="checkbox"/>	<input type="checkbox"/>
Other reason (please state)	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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A9 How likely are you to try or continue to use e-cigarettes in the future?

i. While you are still pregnant:

- Very likely
- Somewhat likely
- Neither likely nor unlikely (neutral)
- Somewhat unlikely
- Very unlikely
- I don't know

ii. Once your baby is born:

- Very likely
- Somewhat likely
- Neither likely nor unlikely (neutral)
- Somewhat unlikely
- Very unlikely
- I don't know

If you currently use e-cigarettes, even if this is not every day, please answer Questions A10 to A17
If you do not currently use e-cigarettes, please go to Question B1 on page 14

A10 How soon after you wake up do you first use your e-cigarette?

- Within 5 minutes
- 6-30 minutes
- 31-60 minutes
- After 60 minutes

Participant ID number

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A11 What type of e-cigarette or vaping device do you use the most?

SELECT ONE OPTION

- A disposable e-cigarette or vaping device (non-rechargeable)
- A rechargeable e-cigarette or vaping device that uses replaceable pre-filled cartridges
- A rechargeable e-cigarette or vaping device with a tank that you can refill with fluids
- A rechargeable modular system that you refill with liquids (you use your own combination of separate parts: battery, atomiser, fluid etc.)
- Don't know

A12 What strength of e-liquid / fluid / juice / cartridge do you usually use?

SELECT ONE OPTION

- Zero (contains no nicotine)
- Low (up to 6mg (0.6%) nicotine)
- Medium (between 7 and 12mg (0.7-1.2%) of nicotine)
- High (between 13 and 20mg (1.3-2.0%) of nicotine)
- Very high (more than 20mg (2.0%) of nicotine)
- Don't know

A13 Please try to estimate how much on average you use your e-cigarette per day

Number of mls of fluid / juice

Number of cartridges

Don't know

A14 Which is your preferred e-cigarette flavour category?

SELECT ONE OPTION

- Tobacco
- Tobacco menthol, menthol or mint
- Some other flavour like fruit, candy, alcohol, coffee, vanilla etc.
- No flavour
- Don't know

Participant ID number

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A15 What is your main reason for using e-cigarettes? (SELECT ONE OPTION)

- To quit smoking
- To cut down smoking
- To use when I cannot or am not allowed to smoke
- To avoid returning to smoking
- Because I enjoy it
- Curiosity / just wanted to try them
- Some other reason. Please state:
- Don't know

A16 When do you tend to use an e-cigarette? (Please tick all that apply)

- When I get a craving to smoke or vape
- When I experience withdrawal symptoms like feeling restless, or irritable
- When I am feeling low
- When socialising
- When I see someone smoking
- First thing in the morning
- After a meal
- When I'm angry or stressed
- When I'm bored
- When I'm somewhere I can't smoke cigarettes
- When I don't want to or can't go outside to smoke (e.g. bad weather)
- Other. Please state:
- None of the above

Participant ID number

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A17 Please indicate how much you agree or disagree with each statement below.

(Select one answer per row)

	Strongly disagree	Moderately disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Moderately agree	Strongly agree
Using an e-cigarette is as satisfying as smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using an e-cigarette reduces / reduced my urge to smoke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using an e-cigarette has helped me to quit smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using an e-cigarette has helped me to reduce the number of cigarettes I smoke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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YOUR SMOKING BEHAVIOUR AND BELIEFS

Everyone should answer this section (Questions B1 to B5)

B1 When did you last smoke any cigarettes or tobacco (even a puff)?

- | | |
|--|---|
| <input type="checkbox"/> In the last 24 hours | <input type="checkbox"/> 1-2 months ago |
| <input type="checkbox"/> 1-6 days ago | <input type="checkbox"/> 2-3 months ago |
| <input type="checkbox"/> 7-30 days ago | <input type="checkbox"/> More than 3 months ago |
| <input type="checkbox"/> I have never smoked cigarettes or tobacco | |

B2 Since finding out you were pregnant, have you tried to stop smoking?

- | | |
|---|--|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| <input type="checkbox"/> I stopped smoking before I became pregnant | <input type="checkbox"/> I have never smoked |

B3 Have you been pregnant before?

- Yes No

If Yes, did you smoke at all during your last pregnancy?

- Yes No I don't remember

B4 This time, were you planning to get pregnant or was it a surprise?

- Planning Was a surprise

Participant ID number

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B8 Are you seriously planning to quit smoking?

- Yes, within the next 2 weeks
- Yes, within the next 30 days
- Yes, within the next 3 months
- No, I am not seriously planning to quit

Participant ID number

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ABOUT YOU

Everyone should answer this section (Questions C1 to C3)

C1 At what age did you leave/finish full time education?

--	--

Years of age

I am still in education

C2 Which of the following qualifications do you have?

None

GCSEs or similar (e.g. level 1 diploma or NVQ level 1/2)

A-levels/AS-levels or similar (e.g. level 2 diploma or NVQ level 3)

Degree or similar (e.g. diploma in higher education or NVQ level 4)

Other (please specify)

--

C3 How would you describe your ethnic group?

White British

Black or Black British Caribbean

White Irish

Black or Black British African

Any other White background

Any other Black background

Mixed - White and Black Caribbean

Chinese

Mixed - White and Asian

Arab

Any other mixed background

Asian or Asian British - Indian

Other ethnic group. Please specify:

Asian or Asian British - Pakistani

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Asian or Asian British - Bangladeshi

Any other Asian background

Participant ID number

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Thank you for completing the questionnaire.

Please hand this to [the research midwife] in clinic who will give you a £10 shopping voucher and may talk with you about the rest of the study.

If you can't find [the research midwife], then please speak to one of the reception staff in clinic who will, if necessary, take your contact details so that [the research midwife] can get in touch with you later.

If you haven't had time to complete the entire questionnaire today, or if you want some more time to think about it, then please ask [the research midwife] or reception staff for a return envelope. Once you have decided, you can return the questionnaire along with your completed details on the attached sheet, and [a researcher from the University of Nottingham] will contact you.

Thank you for your time today. We are very grateful for your help.

Participant ID number

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CONTACT DETAILS

If you would like to continue to take part in the study, or you would like to discuss this further, then please complete your personal details below.

[A researcher from the University of Nottingham] will contact you as soon as possible

Name	
Address	
Telephone	Day: Evening:
	Mobile:
Best time to contact	
Email address	

Appendix 3.2: Pregnancy Lifestyle Survey Follow-up one

 University of Nottingham <small>UK CHINA MALAYSIA</small>																					
<i>Researchers' use only</i>																					
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 <i>Pregnant women's attitudes towards smoking and electronic cigarettes</i>																					
FOLLOW UP 1 QUESTIONNAIRE Final Version: 1.0 Version date: 20 th July 2017																					

Please complete this questionnaire **within the next 2 weeks** and then return it in the envelope provided (no stamp required). Once you have completed and returned the questionnaire, we will send you a £10 shopping voucher to thank you for your time and support.

The information you give us will be anonymous and only used by the Pregnancy Lifestyle Survey researchers.

If you have any questions or concerns about this questionnaire, please call the Smoking and Pregnancy Research Office on 0115 **XXX XXXX**

Thank you for your help

Today's date (please enter the date you completed this):

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dd / mm / yyyy

Participant ID number

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YOUR EXPERIENCE OF E-CIGARETTES

In this section, we would like you to answer some questions about your experiences of and views on e-cigarettes – even if you haven't used them.

Some questions are for everyone and others are for particular individuals (e.g., those currently using e-cigarettes).

Everyone should answer A1 to A8 below. After that, please follow the instructions about which questions to answer. Thank you.

A1 How often did you use an e-cigarette or vaping device during each of the following times? (Please tick one box for each time period)

	Not used at all	Only used once or twice	Used occasionally, but less than weekly	Used less than daily, but at least once a week	Used every day
Since you completed the first questionnaire when you joined this study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Now	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

A2 Do you know anyone who has used an e-cigarette *in pregnancy*? (tick as many as apply)

- Yes, a family member or friend Yes, someone else I know No

A3 Does anyone you know think *you* should use an e-cigarette in pregnancy instead of smoking cigarettes? (tick as many as apply)

- Yes, my partner Yes, another family member or friend Yes, a health professional (e.g., midwife, stop smoking advisor, GP)
- Yes, someone else I know No I have not discussed this with anyone

Participant ID number

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A4 We would like to know your views on using e-cigarettes in pregnancy.

Please indicate how much you agree or disagree with each statement below.

(Select one answer per row)

	Strongly disagree	Moderately disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Moderately agree	Strongly agree
E-cigarettes should be promoted to help pregnant women stop smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I'd be more likely to use an e-cigarette in pregnancy if a health professional recommended it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would feel comfortable using an e-cigarette in public while I am pregnant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would feel comfortable using an e-cigarette in public <i>after</i> having my baby	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E-cigarettes should only be used in the home or private places	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would take part in a research study that involved using an e-cigarette whilst I am pregnant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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A5 We would like to know your views on the safety of e-cigarettes in pregnancy.

Please indicate how much you agree or disagree with each statement below.

(Select one answer per row)

	Strongly disagree	Moderately disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Moderately agree	Strongly agree
Using e-cigarettes in pregnancy harms my unborn baby	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using e-cigarettes in pregnancy is as safe as using nicotine patches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using e-cigarettes in pregnancy is much less harmful than smoking tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nicotine is harmful to my unborn baby	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E-cigarettes should only be available on prescription	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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A6 Below are some reasons people may give for using e-cigarettes *in pregnancy*.

In the first column, please tick the reason that you think is the *most important*. In the second column, tick any other reasons that you think are important for using e-cigarettes in pregnancy.

	Most important reason for using e-cigarettes (tick one only)	Other reasons for using e-cigarettes (tick any you think are important)
To help me quit smoking	<input type="checkbox"/>	<input type="checkbox"/>
To help me cut down the number of tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
They are healthier than tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
They are cheaper than tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
They are less harmful to others around me than tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
They feel similar to smoking	<input type="checkbox"/>	<input type="checkbox"/>
They look fashionable / stylish	<input type="checkbox"/>	<input type="checkbox"/>
They taste and smell nicer than tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
I can use them in places where smoking is banned	<input type="checkbox"/>	<input type="checkbox"/>
It is more acceptable to be seen using e-cigarettes than smoking tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
Other reason (please state)	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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A7 Below are some reasons people may give for **NOT** using e-cigarettes *in pregnancy*.

In the first column, please tick the reason that you think is the *most important*. In the second column, tick any other reasons that you think are important for not using e-cigarettes in pregnancy.

	Most important reason for NOT using e-cigarettes (tick one only)	Other important reasons for NOT using e-cigarettes (tick any you think are important)
Bad stories in the press or on social media put me off them	<input type="checkbox"/>	<input type="checkbox"/>
Family or friends tell me not to use them	<input type="checkbox"/>	<input type="checkbox"/>
They don't get rid of the 'smoking habit'	<input type="checkbox"/>	<input type="checkbox"/>
They don't get rid of nicotine addiction	<input type="checkbox"/>	<input type="checkbox"/>
They don't satisfy my cravings for tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
There isn't enough research on them	<input type="checkbox"/>	<input type="checkbox"/>
I'd be too embarrassed to use them	<input type="checkbox"/>	<input type="checkbox"/>
I'd rather try other ways to quit smoking, such as nicotine patches	<input type="checkbox"/>	<input type="checkbox"/>
I'm worried about side effects	<input type="checkbox"/>	<input type="checkbox"/>
I get different messages from different people so I'm confused	<input type="checkbox"/>	<input type="checkbox"/>
Other reason (please state)	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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A8 How likely are you to try or use e-cigarettes in the future?

i. While you are still pregnant:

- Very likely
- Somewhat likely
- Neither likely nor unlikely (neutral)
- Somewhat unlikely
- Very unlikely
- I don't know

ii. Once your baby is born:

- Very likely
- Somewhat likely
- Neither likely nor unlikely (neutral)
- Somewhat unlikely
- Very unlikely
- I don't know

If you currently use e-cigarettes, even if this is not every day, please answer Questions A9 to A17
If you do not currently use e-cigarettes, please go to Question B1 on page 11

A9 How soon after you wake up do you first use your e-cigarette?

- Within 5 minutes
- 6-30 minutes
- 31-60 minutes
- After 60 minutes

Participant ID number

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A10 What type of electronic cigarette or vaping device do you use the most?
SELECT ONE OPTION

- A disposable e-cigarette or vaping device (non-rechargeable)
- A rechargeable e-cigarette or vaping device that uses replaceable pre-filled cartridges
- A rechargeable e-cigarette or vaping device with a tank that you can refill with fluids
- A rechargeable modular system that you refill with liquids (you use your own combination of separate parts: battery, atomiser, fluid etc.)
- Don't know

A11 What strength of e-liquid / fluid / juice / cartridge do you usually use?
SELECT ONE OPTION

- Zero (contains no nicotine)
- Low (up to 6mg (0.6%) nicotine)
- Medium (between 7 and 12mg (0.7-1.2%) of nicotine)
- High (between 13 and 20mg (1.3-2.0%) of nicotine)
- Very high (more than 20mg (2.0%) of nicotine)
- It contains nicotine, but I don't know what strength
- I don't know if it contains nicotine

A12 Please try to estimate how much on average you use your e-cigarette per day

Number of mls of fluid / juice

--

Number of cartridges

--

Don't know

A13 Have you changed how much you use e-cigarettes since you completed the first questionnaire when you joined the study?
SELECT ONE OPTION

- Yes, I tend to use them less now
- Yes, I tend to use them more now
- No, I tend to use them about the same now
- Not applicable. I wasn't using an e-cigarette when I joined the study
- Don't know / can't remember

Participant ID number

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A14 Which is your preferred e-cigarette flavour category?
SELECT ONE OPTION

- Tobacco
- Tobacco menthol, menthol or mint
- Some other flavour like fruit, candy, alcohol, coffee, vanilla etc.
- No flavour
- Don't know

A15 What is your main reason for using an e-cigarette? **(SELECT ONE OPTION)**

- To quit smoking
- To cut down smoking
- To use when I cannot or am not allowed to smoke
- To avoid returning to smoking
- Because I enjoy it
- Curiosity / just wanted to try them
- Some other reason (please state)
- Don't know

Participant ID number

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A16 When do you tend to use an e-cigarette? (Please tick all that apply)

- When I get a craving to smoke or vape
- When I experience withdrawal symptoms like feeling restless, or irritable
- When I am feeling low
- When socialising
- When I see someone smoking
- First thing in the morning
- After a meal
- When I'm angry or stressed
- When I'm bored
- When I'm somewhere I can't smoke tobacco cigarettes
- When I don't want to or can't go outside to smoke (e.g. bad weather)
- Other. Please state:
- None of the above

A17 Please indicate how much you agree or disagree with each statement below.

(Select one answer per row)

	Strongly disagree	Moderately disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Moderately agree	Strongly agree
Using an e-cigarette is as satisfying as smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using an e-cigarette reduces / reduced my urge to smoke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using an e-cigarette has helped me to quit smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using an e-cigarette has helped me to reduce the number of tobacco cigarettes I smoke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would like to stop using e-cigarettes as well as tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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FEEDING YOUR BABY

Everyone should complete this section (Question B1 to B2)

B1 Which statement best represents the way you plan to feed your new baby in the first week after birth? (SELECT ONE OPTION)

- I intend to breastfeed only (from the breast and/or expressed breast milk)
- I intend to formula feed only
- I intend to combine breastfeeding and formula feeding
- I am unsure

B2 Which statement best represents the way you plan to feed your new baby in the first 6 months after birth? (SELECT ONE OPTION)

- I intend to breastfeed only (from the breast and/or expressed breast milk)
- I intend to formula feed only
- I intend to combine breastfeeding and formula feeding
- I am unsure

YOUR SMOKING BEHAVIOUR AND BELIEFS

Everyone should answer this section (about tobacco smoking) (Questions C1 to C4)

C1 Please tick the box next to the box that best describes your smoking right now

- I don't smoke at all
- I smoke occasionally, but not every day
- I smoke every day, but have cut down during my pregnancy
- I smoke every day, about the same as before my pregnancy
- I smoke every day, and tend to smoke more than before my pregnancy

Participant ID number

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C2 Have you smoked at all since you completed the first questionnaire when you joined this study?

Yes

No

I can't remember

Not applicable – I have never smoked tobacco cigarettes

C3 Since you completed the first study questionnaire, have you tried to stop smoking?

Yes

No

Not applicable - I haven't smoked at all since I completed the first questionnaire

Not applicable - I have never smoked

C4 If you currently smoke, or have stopped smoking, please answer each of the following questions by circling the appropriate number. Please circle one number per question.

	Not at all	A little	Moderately	Very much	Extremely
How determined are you to stop smoking until your baby is born?	1	2	3	4	5
How confident are you that you can stop smoking until your baby is born?	1	2	3	4	5
How determined are you to stop smoking for good?	1	2	3	4	5
How confident are you that you can stop smoking for good?	1	2	3	4	5

If you **SMOKE EVERY NOW & AGAIN** or **MORE OFTEN THAN THIS** please answer questions C5 to C7

If you **DO NOT SMOKE AT THE MOMENT** you have finished – please return the questionnaire in the envelope provided. Thank you for your help.

Participant ID number

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C5 Approximately how many cigarettes do you smoke each day?

- | | |
|--------------------------------|-------------------------------------|
| <input type="checkbox"/> 0-5 | <input type="checkbox"/> 16-20 |
| <input type="checkbox"/> 6-10 | <input type="checkbox"/> 21-30 |
| <input type="checkbox"/> 11-15 | <input type="checkbox"/> 31 or more |

C6 How soon after you wake up do you smoke your first cigarette of the day?

- | | |
|---|---|
| <input type="checkbox"/> Within 5 minutes | <input type="checkbox"/> 31-60 minutes |
| <input type="checkbox"/> 6-30 minutes | <input type="checkbox"/> After 60 minutes |


C7 Are you seriously planning to quit smoking?


- Yes, within the next 2 weeks
- Yes, within the next 30 days
- Yes, within the next 3 months
- No, I am not seriously planning to quit

**Thank you for completing the questionnaire – we are very grateful
for your help.**

Please return in the envelope provided (no stamp required).

Appendix 3.3: Pregnancy Lifestyle Survey Follow-Up two

 <p>University of Nottingham UK CHINA MALAYSIA</p>	<p><i>Researchers' use only</i></p> <p>Participant ID number</p> <table border="1" style="border-collapse: collapse; width: 100%;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">-</td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">-</td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td style="font-size: 8px; text-align: center;">Site number</td> <td colspan="4" style="font-size: 8px; text-align: center;">Participant number</td> <td colspan="5" style="font-size: 8px; text-align: center;">Institute</td> </tr> </table> <p>Date returned</p> <table border="1" style="border-collapse: collapse; width: 100%;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">/</td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">/</td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td style="font-size: 8px; text-align: center;">D</td> <td style="font-size: 8px; text-align: center;">D</td> <td></td> <td style="font-size: 8px; text-align: center;">M</td> <td style="font-size: 8px; text-align: center;">M</td> <td></td> <td style="font-size: 8px; text-align: center;">Y</td> <td style="font-size: 8px; text-align: center;">Y</td> <td style="font-size: 8px; text-align: center;">Y</td> <td style="font-size: 8px; text-align: center;">Y</td> </tr> </table> <p>Researcher's initials</p> <table border="1" style="border-collapse: collapse; width: 100%;"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>			-				-				Site number	Participant number				Institute							/			/					D	D		M	M		Y	Y	Y	Y			
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Pregnant women's attitudes towards smoking and electronic cigarettes

FOLLOW UP 2 QUESTIONNAIRE
Final Version: 2.0
Version date: 30th October 2017

Please complete this questionnaire **within the next 2 weeks** and then return it in the envelope provided (no stamp required). Once you have completed and returned the questionnaire, we will send you a £10 shopping voucher to thank you for your time and support.

The information you give us will be anonymous and only used by the Pregnancy Lifestyle Survey researchers.

If you have any questions or concerns about this questionnaire, please call the Smoking and Pregnancy Research Office on 0115 **XXX XXXX**

Thank you for your help

Today's date (please enter the date you completed this):

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dd / mm / yyyy

Participant ID number

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YOUR EXPERIENCE OF E-CIGARETTES

In this section, we would like you to answer some questions about your experiences of and views on e-cigarettes – even if you haven't used them.

Some questions are for everyone and others are for particular individuals (e.g., those currently using e-cigarettes).

Everyone should answer A1 to A8 below. After that, please follow the instructions about which questions to answer. Thank you.

A1 How often did you use an e-cigarette or vaping device during each of the following times? (Please tick one box for each time period)

	Not used at all	Only used once or twice	Used occasionally, but less than weekly	Used less than daily, but at least once a week	Used every day
In the week before the birth of your baby	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
In the first 2 months after the birth of your baby	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Now	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

A2 Now that you've had your baby, does anyone you know think you should use an e-cigarette instead of smoking cigarettes? (tick as many as apply)

- Yes, my partner Yes, another family member or friend Yes, a health professional (e.g., health visitor, midwife, stop smoking advisor, GP)
- Yes, someone else I know No I have not discussed this with anyone

Participant ID number

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A3 We would like to know your views on using e-cigarettes after having your baby.

Please indicate how much you agree or disagree with each statement below.

(Select one answer per row)

	Strongly disagree	Moderately disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Moderately agree	Strongly agree
E-cigarettes should be promoted to help women who have recently given birth to <i>stop</i> smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E-cigarettes should be promoted to help women who have recently given birth to help prevent them from <i>restarting</i> smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E-cigarettes should be promoted to help people with babies and young children keep their homes smoke free	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Now that I have had my baby, I'd be more likely to use an e-cigarette if a health professional recommended it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Now I have had my baby I would feel more comfortable using an e-cigarette in public compared to when I was pregnant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E-cigarettes should only be used in the home or private places	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would be happy for e-cigarettes to be used in my home when my baby is in the <i>same</i> room	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would be happy for e-cigarettes to be used in my home when my baby is in a <i>different</i> room	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would be concerned that if my child saw me using e-cigarettes it would be setting them a bad example	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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A4 We would like to know your views on the safety of e-cigarettes *after having a baby*.

Please indicate how much you agree or disagree with each statement below.

(Select one answer per row)

	Strongly disagree	Moderately disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Moderately agree	Strongly agree
Using e-cigarettes around my baby may cause them harm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using e-cigarettes around my baby is much less harmful than smoking tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E-cigarettes should only be available on prescription	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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A5 Below are some reasons people may give for using e-cigarettes *after having a baby*.

In the first column, please tick the reason that you think is the *most important*. In the second column, tick any other reasons that you think are important for using e-cigarettes after having a baby.

	Most important reason for using e-cigarettes (tick one only)	Other reasons for using e-cigarettes (tick any you think are important)
To help me quit smoking	<input type="checkbox"/>	<input type="checkbox"/>
To help me cut down the number of tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
They are healthier than tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
They are cheaper than tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
They are less harmful to others around me than tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
They feel similar to smoking	<input type="checkbox"/>	<input type="checkbox"/>
They look fashionable / stylish	<input type="checkbox"/>	<input type="checkbox"/>
They taste and smell nicer than tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
To avoid my home or clothes smelling of tobacco smoke	<input type="checkbox"/>	<input type="checkbox"/>
I can use them in places where smoking is banned	<input type="checkbox"/>	<input type="checkbox"/>
It is more acceptable to be seen using e-cigarettes than smoking tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
Other reason (please state)	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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A6 Below are some reasons people may give for **NOT** using e-cigarettes *after having a baby*.

In the first column, please tick the reason that you think is the *most important*. In the second column, tick any other reasons that you think are important for not using e-cigarettes after having a baby.

	Most important reason for NOT using e-cigarettes (tick one only)	Other important reasons for NOT using e-cigarettes (tick any you think are important)
Bad stories in the press or on social media put me off them	<input type="checkbox"/>	<input type="checkbox"/>
Family or friends tell me not to use them	<input type="checkbox"/>	<input type="checkbox"/>
They don't get rid of the 'smoking habit'	<input type="checkbox"/>	<input type="checkbox"/>
They don't get rid of nicotine addiction	<input type="checkbox"/>	<input type="checkbox"/>
They don't satisfy my cravings for tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>
There isn't enough research on them	<input type="checkbox"/>	<input type="checkbox"/>
I'd be too embarrassed to use them	<input type="checkbox"/>	<input type="checkbox"/>
I'd rather try other ways to quit smoking, such as nicotine patches	<input type="checkbox"/>	<input type="checkbox"/>
I'm worried about side effects	<input type="checkbox"/>	<input type="checkbox"/>
I get different messages from different people so I'm confused	<input type="checkbox"/>	<input type="checkbox"/>
Other reason (please state)	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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A7 How likely are you to try or use e-cigarettes in the future?

- Very likely
- Somewhat likely
- Neither likely nor unlikely (neutral)
- Somewhat unlikely
- Very unlikely
- I don't know

A8 We would like to know about smoking and e-cigarette use in your home.

(Please select one answer for each question)

	Never	Almost never	Sometimes	Fairly often	Very often
How often do you smoke tobacco cigarettes in your home nowadays?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How often do other people smoke tobacco cigarettes in your home nowadays?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How often do you use an e-cigarette in your home nowadays?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How often do other people use an e-cigarette in your home nowadays?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If you currently use e-cigarettes, even if this is not every day, please answer Questions A9 to A17
If you do not currently use e-cigarettes, please go to Question B1 on page 11

A9 How soon after you wake up do you first use your e-cigarette?

- Within 5 minutes
- 6-30 minutes
- 31-60 minutes
- After 60 minutes

Participant ID number

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A10 What type of electronic cigarette or vaping device do you use the most?
SELECT ONE OPTION

- A disposable e-cigarette or vaping device (non-rechargeable)
- A rechargeable e-cigarette or vaping device that uses replaceable pre-filled cartridges
- A rechargeable e-cigarette or vaping device with a tank that you can refill with fluids
- A rechargeable modular system that you refill with liquids (you use your own combination of separate parts: battery, atomiser, fluid etc.)
- Don't know

A11 What strength of e-liquid / fluid / juice / cartridge do you usually use?
SELECT ONE OPTION

- Zero (contains no nicotine)
- Low (up to 6mg (0.6%) nicotine)
- Medium (between 7 and 12mg (0.7-1.2%) of nicotine)
- High (between 13 and 20mg (1.3-2.0%) of nicotine)
- Very high (more than 20mg (2.0%) of nicotine)
- It contains nicotine, but I don't know what strength
- I don't know if it contains nicotine

A12 Please try to estimate how much on average you use your e-cigarette per day

Number of mls of fluid / juice

Number of cartridges

Don't know

A13 Have you changed how much you use e-cigarettes since giving birth?
SELECT ONE OPTION

- Yes, I tend to use them less now
- Yes, I tend to use them more now
- No, I tend to use them about the same now
- Not applicable. I didn't use an e-cigarette during my pregnancy
- Don't know / can't remember

Participant ID number

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A14 Which is your preferred e-cigarette flavour category?
SELECT ONE OPTION

- Tobacco
- Tobacco menthol, menthol or mint
- Some other flavour like fruit, candy, alcohol, coffee, vanilla etc.
- No flavour
- Don't know

A15 What is your main reason for using an e-cigarette? (**SELECT ONE OPTION**)

- To quit smoking
- To cut down smoking
- To use when I cannot or am not allowed to smoke
- To avoid returning to smoking
- Because I enjoy it
- Curiosity / just wanted to try them
- To use instead of smoking tobacco cigarettes around my baby
- Some other reason (please state)
- Don't know

Participant ID number

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A16 When are you likely to use an e-cigarette? (Please tick all that apply)

- When I get a craving to smoke or vape
- When I experience withdrawal symptoms like feeling restless, or irritable
- When I am feeling low
- When socialising
- When I see someone smoking
- First thing in the morning
- After a meal
- When I'm angry or stressed
- When I'm bored
- When I'm somewhere I can't smoke tobacco cigarettes
- When I don't want to or can't go outside to smoke (e.g. bad weather, or can't leave the baby)
- Other. Please state:
- None of the above

Participant ID number

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A17 Please indicate how much you agree or disagree with each statement below.

(Select one answer per row)

	Strongly disagree	Moderately disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Moderately agree	Strongly agree
Using an e-cigarette is as satisfying as smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using an e-cigarette reduces / reduced my urge to smoke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using an e-cigarette has helped me to quit smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using an e-cigarette has helped me to reduce the number of tobacco cigarettes I smoke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I don't want to stop smoking completely. I want to carry on smoking tobacco cigarettes as well as using e-cigarettes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would like to stop using e-cigarettes as well as tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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YOUR BABY

Everyone should complete this section (Questions B1 to B7)

B1 Is your baby one of twins, triplets or other multiple birth?

- No
- Yes, twin
- Yes, triplets or other multiple birth

If you have twins or triplets, please complete the questions in this section about the baby who was born first.

B2 How much did your baby weigh when he/she was born?

Either in pounds and ounces:

<input type="text"/>	<input type="text"/>	lb	<input type="text"/>	<input type="text"/>	oz
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Or in kilograms:

<input type="text"/>	•	<input type="text"/>	<input type="text"/>	kg
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Don't know

B3 Which statement best represents the way you planned to feed your new baby in the first week after birth? (SELECT ONE OPTION)

- I intended to breastfeed only (from the breast and/or expressed breast milk)
- I intended to formula feed only
- I intended to combine breastfeeding and formula feeding
- I was unsure

Participant ID number

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B4 Which statement best represents the way you fed your new baby in the first week after birth? (SELECT ONE OPTION)

- I breastfed exclusively from birth (from the breast and/or expressed breast milk)
- I formula fed exclusively from birth
- I combined breastfeeding and formula feeding from birth

B5 Which statement best represents the way you feed your baby now? (SELECT ONE OPTION)

- I am just breastfeeding (from the breast and/or expressed breast milk)
- I am just formula feeding
- I combine breastfeeding and formula feeding

B6 How old was your baby when they last had breast milk (from the breast or expressed breast milk)? (SELECT ONE OPTION)

- Never had breast milk
- Less than 1 week
- Less than 1 month
- Over 1 month, but I've stopped breastfeeding now
- I'm still breastfeeding

B7 We would like to know your views on e-cigarettes, smoking and breastfeeding.

Please indicate how much you agree or disagree with each statement below.

(Select one answer per row)

	Strongly disagree	Moderately disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Moderately agree	Strongly agree
Mothers should not breastfeed if they smoke tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mothers should not breastfeed if they use e-cigarettes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using e-cigarettes when breastfeeding is safe for the baby	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using e-cigarettes when breastfeeding is as safe for the baby as using nicotine patches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If a mother breastfeeds, it is safer for the baby if she uses an e-cigarette than if she smokes tobacco cigarettes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Participant ID number

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YOUR SMOKING BEHAVIOUR AND BELIEFS

Everyone should answer this section (about tobacco smoking) (Questions C1 to C5)

- C1 Please tick the box next to the statement that best describes your smoking right now
- I don't smoke at all
- I smoke occasionally, but not every day
- I smoke every day, but less than when I was pregnant
- I smoke every day, about the same as when I was pregnant
- I smoke every day, and tend to smoke more than when I was pregnant
- C2 Did you smoke at all in the week before the birth of your baby?
- Yes No
- I can't remember Not applicable - I have never smoked
- C3 Have you smoked at all since the birth of your baby?
- Yes No
- If Yes, how soon after the birth of your baby did you first smoke?
- Within 24 hours 1-2 months
- 1-6 days More than 2 months
- 7-30 days
- C4 Since the birth of your baby, have you tried to stop smoking?
- Yes No
- Not applicable - I haven't smoked since the birth of my baby Not applicable - I have never smoked

Participant ID number

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C5 If you currently smoke, or have stopped smoking, please answer each of the following questions by circling the appropriate number. Please circle one number per question.

	Not at all	A little	Moderately	Very much	Extremely
How determined are you to stop smoking for good?	1	2	3	4	5
How confident are you that you can stop smoking for good?	1	2	3	4	5

C6 Before your last pregnancy had you ever tried any of the following to help you stop smoking? (Please tick all that apply)

- Talked to your GP or a nurse about giving up smoking
- Talked to a midwife about giving up smoking
- Attended a NHS stop smoking service group session
- Attended a solo/individual NHS stop smoking service session (i.e. not with other people)
- Called a stop smoking telephone helpline
- Used Nicotine Replacement Therapy (NRT) (e.g. nicotine patches or gum)
- Set a quit date
- Other. Please state:
- None of the above

C7 When you were pregnant, did you try any of the following to help you stop smoking / remain stopped? (Please tick all that apply)

- Talked to your GP or a nurse about giving up smoking
- Talked to a midwife about giving up smoking
- Attended a NHS stop smoking service group session
- Attended a solo/individual NHS stop smoking service session (i.e. not with other people)
- Called a stop smoking telephone helpline
- Used Nicotine Replacement Therapy (NRT) (e.g. nicotine patches or gum)
- Set a quit date
- Other. Please state:
- None of the above

Participant ID number

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C8 Since having your baby, have you tried any of the following to help you stop smoking / remain stopped? (Please tick all that apply)

- Talked to your GP or a nurse about giving up smoking
- Talked to a midwife or health visitor about giving up smoking
- Attended a NHS stop smoking service group session
- Attended a solo/individual NHS stop smoking service session (i.e. not with other people)
- Called a stop smoking telephone helpline
- Used Nicotine Replacement Therapy (NRT) (e.g. nicotine patches or gum)
- Set a quit date
- Other. Please state:
- None of the above

If you SMOKE EVERY NOW & AGAIN or MORE OFTEN THAN THIS please answer questions C6 to C8
If you DO NOT SMOKE AT THE MOMENT you have finished – please return the questionnaire in the envelope provided. Thank you for your help.

C9 Approximately how many cigarettes do you smoke each day?

- 0-5
- 6-10
- 11-15
- 16-20
- 21-30
- 31 or more

C10 How soon after you wake up do you smoke your first cigarette of the day?

- Within 5 minutes
- 6-30 minutes
- 31-60 minutes
- After 60 minutes

Participant ID number

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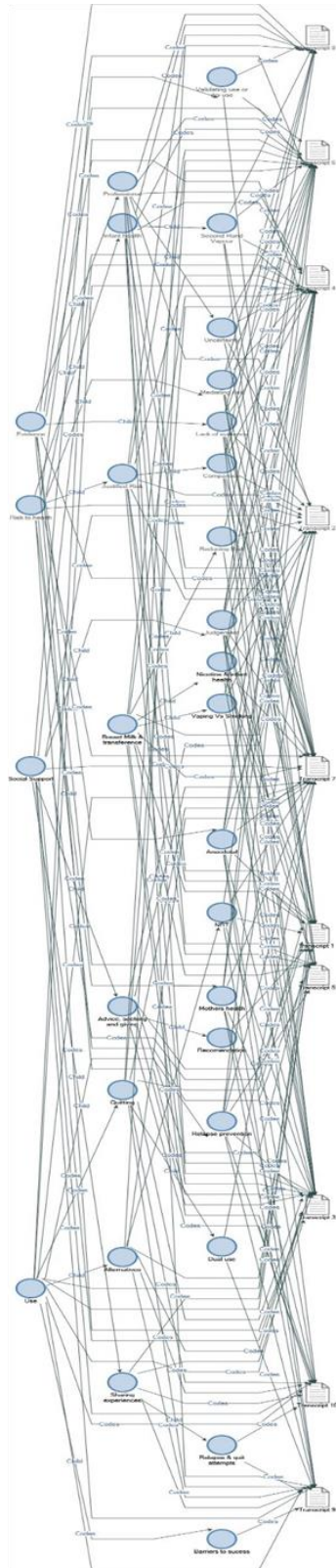
C11 Are you seriously planning to quit smoking?

- Yes, within the next 2 weeks
- Yes, within the next 30 days
- Yes, within the next 3 months
- No, I am not seriously planning to quit

Thank you for completing the questionnaire – we are very grateful for your help.

Please return in the envelope provided (no stamp required).

Appendix 4.1: Integrative themes map



Appendix 5.1: Moderators message

Hello

I'm a PhD student at the University of Nottingham exploring the use of e-cigarettes & vapes in the postpartum period. I'm hoping to explore whether the use of an e-cigarette or vape could reduce smoking postpartum, and by consequence, increase UK breastfeeding rates.

I am currently conducting an online survey looking to understand the experiences of mothers who smoke and/or vape during the postpartum period, and how this may impact on how they chose to feed their babies. The survey is short and should take up to 10 minutes to complete, and has been ethically approved by the University of Nottingham School of Medicine Ethics committee.

I'd be grateful if you could allow me to post a link to the survey in your group? I'm happy to answer any questions you may have, you can contact me directly at msxejj@nottingham.ac.uk

Kindest Regards

Emily Johnston

University of Nottingham

Smoking & Vaping postpartum

Research exploring what it's like to be a smoking or vaping mother – share your experiences

Do you have a baby aged 0-18 months? Do you smoke and/or vape? We want to hear about your experiences!

We are looking for participants for a short online questionnaire to better understand your experiences of smoking, vaping and feeding your baby. The questionnaire will take up to 10 minutes to complete and will be used to form part of a PhD thesis.

To take part simply click the link below

Thank you – your participation is greatly appreciated

Appendix 5.3: Participant information sheet and consent

Smoking & vaping mothers experiences in 2019

46% complete

Information and consent

Introduction/participant information:

I'm Emily Johnston, a PhD student at the University of Nottingham supervised by Dr Sue Cooper, we would like to invite you to take part in a research study that will form part of my PhD. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please carefully read the following information, if you have any questions or would like further information before proceeding, please contact me using the details below.

What is the purpose of the research?

The purpose of this research is to understand the experiences of mothers who smoke and/or vape during the postpartum period, and how this may affect the way they feed their babies. We want to understand more about any judgement that smoking/vaping mothers may experience and any difficulties they may have come across. The survey should take around 10 minutes to complete.

Why have I been invited to take part?

As a mother (who smokes and/or vapes) with a baby aged 0-18 month, we would really appreciate hearing about your experiences.

Do I have to take part?

No. It is up to you to decide if you want to take part in this research. If you agree to participate, we will ask you to tick the box below to give your consent. You are free to withdraw from the study at any time, without giving a reason and without any negative consequences, by advising the researchers of this decision. This would not affect your legal rights.

Confidentiality

All data we collect is anonymous and you will not be asked to provide any personal data. To help ensure your privacy, you will be assigned a volunteer study identification number, and it will be used instead of your name.

The research will be written up as a thesis and academic paper(s). Some direct quotes might be used in these publications, but they will be kept anonymous, to ensure participants cannot be identified from these quotes.

This study has been reviewed and given favourable opinion by the Faculty of Medicine and Health Sciences Research Ethics Committee at the University of Nottingham

If you have a concern about any aspect of this project, please speak to the researcher Emily Johnston, who will do their best to answer your query (contact details below). The researcher should acknowledge your concern within 10 working days and give you an indication of how she intends to deal with it. If you remain unhappy and wish to complain formally, you can do this by contacting the FMHS Research Ethics Committee Administrator, c/o The University of Nottingham, Faculty PVC Office, B Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH. E-mail: FMHS-ResearchEthics@nottingham.ac.uk

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Emily Johnston

Email: msxejj@nottingham.ac.uk

This study is independent research funded by the National Institute for Health Research School for Primary Care Research (NIHR SPCR). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health

Please read the following statements and check the box to give your consent to be part of this study:

I confirm that I have read and understand the information above about this study and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. I understand that should I withdraw more than 7 days after the survey has taken place, then the information collected so far cannot be erased and that this information may still be used in the study analysis. I understand that information collected during the study will be made anonymous before it is stored. It will be uploaded into a secure database on a computer kept in a secure place. Data will be kept for 7 years after the study has ended and then destroyed. I give consent for any quotes I give (anonymised) to be used in the publication of this research. I agree to take part in the above study. * *Required*

Yes

No

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Appendix 5.4: Screening survey

Smoking & vaping mothers experiences in 2019

0% complete

Screening Questionnaire

Do you have a child aged 0-18 months? * Required

Yes No

Have you given birth in the last 18 months? * Required

Yes No

Are you aged 18yrs or over? * Required

Yes No

Do you smoke, vape or use an e-cigarette? * Required

Yes No

Do you, or have you ever, worked for a tobacco or vape/e-cigarette company? * Required

Yes No

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Appendix 5.5: Full questionnaire

Smoking & vaping mothers experiences in 2019

61% complete

Background Questionnaire

For this research we are interested in understanding what it is like to be a new mother who smokes or vapes – particularly in relation to how you feed your baby. Please answer the following questions to help us understand your current situation:

How old is your baby(ies)? Please answer for your youngest child aged 0-18 months. * Required

- Less than 1 month 1-2 months 2-4 months
 4-6 months 6-9 months 9-12 months
 12-18 months

Please select the statement that best describes your use of e-cigarettes/vapes right now: * Required

Please select

Please select the statement that best describes your smoking right now: * Required

Please select

How would you describe your smoking when you were last pregnant?

Please select

How would you describe your e-cig/vape use when you were last pregnant?

Please select

Are you currently breastfeeding? * Required

- Yes No

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Appendix 6.1: Health Visitor study protocol

STUDY PERSONNEL AND CONTACT DETAILS

Sponsor: Contact name	University of Nottingham Ms Angela Shone Research and Innovation University of Nottingham East Atrium Jubilee Conference Centre Triumph Road Nottingham NG8 1DH
Chief investigator:	Emily Johnston, PhD student, Smoking in Pregnancy, School of Medicine Phone: 07484639774 Email: msxejj@nottingham.ac.uk
Co-investigators:	Dr Sue Cooper : mczsec@exmail.nottingham.ac.uk Prof. Tim Coleman: cztic2@exmail.nottingham.ac.uk Dr Katarzyna Campbell: mczkac@exmail.nottingham.ac.uk Prof. Sarah Lewis: mszsal@exmail.nottingham.ac.uk Dr. Sophie Orton: mczso@exmail.nottingham.ac.uk
Study Coordinating Centre:	Name and address of coordinating centre (UoN School of Medicine)

SYNOPSIS

Title	Health Visitors' understanding, beliefs and experiences of discussions with new mothers on Breastfeeding, Smoking & Vaping: qualitative study
Short title	Breastfeeding, Smoking & Vaping: Health Visitor perspectives
Chief Investigator	Emily Johnston
Objectives	<p>To understand Health Visitors perception of their role in asking and advising woman about smoking, breastfeeding and e-cigarettes</p> <ul style="list-style-type: none"> - Understand and explore health visitors understanding of the smoking-breastfeeding association - Explore what conversations HV's are having with mothers about smoking - To explore Health Visitors' attitudes & beliefs about e-cigarette use postpartum - To understand what conversations (if any) Health Visitors are having about e-cigarettes - Identify potential training needs for Health Visitors to be able to discuss e-cigarettes with new mothers - Explore barriers and motivators to discussing smoking, breastfeeding and e-cigarettes
Study Configuration	Qualitative study using semi-structured interviews with Health Visitors
Setting	Face to face & telephone
Number of participants	20-25 Health Visitors in the UK
Eligibility criteria	<p>≥18 years of age</p> <p>Willing to give informed consent</p> <p>Currently working in the NHS as a health visitor</p>
Description of interventions	A semi structured interview with each participant, either in person or via telephone interview
Duration of study	Recruitment to begin in June 2018, participants are only required for one interview, anticipated duration is 6 months from recruitment
Methods of analysis	Semi-structured interviews will be transcribed and analysed in NVivo (11) using a Framework Analysis.

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ABBREVIATIONS

CI	Chief Investigator overall
HV	Health Visitor
CRF	Case Report Form
GCP	Good Clinical Practice
NHS	National Health Service
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
REC	Research Ethics Committee
R&D	Research and Development department
UoN	University of Nottingham

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STUDY BACKGROUND INFORMATION AND RATIONALE

Many women stop smoking during pregnancy but relapse postpartum is common. Smoking cessation in pregnancy may be influenced by the intrinsic motivation to protect the unborn baby from harm, due to the well-known detrimental effects of smoking on the unborn foetus [1-3]. This intrinsic motivation may account for the higher rates of spontaneous quitting amongst pregnant women compared to the general smoking population [4-6], but may explain the high rates of relapse observed postpartum [7], as the intrinsic motivation of delivering a healthy baby has been removed.

Smoking relapse postpartum exposes the infant to potential morbidity and mortality. Infants exposed to tobacco smoke have an increased risk of sudden infant death syndrome [8], respiratory tract illness [9], asthma [10], ear infections [11] and double the risk of developing meningitis [12]. As well as risks to the infant, smoking continues to adversely affect the mother's health; even with low intensity smoking (< 10 cigarettes a day) the risk of all-cause mortality is elevated [13], as well as inhibiting the immune response [14] and increasing the acute risk of respiratory infection [15], cardiovascular [16] and coronary disease [17]. Parental smoking is also a predictor of adolescent smoking, therefore mothers' relapse also increases children's risk of smoking in later life [18].

Studies have consistently reported associations between postpartum smoking and breastfeeding patterns [19-22]. The initiation and continuation of breastfeeding is positively associated with smoking abstinence in postpartum women [23, 24]. Research suggests that the intention to breastfeed acts as a precipitating factor for reducing postpartum relapse [25]. Research has also supported the intention to return to smoking as the strongest predictor of the intention not to breastfeed, as well as mothers who smoke being more likely to wean from the breast early (< 3 months postpartum) [20, 26].

As well as the health benefits of reducing postpartum smoking, increasing the rates of breastfeeding will also improve health outcomes. The prevalence of breastfeeding at 6–8 weeks is a key indicator of child health and wellbeing [27]. Globally, if breastfeeding rates were increased to near-total levels over 800,000 children's lives a year worldwide could be saved, as well as the prevention of 20,000 deaths from breast cancer every year [28]. The UK has one of the lowest breastfeeding rates in the world [29], and as explained above, smoking and breastfeeding rates are linked, so tackling smoking postpartum could increase UK breastfeeding rates.

There is some evidence of the success of smoking cessation interventions in pregnancy but less evidence for what is effective at preventing post-partum relapse to smoking. Pharmacological interventions have some success during pregnancy [30] particularly if supported by behavioural therapy [7, 31]. Behavioural interventions to aid smoking cessation in pregnancy have included peer support [32] (since living with/around smokers is a risk factor for relapse [33]), as well as health care professionals – such as a nurse, midwife, doctor or smoking cessation advisor who provide counselling and advice in combination with self-help literature [34, 35]. However, results for

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maintained abstinence postpartum are mixed – whilst some studies show that abstinence was significantly higher in treatment groups at 12 months postpartum [36], other studies have shown no difference between control and treatment groups [37]. Cash incentives have also been used to improve cessation rates during pregnancy [38].

For women who are at risk of relapse to smoking, or who have started smoking postnatally, trying to minimise harm from their nicotine addiction could be worth exploring. Currently, mothers who relapse to smoking are advised about safe sleeping, washing hands after smoking, maximising the time between smoking and handling the child and maintaining a smoke-free home [39]. Even if a mother only smokes outside the home, mothers who smoke will be transferring harmful toxins via dermal contact, exhaled second hand smoke and via breastmilk [40]– with those infants not receiving breastmilk at increased risk of smoking related morbidity and mortality [41, 42].

A relatively new method of nicotine delivery is the e-cigarette. Whilst mimicking the physical process of smoking [43], e-cigarettes also provide a more naturalistic delivery of nicotine (inhaled) compared to other nicotine delivery products (gum, patches etc.). Research suggests that e-cigarettes pose only a small fraction of the risks of smoking [44], Public Health England (PHE) published a report highlighting that e-cigarettes are at least 95% less harmful than traditional cigarettes [45]. The use of an e-cigarette postpartum could also offer a financial incentive for new mothers, as the cost of an e-cigarette and liquid is much lower than the price of cigarettes [46], and by communicating the reduced health risks we can continue to support the intrinsic motivation to be smoke free that helped maintain abstinence during pregnancy [47].

In our previous research,(as yet unpublished) we have shown women report using e-cigs postpartum to prevent themselves relapsing to smoking, however many women were concerned about the health implications of using e-cigs, with some women preferring to smoke traditional cigarettes owing to the known risks as opposed to the unknown risks of e-cigs. Women were accessing advice from unreliable sources and relying on anecdotal accounts from other lay people to inform their choice about e-cigs. Therefore it is important we ensure they receive advice from reliable sources that are easily accessible to new mothers.

In the UK, a consistent form of postnatal care is by delivered by health visitors via 5 core interactions with women – 1) prior to birth, 2) 2 weeks post birth, 3) 6-8 weeks post birth, 4) 9-12 months post birth and 5) 18 -24months post birth [48]. As well as core visits, health visitors are on hand at weekly weigh in/drop in clinics where mothers can turn up without appointment for advice. Health visitors already discuss breastfeeding, and are under pressure to increase the breastfeeding rates within the UK [49] as well as reducing postpartum smoking rates as part of their 5 core interactions [39]. Therefore Health Visitor input during these visits could be an ideal opportunity to discuss e-cigarettes with mothers who have relapsed or are high risk. Equipping health visitors with the knowledge to discuss e-cigarettes, and helping open a dialogue for mothers who may consider using them via information at drop in clinics

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could reduce relapse to smoking postpartum and/or reduce exposure to cigarette smoke for both mother and baby.

No research currently exists as to what health visitors currently believe about e-cigarettes, what discussions they may be having regarding e-cigarettes, whether they see discussing e-cigs as part of their role and what training they would need in order to do this. Therefore research with health visitors is needed to understand this.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

To understand Health Visitors perception of their role in asking and advising woman about smoking, breastfeeding and e-cigarettes

PRIMARY OBJECTIVE

- Understand and explore health visitors' understanding of the relationship between smoking-breastfeeding
- Explore what conversations HV's are having with mothers about smoking
- To explore Health Visitors' attitudes & beliefs about e-cigarette use postpartum
- To understand what conversations (if any) Health Visitors are having about e-cigarettes

SECONDARY OBJECTIVES

- Identify potential training needs for Health Visitors to be able to discuss e-cigarettes with new mothers
- Understand any barriers or facilitators to the feasibility of a Health Visitor led intervention using e-cigarettes

STUDY DESIGN

STUDY CONFIGURATION

Qualitative study using semi-structured interviews with Health Visitors

STUDY MANAGEMENT

The study will be managed by the CI as part of the fulfilment of a PhD, supervised by a PhD supervisory team. Any identifiable personal data will be password protected in line with GDPR regulations.

All participants will be randomly assigned a different name, any identifying information will not be held with the data in NVivo, and transcripts will be encrypted, anonymised and stored securely within the University of Nottingham network drive.

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

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DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: Recruitment will begin (Pending ethical approval) in June 2018, interviews are expected to be completed by December 2018

Participant Duration: Participants will be asked to take part in a single interview expected to last no longer than 60 minutes, there is no anticipated follow up.

End of the Study

The end of the study will be the last interview of the last participant.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Participants will be recruited from personal contacts within Health Visitor teams, who have previously expressed an interest in being contacted regarding research concerning postpartum return to smoking to capture views from HV working from geographically-varied across the UK, and use a snowballing method to ensure recruitment. The initial approach will be the CI and/or other members of their Health Visiting teams, and information about the study will be sent via email to Health Visiting teams.

The investigator or their nominee, e.g. from the research team (a member of the supervisory team), will inform the participant, of all aspects pertaining to participation in the study.

We will not be including translation services as we are recruiting UK based professional Health Visitors who are expected to be fluent in English.

It will be explained to the potential participant that entry into the study is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Eligibility criteria

Inclusion criteria

≥18 years of age

Ability to give informed consent

Currently working within the NHS as a Health Visitor

Exclusion criteria

Not currently practicing as a Health Visitor

Unable to speak/understand English

Unable to give informed consent due to mental impairment

Expected duration of participant participation

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Study participants will be participating in the study for 1 hour

Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future involvement in research. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

All participants will provide written informed consent, or verbal if a telephone interview is preferred. The Consent Form will be signed and dated by the participant before they enter the study. The Investigator will explain the details of the study and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended Consent Form which will be signed by the participant.

STUDY REGIMEN

Emails and telephone calls will be made to Health Visitors through personal contacts to ask for their support with this research. When a potential participant is identified, the CI (EJ) will contact them to explain the study to see if they might be interested, once eligibility is checked, a provisional appointment for an interview will be made. They will then sent the PIS and consent form. For telephone interviews, the interviewer will check they have read the PIS and ask if they have any questions, and are still happy to take part, consent will then be taken.

For face to face interviews, consent will be obtained prior to the interview using the consent form, during telephone interviews the participants will be asked to confirm they have received and read the participant information sheet and consent forms, and will be asked to verbally consent.

All interviews, whether face to face or telephone, be digitally recorded. Verbal consent will be recorded at the start of the interview and the consent forms will also ask for consent for the recordings to be sent to a transcription company (with whom we have a confidentiality agreement). Participants will be informed that recordings will not be accompanied by identifying information apart from information volunteered during the interviews, and identifying information will be removed from transcriptions. Participants will also be offered information on where to seek further information on e-cigarettes if they wish.

Compliance

Compliance will be acknowledged by the participant volunteering to take part in the study, and subsequently arranging an interview time. If a participant does not answer a telephone interview at the scheduled time or arrive for a face to face interview at the agreed place, they will be contacted to see whether they still wish to be part of the study and whether they would like to rearrange the interview. If they do not respond to the follow up to re-arrange the interview, this will be classed as none compliance and the participant's details will be removed from the study database

Criteria for terminating the study

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The study will be terminated when up to 25 participants have been interviewed depending on theme saturation.

ANALYSES

Methods

Semi-structured interviews will be transcribed verbatim using a professional transcription service with whom we have a confidentiality agreement and transferred into NVivo (11) software. A thematic analysis will be used to analyse the data as described by Braun & Clark [50]. Using a mainly inductive approach we will draw on the aims and objectives of the interview. Data will be organised and summarised under theme and subtheme headings. Within these headings the assortment of opinions, attitudes, understanding and experiences of discussing smoking, breastfeeding and e-cigarettes postpartum will be summarised, and any explanatory connections explored. Interviews will be analysed as the data are collected, so that the initial data analysis can be explored and applied in later interviews and used to refine themes and categories. We will carry out the analysis process until data saturation is reached, and no new themes emerge. One member of the research team (EJ – chief investigator) will code the data and another member (TBC) will double-code a sample of these and discuss these analyses with the wider team.

Sample size and justification

20 health visitors will be recruited as this is both feasible and we anticipate should be sufficient for saturation of the key issues within these themes. In qualitative research there are no specific rules to determine an appropriate sample size, and is often determined by available time and resources as well as study objectives. We will recruit from UK based Health Visiting teams.

ADVERSE EVENTS

The occurrence of an adverse event as a result of participation within this study is not expected and no adverse event data will be collected.

ETHICAL AND REGULATORY ASPECTS

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department, and the Health Research Authority (HRA) if required. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005.

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INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator and the participant shall both sign and date the Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No study-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).

RECORDS

Case Report Forms

Each participant will be assigned a study identity code number, for use on CRFs, other study documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and date of birth (dd/mm/yy)

CRFs will be treated as confidential documents and held securely in accordance with regulations. CRFs shall be restricted to those personnel approved by the Chief or local Investigator and recorded as such in the study records.

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated. The Chief or local Investigator shall sign a declaration ensuring accuracy of data recorded in the CRF.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. A CRF may also completely serve as its own source data. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

The CRF and all source documents shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

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All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The CRF will only collect the minimum required information for the purposes of the study. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and any relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

STUDY CONDUCT

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); accountability of study materials and equipment calibration logs. The Academic Supervisor, shall carry out a site systems audit at least yearly and an audit report shall be made.

STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Academic Supervisor shall carry out monitoring of study data as an ongoing activity.

Entries on CRFs will be verified by inspection against the source data. A sample of CRFs (10% or as per the study risk assessment) will be checked on a regular basis for verification of all entries made. In addition the subsequent capture of the data on the study database will be checked. Where corrections are required these will carry a full audit trail and justification.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

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The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all anonymised audio recordings, study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

The CI and supervisory team will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by SPCR. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. Participants will not be identified in any publications. Where direct quotes are taken, no personally identifiable information will be reported.

USER AND PUBLIC INVOLVEMENT

Advice has been sort from current practicing Health Visitors who will be able to review semi-structured interview plans.

STUDY FINANCES

Funding source

This study is funded by the SPCR

Participant stipends and payments

Participants will not be paid to participate in the study. Travel expenses will be offered for any travel needed.

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SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name) _____

Signature: _____

Date: _____

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Health Visitors' understanding, beliefs and experiences of discussions with new mothers on Breastfeeding, Smoking & Vaping: qualitative study

Final Version 1.0
26 / 06 / 2018

Short title: *Breastfeeding, Smoking & Vaping: Health Visitor perspectives*

IRAS Project ID:

Study Sponsor: University of Nottingham

Sponsor reference:

Funding Source: This paper presents independent research funded by the National Institute for Health Research School for Primary Care Research (NIHR SPCR). The views expressed are those of the authors and not necessarily those of the NIHR, the NHS or the Department of Health and Social Care.

STUDY PERSONNEL AND CONTACT DETAILS

Sponsor: University of Nottingham
Contact name Ms Angela Shone
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University of Nottingham
East Atrium
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Triumph Road
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Co-investigators: Dr Sue Cooper : mczsec@exmail.nottingham.ac.uk
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Dr Katarzyna Campbell:
mczkac@exmail.nottingham.ac.uk
Prof. Sarah Lewis: mszsal@exmail.nottingham.ac.uk
Dr. Sophie Orton: mczso@exmail.nottingham.ac.uk

Study Coordinating Centre: Name and address of coordinating centre
(UoN School of Medicine)

SYNOPSIS

Title	Health Visitors' understanding, beliefs and experiences of discussions with new mothers on Breastfeeding, Smoking & Vaping: qualitative study
Short title	Breastfeeding, Smoking & Vaping: Health Visitor perspectives
Chief Investigator	Emily Johnston
Objectives	<p>To understand Health Visitors perception of their role in asking and advising woman about smoking, breastfeeding and e-cigarettes</p> <ul style="list-style-type: none"> - Understand and explore health visitors understanding of the smoking-breastfeeding association - Explore what conversations HV's are having with mothers about smoking - To explore Health Visitors' attitudes & beliefs about e-cigarette use postpartum - To understand what conversations (if any) Health Visitors are having about e-cigarettes - Identify potential training needs for Health Visitors to be able to discuss e-cigarettes with new mothers - Explore barriers and motivators to discussing smoking, breastfeeding and e-cigarettes
Study Configuration	Qualitative study using semi-structured interviews with Health Visitors
Setting	Face to face & telephone
Number of participants	20-25 Health Visitors in the UK
Eligibility criteria	<p>≥18 years of age</p> <p>Willing to give informed consent</p> <p>Currently working in the NHS as a health visitor</p>
Description of interventions	A semi structured interview with each participant, either in person or via telephone interview
Duration of study	Recruitment to begin in June 2018, participants are only required for one interview, anticipated duration is 6 months from recruitment
Methods of analysis	Semi-structured interviews will be transcribed and analysed in NVivo (11) using a Framework Analysis.

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ABBREVIATIONS

CI	Chief Investigator overall
HV	Health Visitor
CRF	Case Report Form
GCP	Good Clinical Practice
NHS	National Health Service
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
REC	Research Ethics Committee
R&D	Research and Development department
UoN	University of Nottingham

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STUDY BACKGROUND INFORMATION AND RATIONALE

Many women stop smoking during pregnancy but relapse postpartum is common. Smoking cessation in pregnancy may be influenced by the intrinsic motivation to protect the unborn baby from harm, due to the well-known detrimental effects of smoking on the unborn foetus [1-3]. This intrinsic motivation may account for the higher rates of spontaneous quitting amongst pregnant women compared to the general smoking population [4-6], but may explain the high rates of relapse observed postpartum [7], as the intrinsic motivation of delivering a healthy baby has been removed.

Smoking relapse postpartum exposes the infant to potential morbidity and mortality. Infants exposed to tobacco smoke have an increased risk of sudden infant death syndrome [8], respiratory tract illness [9], asthma [10], ear infections [11] and double the risk of developing meningitis [12]. As well as risks to the infant, smoking continues to adversely affect the mother's health; even with low intensity smoking (< 10 cigarettes a day) the risk of all-cause mortality is elevated [13], as well as inhibiting the immune response [14] and increasing the acute risk of respiratory infection [15], cardiovascular [16] and coronary disease [17]. Parental smoking is also a predictor of adolescent smoking, therefore mothers' relapse also increases children's risk of smoking in later life [18].

Studies have consistently reported associations between postpartum smoking and breastfeeding patterns [19-22]. The initiation and continuation of breastfeeding is positively associated with smoking abstinence in postpartum women [23, 24]. Research suggests that the intention to breastfeed acts as a precipitating factor for reducing postpartum relapse [25]. Research has also supported the intention to return to smoking as the strongest predictor of the intention not to breastfeed, as well as mothers who smoke being more likely to wean from the breast early (< 3 months postpartum) [20, 26].

As well as the health benefits of reducing postpartum smoking, increasing the rates of breastfeeding will also improve health outcomes. The prevalence of breastfeeding at 6–8 weeks is a key indicator of child health and wellbeing [27]. Globally, if breastfeeding rates were increased to near-total levels over 800,000 children's lives a year worldwide could be saved, as well as the prevention of 20,000 deaths from breast cancer every year [28]. The UK has one of the lowest breastfeeding rates in the world [29], and as explained above, smoking and breastfeeding rates are linked, so tackling smoking postpartum could increase UK breastfeeding rates.

There is some evidence of the success of smoking cessation interventions in pregnancy but less evidence for what is effective at preventing post-partum relapse to smoking. Pharmacological interventions have some success during pregnancy [30] particularly if supported by behavioural therapy [7, 31]. Behavioural interventions to aid smoking cessation in pregnancy have included peer support [32] (since living with/around smokers is a risk factor for relapse [33]), as well as health care professionals – such as a nurse, midwife, doctor or smoking cessation advisor who provide counselling and advice in combination with self-help literature [34, 35]. However, results for

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maintained abstinence postpartum are mixed – whilst some studies show that abstinence was significantly higher in treatment groups at 12 months postpartum [36], other studies have shown no difference between control and treatment groups [37]. Cash incentives have also been used to improve cessation rates during pregnancy [38].

For women who are at risk of relapse to smoking, or who have started smoking postnatally, trying to minimise harm from their nicotine addiction could be worth exploring. Currently, mothers who relapse to smoking are advised about safe sleeping, washing hands after smoking, maximising the time between smoking and handling the child and maintaining a smoke-free home [39]. Even if a mother only smokes outside the home, mothers who smoke will be transferring harmful toxins via dermal contact, exhaled second hand smoke and via breastmilk [40]– with those infants not receiving breastmilk at increased risk of smoking related morbidity and mortality [41, 42].

A relatively new method of nicotine delivery is the e-cigarette. Whilst mimicking the physical process of smoking [43], e-cigarettes also provide a more naturalistic delivery of nicotine (inhaled) compared to other nicotine delivery products (gum, patches etc.). Research suggests that e-cigarettes pose only a small fraction of the risks of smoking [44], Public Health England (PHE) published a report highlighting that e-cigarettes are at least 95% less harmful than traditional cigarettes [45]. The use of an e-cigarette postpartum could also offer a financial incentive for new mothers, as the cost of an e-cigarette and liquid is much lower than the price of cigarettes [46], and by communicating the reduced health risks we can continue to support the intrinsic motivation to be smoke free that helped maintain abstinence during pregnancy [47].

In our previous research,(as yet unpublished) we have shown women report using e-cigs postpartum to prevent themselves relapsing to smoking, however many women were concerned about the health implications of using e-cigs, with some women preferring to smoke traditional cigarettes owing to the known risks as opposed to the unknown risks of e-cigs. Women were accessing advice from unreliable sources and relying on anecdotal accounts from other lay people to inform their choice about e-cigs. Therefore it is important we ensure they receive advice from reliable sources that are easily accessible to new mothers.

In the UK, a consistent form of postnatal care is by delivered by health visitors via 5 core interactions with women – 1) prior to birth, 2) 2 weeks post birth, 3) 6-8 weeks post birth, 4) 9-12 months post birth and 5) 18 -24months post birth [48]. As well as core visits, health visitors are on hand at weekly weigh in/drop in clinics where mothers can turn up without appointment for advice. Health visitors already discuss breastfeeding, and are under pressure to increase the breastfeeding rates within the UK [49] as well as reducing postpartum smoking rates as part of their 5 core interactions [39]. Therefore Health Visitor input during these visits could be an ideal opportunity to discuss e-cigarettes with mothers who have relapsed or are high risk. Equipping health visitors with the knowledge to discuss e-cigarettes, and helping open a dialogue for mothers who may consider using them via information at drop in clinics

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could reduce relapse to smoking postpartum and/or reduce exposure to cigarette smoke for both mother and baby.

No research currently exists as to what health visitors currently believe about e-cigarettes, what discussions they may be having regarding e-cigarettes, whether they see discussing e-cigs as part of their role and what training they would need in order to do this. Therefore research with health visitors is needed to understand this.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

To understand Health Visitors perception of their role in asking and advising woman about smoking, breastfeeding and e-cigarettes

PRIMARY OBJECTIVE

- Understand and explore health visitors' understanding of the relationship between smoking-breastfeeding
- Explore what conversations HV's are having with mothers about smoking
- To explore Health Visitors' attitudes & beliefs about e-cigarette use postpartum
- To understand what conversations (if any) Health Visitors are having about e-cigarettes

SECONDARY OBJECTIVES

- Identify potential training needs for Health Visitors to be able to discuss e-cigarettes with new mothers
- Understand any barriers or facilitators to the feasibility of a Health Visitor led intervention using e-cigarettes

STUDY DESIGN

STUDY CONFIGURATION

Qualitative study using semi-structured interviews with Health Visitors

STUDY MANAGEMENT

The study will be managed by the CI as part of the fulfilment of a PhD, supervised by a PhD supervisory team. Any identifiable personal data will be password protected in line with GDPR regulations.

All participants will be randomly assigned a different name, any identifying information will not be held with the data in NVivo, and transcripts will be encrypted, anonymised and stored securely within the University of Nottingham network drive.

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

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DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: Recruitment will begin (Pending ethical approval) in June 2018, interviews are expected to be completed by December 2018

Participant Duration: Participants will be asked to take part in a single interview expected to last no longer than 60 minutes, there is no anticipated follow up.

End of the Study

The end of the study will be the last interview of the last participant.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Participants will be recruited from personal contacts within Health Visitor teams, who have previously expressed an interest in being contacted regarding research concerning postpartum return to smoking to capture views from HV working from geographically-varied across the UK, and use a snowballing method to ensure recruitment. The initial approach will be the CI and/or other members of their Health Visiting teams, and information about the study will be sent via email to Health Visiting teams.

The investigator or their nominee, e.g. from the research team (a member of the supervisory team), will inform the participant, of all aspects pertaining to participation in the study.

We will not be including translation services as we are recruiting UK based professional Health Visitors who are expected to be fluent in English.

It will be explained to the potential participant that entry into the study is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Eligibility criteria

Inclusion criteria

≥18 years of age

Ability to give informed consent

Currently working within the NHS as a Health Visitor

Exclusion criteria

Not currently practicing as a Health Visitor

Unable to speak/understand English

Unable to give informed consent due to mental impairment

Expected duration of participant participation

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Study participants will be participating in the study for 1 hour

Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future involvement in research. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

All participants will provide written informed consent, or verbal if a telephone interview is preferred. The Consent Form will be signed and dated by the participant before they enter the study. The Investigator will explain the details of the study and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended Consent Form which will be signed by the participant.

STUDY REGIMEN

Emails and telephone calls will be made to Health Visitors through personal contacts to ask for their support with this research. When a potential participant is identified, the CI (EJ) will contact them to explain the study to see if they might be interested, once eligibility is checked, a provisional appointment for an interview will be made. They will then sent the PIS and consent form. For telephone interviews, the interviewer will check they have read the PIS and ask if they have any questions, and are still happy to take part, consent will then be taken.

For face to face interviews, consent will be obtained prior to the interview using the consent form, during telephone interviews the participants will be asked to confirm they have received and read the participant information sheet and consent forms, and will be asked to verbally consent.

All interviews, whether face to face or telephone, be digitally recorded. Verbal consent will be recorded at the start of the interview and the consent forms will also ask for consent for the recordings to be sent to a transcription company (with whom we have a confidentiality agreement). Participants will be informed that recordings will not be accompanied by identifying information apart from information volunteered during the interviews, and identifying information will be removed from transcriptions. Participants will also be offered information on where to seek further information on e-cigarettes if they wish.

Compliance

Compliance will be acknowledged by the participant volunteering to take part in the study, and subsequently arranging an interview time. If a participant does not answer a telephone interview at the scheduled time or arrive for a face to face interview at the agreed place, they will be contacted to see whether they still wish to be part of the study and whether they would like to rearrange the interview. If they do not respond to the follow up to re-arrange the interview, this will be classed as none compliance and the participant's details will be removed from the study database

Criteria for terminating the study

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The study will be terminated when up to 25 participants have been interviewed depending on theme saturation.

ANALYSES

Methods

Semi-structured interviews will be transcribed verbatim using a professional transcription service with whom we have a confidentiality agreement and transferred into NVivo (11) software. A thematic analysis will be used to analyse the data as described by Braun & Clark [50]. Using a mainly inductive approach we will draw on the aims and objectives of the interview. Data will be organised and summarised under theme and subtheme headings. Within these headings the assortment of opinions, attitudes, understanding and experiences of discussing smoking, breastfeeding and e-cigarettes postpartum will be summarised, and any explanatory connections explored. Interviews will be analysed as the data are collected, so that the initial data analysis can be explored and applied in later interviews and used to refine themes and categories. We will carry out the analysis process until data saturation is reached, and no new themes emerge. One member of the research team (EJ – chief investigator) will code the data and another member (TBC) will double-code a sample of these and discuss these analyses with the wider team.

Sample size and justification

20 health visitors will be recruited as this is both feasible and we anticipate should be sufficient for saturation of the key issues within these themes. In qualitative research there are no specific rules to determine an appropriate sample size, and is often determined by available time and resources as well as study objectives. We will recruit from UK based Health Visiting teams.

ADVERSE EVENTS

The occurrence of an adverse event as a result of participation within this study is not expected and no adverse event data will be collected.

ETHICAL AND REGULATORY ASPECTS

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department, and the Health Research Authority (HRA) if required. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005.

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INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator and the participant shall both sign and date the Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No study-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).

RECORDS

Case Report Forms

Each participant will be assigned a study identity code number, for use on CRFs, other study documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and date of birth (dd/mm/yy)

CRFs will be treated as confidential documents and held securely in accordance with regulations. CRFs shall be restricted to those personnel approved by the Chief or local Investigator and recorded as such in the study records.

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated. The Chief or local Investigator shall sign a declaration ensuring accuracy of data recorded in the CRF.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. A CRF may also completely serve as its own source data. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

The CRF and all source documents shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

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All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The CRF will only collect the minimum required information for the purposes of the study. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and any relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

STUDY CONDUCT

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); accountability of study materials and equipment calibration logs. The Academic Supervisor, shall carry out a site systems audit at least yearly and an audit report shall be made.

STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Academic Supervisor shall carry out monitoring of study data as an ongoing activity.

Entries on CRFs will be verified by inspection against the source data. A sample of CRFs (10% or as per the study risk assessment) will be checked on a regular basis for verification of all entries made. In addition the subsequent capture of the data on the study database will be checked. Where corrections are required these will carry a full audit trail and justification.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

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The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all anonymised audio recordings, study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

The CI and supervisory team will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by SPCR. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. Participants will not be identified in any publications. Where direct quotes are taken, no personally identifiable information will be reported.

USER AND PUBLIC INVOLVEMENT

Advice has been sort from current practicing Health Visitors who will be able to review semi-structured interview plans.

STUDY FINANCES

Funding source

This study is funded by the SPCR

Participant stipends and payments

Participants will not be paid to participate in the study. Travel expenses will be offered for any travel needed.

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SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name) _____

Signature: _____

Date: _____

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